

Hello Suvajyoti,

(b)(4)

Thanks.

Lan

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Monday, October 23, 2023 11:23 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; k232382@docs.fda.gov
Subject: RE: k232380 and k232382 - Tandem - Control IQ 1.5 - (b)(4)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin and Lan,

Thanks for providing the responses.

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>
Sent: Friday, October 20, 2023 4:43 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; k232382@docs.fda.gov
Subject: [EXTERNAL] RE: k232380 and k232382 - Tandem - Control IQ 1.5 - (b)(4)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our responses to your questions attached.

(b)(4)

I will be out of office next Monday and Tuesday (October 23rd & 24th), please send any inquiries to Lan Herrington (cc'ed).

Thank you and have a great weekend,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Monday, October 16, 2023 9:55 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; k232382@docs.fda.gov

Subject: k232380 and k232382 - Tandem - Control IQ 1.5 - (b)(4)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

Please see the following interactive items. Can you please provide your response and updated (b)(4) documents by COB Oct 20, 2023?

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics (DAM)

Office of Science and Engineering Laboratories (OSEL)

Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

✉ : Suvajyoti.Guha@fda.hhs.gov

☎ : 301.796.9573



• • • • •

Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



(b)(4)

Received. Thanks!

From: Christin Dunn <CDunn@tandemdiabetes.com>
Sent: Friday, August 25, 2023 2:05 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Maiorana, Anthony <Anthony.Maiorana@fda.hhs.gov>; Balsam, Joshua <Joshua.Balsam@fda.hhs.gov>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; Lan Herrington <LHerrington@tandemdiabetes.com>
Subject: [EXTERNAL] RE: K232380 and K232382 - miscellaneous interactive questions

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our response to questions 1-4 attached.

Have a great weekend!

Best Regards,
Christin

From: Christin Dunn
Sent: Tuesday, August 22, 2023 3:03 PM
To: 'Guha, Suvajyoti' <Suvajyoti.Guha@fda.hhs.gov>
Cc: 'k232382@docs.fda.gov' <k232382@docs.fda.gov>; 'k232380@docs.fda.gov' <k232380@docs.fda.gov>; 'Maiorana, Anthony' <Anthony.Maiorana@fda.hhs.gov>; 'Balsam, Joshua' <Joshua.Balsam@fda.hhs.gov>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; Lan Herrington <LHerrington@tandemdiabetes.com>
Subject: RE: K232380 and K232382 - miscellaneous interactive questions

Hello Suvajyoti,

Please see our response to Question #5 attached.

Best Regards,
Christin

From: Christin Dunn
Sent: Friday, August 18, 2023 8:23 AM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Maiorana, Anthony <Anthony.Maiorana@fda.hhs.gov>; Balsam, Joshua <Joshua.Balsam@fda.hhs.gov>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; Lan Herrington <LHerrington@tandemdiabetes.com>
Subject: RE: K232380 and K232382 - miscellaneous interactive questions

Hi Suvajyoti,

I'm confirming receipt of your questions.

We will reach out to you if we have any questions.

Thank you,



Christin Dunn
Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different
12400 High Bluff Drive, San Diego CA 92130
tandemdiabetes.com

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Friday, August 18, 2023 6:59 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Maiorana, Anthony <Anthony.Maiorana@fda.hhs.gov>; Balsam, Joshua <Joshua.Balsam@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Subject: K232380 and K232382 - miscellaneous interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

Can you please respond to the following interactive questions? For 1-4 below I request that you provide your responses by COB **August 25, 2023**.

For response 5 below, I request that you provide your response by **COB August 22, 2023** and cc our Human Factors SME Dr. Anthony Maiorana.

(b)(4)

If you have any follow up questions for me related to the above, please direct them to me by 4 PM today eastern time as I will be on leave for part of next week.

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-8573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).



Thank you. We have received your response.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-0573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>
Sent: Monday, September 11, 2023 2:32 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: [EXTERNAL] RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our response to the additional questions sent on September 6th.

Thank you,
Christin

From: Christin Dunn
Sent: Wednesday, September 6, 2023 12:59 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov
Subject: RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Hi Suvajyoti,

I'm confirming receipt of the additional questions.

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Wednesday, September 6, 2023 6:34 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov
Subject: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

Can you please respond to the following interactive questions by COB Sep 11, 2023 –

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics (DAM)

Office of Science and Engineering Laboratories (OSEL)

Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

✉: Suvajyoti.Guha@fda.hhs.gov

☎: 301.796.9573



W O R K I N G

Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



Hi Christin,

I am the lead reviewer for K232380 and K232382. Can you please provide your responses to the following questions by 3 PM Eastern Time Monday August 14 -

K232380

(b)(4)

Thanks, and looking forward to working with you on both submissions.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01D9CC69.2A5FBCD0]<<http://www.fda.gov/>>

[cid:image002.jpg@01D9CC69.2A5FBCD0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01D9CC69.2A5FBCD0] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDs_jPtOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image004.jpg@01D9CC69.2A5FBCD0]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image005.jpg@01D9CC69.2A5FBCD0]
<http://secure-web.cisco.com/1c6NVqVSfV2kjznn-UlA0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdH-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBorWewttCYH7Gm0I2nqxYQoCyl14AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image006.jpg@01D9CC69.2A5FBCD0]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cE1u4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YA15GWcTEweL2ygi-yMZwF9-0wUmd-P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

Hello Suvajyoti,

Pleasure to meet you and I look forward to working with you.

Please see my responses below:

K232380

(b)(4)

Thank you,

[signature_225592142]

Christin Dunn

Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different

12400 High Bluff Drive, San Diego CA 92130

tandemdiabetes.com<<https://tandemdiabetes.com/>>

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Friday, August 11, 2023 12:41 PM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; k232382@docs.fda.gov

Subject: K232380 and K232382 - Lead Reviewer and RTA items

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

I am the lead reviewer for K232380 and K232382. Can you please provide your responses to the following questions by 3 PM Eastern Time Monday August 14 -

(b)(4)

(b)(4)

Thanks, and looking forward to working with you on both submissions.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01D9CC55.BD0F8E20]<<http://www.fda.gov/>>

[cid:image002.jpg@01D9CC55.BD0F8E20]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01D9CC55.BD0F8E20] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJpOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image004.jpg@01D9CC55.BD0F8E20]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image005.jpg@01D9CC55.BD0F8E20]
<http://secure-web.cisco.com/1c6NVqVSfV2kjznn-U1A0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdH-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOwWewttCYH7Gm0I2nqxYQoCyll4AJqcO7Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image006.jpg@01D9CC55.BD0F8E20]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAKeqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAisGWcTEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

2 t:slim X2 Insulin Pump Features

CHAPTER 2

Important Safety Information

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Hi Christin,

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image007.png@01D9E565.D1EEDC50]<<http://www.fda.gov/>>

[cid:image008.jpg@01D9E565.D1EEDC50]<<https://www.facebook.com/FDA>>

[cid:image009.jpg@01D9E565.D1EEDC50] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJPtOn1rp90Xo0UwJUyB1bVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image010.jpg@01D9E565.D1EEDC50]

<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image011.jpg@01D9E565.D1EEDC50]

<http://secure-web.cisco.com/1c6NVqVSfv2kjjnn-UlA0J4oUTRapVCu10_n_AyTYEq2nEyp_lnxIiz0fkdH-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOMGyRK9DisBh6HqQxEQyi07VdBorWewttCYH7Gm0I2nqxYQoCyll4AJqcO7Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image012.jpg@01D9E565.D1EEDC50]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRrxnEXGvvXlGb7eTpskXQlVK2YAi5GWcTEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdhrhcustomerservice%3FID%3D1914%26S%3DE>).

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRrxnEXGvvXlGb7eTpskXQlVK2YAi5GWcTEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdhrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Monday, September 11, 2023 2:32 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: [EXTERNAL] RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our response to the additional questions sent on September 6th.

Thank you,

Christin

From: Christin Dunn

Sent: Wednesday, September 6, 2023 12:59 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>

Subject: RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Hi Suvajyoti,

I'm confirming receipt of the additional questions.

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Wednesday, September 6, 2023 6:34 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>

Subject: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Can you please respond to the following interactive questions by COB Sep 11, 2023 -

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image013.png@01D9E565.D1EEDC50]<<http://www.fda.gov/>>

[cid:image014.jpg@01D9E565.D1EEDC50]<<https://www.facebook.com/FDA>>

[cid:image015.jpg@01D9E565.D1EEDC50] <https://twitter.com/US_FDA>

[cid:image016.jpg@01D9E565.D1EEDC50] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image017.jpg@01D9E565.D1EEDC50] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image018.jpg@01D9E565.D1EEDC50]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92), the 510(k) Summary for the t:slim X2 Insulin Pump with Interoperable Technology (with t:connect mobile app) is provided below:

Submitter Information

Name	Tandem Diabetes Care, Inc. 12400 High Bluff Drive San Diego, CA 92130 Phone: 858-366-6900
Applicant Contact	Christin Dunn Senior Regulatory Affairs Specialist Phone: 858-401-1641 cdunn@tandemdiabetes.com Tandem Diabetes Care, Inc. 12400 High Bluff Drive San Diego, CA 92130
Secondary Contact	Lan Herrington Director, Regulatory Affairs (858) 255-6378 LHerrington@tandemdiabetes.com Tandem Diabetes Care, Inc. 12400 High Bluff Drive San Diego, CA 92130
Date Prepared:	October 26, 2023



Device Identification

Trade name	Control-IQ Technology
Common name	interoperable automated glycemic controller
Regulation Name	interoperable automated glycemic controller
Classification number	21 CFR 862.1356
Product code	QJI
Regulatory class	II
Predicate devices	Control-IQ Technology (K200467)

Intended Use

Control-IQ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold.

Control-IQ technology is intended for the management of Type 1 diabetes mellitus in persons 2 years of age and greater.

Control-IQ technology is intended for single patient use and requires a prescription.

Description

Control-IQ technology (Control-IQ, the device) is a software-only device intended for the management of type 1 diabetes mellitus. The device controls insulin delivery from a compatible alternate controller enabled insulin pump (ACE pump) based on inputs provided by a compatible integrated continuous glucose monitor (iCGM) and inputs provided the user (e.g., carbohydrate intake, exercise, and sleep schedule). Control-IQ technology is meant to be installed on a compatible ACE pump.

Control-IQ Technology has three different modes: Normal, Sleep, and Exercise. The glucose



targets are not customizable in these modes but can change based on the mode selected. During normal mode, Control-IQ Technology aims to control glucose within a target range of 112.5 – 160 mg/dL. During sleep mode, this range is changed to 112.5-120 mg/dL, and it is changed to 140-160 mg/dL during exercise mode.

Control-IQ technology includes an integrated feature whereby iCGM values are automatically populated into the glucose field of the integrated bolus calculator when the Control-IQ technology is active (i.e., the device is operating in closed-loop mode). This feature is disabled when Control-IQ is turned off.

Control-IQ technology requires users to input their weight and their total daily insulin requirement, which should be established with the help of a health care provider before using the device.



Technological Characteristics Compared to Predicate Device

	PREDICATE DEVICE CONTROL-IQ TECHNOLOGY (K200467)	SUBJECT DEVICE (K232382)
Intended Use/Indication For Use	Control-IQ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. Control-IQ technology is intended for the management of Type 1 diabetes mellitus in persons 6 years of age and greater. Control-IQ technology is intended for single patient use and requires a prescription.	Control-IQ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. Control-IQ technology is intended for the management of Type 1 diabetes mellitus in persons 2 years of age and greater. Control-IQ technology is intended for single patient use and requires a prescription.



	Control-IQ technology is indicated for use with NovoLog or Humalog U-100 insulin	
Pump Type	Alternate controller enabled insulin pump	Same
Classification	II	Same
Specific Drug/Biological Use	U-100 Insulin	Same
Profile Delivery	When the predicted CGM value is within the target range, the pump will deliver insulin at the rate determined by the active Personal Profile settings. The user's profile basal rate may be set as high as 15 units/hr when Control-IQ is off, but is clipped to 3 units/hr when Control-IQ is enabled	When the predicted CGM value is within the target range, the pump will deliver insulin at the rate determined by the active Personal Profile settings. The user's profile basal rate may be set as high as 15 units/hr when Control-IQ is off and when Control-IQ is enabled, the same basal rate is applied.
Basal Rate Range	The Personal Profile correction factor is used to determine the predicted basal rate limits of 10 to 200 mg/dL per unit insulin.	The Personal Profile correction factor is used to determine the predicted basal rate limits of 10 to 600 mg/dL per unit insulin.
Basal Attenuation	When Control-IQ technology	Same



	predicts that the sensor glucose value will be at or below the target range 30 minutes in the future, the rate of insulin delivered will begin to decrease to attempt to keep glucose within the target range.	
Automatic Correction Bolus	The upper limit for the automatic correction bolus is 200 mg/dL per unit insulin.	The upper limit for the automatic correction bolus is 600 mg/dL per unit insulin.
Body Weight Setting Range	55 lbs (25 kg) – 308 lbs (140kg)	20 lbs (9 kg) – 440 lbs (200 kg)
TDI Range	User setting of 10 units/day - 100 units/day.	User setting of 5 units/day - 200 units/day.
Extended Bolus	Up to 2-hour duration when Control-IQ is enabled, up to 8 hour duration when Control-IQ is disabled. Extended bolus delivery will be terminated when Control-IQ is enabled.	Up to 8-hour duration while Control-IQ is enabled or disabled and extended boluses are uninterrupted when enabling Control-IQ.
Temporary Basal Rates	In order to use Temp Rates, Control-IQ technology must be turned off	Temp Rates can be enabled without turning Control-IQ Technology off



Performance Data

Software verification and validation testing was performed in accordance with ANSI AAMI IEC 62304:2006/A1:2016 Medical Device Software - Software Life Cycle Processes.

Evaluation and adherence to the Special Controls (21 CFR 862.1356) demonstrate continued assurance of safety and effectiveness of the Subject Device.

Clinical Performance

A pivotal clinical study was conducted to evaluate the safety and effectiveness of Control-IQ Technology in individuals 2-5 years of age. This randomized controlled trial enrolled 102 subjects and the subjects were randomly assigned to Control-IQ or Standard Care (SC) in a 2:1 ratio. The subjects used the t:slim X2 insulin pump with Control-IQ Technology for 13 weeks. Upon completion of the 13 week study, participants could then enroll in an optional 13 week extension phase with the modified Control-IQ technology. Individuals assigned to the SC group were then moved to the Control-IQ group during this extension phase. The primary outcome of the study was CGM measured percent time in range 70-180 mg/dL.

Substantial Equivalence

The changes that have been made to the Control-IQ technology indications for use and software result in a product that is substantially equivalent to the predicate Control-IQ technology device. The intended use and indications for use have been previously cleared on the Tandem device except for the change in age from 6 to 2 years of age and greater. The changes to Control-IQ technology and the change in age are supported by clinical trial data that demonstrates that the devices are substantially equivalent. Moreover, software testing demonstrates that the device performs as expected and in a manner that is substantially equivalent to the predicate device. Thus, the modified Tandem Diabetes Care Control-IQ technology is substantially equivalent to the predicate Tandem Diabetes Care Control-IQ technology (K200467).

Hi Christin,

Can you please respond to the following interactive questions by COB Sep 11, 2023 –

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer
Division of Applied Mechanics (DAM)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993
✉: Suvajyoti.Guha@fda.hhs.gov
☎: 301.796.9573



« » « » « »

Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Hi Suvajyoti,

Request received.

(b)(4)

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Tuesday, October 31, 2023 10:18 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>
Subject: k232380 - Tandem - ACE Pump - Edits for 510k summary

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

I Christin,

Attached are some edits for the 510k summary for the pump.

(b)(4)

(b)(4)

Can you please provide updated version before COB today?

Thanks and please let me know if you have any questions.

Suvajyoti Guha, PhD

Mechanical Engineer
Division of Applied Mechanics (DAM)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993
✉: Suvajyoti.Guha@fda.hhs.gov
☎: 301.796.9573



Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>





510(K) SUMMARY FOR K232380

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92), the 510(k) Summary for the t:slim X2 Insulin Pump with Interoperable Technology is provided below:

Submitter Information

Name	Tandem Diabetes Care, Inc. 12400 High Bluff Drive San Diego, CA 92130 Phone: 858-366-6900
Applicant Contact	Christin Dunn Senior Regulatory Affairs Specialist Phone: 858-401-1641 cdunn@tandemdiabetes.com Tandem Diabetes Care, Inc. 12400 High Bluff Drive San Diego, CA 92130
Secondary Contact	Lan Herrington Director, Regulatory Affairs (858) 255-6378 LHerrington@tandemdiabetes.com Tandem Diabetes Care, Inc. 12400 High Bluff Drive San Diego, CA 92130
Date Prepared:	October 26, 2023



Device Identification

Trade name	t:slim X2 Insulin Pump with Interoperable Technology
Common name	alternate controller enabled insulin infusion pump
Regulation Name	alternate controller enabled insulin infusion pump
Classification number	21 CFR 880.5730
Product code	QFG
Regulatory class	II
Predicate devices	t:slim X2 Insulin Pump with Interoperable Technology (with t:connect mobile app (K203234)

Intended Use

The t:slim X2 Insulin Pump with Interoperable Technology (the Pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

The Pump is intended for single patient, home use and requires a prescription.

The Pump is indicated for use in individuals 2 years of age and greater.

Description

The t:slim X2 Insulin Pump with Interoperable Technology is an ambulatory, battery operated, rate-programmable infusion pump designed for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

The t:slim X2 insulin pump includes a disposable cartridge with a 300 unit reservoir which is filled with insulin by the user with the use of the syringe and needle. The cartridge needs to be changed every 48-72 hours depending on the type of insulin used.

The pump is motor driven to deliver patient programmed basal rates and boluses through an



infusion set into subcutaneous tissue. The desired timing and quantity of insulin delivery (bolus or basal) is programmed by the patient based on their healthcare provider's recommendations.

The pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

The t:connect mobile app enables a user to connect a smartphone to the pump using Bluetooth® wireless technology to display pump information and perform some pump functions on the smartphone as well as display pump notifications. The t:connect mobile app can transmit pump and therapy data from the pump to the cloud as long as the user's smartphone is connected to the internet.

The pump is designed to be able to receive and display alerts and alarms to users based on information received from other interoperable devices.

The pump is compatible with Interoperable Automated Glycemic Controllers, such as Basal-IQ Technology (K193483) and Control IQ Technology (K200467) to aid in diabetes management. The latter is being submitted concurrently.

In addition, the Subject Device is compatible with iCGM systems cleared under K223931 21 CFR 862.1355.



Technological Characteristics Compared to Predicate Device

	Predicate Device T: Slim X2 Insulin Pump with Interoperable Technology (K203234)	Subject Device (K232380)
Intended Use/Indication for Use	The t:slim X2 insulin pump with interoperable technology (the Pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use with NovoLog or Humalog U-100 insulin. The Pump is indicated for use in individuals 6 years of age and greater.	Different: Removal of the compatible insulins NovoLog and Humalog from indications. Moved to compatible insulins section of the user guide. The Pump is indicated for use in individuals 2 years of age and greater.



	Predicate Device T: Slim X2 Insulin Pump with Interoperable Technology (K203234)	Subject Device (K232380)
Technological Characteristics	The t:slim X2 insulin pump with interoperable technology is an ambulatory, battery operated, rate-programmable infusion pump designed for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The device includes a disposable cartridge which is motor driven to deliver patient programmed basal rates and boluses through an infusion set into subcutaneous tissue.	Same
Classification	II	Same
Product Code	QFG	Same
Specific Drug/Biological Use	U-100 Insulin	Same
Pump Type	ACE pump, t:slim X2 system	Same
Components	Infusion Pump, Sterile disposable insulin cartridge	Same



	Predicate Device T: Slim X2 Insulin Pump with Interoperable Technology (K203234)	Subject Device (K232380)
Accessories	Compatible FDA cleared infusion sets 3 mL sterile syringe and 26 gauge needle (for filling cartridge). AC power supply and DC car adaptor power supply with USB. Tandem Device Updater. Alternate USB Cable.	Similar DC car adaptor power supply is not provided with the subject device.

The t:slim X2 insulin pump with interoperable technology is an ambulatory, battery operated, rate-programmable infusion pump designed for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The subject device is the same as the predicate device with the following changes:

- Lowered the age indication to individuals of 2 years of age and greater.

Performance Data

Clinical testing was performed to support the expanded age indication. The clinical data demonstrates that the device shows continued assurance of safety and effectiveness.

Evaluation and adherence of the Special Controls listed in 21 CFR 880.5730 demonstrate the continued assurance of the safety and effectiveness of the device.

Substantial Equivalence

The subject device serves the same function as the predicate device with the addition of the 2–5 year-old population. The clinical testing provided in this 510(k) demonstrate that the t:slim X2 Insulin Pump with Interoperable Technology is the same as the predicate device in safety and effectiveness. Therefore, the subject device has been evaluated to be substantially equivalent to the predicate device and does not raise new or different questions of safety or effectiveness.

Indications for Use

510(k) Number (if known)

k232380

Device Name

t:slim X2 Insulin Pump with Interoperable Technology

Indications for Use (Describe)

The t:slim X2 Insulin Pump with Interoperable Technology (the pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use in individuals 2 years of age and greater.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Hi Christin,

Thanks for reaching out.

In case there are any additional questions or concerns, I am hoping to communicate them over in the next week or so.

Have a great weekend.

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Friday, October 13, 2023 3:34 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232380@docs.fda.gov; k232382@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: [EXTERNAL] Status of K232380 and K232382

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

We have received FDA's decision to proceed forward with interactive review for K232380 and K232382.

Can you please let us know when we can expect to receive additional questions?

Thank You and Best Regards,



Christin Dunn
Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different
12400 High Bluff Drive, San Diego CA 92130
tandemdiabetes.com

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

Hi Suvajyoti,

Please see our response to questions 1-4 attached.

Have a great weekend!

Best Regards,

Christin

From: Christin Dunn

Sent: Tuesday, August 22, 2023 3:03 PM

To: 'Guha, Suvajyoti' <Suvajyoti.Guha@fda.hhs.gov>

Cc: 'k232382@docs.fda.gov' <k232382@docs.fda.gov>; 'k232380@docs.fda.gov' <k232380@docs.fda.gov>; 'Maiorana, Anthony' <Anthony.Maiorana@fda.hhs.gov>; 'Balsam, Joshua' <Joshua.Balsam@fda.hhs.gov>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; Lan Herrington <LHerrington@tandemdiabetes.com>

Subject: RE: K232380 and K232382 - miscellaneous interactive questions

Hello Suvajyoti,

Please see our response to Question #5 attached.

Best Regards,

Christin

From: Christin Dunn

Sent: Friday, August 18, 2023 8:23 AM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>; k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Maiorana, Anthony <Anthony.Maiorana@fda.hhs.gov<mailto:Anthony.Maiorana@fda.hhs.gov>>; Balsam, Joshua <Joshua.Balsam@fda.hhs.gov<mailto:Joshua.Balsam@fda.hhs.gov>>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>; Lan Herrington <LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>

Subject: RE: K232380 and K232382 - miscellaneous interactive questions

Hi Suvajyoti,

I'm confirming receipt of your questions.

We will reach out to you if we have any questions.

Thank you,

[signature_225592142]

Christin Dunn

Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different

12400 High Bluff Drive, San Diego CA 92130

tandemdiabetes.com<<https://tandemdiabetes.com/>>

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>>

Sent: Friday, August 18, 2023 6:59 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<<mailto:CDunn@tandemdiabetes.com>>>

Cc: k232382@docs.fda.gov<<mailto:k232382@docs.fda.gov>>;
k232380@docs.fda.gov<<mailto:k232380@docs.fda.gov>>; Maiorana, Anthony
<Anthony.Maiorana@fda.hhs.gov<<mailto:Anthony.Maiorana@fda.hhs.gov>>>; Balsam, Joshua
<Joshua.Balsam@fda.hhs.gov<<mailto:Joshua.Balsam@fda.hhs.gov>>>

Subject: K232380 and K232382 - miscellaneous interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Can you please respond to the following interactive questions? For 1-4 below I request that you provide your responses by COB August 25, 2023.

For response 5 below, I request that you provide your response by COB August 22, 2023 and cc our Human Factors SME Dr. Anthony Maiorana.

(b)(4)

(b)(4)

If you have any follow up questions for me related to the above, please direct them to me by 4 PM today eastern time as I will be on leave for part of next week.

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image002.png@01D9D743.C03C7AB0]<<http://www.fda.gov/>>

[cid:image003.jpg@01D9D743.C03C7AB0]<<https://www.facebook.com/FDA>>

[cid:image004.jpg@01D9D743.C03C7AB0] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJptOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image005.jpg@01D9D743.C03C7AB0]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image006.jpg@01D9D743.C03C7AB0]
<http://secure-web.cisco.com/1c6NVqVSfv2kjznn-UlA0J4oUTRapVCulO_n_AyTYEq2nEyp_lnxIiz0fkdH-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBoRwewttCYH7Gm0I2nqxYQoCy1l4AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image007.jpg@01D9D743.C03C7AB0]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

Hi Suvajyoti,

Please see our response to the additional questions sent on September 6th.

Thank you,
Christin

From: Christin Dunn
Sent: Wednesday, September 6, 2023 12:59 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov
Subject: RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Hi Suvajyoti,

I'm confirming receipt of the additional questions.

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Wednesday, September 6, 2023 6:34 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov
Subject: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

I Christin,

Can you please respond to the following interactive questions by COB Sep 11, 2023 –

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer
Division of Applied Mechanics (DAM)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WC62 Rm 2233, Silver Spring, MD 20993
✉: Suvajyoti.Guha@fda.hhs.gov
☎: 301.796.9573



Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



Hi Christin,

Can you please send your finalized and complete Labeling documents and 510k summaries for the pump (k232380) and Control IQ (k232382)?

It would be great if you can send it by COB Oct 27, 2023.

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>

?: 301.796.9573

[cid:image001.png@01DA0821.AB28C610]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA0821.AB28C610]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA0821.AB28C610] <https://twitter.com/US_FDA>

[cid:image004.jpg@01DA0821.AB28C610] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01DA0821.AB28C610] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01DA0821.AB28C610]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here

<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Hi again Suvajyoti,

We will be available next Thursday, 1:30 - 2:00 Eastern Time.

Thank you!

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Monday, October 16, 2023 11:53 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Balsam, Joshua
<Joshua.Balsam@fda.hhs.gov>

Subject: K232380 and K232382 - Tandem - Control IQ 1.5 - (b)(4)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi again Christin,

(b)(4)

(b)(4)

Here is our availability for next week -

- * Tuesday 2-2:30 PM, 3-4 PM Eastern
- * Wednesday 11 AM - 12 noon Eastern, 3:30 - 4:00 PM eastern
- * Thursday 1:30 - 3:30 PM Eastern

Can you please let me know your preferred time slot at your earliest convenience, preferably by today/tomorrow?

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, W062 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>

?: 301.796.9573

[cid:image001.png@01DA002D.C5D09340]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA002D.C5D09340]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA002D.C5D09340]<https://twitter.com/US_FDA>

[cid:image004.jpg@01DA002D.C5D09340] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01DA002D.C5D09340] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01DA002D.C5D09340]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Hi Christin,

(b)(4)

Can you please respond to the question about bolus accuracy by COB today, 9/12?

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-8573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>
Sent: Monday, September 11, 2023 2:32 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: [EXTERNAL] RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our response to the additional questions sent on September 6th.

Thank you,
Christin

From: Christin Dunn
Sent: Wednesday, September 6, 2023 12:59 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov
Subject: RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Hi Suvajyoti,

I'm confirming receipt of the additional questions.

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Wednesday, September 6, 2023 6:34 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov
Subject: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

Can you please respond to the following interactive questions by COB Sep 11, 2023 –

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATIS@fda.hhs.gov or 301-796-8118

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics (DAM)

Office of Science and Engineering Laboratories (OSEL)

Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

✉: Suvajyoti.Guha@fda.hhs.gov

☎: 301.796.9573



Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



Thank you, Suvajyoti!

Yes, that time is reasonable.

Have a great weekend,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Friday, October 27, 2023 8:56 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

hanks Christin. Thanks for the heads up on the delay.

Given the time zone difference, it would be appreciated if you can send it by 3 PM Eastern time on Oct 30, 2023. Would that be reasonable?

Thanks,
Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10963 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>
Sent: Friday, October 27, 2023 11:52 AM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Would it be possible for us to send you the labeling documents and 510(k) summaries by COB Monday, October 30th?

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Thursday, October 26, 2023 12:33 PM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov
Subject: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

Can you please send your finalized and complete Labeling documents and 510k summaries for the pump (k232380) and Control IQ (k232382)?

It would be great if you can send it by COB Oct 27, 2023.

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics (DAM)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993
✉: Suvajoti.Guha@fda.hhs.gov
☎: 301.796.9573



Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



Hi again Christin,

(b)(4)

(b)(4)

Here is our availability for next week -

- * Tuesday 2-2:30 PM, 3-4 PM Eastern
- * Wednesday 11 AM - 12 noon Eastern, 3:30 - 4:00 PM eastern
- * Thursday 1:30 - 3:30 PM Eastern

Can you please let me know your preferred time slot at your earliest convenience, preferably by today/tomorrow?

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOoffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOoffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image001.png@01DA0040.2AB89DE0]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA0040.2AB89DE0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA0040.2AB89DE0] <https://twitter.com/US_FDA>

[cid:image004.jpg@01DA0040.2AB89DE0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01DA0040.2AB89DE0] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01DA0040.2AB89DE0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

October 4, 2023</br></br>

Substantive Review Notification - Proceed Interactively

<p>FDA has completed a substantive review of your submission K232380 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.</p>

<p>*** This is a system-generated email notification ***</p>

Hi Suvajyoti,

Please see our response below:

(b)(4)

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Tuesday, September 12, 2023 7:42 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: RE: [EXTERNAL] RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

(b)(4)

Can you please respond to the question about bolus accuracy by COB today, 9/12?

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>
Sent: Monday, September 11, 2023 2:32 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: [EXTERNAL] RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our response to the additional questions sent on September 6th.

Thank you,
Christin

From: Christin Dunn
Sent: Wednesday, September 6, 2023 12:59 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov
Subject: RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Hi Suvajyoti,

I'm confirming receipt of the additional questions.

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Wednesday, September 6, 2023 6:34 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov
Subject: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

I Christin,

Can you please respond to the following interactive questions by COB Sep 11, 2023 –

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer
Division of Applied Mechanics (DAM)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993
✉: Suvajyoti.Guha@fda.hhs.gov
☎: 301.796.9573



Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



Hi again Suvajyoti,

We will be available next Thursday, 1:30 - 2:00 Eastern Time.

Thank you!
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Monday, October 16, 2023 11:53 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Balsam, Joshua <Joshua.Balsam@fda.hhs.gov>
Subject: K232380 and K232382 - Tandem - Control IQ 1.5 - (b)(4)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i again Christin,

(b)(4)

(b)(4)

Here is our availability for next week –

- Tuesday 2-2:30 PM, 3-4 PM Eastern
- Wednesday 11 AM – 12 noon Eastern, 3:30 – 4:00 PM eastern
- Thursday 1:30 – 3:30 PM Eastern

Can you please let me know your preferred time slot at your earliest convenience, preferably by today/tomorrow?

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer
Division of Applied Mechanics (DAM)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993
✉: Suvajyoti.Guha@fda.hhs.gov
☎: 301.796.9573



Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 8/8/2023 6:29:40 PM
To: cdunn@tandemdiabetes.com
CC: DCCLetters@fda.hhs.gov
Subject: K232380 Acknowledgement Letter
Attachments: K232380-Acknowledgement Letter.pdf

August 8, 2023

Thank you for your submission. We have attached your acknowledgement letter for your records. If you have any questions about your acknowledgement letter, please contact us at DCCmailroom@fda.hhs.gov. Please do not reply to this email.

The CDRH Portal is now available:

Instead of shipping your submissions to us, you can now upload them at our [CDRH Portal](#).

*** This is a system-generated email notification ***



**U.S. FOOD & DRUG
ADMINISTRATION**

Acknowledgement Letter

08/08/2023

Christin Dunn, Senior Regulatory Affairs Specialist
Tandem Diabetes Care, Inc.
12400 High Bluff Drive
San Diego, CA 92130
UNITED STATES

Dear Christin Dunn:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: K232380

Received: 08/08/2023

Applicant: Tandem Diabetes Care, Inc.

Device: t:slim X2 Insulin Pump with Interoperable Technology (with t:connect Mobile App)

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.

Sincerely yours,

Center for Devices and Radiological Health

t:slim X2

Insulin Pump

WITH Control-IQ TECHNOLOGY

User Guide



MG/DL

T:SLIM X2 INSULIN PUMP WITH CONTROL-IQ TECHNOLOGY USER GUIDE

Software Version: Control-IQ 7.6

Congratulations on the purchase of your new t:slim X2™ insulin pump with Control-IQ™ technology.

This user guide is designed to assist you with the features and functions of the t:slim X2 insulin pump with Control-IQ technology. It provides important warnings and cautions on proper operation as well as technical information to ensure your safety. It also provides step-by-step instructions on how to properly program, manage and care for your t:slim X2 insulin pump with Control-IQ technology.

Changes in equipment, software, or procedures occur periodically; information describing these changes will be included in future editions of this user guide.

No part of this publication may be reproduced, stored in a retrieval system, nor transmitted in any form or by any means, electronic or mechanical, without the prior written permission of Tandem Diabetes Care.

Please contact Customer Technical Support to obtain a replacement copy of the user guide that is the correct version for your pump. For contact information in your region see the back cover of this user guide.

Tandem Diabetes Care, Inc.
12400 High Bluff Drive
San Diego, CA 92130 USA
tandemdiabetes.com

WARNINGS:

Control-IQ technology should not be used in anyone under the age of two years old. Control-IQ technology should also not be used in patients who require less than a total daily insulin dose of 5 units per day and should not be used by people who weigh less than 20 pounds (9 kilograms), as those are the required minimum values needed in order for Control-IQ technology to operate safely.

TABLE OF CONTENTS

Section 1: Before You Begin

Chapter 1 • Introduction

1.1	Conventions of This Guide	16
1.2	Explanation of Symbols	18
1.3	System Description	20
1.4	About this User Guide	21
1.5	Indications for Use	21
1.6	Compatible Insulins	22
1.7	Compatible iCGMs	22
1.8	Important User Information	22
1.9	Important Pediatric User Information	23
1.10	Emergency Kit	24

Section 2: t:slim X2 Insulin Pump Features

Chapter 2 • Important Safety Information

2.1	t:slim X2 Insulin Pump Warnings	26
2.2	Magnetic Resonance Imaging Safety	29
2.3	Radiology and Medical Procedures and Your t:slim X2 System	29
2.4	t:connect Mobile App Warnings	30
2.5	t:slim X2 Insulin Pump Precautions	30
2.6	t:connect Mobile App Precautions	33
2.7	Tandem Cybersecurity Preventative Measures	34
2.8	Potential Benefits From Using Your Pump	35

2.9	Possible Risks From Using Your Pump	36
2.10	Working with your Healthcare Provider	36
2.11	Verification of Proper Functionality	37

Chapter 3 • Getting to Know Your t:slim X2 Insulin Pump

3.1	What your t:slim X2 Pump Package Includes	40
3.2	Pump Terminology	40
3.3	Explanation of t:slim X2 Insulin Pump Icons	43
3.4	Explanation of Pump Colors	45
3.5	Pump Back Side	46
3.6	Lock Screen	48
3.7	Home Screen	50
3.8	Current Status Screen	52
3.9	Bolus Screen	54
3.10	Options Screen	56
3.11	My Pump Screen	58
3.12	Device Settings Screen	60
3.13	Number Keypad Screen	62
3.14	Letter Keypad Screen	64

Chapter 4 • Getting to Know Your t:connect Mobile App

4.1	Overview	68
4.2	Install the t:connect Mobile App	69
4.3	Connecting to a Smartphone	71
4.4	Set Mobile Notifications	74
4.5	Mobile Connection Security	74
4.6	Lost Pump Connection	75

4.7	Restart the t:connect Mobile App	76
4.8	t:connect Mobile App Dashboard	78
4.9	t:connect Mobile App Bolus Screen	80
4.10	t:connect Mobile App Notifications Screen	82
4.11	t:connect Mobile App Settings	84

Chapter 5 • Getting Started

5.1	Charging the t:slim X2 Pump	88
5.2	Turning the Pump On	89
5.3	Using the Touchscreen	89
5.4	Turning the t:slim X2 Pump Screen On	90
5.5	Turning the Pump Screen Off	90
5.6	Turning the Pump Off	90
5.7	Unlocking the t:slim X2 Pump Screen	90
5.8	Edit Time	91
5.9	Edit Date	91
5.10	Basal Limit	91
5.11	Display Settings	92
5.12	Sound Volume	93
5.13	Turn Security PIN On or Off	93
5.14	Mobile Connection	94

Chapter 6 • Insulin Delivery Settings

6.1	Personal Profiles Overview	96
6.2	Creating a New Profile	96
6.3	Programming a New Personal Profile	99
6.4	Editing or Reviewing an Existing Profile	101
6.5	Duplicating an Existing Profile	102
6.6	Activating an Existing Profile	102
6.7	Renaming an Existing Profile	102

6.8	Deleting an Existing Profile	103
6.9	Starting a Temporary Basal Rate	103
6.10	Stopping a Temp Rate	104

Chapter 7 • Infusion Site Care and Loading Cartridge

7.1	Infusion Site Selection and Care	106
7.2	Cartridge Instructions for Use	108
7.3	Filling and Loading a t:slim X2 Cartridge	108
7.4	Filling Tubing	113
7.5	Filling Cannula	115
7.6	Setting Site Reminder	116

Chapter 8 • Manual Bolus

8.1	Manual Bolus Overview	118
8.2	Initiating a Bolus	119
8.3	Correction Bolus Calculation	119
8.4	Bolus Override	123
8.5	Food Bolus Using Units	123
8.6	Food Bolus Using Grams	123
8.7	Extended Bolus	124
8.8	Max Bolus	125
8.9	Quick Bolus	126
8.10	Canceling or Stopping a Bolus Using the Pump	128
8.11	Bolus Delivery Using the t:connect Mobile App	128
8.12	Correction Bolus Using the t:connect Mobile App	129
8.13	Bolus Override Using the t:connect Mobile App	132
8.14	Food Bolus Using the t:connect Mobile App	132
8.15	Canceling or Stopping a Bolus Using the t:connect Mobile App	133
8.16	Pump Connection Lost	134

Chapter 9 • Starting, Stopping, or Resuming Insulin

9.1	Starting Insulin Delivery	138
9.2	Stopping Insulin Delivery	138
9.3	Resuming Insulin Delivery	138
9.4	Disconnecting When Using Control-IQ Technology	139

Chapter 10 • t:slim X2 Insulin Pump Information and History

10.1	t:slim X2 Pump Info	142
10.2	t:slim X2 Pump History	142
10.3	t:connect Mobile App Info	143

Chapter 11 • t:slim X2 Insulin Pump Reminders

11.1	Low BG Reminder	146
11.2	High BG Reminder	146
11.3	After Bolus BG Reminder	147
11.4	Missed Meal Bolus Reminder	148
11.5	Site Reminder	148

Chapter 12 • User Settable Alerts and Alarms

12.1	Low Insulin Alert	150
12.2	Auto-Off Alarm	150
12.3	Max Basal Alert	151

Chapter 13 • t:slim X2 Insulin Pump Alerts

13.1	Low Insulin Alert	155
13.2	Low Power Alerts	156
13.3	Incomplete Bolus Alert	158
13.4	Incomplete Temp Rate Alert	160
13.5	Incomplete Load Sequence Alerts	161
13.6	Incomplete Setting Alert	164

13.7	Basal Rate Required Alert	165
13.8	Max Hourly Bolus Alert	166
13.9	Max Bolus Alerts	167
13.10	Max Basal Alert	169
13.11	Min Basal Alerts	170
13.12	Connection Error Alert	172
13.13	Pairing Code Timeout	173
13.14	Power Source Alert	174
13.15	Data Error Alert	175
13.16	Pump Connection Lost Alert - t:connect Mobile App	176

Chapter 14 • t:slim X2 Insulin Pump Alarms

14.1	Resume Pump Alarm	179
14.2	Low Power Alarm	180
14.3	Empty Cartridge Alarm	181
14.4	Cartridge Error Alarm	182
14.5	Cartridge Removal Alarm	183
14.6	Temperature Alarm	184
14.7	Occlusion Alarms	185
14.8	Screen On/Quick Bolus Button Alarm	187
14.9	Altitude Alarm	188
14.10	Reset Alarm	189

Chapter 15 • t:slim X2 Insulin Pump Malfunction

15.1	Malfunction	192

Chapter 16 • Taking Care of Your Pump

16.1	Overview	196

Chapter 17 • Lifestyle Issues and Travel

17.1	Overview	198

Section 3: CGM Features

Chapter 18 • Important Safety Information When Using the t:slim X2 Insulin Pump with Dexcom G6 CGM

18.1	Warnings	202
18.2	Precautions	203
18.3	Potential Benefits From Using the t:slim X2 Insulin Pump with CGM	205
18.4	Possible Risks From Using the t:slim X2 Insulin Pump with CGM	206

Chapter 19 • Getting to Know Your CGM System

19.1	CGM Terminology	208
19.2	Explanation of CGM Pump Icons	210
19.3	CGM Lock Screen	212
19.4	CGM Home Screen	214
19.5	My CGM Screen	216

Chapter 20 • CGM Overview

20.1	CGM System Overview	220
20.2	Device Connection Overview	220
20.3	Receiver (t:slim X2 Insulin Pump) Overview	221
20.4	Transmitter Overview	221
20.5	Sensor Overview	222

Chapter 21 • CGM Settings

21.1	About Bluetooth Technology	224
21.2	Disconnecting from the Dexcom Receiver	224

21.3	Setting CGM Volume	224
21.4	CGM Info	227
Chapter 22 • Setting CGM Alerts		
22.1	Setting Your High Glucose Alert and Repeat Feature	230
22.2	Setting Your Low Glucose Alert and Repeat Feature	231
22.3	Rate Alerts	232
22.4	Setting Your Rise Alert	232
22.5	Setting Your Fall Alert	233
22.6	Setting Your Out of Range Alert	233
Chapter 23 • Starting or Stopping a CGM Sensor Session		
23.1	Enter Your Transmitter ID	236
23.2	Start the Sensor	236
23.3	Sensor Startup Period	238
23.4	Automatic Sensor Shut-Off	239
23.5	Ending a Sensor Session Before Automatic Shut-Off	240
23.6	Removing the Sensor and Transmitter	240
Chapter 24 • Calibrating Your CGM System		
24.1	Calibration Overview	242
24.2	Startup Calibration	242
24.3	Calibration BG Value and Correction Bolus	244
24.4	Reasons You May Need to Calibrate	244
Chapter 25 • Viewing CGM Data on Your t:slim X2 Insulin Pump		
25.1	Overview	246
25.2	CGM Trend Graphs	247
25.3	Rate of Change Arrows	248
25.4	CGM History	250

25.5	Missed Readings	250

Chapter 26 • CGM Alerts and Errors

26.1	Startup Calibration Alert	253
26.2	Second Startup Calibration Alert	254
26.3	12 Hour Calibration Alert	255
26.4	Incomplete Calibration	256
26.5	Calibration Timeout	257
26.6	Wait 15 Minute Calibration Error Alert	258
26.7	Calibration Required Alert	259
26.8	CGM High Alert	260
26.9	CGM Low Alert	261
26.10	CGM Fixed Low Alert	262
26.11	CGM Rise Alert	263
26.12	CGM Rapid Rise Alert	264
26.13	CGM Fall Alert	265
26.14	CGM Rapid Fall Alert	266
26.15	Unknown Sensor Glucose Reading	267
26.16	Out of Range Alert	268
26.17	Low Transmitter Battery Alert	269
26.18	Transmitter Error	270
26.19	Failed Sensor Error	271
26.20	CGM Unavailable	272
26.21	CGM System Error	273

Chapter 27 • CGM Troubleshooting

27.1	CGM Pairing Troubleshooting	276
27.2	Calibration Troubleshooting	276
27.3	Unknown Sensor Reading Troubleshooting	276
27.4	Out of Range/No Antenna Troubleshooting	277

27.5	Failed Sensor Troubleshooting	277
27.6	Sensor Inaccuracies	278

Section 4: Control-IQ Technology Features

Chapter 28 • Control-IQ Technology Important Safety Information

28.1	Control-IQ Warnings	282
28.2	Control-IQ Precautions	283

Chapter 29 • Getting to Know Control-IQ Technology

29.1	Responsible Use of Control-IQ Technology	286
29.2	Explanation of Control-IQ Technology Icons	287
29.3	Control-IQ Lock Screen	288
29.4	Control-IQ Home Screen	290
29.5	Control-IQ Screen	292

Chapter 30 • Introduction to Control-IQ Technology

30.1	Control-IQ Technology Overview	296
30.2	How Control-IQ Technology Works	296
30.3	Control-IQ Technology and Activity	305

Chapter 31 • Configuring and Using Control-IQ Technology

31.1	Required Settings	310
31.2	Set Weight	310
31.3	Set Total Daily Insulin	311
31.4	Turn Control-IQ Technology On or Off	311
31.5	Schedule Sleep	311
31.6	Enable or Disable a Sleep Schedule	313
31.7	Manually Start or Stop Sleep	314

31.8	Manually Start or Stop Exercise	314
31.9	Control-IQ Technology Information on Your Screen	315

Chapter 32 • Control-IQ Technology Alerts

32.1	Out of Range Alert – Control-IQ Technology Disabled	319
32.2	Out of Range Alert – Control-IQ Technology Enabled	320
32.3	Control-IQ Technology Low Alert	321
32.4	Control-IQ High Alert	322
32.5	Max Insulin Alert	323

Chapter 33 • Overview of Control-IQ Technology Clinical Studies

33.1	Introduction	326
33.2	Software Version History	327
33.3	The DCLP3 Trial	328
33.4	The DCLP5 Trial	340
33.5	The PEDAP Trial	351
33.6	The PEDAP Extension Phase	361
33.7	The Higher-IQ Trial	370

Section 5: Technical Specifications and Warranty

Chapter 34 • Technical Specifications

34.1	Overview	380
34.2	t:slim X2 Pump Specifications	380
34.3	t:slim X2 Pump Options and Settings	385
34.4	t:slim X2 Pump Performance Characteristics	388
34.5	Electromagnetic Compatibility	393
34.6	Wireless Co-existence and Data Security	393

34.7	t:connect Mobile App Security	394
34.8	Electromagnetic Emissions	395
34.9	Electromagnetic Immunity	396
34.10	Quality of Wireless Service	398
34.11	Wireless Technology	399
34.12	FCC Notice Concerning Interference	400
34.13	Warranty Information	400
34.14	Returned Goods Policy	404
34.15	t:slim X2 Insulin Pump Event Data (Black Box)	404
34.16	Product List	405

Index

406

This Page is Intentionally Left Blank

1 Before You Begin

CHAPTER 1

Introduction

CHAPTER 1 • Introduction

1.1 Conventions of This Guide

The following are conventions used in this user guide (such as terms, icons, text formatting, and other conventions) along with their explanations.

Formatting Conventions

Convention	Explanation
Bolded Text	Text that is in bold in a sentence or step indicates an on-screen icon or physical button name.
Italic Text	Text that is in italics indicates the name of a screen or menu on the pump display.
Numbered Items	Numbered items are step-by-step instructions for how to perform a specific task.
Blue Text	Calls out a reference to a separate user guide location or website link.

Terminology Definitions

Term	Definition
Touchscreen	The front glass screen of your pump, which displays all programming, operating, and alarm/alert information.
Tap	Quickly and lightly touch the screen with your finger.
Press	Use your finger to depress a physical button (the Screen On/Quick Bolus button is the only physical/hardware button on your pump).
Hold	Keep pressing a button or touching an icon or menu until its function is complete.
Menu	A list of options on your touchscreen that allow you to perform specific tasks.
Icon	An image on your touchscreen that indicates an option or item of information, or a symbol on the back of your pump or its packaging.

Symbol Definitions

Symbol	Definition
	Calls out an important note regarding the use or operation of the system.
	Calls out safety precautions which, if ignored, could result in minor or moderate injury.
	Calls out critical safety information which, if ignored, could result in serious injury or death.
	Indicates how the pump responds to the previous instruction.

CHAPTER 1 • Introduction

1.2 Explanation of Symbols

The following are symbols (and their descriptions), which you may find on your pump, pump supplies and/or their packaging. These symbols tell you about the proper and safe use of the pump. Some of these symbols may not be relevant in your region, and are listed for informational purposes only.

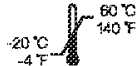
Explanation of t:slim X2 Insulin Pump Symbols

Symbol	Definition
	Caution
	Follow instructions for use
	Consult instructions for use
	For sale by or on the order of a physician only (United States)
	Catalogue number
	Batch code
	International Protection (IP) Code
	Manufacturer

Symbol	Definition
	Type BF Applied Part (patient isolation, not defibrillator protected)
	Non-ionizing Radiation
	Magnetic Resonance (MR) Unsafe; keep away from magnetic resonance imaging (MRI) equipment
	Serial number
	Manufacturer number
	Medical device
	Model number
	Authorized Representative in the European Community

Explanation of t:slim X2 Insulin Pump Symbols (Continued)

Symbol	Definition
	Date of manufacture
	Importer (except United States)
	Direct Current (DC) voltage
	Separate collection for waste electrical and electronic equipment
	Electric Equipment Designed Primarily for Indoor Use
	IEC Class II Equipment
	Use U-100 insulin only
	Wall Power USB Adapter
	Cartridge Removal Tool
	USB Cable

Symbol	Definition
	Indicates the authorized representative in Switzerland
	CE marking of conformity
	Regulatory Compliance Mark
	Humidity limitation
	Temperature limit
	Keep Dry
	Outlet Adapter
	Pump Case
	User Guide

CHAPTER 1 • Introduction

1.3 System Description

The t:slim X2™ insulin pump with Control-IQ™ technology, referred to as the “pump” or the “t:slim X2 pump,” consists of the t:slim X2 insulin pump, the embedded Control-IQ algorithm, and the t:slim X2 3mL (300 units) cartridge. The t:slim X2 pump must be used with a compatible infusion set.

The t:slim X2 pump with Control-IQ technology may be used in combination with a compatible continuous glucose monitor (CGM).

The t:connect™ mobile app can also be used with the System as a method of viewing pump information and limited control of the pump through your smartphone. This functionality is limited to compatible smartphone operating systems and pump software versions.

The Dexcom G6 CGM is compatible with the t:slim X2 insulin pump with Control-IQ technology. The Dexcom G6 transmitter may be referred to as the “transmitter.” The Dexcom G6 sensor may be referred to as the “sensor.” Together, the Dexcom G6 transmitter

and Dexcom G6 sensor may be referred to as the “CGM.”

The pump delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The disposable cartridge is filled with up to 300 units of U-100 insulin and attached to the pump. The cartridge is replaced every 48–72 hours.

The Control-IQ automated insulin dosing feature is an algorithm embedded in the t:slim X2 pump software. This feature enables the t:slim X2 pump to automatically adjust the delivery of insulin based on CGM sensor readings; however, the feature is not a substitute for your own active diabetes management, including giving a bolus for meals. Control-IQ technology utilizes the CGM sensor readings and other data to calculate a predicted glucose value 30 minutes into the future. For more information on how Control-IQ technology is activated, see Chapter 30 Introduction to Control-IQ Technology.

The pump can be used for basal and bolus insulin delivery with or without a CGM. If a CGM is not used, sensor

glucose readings will not be sent to the pump display and you will not be able to use Control-IQ technology.

The sensor is a disposable device that is inserted under the skin to continuously monitor glucose levels. The transmitter connects to the sensor pod and wirelessly sends readings to the pump, which acts as a receiver for the therapeutic CGM, every 5 minutes. The pump shows sensor glucose readings, a trend graph, as well as the direction and rate of change arrows.

The sensor measures glucose in the interstitial fluid under the skin—not in blood, and sensor readings are not identical to readings from a blood glucose (BG) meter.

The t:connect mobile app enables you to connect a smartphone to the pump using *Bluetooth*® wireless technology to display your pump information and perform some pump functions on the smartphone as well as display pump notifications. The t:connect mobile app can transmit pump and therapy data from the pump to the cloud as long as your smartphone is connected to the internet. Download the t:connect

mobile app from Google Play™ or from the App Store® and visit support.tandemdiabetes.com for installation instructions.

NOTE

For an up-to-date list of supported smartphones, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

PRECAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

1.4 About this User Guide

This user guide covers important information on how to operate your System. It provides step-by-step instructions to help you properly program, manage, and care for the System. It also provides important warnings and precautions on proper operation and technical information to ensure your safety.

The user guide is organized into sections. Section 1 provides important

information you need to know before you start using the System. Section 2 covers instructions for using the t:slim X2 pump and using the t:connect mobile app with the pump. Section 3 covers instructions for using CGM with your pump. Section 4 covers instructions for using Control-IQ technology on your pump. Section 5 provides information on the technical specifications of your pump.

The pump screens used in this user guide demonstrate how to use features, and are examples only. They should not be considered suggestions for your individual needs.

For customers in the United States, product information, including electronic versions of the user guide, t:connect Getting Started Guide, t:connect user guides, and a CGM training tutorial, are available at tandemdiabetes.com. Product information for users outside the United States can be provided by your local Tandem distributor.

1.5 Indications for Use

The t:slim X2 insulin pump with interoperable technology (the Pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

The Pump is intended for single patient, home use and requires a prescription.

The Pump is indicated for use in persons two years of age and greater.

Control-IQ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when

CHAPTER 1 • Introduction

the glucose value is predicted to exceed a predefined threshold.

Control-IQ technology is intended for the management of Type 1 diabetes mellitus in persons two years of age and greater.

Control-IQ technology is intended for single patient use and requires a prescription.

1.6 Compatible Insulins

The t:slim X2 insulin pump with Control-IQ technology is designed for use with rapid acting insulin analogs that have been tested and found to be safe for use in the pump:

- NovoLog/NovoRapid U-100 insulin
- Humalog U-100 insulin

NovoLog/NovoRapid is compatible with the system for use up to 72 hours (3 days). Humalog is compatible with the system for use up to 48 hours (2 days).

If you have questions about using other insulins, contact your healthcare provider. Always consult your

healthcare provider and refer to the insulin labeling prior to use.

1.7 Compatible iCGMs

Compatible CGMs include the following iCGMs:

- Dexcom G6 CGM

For information about Dexcom G6 CGM product specifications and performance characteristics, visit the manufacturer's website for applicable product instructions.

The Dexcom G6 sensors and transmitters are sold and shipped separately by Dexcom.

NOTE

The Dexcom G6 CGM currently allows pairing with one medical device at a time (either the t:slim X2 pump or the Dexcom receiver), but you can still use the Dexcom G6 CGM app and your t:slim X2 pump simultaneously using the same transmitter ID.

NOTE

The Mobile Connection setting on your Pump does not relate to the Bluetooth connection

between your CGM and Pump. For connecting a CGM to your Pump, see Section 21.1 About Bluetooth Technology. For connecting your Pump to the t:connect mobile app, see Section 4.3 Connecting to a Smartphone.

NOTE

Product instructions for the Dexcom G6 CGM System includes important information on how to use the Dexcom G6 CGM information (including sensor glucose readings, trend graph, trend arrow, alarm/alerts) to make treatment decisions. Ensure that you have reviewed this information and discussed it with your healthcare provider, who can guide you in correctly using your Dexcom G6 CGM information when making treatment decisions.

1.8 Important User Information

Review all instructions in this user guide before using the System.

If you are not able to use the System according to the instructions in this user guide and other applicable user guides, you may be putting your health and safety at risk.

If you are new to using CGM, continue using your BG meter until you are familiar with CGM usage.

If you are currently using the pump without Dexcom G6 CGM, or if you are currently using Dexcom G6 CGM, it is still very important that you review all instructions in this user guide before using the combined System.

Pay special attention to Warnings and Precautions in this user guide. Warnings and Precautions are identified with a  or  symbol.

If you still have questions after reading this user guide, contact Customer Technical Support 24 hours a day, 7 days a week.

1.9 Important Pediatric User Information

The following recommendations are meant to help younger users and their caregivers program, manage, and care for the System.

Younger children may inadvertently press or tap the pump or the t:connect

mobile app, leading to unintentional delivery of insulin.

It is the responsibility of the healthcare provider and caregiver to determine if the user is appropriate for treatment with this device and the t:connect mobile app.

We recommend reviewing the Quick Bolus and Security PIN capabilities of the pump and determining how they best fit with your care plan. These features are detailed in Chapters 8 Manual Bolus and 5 Getting Started.

Inadvertent dislodgement of the infusion site may occur more frequently with children so consider securing the infusion site and tubing.

WARNING

Control-IQ technology should not be used by people who use less than 5 units of insulin per day and should not be used in patients who weigh less than 20 pounds (9 kilograms), which are the minimum inputs required to initiate Control-IQ technology and for it to operate safely.

WARNING

The t:slim X2 insulin pump with Control-IQ technology should not be used in children under the age of two years old.

WARNING

DO NOT allow small children (either pump users or non-users) to ingest small parts, such as the rubber USB port cover and cartridge components. Small parts could pose a choking hazard. If ingested or swallowed, these small component pieces may cause internal injury or infection.

WARNING

The pump includes parts (such as the USB cable and infusion set tubing) that could pose a strangulation or asphyxiation hazard. Always use the appropriate length of infusion set tubing and arrange cables and tubing to minimize the risk of strangulation. **ENSURE** that these parts are stored in a secure place when not in use.

WARNING

For patients who do not self-manage their disease, the Security PIN function should **ALWAYS** be on when the pump is not being used by a caregiver. The Security PIN function is intended to prevent inadvertent screen taps or button presses that may lead to insulin delivery

CHAPTER 1 • Introduction

or changes in the pump settings. These changes can potentially lead to hypoglycemia (low BG) or hyperglycemia (high BG) events. See Section 5.13 Turn Security PIN On or Off for details on how to turn the Security PIN function on.

⚠ WARNING

For patients whose insulin administration is managed by a caregiver, **ALWAYS** turn off the Quick Bolus feature to avoid inadvertent bolus delivery. If the Security PIN is turned on, the Quick Bolus feature is automatically disabled. Inadvertent screen taps, button presses, or tampering with the insulin pump could result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events. See Section 5.13 Turn Security PIN On or Off for details on how to turn the Security PIN function off.

1.10 Emergency Kit

You should always have an appropriate emergency kit with you. At the very least, this kit should include an insulin syringe and vial of insulin or a prefilled insulin pen as a backup for emergency situations. Talk with your healthcare

provider regarding what items this kit should include.

Some examples of what to include in your everyday emergency kit are:

- BG testing supplies: meter, strips, control solution, lancets, meter batteries
- Fast-acting carbohydrate to treat low BG
- Extra snack for longer coverage than fast-acting carbohydrate
- Glucagon emergency kit
- Rapid-acting insulin and syringes or a prefilled insulin pen and pen needles
- Infusion sets (minimum of 2)
- Insulin pump cartridges (minimum of 2)
- Infusion site preparation products (antiseptic wipes, skin adhesive)
- Diabetes identification card or jewelry

2 t:slim X2 Insulin Pump Features

CHAPTER 2

Important Safety Information

CHAPTER 2 • Important Safety Information

The following includes important safety information related to your t:slim X2™ pump and its components. The information presented in this chapter does not represent all warnings and precautions related to the System. Pay attention to other warnings and precautions listed throughout this user guide as they relate to special circumstances, features, or users.

2.1 t:slim X2 Insulin Pump Warnings

▲ WARNING

DO NOT start to use your pump or the t:connect™ mobile app before reading the user guide. Failure to follow the instructions in this user guide can result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events. If you have questions or need further clarification on your pump use, ask your healthcare provider or call Customer Technical Support.

▲ WARNING

DO NOT start to use your pump before you have been appropriately trained on its use by a certified trainer or through the training materials available online if you are updating your pump.

Consult with your healthcare provider for your individual training needs for the pump. Failure to complete the necessary training on your pump could result in serious injury or death.

▲ WARNING

ONLY use U-100 Humalog or U-100 NovoLog with your pump. Only U-100 Humalog and U-100 NovoLog have been tested and found to be compatible for use in the pump. Use of insulin with greater or lesser concentration can result in an over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT put any other drugs or medications inside your pump cartridge. The pump is designed only for continuous subcutaneous insulin infusion (CSII) using U-100 Humalog or U-100 NovoLog insulin. Use of other drugs or medications can damage the pump and result in injury if infused.

▲ WARNING

DO NOT use manual injections or inhaled insulins while using the pump. Using insulin not provided by the pump can cause the system to over deliver insulin, which can lead to severe hypoglycemia (low BG) events.

▲ WARNING

The pump is not intended for anyone unable or unwilling to:

- » Test blood glucose (BG) levels as recommended by a healthcare provider
- » Demonstrate adequate carbohydrate counting skills
- » Maintain sufficient diabetes self-care skills
- » See healthcare provider(s) regularly

The user must also have adequate vision and/or hearing in order to recognize all functions of the pump, including alerts, alarms, and reminders.

▲ WARNING

DO NOT start to use your pump before consulting with your healthcare provider to determine which features are most appropriate for you. Only your healthcare provider can determine and help you adjust your Basal Rate(s), Carb Ratio(s), Correction Factor(s), Target BG, and duration of insulin action. In addition, only your healthcare provider can determine your CGM settings and how you should use your sensor trend information to help you manage your diabetes. Incorrect settings can result in over delivery or under delivery of

insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

ALWAYS be prepared to inject insulin with an alternative method if delivery is interrupted for any reason. Your pump is designed to deliver insulin reliably, but because it uses only rapid-acting insulin, you will not have long-acting insulin in your body. Failure to have an alternative method of insulin delivery can lead to very high BG or Diabetic Ketoacidosis (DKA).

▲ WARNING

ONLY use cartridges and infusion sets with matching connectors and follow their instructions for use. Failure to do so may result in over delivery or under delivery of insulin and may cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT place your infusion set on any scars, lumps, moles, stretch marks or tattoos. Placing your infusion set in these areas can cause swelling, irritation or infection. This can affect insulin absorption and cause high or low BG.

▲ WARNING

ALWAYS carefully follow the instructions for use accompanying your infusion set for proper insertion and infusion site care, as failure to do so could result in over delivery or under delivery of insulin or infection.

▲ WARNING

NEVER fill your tubing while your infusion set is connected to your body. Always ensure that the infusion set is disconnected from your body before filling the tubing. Failure to disconnect your infusion set from your body before filling the tubing can result in over delivery of insulin. This can cause hypoglycemia (low BG) events.

▲ WARNING

NEVER reuse cartridges or use cartridges other than those manufactured by Tandem Diabetes Care. Use of cartridges not manufactured by Tandem Diabetes Care or reuse of cartridges may result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

ALWAYS twist the tubing connector between the cartridge tubing and the infusion set tubing an extra quarter of a turn to ensure a secure connection. A loose connection can cause

insulin to leak, resulting in under delivery of insulin. If the connection comes loose, disconnect the infusion set from your body before tightening. This can cause hyperglycemia (high BG).

▲ WARNING

DO NOT disconnect the tubing connector between the cartridge tubing and the infusion set tubing. If the connection comes loose, disconnect the infusion set from your body before tightening. Failure to disconnect before tightening can result in over delivery of insulin. This can cause hypoglycemia (low BG).

▲ WARNING

DO NOT remove or add insulin from a filled cartridge after loading onto the pump. This will result in an inaccurate display of the insulin level on the *Home* screen and you could run out of insulin before the pump detects an empty cartridge. This can cause very high BG, or Diabetic Ketoacidosis (DKA).

▲ WARNING

DO NOT deliver a bolus until you have reviewed the calculated bolus amount. If you deliver an insulin amount that is too high or too low, this could cause hypoglycemia (low BG) or hyperglycemia (high BG) events. You can always

CHAPTER 2 • Important Safety Information

adjust the insulin units up or down before you decide to deliver your bolus.

▲ WARNING

ALWAYS use the USB cable provided with your t:slim X2 insulin pump to minimize the risk of fires or burns.

▲ WARNING

DO NOT allow small children (either pump users or non-users) to ingest small parts, such as the rubber USB port cover and cartridge components. Small parts could pose a choking hazard. If ingested or swallowed, these small component pieces may cause internal injury or infection.

▲ WARNING

The pump includes parts (such as the USB cable and infusion set tubing) that could pose a strangulation or asphyxiation hazard. **ALWAYS** use the appropriate length of infusion set tubing and arrange cables and tubing to minimize the risk of strangulation. **ENSURE** that these parts are stored in a secure place when not in use.

▲ WARNING

For patients who do not self-manage their disease, the Security PIN function should **ALWAYS** be on when the pump is not being

used by a caregiver. The Security PIN function is intended to prevent inadvertent screen taps or button presses that may lead to insulin delivery or changes in the pump settings. These changes can potentially lead to hypoglycemic or hyperglycemic events.

▲ WARNING

For patients whose insulin administration is managed by a caregiver, **ALWAYS** turn off the Quick Bolus feature to avoid inadvertent bolus delivery. If the Security PIN is turned on, the Quick Bolus feature is automatically disabled. Inadvertent screen taps, button presses, or tampering with the insulin pump could result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT change your infusion set before bedtime or if you will not be able to test your BG 1–2 hours after the new infusion set is placed. It is important to confirm that the infusion set is inserted correctly and delivering insulin. It is also important to respond quickly to any problems with the insertion to ensure continued insulin delivery.

▲ WARNING

Use of accessories, cables, adapters, and chargers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

▲ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches to any part of the t:slim X2 pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

▲ WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

▲ WARNING

Some skin care products such as lotions, sunscreens, and insect repellents can cause cracks in the plastic used to manufacture the pump and cartridge. **DO NOT** allow these

products to come in contact with the pump or cartridge. **ALWAYS** remove your pump before applying these products and **ALWAYS** wash your hands before handling your pump or cartridge after using such products. **ALWAYS** change your cartridge if it becomes exposed to such products and immediately clean your pump. Failure to do so may result in damage to the pump and cartridge and in some cases over or under delivery of insulin.

2.2 Magnetic Resonance Imaging Safety

▲ WARNING

The System is magnetic resonance (MR) unsafe. You must take off your pump, transmitter, and sensor and leave them outside the procedure room.

2.3 Radiology and Medical Procedures and Your t:connect X2 System

Please review your smartphone manufacturer's instructions before using the t:connect mobile app during any of the procedures listed below.

▲ WARNING

ALWAYS notify the provider/technician about your diabetes and your pump. If you need to discontinue use of the pump for medical procedures, follow your healthcare provider's instructions to replace missed insulin when you reconnect to the pump. Check your BG before disconnecting from the pump and again when you reconnect and treat high BG levels as recommended by your healthcare provider.

▲ WARNING

DO NOT expose your pump, transmitter, or sensor to:

- » X-ray
- » Computed Tomography (CT) scan
- » Positron Emission Tomography (PET) scan
- » Other exposure to radiation

▲ WARNING

There is no need to disconnect for electrocardiograms (EKGs) or colonoscopies. If you have questions, contact Customer Technical Support.

▲ WARNING

DO NOT use the pump if you have a condition which, in the opinion of your healthcare

provider, would put you at risk. Examples of individuals who should not use the pump include those with uncontrolled thyroid disease, renal failure (e.g. dialysis or eGFR <30), hemophilia, or another major bleeding disorder, or unstable cardiovascular disease.

▲ WARNING

DO NOT expose your pump, transmitter, or sensor to:

- » Pacemaker/Automatic Implantable Cardioverter Defibrillator (AICD) placement or reprogramming
- » Cardiac Catheterization
- » Nuclear Stress Test

You must take off your pump, transmitter, and sensor and leave them outside the procedure room if you are going to have any of the above medical procedures.

▲ WARNING

There are other procedures where you should proceed with caution:

- » **Laser Surgery** – Your System can usually be worn during the procedure. However, some lasers can create

CHAPTER 2 • Important Safety Information

interference and cause the System to alarm.

- » **General Anesthesia** – Depending on the equipment being used, you may or may not need to remove your System. Be sure to ask your healthcare provider.

2.4 t:connect Mobile App Warnings

⚠ WARNING

DO NOT start to use the bolus feature of the t:connect mobile app before you have been appropriately trained on its use. Failure to follow the instructions in this user guide and in-app help on the bolus feature of the t:connect mobile app could result in delay of therapy. If the information displayed to you in your t:connect mobile app does not match your signs and symptoms, **ALWAYS** refer to the t:slim X2 insulin pump before making any treatment decisions.

⚠ WARNING

DO NOT use a smartphone that has been jailbroken or rooted, or with Android developer mode on. Data may become vulnerable if you install the t:connect mobile app on a smartphone that has been jailbroken or rooted, or uses an unreleased or pre-released operating

system. Only download the t:connect mobile app on Google Play™ or from the App Store®. See Chapter 4 Getting to Know Your t:connect Mobile App for t:connect mobile app installation.

⚠ WARNING

Any time you request any bolus, you have 10 seconds to cancel the bolus after requesting it to completely avoid insulin delivery. Both the pump and the t:connect mobile app will say “requesting bolus” during this time as long as your pump and the t:connect mobile app are connected. You can cancel the bolus from either the pump or the app regardless of how you requested it.

⚠ WARNING

ALWAYS rely on your pump to make therapy decisions when using a smartphone that is incompatible with the Bolus Delivery feature.

⚠ WARNING

Use of accessories, cables, adapters, and chargers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches to any part of the t:slim X2 pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

2.5 t:slim X2 Insulin Pump Precautions

⚠ PRECAUTION

DO NOT open or attempt to repair your insulin pump. The pump is a sealed device that should be opened and repaired only by Tandem Diabetes Care. Modification could result in a safety hazard. If your pump seal is broken, the pump is no longer watertight and the warranty is voided.

⚠ PRECAUTION

CHANGE your infusion set every 48 hours if using Humalog insulin; every 72 hours if using NovoLog insulin. Wash your hands with anti-bacterial soap before handling the infusion set and thoroughly clean the insertion site on your body to avoid infection. Contact your healthcare provider if you have symptoms of infection at your insulin infusion site.

⚠ PRECAUTION

ALWAYS remove all air bubbles from the pump before beginning insulin delivery. Ensure there are no air bubbles when drawing insulin into the filling syringe, hold the pump with the white fill port pointed up when filling the tubing, and ensure that there are no air bubbles in the tubing when filling. Air in the cartridge and tubing takes space where insulin should be and can affect insulin delivery.

⚠ PRECAUTION

CHECK your infusion site daily for proper placement and leaks. **REPLACE** your infusion set if you notice leaks around the site. Improperly placed sites or leaks around the infusion site can result in under delivery of insulin.

⚠ PRECAUTION

CHECK your infusion set tubing daily for any leaks, air bubbles, or kinks. Air in the tubing, leaks in the tubing, or kinked tubing may restrict or stop insulin delivery and result in under delivery of insulin.

⚠ PRECAUTION

CHECK the tubing connection between your cartridge tubing and infusion set tubing daily to ensure it is tight and secure. Leaks around the

tubing connection can result in under delivery of insulin.

⚠ PRECAUTION

ALWAYS check that your cartridge has enough insulin to last through the night before going to bed. If you are sleeping, you could fail to hear the Empty Cartridge Alarm and miss part of your basal insulin delivery.

⚠ PRECAUTION

CHECK your pump's personal settings regularly to ensure they are correct. Incorrect settings can result in over delivery or under delivery of insulin. Consult with your healthcare provider as needed.

⚠ PRECAUTION

ALWAYS make sure that the correct time and date are set on your insulin pump. Not having the correct time and date setting may affect safe insulin delivery. When editing time, always check that the AM/PM setting is accurate, if applicable. AM is to be used from midnight until 11:59 AM. PM is to be used from noon until 11:59 PM.

⚠ PRECAUTION

CONFIRM that the screen display turns on, you can hear audible beeps, feel the pump vibrate,

and see the green LED light blinking around the edge of the **Screen On/Quick Bolus** button when you connect a power source to the USB port. These features are used to notify you about alerts, alarms, and other conditions that require your attention. If these features are not working, discontinue use of the pump and contact Customer Technical Support.

⚠ PRECAUTION

CHECK your pump regularly for potential alarm conditions that may display. It is important to be aware of conditions that may affect insulin delivery and require your attention so you can respond as soon as possible.

⚠ PRECAUTION

DO NOT use the vibrate feature for alerts and alarms during sleep unless otherwise directed by your healthcare provider. Having the volume for alerts and alarms set to high will help ensure that you don't miss an alert or alarm.

⚠ PRECAUTION

ALWAYS look at the screen to confirm correct programming of the bolus amount when you first use the Quick Bolus feature. Looking at the screen will ensure that you are correctly using the beep/vibration commands to program the intended bolus amount.

CHAPTER 2 • Important Safety Information

⚠ PRECAUTION

DO NOT use your pump if you think it might be damaged due to dropping it or hitting it against a hard surface. Check that the pump is working properly by plugging a power source into the USB port and confirming that the display turns on, you hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the **Screen On/Quick Bolus** button. If you are unsure about potential damage, discontinue use of the pump and contact Customer Technical Support.

⚠ PRECAUTION

AVOID exposure of your pump to temperatures below 41°F (5°C) or above 99°F (37°C). Insulin can freeze at low temperatures or degrade at high temperatures. Insulin that has been exposed to conditions outside of the manufacturer's recommended ranges can affect the safety and performance of the pump.

⚠ PRECAUTION

AVOID submerging your pump in fluid beyond a depth of 3 feet (0.91 m) or for more than 30 minutes (IP27 rating). If your pump has been exposed to fluid beyond these limits, check for any signs of fluid entry. If there are signs of fluid entry, discontinue use of the pump and contact Customer Technical Support.

⚠ PRECAUTION

AVOID areas where there may be flammable anesthetics or explosive gases. The pump is not suitable for use in these areas and there is a risk of explosion. Remove your pump if you need to enter these areas.

⚠ PRECAUTION

MAKE SURE to not move further than the length of the USB cable when you are connected to the pump and to a charging source. Moving further than the length of the USB cable may cause the cannula to be pulled out of the infusion site. For this reason it is recommended not to charge the pump while sleeping.

⚠ PRECAUTION

DISCONNECT your infusion set from your body while on high-speed/high gravity amusement park thrill rides. Rapid changes in altitude or gravity can affect insulin delivery and cause injury.

⚠ PRECAUTION

DISCONNECT your infusion set from your body before flying in an aircraft without cabin pressurization or in planes used for aerobatics or combat simulation (pressurized or not). Rapid changes in altitude or gravity can affect insulin delivery and cause injury.

⚠ PRECAUTION

CONSULT your healthcare provider about lifestyle changes such as weight gain or loss, and starting or stopping exercise. Your insulin needs may change in response to lifestyle changes. Your Basal Rate(s) and other settings may need adjustment.

⚠ PRECAUTION

CHECK your BG using a BG meter following a gradual elevation change of up to each 1,000 feet (305 meters), such as when snow skiing or driving on a mountain road. Delivery accuracy can vary up to 15% until 3 units of total insulin have been delivered or elevation has changed by more than 1,000 feet (305 meters). Changes in delivery accuracy can affect insulin delivery and cause injury.

⚠ PRECAUTION

ALWAYS check with your healthcare provider for specific guidelines if you want or need to disconnect from the pump for any reason. Depending on the length of time and reason you are disconnecting, you may need to replace missed basal and/or bolus insulin. Check your BG before disconnecting from the pump and again when you reconnect, and treat high BG levels as recommended by your healthcare provider.

⚠ PRECAUTION

ENSURE that your personal insulin delivery settings are programmed into the pump before use if you receive a warranty replacement pump. Failure to enter your insulin delivery settings could result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events. Consult your healthcare provider as needed.

⚠ PRECAUTION

ALWAYS dispose of used components such as cartridges, syringes, needles, infusion sets, and CGM sensors following local regulations. Needles should be disposed in an appropriate sharps container. Do not attempt to recap needles. Wash your hands thoroughly after handling used components.

⚠ PRECAUTION

If you choose to use a pump case or other accessories not provided by Tandem, **DO NOT** cover the six vent holes on the back of the pump. Covering the vent holes could affect insulin delivery.

2.6 t:connect Mobile App Precautions**⚠ PRECAUTION**

ALWAYS turn Zoom Mode off when using the t:connect mobile app. If your smartphone has Zoom Mode turned on, you should rely on your pump for all therapy decisions.

⚠ PRECAUTION

If you start a manual bolus request on the pump, you must complete it on the pump. You cannot request a bolus from the t:connect mobile app while a bolus request is active on the pump.

⚠ PRECAUTION

Pump notifications cannot be cleared from your t:connect mobile app. Pump Alerts, Alarms, and Notifications can be viewed on your smartphone, but must be cleared on the t:slim X2 pump.

⚠ PRECAUTION

The t:connect mobile app receives data from the connected pump via a secure Bluetooth wireless technology connection. If the Bluetooth connection between the pump and the t:connect mobile app is lost, the t:connect mobile app will not display current insulin pump information and

cannot be used to request a bolus. To help maintain the wireless connection between the insulin pump and the t:connect mobile app, it is recommended the smartphone running the t:connect mobile app is within five feet of the compatible insulin pump.

⚠ PRECAUTION

ALWAYS ensure your pump has established a Bluetooth wireless connection with your smartphone before you use the t:connect mobile app. Confirm that the information displayed to you matches your signs and symptoms.

⚠ PRECAUTION

Use of the t:connect mobile app together with your insulin pump may impact the battery life of your pump due to the wireless data transmission between the devices.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. If you close or force stop your t:connect mobile app, it will not be running in the background.

CHAPTER 2 • Important Safety Information

⚠ PRECAUTION

DO NOT ignore symptoms of high and low glucose. If your t:connect mobile app readings do not match your symptoms, check your pump display and confirm that your pump has established a Bluetooth connection with your smartphone.

⚠ PRECAUTION

ALWAYS rely on your pump for therapy decisions if:

- » Your smartphone is incompatible with the Bolus Delivery feature of the t:connect mobile app
- » Your smartphone is lost or damaged
- » Your smartphone loses Bluetooth connectivity with your pump

⚠ PRECAUTION

DO NOT update your smartphone operating system prior to confirming that it is compatible with the Bolus Delivery plus Display and Data Upload feature of the t:connect mobile app. If you update to an incompatible operating system version, you will lose the ability to request, stop, or cancel a bolus from the t:connect mobile app.

⚠ PRECAUTION

DISCONTINUE use of the t:connect mobile app if your smartphone is damaged, or if a significant portion of its display is damaged or does not illuminate.

⚠ PRECAUTION

The t:connect mobile app is not intended to replace self-monitoring practices as advised by a physician.

⚠ PRECAUTION

The t:connect mobile app is not intended for use by anyone unable to use a smartphone proficiently. Users must have adequate vision and/or hearing in order to use the t:connect mobile app.

⚠ PRECAUTION

Use of mobile devices not complying with either IEC 60950-1, IEC 62368-1, or an equivalent standard may increase the risk of electrical hazards.

Supported mobile devices and the charging equipment provided by their manufacturers are compliant with appropriate electrical safety standards (IEC 60950-1, IEC 62368-1, or equivalent). For more information on supported devices, please visit

tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

2.7 Tandem Cybersecurity Preventative Measures

Medical devices, like other computer systems, can be vulnerable to cybersecurity risks, potentially impacting the safety and effectiveness of the device. Incorrect use of the t:slim X2 insulin pump or your failure to follow the instructions, precautions, and warnings in this user guide may result in an inoperable pump or expose your t:slim X2 insulin pump to cybersecurity risks.

- Keep your pump, smartphone, and t:connect mobile app in your control or on your person at all times.
- Always disconnect your pump from the computer and USB cable when not using it to upload pump data or perform software updates with the Tandem Device Updater.
- Do not share your pump's serial number or t:connect mobile app

pairing code with any untrusted individual. Do not write these numbers down anywhere they can be accessed by an untrusted individual.

- Do not connect to or allow any third-party devices to pair with your pump that are not included as part of the Tandem system. See 1.3 System Description for a full system description.
- Do not use any software or third-party applications which have not been authorized by Tandem as being safe for use with your pump.
- Only attempt to perform software updates using the authorized Tandem Device Updater.

Contact Tandem's Customer Technical Support if you suspect your pump may have been compromised by any cybersecurity interference or vulnerability.

2.8 Potential Benefits From Using Your Pump

- The pump provides an automated way to deliver basal and bolus insulin. Delivery can be fine-tuned based on up to six customizable Personal Profiles, each with up to 16 time-based settings for Basal Rate, Carb Ratio, Correction Factor, and Target BG. In addition, the temp rate feature allows you to program a temporary Basal Rate change for up to 72 hours.
- The pump gives you the option of delivering a bolus all at once, or delivering a percentage over an extended period of time without navigating to different menus. You can also program a bolus more discreetly using the Quick Bolus feature, which can be used without looking at the pump, and can be programmed in increments of either units of insulin or grams of carbohydrate.
- From the *Bolus* screen, the “calculator within a calculator” feature allows you to enter multiple

carbohydrate values and add them together. The insulin pump's bolus calculator will recommend a bolus based on the entire amount of carbohydrates entered, which can help eliminate guesswork.

- The pump keeps track of the amount of active insulin from food and correction boluses (IOB). When programming additional food or correction boluses, the pump will subtract the amount of IOB from the recommended bolus if your BG is below the target set in your active Personal Profile. This can help prevent insulin stacking, which can lead to hypoglycemia (low BG).
- You can program a number of reminders that will prompt you to retest your BG after a low or high BG is entered, as well as a “Missed Meal Bolus Reminder” which will alert you if a bolus isn't entered during a specified period of time. If activated, these can help reduce the likelihood that you will forget to check your BG or bolus for meals.
- You have the ability to view a variety of data right on your screen,

CHAPTER 2 • Important Safety Information

including the time and amount of your last bolus, your total insulin delivery by day, as well as broken into basal, food bolus, and correction bolus.

2.9 Possible Risks From Using Your Pump

As with any medical device, there are risks associated with using your pump. Many of the risks are common to insulin therapy in general, but there are additional risks associated with continuous insulin infusion and continuous glucose monitoring. Reading your user guide and following the instructions for use are critical for the safe operation of your System. Consult your healthcare provider about how these risks may impact you.

Inserting and wearing an infusion set might cause infection, bleeding, pain or skin irritations (redness, swelling, bruising, itching, scarring, or skin discoloration).

There is a remote chance that an infusion set cannula fragment could remain under your skin if the cannula

breaks while you are wearing it. If you think a cannula has broken under your skin, contact your healthcare provider and call Customer Technical Support.

Other risks associated with infusion sets include occlusions and air bubbles in the tubing or dislodged cannula, which can affect insulin delivery. If your BG does not decrease after initiating a bolus, or you have other unexplained high BG, it is recommended that you check your infusion set for an occlusion or air bubbles, and verify that the cannula has not dislodged. If the condition persists, call Customer Technical Support or seek medical attention as required.

Risks that could result from pump failure include the following:

- possible hypoglycemia (low BG) from over-delivery of insulin due to a hardware defect or software anomaly.
- hyperglycemia (high BG) and ketosis possibly leading to Diabetic Ketoacidosis (DKA) due to pump failure resulting in cessation of insulin delivery due to either a

hardware defect, software anomaly, or infusion set failure. Having a backup method of insulin delivery greatly reduces your risk of severe hyperglycemia or DKA.

2.10 Working with your Healthcare Provider

Any clinical language presented in this user guide is based on the assumption that you have been educated by your healthcare provider on certain terms and how they apply to you in your diabetes management. Your healthcare provider can help you establish diabetes management guidelines that best fit your lifestyle and needs.

Consult your healthcare provider before using the pump to determine which features are most appropriate for you. Only your healthcare provider can determine and help you adjust your Basal Rate(s), insulin-to-carbohydrate ratio(s), Correction Factor(s), Target BG, and duration of insulin action. In addition, only your healthcare provider can determine your CGM settings and how you should use your sensor trend

information to help you manage your diabetes.

2.1.1 Verification of Proper Functionality

Pump Functionality

A power supply (AC adapter with micro-USB connector) is provided with your pump. Before using your pump, ensure that the following occur when you connect a power supply into the USB port of your pump:

- You hear an audible alert
- You see the green light illuminate from the edge around the **Screen On/Quick Bolus** button
- You feel a vibratory alert
- You see a charge symbol (lightning bolt) on the battery level indicator

In addition, before using your pump, ensure the following:

- Press the **Screen On/Quick Bolus** button to turn the screen on so that you can see the display

- When the display screen is on, the touchscreen responds to your finger tap

PRECAUTION

CONFIRM that the pump screen display turns on, you can hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the **Screen On/Quick Bolus** button when you connect a power source to the USB port. These features are used to notify you about alerts, alarms, and other conditions that require your attention. If these features are not working, discontinue use of your pump and contact Customer Technical Support.

t:connect Mobile App Functionality

Before using the t:connect mobile app, when you connect a smartphone to your pump, ensure the data displayed on your t:connect mobile app matches the data displayed on your pump screen.

PRECAUTION

ALWAYS ensure your pump has established a Bluetooth wireless connection with your smartphone before you use the t:connect mobile app. Confirm that the information displayed to you matches your signs and symptoms.

This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 3

Getting to Know Your t:slim X2 Insulin Pump

CHAPTER 3 • Getting to Know Your t:slim X2 Insulin Pump

3.1 What your t:slim X2 Pump Package Includes

Your pump package should include the following items:

1. t:slim X2™ insulin pump
2. pump case
3. t:slim X2 Insulin Pump with Control-IQ™ Technology User Guide
4. USB cable
5. wall power USB adapter
6. cartridge removal tool

If any of these items are missing, contact your local customer support.

If you use a CGM, the Dexcom G6 sensors and transmitters are sold and shipped separately.

Your pump is shipped with a clear screen protector. Do not remove the screen protector.

Your pump comes with a protective cover in the place where the cartridge is normally inserted. This cover must be removed and replaced with a cartridge prior to initiating insulin delivery.

The t:slim X2 3 mL cartridge with t:lock™ connector consists of the reservoir chamber and a micro-delivery chamber for the delivery of very small amounts of insulin. A variety of compatible infusion sets with the t:lock connector are available from Tandem Diabetes Care, Inc. The t:lock connector allows a secure connection between the cartridge and the infusion set. Use only t:slim X2 cartridges and compatible infusion sets with t:lock connectors manufactured for Tandem Diabetes Care, Inc.

Your pump also includes consumable components that may require replacement during the life of your pump, including:

- pump case(s)/clip(s)
- screen protector
- USB rubber door
- USB cable

Supply Reordering

To order cartridges, infusion sets, supplies, accessories, screen protectors, please contact your local customer support or your usual supplier of diabetes products.

3.2 Pump Terminology**Basal**

Basal is a slow continuous delivery of insulin, which keeps glucose levels stable between meals and during sleep. It is measured in units per hour (units/hr).

BG

BG is the abbreviation for blood glucose, which is the level of glucose in the blood, measured in mg/dL.

BG Target

BG target is a specific BG or glucose value goal, an exact number, not a range. When a glucose value is entered in the pump, the calculated insulin bolus will be adjusted up or down as needed to attain this target.

Bolus

A bolus is a quick dose of insulin that is usually delivered to cover food eaten or correct high glucose. With the pump it can be delivered as a Standard, a Correction, an Extended, or a Quick Bolus.

Cannula

The cannula is the part of the infusion set that is inserted under the skin through which insulin is delivered.

Carb

Carb or Carbohydrate refers to sugars and starches that the body breaks down into glucose and uses as an energy source, measured in grams.

Carb Ratio

The carb ratio is the number of grams of carbohydrate that 1 unit of insulin will cover. Also known as insulin-to-carbohydrate ratio.

Correction Bolus

A correction bolus is given to correct high glucose.

Correction Factor

A correction factor is the amount of glucose that is lowered by 1 unit of

insulin. Also known as the Insulin Sensitivity Factor (ISF).

Extended Bolus

An extended bolus is a bolus that is delivered over a period of time. It is commonly used to cover food that takes longer to digest. When administering an extended bolus with your pump, enter the DELIVER NOW portion to dose a percentage of insulin immediately and the remaining percentage over a period time.

Grams

Grams are the measurement for a carbohydrate.

Insulin Duration

Insulin duration is the amount of time that insulin is active and available in the body after a bolus has been delivered. This also relates to the calculation for Insulin on Board (IOB).

Insulin On Board (IOB)

IOB is the insulin that is still active (has the ability to continue to lower the glucose) in the body after a bolus has been delivered.

Load

Load refers to the process of removing, filling, and replacing a new cartridge and infusion set.

Personal Profile

A personal profile is a personalized group of settings that defines the delivery of basal and bolus insulin within specific time segments throughout a 24 hour period.

Quick Bolus

Quick bolus (using the **Screen On/Quick Bolus** button) is a way to deliver a bolus by following beep/vibration commands without navigating through or viewing the pump screen.

Temp Rate

Temp rate is an abbreviation for a temporary basal rate. It is used to increase or decrease the current basal rate for a short period of time to accommodate special situations. 100% is the same basal rate as programmed. 120% means 20% more and 80% means 20% less than the programmed basal rate.

CHAPTER 3 • Getting to Know Your t:slim X2 Insulin Pump

Units

Units are the measurement for insulin.

USB Cable

USB is the abbreviation for Universal Serial Bus. The USB cable connects into the pump's micro USB port.

WARNING

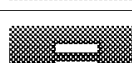
ALWAYS use the USB cable provided with your t:slim X2 insulin pump to minimize the risk of fires or burns.

3.3 Explanation of Insulin X2 Insulin Pump Icons

The following icons may appear on your pump screen:

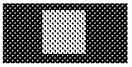
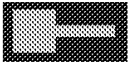
Pump Icon Definitions

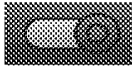
Symbol	Definition
	The amount of charge left in the pump battery.
	A system reminder, alert, error, or alarm is active.
	All insulin deliveries are stopped.
	Basal insulin is programmed and being delivered.
	Bluetooth wireless technology
	Accept. Tap to continue to the next screen or to answer yes to a message on the pump screen.
	Save. Tap to save settings on the screen.
	Delete. Tap to delete characters or digits on a keypad.
	New. Tap to add a new item.

Symbol	Definition
	The amount of insulin remaining in the cartridge.
	A temporary basal rate is active.
	A basal rate of 0 u/hr is active.
	A temporary basal rate of 0 u/hr is active.
	A bolus is being delivered.
	Cancel. Tap to cancel the current operation.
	Decline. Tap to exit the screen or answer no to a message on the pump screen.
	Back. Tap to navigate to the previous screen.
	Total. Tap to total values on a keypad.

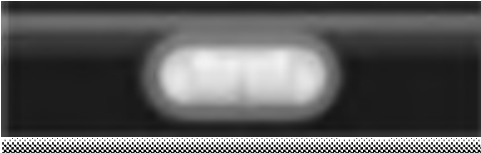
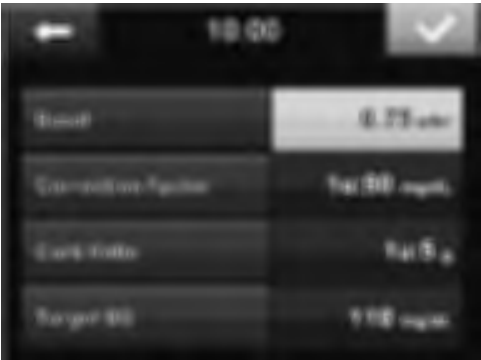
CHAPTER 3 • Getting to Know Your Insulin Pump

Pump Icon Definitions (Continued)

Symbol	Definition
	Space. Tap to enter a space on the character keypad.
	OK. Tap to confirm the current instruction or setting on the screen.
	A food and/or correction bolus was delivered. This icon only appears when a CGM sensor session is active.
	An extended bolus was delivered. The square represents the DELIVER NOW portion of the bolus, and the line represents the DELIVERY LATER portion of the bolus. This icon only appears when a CGM sensor session is active.

Symbol	Definition
	Security PIN has been enabled. See Section 5.13 Turn Security PIN On or Off.
	The associated setting is turned on.
	The associated setting is turned off.

3.4 Explanation of Pump Colors

	Red LED 1 red blink every 30 seconds indicates a malfunction or alarm condition.
	Yellow LED 1 yellow blink every 30 seconds indicates an alert or reminder condition.
	Green LED • 1 green blink every 30 seconds indicates the pump is functioning normally. • 3 green blinks every 30 seconds indicate the pump is charging.
	Orange Highlight When editing settings, changes are highlighted in orange for review before saving.

CHAPTER 3 • Getting to Know Your t:slim X2 Insulin Pump

3.5 Pump Back Side

1. **t:slim X2 Cartridge:** A single-use disposable cartridge can hold up to 300 units (3.0 mL) of insulin.
2. **Vent Holes:** Vent holes help the pump function correctly. It is important that these vents remain uncovered.

PRECAUTION

If you choose to use a pump case or other accessories not provided by Tandem, **DO NOT** cover the six vent holes on the back of the pump. Covering the vent holes could affect insulin delivery.



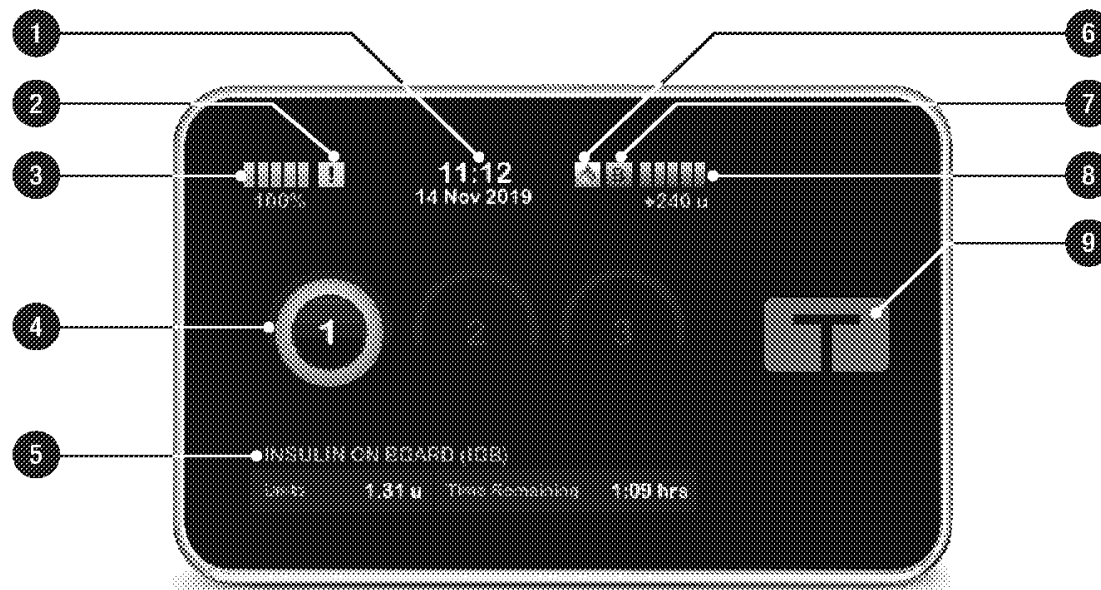
CHAPTER 3 • Getting to Know Your Tandem T2 Insulin Pump

3.6 Lock Screen

The *Lock* screen appears anytime you turn on the screen. You must tap 1–2–3 in sequential order to unlock the pump.

1. **Time and Date Display:** Displays the current time and date.
2. **Alert Icon:** Indicates a reminder, alert or alarm is active behind the *Lock* screen.
3. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
4. **1–2–3:** Unlocks pump screen.
5. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.
6. **Active Bolus Icon:** Indicates a bolus is active.
7. **Status:** Displays current system settings and insulin delivery status.
8. **Insulin Level:** Displays the current amount of insulin in the cartridge.
9. **Tandem Logo:** Returns to the *Home* screen.

CHAPTER 3 • Getting to Know Your tulin X2 Insulin Pump

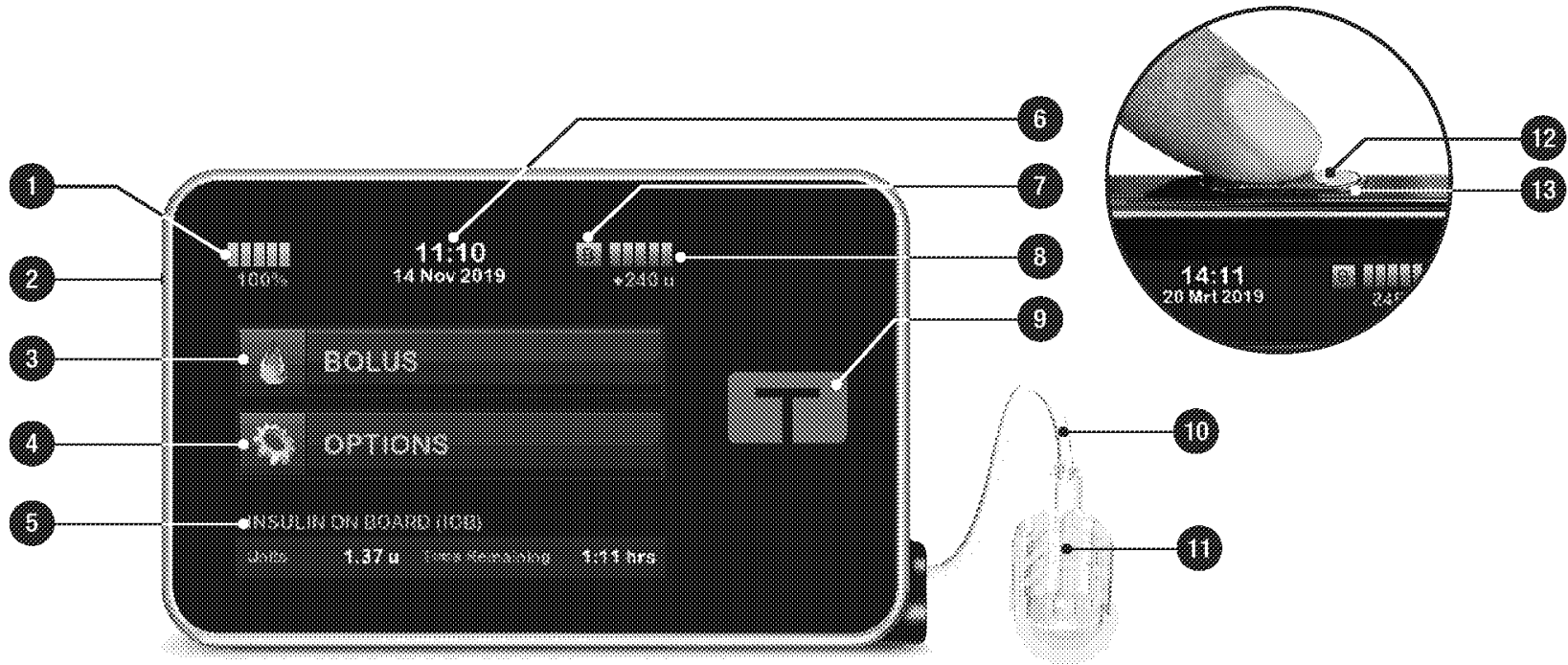


CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.7 Home Screen

1. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
2. **USB Port:** Port to charge your pump battery. Close the cover when not in use.
3. **Bolus:** Program and deliver a bolus.
4. **Options:** Stop/Resume insulin delivery, manage pump and CGM settings, start/stop activities, load a cartridge, and view history.
5. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.
6. **Time and Date Display:** Displays the current time and date.
7. **Status:** Displays current system settings and insulin delivery status.
8. **Insulin Level:** Displays the current amount of insulin in the cartridge.
9. **Tandem Logo:** Returns to the *Home* screen.
10. **Cartridge Tubing:** Tubing that is attached to the cartridge.
11. **Tubing Connector:** Connects the cartridge tubing to the infusion set tubing.
12. **Screen On/Quick Bolus button:** Turns the pump screen on/off or programs a Quick Bolus (if activated).
13. **LED Indicator:** Illuminates when connected to a power supply and indicates proper functionality.

CHAPTER 3 • Getting to Know Your tulin X2 Insulin Pump



CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.8 Current Status Screen

The *Current Status* screen can be accessed from the *Lock* screen and the *Home* screen by tapping the insulin level symbol. It is for display only; no changes can be made from this screen.

1. : Returns to the *Home* screen.
2. **Profile**: Displays current active Personal Profile.
3. **Basal Rate**: Displays current basal rate being delivered in units/hr. If a temp rate is active, this row will change to display current temp rate being delivered in units/hr.
4. **Last Bolus**: Displays amount, date and time of last bolus.
5. **Control-IQ Status**: Displays Control-IQ technology status.
6. **Up/Down Arrow**: Indicates there is more information.
7. **Correction Factor**: Displays current correction factor used to calculate a bolus.
8. **Carb Ratio**: Displays current carb ratio used to calculate a bolus.
9. **Target BG**: Displays current BG target used to calculate a bolus.
10. **Insulin Duration**: Displays current insulin duration setting used to calculate insulin on board.
11. **Last Calibration**: Displays date and time of last calibration.
12. **Time Sensor Started**: Displays date and time of last time sensor started.
13. **Transmitter Battery**: Displays CGM transmitter battery status.
14. **Mobile Connection**: Displays whether the mobile connection is turned on or off, whether a smartphone is paired with the pump, and if so whether the smartphone is actively connected to the pump.

CHAPTER 3 • Getting to Know Your tslim X2 Insulin Pump



CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.9 Bolus Screen

The Bolus screen will default to use units of insulin in calculating a bolus. You may change this setting in your Personal Profile to use grams of carbohydrate instead. Both screens are shown on the next page as examples.

1. : Returns to the *Home* screen.
2. **Insulin:** Enter units of insulin. You may change this setting to use grams of carb. See Section 6.2 Creating a New Profile for details on how to set the Increment Type.
3. **Units:** Displays total units calculated. Tap to enter a bolus request or change (override) a calculated bolus.
4. **View Calculation:** Displays how the insulin dose was calculated using the current settings.
5. **Glucose:** Enter BG or sensor glucose level. This value is populated automatically if each of the following conditions are true:

- Control-IQ technology is turned on and available
- A CGM session is active
- A CGM value is present
- A CGM trend arrow is available on the *CGM Home* screen

NOTE

For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's product instructions. You can also see Section 25.3 Rate of Change Arrows.

You can choose to use this value or enter another value from an alternate testing method.

6. : Moves to next step.
7. **Carbs:** Enter grams of carbohydrate. You may change this setting to use units of insulin. See Section 6.2 Creating a New Profile for details on how to set the Increment Type.

Using Units



Using Grams

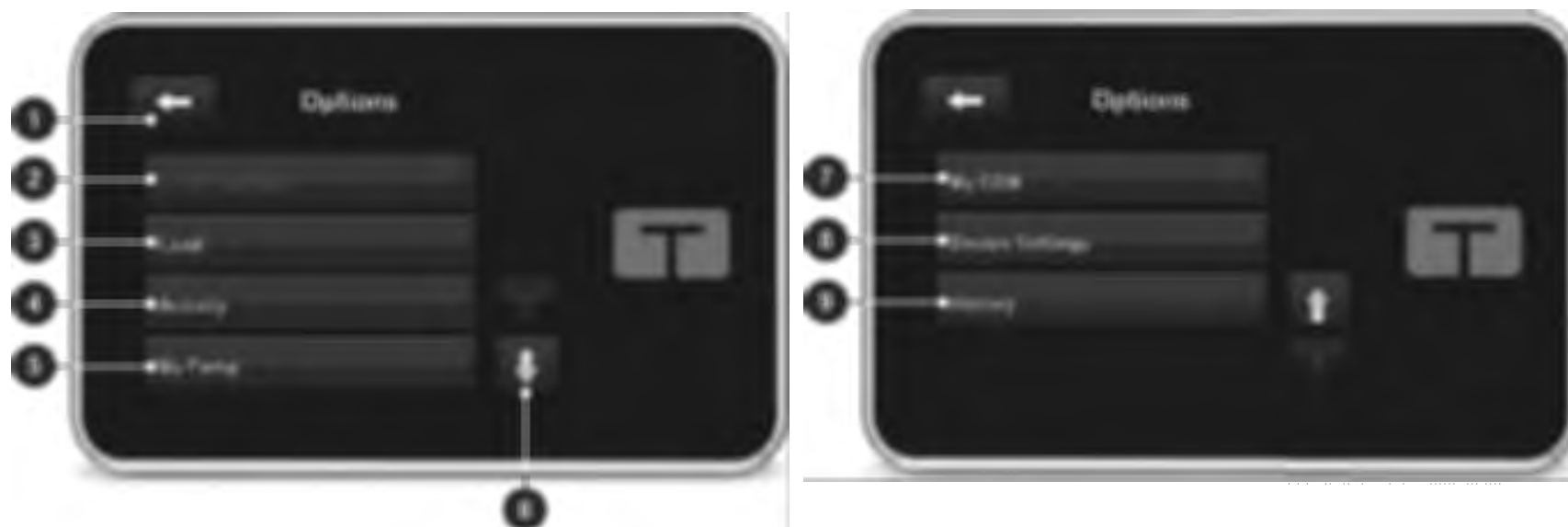


CHAPTER 3 • Getting to Know Your Insulin X2 Insulin Pump

3.10 Options Screen

1. : Returns to the *Home* screen.
2. **Stop Insulin:** Stops insulin delivery. If insulin delivery is stopped, RESUME INSULIN will be displayed.
3. **Load:** Change Cartridge, Fill Tubing, Fill Cannula, and Site Reminder.
4. **Activity:** Programs on Exercise, Sleep, and temporary Basal Rates.
5. **My Pump:** Personal Profiles, Control-IQ, Alerts & Reminders, and Pump Info.
6. **Up/Down Arrow:** Indicates there is more information.
7. **My CGM:** Start/Stop Sensor, Calibrate CGM, CGM Alerts, Transmitter ID, and CGM Info.
8. **Device Settings:** Display settings, Bluetooth settings, Time and Date, Sound Volume, and Security PIN.
9. **History:** Displays historical log of pump and CGM events.

CHAPTER 3 • Getting to Know Your tslim X2 Insulin Pump



CHAPTER 3 • Getting to Know Your Insulin X2 Insulin Pump

3.11 My Pump Screen

1. : Returns to the *Options* screen.
2. **Personal Profiles:** A group of settings that define basal and bolus delivery.
3. **Control-IQ:** Turn on/off Control-IQ technology and enter required values.
4. **Alerts & Reminders:** Customize Pump Reminders and Pump Alerts.
5. **Pump Info:** Displays pump serial number, local customer support service contact information website, and other technical information.



CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.12 Device Settings Screen

1. : Returns to the *Options* screen.
2. **Display Settings:** Customize the Screen Timeout settings.
3. **Bluetooth Settings:** Turn on/off mobile connection.
4. **Time and Date:** Edit the time and date that will be displayed on the pump.
5. **Sound Volume:** Customize the sound volume for pump alarms, pump alerts, reminders, keypad, bolus, quick bolus, fill tubing, and CGM alerts.
6. **Security PIN:** Turn on/off the Security PIN.

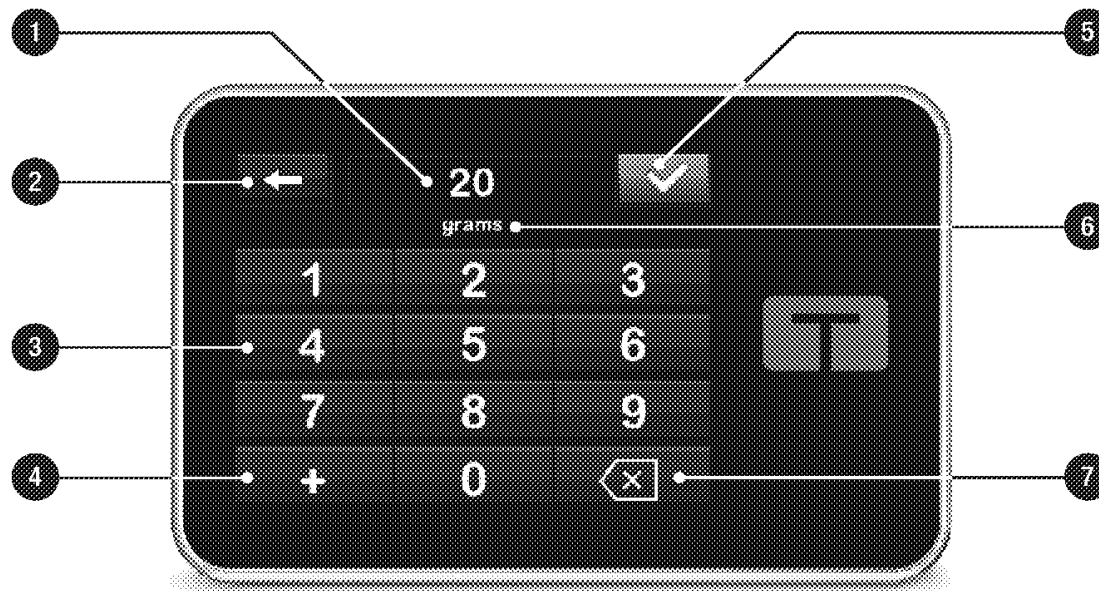
CHAPTER 3 • Getting to Know Your tslim X2 Insulin Pump



CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.13 Number Keypad Screen

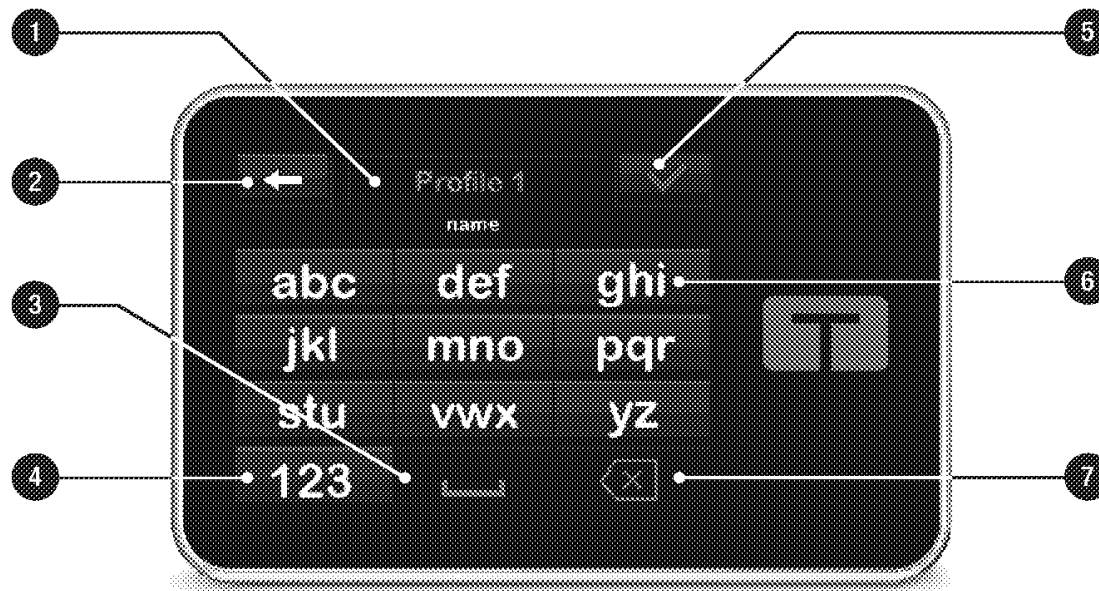
1. **Value Entered.**
2. : Returns to previous screen.
3. **Keypad Numbers.**
4. : Allows numbers to be added on the gram screen. If in units, this displays as a decimal point.
5. : Completes task and saves information entered.
6. **Units/Grams:** Unit of measure associated with the value entered.
7. : Deletes last number entered.



CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.14 Letter Keypad Screen

1. **Name of Profile.**
2. : Returns to previous screen.
3. : Enters a space.
4. **123:** Changes keypad mode from letters (ABC) to numbers (123).
5. : Saves entered information.
6. **Letters:** Tap once for first letter displayed, 2 quick taps for middle letter, and 3 quick taps for third letter.
7. : Deletes last letter or number entered.



This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 4

Getting to Know Your t:connect Mobile App

CHAPTER 4 • Getting to Know Your t:connect Mobile App

4.1 Overview

The t:connect™ mobile app is a companion app for the t:slim X2™ insulin pump. Before you begin, ensure your smartphone and the t:connect mobile app are compatible, and turn off smartphone automatic operating system (OS) updates. The feature set available within the t:connect mobile app is dependent on your pump software version as well as your smartphone model and operating system. Available feature sets are:

- **Display and Data Upload:** This feature set provides a secondary display of your pump and continuous glucose monitoring (CGM) information, including display of your pump alerts and alarms, and enables wireless uploading of pump and CGM data to the Tandem cloud.
- **Bolus Delivery plus Display and Data Upload:** In addition to the Display and Data Upload features, the bolus delivery feature allows you to use the t:connect mobile app to

request a bolus, stop a bolus, and cancel a bolus.

To download the t:connect mobile app, go to Google Play™ or the App Store®. For installation instructions, visit support.tandemdiabetes.com.

NOTE

For an up-to-date list of supported smartphones, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

For more information on the setup and configuration of your smartphone to work with the t:connect mobile app, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

In certain situations, the features of the t:connect mobile app may be restricted, including when using an incompatible smartphone or pump.

⚠ WARNING

ALWAYS rely on your pump to make therapy decisions when using a smartphone that is incompatible with the Bolus Delivery feature.

⚠ PRECAUTION

ALWAYS rely on your pump for therapy decisions when:

- » Your smartphone is incompatible with the Bolus Delivery feature of the t:connect mobile app
- » Your smartphone is lost or damaged
- » Your smartphone loses Bluetooth connectivity with your pump

⚠ PRECAUTION

Pump notifications cannot be cleared from your t:connect mobile app. Pump Alerts, Alarms, and Notifications can be viewed on your smartphone, but must be cleared on the t:slim X2 pump.

⚠ PRECAUTION

DO NOT update your smartphone operating system prior to confirming that it is compatible with the Bolus Delivery plus Display and Data Upload feature of the t:connect mobile app. If you update to an incompatible operating system

version, you will lose the ability to request or control a bolus from the t:connect mobile app.

⚠ PRECAUTION

Discontinue use of the t:connect mobile app if your smartphone is damaged, or if a significant portion of its display is damaged or does not illuminate.

4.2 Install the t:connect Mobile App

⚠ WARNING

DO NOT use a smartphone that has been jailbroken or rooted, or with Android developer mode on. Data may become vulnerable if you install the t:connect mobile app on a smartphone that has been jailbroken or rooted, or uses an unreleased or pre-released operating system. Only download the t:connect mobile app on Google Play™ or from the App Store®.

⚠ PRECAUTION

ALWAYS turn Zoom Mode off when using the t:connect mobile app. If your smartphone has Zoom Mode turned on, you should rely on your pump for all therapy decisions.

Supported mobile devices are compliant with appropriate electrical

safety standards (IEC 60950-1, IEC 62368-1, or equivalent).

⚠ PRECAUTION

Use of mobile devices not complying with either IEC 60950-1, IEC 62368-1, or an equivalent standard may increase the risk of electrical hazards.

Supported mobile devices and the charging equipment provided by their manufacturers are compliant with appropriate electrical safety standards (IEC 60950-1, IEC 62368-1, or equivalent). For more information on supported devices, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

■ NOTE

The t:connect mobile app must run in the background in order to receive and transmit data to and from your pump, as well as to the Tandem cloud. When you connect the t:connect mobile app to the pump, you must disable battery optimization on your smartphone to ensure the t:connect mobile app can receive alerts and alarms. It is recommended to follow your smartphone manufacturer's instructions for charging.

Enable smartphone security (e.g., screen lock, passcode, face recognition) before using the t:connect mobile app to administer a bolus. Never share your security PIN/password or authorize any other person to access your smartphone via their biometric information to avoid unintentional changes in your delivery of insulin.

After you download the t:connect mobile app, locate it on your smartphone and open it. The sign-in screen appears.

- You should allow all permission requests from the t:connect mobile app to ensure you receive all notifications from your pump. (See Section 4.4 Set Mobile Notifications to configure your notification settings.)
- For Android users, to use Bluetooth, the t:connect mobile app may ask for access to your device location; tap **Allow**.

If you have an existing t:connect account, log in using your username and password.

CHAPTER 4 • Getting to Know Your t:connect Mobile App

If you are a new user:

1. Tap **Get Started**.
2. Enter your account information, including name, account type, and login information.

NOTE

For personal accounts, you must be at least 13 years old in accordance with the Children's Online Privacy Protection Act (COPPA), which prohibits collecting information from people under the age of 13 without parental consent. If you are taking care of or acting on behalf of someone younger than 13, select a parent, guardian, or caretaker account.

3. The *Your glucose targets and limits* screen appears. You can set your High Glucose value, your Target Glucose Range values, and your Low Glucose value for display on your reports. The ADA-recommended values are 181, 70-180, and 69 respectively.

NOTE

We encourage you to discuss these values with your healthcare provider before setting

them. You can leave the fields blank during account set-up and enter them later. Setting or changing these values will not change any settings in the pump itself.

Update the t:connect Mobile App

When updates to the t:connect mobile app are available, do not uninstall the app. When you download and install an

update, your t:connect mobile app will still be connected to your t:connect account, the smartphone will still be paired with your pump, and your app settings will remain the same.

If you uninstall the t:connect mobile app, when you re-install the t:connect mobile app, you will be asked to log in using your credentials. Once you are logged in, your t:connect mobile app settings will be restored from the last time you synchronized with the Tandem cloud.

Updating Your Smartphone

Before you manually update your phone operating system, confirm that the t:connect mobile app is compatible with the new operating system. For more information about managing automatic updates, tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

⚠ PRECAUTION

DO NOT update your smartphone operating system prior to confirming that it is compatible with the Bolus Delivery plus Display and Data Upload feature of the t:connect mobile app. If you update to an incompatible operating system

version, you will lose the ability to request or control a bolus from the t:connect mobile app. For more information, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

4.3 Connecting to a Smartphone

You can connect one compatible smartphone to the pump to display pump information and perform some pump functions on that smartphone using the t:connect mobile app.

NOTE

This Mobile Connection setting is not related to your CGM Bluetooth connection. For CGM Bluetooth information, see Section 21.1 About Bluetooth Technology.

When you connect the t:connect mobile app to the pump, you must disable battery optimization on your smartphone to ensure the t:connect mobile app can receive alerts and alarms. It is recommended to follow your smartphone manufacturer's instructions for charging.

NOTE

For more information on the setup and configuration of your smartphone to work with the t:connect mobile app, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

Pair a Smartphone

NOTE

Always use the t:connect mobile app to pair your pump with your smartphone. Do not attempt to use your smartphone's Bluetooth menu.

NOTE

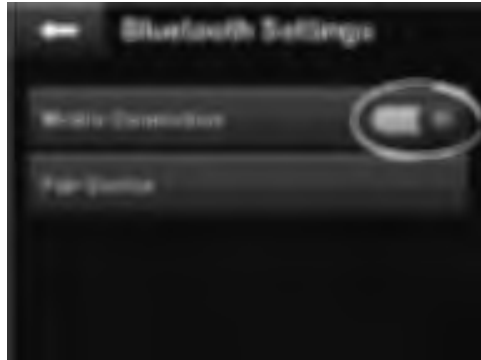
We strongly suggest that you upload pump data to the t:connect web application using the USB cable provided with your pump before you complete the pairing process to ensure all your pump data is uploaded as quickly as possible to the Tandem cloud. The first time you upload data to the Tandem cloud could take many hours over a slow internet connection on your smartphone.

Pair the t:connect mobile app with your pump as follows:

1. From your smartphone, open the t:connect mobile app.
 - » If you have an existing t:connect account, log in using your credentials.
 - » If you are a new user, create an account as shown in Section 4.1 Overview.
- ✓ The t:connect mobile app will prompt you to begin the pairing process.
2. From your pump's *Home* screen:
 - a. Tap **OPTIONS**.
 - b. Tap the **Down Arrow**.
 - c. Tap **Device Settings**.
 - d. Tap **Bluetooth Settings**.
 - e. Tap the on/off toggle next to **Mobile Connection** and tap .

CHAPTER 4 • Getting to Know Your t:connect Mobile App

to confirm. **Pair Device** is now displayed.



3. From the t:connect mobile app on your smartphone:
 - a. Tap **Begin** in the t:connect mobile app. A confirmation prompt will appear.
 - b. Choose the appropriate pump serial number on the *Select your pump* screen and tap **Next**.

NOTE

If you don't know your pump serial number, check your *Pump Info* screen as shown in Section 10.1 t:slim X2 Pump Info.

4. From your pump's *Bluetooth Settings* screen, tap **Pair Device**.
5. Your pump will display a *Mobile App notification* screen. Tap  to generate your device pairing code.

- ✓ Your pump will display a unique pairing code.

NOTE

The code is case sensitive and is only valid for 5 minutes - if more than 5 minutes have passed, tap **Pair Device** again to generate a new code.

NOTE

DO NOT tap **OK** on your pump. Tapping **OK** before completing pairing will cancel the pairing process.

6. From your smartphone, enter the pairing code generated in Step 5 into the t:connect mobile app and tap **Pair with pump**.
- ✓ Your pump will display a confirmation screen.

7. From your smartphone, tap **Sync pump data** in the t:connect mobile app to proceed with your normal pump use. The t:connect mobile app will display your dashboard and begin displaying pump data.

NOTE

If your smartphone does not pair with your pump, check your smartphone's Bluetooth settings, then retry steps 1 - 7. Note that if your smartphone asks you to allow it to communicate with an external device, you should accept.

8. From your pump, tap  to close the *PAIRING CODE* screen. If the pump has successfully paired with your smartphone, the *DEVICE PAIRED* screen is displayed.

Your t:connect mobile app will remain synchronized with your pump as long as a Bluetooth connection is established. The t:connect mobile app uploads your pump's data into the Tandem cloud approximately once per hour whenever it is connected to wi-fi or cellular data, depending on your data use settings. This allows you and your healthcare provider easy access to your

data via the t:connect web application without requiring access to your pump or connection cables.

PRECAUTION

ALWAYS ensure your pump has established a Bluetooth wireless connection with your smartphone before you use the t:connect mobile app. Confirm that the information displayed to you matches your signs and symptoms.

Unpair a Smartphone

You can disconnect a smartphone from a pump:

- If you replace your smartphone, you must unpair your previously paired smartphone from your pump before you can pair your new smartphone.
- If you replace your pump, you must unpair your old pump from your smartphone before you can pair your new pump.

Unpair a smartphone from your pump as follows:

1. From the t:connect mobile app:
 - a. Tap **Settings** on the *Navigation* bar.

- b. Tap **Paired Pump**.
- c. Tap **Unpair pump**. A confirmation prompt will appear.
- d. Tap **Unpair**. The t:connect mobile app displays a banner confirming that your pump has been unpaired and returns you to the pairing screen.

2. From your pump's *Home* screen, disable your pump's Mobile Connection toggle:
 - a. Tap **Options**.
 - b. Tap **Device Settings**.
 - c. Tap **Bluetooth Settings**.
 - d. Tap the on/off toggle next to Mobile Connection and tap  to confirm. **Pair Device** will disappear.
3. From your smartphone, remove your pump from your smartphone's Bluetooth device list.

If your pump is malfunctioning, or you otherwise don't have access to your pump (e.g., the pump has been lost or returned to Tandem), use your t:connect mobile app to unpair your smartphone from your pump as follows:

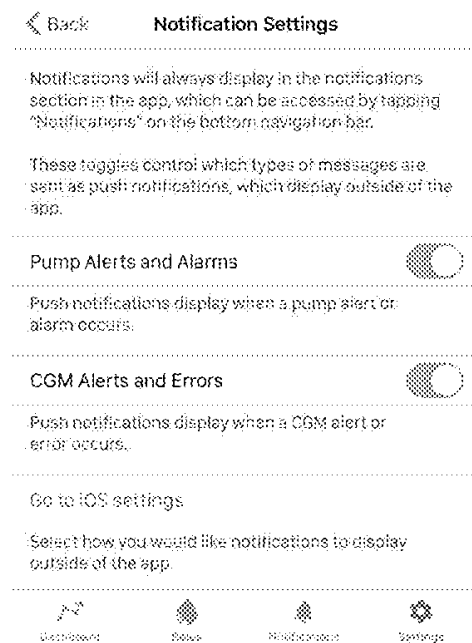
1. Tap **Settings** on the *Navigation* bar.
2. Tap **Paired Pump**.
3. Tap **Unpair pump**. A confirmation prompt will appear.
4. Tap **Unpair**. The t:connect mobile app displays a banner confirming that your pump has been unpaired and returns you to the pairing screen.

Once you have unpaired your smartphone from your pump, you can pair a different combination of smartphone and pump as described in *Pair a Smartphone*.

CHAPTER 4 • Getting to Know Your t:connect Mobile App

4.4 Set Mobile Notifications

The t:connect mobile app can display notifications generated by your pump or sent from the Tandem cloud, including pump alerts, alarms, and reminders. Tap **Settings** on the *Navigation* bar, then tap **Notification Settings** to toggle push notifications as desired. The following example shows possible push notification settings.



To ensure you receive notifications on the t:connect mobile app, confirm the smartphone sound mode is not set to mute, and enable the following settings:

- t:connect mobile app notifications
- Bluetooth

Check your smartphone settings to ensure your t:connect mobile app can connect to the internet.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. For more information, see Section 4.3 *Connecting to a Smartphone*, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

📌 NOTE

Check your smartphone's operating system push notification settings as well as those in the t:connect mobile app to ensure your pump and CGM alerts and alarms are set to your preference.

4.5 Mobile Connection Security

Only one smartphone and t:connect mobile app may pair with your pump. When pairing your pump to a t:connect mobile app, a unique code will be generated and used to secure communications between the pump and smartphone. All transmissions between the pump and smartphone are encrypted. The pump is designed to deny any unauthorized or unrecognized connections.

The pump is designed to check the integrity of all commands and data received from the t:connect mobile app. If the pump receives unexpected commands or data from the t:connect mobile app, the pump will ignore it and continue to operate as intended.

4.6 Lost Pump Connection

When your smartphone is more than five feet from the pump or experiencing Bluetooth connection issues, the t:connect mobile app will not display pump data until you restore the connection between your smartphone and the pump.

⚠ PRECAUTION

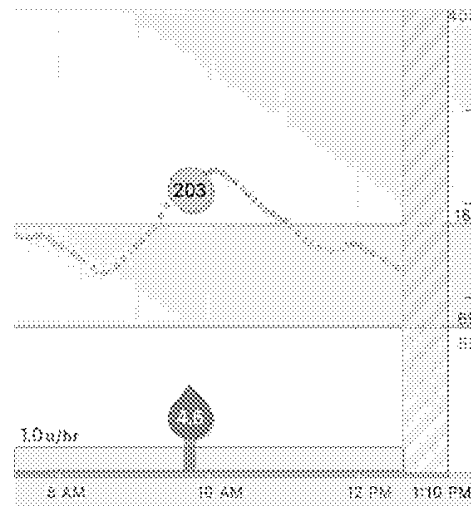
ALWAYS ensure your pump has established a Bluetooth wireless connection with your smartphone before you use the t:connect mobile app. Confirm that the information displayed to you matches your signs and symptoms.

The *Pump Connection Lost* notification banner replaces the current pump

status until you re-establish the Bluetooth connection.



Pump connection lost 30 min ago
You can use your pump until the connection is restored. Turn on Bluetooth in your phone's settings.

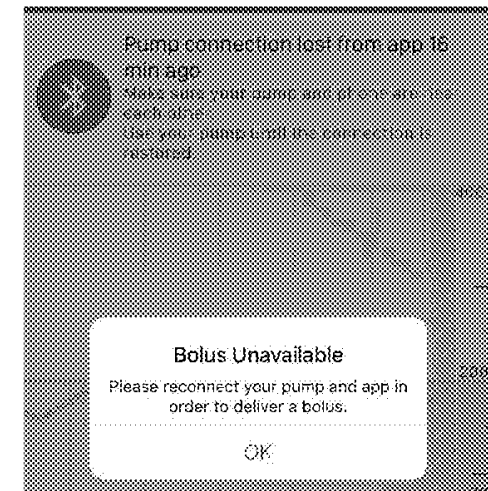


You will also see a gray shaded area on the graph since no data can be displayed when the connection is lost. When the connection is lost, use the pump to administer therapy while troubleshooting the loss of connection.

⚠ PRECAUTION

DO NOT ignore symptoms of high and low glucose. If your t:connect mobile app readings do not match your symptoms, check your pump display and confirm that your pump has established a Bluetooth connection with your smartphone.

If your smartphone and the pump are not connected, tapping **Bolus** on the navigation bar generates a *Bolus Unavailable* alert as shown in the following example.



CHAPTER 4 • Getting to Know Your t:connect Mobile App

Reconnect Bluetooth

When you see the *Pump Connection Lost* notification banner:

- Make sure that your pump and smartphone are within five feet of one another and without any obstruction between the two (including body parts).
- Confirm that Bluetooth technology is enabled on your smartphone.

If the connection is not restored within five minutes, reset the connection between your smartphone and your pump:

1. Force quit or close the t:connect mobile app.
2. Open the t:connect mobile app.
3. If your connection is lost again, disable your smartphone's Bluetooth connection.
4. Enable your smartphone's Bluetooth connection.

5. If your connection is lost again, sign out of your t:connect account.
6. Pair your smartphone with your pump as described in Section 4.3 *Connecting to a Smartphone*.

If the connection is lost again, discontinue use of the t:connect mobile app and contact Customer Technical Support.

4.7 Restart the t:connect Mobile App

If you have persistent issues with the t:connect mobile app, force stop or close the t:connect mobile app to end the current session.

For iOS devices:

1. Double-tap the Home button, or swipe up from the bottom of the screen and hold.
2. Find the t:connect mobile app and swipe up to close.
3. Reopen the t:connect mobile app.

For Android devices:

1. Open your smartphone's Settings menu.
2. Open your smartphone's application manager.
3. Tap **t:connect**. You may need to scroll down your list of applications to locate it among your apps.
4. Tap **Force Stop**.
5. Reopen the t:connect mobile app.

⚠ PRECAUTION

ALWAYS keep your t:connect mobile app running in the background so that pump alerts, alarms, and notifications can be displayed on your smartphone. These notifications are only received when the t:connect mobile app is either active or open in the background. If you close or force stop your t:connect mobile app, it will not be running in the background.

If the issue persists, try re-pairing the pump:

1. From the t:connect mobile app, tap **Settings**.

2. Tap Paired Pump.
3. Tap Unpair Pump.
4. Repeat the pairing process as shown in Section 4.3 Connecting to a Smartphone.

CHAPTER 4 • Getting to Know Your t:connect Mobile App

4.8 t:connect Mobile App Dashboard

1. **Pump Battery Level:** Displays the level of pump battery power remaining. When the pump is connected for charging, the charging icon (lightning bolt) will display.
2. **Most Recent 5-Minute Glucose Reading and Trend Arrow.**
3. **BG Entry:** Your BG value at the moment you entered it into your bolus calculator.
4. **Graph of Most Recent Glucose Readings:** Displays CGM sensor readings for the last 24 hours. You may swipe left and right to see all 24-hours in the graph. This graph also includes blood glucose (BG) readings entered into the bolus calculator.
5. **Delivered Bolus:** The amount of bolus insulin actually delivered for a given bolus event.
6. **Delivered Basal:** The amount of insulin delivered as basal for the past 24-hour period. This includes changes in insulin delivery related to use of Control-IQ™ technology.
7. **Status:** Displays current system settings and insulin delivery status. Swipe up to scroll down in the t:connect mobile app and see complete Status information.
8. **Navigation Bar:** Displays icons representing each mobile app page. The icon for the active t:connect mobile app page is highlighted blue.
9. **Insulin Level:** Displays the current amount of insulin in the cartridge. You can also tap the Insulin Level icon to automatically scroll down and see complete Status information.
10. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.
11. **Dashboard:** Displays pump status bar, current glucose reading, IOB status, CGM graph, time in range information, and current status.
12. **Bolus:** Navigate to the *Bolus* screen to program and deliver a bolus (only available with compatible devices).
13. **Notifications:** Displays active pump alerts, alarms, reminders, and malfunctions. See Section 4.4 Set Mobile Notifications for more information.
14. **Settings:** Navigate to the settings screen, including Glucose Thresholds for Display, App Notification Settings, Data Control settings, Tandem account information, pump pairing and unpairing, About, and Help.

CHAPTER 4 • Getting to Know Your t:connect Mobile App



CHAPTER 4 • Getting to Know Your t:connect Mobile App

4.9 t:connect Mobile App Bolus Screen

1. **Cancel:** Exit the *Bolus* screen and return to the Dashboard.
2. **Units:** Displays total units calculated. Tap to enter a bolus request or change (override) a calculated bolus.
3. **Insulin:** Enter units of insulin. You may change this setting on the pump to use grams of carbohydrate. See Section 8.9 Quick Bolus for more information.
4. **Delivery Calculation:** The amount of bolus insulin actually delivered for a given bolus event, including a breakdown of calculated Correction bolus, input Food bolus, and Insulin On Board (IOB) automatically.
5. **Next:** Accept changes input on the Bolus screen and proceed to the Bolus confirmation screen.
6. **Glucose:** Enter BG or sensor glucose level. This value is

populated automatically if each of the following are true:

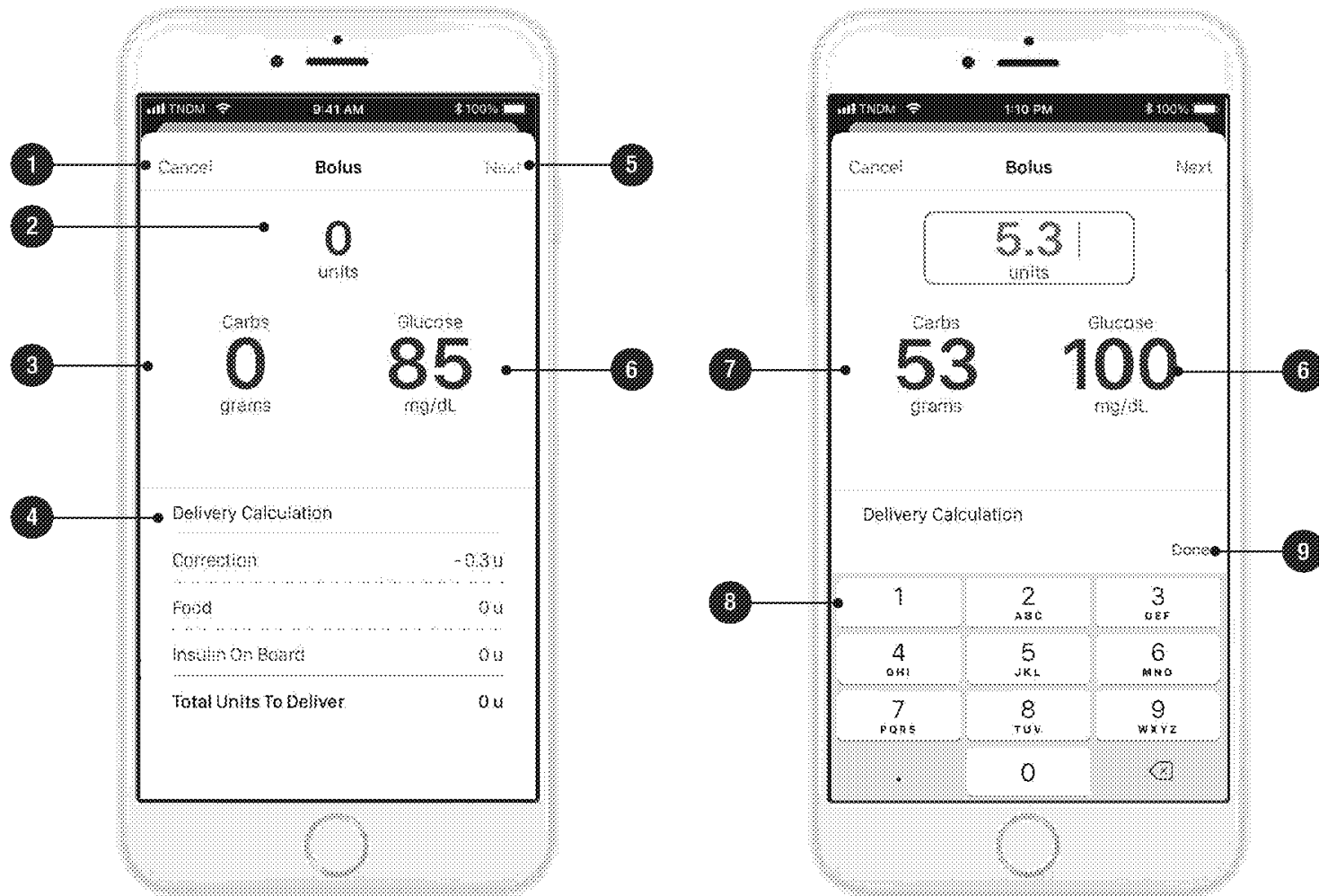
- Control-IQ technology is turned on and available
- A CGM session is active
- A CGM value is present
- A CGM trend arrow is available on the CGM Home screen

 NOTE

For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's user guide. You can also see Section 25.3 Rate of Change Arrows.

7. **Carbs:** Enter grams of carbohydrate. You may change this setting on the pump to use units of insulin. See Section 8.9 Quick Bolus for more information.
8. **Keypad Numbers.**
9. **Done:** Completes task and saves information entered.

CHAPTER 4 • Getting to Know Your t:connect Mobile App



CHAPTER 4 • Getting to Know Your t:connect Mobile App

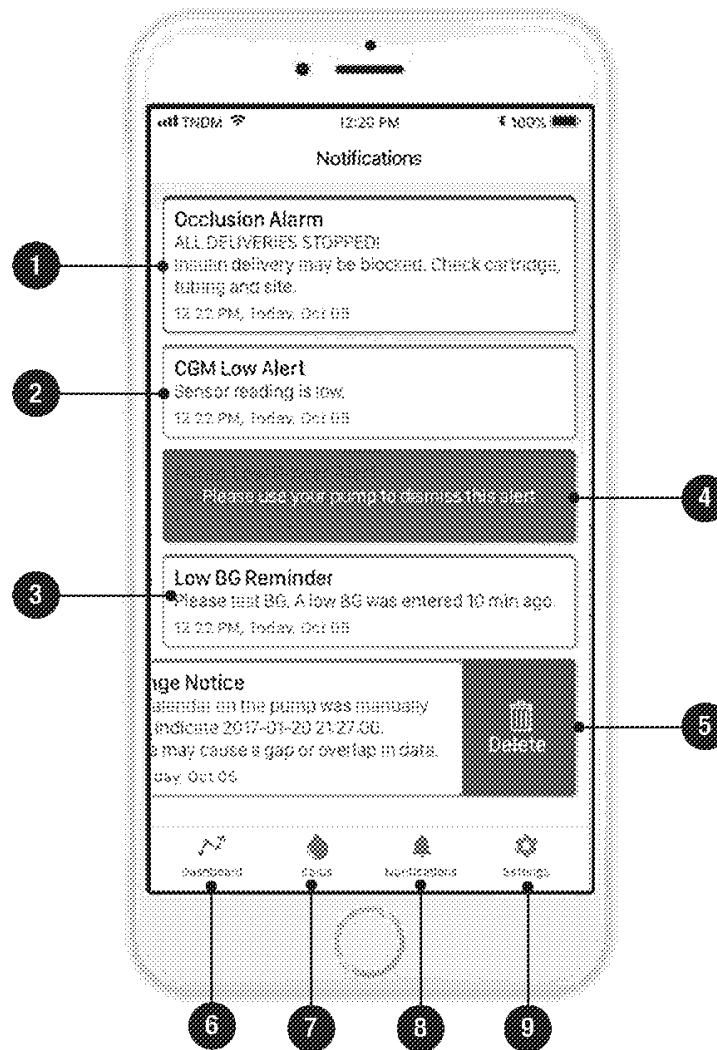
4.18 t:connect Mobile App
Notifications Screen

⚠ PRECAUTION

Pump notifications cannot be cleared from your t:connect mobile app. Pump Alerts, Alarms, and Notifications can be viewed on your smartphone, but must be cleared on the t:slim X2 pump.

1. **Alarm:** Displays a pump alarm. Alarms are outlined in red in the t:connect mobile app.
2. **Alert:** Displays a pump alert. Alerts are outlined in yellow in the t:connect mobile app.
3. **Reminder:** Displays a pump reminder. Reminders are outlined in blue in the t:connect mobile app.
4. **Dismiss:** Appears if you slide an alert notification (yellow outline) with your finger to the left. Tap this icon to dismiss the alert.
5. **Delete:** Appears if you slide a reminder or informational notification (blue outline) with your finger to the left. Tap this icon to delete the reminder or informational message.
6. **Dashboard:** Displays pump status bar, current glucose reading, IOB status, CGM graph, time in range information, and current status.
7. **Bolus:** Navigate to the *Bolus* screen to program and deliver a bolus (only available with compatible devices).
8. **Notifications:** Displays active pump alerts, alarms, reminders, and malfunctions. See Section 4.4 Set Mobile Notifications for more information.
9. **Settings:** Navigate to the settings screen, including Glucose Thresholds for Display, App Notification Settings, Data Control settings, Tandem account information, pump pairing and unpairing, About, and Help.

CHAPTER 4 • Getting to Know Your t:connect Mobile App

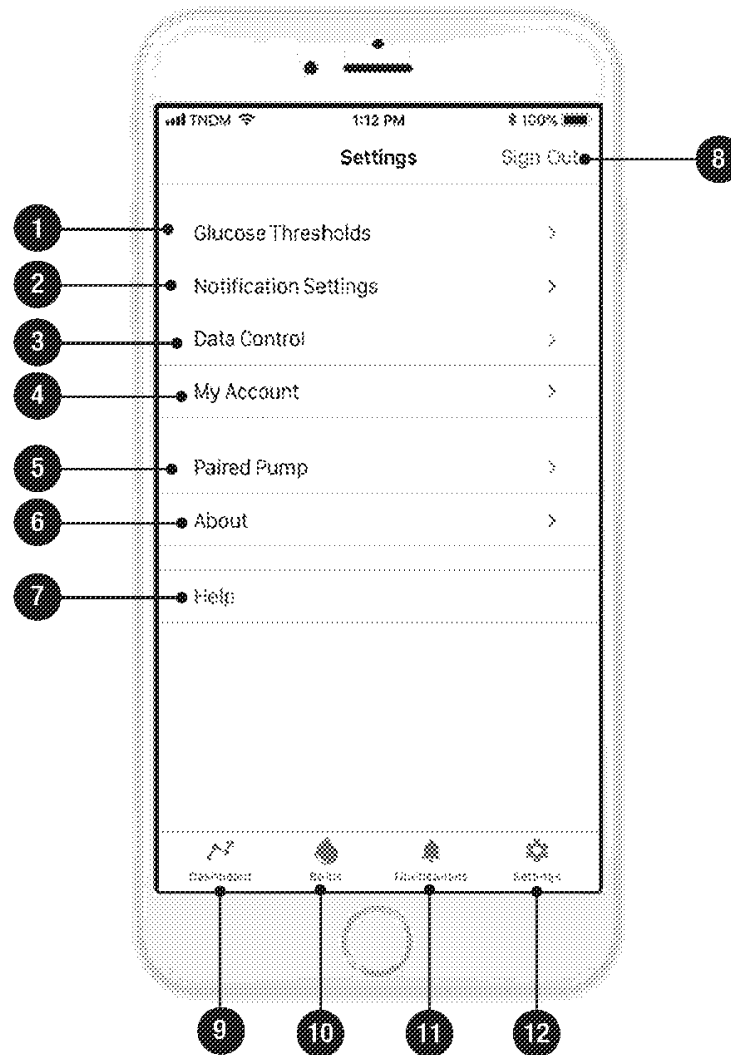


CHAPTER 4 • Getting to Know Your t:connect Mobile App

4.11 t:connect Mobile App Settings

1. **Glucose Thresholds:** Customize the way your data appears on your Dashboard and in the t:connect web application, including high glucose limit, target glucose range, low glucose limit, and how often your cartridge and infusion set should be change.
 2. **Notification Settings:** Set which events trigger notifications (e.g., pump alerts and alarms, CGM alerts and errors).
 3. **Data Control:** Directly access smartphone operating system settings relevant to the t:connect mobile app (e.g., whether to allow cellular data use to upload data).
 4. **My Account:** Edit account information. Any changes to your t:connect account made via the t:connect mobile app also apply to the t:connect web application.
 5. **Paired Pump:** Pair a pump with your smartphone, or unpair a pump from your smartphone.
-  **NOTE**
Always use the t:connect mobile app to pair your pump with your smartphone. Do not attempt to use your smartphone's Bluetooth menu.
6. **About:** Access Tandem contact information, corporate policies, and legal notices.
 7. **Help:** Access in-app help information, including FAQs, the pump user guide, an Icons and Graphics Glossary, and an App Guide that includes information on smartphone compatibility, setting up your smartphone, and troubleshooting information.
 8. **Sign Out:** Sign out of the t:connect mobile app. Tapping **Sign Out** generates a confirmation prompt.
 9. **Dashboard:** Displays pump status bar, current glucose reading, IOB status, CGM graph, time in range information, and current status.
 10. **Bolus:** Navigate to the *Bolus* screen to program and deliver a bolus (only available with compatible devices).
 11. **Notifications:** Displays active pump alerts, alarms, reminders, and malfunctions. See Section 4.4 Set Mobile Notifications for more information.
 12. **Settings:** Navigate to the settings screen, including Glucose Thresholds for Display, App Notification Settings, Data Control settings, Tandem account information, pump pairing and unpairing, About, and Help.

CHAPTER 4 • Getting to Know Your t:connect Mobile App



This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 5

Getting Started

CHAPTER 5 • Getting Started

5.1 Charging the t:slim X2 Pump

The pump is powered by an internal lithium polymer rechargeable battery. A full charge will typically last between 4 and 7 days, depending on your use of CGM and the t:connect™ mobile app. If you utilize both CGM and the t:connect mobile app, your battery is designed to last up to 4 days. Please be aware that the battery life on a single charge can vary considerably depending on individual usage, including insulin delivered, display-on time, and frequency of reminders, alerts, and alarms.

Accessories for charging from wall outlets, as well as from a computer USB port, are included with the pump. Use only the accessories provided to charge your pump. If you lose any of the accessories, or need a replacement, contact Customer Technical Support.

⚠ WARNING

ALWAYS use the USB cable provided with your t:slim X2™ insulin pump to minimize the risk of fires or burns.

The battery level indicator is displayed in the upper left portion of the *Home* screen. The charge amount will increase or decrease by 5% at a time (for example, you will see 100%, 95%, 90%, 85%). When the charge amount is less than 5%, it will begin decreasing 1% at a time (for example, you will see 4%, 3%, 2%, 1%).

When you first receive your pump, you will need to connect it to a charging source before it can be used. Charge the pump until the battery level indicator on the upper left portion of the *Home* screen reads 100% (initial charge can take up to 2.5 hours).

Tandem Diabetes Care recommends that you periodically check the battery level indicator, charge the pump for a short period of time every day (10 to 15 minutes), and avoid frequent full discharges.

■ NOTE

If the battery is fully discharged, the screen may not power on immediately when connected to a charging source. The LED around the **Screen On/Quick Bolus** button will blink green until there is enough charge to power on the touchscreen.

The pump continues to operate normally while charging. You do not need to disconnect from the pump while charging.

⚠ PRECAUTION

MAKE SURE to not move further than the length of the USB cable when you are connected to the pump and to a charging source. Moving further than the length of the USB cable may cause the cannula to be pulled out of the infusion site. For this reason it is recommended not to charge the pump while sleeping.

If you choose to disconnect from the pump while charging, check with your healthcare provider for specific guidelines. Depending on the length of time you are disconnected, you may need to replace missed basal and/or bolus insulin. Check your BG before disconnecting from the pump and again when you reconnect.

To charge the pump from an AC power outlet:

1. Plug the included USB cable into the AC power adapter.
2. Plug the AC power adapter into a grounded AC power outlet.

3. Plug the other end of the cable into the micro USB port on the pump.

To charge the pump using an optional car power USB adapter:

⚠ WARNING

When using an optional car power USB adapter, the charger must be connected to an isolated, battery powered 12 Volt system, such as an automobile. Connecting the DC vehicle adapter charger to 12 Volt DC that is generated by a power supply connected to alternating current (AC) mains is prohibited.

1. Plug the USB cable into the car power USB adapter.
2. Plug the car power USB adapter into a grounded auxiliary power outlet.
3. Plug the other end of the cable into the micro USB port on the pump.

To charge the pump using a USB port on a computer:

Ensure that the computer complies with the IEC 60950-1 (or equivalent) safety standard.

1. Plug the included USB cable into your computer.
2. Plug the other end of the cable into the micro USB port on the pump.

📌 NOTE

Before using a computer to charge the pump, it is recommended that a driver be installed on the computer by downloading the t:connect uploader software from our website at tandemdiabetes.com. This will also allow communication between the pump, the computer, and the t:connect web application.

Depending on your computer, charging time will vary. The pump will display a CONNECTION ERROR ALERT message if it is not charging properly.

When you charge the pump, you will notice the following:

- The screen illuminates
- An audible alert
- The LED (edge around the Screen On/Quick Bolus button) blinks green
- A vibrating alert

- A charge symbol (lightning bolt) on the battery level indicator appears

⚠ PRECAUTION

CONFIRM that the screen display turns on, you can hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the Screen On/Quick Bolus button when you connect a power source to the USB port. These features are used to notify you about alerts, alarms, and other conditions that require your attention. If these features are not working, discontinue use of the t:slim X2™ pump and contact Customer Technical Support.

5.2 Turning the Pump On

Plug in your pump to a charging source. The pump will make an audible noise when it has turned on and is ready for use.

5.3 Using the Touchscreen

To turn on your pump screen, first press the Screen On/Quick Bolus button, then use the pad of your finger to quickly and lightly tap on the screen. Do not use your fingernail or other

CHAPTER 5 • Getting Started

object to interact with the screen. It will not activate the screen or its functions.

Your pump is designed to give you quick and easy access to the functions that you will use in your day-to-day diabetes management whether basic or advanced.

The pump has several safety features to prevent unintentional interaction with the touchscreen. The screen must be unlocked by tapping 1–2–3 in sequence. On all screens, if three non-active areas of the touchscreen are tapped before an active area is tapped, the screen will turn off to prevent accidental screen interactions. There is also a Security PIN feature that can be set up to prevent unintentional access (see Section 5.13 Turn Security PIN On or Off).

NOTE

When using the pump, tap the **Tandem logo** to return to the *Home* screen or tap  to return to the previous screen.

5.4 Turning the t:slim X2 Pump Screen On

To turn on your pump screen, press the **Screen On/Quick Bolus** button, located on the top of the pump, once.

- ✓ The *Lock* screen will be displayed.

5.5 Turning the Pump Screen Off

To turn the pump screen off, press and release the **Screen On/Quick Bolus** button. This turns off the screen, but not the pump.

NOTE

Turn off the pump screen by pressing the **Screen On/Quick Bolus** button before placing the pump back in its case or any pocket/clothing. Always position the pump screen away from the skin when worn under clothing.

The pump continues to function normally when the screen is not on.

5.6 Turning the Pump Off

To turn the pump off completely, plug the pump into a power source and hold the **Screen On/Quick Bolus** button down for 30 seconds.

5.7 Unlocking the t:slim X2 Pump Screen

The *Lock* screen appears anytime you turn on the screen, and after a bolus or temp rate is requested. To unlock the screen:

1. Press **Screen On/Quick Bolus** button.
2. Tap 1.
3. Tap 2.
4. Tap 3.

- ✓ The pump screen is now unlocked. The last screen that was viewed will be displayed.

You must tap 1–2–3 in sequential order to unlock the pump. If you do not tap

1–2–3 in sequential order, the pump will force you to restart the unlock sequence from the beginning.

If the Security PIN feature is enabled, you will need to enter your PIN after unlocking the screen.

5.8 Edit Time

After powering up your pump for the first time, set the current time and date. Refer back to this section if you need to edit the time for either traveling in a different time zone or adjusting for Daylight Savings Time.

⚠ PRECAUTION

ALWAYS make sure that the correct time and date are set on your pump. Not having the correct time and date setting may affect safe insulin delivery. When editing time, always check that the AM/PM setting is accurate, if applicable. AM is to be used from midnight until 11:59 AM. PM is to be used from noon until 11:59 PM.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.

3. Tap **Device Settings**.
4. Tap **Time and Date**.
5. Tap **Edit Time**.
6. Tap **Time**.
7. Using the on-screen keypad, enter the hour and minutes. Verify and tap .
8. Tap **Time of Day** to set AM or PM, or tap the **24-hour Time** on/off toggle setting to on.
9. Verify the correct time is set and tap .

Any edits to Time or Date will not be saved until you tap .

5.9 Edit Date

1. From the *Time and Date* screen tap **Edit Date**.
2. Tap **Day**.

3. Using the on-screen keypad enter the current day. Verify and tap .
4. Tap **Month**.
5. Find and tap the current month displayed on the right. Use **Up/Down Arrow** to view months not displayed.
6. Tap **Year**.
7. Using the on-screen keypad enter the current year. Verify and tap .
8. Verify the correct date is set and tap .

Tap the **Tandem logo** to return to the *Home* screen.

5.10 Basal Limit

The Basal Limit setting allows you to set a limit to the Basal Rate that is set in the Personal Profiles, as well as the amount of insulin that will be delivered when using a Temp Rate.

CHAPTER 5 • Getting Started

You are unable to set any Basal Rates or temp Basal Rates that exceed the Basal Limit. You can set your Basal Limit from 0.2 to 15 units per hour. Work with your healthcare provider to set the proper Basal Limit.

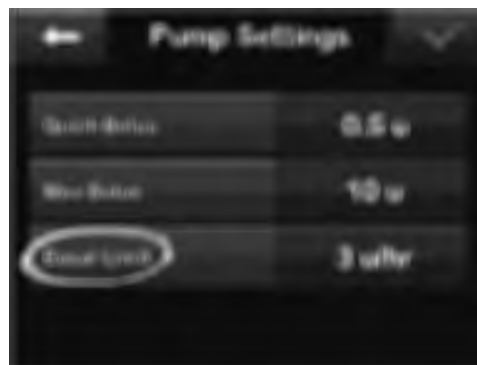
NOTE

If you are setting your Basal Limit after you have set any of your Personal Profiles, you cannot set your Basal Limit lower than any of your existing Basal Rates.

The default Basal Limit is 3 units per hour. If you are updating your pump from a version that did not previously have the Basal Limit setting, the Basal Limit will be set to a value two times the highest Basal Rate setting in your pump.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap **Pump Settings**.

5. Tap **Basal Limit**.



6. Using the on-screen keypad, enter a Basal Limit amount that is between 0.2 – 15 units.
 7. Tap .
 8. Review the Basal Limit value and tap .
 9. Confirm settings and tap .
- ✓ A *SETTING SAVED* screen is temporarily displayed.

5.11 Display Settings

The display settings for your t:slim X2 pump includes Screen Timeout.

You can set the Screen Timeout to the length of time you want the screen to stay on before it automatically turns off. The default for the Screen Timeout is 30 seconds. The options are 15, 30, 60, and 120 seconds.

You can always turn the screen off before it automatically times out by pressing the **Screen On/Quick Bolus** button.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Device Settings**.
4. Tap **Display Settings**.
5. Tap **Screen Timeout**.
6. Select preferred time and tap .

7. Tap the **Tandem** logo to return to the *Home* screen.

5.12 Sound Volume

The Sound Volume is preset to high. Sound Volume can be personalized for Alarms, Alerts, Reminders, Keypad, Bolus, Quick Bolus, and Fill Tubing. Options for Sound Volume include high, medium, low, and vibrate.

⚠ PRECAUTION

DO NOT use the vibrate feature for alerts and alarms during sleep unless otherwise directed by your healthcare provider. Having the volume for alerts and alarms set to high will help ensure that you don't miss an alert or alarm.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Device Settings**.
4. Tap **Sound Volume**.
5. Tap desired option. Use **Up/Down Arrow** to view additional options.

6. Select preferred volume.
7. Continue to make changes for all Sound Volume options by repeating steps 5 and 6.
8. Tap  when all changes are complete.
9. Tap the **Tandem** logo to return to the *Home* screen.

5.13 Turn Security PIN On or Off

The Security PIN is preset to off. With the Security PIN turned on, you cannot unlock and use the pump without entering the Security PIN. To turn on the Security PIN, follow these steps.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Device Settings**.
4. Tap the **Down Arrow**.
5. Tap **Security PIN**.

6. Tap **Security PIN** to toggle the feature on.
7. Tap  to create your Security PIN.
8. Using the keypad, enter a number between four and six digits. A PIN may not begin with the number zero.
9. Tap .
10. Tap  to verify your Security PIN.
11. Use the keypad to repeat and verify the new Security PIN.
12. Tap .
- ✓ A *PIN CREATED* screen is displayed.
13. Tap  to turn the Security PIN on.
14. Tap .

It is possible to change your Security PIN or override an old Security PIN if you forget your Security PIN.

CHAPTER 5 • Getting Started

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the Down Arrow.
3. Tap **Device Settings**.
4. Tap the Down Arrow.
5. Tap **Security PIN**.
6. Tap **Change Security PIN**.
7. Tap .
8. Using the keypad, enter the current Security PIN. If you forget your Security PIN, use the override code **314159**.
 - » The override PIN can be used as many times as needed and never resets or changes to another PIN. It can be used to unlock the pump when the Security PIN feature is on. If desired, you may use this as a valid Security PIN.
9. Tap .
10. Tap  to enter a new Security PIN.

11. Use the keypad to enter a new Security PIN.
12. Tap .
13. Tap  to verify your new Security PIN.
14. Use the keypad to repeat and verify the new Security PIN.
15. Tap .
- ✓ A *PIN UPDATED* screen is displayed.
16. Tap .

pair or unpair your smartphone and your pump.

NOTE

Do not turn the mobile connection on if you are not using or do not have access to the t:connect mobile app. Turning the mobile connection on may impact pump battery life.

5.14 Mobile Connection

You can connect one compatible smartphone to the pump to display pump information and perform some pump functions on that smartphone using the t:connect mobile app. See Section 4.3 Connecting to a Smartphone for detailed instructions to

2 t:slim X2 Insulin Pump Features

CHAPTER 6

Insulin Delivery Settings

CHAPTER 6 • Insulin Delivery Settings

6.1 Personal Profiles Overview

⚠ WARNING

DO NOT start to use your pump before consulting with your healthcare provider to determine which features are most appropriate for you. Only your healthcare provider can determine and help you adjust your Basal Rate(s), Carb Ratio(s), Correction Factor(s), Target BG, and duration of insulin action. In addition, only your healthcare provider can determine your CGM settings and how you should use your sensor trend information to help you manage your diabetes. Incorrect settings can result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

A Personal Profile is a group of settings that define basal and bolus delivery within specific time segments throughout a 24-hour period. Each profile can be personalized with a name. Within a Personal Profile the following can be set:

- **Timed Settings:** Basal Rate, Correction Factor, Carb Ratio and Target BG.

- **Bolus Settings:** Insulin Duration and Carbohydrates setting (on/off).

NOTE

In order to turn on Control-IQ™ technology, the Timed Settings must be complete for every time segment, and the Carbohydrates setting must be turned on in the Bolus Settings.

The t:slim X2™ pump uses the settings in your active profile to calculate the delivery of basal insulin, food boluses and correction boluses based on your Target BG. If you only define a Basal Rate in Timed Settings, your pump will only be able to deliver basal insulin and standard and extended boluses. Your pump will not calculate correction boluses.

Up to six different Personal Profiles can be created and up to 16 different time segments can be set in each Personal Profile. Having several Personal Profiles provides more flexibility for your body and lifestyle. For example, you could have “Weekday” and “Weekend” profiles if you have different insulin delivery needs on weekdays and weekends, based on schedule, food intake, activity, etc.

NOTE

Some of the Personal Profile settings are overridden when Control-IQ technology is turned on. See Chapter 30 Introduction to Control-IQ Technology.

6.2 Creating a New Profile

Creating Personal Profiles

You can create up to six Personal Profiles; however, only one can be active at a time. In the *Personal Profiles* screen, the active profile is positioned at the top of the list and is marked as ON. When you create a Personal Profile, you can set any or all of the following Timed Settings:

- Basal Rate (your Basal Rate in units/ hr)
- Correction Factor (amount 1 unit of insulin lowers BG)
- Carb Ratio (grams of carbohydrate covered by 1 unit of insulin)
- Target BG (your ideal BG level, measured in mg/dL)

Although you do not need to define every setting, some pump features require certain settings to be defined and activated. When you are creating a new profile, your pump prompts you to set up any required settings before you can continue.

The ranges you can set for Timed Settings are:

- Basal (range: 0 and 0.1 to 15 units/hr)

NOTE

The Basal Rate may not exceed the Basal Limit set in Pump Settings (Section 5.10 Basal Limit). If you are setting your Basal Limit after you have set any of your Personal Profiles, you cannot set your Basal Limit lower than any of your existing Basal Rates.

NOTE

If Control-IQ technology is on and the pump has not received a CGM reading for 20 minutes, the system will automatically revert to your programmed basal rate. Examples of CGM readings not being received include when the pump and CGM are out of range, during the sensor startup

period, when a sensor session ends, or when there is a transmitter or sensor error.

WARNING

Control-IQ technology reverts to your programmed basal rate when the pump has not received a CGM reading for 20 minutes. For example, when the pump and CGM are out of range, during the sensor startup period, when a sensor session ends, or when there is a transmitter or sensor error.

- Correction Factor (range: 1 unit:1 mg/dL to 1 unit:600 mg/dL)
- Carb Ratio (range: 1 unit:1 gram to 1 unit:300 grams)

Below a Carb Ratio of 1:10, increments can be entered in 0.1 gram. For example a Carb Ratio of 1:8.2 can be programmed.

- Target BG (range: 70 mg/dL to 250 mg/dL)

In addition, you can set any or all of the following Bolus Settings:

- Insulin Duration (how long a bolus lowers your BG)

- Carbs (ON indicates entering grams of Carb; OFF indicates entering units of insulin)

NOTE

Changing the Carbs setting on the pump changes the bolus calculators on both the pump and the t:connect™ mobile app.

The default settings and ranges for Bolus Settings are as follows:

- Insulin Duration (default: 5 hrs; range: 2 to 8 hrs)

NOTE

When using Control-IQ technology, the insulin duration is set to five hours and cannot be changed. This duration is used for all bolus deliveries as well as for basal adjustments made by Control-IQ technology.

- Carbs (default: dependent on pump history)

NOTE

If you received a new pump with Control-IQ technology, the default setting will be on. If you updated your pump, the default setting will be the same as what you set up on your pump previously. Check to ensure that the

CHAPTER 6 • Insulin Delivery Settings

Carbs setting is on in order to use Control-IQ technology.

Insulin Duration and Insulin on Board (IOB)

Your pump remembers how much insulin your pump has delivered from boluses. It does this by relying on the insulin duration. The insulin duration reflects the amount of time that insulin is actively lowering your BG.

While the insulin duration setting reflects how long insulin from previous boluses lowers your BG, the IOB feature reflects how much insulin is remaining in your body from previous boluses. IOB is always displayed on the *Home* screen and is used in bolus delivery calculations when applicable. When a glucose value is entered during bolus programming, your pump will consider any active IOB and adjusts the calculated bolus if necessary.

The insulin duration time is displayed on the *Home* screen when Control-IQ technology is not enabled.

Consult your healthcare provider to accurately set your insulin duration.

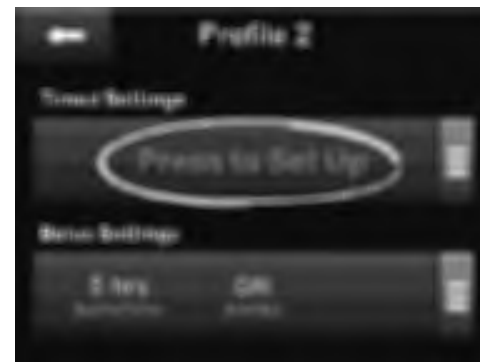
If you have Control-IQ technology enabled, IOB includes all basal delivered above and below the programmed Basal Rate, in addition to all bolus insulin delivered. The insulin duration time is not displayed on the *Home* screen.

Insulin duration is set to 5 hours when Control-IQ technology is enabled and cannot be changed.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap  to create a new profile.
5. Using the on-screen keypad, enter a profile name (up to 16 characters) and tap .

To use the letter keypad, tap once for first letter displayed, two quick taps for middle letter; and three quick taps for the third letter.

6. Tap **Press to Set Up** to begin setting insulin delivery settings.



6.3 Programming a New Personal Profile

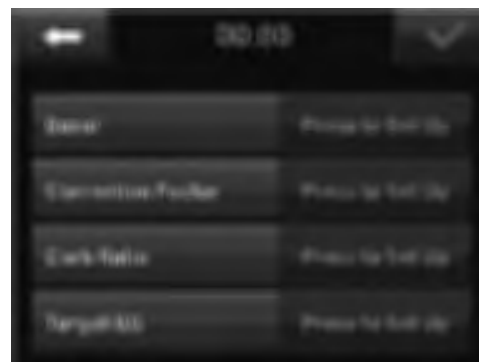
Once the Personal Profile has been created, the settings must be programmed. The first time segment will start at midnight.

- You must program a Basal Rate in order to have a Personal Profile that you can activate.
- You must have Carbs turned on, and you must set a Basal Rate, Correction Factor, Carb Ratio, and Target BG in order to turn Control-IQ technology on.
- Be sure to tap  after entering or changing a value.

PRECAUTION

ALWAYS confirm that the decimal point placement is correct when entering your Personal Profile information. Incorrect decimal point placement can prevent you from getting the proper insulin amount that your healthcare provider has prescribed for you.

Timed Settings



1. Once the new profile has been created, tap **Basal**.
2. Using the on-screen keypad, enter your Basal Rate and tap .

NOTE

If you have previously set a Basal Limit in the Pump Settings, then the Basal Rate entered here must be lower than the Basal Limit entered in the Pump Settings.

3. Tap **Correction Factor**.
4. Using the on-screen keypad, enter your Correction Factor (the mg/dL that 1 unit of insulin will lower BG) and tap .

5. Tap **Carb Ratio**.
6. Using the on-screen keypad, enter your insulin-to-carbohydrate ratio (the grams of carbohydrate to be covered by 1 unit of insulin) and tap .
7. Tap **Target BG**.
8. Using the on-screen keypad, enter your Target BG and tap .

NOTE

Once Control-IQ technology is turned on, the default Target BG is set to 110 mg/dL. For details about target ranges and how Control-IQ technology works, see Chapter 30 Introduction to Control-IQ Technology.

9. Review entered values and tap .
10. Confirm Settings.
 - Tap  if entered data is correct.
 - Tap  to make changes.

CHAPTER 6 • Insulin Delivery Settings

11. Tap  to set the Bolus Settings, or tap  to create additional time segments.



Adding More Time Segments

When adding more time segments, any settings that you entered in the previous time segment are copied and appear in the new segment. This allows you to simply adjust only the specific settings you want, rather than have to enter them all over again.

1. On the *Add Segment* screen, tap **Start Time**.
2. Using the on-screen keypad, enter the time (hour and minutes) that you want the segment to begin, and tap .

3. On the *Add Segment* screen, tap **Time of Day** to select AM or PM, if applicable.

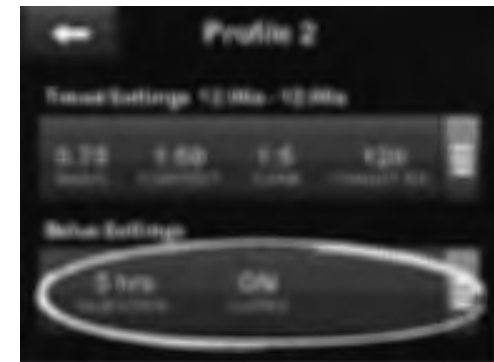
✓ Once a time segment is set beyond 12:00 PM, the default will change to PM.

4. Tap .
5. Repeat steps 1 to 10 from Section 6.2 Creating a New Profile above for each segment you want to create (up to 16).

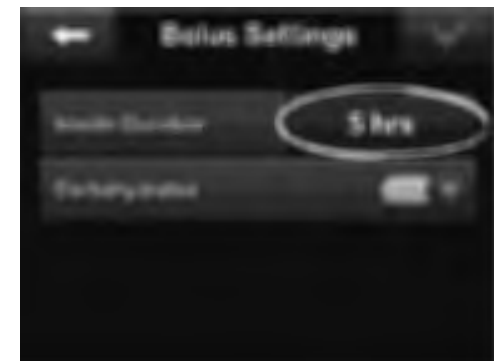
To find time segments in the list that are not displayed on the first screen, tap the **Down Arrow**.

Bolus Settings

1. Tap the **Bolus Settings** panel.



2. Tap **Insulin Duration**.



3. Using the on-screen keypad, enter the desired time for the duration of insulin action (2–8 hrs) and tap .

4. Review entered values and tap .

5. Confirm Settings.

- Tap  if entered data is correct.
- Tap  to make changes.

6. Tap the **Tandem** logo to return to the *Home* screen.

Adding More Personal Profiles

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap .
5. Name the new profile and repeat steps for Timed Settings and Bolus Settings.

NOTE

The Carbohydrates option is turned on by default, but a ratio will still need to be

defined. The Carbohydrates option must be used if Control-IQ technology is enabled.

6.4 Editing or Reviewing an Existing Profile

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to edit or review.
5. Tap **Edit**.

NOTE

To review settings but bypass editing the settings, skip the remaining steps in this section. You can tap  to navigate to the Personal Profiles list or tap the **Tandem** logo to return to the *Home* screen.

6. Tap **Timed Settings** panel.
7. Tap the desired time segment to edit.

8. Tap **Basal**, **Correction Factor**, **Carb Ratio** or **Target BG** to make changes as needed and use the on-screen keypad to enter changes. Tap .

9. View recent changes and tap .

10. Confirm Settings.

- Tap  if entered data is correct.
- Tap  to make changes.

11. Edit other time segments within the Timed Settings by tapping on them and using the same steps described above.

12. Tap  after editing all of the time segments.

13. Tap the **Bolus Settings** panel to change Insulin Duration Carbohydrates as needed. Use the on-screen keypad to enter desired changes. Tap .

14. Confirm Settings.

CHAPTER 6 • Insulin Delivery Settings

- Tap  if entered data is correct.
 - Tap  and make changes.
15. Tap the **Tandem logo** to return to the *Home* screen.

NOTE

To add a time segment, tap  and enter the desired start time.

NOTE

To delete a time segment, tap on the X to the left of the time segment and tap  to confirm.

6.5 Duplicating an Existing Profile

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to duplicate.
5. Tap **Duplicate**.

6. Confirm profile to duplicate by tapping .
7. Using the on-screen keypad, enter the name (up to 16 characters) for the new profile and tap .
- ✓ *Profile Duplicated* screen is displayed.
- ✓ A new Personal Profile will be created with the same settings as the profile copied.
8. Tap the **Timed Settings** or **Bolus Settings** panel to make changes to the new profile.

6.6 Activating an Existing Profile

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to be activated.

- The **Activate** and **Delete** options are disabled for the active profile because the profile is already activated. You cannot delete a profile until you have activated another profile.
- If you have only one profile defined, you do not need to activate it (that profile is automatically activated).

5. Tap **Activate**.

- ✓ A screen to confirm the activation request is displayed.

6. Tap .

- ✓ *Profile Activated* screen is displayed.

6.7 Renaming an Existing Profile

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.

4. Tap the name of the Personal Profile to be renamed.
5. Tap **Down Arrow**, and then **Rename**.
6. Using the on-screen keypad, rename the profile name (up to 16 characters) and tap .
7. Tap the **Tandem** logo to return to the *Home* screen.

6.8 Deleting an Existing Profile

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to be deleted.

NOTE

The active Personal Profile cannot be deleted.

5. Tap **Delete**.

6. Tap .

✓ *Profile Deleted* screen is displayed.

7. Tap the **Tandem** logo to return to the *Home* screen.

6.9 Starting a Temporary Basal Rate

A Temp Rate is used to increase or decrease (by percentage) the current Basal Rate for a period of time. This feature can be helpful for situations such as exercise or illness.

When you enter the *Temp Rate* screen, the default values are 100% (current Basal Rate) and a Duration of 0:15 min. The Temp Rate can be set from a minimum of 0% of current Basal Rate to a maximum of 250% of current Basal Rate in increments of 1%.

Duration can be set from a minimum of 15 minutes to a maximum of 72 hours in increments of 1 minute.

If you program a Temp Rate greater than 0% but less than the minimum allowable Basal Rate of 0.1 units/hr,

you will be notified that the selected rate is too low and that it will be set to the minimum allowable rate for delivery.

If you program a Temp Rate more than the maximum allowable Basal Rate of 15 units/hr, or more than your Basal Limit set up in the Pump Settings, you will be notified that the selected rate is too high and that it will be reduced so that it does not exceed the maximum allowable rate for delivery.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap **Temp Rate**.
4. Tap **Temp Rate** again.
5. Using the on-screen keypad enter desired percentage. The current rate is 100%. An increase is greater than 100% and decrease is less than 100%.
6. Tap .

CHAPTER 6 • Insulin Delivery Settings

7. Tap **Duration**. Using the on-screen keypad enter desired length of time for Temp Rate. Tap .

You can always tap **View Units** to see the actual units to be delivered.

8. Verify settings and tap .

- ✓ The *TEMP RATE STARTED* screen is temporarily displayed.

- ✓ The *Lock* screen will be displayed with the icon indicating a Temp Rate is active.

- An T in an orange box means a Temp Rate is active.
- A T in a red box means a Temp Rate of 0 u/hr is active.

NOTE

If a Temp Rate is active when you stop insulin, including when you change a cartridge or infusion set, the Temp Rate timer will remain active. The Temp Rate will be resumed when insulin delivery is resumed as long as there is time remaining on the Temp Rate Timer.

6.10 Stopping a Temp Rate

To stop an active temp rate:

1. From the *Home* screen, tap **OPTIONS**.
 2. Tap **Activity**.
 3. On the *Activity* screen, tap  on the right side of Temp Rate.
 4. On the confirmation screen, tap .
- ✓ The *TEMP RATE STOPPED* screen appears before returning to the *Activity* screen.

2 t:slim X2 Insulin Pump Features

CHAPTER 7

Infusion Site Care and Loading Cartridge

CHAPTER 7 • Infusion Site Care and Loading Cartridge

7.1 Infusion Site Selection and Care**⚠ WARNING**

ALWAYS use only cartridges and insulin infusion sets with matching connectors and follow their instructions for use. Failure to do so may result in over delivery or under delivery of insulin and may cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

ALWAYS carefully follow the instructions for use accompanying your infusion set for proper insertion and infusion site care, as failure to do so could result in over delivery or under delivery of insulin or infection.

⚠ WARNING

DO NOT place your infusion set on any scars, lumps, moles, stretch marks or tattoos. Placing your infusion set in these areas can cause swelling, irritation or infection. This can affect insulin absorption and cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

DO NOT change your infusion set before bedtime or if you will not be able to test your BG

1–2 hours after the new infusion set is placed. It is important to confirm that the infusion set is inserted correctly and delivering insulin. It is also important to respond quickly to any problems with the insertion to ensure continued insulin delivery.

⚠ PRECAUTION

CHECK your infusion site daily for proper placement and leaks. **REPLACE** your infusion set if you notice leaks around the site, or if you suspect your infusion set cannula may have become dislodged. Improperly placed sites or leaks around the infusion site can result in under delivery of insulin.

General Guidelines**Site Selection**

- Your infusion set can be worn anywhere on your body that you would normally inject insulin. Absorption varies from site to site. Discuss options with your healthcare provider.
- The most commonly used sites are the abdomen, upper buttocks, hips, upper arms, and upper legs.

- The abdomen is the most popular site because of access to fatty tissue. If using the abdominal area, **AVOID**:

- Areas that would constrict the site such as the belt line, waistline, or where you would normally bend.
- Areas 2 inches (5 cm) around your belly button.
- **AVOID** sites with any scars, moles, stretch marks, or tattoos.
- **AVOID** site areas within 3 inches (7.6 cm) of your CGM sensor site.

Site Rotation**⚠ PRECAUTION**

CHANGE your infusion set every 48 hours if using Humalog insulin; every 72 hours if using NovoLog insulin. Wash your hands with anti-bacterial soap before handling the infusion set and thoroughly clean the insertion site on your body to avoid infection. Contact your healthcare provider if you have symptoms of infection at your insulin infusion site.

- The infusion set must be replaced and rotated every 48 hours if using

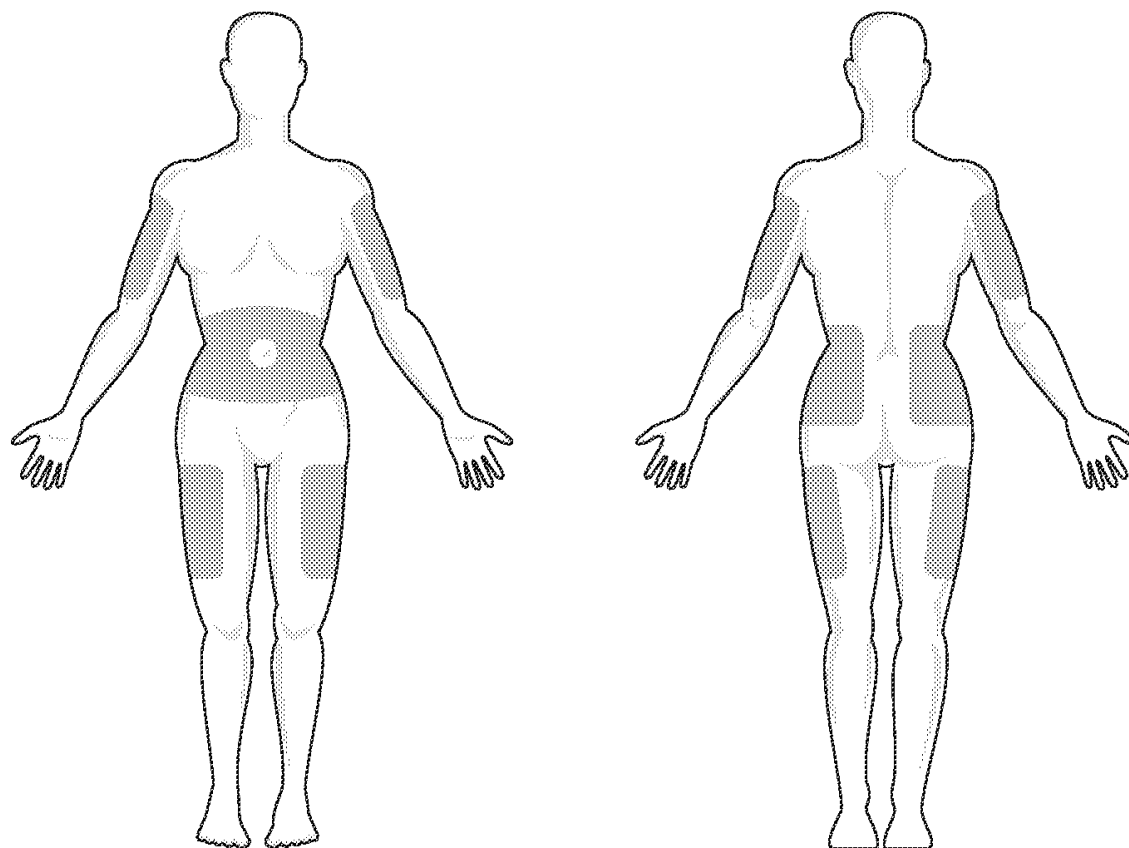
Humalog insulin; every 72 hours if using NovoLog insulin, or more often if needed.

- With experience, you will find areas that not only provide better absorption, but are more comfortable. Keep in mind, using the same areas may cause scarring or lumps which can affect insulin absorption.
- Consult your healthcare provider to establish a rotation schedule that best fits your needs.

Keep it Clean

- When changing your infusion set, use clean techniques to avoid an infection.
- Wash your hands, use antiseptic wipes or infusion site preparation products, and keep the area clean.
- Site preparation products that have both an antiseptic and an adhesive are encouraged.

Areas of Body for Infusion Set Insertion



CHAPTER 7 • Infusion Site Care and Loading Cartridge

7.2 Cartridge Instructions for Use

For complete cartridge labeling, consult the cartridge instructions for use included in the t:slim™ cartridge box.

7.3 Filling and Loading a t:slim X2 Cartridge

This section describes how to fill the cartridge with insulin and load the cartridge into your t:slim X2™ pump. The single-use disposable cartridge can hold up to 300 units (3.0 mL) of insulin.

⚠ WARNING

ONLY use U-100 Humalog or U-100 NovoLog with your pump. Only U-100 Humalog and U-100 NovoLog have been tested and found to be compatible for use in the pump. Use of insulin with greater or lesser concentration can result in an over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

ALWAYS use cartridges manufactured by Tandem Diabetes Care. Use of any other cartridge brand may result in over delivery or under delivery of insulin. This can cause

hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

DO NOT reuse cartridges. Reuse of cartridges may result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

Before you begin, make sure you have the following items:

- 1 unopened cartridge
- 3.0 mL syringe and fill needle
- vial of U-100 Humalog or U-100 NovoLog insulin
- alcohol prep swab
- 1 new infusion set
- infusion set instructions for use

📌 NOTE

The pump will beep or vibrate, depending on your pump settings, while the tubing is filling with insulin. To change the Fill Tubing sound setting, see Section 5.12 Sound Volume.

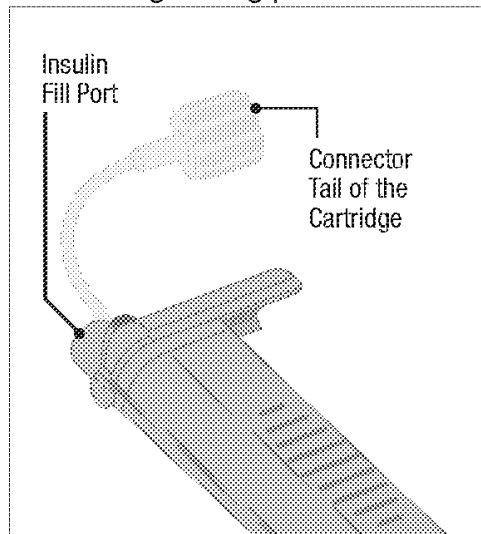
📌 NOTE

DO NOT remove the used cartridge from the pump during the load process until prompted on the pump screen.

📌 NOTE

Control-IQ™ technology will continue to make calculations based on CGM values while the cartridge is being filled. Since there is no insulin delivered during the cartridge fill process, there will be no actual Basal Rate adjustments until the cartridge is filled and loaded back onto the pump. Control-IQ technology will then immediately begin to operate normally.

The illustration identifies the connector and insulin fill port used in the cartridge filling process.



⚠ PRECAUTION

CHANGE your cartridge every 48–72 hours as recommended by your healthcare provider. Wash your hands with anti-bacterial soap before handling the infusion set and thoroughly clean the insertion site on your body to avoid infection. Contact your healthcare provider if you have symptoms of infection at your insulin infusion site.

Instructions for Drawing Insulin from Vial into Syringe

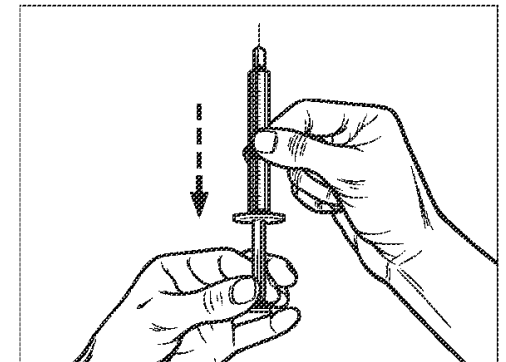
⚠ PRECAUTION

ALWAYS remove all air bubbles from the cartridge before beginning insulin delivery. Ensure there are no air bubbles when drawing insulin into the filling syringe, hold the pump with the white fill port pointed up when filling the tubing, and ensure that there are no air bubbles in the tubing when filling. Air in the system takes space where insulin should be and can affect insulin delivery.

The fill estimate displayed on the pump is the amount of insulin available for delivery. It does not include insulin needed to fill the tubing (up to 30 units) and a small amount of insulin that is not available for delivery. When filling the syringe, add approximately 45 units to the amount of insulin you want available for delivery.

- For example, the pump requires a minimum of 50 units available for delivery after fill tubing has been completed. Fill the syringe with approximately 95 units to have enough to fill your tubing and still have 50 units available for delivery.

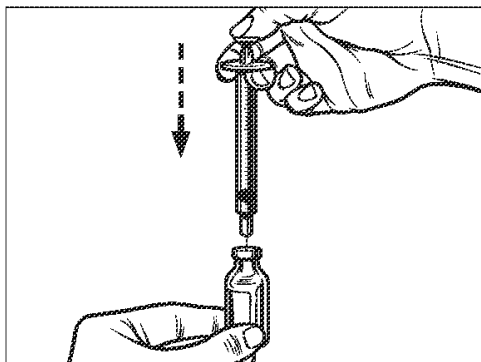
1. Inspect the needle and syringe package for any signs of damage. Discard any damaged product.
2. Wash your hands thoroughly.
3. Wipe the rubber septum of the insulin vial with an alcohol swab.
4. Remove the needle and syringe from their packaging. Securely twist needle onto syringe. Safely remove protective cap from needle by pulling outward.
5. Draw air into syringe up to the amount of insulin desired.



6. With insulin vial upright, insert needle into vial. Inject air from

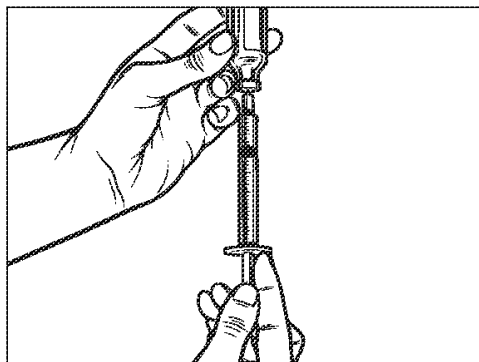
CHAPTER 7 • Insulin Site Care and Loading Cartridge

syringe into vial. Maintain pressure on syringe plunger.

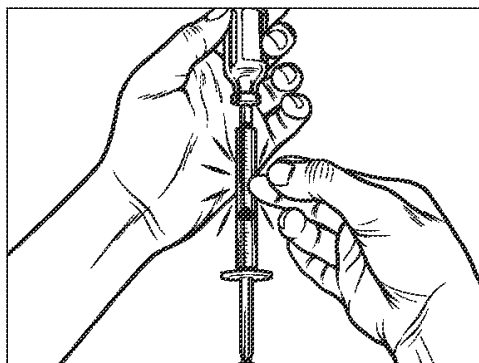


7. With needle still inserted into vial, turn vial and syringe upside down. Release syringe plunger. Insulin will begin to flow from the vial into the syringe.

8. Slowly pull back the plunger to the desired amount of insulin.



9. While the filling needle is still in the vial and upside down, tap the syringe so that any air bubbles rise to the top. Then slowly push the plunger upwards, forcing any air bubbles back into the vial.

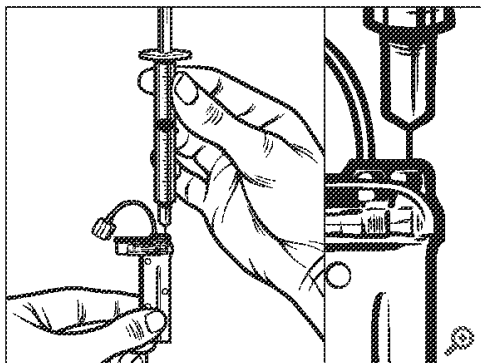


10. Check the syringe for air bubbles and do one of the following:

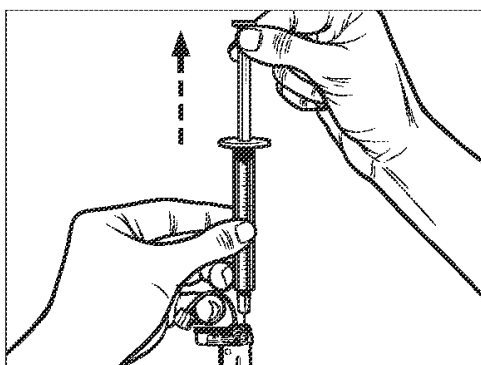
- If there are air bubbles present, repeat step 9.
- If no air bubbles are present, remove the filling needle from the vial.

Instructions for Filling the Cartridge

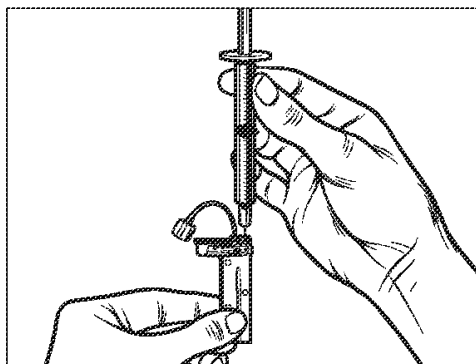
1. Inspect the cartridge package for any signs of damage. Discard any damaged product.
2. Open the package and remove the cartridge.
3. Hold the cartridge upright and gently insert the needle into the white insulin fill port on the cartridge. The needle is not intended to go all the way in, so do not force it.



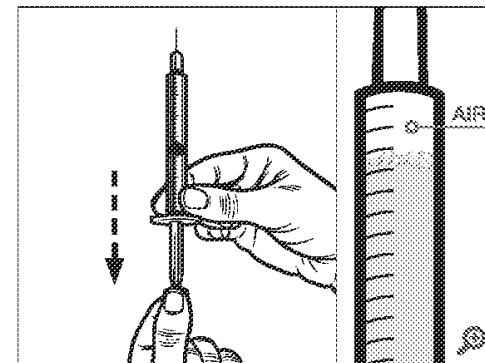
4. Keeping the syringe vertically aligned with the cartridge, and the needle inside the fill port, pull back on the plunger until it is fully retracted. This will remove any residual air from the cartridge. Bubbles will rise toward the plunger.



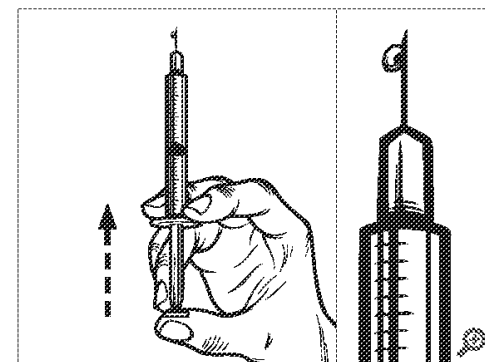
5. Make sure the needle is still in the fill port and release the plunger. Pressure will pull the plunger to its neutral position but it will NOT push any air back inside the cartridge.



6. Withdraw the needle from the fill port.
7. Turn the syringe upright and pull down on the plunger. Flick the barrel to make sure that any air bubbles rise to the top.



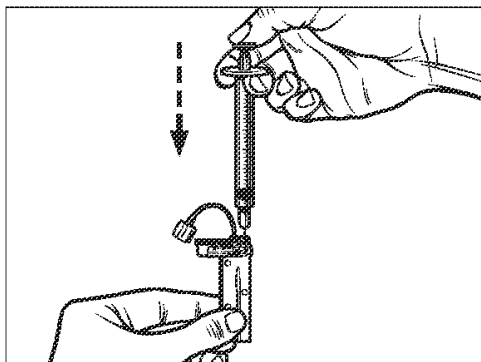
8. Gently press on the plunger to remove air bubbles until insulin fills the needle hub and you see a drop of insulin at the tip of the needle.



9. Re-insert the needle in the fill port and slowly fill the cartridge with insulin. It is normal to feel some

CHAPTER 7 • Infusion Site Care and Loading Cartridge

back pressure as you slowly press on the plunger.



10. Maintain pressure on the plunger while you remove the needle from the cartridge. Check the cartridge for leaks. If you detect insulin leaking, discard the cartridge and repeat entire process with a new cartridge.
11. Always dispose of used needles, syringes, cartridges, and infusion sets following local regulations.

Instructions on How to Install a Cartridge

If this is the very first time you are loading the cartridge, remove the

shipping canister (which is not for human use) from the back of the pump.

1. From the *Home* screen, tap **OPTIONS**.

2. Tap **Load**.

During the load sequence, the **Tandem** logo is disabled. Tapping it will not return to the *Home* screen.

3. Tap **Change Cartridge**.

4. A screen will display to notify you that all insulin deliveries will be stopped. Tap  to continue.

NOTE

This screen will not be displayed if this is the first time loading a new cartridge and you have not started actively pumping.

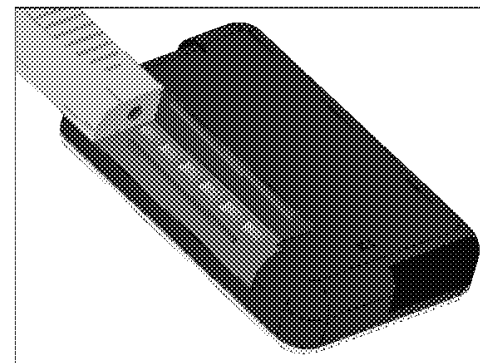
5. Disconnect the infusion set from your body and tap  to continue.

- ✓ *Preparing for Cartridge* screen is displayed.

6. Remove the used cartridge. If needed, place the cartridge removal

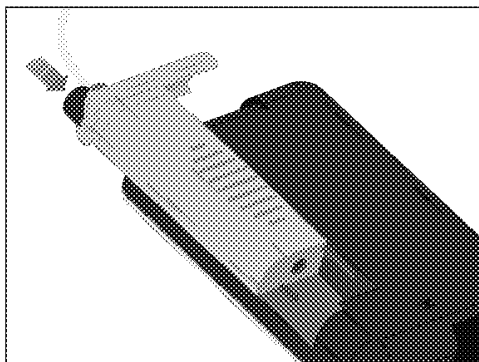
tool or the edge of a coin in the slot at the bottom of the cartridge and twist to aid in the removal of the cartridge.

7. Place the bottom of the cartridge at the end of the pump. Make sure cartridge is lined up to both guide tracks.



8. Push on the circular fill port next to the cartridge tubing to slide the

cartridge onto the pump. Tap the UNLOCK icon when completed.



9. Tap  to continue.

- ✓ *Detecting Cartridge* screen is displayed.
- ✓ After completing the cartridge change, the pump will automatically prompt you to fill the tubing.

10. Tap  to fill the tubing.

⚠ WARNING

DO NOT remove or add insulin from a filled cartridge after loading onto the pump. This will result in an inaccurate display of the insulin level on the *Home* screen and you could run out of insulin before the pump detects an empty

cartridge. This can cause very high BG, or Diabetic Ketoacidosis (DKA).

7.4 Filling Tubing

Filling the Infusion Set Tubing with Insulin

⚠ WARNING

NEVER fill your tubing while your infusion set is connected to your body. Always ensure that the infusion set is disconnected from your body before filling the tubing. Failure to disconnect your infusion set from your body before filling the tubing can result in over delivery of insulin. This can cause hypoglycemia (low BG) events.

This section describes how to fill the infusion set tubing with insulin after you change the cartridge. If you just completed step 10 from the previous section, skip to step 4.

■ NOTE

The pump will beep or vibrate, depending on your pump settings, while the tubing is filling with insulin. To change the Fill Tubing sound setting, see Section 5.12 Sound Volume.

To fill the tubing without changing the cartridge, from the *Home* screen tap **OPTIONS**, tap **Load**, tap **Fill Tubing** and then follow the instructions.

- Tap **NEW** if you installed a new cartridge.
- Tap **FILL** if you did not install a new cartridge and want to continue with filling the tubing.

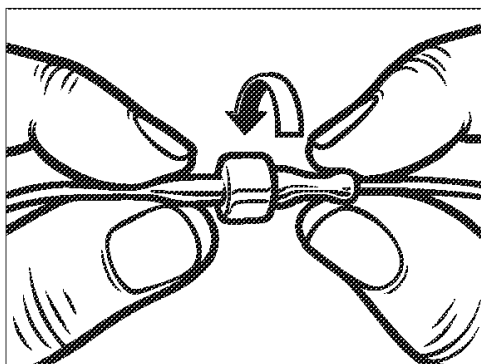
⚠ PRECAUTION

CHECK your infusion set tubing daily for any leaks, air bubbles, or kinks. Air in the tubing, leaks in the tubing, or kinked tubing may restrict or stop insulin delivery and result in under delivery of insulin.

1. Verify that the infusion set is disconnected from your body.
2. Ensure that the new infusion set package is not damaged, and remove the sterile tubing from the package. If the package is damaged or opened, discard properly and use another tubing set. Be careful to keep the tubing connector away from unclean areas.

CHAPTER 7 • Infusion Site Care and Loading Cartridge

3. Attach the infusion set tubing to the tubing connector on the cartridge tubing. Twist clockwise until finger tight and then twist another quarter of a turn to ensure a secure connection.

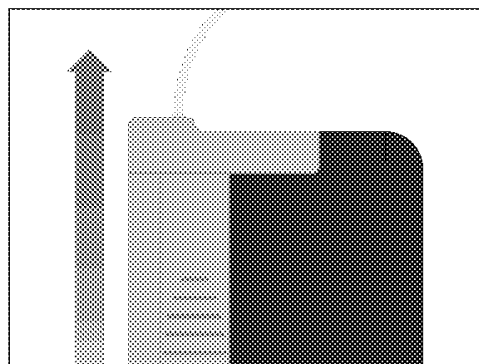


⚠ WARNING

ALWAYS twist the tubing connector between the cartridge tubing and the infusion set tubing an extra quarter of a turn to ensure a secure connection. A loose connection can cause insulin to leak, resulting in under delivery of insulin. This can cause hyperglycemia (high BG) events.

4. Hold the pump vertically to ensure any air in the cartridge will be dispelled first. Tap **START**. The pump will beep and vibrate regularly

while the tubing is being filled, depending on your Sound Volume settings.



- ✓ *Starting Fill* screen is displayed.

The following are approximate amounts of insulin to fill different tubing lengths:

- 10–15 units for 23 inch (60 cm) tubing
- 15–20 units for 32 inch (80 cm) tubing
- 20–25 units for 43 inch (110 cm) tubing

5. Tap **STOP** after 3 drops of insulin are seen at the end of the infusion set tubing.

- ✓ *Stopping Fill* screen is displayed.

- ✓ *Detecting Insulin* screen is displayed.

6. Verify that drops are seen and tap **DONE**.

- If you do not see drops, tap **FILL**. The *Fill Tubing* screen appears, repeat steps 4 and 5 until you see 3 drops of insulin at the end of the tubing.
- The tubing may be filled with a maximum of 30 units of insulin during each fill cycle. If you do not tap **STOP**, a notification screen will appear letting you know that the maximum amount has been filled. Do one of the following:
 - a. If you are finished filling the tubing, tap **DONE**.
 - b. If you want to fill the tubing with more than 30 units, tap **FILL** to

go back to the *Fill Tubing* screen.

- ✓ *Fill Tubing is complete* screen is temporarily displayed.

NOTE

After tubing fill is complete, when the pump returns to the *Home* screen, an estimate of how much insulin is in the cartridge is displayed in the upper right portion of the screen. You will see one of the following on the screen:

- + 40 u More than 40 units detected in the cartridge
- + 60 u More than 60 units detected in the cartridge
- + 120 u More than 120 units detected in the cartridge
- + 180 u More than 180 units detected in the cartridge
- + 240 u More than 240 units detected in the cartridge

After 10 units are delivered, an actual number of units remaining in the cartridge will be displayed on the *Home* screen.

The amount of insulin remaining displayed on the *Home* screen will decrease 5 units at a time (for example, you will see 140, 135, 130, 125). When less than 40 units remain, it will begin decreasing 1 unit at a time (for example, you will see 40, 39, 38, 37) until there is 1 unit remaining.

- ✓ A screen will display to instruct you to insert a new infusion set and connect to the filled tubing.

7.5 Filling Cannula

Filling the Infusion Set Cannula with Insulin

This section describes how to fill the infusion set cannula with insulin after you fill the tubing.

To fill the cannula without filling the tubing, from the *Home* screen, tap **OPTIONS**, tap **Load**, tap **Fill Cannula** and then follow the instructions below.

If you are using a steel needle infusion set, there is no cannula; skip this section.

To Fill the Cannula:

1. Tap **Fill Cannula**.
2. Insert a new infusion set and connect filled tubing to site, then tap .
3. Tap **Edit Fill Amount**.
 - ✓ The cannula fill amount displayed is based on your last cannula fill amount. Filling stops at this amount.
4. Select amount needed for cannula fill.
 - See your infusion set instructions for use for proper cannula fill amount.
 - If the amount needed is not listed, tap **Other amount** and use the on-screen keypad to enter a value between 0.1 to 1.0 unit.
5. Tap **START**.
 - ✓ The *STARTING FILL* screen is displayed.

CHAPTER 7 • Insulin Site Care and Loading Cartridge

- ✓ After fill is complete, *STOPPING FILL* screen is displayed.

NOTE

You can tap **STOP** at any time during the fill process if you want to stop filling the cannula.

- ✓ The screen will return to the *Load* menu if the Site Reminder is turned off.
6. Tap  to resume insulin if finished. Or tap **Site Reminder** to set reminder. If Site Reminder is on, the pump will automatically display the *Site Reminder* screen (see the next section).

7.6 Setting Site Reminder

This section describes how to set the Site Reminder after you fill the cannula.

To set the Site Reminder without filling the cannula, from the *Home* screen, tap **OPTIONS**, tap **Load**, tap **Site Reminder** then follow the instructions below.

1. Tap  if correct. Tap **Edit Reminder** if settings need to be changed.
2. Tap **Remind Me In** and select the number of days (1–3).
- ✓ The default for the Site Reminder is set for 3 days
3. Tap **Remind Me At**. Use the on-screen keypad to enter time and tap .
4. Tap **Time of Day** to change AM or PM, if applicable. Tap .
5. Verify Site Reminder is set correctly and tap .
- ✓ *Setting Saved* screen is displayed.
- ✓ *Load* screen is displayed.
6. Tap .
- ✓ A reminder to test BG in 1 to 2 hours will display.
7. Tap .

NOTE

If this is the first time using your pump and a Personal Profile has not been defined, a screen will notify you that a profile must be activated to resume insulin. Tap **CLOSE**.

- ✓ *RESUMING INSULIN* screen is temporarily displayed.

NOTE

Control-IQ technology will continue to operate while changing a cartridge. If you complete a cartridge change and resume insulin while Control-IQ technology is adjusting insulin, insulin will resume until the next five minute CGM reading. At this time the pump will resume normal operation.

2 t:slim X2 Insulin Pump Features

CHAPTER 8

Manual Bolus

CHAPTER 8

8.1 Manual Bolus Overview**⚠ WARNING**

DO NOT deliver a bolus until you have reviewed the calculated bolus amount. If you deliver an insulin amount that is too high or too low, this could cause hypoglycemia (low BG) or hyperglycemia (high BG) events. You can change the amount of insulin before you deliver your bolus.

⚠ WARNING

Delivering large boluses, or delivering multiple boluses back to back may cause hypoglycemia (low BG) events. Pay attention to IOB and the bolus calculator recommended dose before delivering large or multiple boluses.

⚠ WARNING

If you do not see a reduction in BG after initiating a bolus, it is recommended that you check your infusion set for an occlusion, air bubbles, or for leaks or cannula dislodgement. If the condition persists, call Customer Technical Support or seek medical attention as required.

📌 NOTE

The information in this chapter does NOT apply to boluses delivered automatically by

Control-IQ™ technology. For information about Automatic Bolus Delivery, see Automatic Correction Bolus Delivery in Section 30.2 How Control-IQ Technology Works.

A bolus is a quick dose of insulin that is usually delivered to cover food eaten or to correct high glucose. A bolus can be requested from either the t:slim X2™ insulin pump or the t:connect™ mobile app.

The minimum bolus size is 0.05 units. The maximum bolus size is 25 units. If you attempt to deliver a bolus that is larger than the amount of insulin in the cartridge, a message screen appears indicating that there is not enough insulin to deliver the bolus.

Your t:slim X2 pump offers you the ability to deliver different boluses to cover carbohydrate intake (food bolus) and bring your BG back to target (correction bolus). Food and correction boluses can also be programmed together.

📌 NOTE

If you start a manual bolus request on the pump, you must complete it on the pump. You cannot

request a bolus from the t:connect mobile app while a bolus request is active on the pump.

If Carbs is turned on in your active Personal Profile, you will enter grams of carbohydrate and the bolus will be calculated using your Carb Ratio.

If you are not using Control-IQ technology and Carbs is turned off in your active Personal Profile, you will enter units of insulin to request the bolus.

📌 NOTE

If you deliver a manual bolus, Control-IQ technology will not be able to deliver an automatic correction bolus until 60 minutes after the manual bolus has completed.

Before you use the t:connect™ mobile app to deliver a bolus, ensure your smartphone's security feature (e.g., screen lock, passcode, face recognition) is turned on. Never share your security PIN/password or authorize any other person to access your smartphone via their biometric information to avoid unintentional changes in your delivery of insulin.

NOTE

If your smartphone is not connected to the pump, you can only request a bolus from the pump. For more information on establishing a connection between your smartphone and the pump, see Section 4.3 Connecting to a Smartphone.

PRECAUTION

CHECK your pump's settings regularly to ensure they are correct. Incorrect settings can result in over delivery or under delivery of insulin. Consult your healthcare provider as needed.

8.2 Initiating a Bolus

To request a bolus, tap **BOLUS** on your pump's *Home* screen or tap **Bolus** from the *Navigation* bar in the t:connect mobile app.

WARNING

You have 10 seconds to cancel a bolus after requesting it to completely avoid insulin delivery; both the pump and the t:connect mobile app will say "requesting bolus" during this time. See Section 8.10 Canceling or Stopping a Bolus Using the Pump or Section 8.15 Canceling or Stopping a Bolus Using the t:connect Mobile App for instructions to cancel a bolus.

You can request a bolus using the t:connect mobile app when each of the following conditions are true:

- You have a compatible smartphone (see tandemdiabetes.com/mobilesupport)
- Your smartphone is connected to your pump
- You have a native security feature of your smartphone turned on

See Section 8.11 Bolus Delivery Using the t:connect Mobile App for further instructions to use the t:connect mobile app to request a bolus.

8.3 Correction Bolus Calculation

Once the pump knows your glucose value, it will determine whether to recommend that a correction bolus to be added to any other bolus requested on the *Bolus* screen. The pump can receive your glucose value from manual entry into the pump or the CGM.

When your glucose value is:

- Above Target BG: the insulin for the food bolus and the correction bolus will be added together. If IOB is present, it is subtracted only from the correction portion of the bolus.
- Between 70 mg/dL and Target BG: You will be given an option to reduce the food bolus to account for the lower glucose level. In addition, if IOB is present, it will also be used to reduce the bolus calculation.
- Below 70 mg/dL: The food bolus will be reduced for the low glucose value. In addition, if IOB is present, it will also be used to reduce the bolus calculation.

Always treat hypoglycemia (low BG) with fast-acting carbohydrates according to the instructions of your healthcare provider and then re-test your BG to ensure that the treatment was successful.

CHAPTER 8

Glucose Value Auto-Population with CGM

⚠ PRECAUTION

PAY ATTENTION to the trend information on the *CGM Home* screen, as well as your symptoms, before using CGM values to calculate and deliver a correction bolus. Individual CGM values may not be as accurate as BG meter values.

📌 NOTE

With a CGM that is approved for non-adjunctive use, there is no need to take a fingerstick to make a treatment decision, as long as your symptoms match the CGM readings. The t:slim X2 insulin pump and the t:connect mobile app can automatically use CGM readings in their respective bolus calculators when Control-IQ technology is enabled and there is a valid reading and trend arrow available from the CGM. If your CGM readings don't match your symptoms, it is recommended that you wash your hands thoroughly and use your BG meter to replace the CGM reading in the bolus calculator if the BG meter value matches your symptoms. If you want to align your CGM with your BG meter, you should follow the instructions to calibrate your CGM. Do not take insulin doses too close together, often referred to as stacking insulin. If you have recently given a bolus, you

might wait 60 minutes to see if your readings respond to the bolus.

📌 NOTE

Retrospective analysis of the pivotal study results indicated that there was an increased incidence of CGM values <70 mg/dL five hours after a bolus was delivered when glucose values were auto-populated. See Section 33.10 Additional Analysis of Sensor Glucose Value Auto-Population with CGM for more information.

Your glucose value is automatically entered into the GLUCOSE field on the *Bolus* screen when each of the following conditions are true:

- Control-IQ technology is turned on and available
- A CGM session is active
- A CGM value is present
- A CGM trend arrow is available on the CGM Home screen

📌 NOTE

For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's

product instructions. You can also see Section 25.3 Rate of Change Arrows.

When the CGM reading is automatically populated into the bolus calculator, only the current CGM reading is used to calculate the correction bolus. The trend arrow is not used in the dose calculation. Speak with your healthcare provider for recommendations on how best to utilize the arrows for your correction bolus dosing.

If your healthcare provider has advised you to use the trend arrow to adjust your correction dose, or if you want to change the glucose value used to calculate your correction dose, you can manually override the glucose value auto-populated from your CGM.

To change the glucose value auto-populated from your CGM you can tap on the GLUCOSE value on the

Bolus screen. The following example shows the *Bolus* screen on the pump.



NOTE

If the glucose value auto-populated from your CGM was above or below your Target BG, your pump will present you with the *Above Target* or *Below Target Correction Bolus* confirmation screen.

Correction Bolus Confirmation Screens

To access the *Correction Bolus* confirmation screen on the pump, tap **BOLUS** from the *CGM Home* screen.

- If your CGM value or trend arrow are not available on the *Home* screen, the *Bolus* screen appears.

- If you have a CGM value and trend arrow, the *Correction Bolus* confirmation screen appears (if appropriate).

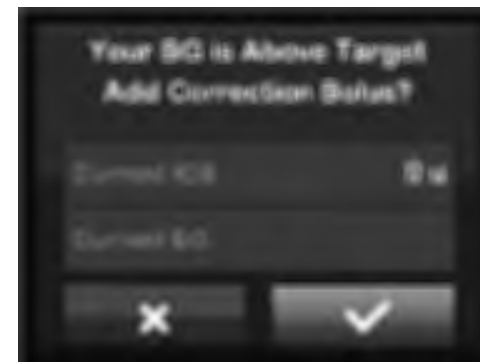
You cannot tap the **Current BG** value on these *Correction Bolus* confirmation screens to change the glucose value auto-populated from your CGM.

Tap either  or  and proceed to the *Bolus* screen to change the glucose value as described above. Once the value is changed, if the manually inputted value is above or below your Target BG, your pump will again present you with the *Above Target* or *Below Target* confirmation screen where you can choose to accept the correction bolus or decline it.

Above Target

If your glucose value is above your Target BG, you can calculate and add a correction bolus to any other bolus you request.

Calculate and add a correction bolus from the pump as follows:



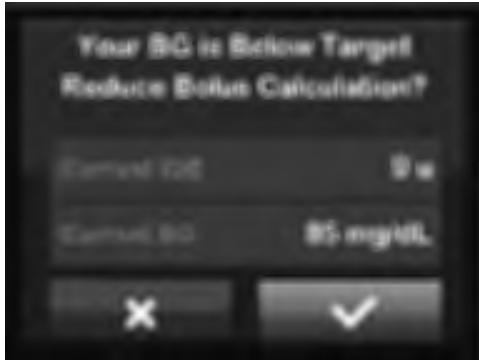
- To accept the correction bolus tap . A correction bolus is calculated and will be added to any food bolus you request on the *Bolus* screen.
- To decline the correction bolus, tap . No correction bolus will be added to any food bolus you request on the *Bolus* screen.

Below Target

If your glucose value is below your Target BG, the pump presents you with the option to calculate and subtract a

CHAPTER 8

correction bolus from any other bolus you request.



Calculate and apply a correction bolus from the pump as follows:

- To accept the correction bolus tap . A correction bolus is calculated and will be subtracted from any food bolus you request on the *Bolus* screen.
- To decline the correction bolus, tap . No correction bolus will be subtracted from any food bolus you request on the *Bolus* screen.

Within Target

If your glucose value is the same value as your Target BG, no *Correction Bolus* screen is displayed.

BG Value Manual Entry

If your glucose value was not auto-populated on the *Bolus* screen based on the conditions needed for that feature, you will need to manually enter your BG value into the pump before confirming bolus delivery. The conditions needed for the auto-populate feature are:

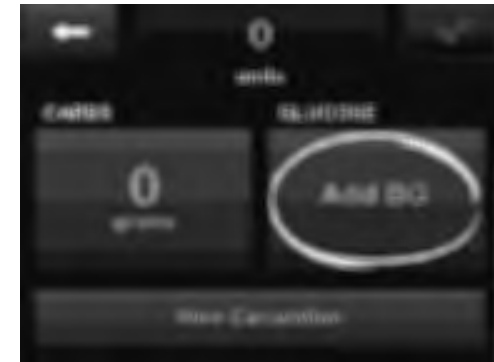
- Control-IQ technology is turned on and available
- A CGM session is active
- A CGM value is present
- A CGM trend arrow is available

NOTE

For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's user guide. You can also see Section 25.3 Rate of Change Arrows.

The *Correction Bolus* confirmation screens are displayed, if appropriate, after you manually enter your BG value on the *Bolus* screen. Manually enter your BG value into the pump as follows:

- From the *Home* screen tap **BOLUS**.
- Tap **Add BG**.



- Using the on-screen keypad, enter your BG value.
- Tap to save the BG value in your pump history.

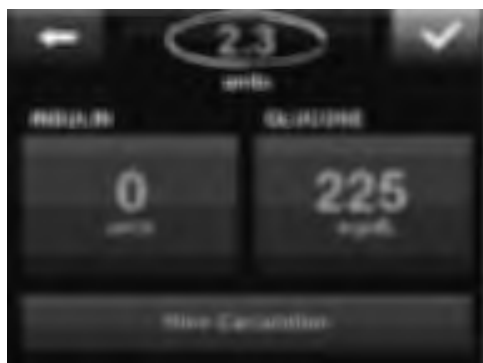
NOTE

This saves the BG value in your pump history whether or not a bolus is delivered.

- Follow the steps in the appropriate Target section above depending on the results of your BG value.

8.4 Bolus Override

You can override the calculated bolus by tapping on the calculated units value and entering the units of insulin you want delivered. The bolus override is always an available option; the following example shows the bolus override on the pump screen.



8.5 Food Bolus Using Units

If you are using Control-IQ technology, skip to Section 8.6 Food Bolus Using Grams. Otherwise, to deliver a food bolus using the pump:

1. From the *Home* screen, tap **BOLUS**.

2. Tap **0 units** on the left side of the screen.
3. Using the on-screen keypad enter units of insulin to be delivered, then tap .

⚠ WARNING

ALWAYS confirm that the decimal point placement is correct when entering bolus information. Incorrect decimal point placement can prevent you from getting the proper amount of insulin that your healthcare provider has prescribed for you.

4. Tap to confirm the units of insulin to be delivered.
 5. Confirm Request.
 - Tap if entered data is correct.
 - Tap to go back to make changes or view calculations.
 6. Tap .
- ✓ The *BOLUS INITIATED* screen is temporarily displayed.

8.6 Food Bolus Using Grams

To deliver a food bolus using the pump:

1. From the *Home* screen, tap **BOLUS**.
2. Tap **0 grams**.
3. Using the on-screen keypad enter grams of carb and tap .
 - To add multiple carb values enter first value, then tap , enter second value, tap . Continue until done.
 - To clear the value entered and start over, tap the back arrow.
4. Check that the grams of carb are entered in the correct location on the screen.
5. Tap to confirm the units of insulin to be delivered.

You can always tap **View Calculation** to display the *Delivery Calculation* screen.

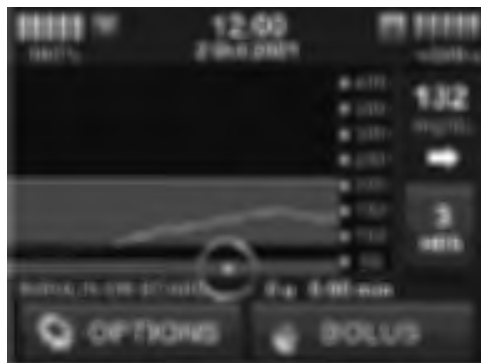
CHAPTER 8

6. Confirm Request.

- Tap  if entered data is correct.
- Tap  to go back to make changes or view calculations.

7. Tap .

- ✓ The *BOLUS INITIATED* screen is temporarily displayed.
- ✓ After the bolus delivery is complete, an icon displays below the CGM graph.

 NOTE

Each bolus icon represents one bolus delivery. Hash marks on the bolus bar denote time increments based on your

graph settings; these hash marks may temporarily obstruct a bolus icon as the graph changes over time.

8.7 Extended Bolus

The Extended Bolus feature allows you to deliver part of the bolus now and part of the bolus slowly over a period of up to 8 hours, or to deliver the whole bolus over an extended period of time. This can be helpful for high fat meals such as pizza or if you have gastroparesis (delayed stomach emptying).

When extending a bolus, any correction bolus amount will always be given in the DELIVER NOW portion. Talk with your healthcare provider to determine if this feature is appropriate for you, as well as for recommendations on the split between now and later and the duration for the later portion.

1. From the *Home* screen, tap **BOLUS**.
2. Tap **0 grams** (or **0 units**).

3. Use the on-screen keypad to enter grams of carb (or units of insulin). Tap .

4. If desired, tap **Add BG**, use the on-screen keypad to enter a glucose value, and tap .

5. Tap  to confirm the units of insulin to be delivered.

You can always tap **View Calculation** to display the *Delivery Calculation* screen.

6. Confirm Request.

- Tap  if entered data is correct.
- Tap  to go back to make changes or view calculations.

7. Tap **EXTENDED** to turn on the extended feature, then tap .

8. Tap **50%** under **DELIVER NOW** to adjust the percentage of the food bolus that is to be delivered immediately.

The percentage value for DELIVER LATER is automatically calculated by the pump. The default is 50% NOW and 50% LATER. The default for DURATION is 2 hours.

9. Use the on-screen keypad to enter the percentage of the bolus to DELIVER NOW and tap .

For the DELIVER NOW portion, the minimum amount is .05 units. If the DELIVER NOW portion is less than .05 units, you will be notified and the DELIVER NOW portion will be set to .05 units.

The DELIVER LATER portion of the extended bolus also has minimum and maximum rates. If you program a DELIVER LATER rate outside of these limits, you are notified and the duration of the DELIVER LATER portion is adjusted.

10. Tap 2 hrs under DURATION.

The default maximum duration for extended bolus delivery is 8 hours.

11. Use the on-screen keypad to adjust the length of time the bolus is to be delivered, then tap .

12. Tap .

You can always tap View Units to display the breakdown of units to be delivered NOW versus LATER.

13. Confirm Request.

- Tap  if entered data is correct.
- Tap  to go back to make changes or view calculations.

14. Tap .

- ✓ The *BOLUS INITIATED* screen is temporarily displayed.

- ✓ After the bolus delivery is complete, an icon displays below the CGM graph.



Only one extended bolus can be active at any given time. However, if the DELIVER LATER portion of an extended bolus is active, you can request another standard bolus.

8.8 Max Bolus

The Max Bolus setting allows you to set a limit to the maximum insulin delivery amount for a single bolus.

The default setting for Max Bolus is 10 units, but can be set to any value between 1 to 25 units. To adjust the Max Bolus setting, follow these steps.

CHAPTER 8

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap **Pump Settings**.
5. Tap **Max Bolus**.



6. Using the on-screen keypad, enter the desired amount for maximum bolus (1–25 units) and tap .

NOTE

If you set the max bolus to 25 units and a bolus larger than 25 units is calculated using your Carb Ratio or Correction Factor, after the bolus is delivered a reminder

screen will appear. The option of delivering the remaining amount of the bolus up to an additional 25 units will be given (see Section 13.9 Max Bolus Alerts). You must confirm delivery of this additional amount from your pump.

8.9 Quick Bolus

The Quick Bolus function enables you to deliver a bolus by simply pressing a button, if enabled. It is a way to deliver a bolus by following beep/vibration commands without navigating through or viewing the pump screen.

Quick Bolus can be set to correspond to either units of insulin or grams of carbohydrate. When Control-IQ technology is enabled, it will use the Quick Bolus as a correction bolus if configured as units of insulin, or as a food bolus if configured as grams of carbohydrate. Control-IQ technology uses the information about carbohydrate intake to optimize insulin delivery after eating.

Configure Quick Bolus

The default for the Quick Bolus function is off. Quick Bolus can be set to either units of insulin or grams of carbohydrate. The increment options are 0.5, 1.0, 2.0, and 5.0 units; or 2, 5, 10 and 15 grams.

NOTE

It is recommended to use grams of carbohydrate in a bolus delivery whenever using Control-IQ technology.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap **Pump Settings**.
5. Tap **Quick Bolus**.
6. Tap **Increment Type**.
7. Tap **units of insulin or grams of carbohydrate** to select. Tap .
8. Tap **Increment Amount**.

9. Select the preferred increment amount.

NOTE

The increment amount is added with each press of the **Screen On/Quick Bolus** button when delivering a quick bolus.

10. Review entered values and tap .

11. Confirm Settings.

- Tap  if entered data is correct.
- Tap  to go back to make changes.

12. Tap the **Tandem** logo to return to the *Home* screen.

Deliver a Quick Bolus

If the Quick Bolus function is turned on, you can deliver a bolus by pressing the **Screen On/Quick Bolus** button to deliver your bolus. Quick boluses are delivered as standard boluses (there is no glucose value entry or extended bolus).

PRECAUTION

ALWAYS check the pump screen to confirm correct programming of the bolus amount when you first use the Quick Bolus feature. Checking the screen will ensure that you are correctly using the beep/vibration commands to program the intended bolus amount.

1. Press and hold the **Screen On/Quick Bolus** button. The *Quick Bolus* screen will appear. Listen for two beeps (if sound volume is set to beep) or feel for vibrations (if sound volume is set to vibrate).
2. Press the **Screen On/Quick Bolus** button for each increment until desired amount is reached. The pump will beep/vibrate for each button press.
3. Wait for the pump to beep/vibrate once for each increment pressed to confirm desired amount.
4. After the pump beeps/vibrates, press and hold the **Screen On/Quick Bolus** button for several seconds to deliver the bolus.

NOTE

If you want to cancel the bolus and return to the *Home* screen, tap  on the *Quick Bolus* screen.

If more than 10 seconds have passed with no input, the bolus is canceled and never delivered. In this case, the Incomplete Bolus Alert will be displayed on your pump and (if applicable) on your smartphone via the t:connect mobile app.

You cannot exceed the Max Bolus setting defined in your Pump Settings when using the Quick Bolus feature. Once you reach the Max Bolus amount, a different tone will sound to notify you (if Quick Bolus is set to vibrate, the pump will stop vibrating in response to additional button presses to notify you). Look at the screen to confirm the bolus amount.

You cannot exceed 20 button presses when using the Quick Bolus feature. Once you reach 20 button presses, a different tone will sound to notify you (if Quick Bolus is

CHAPTER 8

set to vibrate, the pump will stop vibrating in response to additional button presses to notify you). Look at the screen to confirm the bolus amount.

If you hear a different tone at any point during programming or the pump stops vibrating in response to button presses, check the screen to confirm the bolus amount. If the *Quick Bolus* screen does not display the correct bolus amount, use the touchscreen to enter bolus information.

- ✓ The *BOLUS INITIATED* screen is temporarily displayed.

NOTE

If Control-IQ technology is on and has adjusted insulin delivery during a Quick Bolus, the remaining Quick Bolus insulin will be delivered.

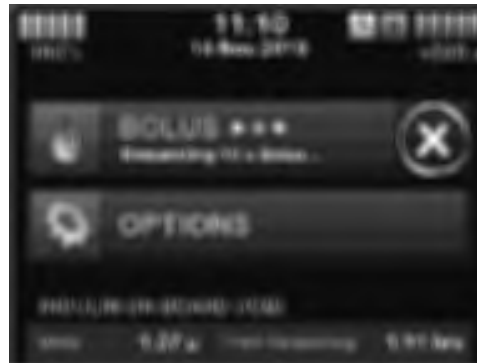
8.10 Canceling or Stopping a Bolus Using the Pump

You have 10 seconds to cancel a bolus after requesting it to completely avoid

insulin delivery; the pump will say “requesting bolus” during this time.

To cancel a bolus request from the pump:

1. Tap 1–2–3 to access the *Home* screen.
2. Tap  to cancel the bolus.



- ✓ **BOLUS** will remain inactive while the bolus is being canceled.

NOTE

Once canceled, **BOLUS** will become active again on the Home screen.

To stop a bolus after delivery has started:

1. Tap 1–2–3 to access the *Home* screen.
2. Tap  to stop delivery.
3. Tap .
- ✓ The *BOLUS STOPPED* screen is displayed and the units delivered are calculated.
- ✓ Units requested and delivered are shown.
4. Tap .

8.11 Bolus Delivery Using the t:connect Mobile App

Before you use the t:connect mobile app to deliver a bolus, enable your smartphone security feature (e.g., screen lock, passcode, face recognition). Never share your security PIN/password or authorize any other person to access your smartphone via

their biometric information to avoid unintentional delivery of insulin.

NOTE

If your smartphone is not compatible with the Bolus Delivery feature set of the t:connect mobile app, you cannot use the t:connect mobile app to request, cancel, or stop a bolus. For an up-to-date list of supported smartphones, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen.

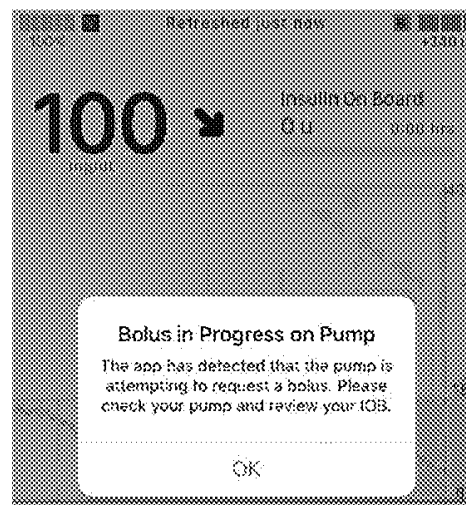
You can use the t:connect mobile app to deliver the following boluses:

- Correction bolus (see Section 8.12 Correction Bolus Using the t:connect Mobile App)
- Override bolus (see Section 8.13 Bolus Override Using the t:connect Mobile App)
- Food bolus using either units of insulin or grams of carbohydrate (see Section 8.14 Food Bolus Using the t:connect Mobile App)

You must use your pump for the following features:

- Extended Bolus (see Section 8.7 Extended Bolus)
- Max Bolus setting (see Section 8.8 Max Bolus)
- Quick Bolus (see Section 8.9 Quick Bolus)

If you request any bolus from the pump, you must complete it on the pump. If you attempt to request a bolus from the t:connect mobile app while a bolus request is active on the pump, the t:connect mobile app will generate the *Bolus in Progress on Pump* notification and prevent you from starting a bolus.



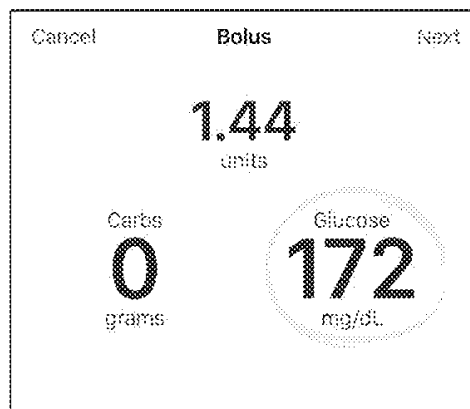
8.12 Correction Bolus Using the t:connect Mobile App

Once the t:connect mobile app knows your glucose value, it will determine whether to recommend that a correction bolus to be added to any other bolus requested on the *Bolus* screen. The t:connect mobile app can receive your glucose value from manual entry into the t:connect mobile app or auto-populate from the CGM. See *Glucose Value Auto-Population with CGM* for more information about automatically populated glucose values.

To change the glucose value auto-populated from your CGM you can tap on the GLUCOSE value on the *Bolus* screen. The following example

CHAPTER 8

shows the *Bolus* screen in the t:connect mobile app.



Correction Bolus Confirmation Screens

To access the Correction Bolus confirmation screen on the t:connect mobile app and enable the Correction Bolus toggle, tap Bolus on the Navigation bar.

- If your CGM value or trend arrow are not available on the Home screen, the Correction Bolus confirmation screen appears after you enter your glucose value into the t:connect mobile app as described above.

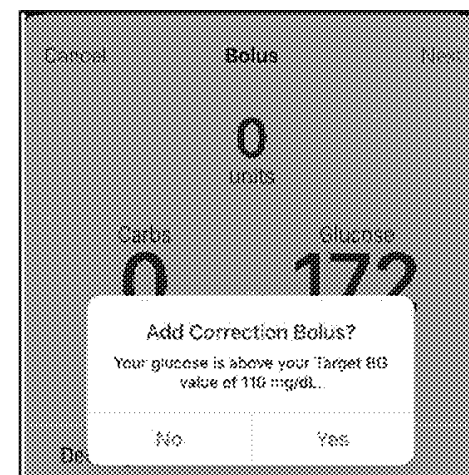
- If you have a CGM value and trend arrow, the Correction Bolus confirmation screen appears when you tap Bolus (if appropriate).

Above Target

If your BG or sensor glucose value is above your Target BG, you can calculate and add a correction bolus to any other bolus you request.

Calculate and add a correction bolus from the t:connect mobile app as follows:

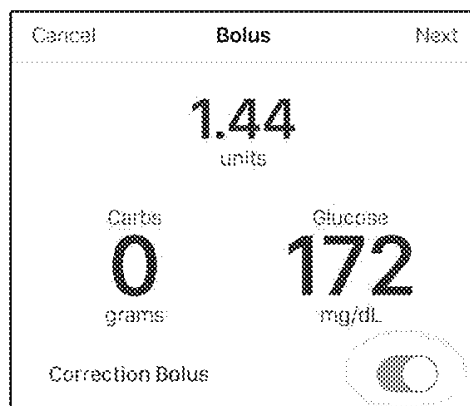
- To accept the correction bolus, tap **Yes** on the *Correction Bolus* confirmation screen.



- To decline the correction bolus, tap **No** on the *Correction Bolus* confirmation screen.

If you tap **Yes**, the Correction Bolus toggle will be turned on. You can later decline the correction bolus by tapping

the Correction Bolus toggle to the OFF position.

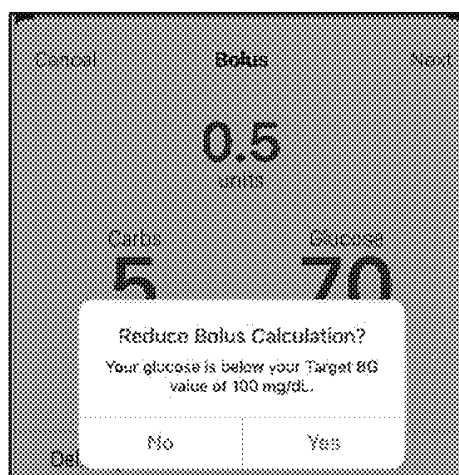


Below Target

If your BG or sensor glucose value is below your Target BG, the t:connect mobile app presents you with the option to subtract a correction bolus from any other bolus you request; any values the t:connect mobile app delivery calculation shows in red are subtracted from the calculated bolus amount.

Calculate and add a correction bolus from the t:connect mobile app as follows:

- To accept the correction bolus, tap **Yes** on the *Correction Bolus* confirmation screen.



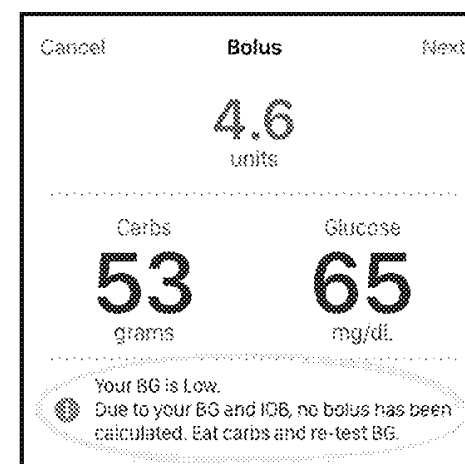
- To decline the correction bolus, tap **No** on the *Correction Bolus* confirmation screen.

If you tap **Yes**, the Correction Bolus toggle will be turned on. You can later decline the correction bolus by tapping the Correction Bolus toggle to the OFF position.

NOTE

If your blood glucose is below 70 mg/dL, the food bolus will be reduced to automatically correct for the low glucose value. In this case,

the Correction toggle will be unavailable, and the t:connect mobile app will display the Low BG Alert in its place.



Within Target

If your BG or sensor glucose value is the same value as your Target BG, no correction bolus will be included in the bolus calculation.

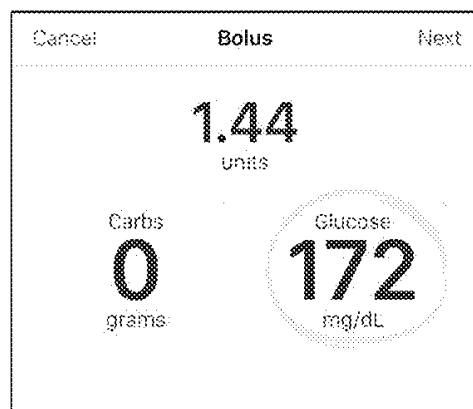
BG Value Manual Entry Using the t:connect Mobile App

Manually enter your BG value into the t:connect mobile app as follows:

- From the navigation bar, tap **Bolus**.

CHAPTER 8

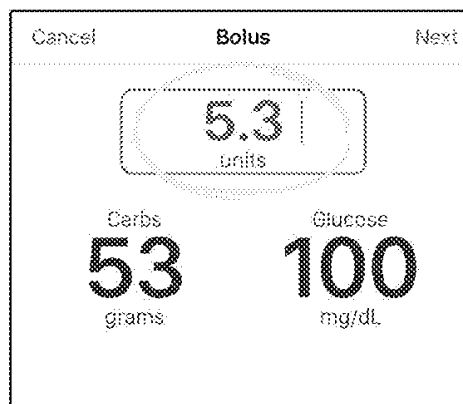
2. Tap Add Glucose.



3. Use the on-screen number keypad to enter your BG value.
4. Tap **Done** (iOS) or **✓** (Android) on the number keypad to save your BG value in your pump history and close the number keypad.
5. Follow the steps in the appropriate Target section above depending on the results of your BG value.

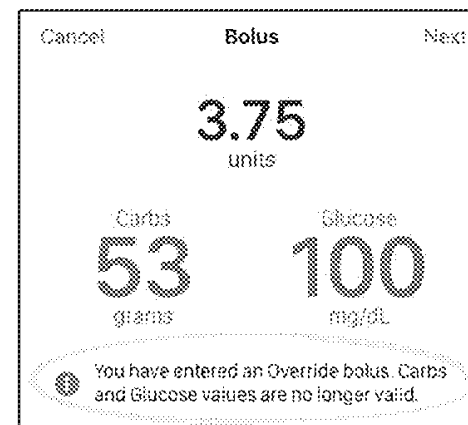
8.13 Bolus Override Using the t:connect Mobile App

You can override the calculated bolus by tapping on the calculated units value and entering the units of insulin you want delivered. The bolus override is always an available option; the following example shows the bolus override in the t:connect mobile app.



If you use the t:connect mobile app to set the override bolus value, the Bolus Override Alert will appear as an

informational message on the *Bolus* screen.



8.14 Food Bolus Using the t:connect Mobile App

To deliver a food bolus using the t:connect mobile app:

1. Tap the **Bolus** icon on the *Navigation* bar.
2. Tap **0 grams** or **0 units** on the left side of the screen, depending on the settings in your active Personal Profile.

3. Use the number keypad to enter units of insulin or grams of carb to be delivered.
4. Tap **Done** (iOS) or  (Android) on the number keypad to close the keypad.
- ✓ The total bolus amount at the top of the screen updates (if applicable).
5. Tap **Next** (iOS) or  (Android) to confirm the units of insulin to be delivered.
- ✓ The *Confirm Bolus* screen is temporarily displayed.
6. Confirm request:
 - Tap **Next** (iOS) or  (Android) if entered data is correct.
 - Tap **Back** (iOS) or **X** (Android) to go back to make changes or view calculations.
7. Tap the **Deliver Bolus** icon.
8. The t:connect mobile app will generate a confirmation prompt;

use your smartphone's security feature to confirm the bolus request or tap **Cancel** to return to the *Bolus* screen.

- ✓ The t:connect mobile app returns you to the dashboard.
- 9. A bolus bar appears above the navigation bar until the entire bolus has been delivered, including a cancel/stop button as well as the bolus type and amount requested.

8.15 Canceling or Stopping a Bolus Using the t:connect Mobile App

⚠ WARNING

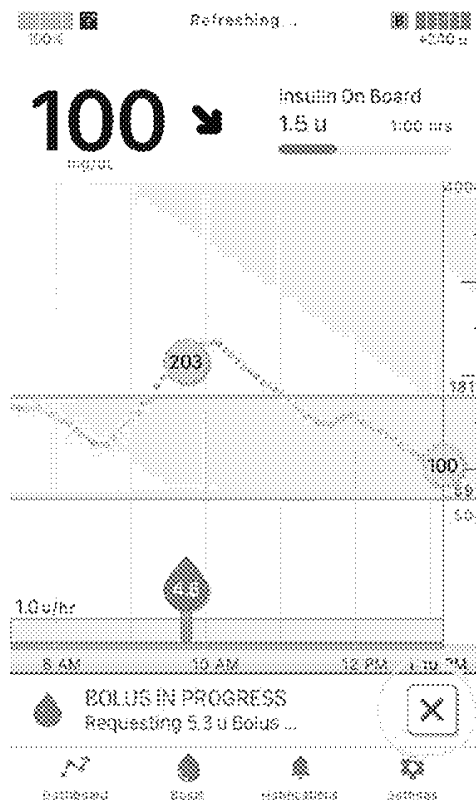
Any time you request a bolus, you have 10 seconds to cancel the bolus after requesting it to completely avoid insulin delivery. Both the pump and the t:connect mobile app will say "requesting bolus" during this time as long as your pump and the t:connect mobile app are connected. You can cancel the bolus from either the pump or the app regardless of how you requested it.

You may cancel or stop any bolus via the t:connect mobile app as long as the t:connect mobile app has a Bluetooth connection to the pump, regardless of whether you initiated the bolus from the pump or the t:connect mobile app.

To cancel a bolus request from the t:connect mobile app:

CHAPTER 8

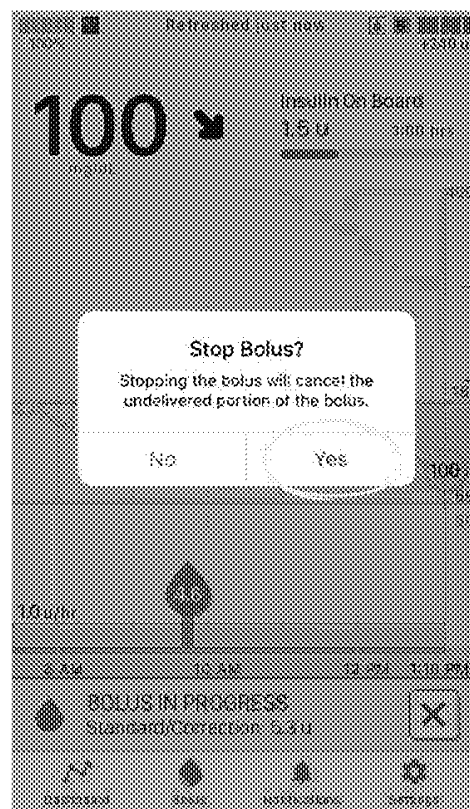
1. Tap  to cancel delivery.



NOTE

The  is always available in the t:connect mobile app as part of the bolus bar during bolus delivery; you don't need to visit the *Bolus* screen to cancel a bolus.

2. Tap **Yes** in the confirmation prompt to cancel the bolus.



- ✓ The Bolus Stopped Alert appears and lists the units delivered as 0.

To stop a bolus after delivery has started:

1. Tap  on the t:connect mobile app bolus bar to stop delivery.
 2. Tap **Yes** on the t:connect mobile app confirmation prompt.
- ✓ The *BOLUS STOPPED* screen is displayed and the units delivered are calculated.
 - ✓ Units requested and delivered are shown.
3. Tap  on the t:connect mobile app informational message.

8.16 Pump Connection Lost

Connection Lost During Bolus Request

If your smartphone becomes disconnected from the pump while you are requesting a bolus before you confirm bolus delivery, the t:connect mobile app generates a Pump Connection Lost Alert. When you

receive this notification, tap **OK** to return to the dashboard.

- No bolus will be delivered. Use the pump to deliver this bolus.
- Check your smartphone's Bluetooth connection and Bluetooth settings.
- You cannot use the t:connect mobile app to request a bolus until you have restored your smartphone's connection to the pump.

Connection Lost During Bolus Delivery

If your smartphone becomes disconnected from the pump while the pump is delivering a bolus, the t:connect mobile app generates a Pump Connection Lost Alert. When you receive this notification, the t:connect mobile app will return you to the dashboard.

- Your pump will still deliver the remainder of the bolus unless you use the pump to stop the bolus.

- You must re-establish the connection between your smartphone and the pump before you use the t:connect mobile app to deliver another bolus. See Section 4.3 Connecting to a Smartphone.

⚠ PRECAUTION

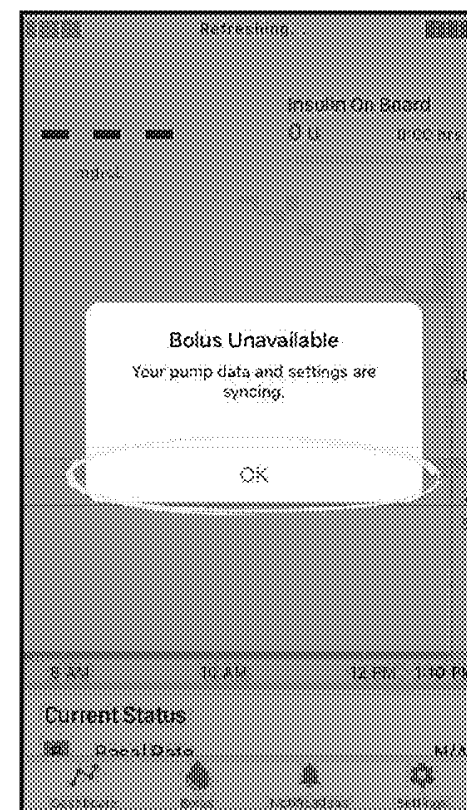
DO NOT ignore symptoms of high and low glucose. If your t:connect mobile app readings do not match your symptoms, check your pump display and confirm that your pump has established a Bluetooth connection with your smartphone.

📌 NOTE

This Mobile Connection setting is not related to your CGM Bluetooth connection. For CGM Bluetooth information, see Section 21.1 About Bluetooth Technology.

Even if the t:connect mobile app has established a connection with the pump, you cannot use the t:connect mobile app to request a bolus until it has received your bolus settings from the pump. If you tap **Bolus** during this time to request a bolus, the t:connect mobile app will generate a Bolus Unavailable Alert as shown in the

following example; tap **OK** to return to the dashboard.



This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 9

Starting, Stopping, or Resuming Insulin

CHAPTER 9 • Starting, Stopping, or Resuming Insulin

9.1 Starting Insulin Delivery

Insulin delivery starts once you have a Personal Profile configured and activated. See Chapter 6 Insulin Delivery Settings for instructions on creating, configuring, and activating a Personal Profile.

9.2 Stopping Insulin Delivery

You can stop all insulin delivery at any time. When you stop all insulin delivery, any active bolus and any active temp rate are immediately stopped. No insulin delivery can take place while your pump is stopped. The pump will present a Resume Pump Alarm to remind you to manually resume insulin after a certain period of time. The default setting for this alarm is 15 minutes.

1. From the *Home* screen, tap **OPTIONS**.
 2. Tap **STOP INSULIN**.
- ✓ A confirmation screen displays.

3. To change the Resume Pump Alarm setting, skip to Step 4. Otherwise, tap  to accept the default setting.
- ✓ The *All Deliveries Stopped* screen appears before returning to the *Home* screen showing the status ALL DELIVERIES STOPPED. A red exclamation mark icon also appears to the right of the time and date.
4. To change the Resume Pump Alarm setting, tap the panel in the middle of the screen.



5. Select the radio button that corresponds with the time you would like the Resume Pump Alarm to display.

- ✓ The pump returns to the confirmation screen.
 - ✓ The pump will save the new alarm time, and will use this setting the next time insulin is manually suspended, unless the pump has been reset, in which case the default setting will be used.
6. Tap .
 - ✓ The *All Deliveries Stopped* screen appears before returning to the *Home* screen showing the status ALL DELIVERIES STOPPED. A red exclamation mark icon also appears to the right of the time and date.

NOTE

If you manually stop insulin delivery, you must manually resume insulin delivery. Control-IQ™ technology does not automatically resume insulin if you stop it manually.

9.3 Resuming Insulin Delivery

If pump screen is not on, press **Screen On/Quick Bolus** button once to turn on your t:slim X2™ pump screen.

1. Tap 1–2–3.
 2. Tap .
- ✓ The *RESUMING INSULIN* screen is temporarily displayed.

– OR –

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **RESUME INSULIN**.
3. Tap .

The *RESUMING INSULIN* screen is temporarily displayed.

9.4 Disconnecting When Using Control-IQ Technology

When you need to disconnect your pump from your body, stop insulin delivery. Stopping insulin delivery tells the system that you are not actively delivering insulin, which also stops Control-IQ technology so that it does not continue to calculate insulin delivery adjustments.

This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 10

t:slim X2 Insulin Pump Information and History

CHAPTER 10 • t:slim X2 Insulin Pump Information and History

10.1 t:slim X2 Pump Info

Your t:slim X2™ pump allows access to information about your pump. In the *Pump Info* screen you have access to items such as your pump Serial Number, Customer Technical Support contact information, website, and software/hardware versions.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Pump Info**.
4. Scroll through the Pump Info using the **Up/Down Arrows**.
5. Tap the **Tandem logo** to return to the *Home* screen.

10.2 t:slim X2 Pump History

Pump History displays a historical log of pump events. At least 90 days of data can be viewed in History. When the maximum number of events is reached,

the oldest events are removed from the history log and replaced with the most recent events. The following can be viewed in Pump History:

Delivery Summary, Total Daily Dose, Bolus, Basal, Load, BG, Alerts and Alarms, Control-IQ, and Complete.

Delivery Summary breaks down total insulin delivery by basal and bolus types into units and percentages. It can be viewed by the selected time period of: Today, 7 Day, 14 Day and 30 Day Average.

Total Daily Dose breaks down basal and bolus delivery into units and percentages for each individual day. You can scroll through each individual day to see your total insulin delivery.

The Bolus, Basal, Load, BG, and Alerts and Alarms are categorized by date. The event details in each report are listed by time.

The Complete section includes all information from each section as well as any changes to settings.

The letter “D” (D: Alert) before an Alert or Alarm indicates the time it was

declared. The letter “C” (C: Alert) indicates the time it was cleared.

Bolus history shows the bolus request, the bolus start time, and the bolus completion time.

- The letters “PB” indicate a bolus requested, canceled, or stopped via the pump.
- The letters “RB” indicate a bolus requested, canceled, or stopped via the t:connect mobile app.

The Control-IQ history shows the historical log of the Control-IQ™ technology status, including when the feature is enabled or disabled, when Basal Rate changes were made, and when Control-IQ technology boluses were delivered. The rate of insulin delivery may change as frequently as every five minutes.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **History**.

4. Tap **Pump History**.
5. Tap desired option.
6. Tap the **Tandem** logo to return to the *Home* screen.

To find the *Help* and *About* screens, from your t:connect mobile app, tap **Settings**.

NOTE

You must access these logs on the pump; the t:connect™ mobile app does not display the pump history logs.

10.3 t:connect Mobile App Info

The t:connect mobile app allows access to information about the t:connect mobile app.

- The *Help* screen gives you access to items such as an in-app guide to t:connect mobile app configuration and use, a list of frequently asked questions, and Customer Technical Support contact information.
- The *About* screen gives you access to items such as the t:connect mobile app instructions for use, legal information, and t:connect mobile app software version.

This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 11

t:slim X2 Insulin Pump Reminders

CHAPTER 11 • Insulin K2 Insulin Pump Reminders

Your pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check your BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

If multiple Reminders, Alerts, and Alarms happen at the same time, Alarms will be displayed first, Alerts will be displayed second, and Reminders will be displayed third. Each must be confirmed separately until all have been acknowledged.

Information in this section will help you learn how to respond to Reminders.

Reminders notify you with a single sequence of three notes or a single vibration depending on the volume/vibrate setting in Sound Volume. They repeat every 10 minutes

until acknowledged. Reminders do not escalate.

11.1 Low BG Reminder

The Low BG Reminder prompts you to re-test your BG after a low glucose value is read. When turning this reminder on, you need to set a low glucose value that triggers the reminder, as well as how much time should pass before the reminder occurs.

The default for this reminder is preset to off. If on, the defaults are Remind Me Below 70 mg/dL, and Remind Me After 15 min, but you can set these values from 70 to 120 mg/dL and 10 to 20 min.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **Low BG**.

6. Low BG is set to on; to turn off, tap **Low BG**.

- a. Tap **Remind Me Below** and using the on-screen keypad, enter a Low BG value (from 70 to 120 mg/dL) that you want to trigger the reminder, then tap .
- b. Tap **Remind Me After** and using the on-screen keypad, enter the time (from 10 to 20 min), then tap .
- c. Tap  when all changes are complete.
- d. Tap the **Tandem logo** to return to the *Home* screen.

To Respond to the Low BG Reminder

To clear the reminder, tap  and then check your glucose.

11.2 High BG Reminder

The High BG Reminder prompts you to re-test your BG after a high glucose

value is read. When you turn this reminder on, you need to set a high glucose value that triggers the reminder, as well as how much time should pass before the reminder occurs.

The default for this reminder is preset to off. If on, the defaults are Remind Me Above 200 mg/dL, and Remind Me After 120 min, but you can set these values from 150 to 300 mg/dL and 1 to 3 hours.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **High BG**.
6. High BG is set to on; to turn off, tap **High BG**.
 - a. Tap **Remind Me Above** and using the on-screen keypad, enter a High BG value (from 150

to 300 mg/dL) that you want to trigger the reminder, then tap



- b. Tap **Remind Me After** and using the on-screen keypad, enter the time (from 1 to 3 hours), then tap
- c. Tap when all changes are complete.

7. Tap the **Tandem** logo to return to the *Home* screen.

To Respond to the High BG Reminder

To clear the reminder tap and then check your glucose.

11.3 After Bolus BG Reminder

The After Bolus BG Reminder prompts you to test your BG at a selected time after bolus delivery. When turning this reminder on, you need to set how much time should pass before the reminder occurs. The default is 1 hour and 30 minutes. It can be set from 1 to 3 hours.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **After Bolus BG**.
6. After Bolus BG is set to on; to turn off, tap **After Bolus BG**.
7. Tap **Remind Me After** and using the on-screen keypad, enter the time (from 1 to 3 hours) that you want to trigger the reminder, then tap .
8. Tap when all changes are complete.
9. Tap the **Tandem** logo to return to the *Home* screen.

To Respond to the After Bolus BG Reminder

To clear the reminder tap and then check BG using your BG meter.

CHAPTER 11 • Using the Tandem Pump Reminders

11.4 Missed Meal Bolus Reminder

The Missed Meal Bolus Reminder lets you know if a bolus was not delivered during a specified time period. Four separate reminders are available. When programming this reminder you need to select the Days, the Start Time, and End Time for each reminder.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **Missed Meal Bolus**.
6. On the Missed Meal Bolus screen, tap which reminder you want to set (Reminder 1 to 4) and do the following:
 - a. Tap **Reminder 1** (or 2, 3, 4).
 - b. Reminder 1 is set to on; to turn off, tap **Reminder 1**.

- c. Tap **Selected Days** and tap the day(s) you want the reminder to be on, then tap .
 - d. Tap **Start Time**, tap **Time** and using the on-screen keypad enter the start time, then tap .
 - e. Tap **Time of Day** to select AM or PM, if applicable, then tap .
 - f. Tap **End Time**, tap **Time** and using the on-screen keypad enter the end time, then tap .
 - g. Tap **Time of Day** to select AM or PM, if applicable, then tap .
 - h. Tap  when all changes are complete.
7. Tap the **Tandem logo** to return to the *Home* screen.

To Respond to the Missed Meal Bolus Reminder

To clear the reminder tap  and deliver a bolus if necessary.

11.5 Site Reminder

The Site Reminder prompts you to change your infusion set. The default for this reminder is preset to off. If on, the reminder can be set for 1 – 3 days and at a time of day selected by you.

For detailed information on the Site Reminder feature, see Section 7.6 *Setting Site Reminder*.

To Respond to the Site Reminder

To clear the reminder tap  and change your infusion set.

2 t:slim X2 Insulin Pump Features

CHAPTER 12

User Settable Alerts and Alarms

CHAPTER 12 • User-Settable Alerts and Alarms

12.1 Low Insulin Alert

Your t:slim X2™ pump keeps track of how much insulin remains in the cartridge and alerts you when it is low. The default for this alert is preset to 20 units. You can set this alert setting anywhere between 10 and 40 units. When the insulin amount reaches the set value, the Low Insulin Alert beeps/vibrates and appears on the screen. After the alert is cleared, the low insulin indicator (a single red bar on the insulin level display on the *Home* screen appears).

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Alerts**.
5. Tap **Low Insulin**.
6. Using the on-screen keypad, enter the number of units (from 10 to 40 units) that you want the Low Insulin

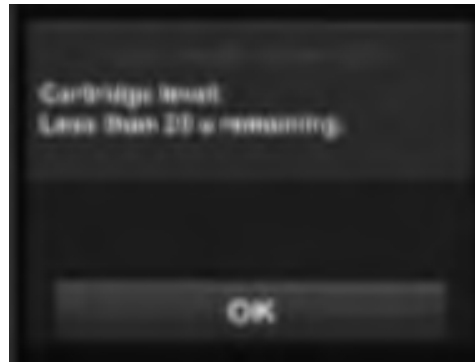
Alert value to be set to, and tap



7. Tap when all changes are complete.

To Respond to the Low Insulin Alert

To clear the alert, tap .

**12.2 Auto-Off Alarm**

Your pump can stop insulin delivery and alert you or whoever is with you if there has been no interaction with the pump within a specified period of time, particularly if you do not wear a CGM or use Control-IQ™ technology.

The default for this alarm is preset to 12 hours. You can set it anywhere between 5 and 24 hours, or off. This alarm notifies you that there has been no interaction with the pump in the specified number of hours and the pump will shut down after 60 seconds.

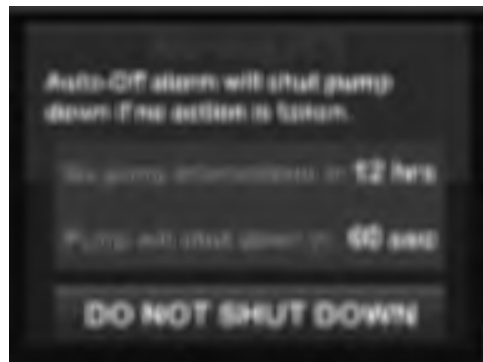
When the number of hours since you have pressed the **Screen On/Quick Bolus** button and tapped any interactive screen option or delivered a Quick Bolus passes the set value, the Auto-Off Alarm beeps and appears on the screen, and insulin delivery stops.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Alerts**.
5. Tap **Auto-Off**.
6. Tap **Auto-Off**. A confirmation screen will appear.
 - Tap to continue.

- Tap  to go back.
- 7. Verify Auto-Off is set to on, then tap **Time**.
- 8. Using the on-screen keypad, enter the number of hours (from 5 – 24 hours) that you want the Auto-Off Alarm to be triggered, and tap .
- 9. Tap , then tap  when all changes are complete.
- 10. Tap the Tandem logo to return to the *Home* screen.

To Respond to Auto-Off Warning

Tap **DO NOT SHUT DOWN**.

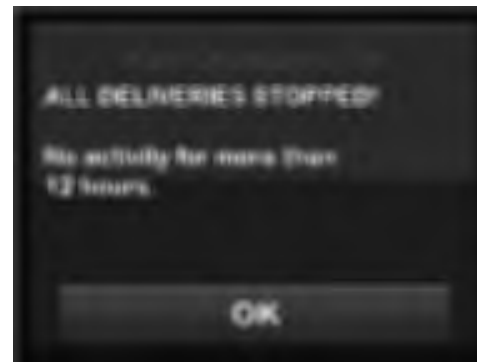


- ✓ The warning clears and the pump returns to normal operation.

If you do not clear the warning within the 60-second countdown period, the Auto-Off Alarm occurs, accompanied by an audible alarm. This alarm notifies you that your pump has stopped delivering insulin.

Auto-Off Alarm Screen

Tap .



- ✓ The *Home* screen appears, indicating a status of All Deliveries Stopped.

You must resume delivery to continue therapy, see Section 9.3 Resuming Insulin Delivery.

12.3 Max Basal Alert

Your pump allows you to set a limit to the Basal Rate that the pump will not allow you to exceed during a Temp Rate.

Once the Basal Limit in the Pump Settings has been set up (see Section 5.10 Basal Limit), you will receive an alert if the following scenarios occur.

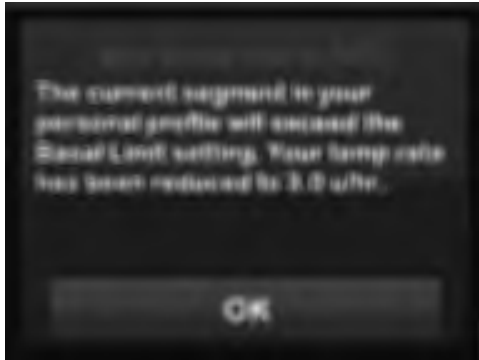
1. A Temp Rate was requested that exceeds the Basal Limit.
2. A Temp Rate is in progress, and a new Personal Profile time segment has begun, causing the Temp Rate to exceed the Basal Limit.

To Respond to Max Basal Alert

Tap  to accept the reduced Temp Rate. The reduced Temp Rate value is

CHAPTER 12 • User Settable Alarms and Alarms

the same Basal Limit value that was set up in Personal Profiles.



2 t:slim X2 Insulin Pump Features

CHAPTER 13

t:slim X2 Insulin Pump Alerts

CHAPTER 13 • t:slim X2 Insulin Pump Alerts

Your pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check you BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

If multiple Reminders, Alerts, and Alarms happen at the same time, Alarms will be displayed first, Alerts will be displayed second, and Reminders will be displayed third. Each must be confirmed separately until all have been confirmed.

Information in this section will help you learn how to respond to Alerts.

Alerts notify you with 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume. They repeat regularly

until acknowledged. Alerts do not escalate.

The t:connect™ mobile app also can provide messages, alerts, and alarms from your t:slim X2™ pump as push notifications on your smartphone. These push notifications will be identical to your pump's display unless otherwise noted in this chapter.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. For more information about connecting your pump and smartphone, see Section 4.3 Connecting to a Smartphone, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

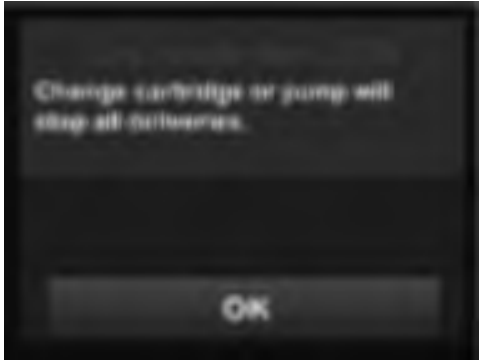
📌 NOTE

There is an additional list of alerts and errors related to CGM use in Chapter 26 CGM Alerts and Errors.

📌 NOTE

There is an additional list of alerts related to Control-IQ™ technology use in Chapter 32 Control-IQ Technology Alerts.

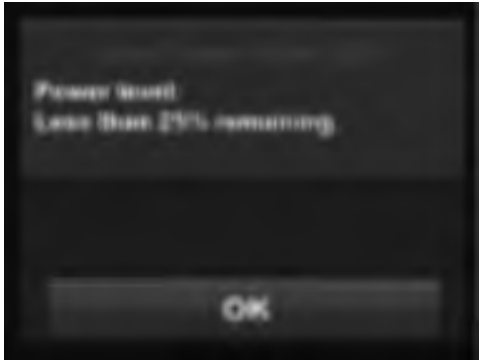
13.1 Low Insulin Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	5 units or less of insulin remain in the cartridge.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Change your cartridge as soon as possible to avoid the EMPTY CARTRIDGE ALARM and running out of insulin.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.2 Low Power Alerts

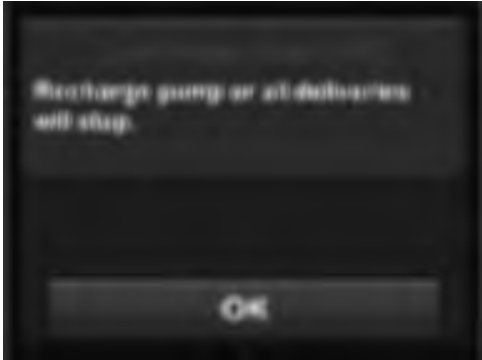
Low Power Alert 1

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Less than 25% of battery power remains.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Charge your pump as soon as possible to avoid the second LOW POWER ALERT.

NOTE

Once the LOW POWER ALERT occurs, the low-power indicator (a single red bar on the battery level display on the *Home* and *Lock* screens) appears.

Low Power Alert 2

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Less than 5% of battery power remains. Insulin delivery will continue for 30 minutes and then the pump will power off and insulin delivery will stop.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Charge your pump immediately to avoid the LOW POWER ALARM and pump power off.

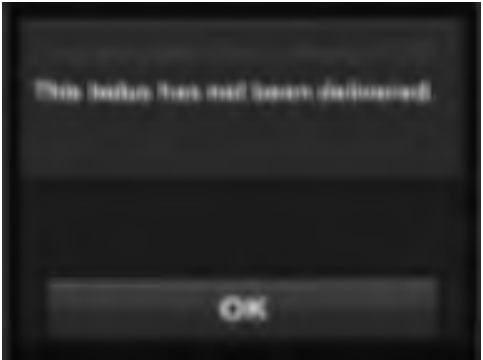
 NOTE

Once the LOW POWER ALERT occurs, the low-power indicator (a single red bar on the battery level display on the *Home* and *Lock* screens) appears.

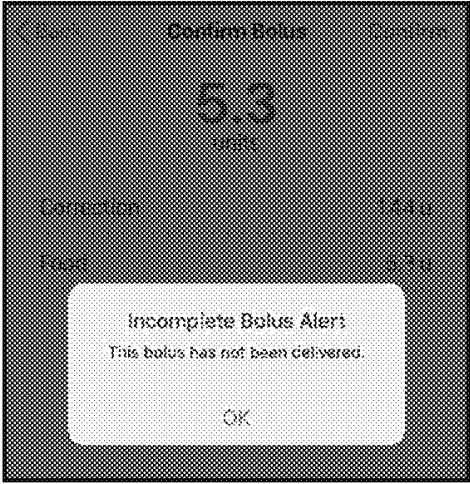
CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.3 Incomplete Bolus Alert

Incomplete Bolus Alert – Pump Screen

Screen	Explanation	
What will I see on the screen? 	What does it mean?	You started a bolus request but did not complete the request within 90 seconds.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . The <i>Bolus</i> screen will appear. Continue with your bolus request.

Incomplete Bolus Alert – t:connect Mobile App

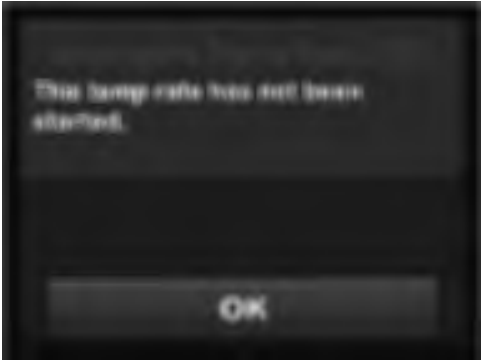
Screen	Explanation	
What will I see in the t:connect mobile app*? 	What does it mean?	You started a bolus request but did not complete the request within 90 seconds.
	How will the t:connect mobile app notify me?	• If the t:connect mobile app is open and on the <i>Bolus</i> screen, an informational message appears. • If you receive the Incomplete Bolus Alert due to interaction with other smartphone features (e.g., answering a call, using another app) or other screens in the t:connect mobile app, you will receive the alert as a notification banner.
	Will the t:connect mobile app re-notify me?	No, the alert remains on the t:connect mobile app screen until you tap OK.
	How should I respond?	Tap OK on the informational message in the t:connect mobile app. The <i>Bolus</i> screen will appear. Continue with your bolus request.

NOTE

The Incomplete Bolus Alert is the only alert in this chapter that appears differently on the pump. All other pump alerts are identical in the t:connect mobile app.

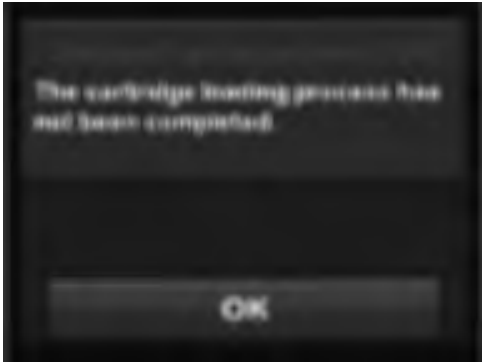
CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.4 Incomplete Temp Rate Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	You started to set up a temp rate but did not complete the request within 90 seconds.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	1. Tap . The <i>Temp Rate</i> screen will appear. Continue setting up your temp rate. 2. Tap  if you do not want to continue setting up your temp rate.

13.5 Incomplete Load Sequence Alerts

Incomplete Cartridge Change Alert

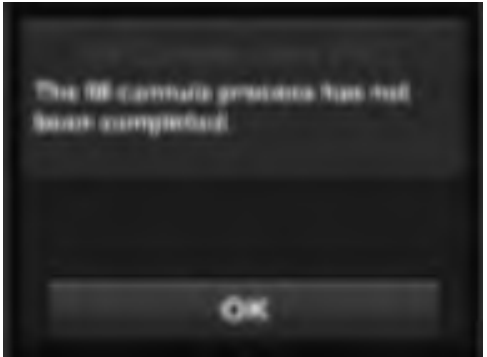
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You selected Change Cartridge from the <i>Load</i> menu but did not complete the process within 3 minutes.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Complete the cartridge change process.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

Incomplete Fill Tubing Alert

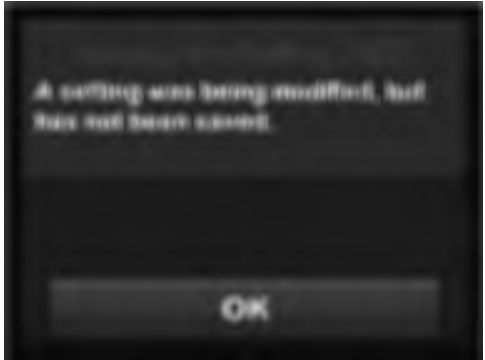
Screen	Explanation	
What will I see on the Screen? 	What does it mean?	You selected Fill Tubing from the <i>Load</i> menu but did not complete the process within 3 minutes.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap . Complete the fill tubing process.

Incomplete Fill Cannula Alert

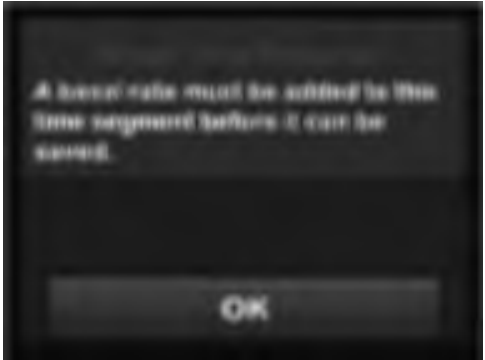
Screen	Explanation	
What will I see on the Screen? 	What does it mean?	You selected Fill Cannula from the <i>Load</i> menu but did not complete the process within 3 minutes.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Complete the cannula fill process.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.6 Incomplete Setting Alert

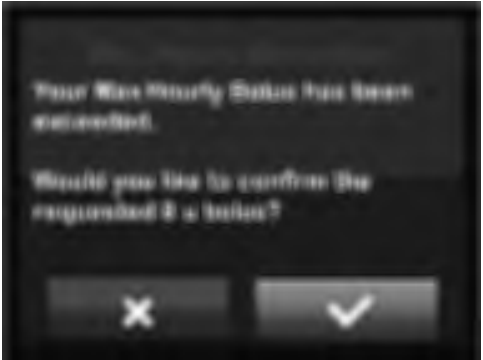
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You started to set up a new Personal Profile or Control-IQ technology setting but did not save or complete the programming within 5 minutes.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap . Complete programming the Personal Profile or Control-IQ technology setting.

13.7 Basal Rate Required Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	You did not enter a Basal Rate in a time segment in Personal Profiles. A Basal Rate must be entered in each time segment (rate can be 0 u/hr).
	How will the System notify me?	Prompt screen only.
	Will the System re-notify me?	No, a Basal Rate must be entered to save the time segment.
	How should I respond?	Tap . Enter a Basal Rate in the time segment.

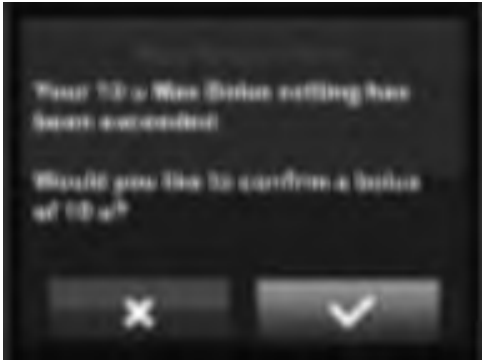
CHAPTER 13 • Insulin X2 Insulin Pump Alerts

13.8 Max Hourly Bolus Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	In the previous 60 minutes, you requested total bolus delivery that is more than 1.5 times your Max Bolus setting.
	How will the System notify me?	Prompt screen only.
	Will the System re-notify me?	No, you must tap  or  to deliver the bolus.
	How should I respond?	• Tap  to return to the <i>Bolus</i> screen and adjust the bolus delivery amount. • Tap  to confirm the bolus.

13.9 Max Bolus Alerts

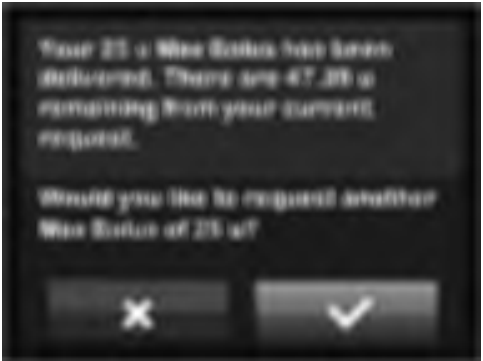
Max Bolus Alert 1

Screen	Explanation	
What will I see on the screen? 	What does it mean?	You requested a bolus larger than the Max Bolus setting in your active Personal Profile.
	How will the System notify me?	Prompt screen only.
	Will the System re-notify me?	No, you must tap  or  to deliver the bolus.
	How should I respond?	• Tap  to return to the <i>Bolus</i> screen and adjust the bolus delivery amount. • Tap  to deliver the amount of your Max Bolus setting.

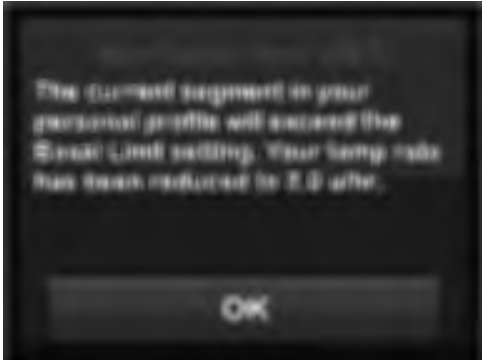
CHAPTER 13 • Insulin X2 Insulin Pump Alerts

Max Bolus Alert 2

The following applies only if you have Carbs turned on in your active Personal Profile and your Max Bolus amount is set to 25 units.

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your Max Bolus is set to 25 units and you requested a bolus larger than 25 units.
	How will the System notify me?	Prompt screen only.
	Will the System re-notify me?	No, you must tap  or  to deliver the remaining amount of the bolus request.
	How should I respond?	Before responding to this Alert, always consider whether your bolus insulin needs have changed since you requested the original bolus. • Tap  to deliver the remaining amount of the bolus request. A confirmation screen will appear. • Tap  if you do not want to deliver the remaining amount of the bolus request.

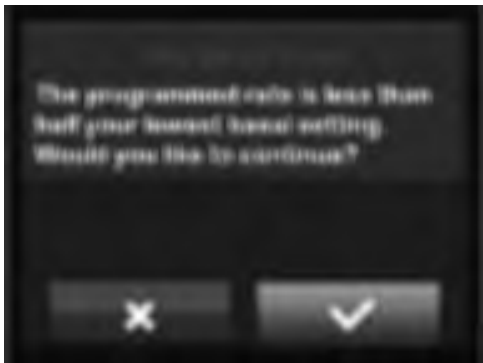
13.10 Max Basal Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	An active Temp Rate exceeds your Basal Limit setting due to a new timed segment activation within Personal Profiles. This alert will only display once your timed segment changes.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibration setting selected in Sound Volume.
	Will the System re-notify me?	No, you must tap  to move forward.
	How should I respond?	Tap  to accept the reduced Temp Rate. The reduced Temp Rate value is the same Basal Limit value that was set up in Personal Profiles.

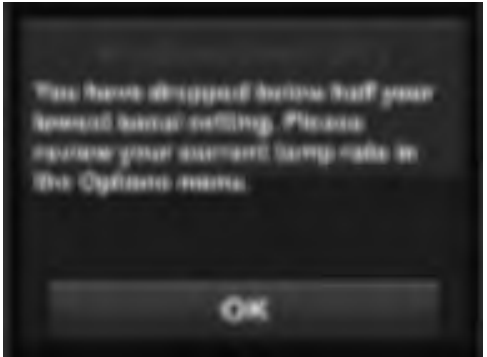
CHAPTER 13 • Insulin X2 Insulin Pump Alerts

13.11 Min Basal Alerts

Min Basal Alert 1

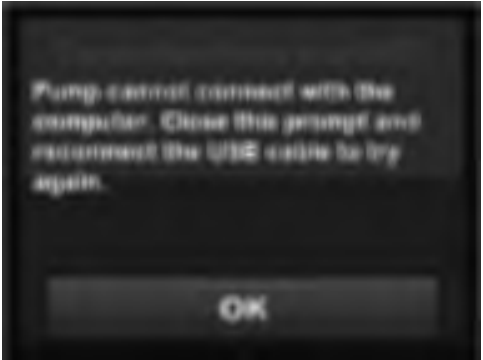
Screen	Explanation	
What will I see on the screen? 	What does it mean?	When entering a Basal Rate or requesting a temp rate, you requested a Basal Rate less than half of the lowest basal rate defined in your Personal Profile.
	How will the System notify me?	Prompt screen only.
	Will the System re-notify me?	No, you must tap  or  to move forward.
	How should I respond?	• Tap  to return to the previous screen to adjust the amount. • Tap  to dismiss the alert and continue with the request.

Min Basal Alert 2

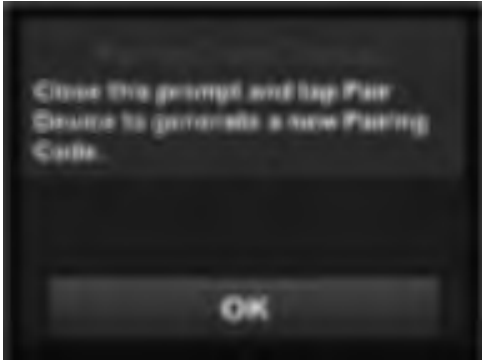
Screen	Explanation	
What will I see on the screen? 	What does it mean?	An active temp rate dropped below half of your lowest basal setting defined in your Personal Profile.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  and review your current temp rate in the <i>Activity</i> menu.

CHAPTER 13 • Insulin X2 Insulin Pump Alerts

13.12 Connection Error Alert

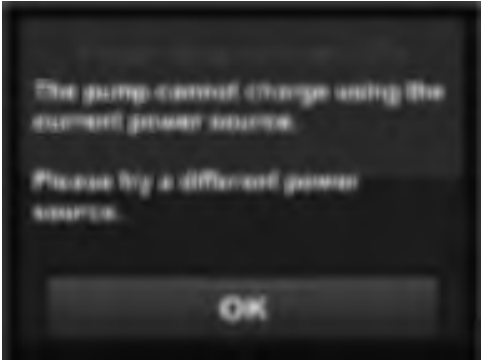
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You connected pump to a computer with the USB cable to charge it or upload data to the t:connect web application and a connection could not be made.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap . Disconnect and reconnect the USB cable to try again.

13.13 Pairing Code Timeout

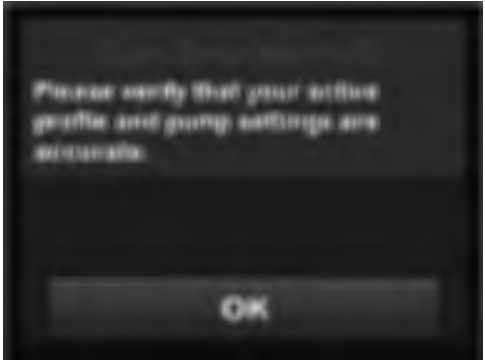
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You attempted to connect a smartphone to the pump, but the pairing process took too long (more than 5 minutes) and was unsuccessful.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	No.
	How should I respond?	Tap  . Try to pair the smartphone again.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.14 Power Source Alert

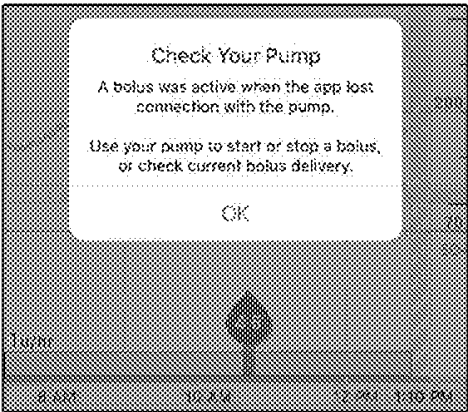
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You connected your pump to a power source that does not have enough power to charge the pump.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Connect the pump to a different power source to charge.

13.15 Data Error Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump encountered a condition that could potentially result in a loss of data.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Check your Personal Profiles and pump settings to verify that they are accurate. See Section 6.4 Editing or Reviewing an Existing Profile.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.16 Pump Connection Lost Alert - t:connect Mobile App

Screen	Explanation	
What will I see in the t:connect mobile app? 	What does it mean?	You started a bolus request in the t:connect mobile app, but your smartphone became disconnected from your pump before or during bolus delivery.
	How will the t:connect mobile app notify me?	• If the t:connect mobile app is open and on the <i>Bolus</i> screen, an informational message appears. • If bolus delivery is in progress, you will receive the alert as a notification banner.
	Will the t:connect mobile app re-notify me?	No, the alert remains on the t:connect mobile app screen until you tap OK.
	How should I respond?	Tap OK to return to the dashboard. • If bolus delivery is in progress, your pump will still deliver the remainder of the bolus unless you use your pump to stop the bolus. • You cannot use the t:connect mobile app to request another bolus until you have restored your smartphone's connection to the pump.

NOTE

The Pump Connection Lost Alert is the only alert in this chapter that appears in the t:connect mobile app but not on the pump.

2 t:slim X2 Insulin Pump Features

CHAPTER 14

t:slim X2 Insulin Pump Alarms

CHAPTER 14 • t:slim X2 Insulin Pump Alarms

⚠ PRECAUTION

CHECK your pump regularly for potential alarm conditions that may display. It is important to be aware of conditions that may affect insulin delivery and require your attention so you can respond as soon as possible.

Your t:slim X2™ pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check your BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

If multiple Reminders, Alerts, and Alarms happen at the same time, Alarms will be displayed first, Alerts will be displayed second, and Reminders will be displayed third. Each must be confirmed separately until all have been confirmed.

Information in this section will help you learn how to respond to Alarms.

Alarms notify you with 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume. If not acknowledged, alarms escalate to highest volume and vibe. Alarms repeat regularly until the condition that caused the alarm is corrected.

The t:connect™ mobile app also can provide messages, alerts, and alarms from your t:slim X2 pump as push notifications on your smartphone. These push notifications will be identical to your pump's display unless otherwise noted in this chapter.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. For more information about connecting your pump and smartphone, see Section 4.3 *Connecting to a Smartphone*, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

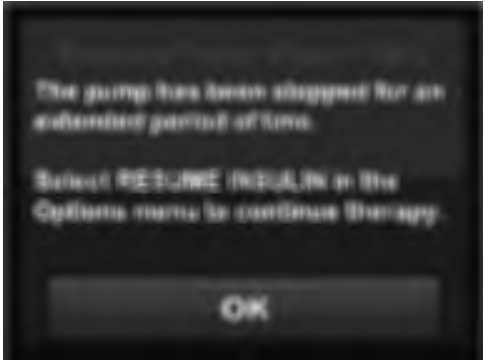
📌 NOTE

There is a list of alerts and errors related to CGM use in Chapter 26 *CGM Alerts and Errors*.

📌 NOTE

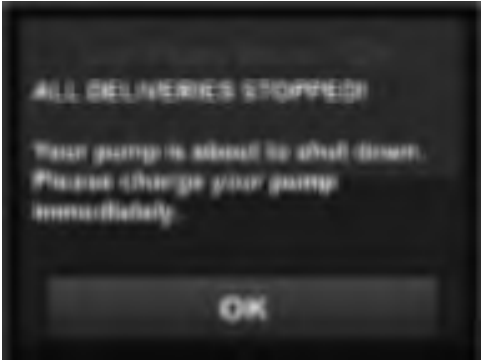
There is a list of alerts related to Control-IQ™ technology use in Chapter 32 *Control-IQ Technology Alerts*.

14.1 Resume Pump Alarm

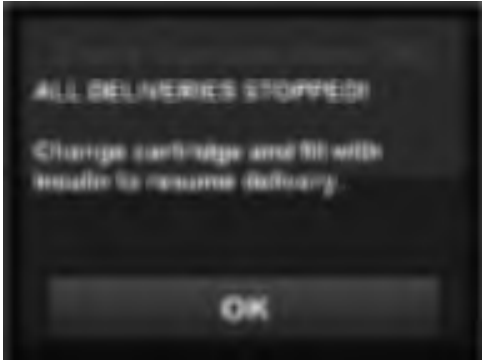
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You selected STOP INSULIN in the <i>Options</i> menu and insulin delivery has been stopped for more than 15 minutes.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes. • If not acknowledged by tapping , the System will re-notify you every 3 minutes at highest volume and vibrate. • If acknowledged by tapping , the System will re-notify you in 15 minutes.
	How should I respond?	To resume insulin, from the <i>Options</i> menu, tap RESUME INSULIN and tap  to confirm.

CHAPTER 14 • Insulin K2 Insulin Pump Alarms

14.2 Low Power Alarm

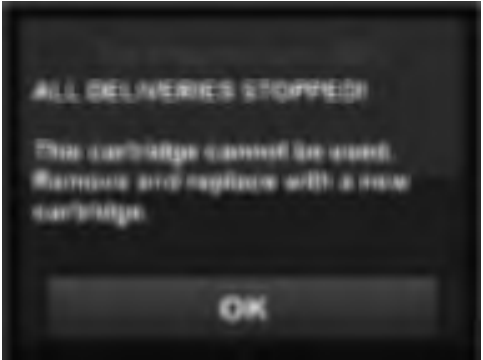
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected a power level of 1% or less remaining and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until no power remains and the pump shuts down.
	How should I respond?	Tap  . Charge your pump immediately to resume insulin delivery.

14.3 Empty Cartridge Alarm

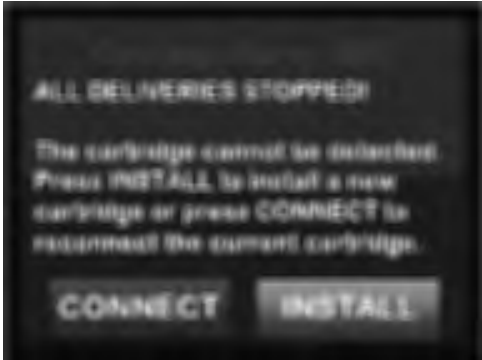
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected that the cartridge is empty and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you change the cartridge.
	How should I respond?	Tap  . Change your cartridge immediately by tapping OPTIONS from the <i>Home</i> screen, then Load and follow the instructions in Section 7.3 Filling and Loading a <i>t:slim</i> X2 Cartridge.

CHAPTER 14 • t:slim X2 Insulin Pump Alarms

14.4 Cartridge Error Alarm

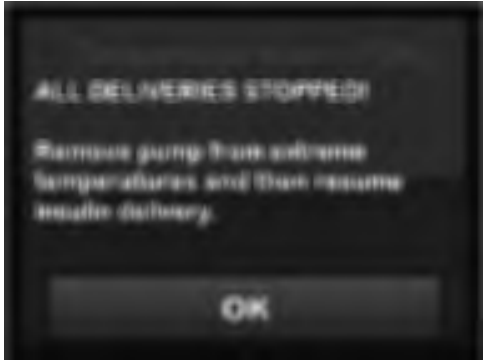
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected that the cartridge could not be used and all deliveries have stopped. This can be caused by cartridge defect, not following the proper procedure to load the cartridge, or over filling the cartridge (with more than 300 units of insulin).
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you change the cartridge.
	How should I respond?	Tap . Change your cartridge immediately by tapping OPTIONS from the <i>Home</i> screen, then Load and follow the instructions in Section 7.3 Filling and Loading a t:slim X2 Cartridge.

14.5 Cartridge Removal Alarm

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected that the cartridge has been removed and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you reconnect the current cartridge or change the cartridge.
	How should I respond?	Tap CONNECT to reattach the current cartridge. Tap INSTALL to load a new cartridge.

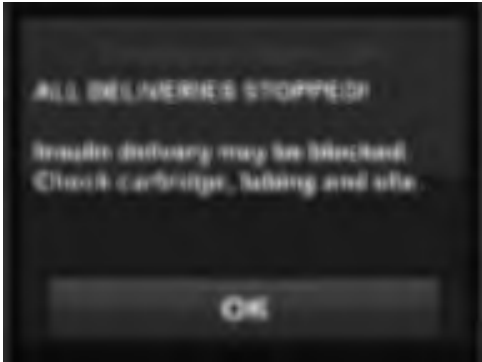
CHAPTER 14 • Insulin K2 Insulin Pump Alarms

14.6 Temperature Alarm

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected an internal temperature below 35°F (2°C) or above 113°F (45°C) or a battery temperature below 35°F (2°C) or above 125°F (52°C) and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until a temperature in the operating range is detected.
	How should I respond?	Tap . Remove the pump from the extreme temperature and then resume insulin delivery.

14.7 Occlusion Alarms

Occlusion Alarm 1

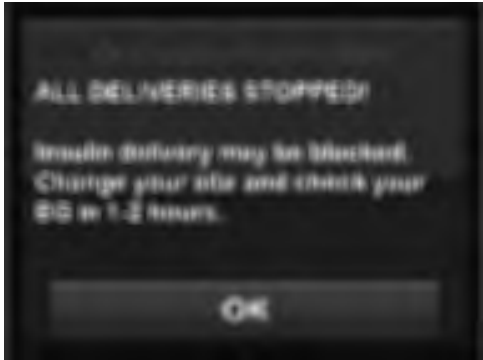
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected that insulin delivery is blocked and all deliveries have stopped. See Section 34.4 t:slim X2 Pump Performance Characteristics for more information on how long it can take the system to detect an occlusion.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you resume insulin delivery.
	How should I respond?	Tap  . Check the cartridge, tubing, and infusion site for any sign of damage or blockage and correct the condition. To resume insulin, from the <i>Options</i> menu, tap RESUME INSULIN and tap  to confirm.

NOTE

If the occlusion alarm occurs during bolus delivery, after tapping , a screen will appear letting you know how much of the requested bolus was delivered before the occlusion alarm. When the occlusion is cleared, some or all of the previously requested insulin volume may be delivered. Test your BG at the time of alarm and follow your healthcare provider's instructions for managing potential or confirmed occlusions.

CHAPTER 14 • Insulin K2 Insulin Pump Alarms

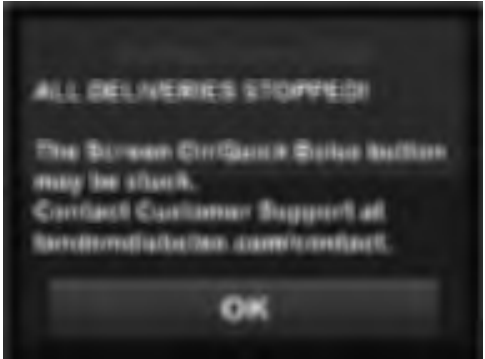
Occlusion Alarm 2

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected a second occlusion alarm shortly after the first occlusion alarm and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you resume insulin delivery.
	How should I respond?	Tap  . Change the cartridge, tubing, and infusion site to ensure proper delivery of insulin. Resume insulin after changing the cartridge, tubing, and infusion site.

■ NOTE

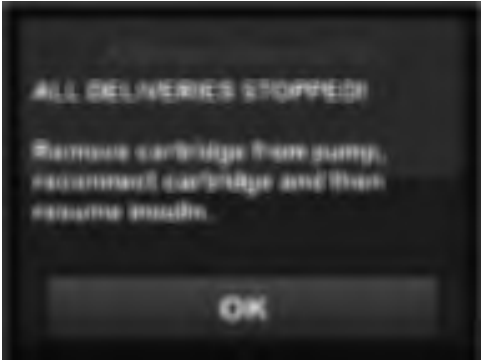
If the second occlusion alarm occurs during bolus delivery, after tapping , a screen will appear letting you know that the amount of bolus delivery could not be determined and was not added to your IOB.

14.8 Screen On/Quick Bolus Button Alarm

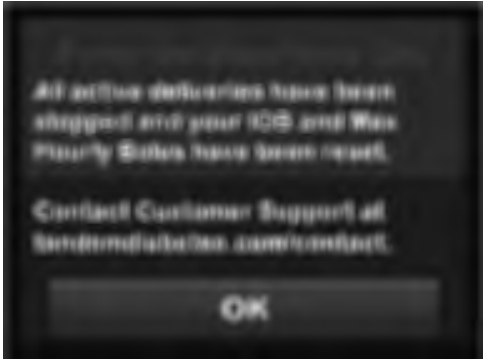
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The Screen On/Quick Bolus button (on the top of your pump) is stuck or not functioning properly and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until the condition is corrected.
	How should I respond?	Tap  . Contact Customer Technical Support.

CHAPTER 14 • Insulin K2 Insulin Pump Alarms

14.9 Altitude Alarm

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected a pressure difference between inside the cartridge and the surrounding air within the validated operating range of -1,300 feet to 10,000 feet (-396 meters to 3,048 meters) and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until the condition is corrected.
	How should I respond?	Tap . Remove the cartridge from the pump (this will allow the cartridge to fully vent) and then reconnect the cartridge.

14.10 Reset Alarm

Screen	Explanation	
	What does it mean?	Your pump experienced a reset and all deliveries have been stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you tap  .
	How should I respond?	Tap  . Contact Customer Technical Support.

This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 15

t:slim X2 Insulin Pump Malfunction

CHAPTER 15 • Insulin X2 Insulin Pump Malfunction

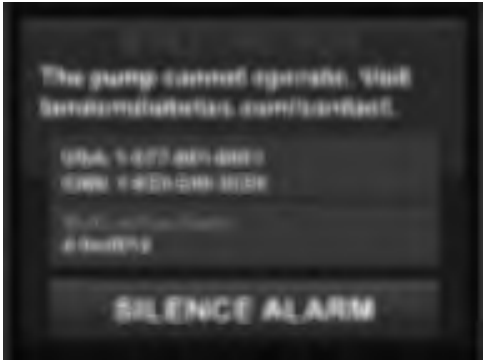
15.1 Malfunction

If your pump detects a system error, the *MALFUNCTION* screen appears and all deliveries are stopped. Contact Customer Technical Support.

Malfunctions notify you with 3 sequences of 3 notes at highest volume and 3 vibrations. They repeat at regular intervals until acknowledged by tapping **SILENCE ALARM**.

⚠ PRECAUTION

ALWAYS check with your healthcare provider for specific guidelines if you want or need to disconnect from the pump for any reason. Depending on the length of time and reason you are disconnecting, you may need to replace missed basal and/or bolus insulin. Check your BG before disconnecting from the pump and again when you reconnect, and treat high and low BG levels as recommended by your healthcare provider.

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected a system error and all deliveries have been stopped.
	How will the System notify me?	3 sequences of 3 notes at highest volume and 3 vibrations.
	Will the System re-notify me?	Yes, every 3 minutes until you acknowledge the malfunction by tapping SILENCE ALARM .
	How should I respond?	• Write down the Malfunction Code number that appears on the screen. • Tap SILENCE ALARM. The <i>MALFUNCTION</i> screen will remain on the pump even though the alarm is silenced. • Contact Customer Technical Support and provide the Malfunction Code number that you wrote down.

This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 16

Taking Care of Your Pump

CHAPTER 16 • Taking Care of Your Pump

16.1 Overview

This section provides information on caring for and maintaining your pump.

Cleaning Your Pump

When cleaning your pump, use a damp lint-free cloth. Do not use household or industrial cleaners, solvents, bleach, scouring pads, chemicals, or sharp instruments. Never submerge the pump in water or use any other liquid to clean it. Do not place the pump in the dishwasher or use hot water to clean it. If needed, use only a very mild detergent, such as a bit of liquid soap with warm water. When drying your pump, use a soft towel; never place your pump in a microwave oven or baking oven to dry it.

Maintaining Your Pump

The pump requires no preventative maintenance.

Inspecting Your Pump for Damage**▲ PRECAUTION**

DO NOT use your pump if you think it might be damaged due to dropping it or hitting it against a hard surface. Check that the pump is working properly by plugging a power source into the USB port and confirming that the display turns on, you hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the **Screen On/Quick Bolus** button. If you are unsure about potential damage, discontinue use of the pump and contact Customer Technical Support.

If you drop your pump or it has been hit against something hard, ensure that it is still working properly. Check that the touchscreen is working and clear, and that the cartridge and infusion set are properly in place. Check for leaks around the cartridge and at the tubing connector to the infusion set. Immediately contact Customer Technical Support if you notice any cracks, chips, or other damage.

Storing Your Pump

If you need to stop using your pump for a long period of time, you can place the

pump in storage mode. To place the pump in storage mode, connect the pump to a power source and then press and hold down the **Screen On/Quick Bolus** button for 30 seconds. The pump will beep 3 times before going into storage mode. Disconnect the pump from the power source.

Keep the pump protected when not in use. Store at temperatures between -4°F (-20°C) and 140°F (60°C) and at relative humidity levels between 20% and 90%.

To bring the pump out of storage mode, simply connect the pump to a power source.

Disposing of System Components

Consult Customer Technical Support for instructions for disposal of devices containing electronic waste such as your pump. Follow local regulations for disposal of potentially biohazardous materials such as used cartridges, needles, syringes, infusion sets, and sensors.

2 t:slim X2 Insulin Pump Features

CHAPTER 17

Lifestyle Issues and Travel

CHAPTER 17 • Lifestyle Issues and Travel

17.1 Overview

While the convenience and flexibility of the pump allow most users to participate in a variety of activities, some lifestyle changes may be required. Additionally, your insulin needs may change in response to lifestyle changes.

⚠ PRECAUTION

CONSULT your healthcare provider about lifestyle changes such as weight gain or loss, and starting or stopping exercise. Your insulin needs may change in response to lifestyle changes. Your Basal Rate(s) and other settings may need adjustment.

Physical Activity

The pump can be worn during most forms of exercise, such as running, cycling, hiking, and resistance training. During exercise, the pump can be worn in the provided case, your pocket, or other third-party “sport cases.” When choosing third-party pump cases or stickers, do not cover the six vent holes on the back of the pump.

⚠ PRECAUTION

If you choose to use a pump case or other accessories not provided by Tandem, **DO NOT** cover the six vent holes on the back of the pump. Covering the vent holes could affect insulin delivery.

For activities where contact is a concern, such as baseball, hockey, martial arts, or basketball, you can disconnect from your pump for short periods of time. If planning to disconnect from your pump, discuss a plan with your healthcare provider to compensate for any basal insulin delivery you miss while disconnected, and be sure to continue to check your BG levels. Even if you disconnect your tubing from your infusion site, the pump should continue to receive data from the transmitter as long as it is within the 20-foot (6-meter) range without obstruction.

Aquatic Activities**⚠ PRECAUTION**

AVOID submerging your pump in fluid beyond a depth of 3 feet (0.91 meters) or for more than 30 minutes (IP27 rating). If your pump has been exposed to fluid beyond these limits, check for

any signs of fluid entry. If there are signs of fluid entry, discontinue use of the pump and contact Customer Technical Support.

Your pump is watertight to a depth of 3 feet (0.91 meters) for up to 30 minutes (IP27 rating), but it is not waterproof. Your pump should not be worn while swimming, scuba diving, surfing, or during any other activities that could submerge the pump for an extended period of time. Your pump should not be worn in hot tubs or saunas.

Extreme Altitudes

Some activities, such as hiking, skiing or snowboarding, could expose your pump to extreme altitudes. The pump has been tested at altitudes up to 10,000 feet (3,048 meters) at standard operating temperatures.

Extreme Temperatures

You should avoid activities which could expose your pump to temperatures below 41°F (5°C) or above 98.6°F (37°C), as insulin can freeze at low temperatures or degrade at high temperatures.

Other Activities Which Require Removing Your Pump

⚠ PRECAUTION

If you remove your pump for 30 minutes or longer, it is recommended that you suspend insulin delivery. If insulin is not suspended, Control-IQ™ technology will continue to operate while the pump is removed, and will continue to dose insulin.

There are other activities, such as bathing and intimacy, when it may be more convenient for you to remove your pump. It is safe to do so for short periods of time. If planning to disconnect from your pump, discuss a plan with your healthcare provider for compensating for any basal delivery you miss while disconnected, and be sure to check your BG levels frequently. Missing basal delivery could cause your BG to rise.

Travel

The flexibility afforded by an insulin pump can simplify some aspects of travel, but it still requires planning. Be sure to order your pump supplies before your trip so that you have

enough supplies with you while you're away from home. In addition to pump supplies, you should also always bring the following items:

- The items listed in the Emergency Kit described in Section 1.10 Emergency Kit.
- A prescription for both rapid-acting and long-acting insulin of the type recommended by your healthcare provider in case you need to take insulin by injection.
- A letter from your healthcare provider explaining the medical need for your insulin pump and other supplies.

Traveling by Air

⚠ PRECAUTION

DO NOT expose your pump to X-ray screening used for carry-on and checked luggage. Newer full body scanners used in airport security screening are also a form of X-ray and your pump should not be exposed to them. Notify the security agent that your pump cannot be exposed to X-ray machines and request an alternate means of screening.

Your pump has been designed to withstand common electromagnetic interference including airport metal detectors.

The pump is safe for use on commercial airlines. The pump is a Medical Portable Electronic Device (M-PED). The system complies with radiated emissions requirements defined in RTCA/DO-160G, Section 21, Category M. Any M-PED which meet the requirements of this standard in all modes of operation may be used on board aircraft without the need for further testing by the operator.

Pack your pump supplies in your carry-on luggage. **DO NOT** pack your supplies in checked luggage as it could get delayed or lost.

If traveling, contact Customer Technical Support prior to your trip to obtain a travel loaner pump in case your pump malfunctions outside of Tandem's replacement area.

If you enable Airplane mode on your smartphone, you must maintain an active Bluetooth connection between your smartphone and your pump to use

CHAPTER 17 • Lifestyle Issues and Travel

the t:connect™ mobile app. You can always use your pump to deliver a bolus if you cannot connect your smartphone and pump. Please check with your airline carrier and smartphone manufacturer instructions prior to traveling to determine conditions for using Bluetooth.

⚠ WARNING

ALWAYS use your t:slim X2™ insulin pump for therapy decisions if your Bluetooth connection between your smartphone and pump is disabled.

📌 NOTE

The t:connect mobile app requires an active Bluetooth connection to connect with your pump. If you turn on Airplane mode, make sure you keep Bluetooth enabled to connect to your pump.

3 CGM Features

CHAPTER 18

Important Safety Information When Using the t:slim X2 Insulin Pump with Dexcom G6 CGM

CHAPTER 18 • Important Safety Information When Using the t:slim X2 Insulin Pump with Dexcom G6 CGM

The following includes important safety information related to your CGM and its components. The information presented in this chapter does not represent all warnings and precautions related to the CGM. Visit Dexcom's website for applicable product instructions that also present warnings and precautions.

18.1 Warnings

Using Dexcom G6 with Your t:slim X2™ Insulin Pump

▲ WARNING

DO NOT ignore symptoms of high and low glucose. If your sensor glucose alerts and readings do not match your symptoms, measure your BG with a BG meter even if your sensor is not reading in the high or low range.

▲ WARNING

DO NOT ignore sensor wire fractures. Sensors may fracture on rare occasions. If a sensor wire breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation (redness, swelling, or pain) at the insertion site. If you experience a

broken sensor wire, please report this to Customer Technical Support.

▲ WARNING

DO NOT use Dexcom G6 CGM in pregnant women or persons on dialysis. The System is not approved for use in pregnant women or persons on dialysis and has not been evaluated in these populations. Sensor glucose readings may be inaccurate in these populations and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT use Dexcom G6 CGM in critically ill patients. It is not known how different conditions or medications common to the critically ill population may affect the performance of the System. Sensor glucose readings may be inaccurate in critically ill patients, and solely relying on the sensor glucose alerts and readings for treatment decisions could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT insert the sensor in sites other than the abdomen (belly) or upper buttocks (for ages 2–17 only). Other sites have not been studied and are not approved. Use in other sites might cause

sensor glucose readings to be inaccurate and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT expect CGM alerts until after the 2-hour startup. You will **NOT** get any sensor glucose readings or alerts until after the 2-hour startup ends. During this time you might miss severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT use your transmitter if it is damaged/cracked. This could create an electrical safety hazard or malfunction, which might cause electrical shocks.

▲ WARNING

STORE the Dexcom G6 CGM sensor at temperatures between 36°F (2.2°C) to 86°F (30°C) for the length of the sensor's shelf life. You may store the sensor in the refrigerator if it is within this temperature range. The sensor should not be stored in a freezer. Storing the sensor improperly might cause the sensor glucose readings to be inaccurate, and you might miss severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

CHAPTER 18 • Important Safety Information When Using the t:slim X2 Insulin Pump with Dexcom G6 CGM

⚠ WARNING

DO NOT allow young children to hold the sensor, transmitter or transmitter kit box without adult supervision. The sensor and transmitter include small parts that may pose a choking hazard.

⚠ WARNING

If a sensor session is ended, either automatically or manually, you will not receive any CGM alerts. In order to receive CGM alerts, a sensor session must be started and transmitting sensor values to the pump based on a sensor code or sensor calibration.

18.2 Precautions**Using Dexcom G6 CGM with Your t:slim X2 Insulin Pump****⚠ PRECAUTION**

DO NOT open the sensor package until you have washed your hands with soap and water, and let them dry. You may contaminate the insertion site and suffer an infection if you have dirty hands while inserting the sensor.

⚠ PRECAUTION

DO NOT insert the sensor until you have cleaned the skin with a topical antimicrobial solution, such as isopropyl alcohol, and allowed the skin to dry. Inserting into unclean skin might lead to infection. Do not insert the sensor until the cleaned area is dry so the sensor adhesive will stick better.

⚠ PRECAUTION

AVOID using the same spot repeatedly for sensor insertion. Rotate your sensor placement sites, and do not use the same site for two sensor sessions in a row. Using the same site might cause scarring or skin irritation.

⚠ PRECAUTION

AVOID inserting the sensor in areas that are likely to be bumped, pushed or compressed, or areas of skin with scarring, tattoos, or irritation as these are not ideal sites to measure glucose. Insertion in those areas might affect accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

AVOID injecting insulin or placing an infusion set within 3 inches (7.6 cm) of the sensor. The insulin might affect sensor accuracy and could

result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

DO NOT use the sensor if its sterile package has been damaged or opened. Using an unsterile sensor might cause infection.

⚠ PRECAUTION

PAY ATTENTION to the trend information on your *CGM Home* screen, as well as your symptoms, before using CGM values to calculate and deliver a correction bolus. Individual CGM values may not be as accurate as BG meter values.

⚠ PRECAUTION

To calibrate the Dexcom G6 CGM, **ALWAYS** enter the exact BG value that your BG meter displays within 5 minutes of a carefully performed BG measurement. Do not enter sensor glucose readings for calibration. Entering incorrect BG values, BG values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

CHAPTER 18 • Important Safety Information When Using the Insulin X2 Insulin Pump with Dexcom G6 CGM

⚠ PRECAUTION

DO NOT calibrate if your BG is changing at a significant rate, typically more than 2 mg/dL per minute. Do not calibrate when your receiver screen is showing the rising or falling single arrow or double arrow, which indicates that your BG is rapidly rising or falling. Calibrating during significant rise or fall of BG may affect sensor accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

The Dexcom G6 CGM accuracy may be affected when your sensor glucose is changing at a significant rate (i.e., 2 to 3 mg/dL/min or more than 3 mg/dL each minute), such as during exercise or after a meal.

⚠ PRECAUTION

AVOID separating the transmitter and pump by more than 20 feet (6 meters). The transmission range from the transmitter to the pump is up to 20 feet (6 meters) without obstruction. Wireless communication does not work well through water so the range is reduced if you are in a pool, bathtub, or on a water bed, etc. To ensure communication, it is suggested that you face your pump screen out and away from the body, and wear the pump on the same side of the

body that you wear your CGM. Types of obstruction differ and have not been tested. If your transmitter and pump are farther than 20 feet (6 meters) apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

DO NOT use alternative BG site testing (blood from your palm or forearm, etc.) for calibration. Alternative site BG values may be different than those taken from a fingerstick BG value and may not represent the timeliest BG value. Use a BG value taken only from a fingerstick for calibration. Alternative site BG values might affect sensor accuracy and result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

ENSURE that your transmitter ID is programmed into the pump before you use the System if you receive a warranty replacement pump. The pump cannot communicate with the transmitter unless the transmitter ID is entered. If the pump and transmitter are not communicating, you will not receive sensor glucose readings and you

might miss severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

DO NOT discard your transmitter. It is reusable. The same transmitter is used for each session until you have reached the end of the transmitter battery life.

⚠ PRECAUTION

The Dexcom G6 sensor is not compatible with older versions of transmitters or receivers. Do not mix transmitters, receivers, and sensors from different generations.

⚠ PRECAUTION

Taking medications with acetaminophen while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

⚠ PRECAUTION

Hydroxyurea is a medication used in the treatment of diseases including cancer and sickle cell anemia. It is known to interfere with glucose readings from the Dexcom sensor. The use of hydroxyurea will result in sensor glucose readings that are higher than actual glucose

CHAPTER 18 • Important Safety Information When Using the t:slim X2 Insulin Pump with Dexcom G6 CGM

levels. The level of inaccuracy in sensor glucose readings is based on the amount of hydroxyurea in the body. Relying on sensor glucose values while taking hydroxyurea could result in missed hypoglycemia alerts or errors in diabetes management, such as giving a higher dose of insulin than necessary to correct falsely high sensor glucose values. It can also result in errors when reviewing, analyzing and interpreting historical patterns for assessing glucose control. **DO NOT** use the Dexcom CGM readings to make diabetes treatment decisions or assess glucose control when taking hydroxyurea. Use your BG meter and consult with your healthcare provider about alternative glucose monitoring approaches.

18.3 Potential Benefits From Using the t:slim X2 Insulin Pump with CGM

When paired with Dexcom G6 transmitter and sensor, your pump can receive CGM readings every 5 minutes, which are displayed as a trend graph on the *CGM Home* screen. You can also program your pump to alert you when your CGM readings are above or below a given level, or are rising or falling quickly. Unlike the readings from

a standard BG meter, CGM readings allow you to view trends in real time, as well as capture information when you would otherwise be unable to check your blood sugar, such as while you are asleep. This information can be useful for you and your healthcare provider when considering changes to your therapy. In addition, the programmable alerts can help you to spot potential low or high BG sooner than you would using a only a BG meter.

- In some studies, CGM was shown to increase time in the target glucose range. Subjects in these studies had better diabetes control (lowered A1C values, reduced glycemic variability and time spent in low and high BG ranges)^{1, 2, 3} which can help reduce diabetes related complications.^{4, 5} These benefits can be seen especially with using real-time CGM at least six days per week² and were sustained over time.⁶ In some cases, patients perceived an increase in their quality of life and peace of mind when using real-time CGM as well as reporting a high satisfaction with CGM.⁷

¹ Garg S, Zisser H, Schwartz S, et al. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. *Diabetes Care*. 2006; 29(1):44-50.

² JDRF CGM Study Group. Continuous glucose monitoring and intensive treatment of type 1 diabetes. *NEJM*. 2008; 359:1464-76.

³ Battelino T, Phillip M, Bratina N, et al. Effect of continuous glucose monitoring of hypoglycemia in type 1 diabetes. *Diabetes Care* 2011; 34(4):795-800.

⁴ The Diabetes Control and Complications Research Group. The effect of intensive treatment of diabetes on the development and progression of long- term complications of insulin-dependent diabetes mellitus. *NEJM*. 1993; 329:997-1036.

⁵ Ohkubo Y, Kishikawa H, Araki E, et al. Intensive insulin therapy prevents progression of diabetic microvascular complications in Japanese patients with non-insulin dependent diabetes mellitus: a randomized prospective

CHAPTER 18 • Important Safety Information When Using the tslim X2 Insulin Pump with Dexcom G6 CGM

6-year study. *Diabetes Res Clin Pract.* 1995; 28(2):103-117.

⁶ JDRF CGM Study Group. Sustained benefit of continuous glucose monitoring on A1c, glucose profiles, and hypoglycemia in adults with type 1 diabetes. *Diabetes Care* 2009; 32(11):2047-2049.

⁷ JDRF CGM Study Group. Quality-of-Life measures in children and adults with type 1 diabetes. *Diabetes Care* 2010; 33(10):2175-2177.

18.4 Possible Risks From Using the tslim X2 Insulin Pump with CGM

Inserting the sensor and wearing the adhesive patch might cause infection, bleeding, pain and skin irritations (redness, swelling, bruising, itching, scarring, or skin discoloration).

There is a remote chance that a sensor wire fragment could remain under your skin if the sensor wire breaks while you are wearing it. If you think a sensor wire has broken under your skin, contact your healthcare provider and call Customer Technical Support.

Other risks associated with CGM use include the following:

- You will not get sensor glucose alerts when the alert function is turned off, your transmitter and pump are out of range, or when your pump is not showing sensor glucose readings. You might not notice alerts if you are unable to hear them or feel the vibration.
- There are a number of risks as a result of the fact that the Dexcom G6 CGM takes readings from fluid below the skin (interstitial fluid) instead of blood. There are differences in how glucose is measured in the blood compared to how it is measured in interstitial fluid, and glucose is absorbed into the interstitial fluid slower than it is absorbed into the blood, which can cause CGM readings to lag behind readings from a BG meter.

3 CGM Features

CHAPTER 19

Getting to Know Your CGM System

CHAPTER 19 • Getting to Know Your CGM System

19.1 CGM Terminology**Alternate Site BG Testing**

Alternate site BG testing is when you take a BG value on your BG meter using a blood sample from an area on your body other than your fingertip. Do not use alternate site testing to calibrate your sensor.

Applicator

The applicator is a disposable piece that comes attached to the sensor pod and inserts the sensor under the skin. There is a needle inside the applicator that is removed after you insert the sensor.

Calibration

Calibration is when you enter BG values from a BG meter into the System. Calibrations may be needed for your System to show continuous glucose readings and trend information.

CGM

Continuous glucose monitoring.

CGM Reading

A CGM reading is a sensor glucose reading shown on your pump. This

reading is in mg/dL units and is updated every 5 minutes.

HypoRepeat

HypoRepeat is an optional CGM auditory and vibration alert setting that keeps repeating the fixed low alert every 5 seconds until your sensor glucose value rises above 55 mg/dL or you confirm it. This alert can be helpful if you want extra awareness for severe lows.

mg/dL

Milligrams per deciliter. The standard unit of measure for sensor glucose readings.

Receiver

When the Dexcom G6 CGM is used with the pump to display CGM readings, the insulin pump replaces the receiver for the therapeutic CGM. A smartphone with the Dexcom app may be used in addition to the pump to receive sensor readings.

Rise and Fall (Rate of Change) Alerts

Rise and fall alerts occur based on how much and how fast your glucose levels rise or fall.

RF

RF is the abbreviation for radio frequency. RF transmission is used to send glucose information from the transmitter to the pump.

Sensor

The sensor is the part that of the CGM includes an applicator and wire. The applicator inserts the wire under your skin, and the wire measures glucose levels in your tissue fluid.

Sensor Glucose Data Gaps

Glucose data gaps occur when your System is unable to provide a sensor glucose reading.

Sensor Glucose Trends

Glucose trends let you see the pattern of your glucose levels. The trend graph shows where your glucose levels have been during the time shown on the screen and where your glucose levels are now.

Sensor Pod

The sensor pod is the small plastic base of the sensor attached to your skin that holds the transmitter in place.

Startup Period

The startup period is the 2-hour period after you tell the System you inserted a new sensor. Sensor glucose readings are not provided during this time.

Transmitter

The transmitter is the part of the CGM that snaps into the sensor pod and wirelessly sends glucose information to your pump.

Transmitter ID

The transmitter ID is a series of numbers and/or letters that you enter into your pump to let it connect and communicate with the transmitter.

Trend (Rate of Change) Arrows

Trend arrows show how fast your glucose levels are changing. There are seven different arrows that show when your glucose direction and speed change.

CHAPTER 18 • Getting to Know Your CGM System

19.2 Explanation of CGM Pump Icons

The following CGM icons may appear on your pump screen:

CGM Icon Definitions

Symbol	Meaning
	Unknown sensor reading.
	CGM sensor session is active, but the transmitter and pump are out of range.
	The CGM sensor has failed.
	The CGM sensor session has ended.
	Wait 15 minutes calibration error.
	Startup calibration is required (2 BG values).
	Additional startup calibration is required.
	CGM calibration is required.

Symbol	Meaning
	Transmitter error.
	CGM sensor session is active, and the transmitter is communicating with the pump.
	CGM sensor session is active, but the transmitter is not communicating with the pump.
	Sensor startup 0–30 minutes.
	Sensor startup 31–60 minutes.
	Sensor startup 61–90 minutes.
	Sensor startup 91–119 minutes.

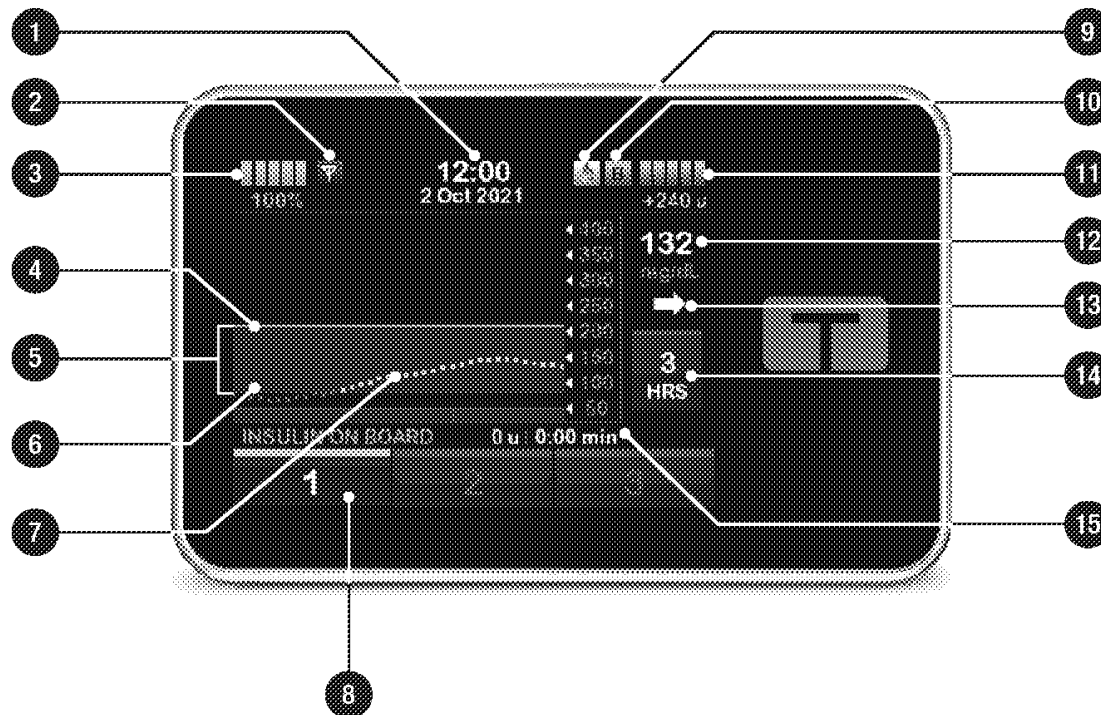
This Page is Intentionally Left Blank

CHAPTER 19 • Getting to Know Your CGM System

19.3 CGM Lock Screen

The *CGM Lock* screen appears anytime you turn on the screen and you are using your pump with a CGM.

1. **Time and Date Display:** Displays the current time and date.
2. **Antenna:** Indicates communication status between pump and transmitter.
3. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
4. **High Glucose Alert Setting.**
5. **Sensor Glucose Target Range.**
6. **Low Glucose Alert Setting.**
7. **Graph of Most Recent Sensor Glucose Readings.**
8. **1–2–3:** Unlocks pump screen.
9. **Active Bolus Icon:** Indicates a bolus is being delivered.
10. **Status:** Displays current system settings and insulin delivery status.
11. **Insulin Level:** Displays the current amount of insulin in the cartridge.
12. **Most Recent 5-Minute Sensor Glucose Reading.**
13. **Trend Arrow:** Indicates direction and rate of change.
14. **Trend Graph Time (HRS):** 1, 3, 6, 12 and 24 hour views available.
15. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.



CHAPTER 19 • Getting to Know Your CGM System

19.4 CGM Home Screen

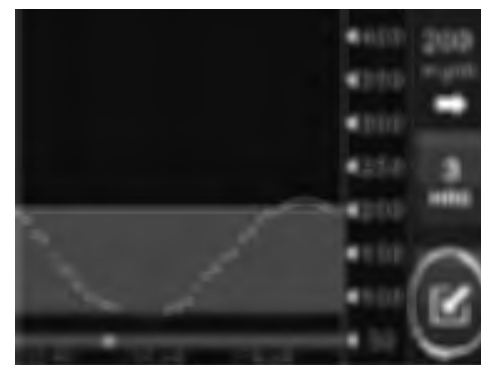
1. **Time and Date Display:** Displays the current time and date.
2. **Antenna:** Indicates communication status between pump and transmitter.
3. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
4. **High Glucose Alert Setting.**
5. **Sensor Glucose Target Range.**
6. **Low Glucose Alert Setting.**
7. **Graph of Most Recent Sensor Glucose Readings.**
8. **Options:** Stop/Resume insulin delivery, manage pump and CGM settings, start/stop activities, load a cartridge, and view history.
9. **Bolus icon:** Denotes a bolus delivery. Each bolus icon represents one bolus delivery even if the icon is temporarily obstructed by the hash marks on the bolus bar as the graph changes over time.
10. **Bolus:** Program and deliver a bolus.
11. **Status:** Displays current system settings and insulin delivery status.
12. **Insulin Level:** Displays the current amount of insulin in the cartridge.
13. **Most Recent 5-Minute Sensor Glucose Reading.**
14. **Trend Arrow:** Indicates direction and rate of change.
15. **Trend Graph Time (HRS):** 1, 3, 6, 12 and 24 hour views available.
16. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.

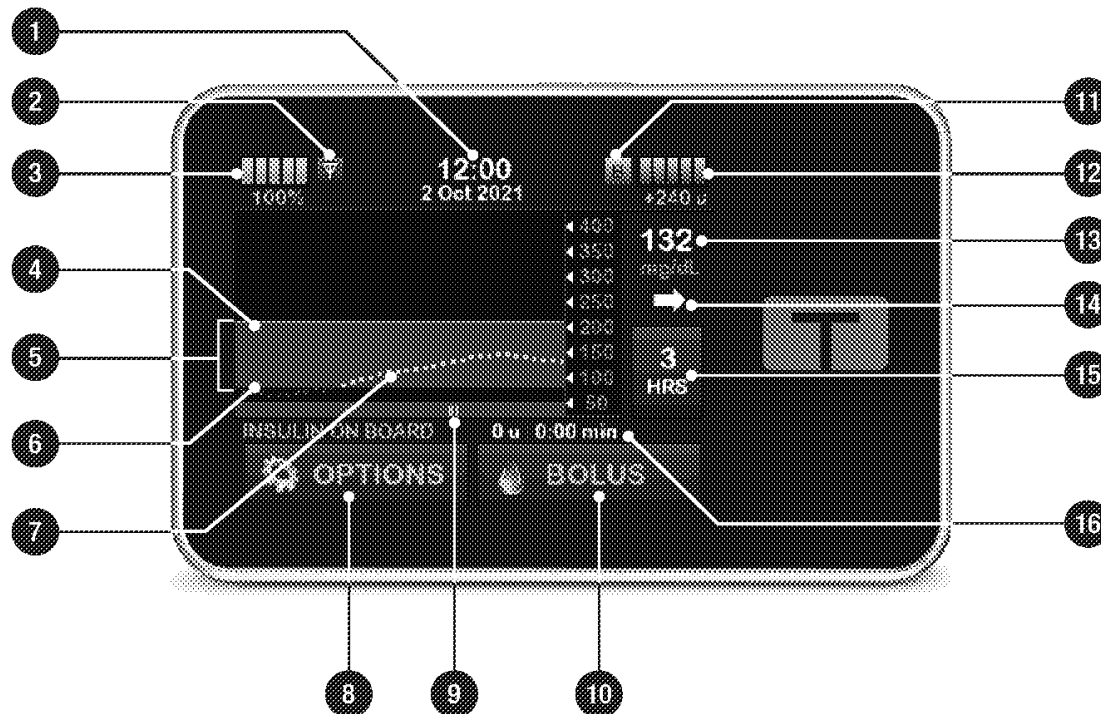
To view CGM information on the full screen:

From the *CGM Home* screen tap anywhere on the CGM trend graph.



Tap the “minimize” icon to return to the *CGM Home* screen.





CHAPTER 19 • Getting to Know Your CGM System

19.5 My CGM Screen

1. **Start Sensor:** Starts a CGM session. If sensor is active, STOP SENSOR will be displayed.
2. **Calibrate CGM:** Enter a calibration BG value. Only active when sensor session is active.
3. **CGM Alerts:** Customize CGM Alerts.
4. **Transmitter ID:** Enter the transmitter ID.
5. **CGM Info:** View the CGM information.



This Page is Intentionally Left Blank

3 CGM Features

CHAPTER 20

CGM Overview

CHAPTER 20 • CGM Overview

20.1 CGM System Overview

This section of the user guide covers instructions for using a CGM with your t:slim X2™ pump. Use of a CGM is optional, but in order to use Control-IQ™ technology, CGM is required. When used, CGM allows readings from your sensor to be displayed on your pump screen. To make treatment decisions during a new sensor startup period, you will also need a commercially available BG meter to use with your System.

As an example, a compatible CGM is the Dexcom G6 CGM System, which consists of a sensor, transmitter, and a receiver.

The Dexcom G6 sensor is a disposable device that is inserted under the skin to continuously monitor glucose levels from interstitial fluid (the fluid under your skin). The Dexcom G6 transmitter connects to the sensor using Bluetooth wireless technology communication and sends readings to the pump display every 5 minutes. The pump display shows sensor glucose readings, a trend graph, and the direction and

rate of change arrows. For information about inserting a Dexcom G6 CGM sensor, placing a Dexcom G6 transmitter, and Dexcom G6 product specifications, visit the manufacturer's website for applicable product instructions and training information.

You can also program your pump to alert you when your CGM readings are above or below a given level, or are rising or falling quickly. If CGM readings become 55 mg/dL or lower, the CGM Fixed Low Alert will sound. This alert is not customizable.

20.2 Device Connection Overview

The Dexcom G6 CGM only allows pairing with one medical device at a time (either the t:slim X2 pump or the Dexcom receiver), but you can still use the Dexcom G6 CGM app and your pump simultaneously using the same transmitter ID. The Dexcom G6 CGM does not connect directly to the t:connect™ mobile app. CGM readings in the t:connect mobile app are provided through the t:slim X2 insulin pump connection.

You can also use both the Dexcom G6 mobile app and t:connect mobile app at the same time. The Dexcom G6 mobile app can be used to start and stop sensor sessions as well as connect with the other Dexcom compatible services. The Dexcom G6 CGM does not connect directly to the t:connect mobile app; CGM readings in the t:connect mobile app are provided via the t:slim X2 pump connection.

Unlike the readings from a standard BG meter, CGM readings allow you to view trends in real time, as well as capture information when you would otherwise be unable to check your BG, such as while you are asleep. This information can be useful for you and your healthcare provider when considering changes to your therapy. In addition, the programmable alerts can help you to spot potential low or high glucose sooner than you would using a only a BG meter.

20.3 Receiver (t:slim X2 Insulin Pump) Overview

To review the icons and controls displayed on the *Home* screen with CGM enabled, see Section 19.4 CGM Home Screen.

20.4 Transmitter Overview

This section provides information about CGM devices that have a separate transmitter. The information contained in this section is specific to the Dexcom G6 CGM and is provided as an example. For information about the Dexcom G6 transmitter, visit the manufacturer's website for applicable product instructions.

Snapping into the transmitter holder, the transmitter wirelessly sends sensor glucose information to your pump. If you have a new transmitter, only open the package when you are ready to use it.

Even if you disconnect your tubing from your infusion site, the pump should continue to receive data from the

transmitter as long as it is within the 20-foot (6 meter) range without obstruction.

If your transmitter is damaged or cracked, do not use it. Immediately contact Customer Technical Support if you notice any cracks or other damage. Do not use the sensor if its sterile package has been damaged or opened.

Transmitter features:

- Reusable
 - Do not discard after sensor session.
 - Only for you, don't share a transmitter.
- Water resistant
- Can transmit data to your pump for up to 20 feet (6 meters). Range is less if you are in or under water.
- Battery lasts approximately 90 days. Pump or smart device prompts you when battery is running low.

- Serial number is on the back
- M-PED designation
 - Emission levels meet IATA standards.
 - May be used on board aircraft without any further testing by the operator.

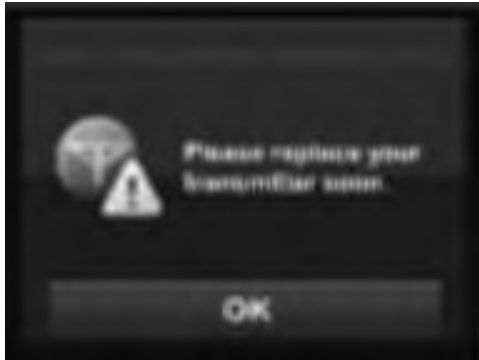
⚠ PRECAUTION

DO keep your transmitter and pump within 20 feet (6 meters) with no obstacles (like walls or metal) between them. Otherwise, they may not be able to communicate. If water is between your transmitter and the pump (for example, if you're showering or swimming) keep them closer to each other. The range is reduced because Bluetooth technology doesn't work as well through water. To ensure communication, it is suggested that you face your pump screen out and away from the body, and wear the pump on the same side of the body that you wear your CGM.

The transmitter battery will last 90 days. Once you see the Low Transmitter Battery Alert, replace the transmitter as soon as possible. Your transmitter

CHAPTER 20 • CGM Overview

battery may drain as quickly as 7 days after this alert occurs.



submerged for up to 8 feet (2.4 meters) and up to 24 hours. Underwater use will affect the ability to communicate with the pump, so the range will be much less than during normal use. Extended contact with water could weaken the adhesive used by your infusion sets and Dexcom CGM sensors and cause them to fall off prematurely.

20.5 Sensor Overview

This section provides information about CGM devices that have a separate sensor. The information contained in this section is specific to the Dexcom G6 CGM and is provided as an example. For information about the Dexcom G6 sensor, visit the manufacturer's website for applicable product instructions.

The Dexcom G6 sensor is water resistant when showering, bathing or swimming if the transmitter is fully snapped in. The sensor has been tested to be water resistant when

3 CGM Features

CHAPTER 21

CGM Settings

CHAPTER 21 • CGM Settings

21.1 About Bluetooth Technology

Bluetooth Low Energy technology is a type of wireless communication used in cell phones and many other devices. Your t:slim X2™ pump uses Bluetooth wireless technology communication to wirelessly pair together with other devices, such as a CGM or smartphone running the t:connect™ mobile app. This allows the pump to wirelessly communicate with paired devices securely and only with each other.

21.2 Disconnecting from the Dexcom Receiver

The Dexcom G6 CGM only allows pairing with one medical device at a time. Ensure your transmitter is not connected to the receiver before pairing with the pump by doing the following:

Before entering your CGM transmitter ID into the pump, turn off the Dexcom G6 receiver and wait 15 minutes. This allows the Dexcom G6 transmitter to forget the connection currently in place with the Dexcom G6 receiver.

NOTE

It is not enough to Stop the Sensor Session on your Dexcom receiver prior to pairing to the pump. The receiver power must be completely off in order to avoid connection problems.

You may still use a smartphone with the Dexcom G6 CGM app and your pump simultaneously with the same transmitter ID.

21.3 Setting CGM Volume

You can set the sound pattern and volume for CGM alerts and prompts to meet your individual needs. Reminders, alerts, and alarms for pump functions are separate from alerts and errors for CGM functions and do not follow the same pattern and volume.

To set your sound volume, see Section 5.12 Sound Volume.

CGM Volume options:**Vibrate**

You can set your CGM to alert you with vibration rather than sound. The only exception to this is the Fixed Low Alert at 55 mg/dL, which alerts you as a

vibration first, followed by beeps 5 minutes later if not confirmed.

Soft

When you want your alert to be less noticeable. This sets all alerts and alarms to lower volume beeps.

Normal

The default profile when you receive your pump. This sets all alerts and alarms to higher volume beeps.

HypoRepeat

Very similar to normal profile, but it continuously repeats the Fixed Low Alert every 5 seconds until your sensor glucose reading rises above 55 mg/dL or the alert is confirmed. This can be helpful if you want extra alerts for severe low sensor glucose readings.

The CGM volume setting that you choose applies to all CGM alerts, errors, and prompts which have their own unique sound pattern, tone and volume. This allows you to identify each alert and error and its meaning.

The Fixed Low Alert at 55 mg/dL cannot be turned off or changed.

The Soft, Normal, and HypoRepeat options have the following sequence:

- The first alert is vibrate only.
- If the alert is not confirmed in 5 minutes, the system vibrates and beeps.
- If the alert is not confirmed in 5 more minutes, the system vibrates and beeps louder. This continues at the same volume every 5 minutes until confirmed.
- If the alert is confirmed and your sensor glucose readings continue to be at or below 55 mg/dL your system repeats the alert sequence in 30 minutes (HypoRepeat option only).

CHAPTER 21 • CGM Settings

Sound Option Descriptions

CGM Volume	Vibrate	Soft	Normal	HypoRepeat
High Alert	2 long vibrates	2 long vibrates + 2 low beeps	2 long vibrates + 2 medium beeps	2 long vibrates + 2 medium beeps
Low Alert	3 short vibrates	3 short vibrates + 3 low beeps	3 short vibrates + 3 medium beeps	3 short vibrates + 3 medium beeps
Rise Alert	2 long vibrates	2 long vibrates + 2 low beeps	2 long vibrates + 2 medium beeps	2 long vibrates + 2 medium beeps
Fall Alert	3 short vibrates	3 short vibrates + 3 low beeps	3 short vibrates + 3 medium beeps	3 short vibrates + 3 medium beeps
Out of Range Alert	1 long vibrate	1 long vibrate + 1 low beep	1 long vibrate + 1 medium beep	1 long vibrate + 1 medium beep
Fixed Low Alert	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps + pause + repeat sequence
All Other Alerts	1 long vibrate	1 long vibrate + 1 low beep	1 long vibrate + 1 medium beep	1 long vibrate + 1 medium beep

To Select Your CGM Volume:

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Device Settings**.
4. Tap **Sound Volume**.
5. Tap the **Down Arrow**.
6. Tap **CGM Alerts**.
7. Tap **Vibrate**, **Soft**, **Normal** or **HypoRepeat** to select.
- ✓ Once a value is selected, the pump will return to the previous screen.
8. Tap .

- Hardware Revision
- BLE Hardware ID
- Software Number

You can view this information at any time.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap the **Down Arrow**.
5. Tap **CGM Info**.

21.4 CGM Info

CGM Info contains important information about your device. The following can be found in CGM Info:

- Firmware Revision

This Page is Intentionally Left Blank

3 CGM Features

CHAPTER 22

Setting CGM Alerts

CHAPTER 22 • Setting CGM Alerts

Setting Your CGM Alerts

You can create personal settings for how and when you want the System to tell you what is happening.

 NOTE

The following applies to setting CGM alerts on the pump. If you are using a CGM app, any alerts that have been set up in the app are not automatically transferred to the pump and must be set up separately.

The High and Low Alerts tell you when your sensor glucose readings are outside your target glucose range.

Rise and Fall (rate of change) Alerts let you know when your glucose levels are changing fast.

The System also has a 55 mg/dL Fixed Low Alert that cannot be changed or turned off. This safety feature tells you your sensor glucose level may be dangerously low.

The Out of Range Alert notifies you when the transmitter and pump are not communicating. Keep the transmitter and the pump within 20 feet (6 meters) of each other without obstruction.

When the transmitter and the pump are too far apart, you will not get sensor glucose readings or alerts.

High and Low Glucose Alerts

You can personalize the High and Low Alerts which tell you when your sensor glucose readings are outside of your target sensor glucose range. When you have both your High and Low Alerts turned on, a gray zone on your trend graph shows your target range. The default for the High Alert is on, 200 mg/dL. The default for the Low Alert is on, 80 mg/dL. Consult with your healthcare provider before setting the High and Low Glucose Alert setting.

22.1 Setting Your High Glucose Alert and Repeat Feature

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap **CGM Alerts**.

5. Tap **High and Low**.

6. To Set the High Alert, tap **High Alert**.

7. Tap **Alert Me Above**.

The default setting for the High Alert is 200 mg/dL.

 NOTE

To turn off the High Alert, tap the on/off toggle.

8. Using the on-screen keypad, enter the value above which you want to be notified. It can be set between 120 and 400 mg/dL in 1 mg/dL increments.

9. Tap .

The repeat feature allows you to set a time for the High Alert to sound again and display on your pump as long as your sensor glucose reading remains above the High Alert value. The default value is: Never (the alert will not sound again). You can set the repeat feature to sound again every 15 minutes, 30 minutes, 1

hour, 2 hours, 3 hours, 4 hours, or 5 hours when your sensor glucose reading remains above the High Alert value.

To Set Up the Repeat Feature:

10. Tap **Repeat**.

11. To select the repeat time, tap the time you want the alert to sound again. For instance, if you select 1 hr, the alert will sound every hour as long as your sensor glucose reading remains above the High Alert value.

Use the up and down arrows to view all Repeat options.

✓ Once a value is selected, the pump will return to the previous screen.

12. Tap .

22.2 Setting Your Low Glucose Alert and Repeat Feature

1. From the *Home* screen, tap **OPTIONS**.

2. Tap the **Down Arrow**.

3. Tap **My CGM**.

4. Tap **CGM Alerts**.

5. Tap **High and Low**.

6. To Set the Low Alert, tap **Low Alert**.

7. Tap **Alert Me Below**.

The default setting for the Low Alert is 80 mg/dL.

NOTE

To turn off the Low Alert, tap the on/off toggle.

8. Using the on-screen keypad, enter the value below which you want to be notified. It can be set between 60 and 100 mg/dL in 1 mg/dL increments.

9. Tap .

The repeat feature allows you to set a time for the Low Alert to sound again and display on your pump as long as your sensor glucose reading

remains below the Low Alert value. The default value is: Never (the alert will not sound again). You can set the repeat feature to sound again every 15 minutes, 30 minutes, 1 hour, 2 hours, 3 hours, 4 hours, or 5 hours when your sensor glucose reading remains below the Low Alert value.

To Set Up the Repeat Feature:

10. Tap **Repeat**.

11. To select the repeat time, tap the time you want the alert to sound again. For instance, if you select 1 hr, the alert will sound every hour as long as your sensor glucose reading remains below the Low Alert Value.

Use the up and down arrows to view all repeat options.

✓ Once a value is selected, the pump will return to the previous screen.

12. Tap .

CHAPTER 22 • Setting CGM Alerts

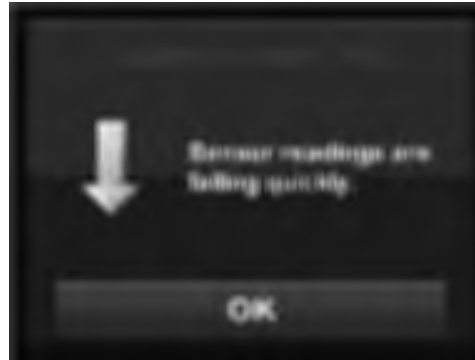
22.3 Rate Alerts

Rate alerts tell you when your glucose levels are rising (Rise Alert) or falling (Fall Alert) and by how much. You can choose to be alerted when your sensor glucose reading is rising or falling 2 mg/dL or more per minute, or 3 mg/dL or more per minute. The default value for both the Fall Alert and the Rise Alert is off. When turned on, the default is 3 mg/dL. Consult with your healthcare provider before setting the Rise and Fall Alerts.

Examples

If you set your Fall Alert to 2 mg/dL per minute and your sensor glucose readings fall at this rate or faster, the CGM Fall Alert with one arrow pointing down shows. The pump vibrates or

beeps according to your CGM volume selection.



If you set your Rise Alert to 3 mg/dL per minute and your sensor glucose readings rise at this rate or faster, the CGM Rise Alert with two arrows pointing up shows. The pump vibrates or beeps according to your CGM volume selection.



22.4 Setting Your Rise Alert

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap **CGM Alerts**.
5. Tap **Rise and Fall**.
6. Tap **Rise Alert**.
7. To select the default of 3 mg/dL/min, tap

To change your selection, tap **Rate**.

NOTE

To turn off the Rise Alert, tap the on/off toggle.

8. Tap **2 mg/dL/min** to select.
- ✓ Once a value is selected, the pump will return to the previous screen.
9. Tap

22.5 Setting Your Fall Alert

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap **CGM Alerts**.
5. Tap **Rise and Fall**.
6. Tap **Fall Alert**.
7. To select the default of 3 mg/dL/min, tap .

To change your selection, tap **Rate**.

NOTE

To turn off the Fall Alert, tap the on/off toggle.

8. Tap **2 mg/dL/min** to select.
- ✓ Once a value is selected, the pump will return to the previous screen.
9. Tap .

22.6 Setting Your Out of Range Alert

The range from the transmitter to the pump is up to 20 feet (6 meters) without obstruction.

The Out of Range Alert lets you know when your transmitter and pump are not communicating with each other. This alert is on by default.

PRECAUTION

We recommend that you keep the CGM Out of Range Alert turned on to notify you if your CGM is disconnected from your pump whenever you are not actively monitoring your pump status. Your CGM is providing the data that Control-IQ™ technology requires to make predictions to automate insulin dosing.

Keep the transmitter and the pump within 20 feet (6 meters) of each other without obstruction. To ensure communication, it is suggested that you face your pump screen out and away from the body, and wear the pump on the same side of the body that you wear your CGM. When the transmitter and pump are not communicating, you will not get sensor glucose readings or

alerts. The default value is on and will alert after 20 minutes.

The Out Of Range symbol appears on the pump *Home* screen and on the *Out of Range Alert* screen (if turned on) when the transmitter and pump are not communicating. The amount of time out of range also shows on the alert screen. It will continue to re-alert until the transmitter and pump are back in range.

NOTE

Control-IQ technology will continue to operate for the first 15 minutes that the transmitter and pump are out of range. Once the Out of Range condition is present for 20 minutes, Control-IQ technology will stop operation until the two devices are within range.

To Set Your Out of Range Alert:

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap **CGM Alerts**.

CHAPTER 22 • Setting CGM Alerts

5. Tap **Out of Range**.

The default is set to on and the time is set to 20 minutes.

6. To change the time, tap **Alert After**.

7. Using the on-screen keypad, enter the time after which you want to be alerted (between 20 minutes and 3 hours and 20 minutes) then tap



8. Tap .

3 CGM Features

CHAPTER 23

Starting or Stopping a CGM Sensor Session

CHAPTER 23 • Starting or Stopping a CGM Sensor Session

23.1 Enter Your Transmitter ID

To activate the Bluetooth wireless technology communication, you need to enter the unique transmitter ID into your pump. Once the transmitter ID has been entered into your pump, the two devices can be paired, allowing your sensor glucose readings to be displayed on your pump.

If you need to replace your transmitter, you will need to enter the new transmitter ID into your pump. If you need to replace your pump, you will need to re-enter the transmitter ID into your pump.

1. Remove the transmitter from its packaging.

⚠ WARNING

DO NOT use your transmitter if it is damaged/cracked. This could create an electrical safety hazard or malfunction, which might cause electrical shocks.

2. From the *Home* screen, tap **OPTIONS**.

3. Tap the Down Arrow.

4. Tap **My CGM**.

5. Tap **Transmitter ID**.

6. Using the on-screen keypad, enter the unique transmitter ID.

The transmitter ID can be found on the back of your transmitter or on the transmitter box.

The letters I, O, V, and Z are not used in transmitter IDs and should not be entered. If one of these letters is entered, you will be notified that an invalid ID was entered and prompted to enter a valid ID.

7. Tap .

8. To make sure that the correct transmitter ID is entered, you will be prompted to enter it a second time.

9. Repeat step 6 above, then tap .

If the transmitter IDs you entered do not match you will be prompted to start the process again.

- ✓ Once matching values have been entered, you will be returned to the *My CGM* screen and the transmitter ID you entered will be highlighted in orange.

23.2 Start the Sensor

To start a CGM session, follow the steps below.

1. From the *Home* screen, tap **OPTIONS**.

2. Tap the Down Arrow.

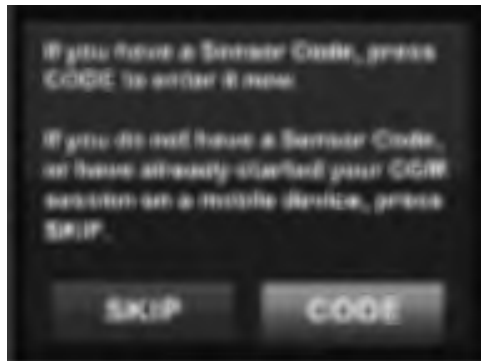
3. Tap **My CGM**.

4. Tap **START SENSOR**.

- ✓ Once you start a sensor session, the **START SENSOR** option is replaced with **STOP SENSOR**.

The following screen displays prompting you to either enter the sensor code, or to skip this step. If you choose to enter the sensor code, you will not be prompted to calibrate for the duration of the sen-

sensor session. For information about Dexcom G6 CGM sensor codes, visit the manufacturer's website for applicable user guides.



Tap **CODE** to enter the 4-digit sensor code. If you don't have a code, or if you have already started a sensor session with the Dexcom G6 CGM app, you can tap **SKIP**.

If you don't enter a code into the t:slim X2™ pump, you will need to calibrate your sensor every 24 hours. A prompt to calibrate will be displayed on the pump.

5. Tap  to confirm.

- ✓ The *SENSOR STARTED* screen will appear to let you know your sensor startup has begun.
 - ✓ Your pump will return to the *CGM Home* screen with the 3 hour trend graph and the sensor startup countdown symbol displayed.
6. Check your pump *CGM Home* screen 10 minutes after starting your sensor session to make sure your pump and transmitter are communicating. The antenna symbol should be to the right of the battery indicator and should be white.
 7. If you see the out of range symbol below the insulin level indicator, and the antenna symbol is grayed out, follow these troubleshooting tips:
 - a. Make sure your pump and transmitter are within 20 feet (6 meters) of each other without obstruction. Re-check in 10 minutes to see if the out of range symbol is still active.

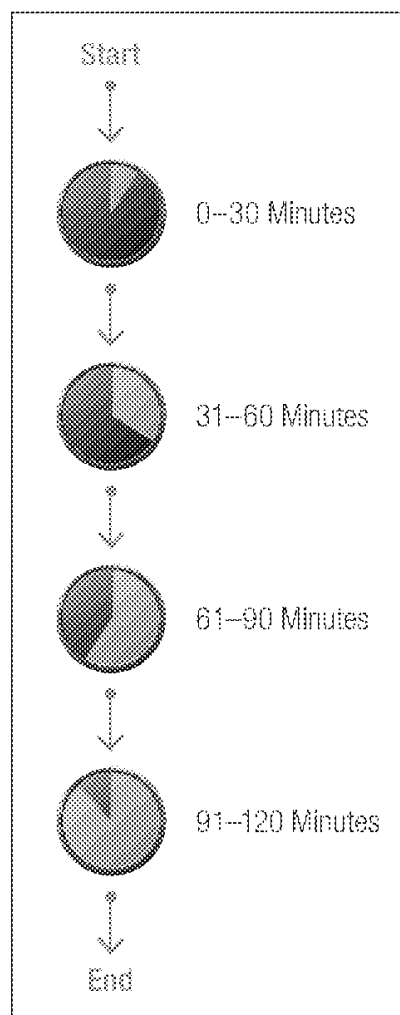
- b. If the pump and transmitter are still not communicating, check the *My CGM* screen to make sure the correct transmitter ID is entered.
- c. If the correct transmitter ID is entered and the pump and transmitter are still not communicating, contact Customer Technical Support.

CHAPTER 23 • Starting or Stopping a CGM Sensor Session

23.3 Sensor Startup Period

As an example, the Dexcom G6 sensor needs a 2-hour startup period to adjust to being under your skin. You will not get sensor glucose readings or alerts until the 2-hour startup period ends. For information about Dexcom G6 CGM sensor startup periods, visit the manufacturer's website for applicable product instructions.

During the startup period, the *CGM Home* screen on your pump shows a 2-hour countdown symbol in the upper right portion of the screen. The countdown symbol fills in over time to show that you are getting closer to the active sensor session.

Sensor Startup Period Timeline**⚠ WARNING**

Continue to use a BG meter and test strips in order to make treatment decisions during the 2-hour startup period.

📌 NOTE

During the sensor startup period, Control-IQ technology will not affect the Basal Rates or deliver automatic correction boluses. The sensor must be actively providing readings for Control-IQ technology to operate.

Examples

For example, if you started your sensor session 20 minutes ago, you would see this countdown symbol on the *CGM Home* screen.



If you started your sensor session 90 minutes ago, you would see this countdown symbol on the *CGM Home* screen.



At the end of the 2-hour startup period, the countdown symbol will be replaced with the current CGM reading.



Follow the instructions in the next chapter to calibrate your sensor. Skip the calibration instructions if you entered a sensor code. You may enter a calibration into the System at any time, even if you have already entered sensor code. Pay attention to your symptoms, and if they do not match the current CGM readings, you may choose to enter a calibration.

Ending Your Sensor Session

When the sensor session ends, you will need to replace the sensor and start a new sensor session. In some cases your sensor session may end early. You may also choose to end the sensor session early. However, if you end a sensor session early, you cannot re-start the session with that same sensor. A new sensor must be used.

NOTE

DO NOT throw away the transmitter at the end of a sensor session. Continue use of the transmitter until the pump notifies you that the transmitter battery is about to expire. Wipe the outside of the transmitter with isopropyl alcohol between sensor sessions.

Sensor glucose alerts and alarms do not work after the sensor session ends. Once the sensor session has ended, CGM readings are not available. If you are using Control-IQ technology, it becomes inactive when a CGM sensor session is ended.

23.4 Automatic Sensor Shut-Off

Your t:slim X2 pump tells you how much time you have left until your sensor session is complete. The *SENSOR EXPIRING SOON* screen shows at 6 hours remaining, 2 hours remaining, and 30 minutes remaining before your session ends. You will continue to receive sensor glucose readings after each reminder.

When you see the *SENSOR EXPIRING SOON* screen:

1. Tap **OK** to return to the previous screen.
- ✓ The *SENSOR EXPIRING SOON* screen will show again when there are 2 hours remaining, and when there are 30 minutes remaining.

CHAPTER 23 • Starting or Stopping a CGM Sensor Session

- ✓ After the final 30 minutes, the *REPLACE SENSOR* screen is displayed.
- 2. Tap .
- ✓ The *CGM Home* screen will appear with the Replace Sensor icon in the place where sensor glucose readings normally show.

New sensor glucose readings do not show on your pump after your sensor session ends. You must remove your sensor and insert a new sensor.

23.5 Ending a Sensor Session Before Automatic Shut-Off

You can end your sensor session at any time before the automatic sensor shutoff. To end your sensor session early:

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.

4. Tap **STOP SENSOR**.

5. Tap  to confirm.

- ✓ The *SENSOR STOPPED* screen is temporarily displayed.
- ✓ The *CGM Home* screen will appear with the Replace Sensor icon in the place where sensor glucose readings normally show.

New sensor glucose readings do not show on your pump after your sensor session ends. You must remove your sensor and insert a new sensor.

23.6 Removing the Sensor and Transmitter

⚠ WARNING

DO NOT ignore broken or detached sensor wires. A sensor wire could remain under your skin. If a sensor wire breaks off under your skin and you can't see it, don't try to remove it. Contact your healthcare provider. Also seek professional medical help if you have symptoms of infection or inflammation (redness, swelling, or pain) at the insertion site. If you experience a

broken sensor, please report this to Customer Technical Support.

For information about removing the Dexcom G6 sensor and Dexcom G6 transmitter, visit the manufacturer's website for applicable product instructions.

3 CGM Features

CHAPTER 24

Calibrating Your CGM System

CHAPTER 24 • Calibrating Your CGM System

24.1 Calibration Overview

If you did not enter a CGM sensor code when starting a sensor session, you will be prompted to calibrate at the following intervals:

- 2-hour startup: 2 calibrations 2 hours after you start your sensor session
- 12-hour update: 12 hours after the 2 hour start up calibration
- 24-hour update: 24 hours after the 2 hour start up calibration
- Every 24 hours: every 24 hours after the 24-hour update
- When notified

On the first day of your sensor session, you must enter four BG values into your pump to calibrate. You must enter one BG value to calibrate every 24 hours after your first startup calibration. The pump will remind you when the System needs these calibrations. In addition, you may be prompted to enter additional BG values to calibrate as needed.

⚠ PRECAUTION

DO NOT calibrate when your trend arrow is up, double-up, down, or double-down because your BG is changing at more than 2 mg/dL per minute.

When calibrating, you must enter your BG values into the pump by hand. You can use any commercially available BG meter. You must calibrate with accurate BG meter values to get accurate sensor glucose readings.

Follow these important instructions when obtaining BG values for calibration:

- BG values used for calibration must be between 40 to 400 mg/dL and must have been taken within the past 5 minutes.
- Your sensor cannot be calibrated if the glucose value from your BG meter is less than 20 mg/dL or greater than 600 mg/dL. For safety reasons, it is recommended that you treat your BG value before calibrating.
- Make sure a sensor glucose reading shows in the upper right

portion of the *CGM Home* screen before calibrating.

- Make sure the antenna symbol is visible to the right of the battery indicator on the *CGM Home* screen and is active (white, not greyed out) before calibrating.
- Always use the same BG meter to calibrate that you routinely use to measure your BG. Do not switch your BG meter in the middle of a sensor session. BG meter and strip accuracy vary between BG meter brands.
- The accuracy of the BG meter used for calibration may affect the accuracy of sensor glucose readings. Follow your BG meter manufacturer's instructions for BG testing.

24.2 Startup Calibration

If you did not enter a sensor code when starting the sensor session, the system will prompt you to calibrate to provide accurate information.

NOTE

The instructions in this section do not apply if you entered the sensor code when you started the sensor session.

Two hours after you start the sensor session, the *CALIBRATE CGM* screen will appear, letting you know that two separate BG values from your BG meter must be entered. You will not see sensor glucose readings until the pump accepts the BG values.

1. From the *CALIBRATE CGM* screen, Tap .
- ✓ The *CGM Home* screen will appear with two blood drops in the upper right portion of the screen. The two blood drops will stay on the screen until you enter two separate BG values to calibrate.
2. Wash and dry your hands, make sure your BG test strips have been stored properly and are not expired, and make sure your BG meter is properly coded (if required).
3. Take a BG measurement using your BG meter. Carefully apply the blood

sample to the test strip following your BG meter manufacturer's instructions.

⚠ PRECAUTION

DO use fingertips to calibrate from your BG meter. Blood from other places may be less accurate and not as timely.

4. Tap **OPTIONS**.
5. Tap the **Down Arrow**.
6. Tap **My CGM**.
7. Tap **Calibrate CGM**.
8. Using the on-screen keypad, enter the BG value from your BG meter.

⚠ PRECAUTION

To calibrate the System, **DO** enter the exact BG value displayed on your BG meter within 5 minutes of a carefully performed BG meter. Do not enter the sensor glucose readings for calibration. Entering incorrect BG values, BG values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe

hypoglycemia (low BG) or hyperglycemia (high BG) events.

9. Tap .
10. Tap  to confirm the calibration.

Tap  if the BG value does not exactly match the reading from your BG meter. The on-screen keypad will reappear. Enter the exact reading from your BG meter.
- ✓ The *CALIBRATION ACCEPTED* screen will appear.
- ✓ The *My CGM* screen will appear.
11. Tap **Calibrate CGM** to enter your second BG value.

✓ The on-screen keypad will appear.
12. Wash and dry your hands, make sure your BG test strips have been stored properly and are not expired, and make sure your BG meter is properly coded (if required).
13. Take a BG measurement using your BG meter. Carefully apply the blood

CHAPTER 24 • Calibrating Your CGM System

sample to the test strip following your BG meter manufacturer's instructions.

14. Follow steps 8–10 to enter your second BG value.

24.3 Calibration BG Value and Correction Bolus

Your t:slim X2™ pump uses the BG value entered for calibration to determine if a correction bolus is needed, or to provide other important information about your insulin on board and BG.

- If you enter a calibration value that is above your Target BG in Personal Profiles, the *Above Target Correction Bolus* confirmation screen will appear. To add a correction bolus, tap . Follow the instructions in Section 8.3 *Correction Bolus Calculation* to deliver a correction bolus.
- If you enter a calibration value that is below your Target BG in Personal Profiles, a message screen will indicate “Your BG is Below Target”,

and other important information will appear on the screen.

- If you enter your Target BG as a calibration value, the pump will return to the *CGM Home* screen.

24.4 Reasons You May Need to Calibrate

You may need to calibrate if your symptoms do not match the glucose values provided by your CGM.

If you see the *CALIBRATION ERROR* screen, you will be prompted to enter a BG value to calibrate in either 15 minutes or 1 hour, depending on the error.

NOTE

Although it is not required, and you will not be prompted to calibrate, you may enter a calibration into the System at any time, even if you have already entered a sensor code. Pay attention to your symptoms, and if they do not match the current CGM readings, you may choose to enter a calibration.

3 CGM Features

CHAPTER 25

Viewing CGM Data on Your t:slim X2 Insulin Pump

CHAPTER 25 • Viewing CGM Data on Your Lilliput X2 Insulin Pump

25.1 Overview

⚠ WARNING

DO NOT ignore how you feel. If your sensor glucose alerts and readings do not match what you're feeling, use your BG meter to make diabetes treatment decisions or, if needed, seek immediate medical attention.

The pump screens in this section illustrate the screen when Control-IQ™ technology is off. For information about CGM screens when Control-IQ technology is on, see Section 31.9 Control-IQ Technology Information on Your Screen.

During an active sensor session, CGM readings are sent to your pump every 5 minutes. This section teaches you how to view your sensor glucose readings and trend information. The trend graph provides additional information that your BG meter does not. It shows your current sensor glucose value, the direction it is changing and how fast it is changing. The trend graph can also show you where your sensor glucose has been over time.

Your BG meter measures glucose in your blood. Your sensor measures glucose from interstitial fluid (the fluid under your skin). Because glucose from different fluids is measured, readings from your BG meter and sensor may not match.

The greatest benefit you get from using continuous glucose monitoring will come from trending information. It is important that you focus on the trends and rate of change on your receiver or pump rather than the exact sensor glucose reading.

Press the **Screen On/Quick Bolus** button to turn the screen on. If a CGM session is active, you will see the *CGM Home* screen with the 3 hour trend graph displayed.



- The current time and date are shown at the top of the screen in the middle.
- Each “dot” on the trend graph is a sensor glucose reading reported every 5 minutes.
- Your High Alert setting shows as an orange line across the trend graph.
- Your Low Alert setting shows as a red line across the trend graph.
- The gray zone highlights your target sensor glucose range, between your High and Low Alert settings.
- Sensor glucose readings are shown in milligrams per deciliter (mg/dL).
- If your sensor glucose reading is between your High and Low Alert settings, it is shown in white.
- If your sensor glucose reading is above your High Alert setting, it is shown in orange.
- If your sensor glucose reading is below your Low Alert setting, it is shown in red.

- If your sensor glucose reading is 55 mg/dL or lower, it is shown in red, regardless of the Low Alert setting.
- The dots on the trend graph display as different colors based on your High and Low Alert settings: white if between High and Low Alert settings, orange if above High Alert setting, red if below Low Alert setting.

25.2 CGM Trend Graphs

You can view your past sensor glucose trend information on your *CGM Home* screen.

1, 3, 6, 12, and 24 hour trend views can be seen. The 3 hour Trend Graph is the default view and will be shown on the *CGM Home* screen even if a different trend graph was shown when the screen turned off.

Your trend graph shows a flat line or dots at 50 or 400 mg/dL when your glucose is outside this range.

To view different Trend Graph times, tap on the Trend Graph Time (HRS) to cycle through the options.

3 Hour Trend Graph (default view) shows you your current sensor glucose reading along with the last 3 hours of sensor glucose readings.



6 Hour Trend Graph shows you your current sensor glucose reading along with the last 6 hours of sensor glucose readings.



12 Hour Trend Graph shows you your current sensor glucose reading along with the last 12 hours of sensor glucose readings.

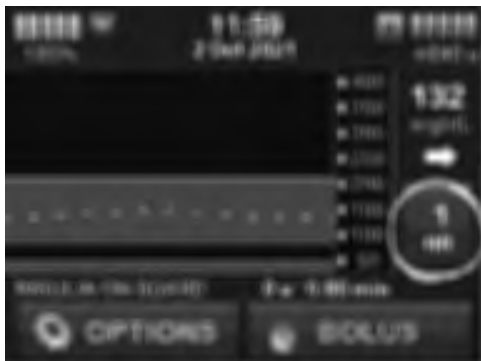


24 Hour Trend Graph shows you your current sensor glucose reading along with the last 24 hours of sensor glucose readings.



CHAPTER 25 • Viewing CGM Data on Your Insulin Pump

1 Hour Trend Graph shows you your current sensor glucose reading along with the last 1 hour of sensor glucose readings.



LOW shows when your most recent sensor glucose reading is less than 40 mg/dL.



HIGH shows when your most recent sensor glucose reading is greater than 400 mg/dL.



25.3 Rate of Change Arrows

Your rate of change arrows add detail about the direction and speed of sensor glucose change over the last 15–20 minutes.

The trend arrows show below your current sensor glucose reading.



Do not overreact to the rate of change arrows. Consider recent insulin dosing, activity, food intake, your overall trend graph and your BG value before taking action.

If there are missed communications between the sensor and your pump during the last 15–20 minutes due to being out of range or due to an error condition, an arrow may not display. If the trend arrow is missing, and you are concerned that your BG level may be rising or falling, take a BG measurement using your BG meter.

The table below shows the different trend arrows your receiver or pump displays:

Trend Arrow Definitions

	Constant: Your sensor glucose is steady (not increasing/decreasing more than 1 mg/dL each minute). Your sensor glucose could increase or decrease by up to 15 mg/dL in 15 minutes.		Slowly falling: Your sensor glucose is falling 1–2 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease up to 30 mg/dL in 15 minutes.
	Slowly rising: Your sensor glucose is rising 1–2 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase up to 30 mg/dL in 15 minutes.		Falling: Your sensor glucose is falling 2–3 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease up to 45 mg/dL in 15 minutes.
	Rising: Your sensor glucose is rising 2–3 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase up to 45 mg/dL in 15 minutes.		Rapidly falling: Your sensor glucose is falling more than 3 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease more than 45 mg/dL in 15 minutes.
	Rapidly rising: Your sensor glucose is rising more than 3 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase more than 45 mg/dL in 15 minutes.	No Arrow	No rate of change information: The System cannot calculate how fast your sensor glucose is rising or falling at this time.

CHAPTER 25 • Viewing CGM Data on Your Lilliput X2 Insulin Pump

25.4 CGM History

CGM History displays the historical log of CGM events. At least 90 days of data can be viewed in History. When the maximum number of events is reached, the oldest events are removed from the history log and replaced with the most recent events. The following history sections can be viewed:

- Sessions and Calibrations
- Alerts and Errors
- Complete

Each section above is organized by date. If there are no events associated with a date, the day will not be shown in the list.

The Sessions and Calibrations section includes the start time and date for each Sensor Session, the stop time and date for each Sensor Session, and all calibration BG values entered.

The Alerts and Errors section includes the date and time for all Alerts and Errors that occurred. The letter “D” (D: Alert) before an Alert or Alarm indicates

the time it was declared. The letter “C” (C: Alert) indicates the time it was cleared.

The Complete section includes all information from the Sessions and Calibrations and Alerts and Errors sections as well as any changes to settings.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **History**.
4. Tap **CGM History**.
5. Tap section you want to view. Each section is organized by date. Tap the date to view events from that day. Use the **Down Arrow** to scroll to more dates.

25.5 Missed Readings

If your pump misses CGM readings for a period of time, you will see three dashes where the CGM reading typically displays on the *CGM Home*

screen and on the *CGM Lock* screen. The system will automatically attempt to backfill missing data points up to 6 hours in the past when connectivity is restored and readings begin to appear. If the sensor glucose number or trend arrow is missing, and you are concerned that your BG level may be rising or falling, take a BG measurement using your BG meter.

NOTE

Control-IQ technology will continue to operate for the first 15 minutes after CGM readings become unavailable. If connectivity is not restored after 20 minutes, Control-IQ technology will stop operation until CGM readings are available. While Control-IQ technology is not operating, your pump will continue to deliver insulin according to your Personal Profile settings. Once CGM readings are available, Control-IQ technology will automatically resume. For more information, see Chapter 30 *Introduction to Control-IQ Technology*.

3 CGM Features

CHAPTER 26

CGM Alerts and Errors

CHAPTER 26 • CGM Alerts and Errors

Information in this section will help you learn how to respond to CGM alerts and errors. It applies only to the CGM portion of your System. CGM alerts and errors do not follow the same pattern of vibration and beeps as insulin delivery reminders, alerts, and alarms.

The t:connect™ mobile app also can provide messages, alerts, and alarms from your t:slim X2™ pump as push notifications on your smartphone. These push notifications will be identical to your pump's display unless otherwise noted in this chapter.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. For more information about connecting your pump and smartphone, see Section 4.3 *Connecting to a Smartphone*, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

For information on insulin delivery reminders, alerts, and alarms, see

Chapters 13 t:slim X2 Insulin Pump Alerts, 14 t:slim X2 Insulin Pump Alarms, and 15 t:slim X2 Insulin Pump Malfunction.

For information on Control-IQ™ technology alerts, see Chapter 32 *Control-IQ Technology Alerts*.

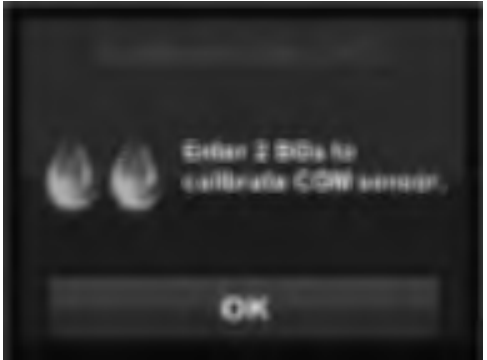
⚠ WARNING

If a sensor session is ended, either automatically or manually, Control-IQ technology is unavailable and will not adjust insulin. In order for Control-IQ technology to be enabled, a sensor session must be started and transmitting sensor values to the pump based on a sensor code or sensor calibration.

⚠ PRECAUTION

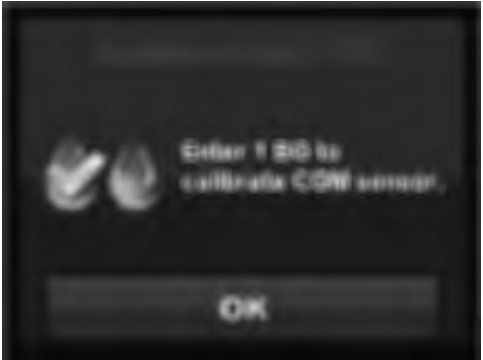
You must customize the CGM alert settings on your t:slim X2 pump and the Dexcom G6 CGM app separately. The alert settings apply to the smartphone and pump separately.

26.1 Startup Calibration Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	2-hour CGM startup period is complete. This will only appear if you did not enter a sensor code.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the System re-notify me?	Yes, every 15 minutes until you calibrate.
	How should I respond?	Tap  and enter 2 separate BG values to calibrate the system and start your CGM session.

CHAPTER 26 • CGM Alerts and Errors

26.2 Second Startup Calibration Alert

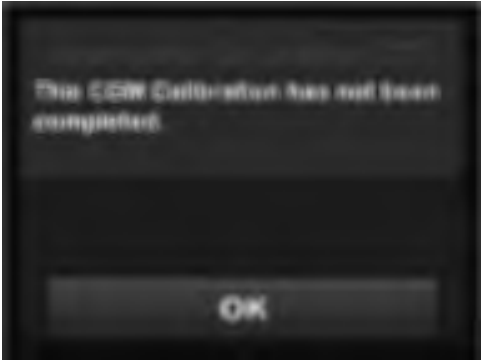
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The System needs an additional BG value to complete startup calibration. This will only appear if you did not enter a sensor code.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the System re-notify me?	Yes, every 15 minutes until second calibration is entered.
	How should I respond?	Tap  and enter a BG value to calibrate the System and start your CGM session.

26.3 12 Hour Calibration Alert

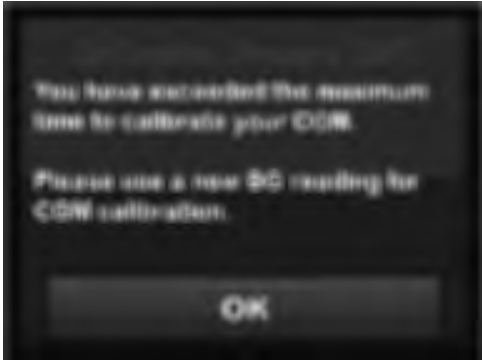
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The System needs a BG value to calibrate. This will only appear if you did not enter a sensor code.
	How will the System notify me?	On screen only with no vibration or beep.
	Will the System re-notify me?	Yes, every 15 minutes.
	How should I respond?	Tap  and enter a BG value to calibrate the system.

CHAPTER 26 • CGM Alerts and Errors

26.4 Incomplete Calibration

Screen	Explanation	
What will I see on the screen? 	What does it mean?	If you start to enter a calibration value using the keypad and do not complete the entry within 90 seconds, this screen appears.
	How will the System notify me?	2 beeps or vibrations depending on Sound Volume selected.
	Will the System re-notify me?	Yes, every 5 minutes until confirmed.
	How should I respond?	Tap  and complete your calibration by entering the value using the on-screen keypad.

26.5 Calibration Timeout

Screen	Explanation	
What will I see on the screen? 	What does it mean?	If you start to enter a calibration value using the keypad and do not complete the entry within 5 minutes, this screen appears.
	How will the System notify me?	2 beeps or vibrations depending on Sound Volume selected.
	Will the System re-notify me?	Yes, every 5 minutes until confirmed.
	How should I respond?	Tap  and obtain a new BG value using your BG meter. Enter the value using the on-screen keypad to calibrate the System.

CHAPTER 26 • CGM Alerts and Errors

26.6 Wait 15 Minute Calibration Error Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The sensor cannot calibrate.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the System re-notify me?	No.
	How should I respond?	Tap  to confirm. Wait 15 minutes then enter 1 more BG value. Wait 15 more minutes. If error screen still appears, enter 1 more BG value. Wait 15 minutes. If no sensor glucose readings appear, the sensor needs to be replaced.

26.7 Calibration Required Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The System needs a BG value to calibrate. Sensor glucose readings will not be displayed at this time.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the System re-notify me?	Yes, every 15 minutes.
	How should I respond?	Tap  and enter a BG value to calibrate the System.

CHAPTER 26 • CGM Alerts and Errors

26.8 CGM High Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your most recent sensor glucose reading is at or above the High Alert setting.
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes until confirmed or your sensor glucose value drops below the Alert level.
	Will the System re-notify me?	Only if you have turned on the Repeat feature.
	How should I respond?	Tap  to confirm.

26.9 CGM Low Alert

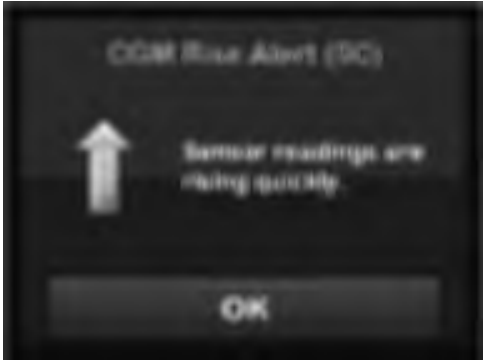
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your most recent sensor glucose reading is at or below the Low Alert setting.
	How will the System notify me?	3 vibrations, then 3 vibrations/beeps every 5 minutes until confirmed or your sensor glucose value goes above the Alert level.
	Will the System re-notify me?	Only if you have turned on the Repeat feature.
	How should I respond?	Tap  to confirm.

CHAPTER 26 • CGM Alerts and Errors

26.10 CGM Fixed Low Alert

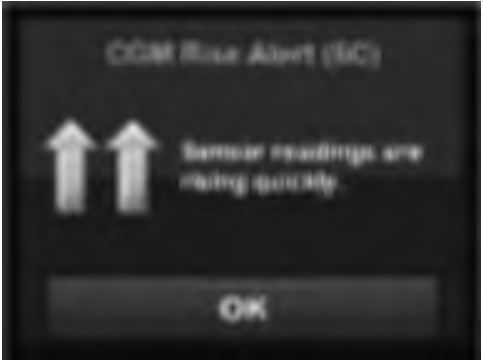
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your most recent sensor glucose reading is at or below 55 mg/dL.
	How will the System notify me?	4 Vibrations, then 4 vibrations/beeps every 5 minutes until confirmed or your sensor glucose value goes above 55 mg/dL.
	Will the System re-notify me?	Yes, 30 minutes after each confirmation until your sensor glucose value goes above 55 mg/dL.
	How should I respond?	Tap  to confirm.

26.11 CGM Rise Alert

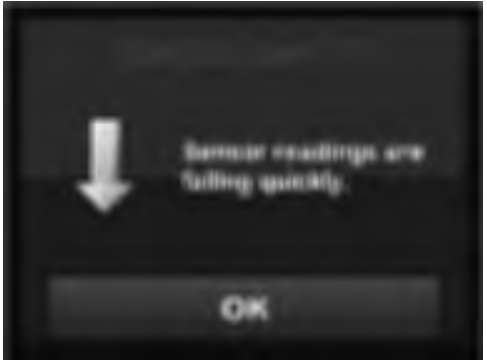
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your sensor glucose levels are rising at 2 mg/dL per minute or faster (at least 30 mg/dL in 15 minutes).
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes or until confirmed.
	Will the System re-notify me?	No.
	How should I respond?	Tap  to confirm.

CHAPTER 26 • CGM Alerts and Errors

26.12 CGM Rapid Rise Alert

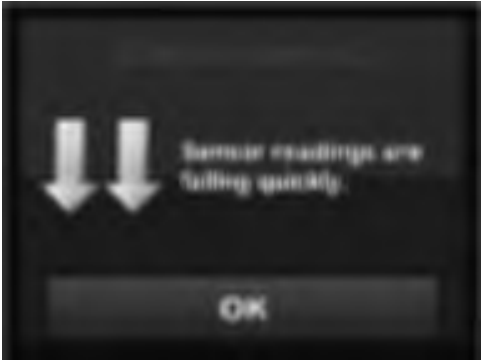
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your sensor glucose levels are rising at 3 mg/dL per minute or faster (at least 45 mg/dL in 15 minutes).
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes or until confirmed.
	Will the System re-notify me?	No.
	How should I respond?	Tap  to confirm.

26.13 CGM Fail Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your sensor glucose levels are falling at 2 mg/dL per minute or faster (at least 30 mg/dL in 15 minutes).
	How will the System notify me?	3 vibrations, then 3 vibrations/beeps every 5 minutes or until confirmed.
	Will the System re-notify me?	No.
	How should I respond?	Tap  to confirm.

CHAPTER 26 • CGM Alerts and Errors

26.14 CGM Rapid Fall Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your sensor glucose levels are falling at 3 mg/dL per minute or faster (at least 45 mg/dL in 15 minutes).
	How will the System notify me?	3 vibrations, then 3 vibrations/beeps every 5 minutes or until confirmed.
	Will the System re-notify me?	No.
	How should I respond?	Tap  to confirm.

26.15 Unknown Sensor Glucose Reading

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The sensor is sending sensor glucose readings that the System does not understand. You will not receive sensor glucose readings.
	How will the System notify me?	On screen only with no vibration or beep.
	Will the System re-notify me?	The 3 dashes will remain on the screen until a new sensor glucose reading is received and displayed in their place. If no sensor glucose readings are received after 20 minutes, the CGM Unavailable Alert will trigger. See Section 26.20 CGM Unavailable.
	How should I respond?	Wait 30 minutes for more information from the system. Do not enter BG values for calibration. The system will not use BG values for calibration when "- - -" appears on the screen.

CHAPTER 26 • CGM Alerts and Errors

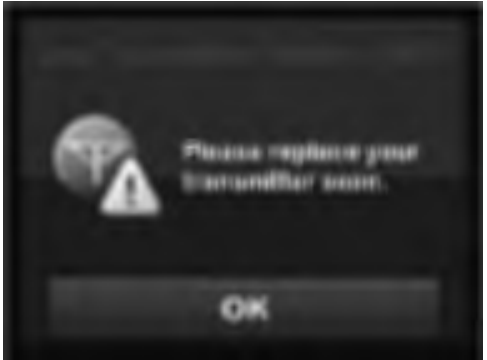
26.16 Out of Range Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The transmitter and pump are not communicating. The pump will not receive sensor glucose readings, and Control-IQ technology is not able to predict sensor glucose levels or adjust insulin delivery.
	How will the System notify me?	1 vibrate, then vibration/beep every 5 minutes until the transmitter and pump are back in range.
	Will the System re-notify me?	Yes, if the transmitter and pump remain out of range.
	How should I respond?	Tap  to confirm and move the transmitter and pump closer together, or remove the obstruction between them.

⚠ WARNING

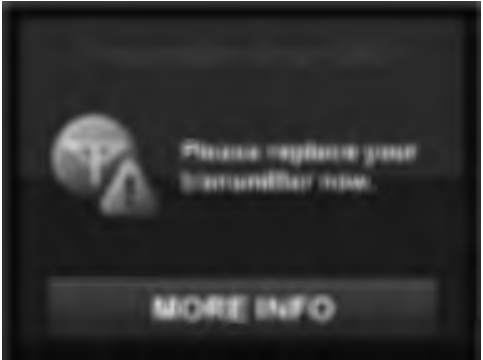
Control-IQ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate settings in your active Personal Profile.

26.17 Low Transmitter Battery Alert

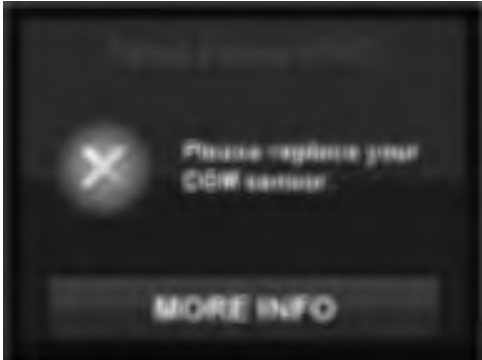
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Transmitter battery is low.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the System re-notify me?	Yes, the alarm will notify you when there are 21, 14, and 7 days of transmitter battery life remaining.
	How should I respond?	Tap  to confirm. Replace the transmitter as soon as possible.

CHAPTER 26 • CGM Alerts and Errors

26.18 Transmitter Error

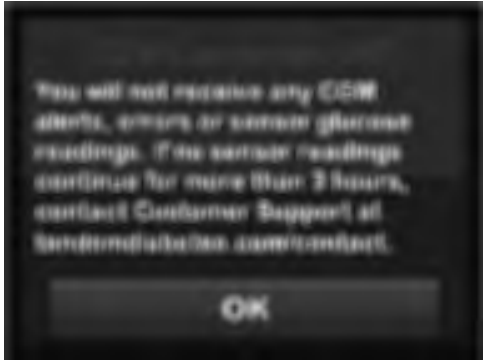
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The transmitter has failed and the CGM session has stopped.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes.
	Will the System re-notify me?	No.
	How should I respond?	Tap MORE INFO. A screen notifying you that your CGM session has stopped but insulin delivery continues will appear. Replace the transmitter immediately.

26.19 Failed Sensor Error

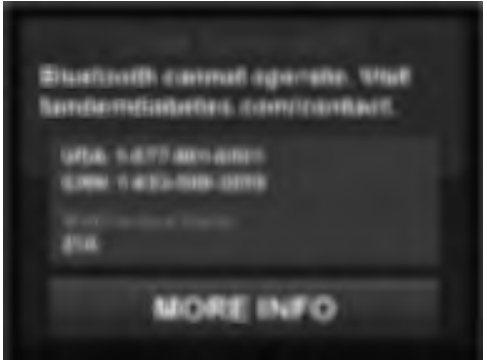
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The sensor is not working properly and the CGM session has stopped.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes.
	Will the System re-notify me?	No.
	How should I respond?	Tap MORE INFO . A screen notifying you that your CGM session has stopped but insulin delivery continues will appear. Replace the sensor and begin a new CGM session.

CHAPTER 26 • CGM Alerts and Errors

26.20 CGM Unavailable

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your CGM session has been stopped for more than 20 minutes and the CGM can no longer be used.
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes or until confirmed.
	Will the System re-notify me?	Yes, every 20 minutes until the CGM session is available. If the condition persists for 3 hours, the Failed Sensor alert will be displayed. See Section 26.19 Failed Sensor Error.
	How should I respond?	Tap  and contact Customer Technical Support.

26.21 CGM System Error

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your CGM System is not working properly; the CGM session has stopped and the CGM can no longer be used.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes.
	Will the System re-notify me?	No.
	How should I respond?	Tap MORE INFO . A screen notifying you that your CGM System cannot operate but insulin delivery continues will appear. Call Customer Technical Support.

This Page is Intentionally Left Blank

3 CGM Features

CHAPTER 27

CGM Troubleshooting

CHAPTER 27 • CGM Troubleshooting

This chapter provides helpful tips and instructions to help you fix issues you may have while using the CGM portion of your System.

If the troubleshooting steps in this chapter do not fix your issue, contact Customer Technical Support.

The following tips are specific to troubleshooting the Dexcom G6 CGM connected to your pump. For more information about Dexcom G6 CGM troubleshooting, visit the manufacturer's website for applicable product instructions.

27.1 CGM Pairing Troubleshooting

Possible issue:

Difficulty pairing your Dexcom G6 CGM with your t:slim X2™ insulin pump.

Troubleshooting tip:

The Dexcom G6 CGM only allows pairing with one medical device at a time. Ensure your CGM is not connected to the Dexcom receiver before pairing with the pump. You may still use a smartphone with the Dexcom

G6 CGM app and your t:slim X2 insulin pump simultaneously with the same transmitter ID. See Section 21.2 Disconnecting from the Dexcom Receiver.

27.2 Calibration Troubleshooting

To ensure proper calibration of your CGM, follow these important tips.

Before you take a BG value for calibration, wash your hands, make sure your BG test strips have been stored properly and are not expired, and make sure that your meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions that came with your BG meter or test strips.

Do not calibrate if you see the Out of Range symbol in the place where your sensor glucose readings are normally shown on the screen.

Do not calibrate if you see “- - -” in the place where your sensor glucose readings are normally shown on the screen.

Do not calibrate if your BG value is below 20 mg/dL or above 600 mg/dL.

27.3 Unknown Sensor Reading Troubleshooting

When your CGM cannot provide a sensor glucose reading “- - -” shows in the place where your sensor glucose is normally shown on the screen. This means that the System does not understand the sensor signal temporarily.

Often the System can correct the problem and continue providing sensor glucose readings. If it has been at least 3 hours since your last sensor glucose reading, contact Customer Technical Support.

Do not enter any BG values for calibration when you see “- - -” on your screen. The System will not use a BG value for calibration when this symbol is on your screen.

If you see “- - -” often during a sensor session, follow the troubleshooting tips below before inserting another sensor.

- Make sure your sensor is not expired.
- Make sure your sensor pod is not dislodged or peeling up.
- Make sure your transmitter is snapped in completely.
- Make sure nothing is rubbing the sensor pod (e.g., clothing, seat belts, etc.).
- Make sure to select a good insertion site.
- Make sure your insertion site is clean and dry before sensor insertion.
- Wipe the bottom of the transmitter with a damp cloth or isopropyl alcohol wipe. Place the transmitter on a clean, dry cloth and air dry for 2–3 minutes.

27.4 Out of Range/No Antenna Troubleshooting

▲ WARNING

Control-IQ™ technology can only adjust insulin delivery when your CGM is in range. If you go

out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate settings in your active Personal Profile

▲ PRECAUTION

AVOID separating the transmitter and the pump by more than 20 feet (6 meters). The transmission range from the transmitter to the pump is up to 20 feet (6 meters) without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and pump are farther than 20 feet (6 meters) apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

If you see the Out of Range icon on your screen in the place where your sensor glucose reading normally shows, then your t:slim X2 pump is not communicating with your transmitter and sensor glucose readings will not show on your screen. Each time you start a new sensor session, wait 10 minutes for your t:slim X2 pump to start communicating with your transmitter.

When a sensor session is active, you may sometimes experience loss of communication for 10 minutes at a time. This is normal.

If you see the Out of Range icon for more than 10 minutes, move your t:slim X2 pump and CGM transmitter closer together and remove any obstructions. Wait 10 minutes and communication should be restored.

You must enter your transmitter ID correctly into your pump to receive sensor glucose readings (see Section 23.1 Enter Your Transmitter ID). Make sure you have removed your sensor and stopped your sensor session before checking or changing your transmitter ID. You cannot change your transmitter ID during a sensor session.

If you are still having trouble getting sensor glucose readings, contact Customer Technical Support.

27.5 Failed Sensor Troubleshooting

The System may detect issues with your sensor where it cannot determine your glucose reading. The sensor

CHAPTER 27 • CGM Troubleshooting

session ends and the *FAILED SENSOR* screen shows on your t:slim X2 pump. If you see this screen, it means your CGM session has ended.

- Remove your sensor and insert a new sensor.
- To help improve future sensor performance, follow the troubleshooting tips below.
- Make sure your sensor is not expired.
- Make sure your sensor pod is not dislodged or peeling up.
- Make sure your transmitter is snapped in completely.
- Make sure nothing is rubbing the sensor pod (e.g., clothing, seat belts, etc.).
- Make sure you have selected a good insertion site.

27.6 Sensor Inaccuracies

Inaccuracies are usually related to your sensor only and not to your transmitter or pump. Your sensor glucose readings

are meant to be used for trending purposes only. The sensor measures glucose in the fluid under the skin—not in blood, and sensor glucose readings are not identical to readings from your BG meter.

⚠ PRECAUTION

To calibrate the System, **DO** enter the exact BG value that your BG meter displays within 5 minutes of a carefully performed BG measurement. Do not enter sensor glucose values for calibration. Entering incorrect BG values, BG values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

If the difference between your sensor glucose reading and BG value is greater than 20% of the BG value for sensor readings >80 mg/dL or greater than 20 mg/dL for sensor readings <80 mg/dL, wash your hands and take another BG measurement. If the difference between this second BG measurement and the sensor is still greater than 20% for sensor readings >80 mg/dL or greater than 20 mg/dL for sensor readings <80 mg/dL,

recalibrate your sensor using the second BG value. The sensor glucose reading will correct over the next 15 minutes. If you see differences between your sensor glucose readings and BG values outside of this acceptable range, follow the troubleshooting tips below before inserting another sensor:

- Make sure your sensor is not expired.
- Make sure you do not calibrate when “- -” or the Out of Range icon are on the screen.
- Do not use alternative BG site testing (blood from your palm or forearm, etc.) for calibration as alternative site readings may be different than those from a BG value. Use a BG value only from your fingers for calibration.
- Use only BG values between 20–600 mg/dL for calibration. If one or more of your values is outside of this range, the receiver will not calibrate.
- Use the same BG meter you routinely use to measure your BG to

calibrate. Do not switch your BG meter in the middle of a sensor session. BG meter and strip accuracy vary between BG meter brands.

- Before taking a BG measurement for calibration, wash your hands, make sure your BG test strips have been stored properly and are not expired, and make sure that your BG meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions provided with your BG meter or test strips.
- Make sure you are using your BG meter following the manufacturer's instructions to get accurate BG values for calibration.

This Page is Intentionally Left Blank

4 Control-IQ Technology Features

CHAPTER 28

Control-IQ Technology Important Safety Information

CHAPTER 28 • Control-IQ Technology Important Safety Information

The following includes important safety information related to Control-IQ™ technology. The information presented in this chapter does not represent all warnings and precautions related to the System. Pay attention to other warnings and precautions listed throughout this user guide as they relate to special circumstances, features, or users.

28.1 Control-IQ Warnings

▲ WARNING

Control-IQ technology has not been evaluated in pregnant women or persons on dialysis. Sensor glucose readings may be inaccurate in these populations and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

Control-IQ technology has not been evaluated in critically ill patients. It is not known how different conditions or medications common to the critically ill population may affect the performance of the Control-IQ technology. Sensor glucose readings may be inaccurate in critically ill patients, and solely relying on the sensor glucose alerts and readings for treatment

decisions could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

Control-IQ technology should not be used by people who use less than 5 units of insulin per day and should not be used by people who weigh less than 20 pounds (9 kilograms), which are the minimum inputs required to initiate Control-IQ technology and for it to operate safely.

▲ WARNING

The t:slim X2™ insulin pump with Control-IQ technology should not be used in children under the age of two years old.

▲ WARNING

Control-IQ technology reverts to your programmed basal rate when the pump has not received a CGM reading for 20 minutes. For example, when the pump and CGM are out of range, during the sensor startup period, when a sensor session ends, or when there is a transmitter or sensor error.

▲ WARNING

If a sensor session is ended, either automatically or manually, Control-IQ technology is

unavailable and will not adjust insulin. In order for Control-IQ technology to be enabled, a sensor session must be started and transmitting sensor values to the pump based on a sensor code or sensor calibration.

▲ WARNING

DO NOT use manual injections or inhaled insulins while using Control-IQ technology. Using insulin not provided by the pump while using closed loop therapy can cause the system to over deliver insulin, which can lead to severe hypoglycemia (low BG) events.

▲ WARNING

DO NOT use Control-IQ technology if you are taking hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anemia. The use of hydroxyurea will result in sensor glucose readings that are higher than actual glucose levels. The level of inaccuracy in sensor glucose readings is based on the amount of hydroxyurea in the body. Control-IQ technology relies on sensor glucose readings to adjust insulin, provide automatic correction boluses, and provide high and low glucose alerts. If Control-IQ technology receives sensor readings that are higher than actual glucose levels, it could result in missed hypoglycemia alerts and errors in diabetes

management, such as delivery of excess basal insulin and correction boluses, including automatic correction boluses. Hydroxyurea can also result in errors when reviewing, analyzing and interpreting historical patterns for assessing glucose control. Use your BG meter and consult with your healthcare provider about alternative glucose monitoring approaches.

28.2 Control-IQ Precautions

⚠ PRECAUTION

If you remove your pump for 30 minutes or longer, it is recommended that you suspend insulin delivery. If insulin is not suspended, Control-IQ technology will continue to operate while the pump is removed, and will continue to dose insulin.

⚠ PRECAUTION

We recommend that you keep the CGM Out of Range Alert turned on to notify you if your CGM is disconnected from your pump whenever you are not actively monitoring your pump status. Your CGM is providing the data that Control-IQ technology requires to make predictions to automate insulin dosing.

This Page is Intentionally Left Blank

4 Control-IQ Technology Features

CHAPTER 29

Getting to Know Control-IQ Technology

CHAPTER 29 • Getting to Know Control-IQ Technology

29.1 Responsible Use of Control-IQ Technology

Systems like the t:slim X2™ insulin pump with Control-IQ™ technology are not substitutes for the active management of diabetes, including manually bolusing for meals. There are common scenarios in which automated systems cannot prevent a hypoglycemic event. Control-IQ technology relies on current CGM sensor readings to function and will not be able to predict sensor glucose values and suspend insulin delivery if a patient's CGM is not functioning properly or their pump is unable to receive the CGM signal. Patients should be instructed to always use the components of the pump system (pump, cartridges, CGM, and infusion sets) according to the applicable instructions for use and check them regularly to make sure they are functioning as expected. Patients should always pay attention to their sensor glucose values, actively monitor and manage BG, and treat accordingly.

29.2 Explanation of Control-IQ Technology Icons

If you have a CGM session active and are using Control-IQ technology, you may see the following additional icons on your pump screen:

Control-IQ Technology Icon Definitions

Symbol	Meaning
	Control-IQ technology is enabled but not actively increasing or decreasing basal insulin delivery.
	Control-IQ technology is increasing basal insulin delivery.
	Control-IQ technology is decreasing basal insulin delivery.
	Control-IQ technology has stopped basal insulin delivery.
	Control-IQ technology is delivering an automatic correction bolus.
	The Sleep Activity is enabled.
	Control-IQ technology delivered an automatic correction bolus.

Symbol	Meaning
	Basal insulin is programmed and being delivered.
	Control-IQ technology is increasing basal insulin delivery.
	Control-IQ technology is decreasing basal insulin delivery.
	Basal insulin delivery is stopped and a Basal Rate of 0 u/hr is active.
	Control-IQ technology is delivering an automatic correction bolus.
	The Exercise Activity is enabled.

CHAPTER 29 • Getting to Know Control-IQ Technology

29.3 Control-IQ Lock Screen

The *Control-IQ Lock* screen appears any time you turn on the screen and you are using your pump with a CGM and Control-IQ technology enabled.

The *Control-IQ Lock* screen is the same as the *CGM Lock* screen, with the following additions. See Section 19.3 CGM Lock Screen.

1. **Control-IQ Technology Status:** Indicates the status of Control-IQ technology.
2. **CGM Graph Shading:** Red shading indicates Control-IQ technology is, or was, delivering 0 units of insulin for the period indicated.



CHAPTER 29 • Getting to Know Control-IQ Technology

29.4 Control-IQ Home Screen

The *Home* screen with Control-IQ technology enabled is identical to the *CGM Home* screen, with the following additions. See Section 19.4 CGM Home Screen.

1. **Control-IQ Technology Status:**
Indicates the status of Control-IQ technology.
2. **Control-IQ Activity Status:**
Indicates an Activity is enabled.
3. **CGM Graph Shading:** Red shading indicates Control-IQ technology is, or was, delivering 0 units of insulin for the period indicated.



CHAPTER 29 • Getting to Know Control-IQ Technology

29.5 Control-IQ Screen

1. **Control-IQ Technology on/off:**
Turns on, or off, Control-IQ technology.
2. **Weight:** Displays your current weight. This value is manually entered in on the numerical keypad.

NOTE

Your weight should be representative of what you weigh when you start Control-IQ technology. Weight can be updated when you visit your healthcare provider. The minimum value for weight is 20 pounds (9 kilograms). The maximum value for weight is 440 pounds (200 kilograms).

3. **Total Daily Insulin:** Displays your current total daily insulin value in units. This value is manually entered in on the numerical keypad.

NOTE

If you don't know your Total Daily Insulin (TDI), speak with your healthcare provider to get this value. The minimum value for TDI is 5 units. The maximum value for TDI is 200 units.



This Page is Intentionally Left Blank

4 Control-IQ Technology Features

CHAPTER 30

Introduction to Control-IQ Technology

CHAPTER 30 • Introduction to Control-IQ Technology

30.1 Control-IQ Technology Overview

Control-IQ™ technology is a feature of the t:slim X2™ pump that automatically adjusts insulin dosing in response to readings from a CGM. The pump can be used with or without Control-IQ technology enabled. The following sections describe how Control-IQ technology works and how it responds to CGM values while you are awake, sleeping, and exercising.

⚠ PRECAUTION

You must continue to take boluses to cover food eaten or to correct a high sensor glucose value. Read all Control-IQ technology instructions before activating Control-IQ technology.

📌 NOTE

The target CGM ranges used by Control-IQ technology are not customizable.

📌 NOTE

The Insulin On Board (IOB) Time Remaining, which indicates how long the total units of insulin from food and correction boluses will be active in the body, is not displayed when Control-IQ technology is enabled due to the

variability of insulin delivery when automatically responding to CGM values. The IOB units will always be displayed on the *Home* and *Lock* screens.

30.2 How Control-IQ Technology Works**⚠ WARNING**

Control-IQ technology is not a substitute for understanding and being ready at any time to take over manual control of your current or future diabetes therapy.

⚠ WARNING

Control-IQ technology is not designed to prevent all hypoglycemia (low BG) or hyperglycemia (high BG).

⚠ WARNING

Control-IQ technology adjusts the delivery of insulin, but does not treat low BG. Always pay attention to your symptoms, manage your BG level, and treat according to the recommendations of your healthcare provider.

⚠ WARNING

Do not use Control-IQ technology unless recommended by your healthcare provider.

⚠ WARNING

Do not use Control-IQ technology until you have received training.

⚠ WARNING

Control-IQ technology relies on current CGM sensor readings and will not be able to accurately predict BG levels and adjust insulin delivery if for any reason your CGM is not functioning properly, or does not transmit three of the last four sensor values to your pump.

⚠ PRECAUTION

We recommend that you enable the High Glucose Alert and the Low Glucose Alert when using Control-IQ technology so that you will be notified if sensor glucose readings are outside of your target range, and you can treat high or low BG according to your healthcare provider's recommendations.

Control-IQ technology responds to the actual CGM readings as well as predicts CGM values 30 minutes in the future. Insulin delivery is automatically adjusted based on the predicted CGM value, your active Personal Profile, and whether or not a Control-IQ technology Activity is enabled.

NOTE

Control-IQ technology activity types are not automatically enabled, and must be set up as a scheduled occurrence or turned on as needed. For more information, see sections 31.5 Schedule Sleep, 31.7 Manually Start or Stop Sleep, and 31.8 Manually Start or Stop Exercise.

Control-IQ technology adjusts insulin delivery in several ways to help keep your actual glucose value within the target range. It will decrease or suspend insulin delivery when predicted sensor glucose values are below a preset treatment value, increase insulin delivery when predicted sensor glucose values are above a preset treatment value, and automatically deliver a correction bolus once per hour, as needed. The automatic correction bolus is based on a predicted sensor glucose value. There are maximum insulin delivery limits based on your Personal Profile settings. These different insulin delivery actions are described below. Each of the insulin delivery adjustments occurs in different ways depending on whether you are using the Sleep Activity, using the Exercise Activity, or neither. For more detail on how insulin adjustments are

made for different activities see Sections Control-IQ Technology With No Activity Enabled, Control-IQ Technology During Sleep, and Control-IQ Technology During Exercise Activity in this chapter.

Personal Profile Basal Rate Delivery

When the predicted CGM value is within the treatment value range (112.5 mg/dL – 160 mg/dL), the pump will deliver insulin at the rate determined by the active Personal Profile settings.

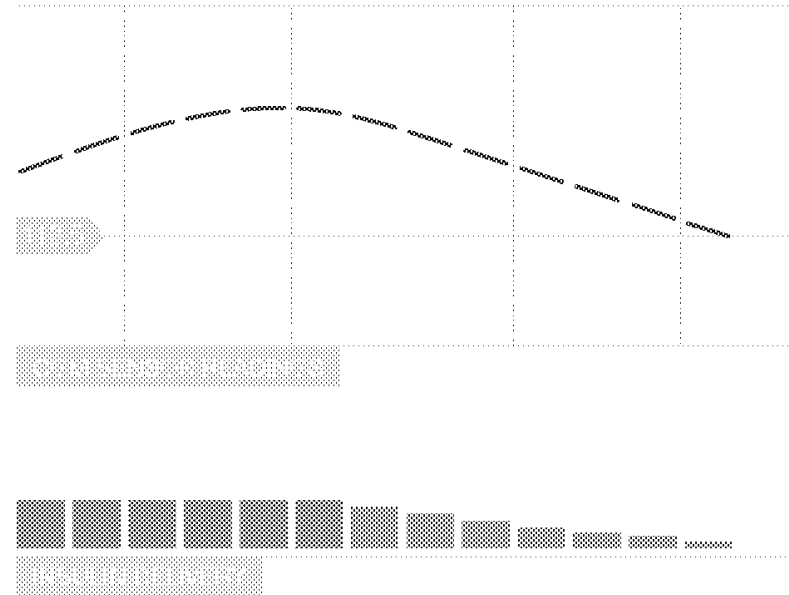
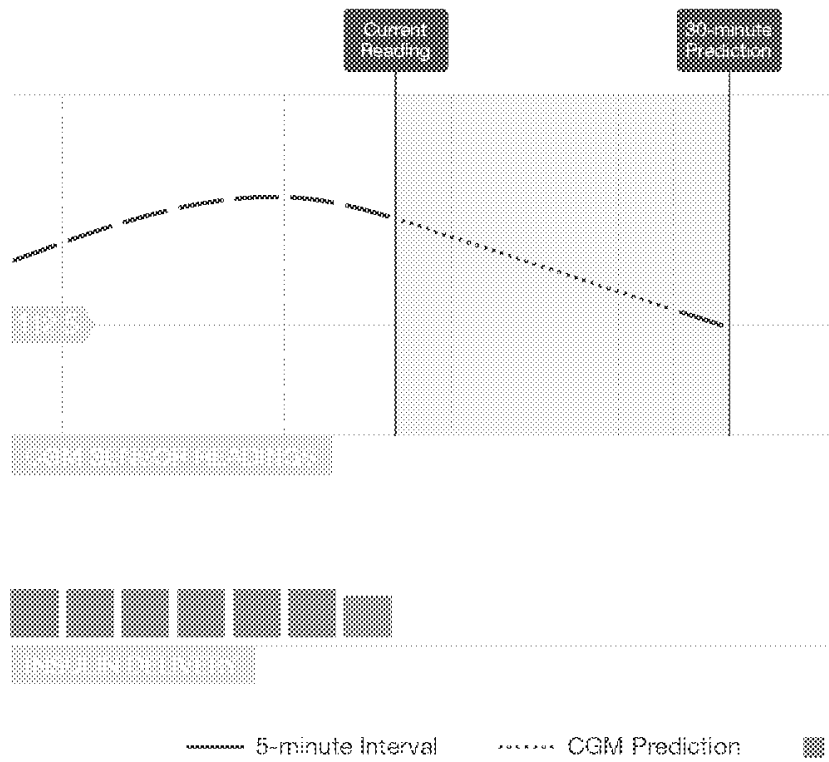
All Personal Profile settings must be completed in order to use Control-IQ technology. See Chapter 6 Insulin Delivery Settings for more information about Personal Profiles.

Decreased Insulin Delivery

When Control-IQ technology predicts that your sensor glucose value will be at or below a preset treatment value (112.5 mg/dL) 30 minutes in the future, the rate of insulin delivery will start decreasing to attempt to keep the actual sensor glucose values within the target range. The following diagrams depict how the system uses 30 minute

predictions to gradually decrease insulin delivery compared to the personal profile Basal Rate. The diagram on the left depicts the prediction, the diagram on the right depicts how the insulin and CGM readings might look if the CGM graph continued on the trend.

CHAPTER 35 • Introduction to Control-IQ Technology



NOTE

Diagrams are for illustrative purposes only and are not intended to reflect actual results.

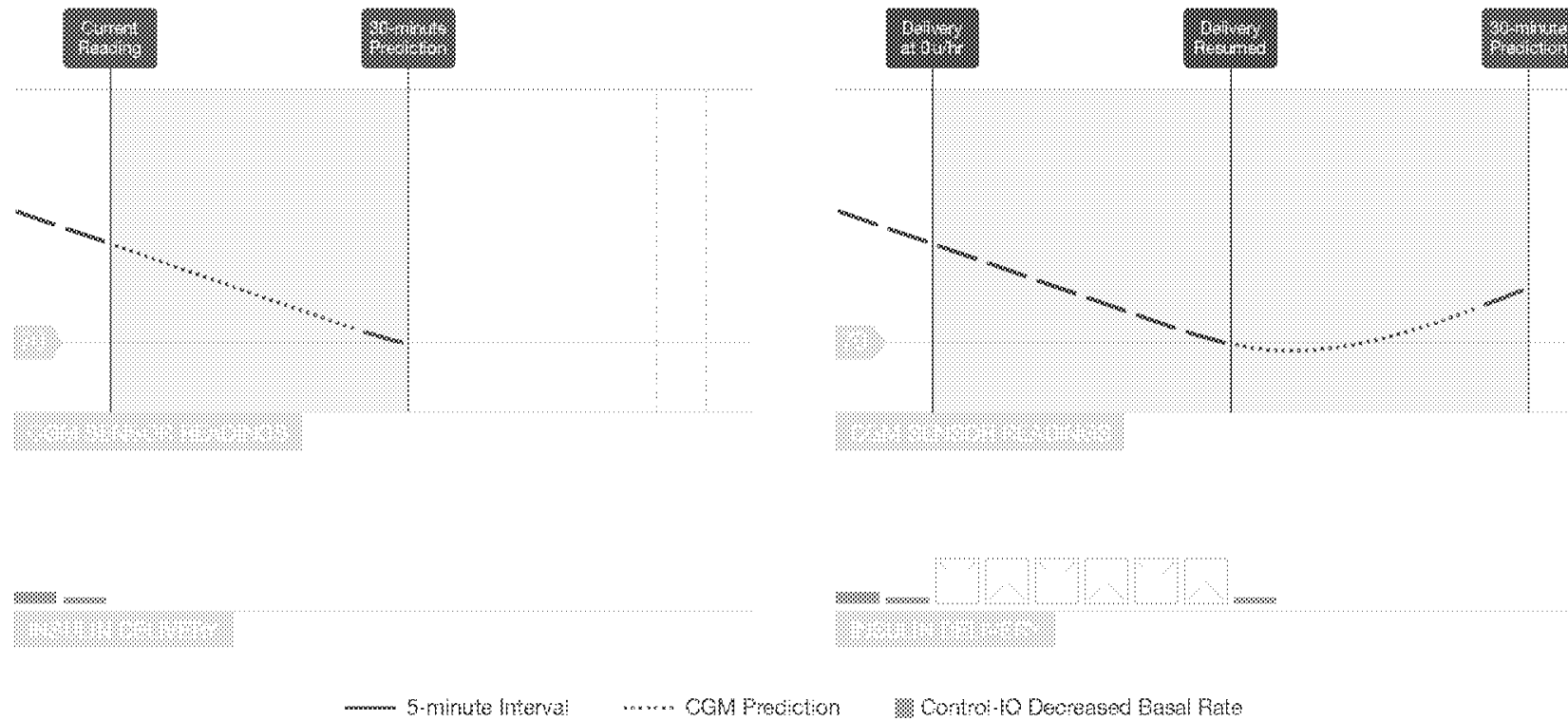
Insulin Decreased or Delivering 0 Units per Hour

Control-IQ technology can reduce the basal delivery to a percent of the Basal Rate in addition to completely suspending. When Control-IQ technology predicts that your sensor glucose value will be lower than a preset treatment value (70 mg/dL) 30 minutes in the future, insulin delivery will decrease and may set the Basal Rate at 0 units per hour if necessary to attempt to keep the actual sensor glucose values within the target range. Manual boluses can still be delivered when Control-IQ technology is decreasing or suspending insulin. The following diagrams depict an illustration of when Control-IQ technology might set the insulin delivery rate to 0 units per hour, and when it will resume at a decreased rate after the 30 minute prediction is above the target sensor glucose value.

■ NOTE

When Control-IQ technology sets the Basal Rate to 0 units per hour, bolus deliveries will continue. This includes starting a new bolus and any remaining bolus from an extended bolus delivery.

CHAPTER 35 • Introduction to Control-IQ Technology



NOTE

Diagrams are for illustrative purposes only and are not intended to reflect actual results.

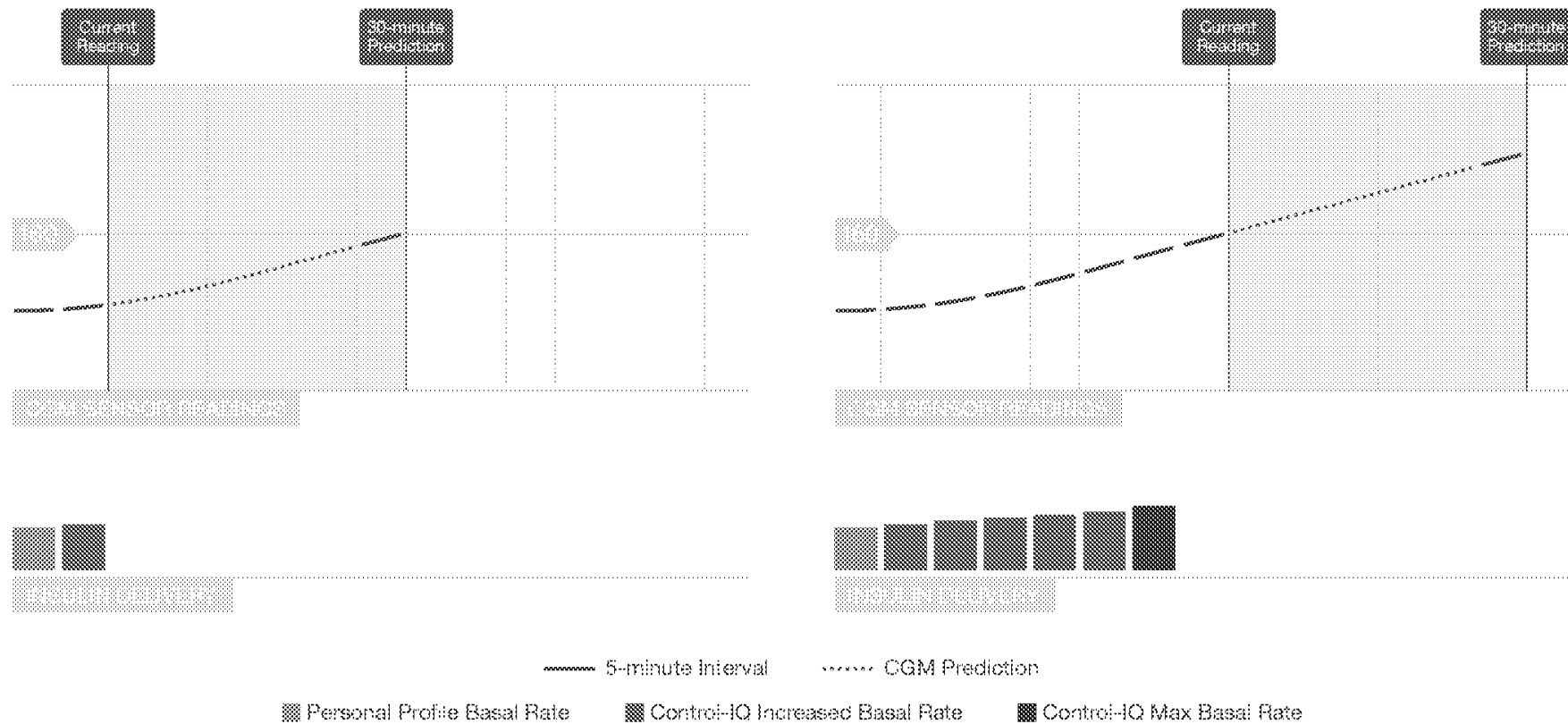
Increasing Insulin Delivery

When Control-IQ technology predicts that your sensor glucose value will be at or above a preset treatment value (160 mg/dL) 30 minutes in the future, the rate of insulin delivery will start increasing to attempt to keep the actual CGM values within the target CGM range. The following diagrams depict when Control-IQ technology might be increasing and delivering at the maximum increased Basal Rate.

Maximum Insulin Delivery

When Control-IQ technology predicts that your sensor glucose value will be above a preset treatment value (160 mg/dL) 30 minutes in the future, but the maximum rate of insulin delivery has been reached, Control-IQ technology stops increasing the insulin delivery rate. The maximum insulin delivery rate is a calculated value that is dependent on an individual's Correction Factor setting (found in the active Personal Profile), the Total Daily Insulin estimated by Control-IQ technology based on actual total daily insulin values, and the current insulin on board (IOB).

CHAPTER 35 • Introduction to Control-IQ Technology



NOTE

Diagrams are for illustrative purposes only and are not intended to reflect actual results.

Automatic Correction Bolus Delivery

When Control-IQ technology predicts that your CGM value will be at or above a preset treatment value (180 mg/dL) 30 minutes in the future, and when Control-IQ technology is either Increasing Insulin Delivery or delivering Maximum Insulin Delivery, the pump will automatically deliver correction boluses to attempt to achieve the target range.

The automatic correction bolus will deliver a total correction bolus calculated based on the Personal Profile Correction Factor and predicted CGM reading. The target sensor glucose for the automatic correction bolus is 110 mg/dL. Automatic correction bolus delivery occurs at most once every 60 minutes, and will not be delivered within 60 minutes of the start, cancellation, or completion of an automatic bolus or manual bolus. For an extended bolus, this 60 minutes does not start until after the DELIVER NOW duration has completed. The percentage and duration between boluses is designed to avoid insulin stacking that may cause unsafe reductions in sensor glucose values.

NOTE

Each automatic correction bolus delivery can be manually canceled or stopped during the delivery in the same way that a Manual Bolus can be stopped. See Section 8.10 Canceling or Stopping a Bolus Using the Pump and Section 8.15 Canceling or Stopping a Bolus Using the t:connect Mobile App.

NOTE

The maximum amount of insulin that an automatic correction bolus will deliver is 6 units. This value cannot be increased, but you may choose to deliver a manual bolus after the automatic correction bolus delivery is complete.

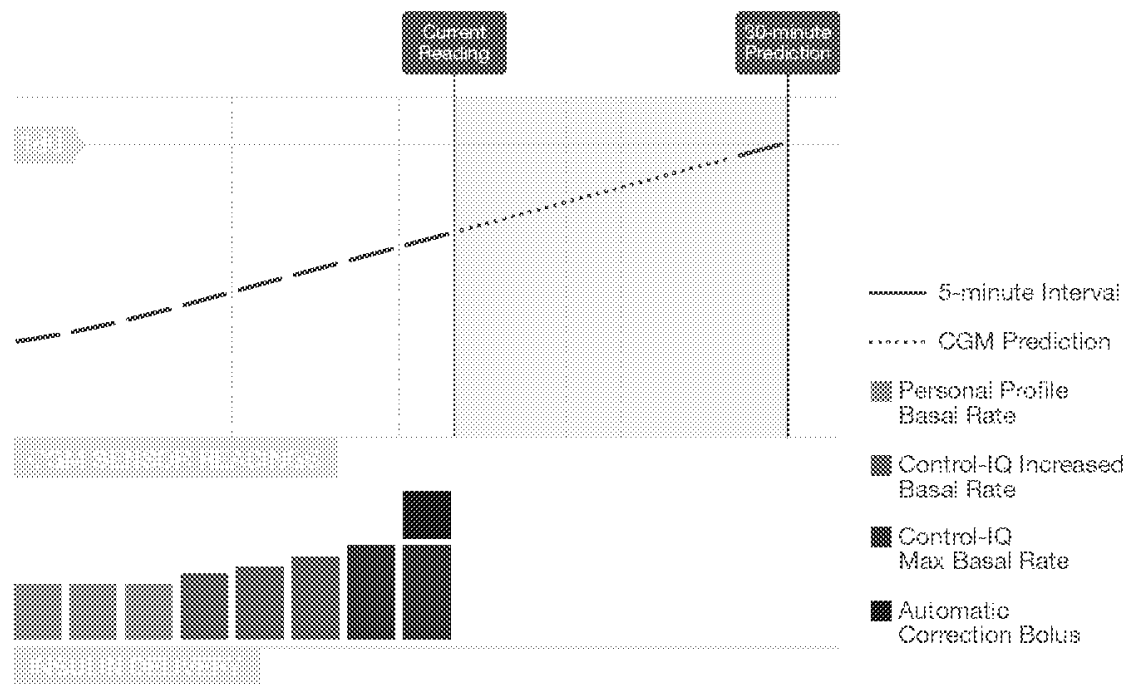
PRECAUTION

The pump does not activate sound or vibration to indicate when an automatic correction bolus delivery has started. The following pump screens indicate that an automatic correction

bolus is being delivered and that an automatic correction bolus was delivered, respectively.



CHAPTER 35 • Introduction to Control-IQ Technology



NOTE

Diagrams are for illustrative purposes only and are not intended to reflect actual results.

30.3 Control-IQ Technology and Activity

When Control-IQ technology is turned on you can choose to activate Sleep or Exercise to help the System adjust the automated insulin dosing settings as described in previous sections.

If you have not started either Sleep or Exercise, the System will use the settings described in the following section.

Control-IQ Technology With No Activity Enabled

The CGM range targeted by Control-IQ technology with no Activity enabled is 112.5–160 mg/dL. This range is wider than the Sleep and Exercise ranges to account for the variability of factors that affect CGM values while people are awake and not exercising.

Decreasing Insulin With No Activity Enabled

Insulin is decreased when Control-IQ technology predicts a CGM reading of ≤ 112.5 mg/dL 30 minutes in the future.

Suspended Insulin With No Activity Enabled

Insulin is set to 0 units/hour when Control-IQ technology predicts a CGM reading ≤ 70 mg/dL 30 minutes in the future.

Increasing Insulin With No Activity Enabled

Insulin is increased when Control-IQ technology predicts a CGM reading of ≥ 160 mg/dL 30 minutes in the future.

Automatic Correction Bolus With No Activity

When no Activity is enabled, Control-IQ technology will deliver automatic correction boluses as described in the Automatic Correction Bolus Delivery section of this chapter.

Control-IQ Technology During Sleep

The Control-IQ technology Sleep Activity range is targeted during scheduled sleep times and when the Sleep Activity is manually started (until it is stopped). See Chapter 31 Configuring and Using Control-IQ Technology and see Section Enable a Sleep Schedule for instructions on setting the hours you plan to sleep and

Section Manually Start Sleep for starting the Sleep Activity manually in that chapter.

The CGM range targeted by Control-IQ technology during the Sleep Activity is 112.5 mg/dL–120 mg/dL. This range is smaller than the target range with no Activity enabled since there are fewer variables that affect CGM values while you are sleeping. During the Sleep Activity, Control-IQ technology will not deliver automatic boluses.

Decreasing Insulin During Sleep Activity

Insulin is decreased when Control-IQ technology predicts a CGM reading of ≤ 112.5 mg/dL 30 minutes in the future.

Suspended Insulin During Sleep Activity

Insulin is set to 0 units/hour when Control-IQ technology predicts a CGM reading ≤ 70 mg/dL 30 minutes in the future.

Increasing Insulin During Sleep Activity

Insulin is increased when Control-IQ technology predicts a CGM reading of ≥ 120 mg/dL 30 minutes in the future.

CHAPTER 30 • Introduction to Control-IQ Technology

Automatic Correction Bolus During Sleep Activity

Automatic correction boluses will not be delivered while Sleep is enabled.

When Control-IQ technology switches back to the settings with no Activity enabled, whether according to scheduled wake time or due to manually stopping Sleep, the transition from the targeted sleep CGM range to targeted settings with no Activity enabled CGM range occurs slowly and can take 30-60 minutes. This helps ensure that actual CGM values transition gradually.

Control-IQ Technology During Exercise Activity

During the Exercise Activity, Control-IQ technology uses the target CGM range 140 mg/dL–160 mg/dL. This target range is smaller and higher than the target range with no Activity enabled to accommodate the likely natural drop in glucose following exercise.

If the Exercise Activity is on when a Sleep Schedule is due to begin, the Sleep Schedule does not start. In this

scenario you must manually start Sleep once you turn Exercise off.

Decreasing Insulin During Exercise Activity

Insulin is decreased when Control-IQ technology predicts a CGM reading of ≤ 140 mg/dL 30 minutes in the future.

Suspended Insulin During Exercise Activity

Insulin is set to 0 units/hour when Control-IQ technology predicts a CGM reading ≤ 80 mg/dL 30 minutes in the future.

Increasing Insulin During Exercise Activity

Insulin is increased when Control-IQ technology predicts a CGM reading of ≥ 160 mg/dL 30 minutes in the future.

Automatic Correction Bolus During Exercise Activity

When the Exercise Activity is enabled, Control-IQ technology will deliver automatic correction boluses as described in the Automatic Correction Bolus Delivery section of this chapter.

See Chapter 31 Configuring and Using Control-IQ Technology for instructions on starting or stopping Exercise.

For a summary of all treatment values and how they are different for each Activity, see the diagram on the next page.

			 Control-IQ	 Sleep Activity	 Exercise Activity
  Delivers	Delivers an automatic correction bolus if sensor glucose is predicted to be above ____ mg/dL.		180	---	180
  Increases	Increases basal insulin delivery if sensor glucose is predicted to be above ____ mg/dL.		160	120	160
  Maintains	Maintains active Personal Profile settings when sensor glucose is between ____ - ____ mg/dL.		112.5 - 160	112.5 - 120	140 - 160
  Decreases	Decreases basal insulin delivery if sensor glucose is predicted to be below ____ mg/dL.		112.5	112.5	140
  Stops	Stops basal insulin delivery if sensor glucose is predicted to be below ____ mg/dL.		70	70	80

This Page is Intentionally Left Blank

4 Control-IQ Technology Features

CHAPTER 31

Configuring and Using Control-IQ Technology

CHAPTER 31 • Configuring and Using Control-IQ Technology

31.1 Required Settings**Required Personal Profile Settings**

In order to use Control-IQ™ technology, the following Personal Profile settings must be configured. See Chapter 6 Insulin Delivery Settings for instructions about setting these values.

- Basal Rate
- Correction Factor
- Carb Ratio
- Target BG
- Carbohydrates turned on in Bolus Settings

Required Control-IQ Technology Pump Settings

In addition to the required Personal Profile settings, there are two values specific to Control-IQ technology that must be set. These are:

- Weight
- Total Daily Insulin

Recommended Control-IQ Technology Pump Settings

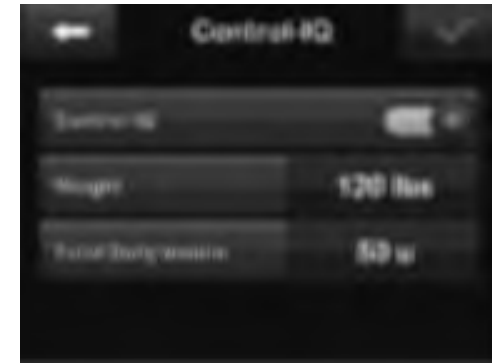
Although Sleep can be started and stopped manually, it is recommended that you schedule sleep. This chapter explains how to do both. The following settings are required to schedule sleep:

- Selected Days
- Start Time
- End Time

31.2 Set Weight

Control-IQ technology cannot be turned on unless Weight is entered. The Weight value may be updated when you visit your healthcare provider.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Control-IQ**.
 - ✓ The *Control-IQ* screen is displayed.



4. Tap **Weight**.
5. Tap **Pounds** or **Kilograms** to set the unit of weight.
6. Tap .
7. Enter the weight value on the numeric keypad. Weight can be set from a minimum of 20 pounds (9 kilograms) to a maximum of 440 pounds (200 kilograms).
8. Tap .
9. If you are done with the Control-IQ settings, tap .
 - ✓ The **SETTING SAVED** screen is temporarily displayed.

31.3 Set Total Daily Insulin

Control-IQ technology cannot be turned on unless Total Daily Insulin is entered. The Total Daily Insulin value is used by Control-IQ technology to calculate the maximum insulin delivery rate and to maintain a safe and effective increase in insulin dose.

The Total Daily Insulin value may be updated when you visit your healthcare provider.

NOTE

Once you have used Control-IQ technology, it will maintain and use the actual total insulin delivered, including the adjustments made to basal and all types of boluses while using the System. It is important to update the Total Daily Insulin setting in the *Control-IQ* screen when you visit your healthcare provider. This value is used for the 2-hour maximum insulin alert.

An estimate of Total Daily Insulin should be entered. Include all types of insulin (basal and bolus) delivered in a 24-hour period. Consult your healthcare provider if you need assistance estimating your insulin requirements.

Enter your Total Daily Insulin Value

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Control-IQ**.
4. Tap **Total Daily Insulin**.
5. Use the numeric keypad to enter the total units of insulin typically required in a 24-hour period. Total Daily Insulin can be set from a minimum of 5 units to a maximum of 200 units.
6. Tap .
7. If you are done with the Control-IQ settings, tap .
- ✓ The **SETTING SAVED** screen is temporarily displayed.
8. When you are done setting up Control-IQ, tap the **Tandem logo** to return to the *CGM Home* screen.

31.4 Turn Control-IQ Technology On or Off

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Control-IQ**.
4. To turn Control-IQ on, tap the toggle next to **Control-IQ**.
5. To turn Control-IQ off, tap the toggle next to **Control-IQ**.
 - Tap  to confirm and turn Control-IQ off.
 - Tap  to leave Control-IQ on.

31.5 Schedule Sleep

Control-IQ technology operates differently during Sleep than with no Activity enabled. Sleep can be scheduled to turn on and off automatically, or it can be turned on and off manually. This section covers how to set Sleep to turn on and off

CHAPTER 31 • Configuring and Using Control-IQ Technology

automatically. For detailed information about how to use Control-IQ technology, see Chapter 30 Introduction to Control-IQ Technology.

You can configure two different Sleep Schedules to account for changes in lifestyle, such as a weekday sleep schedule and a weekend sleep schedule.

NOTE

If you manually start Sleep before a Sleep Schedule begins, it does not impact the scheduled wake time. For example, if your Sleep Schedule is set from 10pm to 6am (22:00 to 6:00), and you start Sleep manually at 9pm (21:00), Sleep will end at 6am (6:00) as scheduled; unless manually stopped.

NOTE

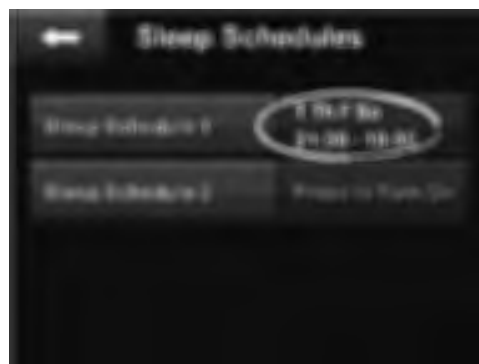
Exercise and Sleep may not be enabled at the same time. If Exercise is active at the time a Sleep Schedule begins, the Sleep Schedule will not enable. However, once Exercise is disabled, the Sleep Schedule will start automatically.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.

3. Tap **Sleep Schedules**.

4. Select which Sleep Schedule to configure.

- If no Sleep Schedules are configured, tap **Sleep Schedule 1**.
- If you are editing an existing schedule, tap the schedule summary that displays to the right of the sleep schedule you want to edit.

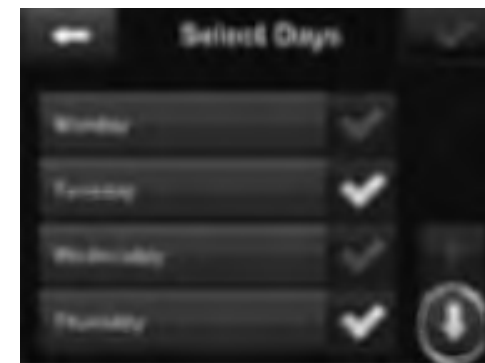


5. On the Sleep Schedule screen, tap **Selected Days**. The default is the current day of the week only, according to the day of the week set on the pump.

6. On the Select Days screen, tap the **checkmark** to the right of each day of the week that you want included in the Sleep Schedule.

When a checkmark is green, the corresponding day of the week is active. To deactivate a day, tap the associated checkmark again so that it turns gray.

Tap the **Down Arrow** to see more days of the week.



7. When you are finished selecting the days, tap .

NOTE

If no days are selected when you tap , the schedule is set to off and the remaining

sleep schedule settings are not displayed. The remaining instructions do not apply to an incomplete schedule.

8. Tap **Start Time**.
9. Tap **Time**. The numbered keypad is displayed.
10. Enter the time you would like the Sleep Schedule to start by entering the number(s) for the hour followed by the minutes. For example, tap 9 3 0 to set the time to 9:30 or 2 1 0 0 to set the time to 21:00.
11. Tap . You are returned to the *Start Time* screen.
12. Tap **AM** or **PM** to set the Time of Day, if applicable.
13. Tap . You are returned to the *Sleep Schedule 1* screen.
14. Tap **End Time**.
15. Tap **Time**. The numbered keypad is displayed.

16. Enter the time you would like the Sleep Schedule to end and tap . You are returned to the *End Time* screen.

17. Tap **AM** or **PM** to set the Time of Day, if applicable.
18. Tap . The *Sleep Schedule 1* screen is displayed.
19. Tap  to save the schedule.
- ✓ The SETTING SAVED screen is temporarily displayed, followed by the *Sleep Schedules* screen.
20. When you are done configuring sleep, tap  to return to the *Activity* screen or tap the **Tandem** logo to return to the *Home* screen.

31.6 Enable or Disable a Sleep Schedule

Once a Sleep Schedule is configured, it is enabled by default when it is saved. If you have multiple Sleep Schedules configured, you can change the

enabled Sleep Schedule or turn them off completely.

Enable a Sleep Schedule

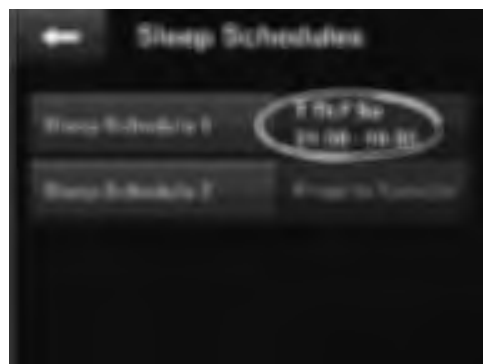
1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap **Sleep Schedules**.
4. Tap the schedule summary next to the name of the Sleep Schedule you want to enable. (If no sleep schedules are configured, see Section 31.5 Schedule Sleep.)
5. Tap the toggle next to the schedule name.
6. Tap .

Disable a Sleep Schedule

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap **Sleep Schedules**.

CHAPTER 31 • Configuring and Using Control-IQ Technology

Tap the schedule summary next to the Sleep Schedule you want to disable.



4. Tap the toggle.

5. Tap .

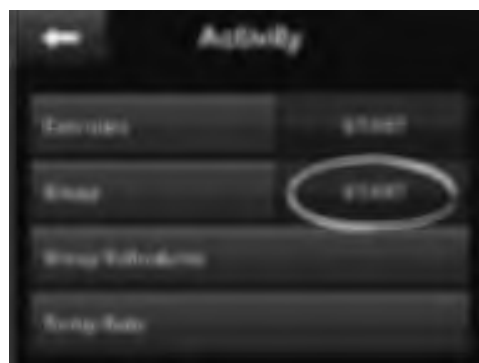
31.7 Manually Start or Stop Sleep

In addition to scheduling sleep, Sleep can be manually started and/or stopped.

Sleep time determines when Control-IQ technology, if enabled, switches to Sleep activity. Control-IQ technology must be on and a CGM session must be active to start Sleep.

Manually Start Sleep

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap the **START** text next to **Sleep**.

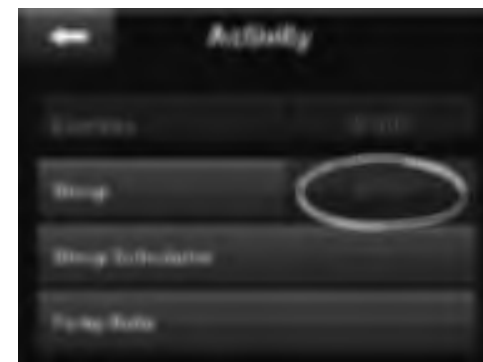


- ✓ A SLEEP STARTED screen is temporarily displayed. The Sleep icon is displayed on the *Home* screen.

Manually Stop Sleep

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.

3. Tap the **STOP** text next to **Sleep**.



- ✓ A SLEEP STOPPED message is temporarily displayed. The Sleep icon is removed from the *Home* screen.

31.8 Manually Start or Stop Exercise

Start Exercise

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap the **START** text next to **Exercise**.

- ✓ An EXERCISE STARTED message is temporarily displayed. The Exercise icon is displayed on the *Home* screen.

Stop Exercise

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap the **STOP** text next to **Exercise**.

- ✓ An EXERCISE STOPPED message is temporarily displayed. The Exercise icon is removed from the *Home* screen.

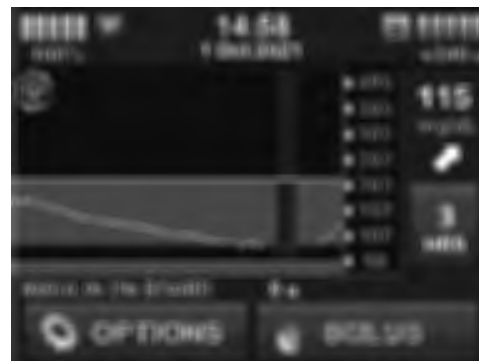
31.9 Control-IQ Technology Information on Your Screen

Control-IQ Technology Status Icon

When Control-IQ technology is on, the CGM Trend Graph displays a diamond icon in the top left corner. This icon uses different colors to communicate information about how Control-IQ technology is operating. Each different

color and its meaning can be found in Section 29.2 Explanation of Control-IQ Technology Icons.

When Control-IQ technology is on but not active (i.e. insulin is being delivered normally), the diamond icon is gray as depicted below. Regardless of the color, the icon always appears in the same place.



Exercise and Sleep Icons

When Exercise or Sleep is turned on, the respective icon displays in the same place on the screen, since they can never be active at the same time. The following image shows the sleep icon

active on the CGM Trend Graph screen.



When Exercise is on, the Exercise icon is displayed in the same location.

Basal Status Icons

There are several basal status icons that display in different colors, each of which communicates information about how Control-IQ technology is operating. Each different color and its meaning can be found in Section 29.2 Explanation of Control-IQ Technology Icons.

CHAPTER 31 • Configuring and Using Control-IQ Technology

The following image highlights where the basal status icons display.



Automatic Correction Bolus Status Icon

When Control-IQ technology is on and delivering an automatic correction bolus, an icon displays to the left of the basal status icon. (The manual bolus icon displays in the same place on the screen; see the Section 3.3 Explanation of t:slim X2 Insulin Pump Icons for the manual bolus icon image.) The following image shows the location of the bolus icon.

NOTE

The text **BOLUS** followed by 3 ellipses displays below the CGM graph. The **Control-IQ** text

appearing below **BOLUS** indicates that there is an automatic correction bolus delivered by Control-IQ technology. The amount of the bolus is also displayed.



CGM Trend Graph Insulin Delivery Suspended

Portions of the CGM Trend Graph that display a red band in the background indicate the times when Control-IQ technology was delivering 0 units/hour.

Each dot on the CGM graph represents a five-minute increment.



4 Control-IQ Technology Features

CHAPTER 32

Control-IQ Technology Alerts

CHAPTER 32 • Control-IQ Technology Alerts

Information in this section will help you learn how to respond to Control-IQ™ technology alerts and errors. It applies only to the Control-IQ technology within your System. The Control-IQ technology alerts follow the same pattern as other pump alerts according to your Sound Volume selection.

The t:connect™ mobile app also can provide messages, alerts, and alarms from your t:slim X2™ pump as push notifications on your smartphone. These push notifications will be identical to your pump's display unless otherwise noted in this chapter.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. For more information about connecting your pump and smartphone, see Section 4.3 Connecting to a Smartphone, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

For information on insulin delivery reminders, alerts, and alarms see Chapters 13 t:slim X2 Insulin Pump Alerts, 14 t:slim X2 Insulin Pump Alarms, and 15 t:slim X2 Insulin Pump Malfunction.

For information on CGM Alerts and Errors, see Chapter 26 CGM Alerts and Errors.

32.1 Out of Range Alert – Control-IQ Technology Disabled

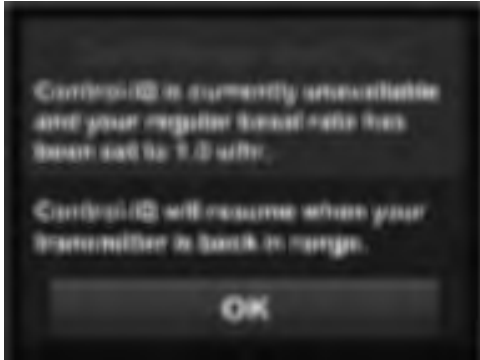
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The transmitter and pump are not communicating. The pump will not receive sensor glucose readings, and Control-IQ technology is not able to predict sensor glucose levels or adjust insulin delivery.
	How will the System notify me?	1 vibrate, then vibration/beep every 5 minutes until the transmitter and pump are back in range.
	Will the System re-notify me?	Yes, if the transmitter and pump remain out of range.
	How should I respond?	Tap  to confirm and move the transmitter and pump closer together, or remove the obstruction between them.

⚠ WARNING

Control-IQ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate settings in your active Personal Profile.

CHAPTER 32 • Control-IQ Technology Alerts

32.2 Out of Range Alert – Control-IQ Technology Enabled

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Control-IQ technology is turned on, but the transmitter and pump are not communicating. The pump will not receive sensor glucose readings. Control-IQ technology will continue to adjust basal rates and deliver automatic correction boluses for the first 20 minutes that the transmitter and pump are out of range. Control-IQ technology will resume automated insulin dosing once the transmitter and pump are back within range.
	How will the System notify me?	1 vibrate, then vibration/beep every 5 minutes until the transmitter and pump are back in range.
	Will the System re-notify me?	Yes, if the transmitter and pump remain out of range.
	How should I respond?	Tap  to confirm and move the transmitter and pump closer together, or remove the obstruction between them.

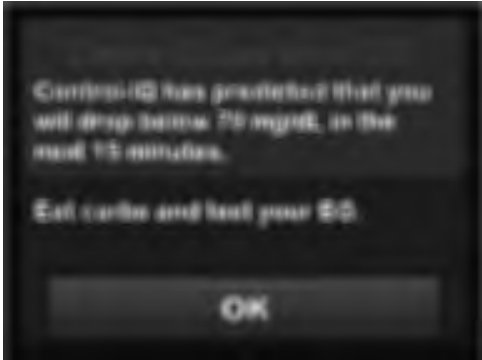
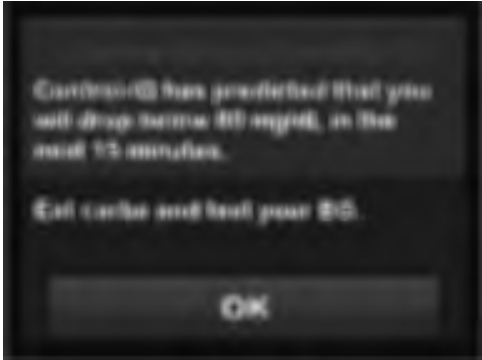
⚠ WARNING

Control-IQ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate settings in your active Personal Profile.

📌 NOTE

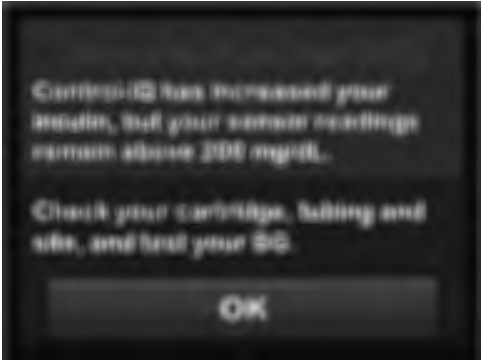
It is recommended that you keep the Out of Range Alert turned on and set to 20 minutes. If your pump and CGM are not connected for 20 minutes, Control-IQ technology will not work. Control-IQ technology will begin working immediately when the transmitter and pump are back within range.

32.3 Control-IQ Technology Low Alert

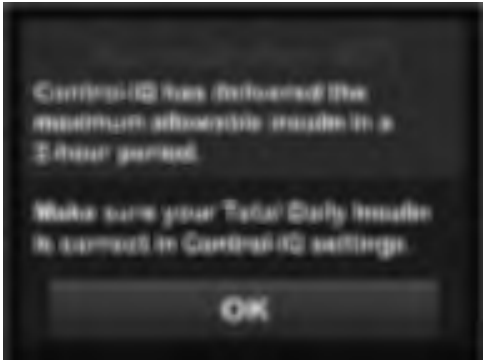
Screen	Explanation	
What will I see on the screen?  	What does it mean?	Control-IQ Low Alert has predicted that your sensor glucose reading will drop below 70 mg/dL, or below 80 mg/dL if Exercise is enabled, in the next 15 minutes.
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes until acknowledged.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Eat carbs and test your BG. Tap  to close the alert screen.

CHAPTER 32 • Control-IQ Technology Alerts

32.4 Control-IQ High Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Control-IQ technology has three hours of CGM data available and has increased insulin delivery, but detects a sensor glucose reading above 200 mg/dL and does not predict that the sensor glucose reading will decrease in the next 30 minutes.
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes until acknowledged.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged, and then every 2 hours if the issue still persists.
	How should I respond?	Check your cartridge, tubing, and site, and test your BG. Treat your high sensor glucose as necessary. Tap  to close the alert screen.

32.5 Max Insulin Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The pump has delivered the maximum allowable 2 hour insulin amount based on your Total Daily Insulin setting. You see this alert when Control-IQ technology has delivered 50% of your Total Daily Insulin (through basal and/or bolus deliveries) over the previous rolling 2 hour window, and detects this condition for 20 minutes in a row. Control-IQ technology will suspend insulin delivery for a minimum of 5 minutes, and then resume insulin delivery once the condition is no longer detected.
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes until acknowledged.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap .

This Page is Intentionally Left Blank

4 Control-IQ Technology Features

CHAPTER 33

Overview of Control-IQ Technology Clinical Studies

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.1 Introduction

The following data represents the clinical performance of the t:slim X2™ insulin pump with Control-IQ™ technology in multiple studies.

The first pivotal study (DCLP3) included participants ≥ 14 years old. A second pivotal study (DCLP5) included participants 6 years to 13 years old. A third pivotal study (PEDAP) included participants 2 years to < 6 years old. These three studies used the original version of Control-IQ technology (Control-IQ 1.0) and were all randomized control trials (RCTs).

Two more pivotal trials were subsequently performed. The PEDAP trial was extended for a 3-month extension phase where all participants used the study device. High insulin use was evaluated in the Higher-IQ trial, a single arm study. These two studies used an updated version of Control-IQ technology (Control-IQ 1.5).

All participants in all of these studies used the Dexcom G6 CGM.

Control-IQ technology has not been evaluated in children under 2 years of age. The safety and/or effectiveness of Control-IQ technology in children under 2 years of age is unknown.

33.2 Software Version History

Control-IQ 1.5 introduced changes to allow for a wider range of weight and total daily insulin (TDI) input. Other changes were implemented and are outlined in the table below.

Parameter	Control-IQ 1.0	Control-IQ 1.5
Minimum Total Daily Insulin Entry	10 units	5 units
Maximum Total Daily Insulin Entry	100 units	200 units
Minimum Weight Entry	55 pounds	20 pounds
Maximum Weight Entry	308 pounds	440 pounds
Correction Factor Range Accepted by Algorithm	1:10 to 1:200	1:10 to 1:600
Maximum Extended Bolus Duration	2 hours	8 hours
Temporary Basal Rates with Closed-Loop Active	No	Yes
Basal Rate Clipping*	Yes	No
<i>*Limited to 3 units/hour when delivering programmed basal rate</i>		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.3 The DCLP3 Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 6 months under normal conditions in adults and adolescents 14 years of age or older. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to the use of sensor augmented pump (SAP) therapy alone (the control arm), labeled as Control-IQ and SAP in the tables in this section.

168 participants were randomly assigned to use Control-IQ technology or SAP for the study in a 2:1 ratio. The Control-IQ technology arm included 112 participants and the SAP arm included 56 participants. All 168 participants completed the trial.

Baseline characteristics of study participants are provided in this section. The study population consisted of patients with a clinical diagnosis of type 1 diabetes, 14 to 71 years of age, treated with insulin via an insulin pump or injections for at least one year.

Females known to be pregnant were not included.

The summary statistics presented for the DCLP3 describe the primary outcome measure of the sensor glucose time in range between 70-180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study is not designed to determine difference in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm used the original Control-IQ algorithm (Control-IQ 1.0).

The primary outcome sensor time in range 70-180 mg/dL showed a mean adjusted difference 11% improvement with Control-IQ technology use compared to the control arm.

There was one episode of Diabetic Ketoacidosis (DKA), caused by infusion site failure in the Control-IQ arm. There were no severe hypoglycemic events in the DCLP3 with Control-IQ technology use. No other serious adverse events related to the device were reported.

DCLP3: Baseline Characteristics including Demographics at Enrollment (N=168)

Characteristic		Control-IQ (n=112)	SAP (n=56)
Age (years)			
	Mean $\pm$ SD	33 $\pm$ 16	33 $\pm$ 17
	Range	14 to 71	14 to 63
	<18 years	31 (28%)	17 (30%)
	$\geq$ 18 years	81 (72%)	39 (70%)
Sex – Female n (%)		54 (48%)	30 (54%)
Race / Ethnicity*			
	White non-Hispanic	94 (86%)	53 (95%)
	Black / African American	4 (4%)	0 (0%)
	Asian	3 (3%)	2 (4%)
	Native Hawaiian / Other Pacific Islander	1 (<1%)	0 (0%)
	More than one race	7 (6%)	1 (2%)
Income [†]			
	<\$50,000	10 (11%)	2 (4%)
	\$50,000 – <\$100,000	24 (27%)	18 (36%)
	$\geq$ \$100,000	55 (62%)	30 (60%)
Education [‡]			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

DCLP3: Baseline Characteristics including Demographics at Enrollment (N=168) (Continued)

Characteristic		Control-IQ (n=112)	SAP (n=56)
	≤High School Diploma	3 (3%)	6 (11%)
	Associates Degree or Some College	13 (12%)	7 (13%)
	Bachelor's Degree	51 (46%)	21 (38%)
	Master's Degree	32 (28%)	17 (30%)
	Doctoral or Professional Degree	13 (12%)	5 (9%)
Health Insurance [§]			
	Private	102 (94%)	50 (91%)
	CHP or another government / Medicaid	5 (5%)	5 (9%)
	None	2 (2%)	0 (0%)
*Three subjects in the Control-IQ technology arm did not provide race information. †Twenty-three subjects in the Control-IQ technology arm and 6 in SAP arm did not provide income information. ‡Highest level completed by the subject, or the primary caregiver if the participant was <18 years old. One subject in the Control-IQ technology arm did not provide education information. §Three subjects in the Control-IQ technology arm and one in the SAP arm did not provide insurance information.			

Adverse Effects

The following tables provide a full list of adverse events that occurred during the main part of the DCLP3 study:

DCLP3: Types of Adverse Events by Treatment Arm (N=168)

		Number of Events	
		Control-IQ (n=112)	SAP (n=56)
Total Number of Adverse Events		13	3
Adverse Events Related to Study Device			
	Ketosis (Infusion Site Failure)	3	0
	Hyperglycemia (Infusion Site Failure)	4	2
	Hyperglycemia (Defected Cartridge)	1	0
	Diabetic Ketoacidosis (Infusion Set Failure)	1	0
Adverse Effects Not Related to a Study Device			
	Hyperglycemia (User Error)	3	0
	Hyperglycemia (Respiratory Infection)	0	1
	Coronary Bypass Surgery	1	0
	Otitis Externa	1	0
	Concussion	1	0

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Adverse Effects

The following table provides a list of only hyperglycemia or ketosis events during the DCLP3 study:

DCLP3: Hyperglycemia/Ketosis Events by Treatment Arm (N=168)

	Number of Events	
	Control-IQ (n=112)	SAP (n=56)
Ketosis (Infusion Site Failure)	3	0
Hyperglycemia (Infusion Site Failure)	4	2
Hyperglycemia (Defected Cartridge)	1	0
Diabetic Ketoacidosis (Infusion Set Failure)	1	0
Hyperglycemia (User Error)*	3	0
Hyperglycemia (Respiratory Infection)	0	1
<i>*Discontinued pump, forgot to replace</i>		

Intervention Compliance

The following table provides an overview of how often the t:slimX2 insulin pump with Control-IQ technology was used in the Control-IQ arm:

DCLP3: Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over the 6-Month Period (n=112)

	Average Pump Use*	Average Time Control-IQ Available**
Weeks 1–4	100%	91%
Weeks 5–8	99%	91%
Weeks 9–12	100%	91%
Weeks 12–16	99%	91%
Weeks 17–20	99%	91%
Weeks 21–End	99%	82%
Overall	99%	89%
*The denominator is the total possible time within the 6-month study period. **Control-IQ Available is calculated as the percent of time when Control-IQ technology was available and operating normally during the 6-month study period.		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Primary Analysis

The primary outcome of the DCLP3 was to compare the CGM sensor values in range between 70 - 180 mg/dL between the Control-IQ technology and the SAP arms. The data represent the overall system performance 24-hours per day.

DCLP3: Comparison of CGM Values Between Control-IQ and SAP Users (N=168)

Characteristic	Control-IQ	SAP	Difference Between Study Arm and Control Arm
Average Sensor Glucose (std dev)	156 mg/dL (19 mg/dL)	170 mg/dL (25 mg/dL)	-14 mg/dL
Average % 70–180 mg/dL (std dev)	71.4% (11.7%)	59.2% (14.6%)	+11%
Average % >180 mg/dL (std dev)	27% (12%)	38.5% (15.2%)	-10%
Average % <70 mg/dL (std dev)	1.59% (1.15%)	2.25% (1.46%)	-0.88%
Average % <54 mg/dL (std dev)	0.29% (0.29%)	0.35% (0.32%)	-0.10%

The following table describes the average time participants in both the Control-IQ technology arm and the SAP arm spent with sensor glucose levels between 70 - 180 mg/dL by month at baseline and during the study period:

DCLP3: Percentage of Time in Range per Study Arm by Month (N=168)

Month	Control-IQ	SAP
Baseline	61%	59%
Month 1	73%	62%
Month 2	72%	60%
Month 3	71%	60%
Month 4	72%	58%
Month 5	71%	58%
Month 6	70%	58%

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Secondary Analysis

The following table shows secondary analysis comparing the percent of time that participants spent at the indicated sensor glucose levels during the daytime and nighttime for the DCLP3:

DCLP3: Secondary Analysis by Time of Day (N=168)

Characteristic	Unit of Measure	Daytime		Nighttime	
		Control-IQ	SAP	Control-IQ	SAP
Overall Sensor Glucose Control	Average Sensor Glucose (std dev)	158 mg/dL (20 mg/dL)	170 mg/dL (26 mg/dL)	150 mg/dL (18 mg/dL)	170 mg/dL (27 mg/dL)
	Average % Sensor Glucose 70 – 180 mg/dL (std dev)	69.8% (12.4%)	59.4% (14.6%)	76.1% (12.4%)	58.5% (16.2%)

The following table compares the percent of time spent between 70 - 180 mg/dL across the different baseline HbA1c values observed in the DCLP3 study in both treatment arms:

Percentage of Time in Range per Study Arm by Baseline HbA1c (N=168)

Baseline HbA1c	Time in Range	
	Control-IQ	SAP
≤6.5	85%	78%
6.6–7.0	76%	69%
7.1–7.5	71%	49%
7.6–8.0	69%	56%
≥8.1	60%	47%

The following table compares the average HbA1c values for all DCLP3 participants at baseline, after 13 weeks, and after 26 weeks. There was a relative difference of -0.33% between the Control-IQ arm and the SAP arm:

Comparison of HbA1c Values (N=168)

Time Period	Control-IQ	SAP
Baseline	7.40	7.40
After 13 Weeks	7.02	7.36
After 26 Weeks	7.06	7.39

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

The following table compares the change in HbA1c values for participants over the course of the DCLP3:

DCLP3: Change in HbA1c Values from Randomization to 26 Weeks (N=168)

			Number of Subjects (% of Subjects) with Change in HbA1c									
			Decrease >1%		Decrease 0 to 1%		No Change		Increase 0 to 1%		Increase >1%	
			n	%	n	%	n	%	n	%	n	%
Baseline Central Lab HbA1c		n										
5% ≤ HbA1c < 6%	Treatment	8	0	0%	1	13%	0	0%	7	88%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%
6% ≤ HbA1c < 7%	Treatment	30	0	0%	18	60%	3	10%	9	30%	0	0%
	Control	19	0	0%	10	53%	0	0%	9	47%	0	0%
7% ≤ HbA1c < 8%	Treatment	45	4	9%	33	73%	2	4%	5	11%	1	2%
	Control	22	0	0%	11	50%	1	5%	8	36%	2	9%
8% ≤ HbA1c < 9%	Treatment	22	5	23%	15	68%	1	5%	1	5%	0	0%
	Control	13	0	0%	8	62%	0	0%	4	31%	1	8%
9% ≤ HbA1c < 10%	Treatment	4	1	25%	2	50%	0	0%	1	25%	0	0%
	Control	1	0	0%	0	0%	0	0%	1	100%	0	0%
HbA1c ≥ 10%	Treatment	2	2	100%	0	0%	0	0%	0	0%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%

DCLP3: Change in HbA1c Values from Randomization to 26 Weeks (N=168) (Continued)

			Number of Subjects (% of Subjects) with Change in HbA1c									
Overall	Treatment	111	12	11%	69	62%	6	5%	23	21%	1	<1%
	Control	55	0	0%	29	53%	1	2%	22	40%	3	5%

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.4 The DCLP5 Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in children age 6 to 13 years of age. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to the use of SAP therapy alone (the control group).

The study design was very similar to DCLP3. In DCLP5, participants (N=101) were randomly assigned to Control-IQ or SAP in a 3:1 ratio. In this study, the Control-IQ arm included 78 participants. Like the DCLP3, this study population had a clinical diagnosis of type 1 diabetes. Unlike the DCLP3, the DCLP5 had participants 6 to 13 years of age. They were treated with insulin via an insulin pump or injections for at least one year. They weighed ≥ 25 kilograms and ≤ 140 kilograms and took at least 10 units of insulin a day. Females known to be pregnant were not included. Participants were required to be living with at least one parent or guardian knowledgeable about

diabetes and managing diabetes-related emergencies and willing to participate in all training sessions.

No participants were enrolled in the DCLP5 study who had inpatient psychiatric treatment in the past 6 months, the presence of a known adrenal disorder, untreated thyroid disease, cystic fibrosis, severe infectious process not anticipated to resolve prior to study procedures (e.g. meningitis, pneumonia, osteomyelitis), any skin condition in the area of insertion that prevents safe sensor or pump placement (e.g. bad sunburn, pre-existing dermatitis, intertrigo, psoriasis, extensive scarring, cellulitis), abnormal liver function tests (transaminase >3 times the upper limit of normal), or abnormal renal function test results (estimated glomerular filtration rate [GFR] <60 mL/minute/1.7m²). Participants were also excluded for use of any medication, any carcinogenic disease, or other significant medical disorder if that injury, medication, or disease in the judgment of the investigator would affect the completion of the protocol.

The summary statistics presented for the DCLP5 describe the primary outcome measure of the sensor glucose time in range between 70-180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study is not designed to determine difference in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm use the original Control-IQ algorithm (Control-IQ 1.0).

There were no episodes of DKA in the DCLP5. There were no severe hypoglycemic events in the DCLP5 with Control-IQ technology use. No other serious adverse events related to the device were reported.

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
Age (years)			
	6 – 9	21 (27%)	8 (35%)
	10 – 13	57 (73%)	15 (65%)
	Median (IQR)	11 (9, 12)	10 (8, 13)
	Range	6 to 13	6 to 13
Sex – Female n (%)		38 (49%)	12 (52%)
Race / Ethnicity			
	White non-Hispanic	64 (82%)	18 (78%)
	Hispanic or Latino	6 (8%)	2 (9%)
	Black / African American	0 (0%)	0 (0%)
	Asian	1 (1%)	1 (4%)
	More than one race	7 (9%)	2 (9%)
Annual Household Income			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101) (Continued)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
	<\$25,000	0 (0%)	0 (0%)
	\$25,000 – <\$35,000	2 (3%)	0 (0%)
	\$35,000 – <\$50,000	1 (1%)	2 (10%)
	\$50,000 – <\$75,000	5 (7%)	0 (0%)
	\$75,000 – <\$100,000	13 (18%)	4 (19%)
	\$100,000 – <\$200,000	27 (36%)	8 (38%)
	≥\$200,000	26 (35%)	7 (33%)
Parent Education			
	≤High School Diploma	2 (3%)	0 (0%)
	Associates Degree or Some College	5 (6%)	1 (4%)
	Bachelor's Degree	32 (41%)	9 (39%)
	Master's Degree	34 (44%)	11 (48%)
	Doctoral or Professional Degree	5 (6%)	2 (9%)
Health Insurance			

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101) (Continued)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
	Private	70 (90%)	21 (91%)
	CHP or another government / Medicaid	6 (8%)	1 (4%)
	Military	2 (3%)	1 (4%)
	Other	0 (0%)	0 (0%)
	None	0 (0%)	0 (0%)
*Missing data (CLC/SAP): annual household income 4 (5%)/2 (9%), total daily insulin 1 (1%)/0 (0%). All other variables have no missing data.			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Adverse Effects

The following tables provide a full list of adverse events that occurred during the main part of the DCLP5 study:

DCLP5: Types of Adverse Events by Treatment Arm (N=101)

		Number of Events	
		Control-IQ (n=78)	SAP (n=23)
Total Number of Adverse Events		16	3
Adverse Events Related to Study Device			
	Ketosis (Infusion Site Failure)	8	0
	Abscess at Sensor Site (CGM Sensor)	0	2
	Hyperglycemia (Defected Cartridge)	1	0
Adverse Effects Not Related to a Study Device			
	Hypoglycemia (User Error)	1	0
	Ketosis (User Error)	2	1
	Ketosis (Gastroenteritis)	1	0
	Hyperglycemia (User Error)	2	0
	Accidental Over-Delivery of Insulin (User Error)*	1	0
*One subject primed tubing while connected to body. This was a serious adverse event, requiring treatment in the emergency room for hypoglycemia prevention.			

The following table provides a list of only hyperglycemia or ketosis events during the DCLP5 study:

DCLP5: Hyperglycemia/Ketosis Events by Treatment Arm (N=101)

	Number of Events	
	Control-IQ (n=78)	SAP (n=23)
Ketosis (Infusion Site Failure)	8	0
Hyperglycemia (Defected Cartridge)	1	0
Ketosis (User Error)*	2	1
Ketosis (Gastroenteritis)	1	0
Hyperglycemia (User Error) [†]	2	0
<i>*Improper cartridge fill</i> <i>[†]Failed to recharge pump battery</i>		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used in the Control-IQ arm:

DCLP5: Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over the 4-Month Period (n=78)

	Average Time Control-IQ Available*
Weeks 1–4	93.4%
Weeks 5–8	93.8%
Weeks 9–12	94.1%
Weeks 13–End	94.4%
Overall	92.8%
*Control-IQ Available is calculated as the percent of time when Control-IQ technology was available and operating normally during the 4-month study period.	

Primary Analysis

The primary outcome of the DCLP5 was to compare the CGM sensor values in range between 70 - 180 mg/dL between the Control-IQ technology arms and the SAP arms. The data represent the overall system performance 24 hours per day.

DCLP5: Comparison of CGM Values Between Control-IQ and SAP Users (N=101)

Characteristic	Control-IQ	SAP	Difference Between Study Arm and Control Arm
Average Sensor Glucose (std dev)	162 mg/dL (18 mg/dL)	179 mg/dL (26 mg/dL)	-17 mg/dL
Average % 70–180 mg/dL (std dev)	67% (10%)	55% (13%)	+11%
Average % >180 mg/dL (std dev)	31% (10%)	43% (14%)	-10%
Average % <70 mg/dL (std dev)	1.8% (1.38%)	2.1% (1.18%)	-0.40%
Average % <54 mg/dL (std dev)	0.34% (0.35%)	0.38% (0.35%)	-0.07%

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

The following table describes the average time participants in both the Control-IQ technology arm and the SAP arm spent with sensor glucose levels between 70 - 180 mg/dL by month at baseline and during the study period.

DCLP5: Percentage of Time in Range per Study Arm by Month (N=101)

Month	Control-IQ	SAP
Baseline	53%	51%
Month 1	68%	56%
Month 2	68%	54%
Month 3	67%	56%
Month 4	66%	55%

Secondary Analysis

Secondary analysis comparing the percent of time that participants spent at the indicated sensor glucose levels during the daytime and nighttime for the DCLP5 are shown below:

DCLP5: Secondary Analysis by Time of Day (N=101)

Characteristic	Unit of Measure	Daytime		Nighttime	
		Control-IQ	SAP	Control-IQ	SAP
Overall Sensor Glucose Control	Average Sensor Glucose (std dev)	167 mg/dL (21 mg/dL)	179 mg/dL (27 mg/dL)	146 mg/dL (16 mg/dL)	180 mg/dL (27 mg/dL)
	Average % Sensor Glucose 70 – 180 mg/dL (std dev)	63% (11%)	56% (14%)	80% (9%)	54% (16%)

The following table compares the change in HbA1c values for participants over the course of the DCLP5:

DCLP5: Change in HbA1c Values from Randomization to 16 Weeks (N=101)

			Number of Subjects (% of Subjects) with Change in HbA1c									
			Decrease >1%		Decrease 0 to 1%		No Change		Increase 0 to 1%		Increase >1%	
			n	%	n	%	n	%	n	%	n	%
Baseline Central Lab HbA1c		n										
5% ≤ HbA1c < 6%	Treatment	3	0	0%	0	0%	2	67%	1	33%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

DCLP5: Change in HbA1c Values from Randomization to 16 Weeks (N=101) (Continued)

			Number of Subjects (% of Subjects) with Change in HbA1c									
6% ≤ HbA1c < 7%	Treatment	18	0	0%	9	50%	1	6%	8	44%	0	0%
	Control	3	0	0%	1	33%	0	0%	2	67%	0	0%
7% ≤ HbA1c < 8%	Treatment	28	3	11%	20	71%	0	0%	5	18%	0	0%
	Control	8	0	0%	5	63%	0	0%	2	25%	1	13%
8% ≤ HbA1c < 9%	Treatment	20	11	55%	9	45%	0	0%	0	0%	0	0%
	Control	10	0	0%	7	70%	0	0%	3	30%	0	0%
9% ≤ HbA1c < 10%	Treatment	7	5	71%	1	14%	0	0%	1	14%	0	0%
	Control	1	0	0%	1	100%	0	0%	0	0%	0	0%
HbA1c ≥ 10%	Treatment	1	0	0%	1	100%	0	0%	0	0%	0	0%
	Control	1	0	0%	1	100%	0	0%	0	0%	0	0%
Overall	Treatment	77	19	25%	40	52%	3	4%	15	19%	0	0%
	Control	23	0	0%	15	65%	0	0%	7	30%	1	4%

33.5 The PEDAP Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 4 months under normal conditions in preschoolers 2 to <6 years of age. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to Standard Care (SC, the control group), which included SAP therapy and multiple daily injection (MDI) therapy.

The study design was otherwise very similar to DCLP3 and DCLP5. In PEDAP, participants (N=102) were randomly assigned to Control-IQ or SC in a 2:1 ratio.

In this study, the Control-IQ arm included 69 participants, and the SC arm included 34 participants. The study population was similar to the DCLP5 in that the participants had a clinical diagnosis of type 1 diabetes, but they were younger, 2 to 5 years of age. They were treated with insulin via an insulin pump or injections for at least 6 months. They weighed at least 20

pounds (9 kilograms) and took at least 5 unites of insulin per day.

Participants were required to be living with at least one parent or guardian knowledgeable about diabetes and managing diabetes-related emergencies and willing to participate in all training sessions. No participants were enrolled in the PEDAP study who had a history of adrenal insufficiency, untreated thyroid disease, use of oral or injectable steroids within the last 8 weeks, history of chronic renal disease or currently on hemodialysis, hemophilia or any other bleeding disorder, history of >1 severe hypoglycemic event with seizure or loss of consciousness in the last 3 months, history of >1 DKA event in the last 6 months not related to illness, infusion set failure, or initial diagnosis, known ongoing adhesive intolerance, or condition, which in the opinion of the investigator or designee, would put the participant or study at risk. Concurrent use of any non-insulin glucose lowering agent (including GLP-1 agonists, Symlin, DPP-4 inhibitors, and sulfonylureas) was not allowed.

The summary statistics presented for the PEDAP describe the primary outcome measure of the sensor glucose time in range between 70 - 180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study was not designed to determine differences in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow lower weight and total daily insulin dose entry.

The primary outcome sensor time in range 70 - 180 mg/dL showed a mean adjusted difference 12.4% improvement with Control-IQ technology use of the SAP arm, very

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

similar to that seen in the DCLP3 and DCLP5.

There was one episode of DKA, caused by infusion site failure, in the PEDAP Control-IQ arm. There were two cases of severe hypoglycemia in the Control-IQ technology arm and one case in the SC arm. No other serious adverse events related to the device were reported.

Baseline Characteristics

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
Age (years)				
	Mean $\pm$ SD	3.94 $\pm$ 1.24	3.84 (1.23)	4.06 (1.25)
	Range	2.00 to 5.98	2.00 to 5.98	2.02 to 5.90
	2 to <4	47 (46%)	31 (46%)	16 (47%)
	4 to <6	55 (54%)	37 (54%)	18 (53%)
Weight (kg)				
	Mean (SD)	17.7 (4.2)	17.7 (4.7)	17.7 (3.3)
	Range	11.1 to 44.7	11.1 to 44.7	11.8 to 23.9
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase				
	Median (IQR)	0.66 (0.54, 0.79)	0.66 (0.55, 0.77)	0.66 (0.51, 0.80)
	Range	0.26 to 2.12	0.26 to 2.12	0.31 to 1.64
Sex – Female n (%)		52 (51%)	33 (49%)	19 (56%)
Race / Ethnicity				

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102) (Continued)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
	White non-Hispanic	75 (74%)	50 (74%)	25 (74%)
	Black / African American	6 (6%)	4 (6%)	2 (6%)
	Asian	2 (2%)	1 (1%)	1 (3%)
	More than one race	3 (3%)	2 (3%)	1 (3%)
Income*				
	<\$50,000	14 (14%)	8 (12%)	6 (19%)
	\$50,000 – <\$100,000	31 (33%)	19 (30%)	12 (38%)
	≥\$100,000	51 (53%)	37 (57%)	14 (44%)
Parent Education				
	≤High School Diploma	9 (9%)	6 (9%)	3 (9%)
	Technical/Vocational	3 (3%)	2 (3%)	1 (3%)
	Associate Degree	11 (11%)	6 (9%)	5 (15%)
	College Graduate (Bachelor's or higher)	35 (34%)	22 (32%)	13 (38%)
	Advanced Degree (Masters, PhD, MD, etc.)	44 (43%)	32 (47%)	12 (35%)
Health Insurance				

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102) (Continued)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
	Private [‡]	78 (77%)	52 (76%)	26 (79%)
	CHP or another government / Medicaid [†]	22 (24%)	15 (22%)	7 (21%)
	None	1 (<1%)	1 (1%)	0 (0%)
*Missing data (CLC/SC): Health insurance 0/1, annual household income 4/2, BMI percentile 2/0, HbA1c 4/2. All other variables have no missing data. [†]For participants with Private Insurance, 7 participants also had Medicaid, 1 participant also had Medicare, and 1 participant also had other government insurance. [‡]For participants with Medicaid, 1 participant also had other government insurance.				

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Adverse Effects

The following table provides a full list of adverse events that occurred during the main part of the PEDAP study.

PEDAP: Types of Adverse Events by Treatment Arm (N=102)

		Number of Events	
		Control-IQ (n=68)	SC (n=34)
Total Number of Adverse Events		71	14
Severe Hypoglycemic (SH) Events*		2	1
Diabetic Ketoacidosis (DKA) Events [†]		1	0
Other Serious Adverse Events [‡] (SAEs)		0	1
Other Adverse Events <i>N Events/N Participants</i>		68/40	12/9
	Hyperglycemia with or without Ketosis Related to Study Device	39/26	0
	Hyperglycemia with or without Ketosis Not Related to Study Device	12/9	8/7
	Hypoglycemia (not severe)	2/2	0/0
	Burn	1/1	0/0

PEDAP: Types of Adverse Events by Treatment Arm (N=102) (Continued)

		Number of Events	
		Control-IQ (n=68)	SC (n=34)
	COVID-19	3/3	0/0
	Fall	1/1	0/0
	Fractured Finger	1/1	0/0
	Gastroenteritis	2/2	2/2
	Hematuria	1/1	0/0
	Medical Device Site Bleeding	1/1	0/0
	Skin Infection	3/2	0/0
	Streptococcal Sore Throat	1/1	0/0
	Upper Respiratory Infection	1/1	0/0
	Vomiting	0/0	2/1
*A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions. †DKA events meeting DCCT criteria. ‡One participant in the SC group was hospitalized for an asthma flare.			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the PEDAP trial in the intervention arm.

PEDAP Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over 13-week Period (n=68)

	Average Time Control-IQ In Use*
Weeks 1–4	92%
Weeks 5–8	95% (n=67)
Weeks 9–13	95% (n=67)
Overall	94%
*The denominator is the number of days between the beginning of the fourth day after randomization and the end of the day before the 13-week visit, or the end of the day before the last contact date for the participant who dropped out.	

Primary Analysis

The primary outcome of PEDAP was to compare the CGM sensor values in range between 70 - 180 mg/dL between the Control-IQ technology arm and the SC arm. The data represent the overall system performance 24 hours per day.

PEDAP: Percent Time in Range: Primary Endpoint Tested for Superiority (N=101)

Time and Change	Control-IQ (n=67)	SC (n=34)
Baseline	57% (18)	55% (15)
13 Weeks	69% (11) (n=68)	56% (13)
Change from Baseline mean (SD)	12.5% (11.8)	1.0% (6.6)
13 week Adjusted Group Difference (95% CI) [p-value]	12.4% (9.5, 15.3) [<0.001]	

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Secondary Analysis

Change in HbA1c values to baseline subgroups follows:

PEDAP: Change in HbA1c Values to Baseline Subgroups (Treatment n=59, Control n=31)

		N	Baseline mean (SD)	Change from Baseline Mean (SD)
Baseline HbA1c				
<7.0%	Treatment	21	6.4 (0.5)	-0.08 (0.33)
	Control	8	6.5 (0.3)	-0.18 (0.37)
7% ≤ HbA1c < 8%	Treatment	19	7.5 (0.3)	-0.51 (0.34)
	Control	8	7.4 (0.2)	-0.01 (0.36)
HbA1c ≥ 8%	Treatment	19	8.9 (0.9)	-1.22 (0.81)
	Control	15	8.5 (0.4)	-0.31 (0.40)
Overall	Treatment	59	8.9 (0.9)	-1.22 (0.81)
	Control	15	8.5 (0.4)	-0.31 (0.40)

33.6 The PEDAP Extension Phase

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in preschoolers 2 to <6 years of age. The PEDAP extension phase allowed participants in the preceding PEDAP RCT to continue in the trial for an additional 13 weeks during an Extension Phase (N=96), with all participants using Control-IQ use for 3 more months. A subset of participants also performed meal and exercise challenges during the study.

Participants used either Closed-Loop Control (CLC) for the RCT and the extension phase of the study (CLC-CLC), or used Standard Care (SC) for the RCT arm of the study, then switched to CLC during the extension phase (SC-CLC).

Participants in the CLC-CLC arm (N=63, those who continued with Control-IQ) were compared to the SC-CLC group (who were in the standard care arm for the RCT, who

then switched to Control-IQ for the extension, N=33).

The summary statistics presented for the PEDAP Extension Phase describe key CGM outcomes, as well as analysis of secondary endpoints.

All participants in the PEDAP extension phase used the updated Control-IQ algorithm (Control-IQ 1.5).

Key CGM outcomes showed, in the CLC-CLC group, time in range 70 - 180 mg/dL increased from 57% at PEDAP RCT baseline to 70% at the end of the 13-week RCT, and this was sustained during the Extension Phase at 70%, with no significant change comparing the CLC use in the RCT phase to CLC use in the Extension Phase.

In the SC-CLC group, time in range 70 - 180 mg/dL was 55% at the PEDAP RCT baseline, 56% during the RCT, and 68% during the Extension Phase. Comparing standard care from the RCT with use of CLC in the extension, the mean difference in time in range 70 -180 mg/dL was 11.8%.

There were two cases of severe hypoglycemia in the 63 participants in the CLC-CLC group (3%) unrelated to the study device, and no cases among the 33 participants in the SC-CLC group. No cases of DKA were reported. No other serious adverse events related to the device were reported.

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Baseline Characteristics

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
Age at Beginning of Extension Phase (years)				
	Mean (SD)	4.17 (1.23)	4.10 (1.23)	4.32 (1.23)
	Range	2.30 to 6.33	2.33 to 6.33	2.35 to 6.22
	2 to <4	44 (46%)	29 (46%)	15 (45%)
	4 to <6	44 (46%)	31 (49%)	13 (39%)
	6 to <7	8 (8%)	3 (5%)	5 (15%)
Sex – Female n (%)		51 (53%)	32 (51%)	19 (58%)
Weight (kg)				
	Mean (SD)	18.5 (4.4)	18.7 (4.9)	18.2 (3.3)
	Range	12.2 to 47.2	12.7 to 47.2	12.2 to 24.4
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase				
	Median (IQR)	0.69 (0.59, 0.82)	0.69 (0.59, 0.80)	0.69 (0.55, 0.94)
	Range	0.42 to 1.70	0.42 to 1.70	0.44 to 1.38
Race / Ethnicity				

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96) (Continued)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
	White non-Hispanic	81 (84%)	53 (85%)	28 (85%)
	Black / African American	5 (5%)	3 (5%)	2 (6%)
	Asian	2 (2%)	1 (2%)	1 (3%)
	More than one race	8 (8%)	6 (10%)	2 (6%)
Hispanic Ethnicity		14 (15%)	9 (14%)	5 (15%)
Income at RCT Baseline*				
	<\$50,000	13 (14%)	7 (11%)	6 (19%)
	\$50,000 to \$100,000	31 (34%)	19 (33%)	12 (39%)
	>\$100,000	46 (51%)	33 (56%)	13 (42%)
Parent Education at RCT Baseline				
	High School graduate/diploma/GED	7 (7%)	4 (6%)	3 (9%)
	Technical/Vocational	3 (3%)	2 (3%)	1 (3%)
	Associate Degree	11 (11%)	6 (10%)	5 (15%)
	College Graduate (Bachelor's or equivalent)	34 (35%)	22 (35%)	12 (36%)
	Advanced Degree (Masters, PhD, MD, etc.)	41 (43%)	29 (46%)	12 (36%)
Health Insurance at RCT Baseline*				

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96) (Continued)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
	Private [‡]	74 (78%)	49 (78%)	25 (78%)
	Medicare / Medicaid [†]	13 (14%)	9 (14%)	4 (12%)
	Other Government Insurance	8 (8%)	5 (8%)	3 (9%)
*Missing data (CLC-CLC/SC-CLC): Health insurance 0/1, annual household income 4/2. All other variables have no missing data. [†].For participants with Private Insurance, 6 participants also had Medicaid, 1 participant also had Medicare, and 1 participant also had other government insurance. [‡].For participants with Medicaid, 1 participant also had other government insurance.				

Adverse Effects

The following table provides a full list of adverse events that occurred during the PEDAP extension phase. There were no DKA events:

Summary of Adverse Events During PEDAP Extension Phase (N=96)

		Number of Events	
		CLC-CLC (n=63)	SC-CLC (n=33)
Total Number of Adverse Events		46	29
Severe Hypoglycemic (SH) Events* <i>N Events/N Participants</i>		2/2	0/0
Other Serious Adverse Events [†] (SAEs) <i>N Events/N Participants</i>		1/1	0/0
Other Adverse Events <i>N Events/N Participants</i>		43/34	29/16
	Hyperglycemia with or without Ketosis Related to Study Device	20/18	8/8
	Hyperglycemia with or without Ketosis Not Related to Study Device	10/8	12/4
	Hypoglycemia (not severe)	1/1	0/0
	Allergy NOS	1/1	0/0

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Summary of Adverse Events During PEDAP Extension Phase (N=96) (Continued)

		Number of Events	
		CLC-CLC (n=63)	SC-CLC (n=33)
	Cellulitis	0/0	1/1
	COVID-19	3/3	0/0
	Fever	0/0	1/1
	Gastroenteritis	2/2	2/2
	Head Injury	0/0	1/1
	Influenza	1/1	0/0
	Laceration	0/0	1/1
	Pneumonia	1/1	0/0
	Skin Infection	1/1	2/2
	Upper Respiratory Infection	1/1	0/0
	Viral Syndrome	1/1	0/0
	Vomiting	1/1	1/1
*A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions. † One participant in the CLC-CLC group was hospitalized for muscle pain			

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the PEDAP extension phase. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ 1.5).

PEDAP Extension Phase Median Percentage of Time of Closed-Loop System Use

	CLC-CLC	SC-CLC
Weeks 1–13*	94% (n=63)	NA (n=33)
Weeks 14–17	96% (n=63)	96% (n=33)
Weeks 18–21	96% (n=62)	96% (n=32)
Weeks 22–26	96% (n=61)	96% (n=31)
Weeks 14–26**	96% (n=63)	95% (n=33)
<i>*The denominator for Weeks 1–13 is the number of days between the beginning of the fourth day after the randomization and the end of the day before the 13-week visit.</i> <i>**Denominator for Weeks 14–26 is the number of days between the beginning of the fourth day after the Extension Training visit and the end of the day before the 26-week visit, or the end of the day before the last contact date for the participants who dropped out.</i>		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Key CGM Outcomes

Time in range 70 - 180 mg/dL for all phases of the trial is shown below. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ 1.5).

PEDAP Extension Phase: Percent Time in Range 70 - 180 mg/dL: Primary Endpoint Tested for Superiority (N=96)

Time and Change	CLC-CLC (n=63)	SC-CLC (n=33)
RCT Baseline	57% (18) n=62	55% (15)
Weeks 1-13	70% (11)	56% (13)
Weeks 14-26	70% (11)	68% (9)
26 week Adjusted Group Difference (95% CI) [p-value]*	0.1% (-1.2, 1.4) [0.86]	
*The point estimate and 95% confidence interval for the difference were calculated from a direct likelihood model. This model adjusted for the RCT baseline value of the metric, age, prior CGM and pump use, and site as a random effect. P-values and confidence intervals were adjusted to control the false discovery rate.		

Secondary Analysis

The following table shows secondary analysis of HbA1c outcomes. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ 1.5):

PEDAP Extension Phase: HbA1c Outcomes*

		N	Baseline mean (SD)
Baseline HbA1c			
RCT Baseline	CLC-CLC	59	7.6 (1.2)
	SC-CLC	32	7.7 (0.9)
Week 13	CLC-CLC	58	7.0 (0.7)
	SC-CLC	32	7.5 (0.9)
Week 26	CLC-CLC	55	7.1 (0.8)
	SC-CLC	28	7.2 (0.7)
*CLC-CLC group used closed-loop control for both the RCT and the extension phase. SC-CLC used standard care for the RCT and closed-loop control for the extension phase.			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.7 The Higher-IQ Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in adults with high insulin needs.

The Higher-IQ study enrolled adults (N=34) with type 1 diabetes using at least one basal rate greater than 3 units/hour, in a single arm, prospective study of Control-IQ technology use for 13 weeks. All participants also performed meal and exercise challenges during the study.

Participants were at least 18 years of age, had type 1 diabetes for at least 1 year, were users of an insulin pump for at least 3 months, had a hemoglobin AC1c 10.5% and had a weight $\leq$ 440 pounds.

Baseline characteristics of study participants are provided below. Participants with more than 1 episode of severe hypoglycemia or DKA in the last 6 months were not included. Females known to be pregnant were not included. Participants with

hemophilia or any other bleeding disorder, history of adrenal insufficiency, untreated thyroid disease, chronic kidney disease which could affect CGM accuracy, history of gastroparesis, or a condition, which in the opinion of the investigator or designee, would put the participant or study at risk were not included.

Treatment with sulfonylureas, meglitinides, or Symlin was not permitted. Participants taking GLP-1 receptor agonists, DPP-4 inhibitors, and/or SGLT-2 inhibitors were allowed to continue these medications if they were on a stable dose for the last 3 months,

The summary statistics presented for Higher-IQ describe key CGM outcomes, as well as analysis of change in HbA1c.

All participants in the Higher-IQ study used the updated Control-IQ algorithm (Control-IQ 1.5).

Key CGM outcomes showed time in range 70 - 180 mg/dL was 64.75% overall, with time in hypoglycemia of 1.04%.

HbA1c decreased from 7.69% at baseline to 6.87% after 13 weeks of Control-IQ use, a decrease of 0.82%.

There were no DKA or severe hypoglycemia events in the study. No other serious adverse events related to the device were reported.

Higher-IQ Baseline Characteristics Including Demographics at Enrollment (N=34)

Characteristic		Single Arm Study (N=34)		
Age (years)				
	Mean (SD)	39.9 (11.9)		
	Range	20 to 66		
Sex – Female n (%)		41.2%		
Weight (kg)				
	Mean (SD)	114.8 (17.4)		
	Range	85.1 to 169.3		
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase				
	Median (IQR)	0.69 (0.59, 0.82)	0.69 (0.59, 0.80)	0.69 (0.55, 0.94)
	Range	0.42 to 1.70	0.42 to 1.70	0.44 to 1.38
Race / Ethnicity				
	White non-Hispanic	34 (100%)		
	Black / African American	2 (5.9%)		
	Native Hawaiian or Other Pacific Islander	1 (2.9%)		
Hispanic Ethnicity		3 (8.8%)		
Highest Level of Education				

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Higher-IQ Baseline Characteristics Including Demographics at Enrollment (N=34)

Characteristic		Single Arm Study (N=34)
	Less than high school	1 (2.9%)
	High School graduate/diploma/GED	4 (11.8%)
	Some college but no degree	8 (23.5%)
	Associate Degree	3 (8.8%)
	College Graduate (Bachelor's or equivalent)	13 (38.2%)
	Advanced Degree (Masters, PhD, MD, etc.)	5 (14.7%)

Adverse Effects

The following table provides a full list of adverse events that occurred during the Higher-IQ study:

Higher-IQ – All Adverse Events (N=34)

		Number of Events
		All Participants Used Control-IQ
Total Number of Adverse Events		38
Severe Hypoglycemic (SH) Events*		0
Diabetic Ketoacidosis (DKA) Events [†]		0
Other Serious Adverse Events [‡] (SAEs)		1
Other Adverse Events <i>N Events/N Participants</i>		37/18
	Hyperglycemia with or without Ketosis Related to Study Device	1/1
	Hyperglycemia with or without Ketosis Not Related to Study Device	0/0
	Bronchitis	1/1
	Chronic Kidney Disease	1/1
	Cough	1/1
	COVID-19	2/2
	Dyslipidemia	1/1
	Hypertension	1/1
	Influenza	3/3

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Higher-IQ – All Adverse Events (N=34) (Continued)

		Number of Events
		All Participants Used Control-IQ
	Ligament Sprain	1/1
	Migraine	1/1
	Myalgia	1/1
	Nausea/Vomiting	2/2
	Oropharyngeal Pain	1/1
	Otitis Externa	1/1
	Otitis Media	2/2
	Pharyngitis Streptococcal	1/1
	Skin Abrasion	1/1
	Sleep Apnea Syndrome	1/1
	Stiff Person Syndrome	1/1
	Tooth Abscess	1/1
	Tooth Fracture	1/1
	Tympanic Membrane Perforation	1/1
	Upper Respiratory Tract Infection	10/7

Higher-IQ – All Adverse Events (N=34) (Continued)

	Number of Events
	All Participants Used Control-IQ
<i>*A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.</i> <i>†DKA events meeting DCCT criteria.</i> <i>‡One participant was hospitalized for new onset atrial fibrillation.</i>	

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the Higher-IQ trial:

Higher-IQ Intervention Adherence over the 13-week Study Period (N=34)

	Sensor Use (%)	Closed-Loop System Use (%)
Mean (SD)	97.9%	93%

Key CGM Outcomes

Key CGM outcomes are shown below, for overall, daytime, and overnight:

Higher-IQ: Percentage of Time in Glycemic Ranges (N=34)

CGM Time in Range Mean % (SD)	Overall	Daytime	Overnight
BG 70-180mg/dL	64.75% (10.75)	63.47% (10.89)	68.47% (14.81)
BG >180mg/dL	34.21% (11.05)	35.62% (11.25)	30.09% (15.01)
BG ≥250mg/dL	10.45% (6.78)	10.74% (6.29)	9.58% (10.39)
BG 70-140mg/dL	37.87% (10.75)	36.96% (10.81)	40.55% (14.43)
BG <54mg/dL	0.20% (0.22)	0.15% (0.17)	0.35% (0.42)
BG <70 mg/dL	1.04% (0.98)	0.90% (0.90)	1.44% (1.48)

Secondary Analysis

Higher-IQ: Change in Central Lab HbA1c at 13 Weeks (N=34)

	Baseline	13 Weeks	Change from Baseline	P Value
HbA1c (%) Mean (SD)	7.69 (1.08)	6.87 (0.57)	-0.82 (0.73)	p<0.001

This Page is Intentionally Left Blank

5 Technical Specifications and Warranty

CHAPTER 34

Technical Specifications

CHAPTER 34 • Technical Specifications

34.1 Overview

This section provides tables of technical specifications, performance characteristics, options, settings, and electromagnetic compliance information for the t:slim X2™ pump. The specifications in this section meet the international standards set forth in IEC 60601-1 and IEC 60601-2-24.

34.2 t:slim X2 Pump Specifications**t:slim X2 Pump Specifications**

Specification Type	Specification Details
Classification	External PSU: Class II, Infusion Pump. Internally-powered equipment, Type BF applied part. The risk of ignition of flammable anesthetics and explosive gases by the pump is remote. While this risk is remote, it is not recommended to operate the t:slim X2 pump in the presence of flammable anesthetics or explosive gases.
Size	3.13" x 2.0" x 0.6" (L x W x H) - (7.95 cm x 5.08 cm x 1.52 cm)
Weight (with full disposable)	3.95 ounces (112 grams)
Operating Conditions	Temperature: 41°F (5°C) to 98.6°F (37°C) Humidity: 20% to 90% RH non-condensing
Storage Conditions	Temperature: -4°F (-20°C) to 140°F (60°C) Humidity: 20% to 90% RH non-condensing
Atmospheric Pressure	-1,300 feet to 10,000 feet (-396 meters to 3,048 meters)
Moisture Protection	IP27: Watertight to a depth of 3 feet (0.91 meters) for up to 30 minutes
Cartridge Volume	3.0 mL or 300 units
Cannula Fill Amount	0.1 to 1.0 units of insulin

t:slim X2 Pump Specifications (Continued)

Specification Type	Specification Details
Insulin Concentration	U-100
Alarm Type	Visual, audible, and vibratory
Basal Delivery Accuracy at all Flow Rates (tested per IEC 60601-2-24)	$\pm 5\%$ The pump is designed to vent automatically when there is a pressure difference between inside the cartridge and the surrounding air. In certain conditions, such as a gradual elevation change of 1,000 feet (305 meters), the pump may not vent immediately and delivery accuracy can vary up to 15% until 3 units have been delivered or elevation changes by more than 1,000 feet (305 meters).
Bolus Delivery Accuracy at all Volumes (tested per IEC 60601-2-24)	$\pm 5\%$
Patient Protection from Air Infusion	The pump provides subcutaneous delivery into interstitial tissue and does not deliver intravenous injections. Clear tubing aids in detecting air.
Maximum Infusion Pressure Generated and Occlusion Alarm Threshold	30 PSI
Frequency of Basal Delivery	5 minutes for all Basal Rates
Retention Time of Electronic Memory when Internal System Battery is Fully Discharged (including Alarm Settings and Alarm History)	Greater than 30 days
Infusion Set used for Testing	Unomedical Comfort Infusion Set
Typical Operating Time when System is Operating at Intermediate Rate	During normal use, the intermediate rate is 2 units/hr; battery charge can be reasonably expected to last between 4 and 7 days, depending on your use of CGM and the t:connect™ mobile app features from a fully charged state to a totally discharged state

CHAPTER 34 • Technical Specifications

t:slim X2 Pump Specifications (Continued)

Specification Type	Specification Details
Handling of Over-Infusion or Under-Infusion	The method of delivery isolates the insulin chamber from the patient and the software performs frequent monitoring of system status. Multiple software monitors provide redundant protection against unsafe conditions. Over-infusion is mitigated by monitoring glucose, (whether via CGM, BG meter, or both), layering of redundancies and confirmations, and numerous other safeguard alarms. Users are required to review and confirm the details of all bolus deliveries, Basal Rates, and temp rates to ensure certainty before initiating a delivery. In addition, once bolus deliveries are confirmed, the user is given 5 seconds to cancel the delivery before it is started. An optional Auto-Off alarm triggers when the user has not interacted with the pump's user interface for a predefined period of time. Under-infusion is mitigated by occlusion detection and BG monitoring as BG entries are recorded. Users are prompted to treat high BG conditions with a correction bolus.
Bolus Volume at Release of Occlusion (2 units per hour Basal)	Less than 3 units with Unomedical Comfort (110cm) Infusion Set
Residual Insulin Remaining in the Cartridge (unusable)	Approximately 15 units
Minimum Audible Alarm Volume	45 dBA at 1 meter

■ NOTE

Accuracies stated in this table are valid for all Tandem Diabetes Care, Inc. branded infusion sets including: AutoSoft™ 90, AutoSoft™ XC, AutoSoft™ 30, VariSoft™, and TruSteel™ branded infusion sets.

USB Charging/Download Cable Specifications

Specification Type	Specification Detail
Tandem P/N	004113
Length	6 feet (2 meters)
Type	USB A to USB Micro B

Power Supply/Charger, AC, Wall Mount, USB Specifications

Specification Type	Specification Detail
Tandem P/N	007866
Input	100 to 240 Volts AC, 50/60 Hz
Output Voltage	5 Volts DC
Max Output Power	5 Watts
Output Connector	USB type A

Computer, USB Connector, Specifications

Specification Type	Specification Detail
Output Voltage	5 Volts DC
Output Connector	USB type A
Safety Standard Compliance	60950-1 or 60601-1 or equivalent

CHAPTER 34 • Technical Specifications

Requirements for Charging from a Computer

The t:slim X2 pump is designed to be connected to a host computer for battery charging and data transfer. The following minimum characteristics are required of the host computer:

- USB 1.1 port (or later)
- Computer compliant with 60950-1 or equivalent safety standard

Connecting the pump to a host computer that is attached to other equipment could result in previously unidentified risks to the patient, operator, or a third party. The user should identify, analyze, evaluate, and control these risks.

Subsequent changes to the host computer could introduce new risks and require additional analysis. These changes can include but are not limited to changing the configuration of the computer, connecting additional items to the computer, disconnecting items from the computer, and updating or upgrading equipment connected to the computer.

▲ WARNING

ALWAYS use the USB cable provided with your t:slim X2 insulin pump to minimize the risk of fires or burns.

34.3 t:slim X2 Pump Options and Settings

t:slim X2 Pump Options and Settings

Option/Setting Type	Option/Setting Detail
Time	May be set to 12-hour or 24-hour clock (default is 12-hour clock)
Basal Rate Setting Range	0.1 – 15 units/hr
Insulin Delivery Profiles (Basal and Bolus)	6
Basal Rate Segments	16 per delivery profile
Basal Rate Increment	0.001 at programmed rates equal to or greater than 0.1 units/hr
Temp Basal Rate	15 minutes to 72 hours with 1 minute resolution with a range of 0% to 250%
Bolus Setup	Can deliver based on carb input (grams) or insulin input (units). The range for carbs is 1 to 999 grams, the range for insulin is 0.05 to 25 units
Insulin-to-Carb (IC) Ratio	16 time segments per 24-hour period; Ratio: 1 unit of insulin per x grams of carb; 1:1 to 1:300 (can be set by 0.1 below 10)
BG Target Value	16 time segments. 70 to 250 mg/dL in 1 mg/dL increments
Correction Factor	16 time segments; Ratio: 1 unit of insulin reduces BG x mg/dL; 1:1 to 1:600 (1 mg/dL increments)
Duration of Insulin Action	1 time segment; 2 to 8 hours in 1-minute increments (default is 5 hrs)
Bolus Increment	0.01 at volumes greater than 0.05 units
Quick Bolus Increments	When set to units of insulin: 0.5, 1, 2, 5 units (default is 0.5 units); or when set to grams of carb: 2, 5, 10, 15 grams (default is 2 g)

CHAPTER 34 • Technical Specifications

t:slim X2 Pump Options and Settings (Continued)

Option/Setting Type	Option/Setting Detail
Maximum Extended Bolus Time	8 hours
Maximum Bolus Size	25 units
Maximum Automatic Bolus Size	6 units
Low Cartridge Volume Indicator	Status indicator visible on <i>Home</i> screen; Low Insulin Alert is user adjustable from 10 to 40 units (default is 20 units).
Auto-Off Alarm	On or Off (default is on); user-adjustable (5 to 24 hours; default is 12 hours, which you can change when option is set to on).
History Storage	At least 90 days of data
Language	Dependent on region of use. May be set to English, Czech, Danish, Dutch, Finnish, French, German, Italian, Norwegian, Portuguese, Spanish, or Swedish (default is English).
Security PIN	Protects from unintentional access, and blocks access to quick bolus when enabled (default is off).
Screen Lock	Protects from unintentional screen interactions.
Site Reminder	Prompts user to change infusion set. Can be set for 1 to 3 days at a time selected by user (default is off).
Missed Meal Bolus Reminder	Prompts user if a bolus has not occurred during the period of time the reminder is set for. 4 reminders available (default is off).
After Bolus Reminder	Prompts user to test BG at a selected time period after a bolus has been delivered. Can be set between 1 to 3 hours (default is off).
High BG Reminder	Prompts user to retest BG after a High BG has been entered. User selects High BG value and time for reminder. (default is off).

t:slim X2 Pump Options and Settings (Continued)

Option/Setting Type	Option/Setting Detail
Low BG Reminder	Prompts user to retest BG after a Low BG has been entered. User selects Low BG value and time for reminder. (default is off).

34.4 t:slim X2 Pump Performance Characteristics

The t:slim X2 insulin pump delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The following accuracy data was collected on both types of delivery in laboratory studies performed by Tandem.

Basal Delivery

To assess basal delivery accuracy, 32 t:slim X2 pumps were tested by delivering at low, medium, and high Basal Rates (0.1, 2.0, and 15 U/hr). Sixteen of the pumps were new, and 16 had been aged to simulate four years of regular use. For both aged and unaged pumps, eight pumps were tested with a new cartridge, and eight with a cartridge which underwent two years of real time aging. Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid at various time points was used to assess pumping accuracy.

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for low, medium, and high Basal Rate settings for all pumps tested. For the medium and high basal rates, accuracy is reported from the time basal delivery started with no warm-up period. For the minimum Basal Rate, accuracy is reported after a 1-hour warm-up period. For each time period, the tables show the volume of insulin requested in the first row and the volume that was delivered as measured by the scale in the second row.

Low Basal Rate Delivery Performance (0.1 U/hr)

Basal Duration (Number of Units Delivered with 0.1 U/hr Setting)	1 hour (0.1 U)	6 hours (0.6 U)	12 hours (1.2 U)
Amount Delivered [min, max]	0.12 U [0.09, 0.16]	0.67 U [0.56, 0.76]	1.24 U [1.04, 1.48]

Medium Basal Rate Delivery Performance (2.0 U/hr)

Basal Duration (Number of Units Delivered with 2 U/hr Setting)	1 hour (2 U)	6 hours (12 U)	12 hours (24 U)
Amount Delivered [min, max]	2.1 U [2.1, 2.2]	12.4 U [12.0, 12.8]	24.3 U [22.0, 24.9]

High Basal Rate Delivery Performance (15 U/hr)

Basal Duration (Number of Units Delivered with 15 U/hr Setting)	1 hour (15 U)	6 hours (90 U)	12 hours (180 U)
Amount Delivered [min, max]	15.4 U [14.7, 15.7]	90.4 U [86.6, 93.0]	181 U [175.0, 187.0]

Bolus Delivery

To assess bolus delivery accuracy, 32 t:slim X2 pumps were tested by delivering consecutive low, medium, and high bolus volumes (0.05, 2.5, and 25 units). Sixteen of the pumps were new, and 16 had been aged to simulate four years of regular use. For both aged and unaged pumps, eight pumps were tested with a new cartridge, and eight with a cartridge which underwent two years of real time aging. Water was used as a substitute for insulin for this testing. The water was pumped into a container on a scale, and the weight of the liquid at various time points was used to assess pumping accuracy.

Delivered bolus volumes were compared to the requested bolus volume delivery for minimum, intermediate, and maximum bolus volumes. The tables below show average, minimum and maximum bolus sizes observed as well as the number of boluses which were observed to be within the specified range of each target bolus volume.

CHAPTER 34 • Technical Specifications

Summary of Bolus Delivery Performance (n=32 pumps)

Individual Bolus Accuracy Performance	Target Bolus Size [Units]	Mean Bolus Size [Units]	Min Bolus Size [Units]	Max Bolus Size [Units]
Min Bolus Delivery Performance (n=800 boluses)	0.050	0.050	0.000	0.114
Intermediate Bolus Delivery Performance (n=800 boluses)	2.50	2.46	0.00	2.70
Max Bolus Delivery Performance (n=256 boluses)	25.00	25.03	22.43	25.91

Low Bolus Delivery Performance (0.05U) (n=800 boluses)

	Units of Insulin Delivered After a 0.05 U Bolus Request									
	<0.0125 (<25%)	0.0125– 0.0375 (25–75%)	0.0375– 0.045 (75–90%)	0.045– 0.0475 (90–95%)	0.0475– 0.0525 (95–105%)	0.0525– 0.055 (105–110%)	0.055– 0.0625 (110–125%)	0.0625– 0.0875 (125–175%)	0.0875– 0.125 (175–250%)	>0.125 (>250%)
Number and Percent of Boluses Within Range	21/800 (2.6%)	79/800 (9.9%)	63/800 (7.9%)	34/800 (4.3%)	272/800 (34.0%)	180/800 (22.5%)	105/800 (13.1%)	29/800 (3.6%)	17/800 (2.1%)	0/800 (0.0%)

Intermediate Bolus Delivery Performance (2.5U) (n=800 boluses)

	Units of Insulin Delivered After a 2.5 U Bolus Request									
	<0.625 (<25%)	0.625– 1.875 (25–75%)	1.875– 2.25 (75–90%)	2.25– 2.375 (90–95%)	2.375– 2.625 (95–105%)	2.625– 2.75 (105–110%)	2.75– 3.125 (110–125%)	3.125– 4.375 (125–175%)	4.375– 6.25 (175–250%)	>6.25 (>250%)
Number and Percent of Boluses Within Range	9/800 (1.1%)	14/800 (1.8%)	11/800 (1.4%)	8/800 (1.0%)	753/800 (94.1%)	5/800 (0.6%)	0/800 (0.0%)	0/800 (0.0%)	0/800 (0.0%)	0/800 (0.0%)

High Bolus Delivery Performance (25U) (n=256 boluses)

	Units of Insulin Delivered After a 25 U Bolus Request									
	<6.25 (<25%)	6.25– 18.75 (25–75%)	18.75– 22.5 (75–90%)	22.5– 23.75 (90–95%)	23.75– 26.25 (95–105%)	26.25– 27.5 (105–110%)	27.5– 31.25 (110–125%)	31.25– 43.75 (125–175%)	43.75– 62.5 (175–250%)	>62.5 (>250%)
Number and Percent of Boluses Within Range	0/256 (0.0%)	0/256 (0.0%)	1/256 (0.4%)	3/256 (1.2%)	252/256 (98.4%)	0/256 (0.0%)	0/256 (0.0%)	0/256 (0.0%)	0/256 (0.0%)	0/256 (0.0%)

CHAPTER 34 • Technical Specifications

Rate of Delivery

Characteristic	Value
25 Unit Bolus Delivery Speed	2.97 Units/min Typical
2.5 Unit Bolus Delivery Speed	1.43 Units/min Typical
20 Unit Prime	9.88 Units/min Typical

Bolus Duration

Characteristic	Value
25 Unit Bolus Duration	8 minutes 26 seconds Typical
2.5 Unit Bolus Duration	1 minute 45 seconds Typical

Time to Occlusion Alarm*

Operating Rate	Typical	Maximum
Bolus (3 units or Greater)	1 minute 2 seconds	3 Minutes
Basal (2 units/hr)	1 Hour 4 Minutes	2 Hours
Basal (0.1 units/hr)	19 Hours 43 Minutes	36 Hours
*The time to occlusion alarm is based on insulin volume not delivered. During an occlusion event, boluses of less than 3 units may not trigger an occlusion alarm if no basal insulin is being delivered. The bolus amount will reduce the time to occlusion depending on the Basal Rate.		

34.5 Electromagnetic Compatibility

The information contained in this section is specific to the System. This information provides reasonable assurance of normal operation, but does not guarantee such under all conditions. If the System must be used in close proximity with other electrical equipment, the System should be observed in this environment to verify normal operation. Special precautions for electromagnetic compatibility must be taken when using medical electrical equipment. The System must be placed into service with adherence to the EMC information provided here.

▲ WARNING

Use of accessories, cables, adapters, and chargers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

▲ WARNING

ALWAYS use the USB cable provided with your t:slim X2 insulin pump to minimize the risk of fires or burns.

For IEC 60601-1 testing, Essential Performance for the System is defined as follows:

- The System will not over deliver a clinically significant amount of insulin.
- The System will not under deliver a clinically significant amount of insulin without notification to the user.
- The System will not deliver a clinically significant amount of insulin after occlusion release.
- The System will not discontinue reporting CGM data without notification to the user.

This section contains the following tables of information:

- Wireless Co-existence and Data Security
- Electromagnetic Emissions
- Electromagnetic Immunity
- Wireless Technology

34.6 Wireless Co-existence and Data Security

The System is designed to work safely and effectively in the presence of wireless devices typically found at home, work, retail stores, and places of leisure where daily activities occur.

▲ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches to any part of the t:slim X2 pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The System is designed to send and accept Bluetooth wireless technology communication. Communication is not established until you enter the appropriate credentials into your pump.

The System and system components are designed to ensure data security and patient confidentiality using a series of cybersecurity measures, including device authentication, message encryption, and message validation.

CHAPTER 34 • Technical Specifications

34.7 t:connect Mobile App Security

The smartphone's biometric security or other native authentication prevents unauthorized access. Never share your security PIN/password or authorize any other person to access your smartphone via their biometric information to avoid unintentional changes in your delivery of insulin.

⚠ WARNING

DO NOT use a smartphone that has been jailbroken or rooted, or with Android developer mode on. Data may become vulnerable if you install the t:connect mobile app on a smartphone that has been jailbroken or rooted, or uses an unreleased or pre-release operating system. Only download the t:connect mobile app on Google Play™ or from the App Store®. See Section 4.3 Connecting to a Smartphone for t:connect mobile app installation.

If the app becomes corrupted or compromised, uninstall the t:connect mobile app and follow the instructions in Section 4.3 Connecting to a Smartphone to regain a known configuration of the t:connect mobile app.

Once supported, Tandem intends to support a particular smartphone and OS combination for at least one year. When the mobile app is no longer compatible with a particular smartphone or OS, no further security updates will be provided.

■ NOTE

For an up-to-date list of supported mobile devices and operating systems, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

Please report any cybersecurity incident or vulnerability to Tandem Customer Technical Support as soon as you discover it.

34.8 Electromagnetic Emissions

The System is intended for use in the electromagnetic environment specified below. Always make sure that the System is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions, CISPR 11	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions, CISPR 11	Class B	The System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions, IEC 61000-3-2	N/A	
Voltage Fluctuations/Flicker Emissions, IEC 61000-3-3	N/A	

CHAPTER 34 • Technical Specifications

34.9 Electromagnetic Immunity

The System is intended for use in home healthcare electromagnetic environments.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air
Electrical Fast Transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines (100 kHz repetition frequency)	± 2 kV for power supply lines ± 1 kV for input/output lines (100 kHz repetition frequency)
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level
Proximity Field from Wireless Transmitters	385 MHz: 27 V/m @ 18 Hz Pulse modulation 450 MHz: 28 V/m @ FM modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz Pulse modulation 810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz Pulse modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz Pulse Modulation 2450 MHz: 28 V/m @ 217 Hz Pulse modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz Pulse modulation	385 MHz: 27 V/m @ 18 Hz Pulse modulation 450 MHz: 28 V/m @ FM modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz Pulse modulation 810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz Pulse modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz Pulse Modulation 2450 MHz: 28 V/m @ 217 Hz Pulse modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz Pulse modulation
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	70% UR (30% dip in Ur) for 25 cycles 0% Ur (100% dip in Ur) for 1 cycle at 0 degrees 0% Ur (100% dip in Ur) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% Ur (100% dip in Ur) for 250 cycles	70% UR (30% dip in Ur) for 25 cycles 0% Ur (100% dip in Ur) for 1 cycle at 0 degrees 0% Ur (100% dip in Ur) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% Ur (100% dip in Ur) for 250 cycles
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	400 A/m (IEC 60601-2-24)

CHAPTER 34 • Technical Specifications

34.10 Quality of Wireless Service

The manufacturer defines the quality of service of the System as the percent of readings successfully received by the pump, where the CGM transmitter and pump attempt to communicate every 5 minutes. One of the System's essential performance requirements states that the System will not discontinue reporting data and/or information from the CGM to the user without notification.

The System notifies the user of a missed reading, or when the transmitter and pump are out of range of one another in several ways. The first is when a dot is missed on the CGM Trend Graph which will occur within five minutes of the previous reading. The second indication occurs after 10 minutes when the Out of Range Icon is displayed on the *CGM Home* screen. The third is a user settable alert that will notify the user when the transmitter and pump are out of range of one another. Setting this alert is defined in Section 22.6 Setting Your Out of Range Alert.

The System performance requirements state that 90% of readings will be successfully transferred to the pump display while the transmitter and pump are within 20 feet (6 meters) of each other, and no more than 12 consecutive readings (1 hour) will be missed.

For proper use of the t:connect mobile app, the pump and smartphone require successful wireless communication every 5 minutes. The quality of wireless service between the pump and smartphone hosting the t:connect mobile application is assured within 20 feet, unless there is wireless interference caused by other devices in the 2.4 GHz band. This interference may impact the smartphone's ability to maintain this quality of service. To improve the quality of service in the presence of other devices operating in the 2.4 GHz band, decrease the distance between the smartphone and the pump. If connectivity is lost, the t:connect mobile application will provide notification; use your Pump until connectivity improves.

34.11 Wireless Technology

The t:slim X2 insulin pump utilizes wireless technology with the following characteristics:

Wireless Technology Specifications

Specification Type	Specification Detail
Wireless Technology	Bluetooth Low Energy (BLE) version 5.0
Tx/Rx Frequency Range	2.360 to 2.500 GHz
Bandwidth (per channel)	2 MHz
Radiated Output Power (maximum)	+8 dBm
Modulation	Gaussian Frequency-Shift Keying
Data Rate	2 Mbps
Data Communication Range (maximum)	20 feet

CHAPTER 34 • Technical Specifications

34.12 FCC Notice Concerning Interference

The transmitter covered by this user guide has been certified under FCC ID: PH29433.

Although the transmitter has been approved by the United States Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from the transmitter will be free from interference.

Compliance Statement (Part 15.19)

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Warning (Part 15.21)

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC Interference Statement (Part 15.105 (b))

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This portable transmitter with its antenna complies with FCC/IC RF exposure limits for general population/uncontrolled exposure.

34.13 Warranty Information**Warranty****t:slim X2 Insulin Pump**

This warranty is valid only in the United States.

Tandem Diabetes Care, Inc. ("Tandem") warrants the t:slim X2 insulin pump against defects in materials and workmanship, under normal use, for the period of 4 years from the original date of shipment of the pump to the

original end use purchaser (the “Warranty Period”). For any defective t:slim X2 pump covered by the foregoing warranty, Tandem will, at its discretion, repair the pump or replace it with a new or refurbished t:slim X2 pump, subject to the conditions and exclusions stated herein. Repair or replacement of a t:slim X2 pump will not extend the original 4 year warranty, which will continue to apply. If your t:slim X2 pump is replaced, then you must return your original pump to Tandem in accordance with Tandem’s instructions. In the event the defective t:slim X2 pump is not returned, then this warranty shall be void and you will not be entitled to future pump replacement or repairs.

The warranty is valid only if the t:slim X2 pump is used in accordance with Tandem’s instructions for use and this user guide and will not apply if:

- damage results from changes or modifications made to the t:slim X2 insulin pump by the user or third persons after the date of manufacture;

- damage results from service or repairs performed to any part of the t:slim X2 pump by any person or entity other than Tandem;
- the t:slim X2 pump seal is broken;
- a non-Tandem cartridge is used with the t:slim X2 pump;
- damage consists of scratches and wear to surfaces and other externally exposed parts due to wear and tear;
- damage results from an event or accident beyond the control of Tandem; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse.

From time-to-time Tandem may offer software updates for your t:slim X2 pump to help to ensure the up-to-date functionality of your pump or software that are intended to add new features to your t:slim X2 pump. Tandem reserves the right to offer those

updates, if any, in its sole discretion either at no charge or for an additional fee to be determined at a future date. To the extent that an update is offered at no charge, it is considered to be included in the original cost of your pump. Any future software updates will be subject to your acceptance of other terms and conditions that may be applicable at that time, including additional terms that may modify or limit the terms of this Warranty.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the t:slim X2 pump covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate.

This warranty only applies to the t:slim X2 pump and does not apply to other products or accessories. This warranty is valid only in the United States. No employee of Tandem or any other party is authorized to make any warranty in addition to those made in this Warranty.

The remedies provided for in this warranty are the exclusive remedies available for any warranty claims.

CHAPTER 34 • Technical Specifications

Neither Tandem nor its suppliers or distributors shall be liable for losses, liabilities, claims or damages of any kind or nature whatsoever, including, without limitation, any indirect, incidental, consequential, or special damages of any kind caused by or arising out of a defect in the product. All other warranties, express or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

Warranty

t:slim X2 3mL Cartridges

This warranty is valid only in the United States.

Tandem Diabetes Care, Inc. ("Tandem") warrants its cartridge against defects in materials and workmanship for one use during the period of 3 days after the individual cartridge sterile packaging has been opened, not to exceed 6 months from date of shipment of the cartridge to the end user (the "Warranty Period"). During the Warranty Period, Tandem will replace any defective cartridge, subject to the conditions and exclusions stated herein.

The warranty is valid only if the cartridges are used in accordance with the accompanying instructions for use and user guide and will not apply if:

- the cartridge has been used for more than a single-time use by a single end-user;
- damage results during the improper opening of the sterile package not in conformance with the procedures outlined in the associated instructions for use;
- the sterile package is compromised while in the control of the user by any means other than purposeful opening by the user at the time of intended product use;
- damage results from changes or modifications made to the cartridge by the user or third persons after the date of manufacture;
- damage results from service or repairs performed to any part of the cartridge by any person or entity other than Tandem;

- damage is caused by use of the cartridge with any non-Tandem insulin pump;
- damage results from an event or accident beyond the control of Tandem; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty does not apply to insulin pumps and other accessories. This warranty is valid only in the United States. No employee of Tandem or any other party is authorized to make any warranty in addition to those made in this Warranty.

The remedies provided for in this warranty are the exclusive remedies available for any warranty claims.

Neither Tandem nor its suppliers or distributors shall be liable for losses, liabilities, claims or damages of any kind or nature whatsoever, including, without limitation, any indirect, incidental, consequential, or special damages of any kind caused by or arising out of a defect in the product. All other warranties, express or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

Warranty t:lock™ Infusion Sets

This warranty is valid only in the United States.

Tandem Diabetes Care, Inc. ("Tandem") warrants its infusion sets against defects in materials and workmanship for one use during the period of 3 days after the individual infusion set sterile packaging has been opened, not to exceed 6 months from date of shipment of the infusion set to the end user (the "Warranty Period"). During the Warranty Period, Tandem will replace any defective infusion set, subject to the conditions and exclusions stated herein.

The warranty is valid only if the infusion sets are used in accordance with the accompanying instructions for use and user guide provided with your insulin pump and will not apply if:

- the infusion set has been used for more than a single-time use by a single end-user;
- the sterile package is compromised while in the control of the user by any means other than purposeful opening by the user at the time of intended product use;
- damage results during the improper opening of the sterile package not in conformance with the procedures outlined in the accompanying instructions for use;
- damage results from changes or modifications made to the infusion set by the user or third persons after the date of manufacture;
- damage results from service or repairs performed to any part of the infusion set by any person or entity other than Tandem;

- damage is caused by use of the t:lock infusion set with any non-Tandem insulin pump;
- damage results from an event or accident beyond the control of Tandem; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty does not apply to insulin pumps and other accessories. No employee of Tandem or any other party, including without limitation any authorized distributor, is authorized to make any warranty in addition to those made in this warranty.

The remedies provided for in this warranty are the exclusive remedies available for any warranty claims.

CHAPTER 34 • Technical Specifications

Neither Tandem nor its suppliers or distributors shall be liable for losses, liabilities, claims or damages of any kind or nature whatsoever, including, without limitation, any indirect, incidental, consequential, or special damages of any kind caused by or arising out of a defect in the product. All other warranties, express or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

CGM Warranty

Tandem Diabetes Care does not sell CGM sensors or transmitters and therefore provides no warranty for CGM sensors or transmitters used with the t:slim X2 insulin pump. For more information about CGM warranty information, visit the manufacturer's website.

34.14 Returned Goods Policy

The following represents the returned goods policy applicable only to customers in the United States.

Any insulin pump product ("Pump") that was originally purchased from Tandem

Diabetes Care, Inc. ("Tandem") or one of its authorized distributors within the United States may be returned to Tandem only for the following reasons: (1) during the applicable Warranty Period, if the customer experiences an issue with the Pump that is covered by the Warranty, then Tandem will repair or replace the Pump as provided under the Warranty above, or (2) during the ninety (90) day period after the shipment of the Pump, if the customer discovers that the Pump is not suited for the customer based on a valid, good faith medical reason which has been confirmed by the customer's physician, then Tandem or the authorized distributor will accept the return of the Pump and provide a refund to the customer and/or its insurance company for the amount actually paid for the Pump. Tandem will not accept or be obligated to accept for return any Pump for any other reason. To assure prompt handling when returning a Pump, the customer must first obtain a returned materials authorization (RMA) number from Tandem's or its authorized distributor's Customer Service Department. This RMA number must be clearly written on the outer box. If

Tandem provides a label, the label must be attached or taped to the outer box. If no label is provided, Tandem recommends shipping via insured ground service with a tracking number. Tandem is not responsible for lost or damaged packages.

To obtain an RMA number and shipping address, please contact Tandem Customer Technical Support. Returns pre-authorized by Tandem's authorized distributors should be sent to the distributor authorizing the return, unless other instructions are provided. Returns made without the RMA number will be returned to the customer, freight collect. This policy is subject to applicable law.

34.15 t:slim X2 Insulin Pump Event Data (Black Box)

Your t:slim X2 pump's event data is monitored and logged on the pump. The information stored on the pump may be obtained and used by Customer Technical Support and other internal Tandem personnel in accordance with our Privacy Notice for troubleshooting purposes when a

pump is uploaded to a data management application that supports use of the t:slim X2 pump, or if the pump is returned. Others who may assert a legal right to know, or who obtain your consent to know such information may also have access to read and use this data. Our Privacy Notice is available on our website and through our other applications. The Privacy Notice is available at tandemdiabetes.com/privacy/privacy-policy.

34.16 Product List

For a complete product list, please contact Customer Technical Support.

Insulin Delivery

- t:slim X2 insulin pump with Control-IQ technology
- t:case (pump cover with clip)
- t:slim X2 user guide
- USB cable
- USB charger with power plugs

- cartridge removal tool

Consumables

- cartridge
- t:slim X2 cartridge (t:lock™ connector) with filling syringe and needle
- infusion set (all with t:lock connector)

Infusion sets are available in different cannula sizes, tubing lengths, insertion angles, and may come with or without an insertion device. Some infusion sets have a soft cannula and others have a steel needle.

Contact your local customer support service for available sizes and lengths of the following infusion sets with t:lock connectors:

- AutoSoft 90 infusion set
- AutoSoft 30 infusion set
- VariSoft infusion set
- TruSteel infusion set

Optional Accessories/Replacement Parts

- t:case pump cover (black, blue, pink, purple, turquoise, olive)
- t:holster
- t:slim USB charging cable
- t:slim USB charger
- power plug for t:slim USB charger
- cartridge removal tool
- t:slim screen protector
- USB rubber door

INDEX

A

AC power adapter	88
Accessories	88
Active Bolus Icon	48, 212
After Bolus BG Reminder	147
Air Bubbles	
Check Tubing	113
Removing Before Delivery	109
Airport Security	199
Alarms	177
Altitude Alarm	188
Auto-Off Alarm	150
Cartridge Error Alarm	182
Cartridge Removal Alarm	183
Empty Cartridge Alarm	181
Low Power Alarm	180
Occlusion Alarms	185, 186
Reset Alarm	189
Resume Pump Alarm	179
Screen On/Quick Bolus Button Alarm	187
Temperature Alarm	184
Alerts	153

Alert Icon, Where to Find	48
Alerts & Reminders	58
Basal Rate Required Alert	165
CGM	229, 251
CGM Rise and Fall	232
CGM, 12 Hour Calibration Alert	255
CGM, Calibrate CGM Alert	259
CGM, Calibration Error Alert	258
CGM, Calibration Timeout Alert	257
CGM, Failed Sensor	271
CGM, Fall Alert	265, 266
CGM, High Alert	260
CGM, Incomplete Calibration Alert	256
CGM, Low Alert	261, 262
CGM, Low Transmitter Battery Alert	269
CGM, Out of Range Alert	268, 319, 320
CGM, Rise Alert	263, 264
CGM, Second Startup Calibration Alert	254
CGM, Startup Calibration Alert	253
CGM, System Error	273
CGM, Transmitter Error	270
CGM, Unavailable	272
Connection Error Alert	172
Control-IQ Technology	317
Control-IQ Technology, High Alert	322
Control-IQ Technology, Low Alert	321

Control-IQ Technology, Max Insulin Alert	323
Data Error Alert	175
High Glucose Alert, Set	230
Incomplete Bolus Alert	158
Incomplete Cartridge Change Alert	161
Incomplete Fill Cannula Alert	163
Incomplete Fill Tubing Alert	162
Incomplete Load Sequence Alerts	161
Incomplete Personal Profile Alert	164
Incomplete Setting Alert	164
Incomplete Temp Rate Alert	160
Low Glucose Alert, Set	231
Low Insulin Alert	150, 155
Low Power Alerts	156, 157
Max Bolus Alerts	167, 168
Max Hourly Bolus Alert	166
Min Basal Alerts	170, 171
Out of Range Alert, Set	233
Power Source Alert	174
Alternate Site BG Testing	208
Altitude	198
Altitude Alarm	188
Aquatic Activities, Pump	198
Arrows	
CGM Trends	249
Up/Down Arrows	56

Auto-Off Alarm	150

B

Basal	40
Basal Rate Required Alert	165
Current Basal Rate	52
Delivery Accuracy	381
Frequency of Delivery	381
in Personal Profiles	99
Set a Temp Rate	103
Stop a Temp Rate	104
Temp Basal Rate	41
Timed Settings	97
Basal Rate Required Alert	165
Battery	88
Battery Level	48, 50
Battery, Charge	89
BG	40
High BG Reminder	146
Low BG Reminder	146
Target BG	40, 96
Target BG in Personal Profiles	99
BG Reminder	147
Bluetooth	224

Bolus	41, 117
Active Bolus Icon	48, 212
After Bolus BG Reminder	147
Bolus Overview	118
Bolus Screen	54
Cancel a Bolus	128, 133
Correction Bolus	41
Delivery Accuracy	381
Extended Bolus	41, 124
Food Bolus Using Grams	123
Food Bolus Using Units	123
in Personal Profiles	100
Quick Bolus	41
Stop a Bolus	128, 133
Timed Settings	97

C

Calculation	54
Calibrate CGM Alert	259
Calibration Alert, 12 Hour	255
Calibration Error Alert	258
Calibration Timeout Alert	257
Cancel a Bolus	128, 133
Cannula	41

Cannula, Fill Cannula	115
Carb Ratio	41
Current Status	52
in Personal Profiles	99
Timed Settings	97
Carbohydrate	41
Carbohydrates	
Carbs, in Personal Profiles	97
Food Bolus Using Grams	123
Food Bolus, on Bolus Screen	54
Carbs	41
Carbs, on Bolus Screen	54
Caring for Your Pump	195
Cartridge	108
Cartridge Tubing	50
Change Cartridge	112
Fill Cartridge	110
Load Cartridge	108, 112
Load the Cartridge	41
Cartridge Error Alarm	182
Cartridge Removal Alarm	183
Cartridge, Warranty	402
CGM	
12 Hour Calibration Alert	255
Alerts and Errors	251

Automatic Sensor Shut-Off	239	History, View	250
Calibrate Blood Glucose Value	244	Incomplete Calibration Alert	256
Calibrate CGM Alert	259	Low BG Alert Default	231
Calibrating Your CGM	241	Low BG Alert Repeat	231
Calibration Error Alert	258	Low Glucose Alert, Set	231
Calibration Overview	242	Low Transmitter Battery Alert	269
Calibration Prompts	210	My CGM Screen	216
Calibration Timeout Alert	257	Out of Range Alert	268, 319, 320
CGM Fall Alert	265, 266	Out of Range Alert, Set	233
CGM High Alert	260	Out of Range/No Antenna, Troubleshooting	277
CGM Info	227	Pair Your CGM	224, 236
CGM Low Alert	261, 262	Rate of Change Arrows	248
CGM Rise Alert	263, 264	Receiver	221
CGM Settings	224	Rise and Fall Alerts	232
CGM System Error	273	Second Startup Calibration Alert	254
CGM Unavailable	272	Sensor Inaccuracies, Troubleshooting	278
Default Volume	224	Sensor Startup Period	238
End a Sensor Session	240	Set Correction Bolus	244
Enter Transmitter ID	224, 236	Set Volume	224
Failed Sensor	271	Start Calibration	242
Failed Sensor, Troubleshooting	277	Start or Stop a CGM Sensor	235
Glucose Trend Arrows	248	Startup Calibration Alert	253
Glucose Trend Graphs	247	Status Symbols	210
High BG Alert Default	230	System Overview	220
High BG Alert Repeat	230	Transmitter Error	270
High Glucose Alert, Set	230	Transmitter ID	236

Troubleshooting	275	Calculate Total Daily Insulin	311
Unknown Sensor Reading	267	During Exercise	306
Unknown Sensor Reading, Troubleshooting	276	During Sleep	305
View Data on Pump, Overview	246	High Alert	322
CGM Fall Alert	265, 266	Home Screen	290
CGM High Alert	260	How it Works	296
CGM ID	236	Increasing Insulin Delivery	301
CGM Low Alert	261, 262	Information on Your Screen	315
CGM Rise Alert	263, 264	Insulin Decreased	297
CGM Safety Information	202	Insulin Suspended	299
CGM System Error	273	Low Alert	321
CGM Unavailable	272	Manually Start or Stop Sleep	314
Charge		Max Insulin Alert	323
AC Power Outlet	88	Maximum Insulin Delivery	301
Car Adapter	89	No Activity Enabled	305
Computer	89	Overview	296
Charge the Pump	88	Personal Profile Basal Rate Delivery	297
Cleaning Your System	196	Required Settings	310
Colors		Responsible Use	286
Explanation of Pump Colors	45	Schedule Sleep	311
Computer Charging Specifications	384	Set Weight	310
Connection Error Alert	172	Start or Stop Exercise	314
Contents, of Pump Package	40	Total Daily Insulin	292
Control-IQ Technology		Turn On or Off	311
Automatic Correction Bolus Delivery	303	Weight	292
		Control-IQ Technology Safety Information	282

Correction Bolus	41
Correction Factor	41, 97
in Personal Profiles	99
Timed Settings	97
Current Status Screen	52

D

Data Error Alert	175
Data, View CGM Overview	246
Date	
Date and Time Display	48
Edit Date	91
Default	
Auto-Off Alarm	150
Basal Temp Rate	103
CGM Default Volume	224
CGM Fall Alert	232
CGM Out of Range Alert	233
CGM Rise Alert	232
Extended Bolus	124
High BG Reminder	147
High Glucose Alert	230
Low BG Reminder	146
Low Glucose Alert	231

Low Insulin Alert	150
Quick Bolus	126
Screen Timeout	92
Site Reminder	148

Delete Personal Profile	103
Delivery Summary	142
Device Settings	60, 92
Disconnect When Filling	113
Display Settings	92
Disposing of System Components	196

E

Edit	
Edit Date	91
Edit Time	91
Site Reminder	116
Electromagnetic Compatibility	393
Electromagnetic Emissions	395
Electromagnetic Immunity	396
Empty Cartridge Alarm	181
End CGM Sensor Session	240
Extended Bolus	41, 124
Default	124

F

Failed Sensor Error	271
Fall Alert, Set	233
Fill	
Fill Cannula	115
Fill Cartridge	110
Fill Port	109, 110
Fill Tubing	113

G

Glucose Rate of Change Arrows	248
Glucose Trend Graphs	247
Grams	
Food Bolus, on Bolus Screen	54
Food Bolus, using	123

H

Healthcare Provider	36
High Alert	
Control-IQ Technology	322
High BG Reminder	146

History

CGM History	250
Control-IQ Technology History	142
Pump History	142
Home Screen	50
Home Screen, CGM	214
Home Screen, Control-IQ Technology	290

I

Icons

Explanation of Icons	43, 210, 287
Incomplete Bolus Alert	158
Incomplete Calibration Alert	256
Incomplete Cartridge Change Alert	161
Incomplete Fill Cannula Alert	163
Incomplete Fill Tubing Alert	162
Incomplete Load Sequence Alerts	161
Incomplete Setting Alert	164
Incomplete Temp Rate Alert	160
Infusion Set Risks	36, 106
Infusion Site Care	106
Infusion Site Care, Pediatric	23
Insulin	

Insulin Duration	97
Insulin Level Display	48, 115
Insulin On Board (IOB)	41, 48
Insulin On Board (IOB) Display	48
Resume Insulin Delivery	138
Stop Insulin Delivery	138, 139
Insulin Duration, in Personal Profiles	97
Insulin on Board (IOB), in Personal Profiles	98
Interference, FCC Notice	400

K

Keypad	62, 64
Letter Keypad	64
Number Keypad	62

L

LED	45
LED, location on Home Screen	50
Lifestyle Issues	197
Load Cartridge	108, 112
Low BG Reminder	146
Low Insulin Alert	150, 155

Low Power Alarm	180
Low Power Alerts	156, 157
Low Transmitter Battery Alert	269

M

Maintaining Your Pump	195
Malfunction	192
Manual Bolus	118
Max Basal Alert	151
Max Bolus	125
Max Bolus Alerts	167, 168
Max Hourly Bolus Alert	166
Max Insulin Alert	
Control-IQ Technology	323
Min Basal Alerts	170, 171
Missed Meal Bolus Reminder	148
My Pump Screen	58

O

Occlusion Alarms	185, 186
Options Screen	56
Out of Range Alert	268, 319, 320

Overview

CGM Overview	220

P

Pediatric

Infusion Site Care	23
Security PIN	23

Personal Profiles

Activate a Profile	102
Add Profiles	101
Copy an Existing	102
Create a New Profile	96
Delete a Profile	103
Edit or View	101
Personal Profiles Overview	96
Program a Personal Profile	99
Rename a Profile	102

Power Adapter, AC	88

Power Source Alert	174

Pump History	142

Pump History, Delivery Summary	142

Pump Info	142

Pump Info, Serial Number	142

Pump Package Contents	40

Pump Performance, Specifications	388

Pump Settings, Specifications	385

Pump Specifications	380

Q

Quick Bolus	41, 126
Pediatric	23

R

Receiver, CGM	221

Reminders	145

After Bolus BG	147

Alerts & Reminders	58

High BG	146

Low BG	146

Missed Meal Bolus	148

Site Reminder	116, 148

Reset Alarm	189

Resume Insulin Delivery	138

Resume Pump Alarm	179

Returned Goods Policy	404

Rise Alert, Set	232

Risks from Using the Pump	36
Risks from Using the System	206

S

Safety Information

CGM	201
Control-IQ Technology	281
Pump	25

Screen On/Quick Bolus Button Alarm	187

Screen Protector	40

Screen Timeout, set	92

Screens

Bolus Screen	54
CGM Home Screen	214
CGM Lock Screen	212
Control-IQ Technology	292
Control-IQ Technology Home Screen	290
Control-IQ Technology Lock Screen	288
Current Status Screen	52
Device Settings	60
Home Screen	50
Letter Keypad Screen	64
Lock Screen	48
My CGM Screen	216

My Pump Screen	58
Number Keypad Screen	62
Options Screen	56
Unlock	90
Second Startup Calibration Alert, CGM	254
Security PIN	93
Pediatric	23
Sensor	
Applicator	208
Automatic Shut-Off	239
Failed Sensor, Troubleshooting	277
Out of Range Alert	268, 319, 320
Out of Range/No Antenna, Troubleshooting	277
Troubleshooting	275
Troubleshooting Sensor Reading	276
Unknown Reading	267
Sensor Startup Period	238
Sensor, Start a Session	236
Sensor, Start Calibration	242
Serial Number	18, 142
Set CGM Volume	224
Settings, Pump Setting Specifications	385
Site Reminder	
Set Site Reminder	148
Site Reminder, Set	116

Sound 93**Specifications**

Computer Charging	384
Electromagnetic Compatibility	393
Electromagnetic Emissions	395
Electromagnetic Immunity	396
Pump	380
Pump Performance	388
Water Resistance	380
Startup Calibration Alert	253
Stop a Bolus	128, 133
Stop a Temp Rate	104
Stop CGM Sensor Session	240
Stop Insulin Delivery	138, 139
Storing Your System	196
Supply Reordering	40

T

Tandem Logo	50, 90
Target BG	40
in Personal Profiles	96, 99
Timed Settings	97
Technical Specifications	379
Temp Rate	

Stop a Temp Rate	104
Temp Rate, Set a Temp Basal Rate	103
Temperature Alarm	184
Temperature, Extreme	198
Time	
Date and Time Display	48
Edit Time	91
Time Segments	96
Time Segments, in Personal Profiles	99
Time Segments	
add to Personal Profile	100
Timed Settings	97
in Personal Profiles	99
Transmitter	
Safety Lock	208
Transmitter Error	270
Transmitter ID	236
Travel	199
Traveling, by Air	199
Trend Graphs, Glucose Trends, Arrows	247
Troubleshooting CGM	275
Tubing	
Cartridge Tubing	50
Fill Tubing	113
Tubing Connector	50, 109, 114

U

Units	42
Food Bolus, on Bolus Screen	54
Food Bolus, Using Units	123
Units, on Bolus Screen	54
Unknown Sensor Reading	267
Unlock the Screen	90
USB	
USB Adapter	89
USB Cable	40, 89
USB Port	50, 89

V

View Calculation	54
Volume	93

W

Warranty	
Cartridges	402
Pump Warranty	400
Water Resistance, Pump	198

Watertight, Pump	198

PATENTS AND TRADEMARKS

Covered by one or more patents. For a list of patents, see tandemdiabetes.com/legal/intellectual-property.

Tandem Diabetes Care, the Tandem Diabetes Care logo, t:connect, t:slim X2, and Control-IQ are either registered trademarks or trademarks of Tandem Diabetes Care, Inc., in the U.S. and/or other countries. t:lock, t:slim X2, AutoSoft, TruSteel, and VariSoft are trademarks of Tandem Diabetes Care, Inc. Dexcom and Dexcom G6 are either registered trademarks or trademarks of Dexcom, Inc. in the United States and/or other countries. The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Tandem Diabetes Care, Inc. is under license. All other third party marks are the property of their respective owners.

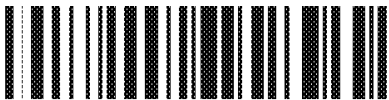




UNITED STATES:
(877) 801-6901
tandemdiabetes.com

CANADA:
(833) 509-3598
tandemdiabetes.ca

OTHER COUNTRIES:
tandemdiabetes.com/contact



1012260_B
AW-1012259_B
2023-OCT-26

© 2023 Tandem Diabetes Care, Inc. All rights reserved.

Hello Suvajyoti,

Please see our response to Question #5 attached.

Best Regards,
Christin

From: Christin Dunn
Sent: Friday, August 18, 2023 8:23 AM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Maiorana, Anthony <Anthony.Maiorana@fda.hhs.gov>; Balsam, Joshua <Joshua.Balsam@fda.hhs.gov>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; Lan Herrington <LHerrington@tandemdiabetes.com>
Subject: RE: K232380 and K232382 - miscellaneous interactive questions

Hi Suvajyoti,

I'm confirming receipt of your questions.

We will reach out to you if we have any questions.

Thank you,



Christin Dunn
Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different
12400 High Bluff Drive, San Diego CA 92130
tandemdiabetes.com

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Friday, August 18, 2023 6:59 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Maiorana, Anthony <Anthony.Maiorana@fda.hhs.gov>; Balsam, Joshua <Joshua.Balsam@fda.hhs.gov>
Subject: K232380 and K232382 - miscellaneous interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

I Christin,

Can you please respond to the following interactive questions? For 1-4 below I request that you provide your responses by COB **August 25, 2023**.

For response 5 below, I request that you provide your response by COB **August 22, 2023** and cc our Human Factors SME Dr. Anthony Maiorana.

(b)(4)

(b)(4)

If you have any follow up questions for me related to the above, please direct them to me by 4 PM today eastern time as I will be on leave for part of next week.

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).



Hi Suvajyoti,

Would it be possible for us to send you the labeling documents and 510(k) summaries by COB Monday, October 30th?

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Thursday, October 26, 2023 12:33 PM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov

Subject: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Can you please send your finalized and complete Labeling documents and 510k summaries for the pump (k232380) and Control IQ (k232382)?

It would be great if you can send it by COB Oct 27, 2023.

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image001.png@01DA08B2.E30CD1C0]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA08B2.E30CD1C0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA08B2.E30CD1C0] <https://twitter.com/US_FDA>

[cid:image004.jpg@01DA08B2.E30CD1C0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01DA08B2.E30CD1C0] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01DA08B2.E30CD1C0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Hi Suvajyoti,

Please see our response to the additional questions sent on September 6th.

Thank you,

Christin

From: Christin Dunn

Sent: Wednesday, September 6, 2023 12:59 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov

Subject: RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Hi Suvajyoti,

I'm confirming receipt of the additional questions.

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Wednesday, September 6, 2023 6:34 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>

Subject: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Can you please respond to the following interactive questions by COB Sep 11, 2023 -

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image001.png@01D9E4A3.4CDB4160]<<http://www.fda.gov/>>

[cid:image002.jpg@01D9E4A3.4CDB4160]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01D9E4A3.4CDB4160] <https://twitter.com/US_FDA>

[cid:image004.jpg@01D9E4A3.4CDB4160] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01D9E4A3.4CDB4160] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01D9E4A3.4CDB4160]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here

<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

t:slim X2

Insulin Pump

WITH Control-IQ TECHNOLOGY

User Guide



MG/DL

T:SLIM X2 INSULIN PUMP WITH CONTROL-IQ TECHNOLOGY USER GUIDE

Software Version: Control-IQ 7.6

Congratulations on the purchase of your new t:slim X2™ insulin pump with Control-IQ™ technology.

This user guide is designed to assist you with the features and functions of the t:slim X2 insulin pump with Control-IQ technology. It provides important warnings and cautions on proper operation as well as technical information to ensure your safety. It also provides step-by-step instructions on how to properly program, manage and care for your t:slim X2 insulin pump with Control-IQ technology.

Changes in equipment, software, or procedures occur periodically; information describing these changes will be included in future editions of this user guide.

No part of this publication may be reproduced, stored in a retrieval system, nor transmitted in any form or by any means, electronic or mechanical, without the prior written permission of Tandem Diabetes Care.

Please contact Customer Technical Support to obtain a replacement copy of the user guide that is the correct version for your pump. For contact information in your region see the back cover of this user guide.

Tandem Diabetes Care, Inc.
12400 High Bluff Drive
San Diego, CA 92130 USA
tandemdiabetes.com

WARNINGS:

Control-IQ technology should not be used in anyone under the age of two years old. Control-IQ technology should also not be used in patients who require less than a total daily insulin dose of 5 units per day and should not be used by people who weigh less than 20 pounds (9 kilograms), as those are the required minimum values needed in order for Control-IQ technology to operate safely.

TABLE OF CONTENTS

Section 1: Before You Begin

Chapter 1 • Introduction

1.1	Conventions of This Guide	16
1.2	Explanation of Symbols	18
1.3	System Description	20
1.4	About this User Guide	21
1.5	Indications for Use	21
1.6	Compatible Insulins	22
1.7	Compatible iCGMs	22
1.8	Important User Information	22
1.9	Important Pediatric User Information	23
1.10	Emergency Kit	24

Section 2: t:slim X2 Insulin Pump Features

Chapter 2 • Important Safety Information

2.1	t:slim X2 Insulin Pump Warnings	26
2.2	Magnetic Resonance Imaging Safety	29
2.3	Radiology and Medical Procedures and Your t:slim X2 System	29
2.4	t:connect Mobile App Warnings	30
2.5	t:slim X2 Insulin Pump Precautions	30
2.6	t:connect Mobile App Precautions	33
2.7	Tandem Cybersecurity Preventative Measures	34
2.8	Potential Benefits From Using Your Pump	35

2.9	Possible Risks From Using Your Pump	36
2.10	Working with your Healthcare Provider	36
2.11	Verification of Proper Functionality	37

Chapter 3 • Getting to Know Your t:slim X2 Insulin Pump

3.1	What your t:slim X2 Pump Package Includes	40
3.2	Pump Terminology	40
3.3	Explanation of t:slim X2 Insulin Pump Icons	43
3.4	Explanation of Pump Colors	45
3.5	Pump Back Side	46
3.6	Lock Screen	48
3.7	Home Screen	50
3.8	Current Status Screen	52
3.9	Bolus Screen	54
3.10	Options Screen	56
3.11	My Pump Screen	58
3.12	Device Settings Screen	60
3.13	Number Keypad Screen	62
3.14	Letter Keypad Screen	64

Chapter 4 • Getting to Know Your t:connect Mobile App

4.1	Overview	68
4.2	Install the t:connect Mobile App	69
4.3	Connecting to a Smartphone	71
4.4	Set Mobile Notifications	74
4.5	Mobile Connection Security	74
4.6	Lost Pump Connection	75

4.7	Restart the t:connect Mobile App	76
4.8	t:connect Mobile App Dashboard	78
4.9	t:connect Mobile App Bolus Screen	80
4.10	t:connect Mobile App Notifications Screen	82
4.11	t:connect Mobile App Settings	84

Chapter 5 • Getting Started

5.1	Charging the t:slim X2 Pump	88
5.2	Turning the Pump On	89
5.3	Using the Touchscreen	89
5.4	Turning the t:slim X2 Pump Screen On	90
5.5	Turning the Pump Screen Off	90
5.6	Turning the Pump Off	90
5.7	Unlocking the t:slim X2 Pump Screen	90
5.8	Edit Time	91
5.9	Edit Date	91
5.10	Basal Limit	91
5.11	Display Settings	92
5.12	Sound Volume	93
5.13	Turn Security PIN On or Off	93
5.14	Mobile Connection	94

Chapter 6 • Insulin Delivery Settings

6.1	Personal Profiles Overview	96
6.2	Creating a New Profile	96
6.3	Programming a New Personal Profile	99
6.4	Editing or Reviewing an Existing Profile	101
6.5	Duplicating an Existing Profile	102
6.6	Activating an Existing Profile	102
6.7	Renaming an Existing Profile	102

6.8	Deleting an Existing Profile	103
6.9	Starting a Temporary Basal Rate	103
6.10	Stopping a Temp Rate	104

Chapter 7 • Infusion Site Care and Loading Cartridge

7.1	Infusion Site Selection and Care	106
7.2	Cartridge Instructions for Use	108
7.3	Filling and Loading a t:slim X2 Cartridge	108
7.4	Filling Tubing	113
7.5	Filling Cannula	115
7.6	Setting Site Reminder	116

Chapter 8 • Manual Bolus

8.1	Manual Bolus Overview	118
8.2	Initiating a Bolus	119
8.3	Correction Bolus Calculation	119
8.4	Bolus Override	123
8.5	Food Bolus Using Units	123
8.6	Food Bolus Using Grams	123
8.7	Extended Bolus	124
8.8	Max Bolus	125
8.9	Quick Bolus	126
8.10	Canceling or Stopping a Bolus Using the Pump	128
8.11	Bolus Delivery Using the t:connect Mobile App	128
8.12	Correction Bolus Using the t:connect Mobile App	129
8.13	Bolus Override Using the t:connect Mobile App	132
8.14	Food Bolus Using the t:connect Mobile App	132
8.15	Canceling or Stopping a Bolus Using the t:connect Mobile App	133
8.16	Pump Connection Lost	134

Chapter 9 • Starting, Stopping, or Resuming Insulin

9.1	Starting Insulin Delivery	138
9.2	Stopping Insulin Delivery	138
9.3	Resuming Insulin Delivery	138
9.4	Disconnecting When Using Control-IQ Technology	139

Chapter 10 • t:slim X2 Insulin Pump Information and History

10.1	t:slim X2 Pump Info	142
10.2	t:slim X2 Pump History	142
10.3	t:connect Mobile App Info	143

Chapter 11 • t:slim X2 Insulin Pump Reminders

11.1	Low BG Reminder	146
11.2	High BG Reminder	146
11.3	After Bolus BG Reminder	147
11.4	Missed Meal Bolus Reminder	148
11.5	Site Reminder	148

Chapter 12 • User Settable Alerts and Alarms

12.1	Low Insulin Alert	150
12.2	Auto-Off Alarm	150
12.3	Max Basal Alert	151

Chapter 13 • t:slim X2 Insulin Pump Alerts

13.1	Low Insulin Alert	155
13.2	Low Power Alerts	156
13.3	Incomplete Bolus Alert	158
13.4	Incomplete Temp Rate Alert	160
13.5	Incomplete Load Sequence Alerts	161
13.6	Incomplete Setting Alert	164

13.7	Basal Rate Required Alert	165
13.8	Max Hourly Bolus Alert	166
13.9	Max Bolus Alerts	167
13.10	Max Basal Alert	169
13.11	Min Basal Alerts	170
13.12	Connection Error Alert	172
13.13	Pairing Code Timeout	173
13.14	Power Source Alert	174
13.15	Data Error Alert	175
13.16	Pump Connection Lost Alert - t:connect Mobile App	176

Chapter 14 • t:slim X2 Insulin Pump Alarms

14.1	Resume Pump Alarm	179
14.2	Low Power Alarm	180
14.3	Empty Cartridge Alarm	181
14.4	Cartridge Error Alarm	182
14.5	Cartridge Removal Alarm	183
14.6	Temperature Alarm	184
14.7	Occlusion Alarms	185
14.8	Screen On/Quick Bolus Button Alarm	187
14.9	Altitude Alarm	188
14.10	Reset Alarm	189

Chapter 15 • t:slim X2 Insulin Pump Malfunction

15.1	Malfunction	192

Chapter 16 • Taking Care of Your Pump

16.1	Overview	196

Chapter 17 • Lifestyle Issues and Travel

17.1	Overview	198

Section 3: CGM Features

Chapter 18 • Important Safety Information When Using the t:slim X2 Insulin Pump with Dexcom G6 CGM

18.1	Warnings	202
18.2	Precautions	203
18.3	Potential Benefits From Using the t:slim X2 Insulin Pump with CGM	205
18.4	Possible Risks From Using the t:slim X2 Insulin Pump with CGM	206

Chapter 19 • Getting to Know Your CGM System

19.1	CGM Terminology	208
19.2	Explanation of CGM Pump Icons	210
19.3	CGM Lock Screen	212
19.4	CGM Home Screen	214
19.5	My CGM Screen	216

Chapter 20 • CGM Overview

20.1	CGM System Overview	220
20.2	Device Connection Overview	220
20.3	Receiver (t:slim X2 Insulin Pump) Overview	221
20.4	Transmitter Overview	221
20.5	Sensor Overview	222

Chapter 21 • CGM Settings

21.1	About Bluetooth Technology	224
21.2	Disconnecting from the Dexcom Receiver	224

21.3	Setting CGM Volume	224
21.4	CGM Info	227
Chapter 22 • Setting CGM Alerts		
22.1	Setting Your High Glucose Alert and Repeat Feature	230
22.2	Setting Your Low Glucose Alert and Repeat Feature	231
22.3	Rate Alerts	232
22.4	Setting Your Rise Alert	232
22.5	Setting Your Fall Alert	233
22.6	Setting Your Out of Range Alert	233
Chapter 23 • Starting or Stopping a CGM Sensor Session		
23.1	Enter Your Transmitter ID	236
23.2	Start the Sensor	236
23.3	Sensor Startup Period	238
23.4	Automatic Sensor Shut-Off	239
23.5	Ending a Sensor Session Before Automatic Shut-Off	240
23.6	Removing the Sensor and Transmitter	240
Chapter 24 • Calibrating Your CGM System		
24.1	Calibration Overview	242
24.2	Startup Calibration	242
24.3	Calibration BG Value and Correction Bolus	244
24.4	Reasons You May Need to Calibrate	244
Chapter 25 • Viewing CGM Data on Your t:slim X2 Insulin Pump		
25.1	Overview	246
25.2	CGM Trend Graphs	247
25.3	Rate of Change Arrows	248
25.4	CGM History	250

25.5	Missed Readings	250

Chapter 26 • CGM Alerts and Errors

26.1	Startup Calibration Alert	253
26.2	Second Startup Calibration Alert	254
26.3	12 Hour Calibration Alert	255
26.4	Incomplete Calibration	256
26.5	Calibration Timeout	257
26.6	Wait 15 Minute Calibration Error Alert	258
26.7	Calibration Required Alert	259
26.8	CGM High Alert	260
26.9	CGM Low Alert	261
26.10	CGM Fixed Low Alert	262
26.11	CGM Rise Alert	263
26.12	CGM Rapid Rise Alert	264
26.13	CGM Fall Alert	265
26.14	CGM Rapid Fall Alert	266
26.15	Unknown Sensor Glucose Reading	267
26.16	Out of Range Alert	268
26.17	Low Transmitter Battery Alert	269
26.18	Transmitter Error	270
26.19	Failed Sensor Error	271
26.20	CGM Unavailable	272
26.21	CGM System Error	273

Chapter 27 • CGM Troubleshooting

27.1	CGM Pairing Troubleshooting	276
27.2	Calibration Troubleshooting	276
27.3	Unknown Sensor Reading Troubleshooting	276
27.4	Out of Range/No Antenna Troubleshooting	277

27.5	Failed Sensor Troubleshooting	277
27.6	Sensor Inaccuracies	278

Section 4: Control-IQ Technology Features

Chapter 28 • Control-IQ Technology Important Safety Information

28.1	Control-IQ Warnings	282
28.2	Control-IQ Precautions	283

Chapter 29 • Getting to Know Control-IQ Technology

29.1	Responsible Use of Control-IQ Technology	286
29.2	Explanation of Control-IQ Technology Icons	287
29.3	Control-IQ Lock Screen	288
29.4	Control-IQ Home Screen	290
29.5	Control-IQ Screen	292

Chapter 30 • Introduction to Control-IQ Technology

30.1	Control-IQ Technology Overview	296
30.2	How Control-IQ Technology Works	296
30.3	Control-IQ Technology and Activity	305

Chapter 31 • Configuring and Using Control-IQ Technology

31.1	Required Settings	310
31.2	Set Weight	310
31.3	Set Total Daily Insulin	311
31.4	Turn Control-IQ Technology On or Off	311
31.5	Schedule Sleep	311
31.6	Enable or Disable a Sleep Schedule	313
31.7	Manually Start or Stop Sleep	314

31.8	Manually Start or Stop Exercise	314
31.9	Control-IQ Technology Information on Your Screen	315

Chapter 32 • Control-IQ Technology Alerts

32.1	Out of Range Alert – Control-IQ Technology Disabled	319
32.2	Out of Range Alert – Control-IQ Technology Enabled	320
32.3	Control-IQ Technology Low Alert	321
32.4	Control-IQ High Alert	322
32.5	Max Insulin Alert	323

Chapter 33 • Overview of Control-IQ Technology Clinical Studies

33.1	Introduction	326
33.2	Software Version History	327
33.3	The DCLP3 Trial	328
33.4	The DCLP5 Trial	340
33.5	The PEDAP Trial	351
33.6	The PEDAP Extension Phase	361
33.7	The Higher-IQ Trial	370

Section 5: Technical Specifications and Warranty

Chapter 34 • Technical Specifications

34.1	Overview	380
34.2	t:slim X2 Pump Specifications	380
34.3	t:slim X2 Pump Options and Settings	385
34.4	t:slim X2 Pump Performance Characteristics	388
34.5	Electromagnetic Compatibility	393
34.6	Wireless Co-existence and Data Security	393

34.7	t:connect Mobile App Security	394
34.8	Electromagnetic Emissions	395
34.9	Electromagnetic Immunity	396
34.10	Quality of Wireless Service	398
34.11	Wireless Technology	399
34.12	FCC Notice Concerning Interference	400
34.13	Warranty Information	400
34.14	Returned Goods Policy	404
34.15	t:slim X2 Insulin Pump Event Data (Black Box)	404
34.16	Product List	405

Index

406

This Page is Intentionally Left Blank

1 Before You Begin

CHAPTER 1

Introduction

CHAPTER 1 • Introduction

1.1 Conventions of This Guide

The following are conventions used in this user guide (such as terms, icons, text formatting, and other conventions) along with their explanations.

Formatting Conventions

Convention	Explanation
Bolded Text	Text that is in bold in a sentence or step indicates an on-screen icon or physical button name.
Italic Text	Text that is in italics indicates the name of a screen or menu on the pump display.
Numbered Items	Numbered items are step-by-step instructions for how to perform a specific task.
Blue Text	Calls out a reference to a separate user guide location or website link.

Terminology Definitions

Term	Definition
Touchscreen	The front glass screen of your pump, which displays all programming, operating, and alarm/alert information.
Tap	Quickly and lightly touch the screen with your finger.
Press	Use your finger to depress a physical button (the Screen On/Quick Bolus button is the only physical/hardware button on your pump).
Hold	Keep pressing a button or touching an icon or menu until its function is complete.
Menu	A list of options on your touchscreen that allow you to perform specific tasks.
Icon	An image on your touchscreen that indicates an option or item of information, or a symbol on the back of your pump or its packaging.

Symbol Definitions

Symbol	Definition
	Calls out an important note regarding the use or operation of the system.
	Calls out safety precautions which, if ignored, could result in minor or moderate injury.
	Calls out critical safety information which, if ignored, could result in serious injury or death.
	Indicates how the pump responds to the previous instruction.

CHAPTER 1 • Introduction

1.2 Explanation of Symbols

The following are symbols (and their descriptions), which you may find on your pump, pump supplies and/or their packaging. These symbols tell you about the proper and safe use of the pump. Some of these symbols may not be relevant in your region, and are listed for informational purposes only.

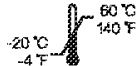
Explanation of t:slim X2 Insulin Pump Symbols

Symbol	Definition
	Caution
	Follow instructions for use
	Consult instructions for use
	For sale by or on the order of a physician only (United States)
	Catalogue number
	Batch code
	International Protection (IP) Code
	Manufacturer

Symbol	Definition
	Type BF Applied Part (patient isolation, not defibrillator protected)
	Non-ionizing Radiation
	Magnetic Resonance (MR) Unsafe; keep away from magnetic resonance imaging (MRI) equipment
	Serial number
	Manufacturer number
	Medical device
	Model number
	Authorized Representative in the European Community

Explanation of t:slim X2 Insulin Pump Symbols (Continued)

Symbol	Definition
	Date of manufacture
	Importer (except United States)
	Direct Current (DC) voltage
	Separate collection for waste electrical and electronic equipment
	Electric Equipment Designed Primarily for Indoor Use
	IEC Class II Equipment
	Use U-100 insulin only
	Wall Power USB Adapter
	Cartridge Removal Tool
	USB Cable

Symbol	Definition
	Indicates the authorized representative in Switzerland
	CE marking of conformity
	Regulatory Compliance Mark
	Humidity limitation
	Temperature limit
	Keep Dry
	Outlet Adapter
	Pump Case
	User Guide

CHAPTER 1 • Introduction

1.3 System Description

The t:slim X2™ insulin pump with Control-IQ™ technology, referred to as the “pump” or the “t:slim X2 pump,” consists of the t:slim X2 insulin pump, the embedded Control-IQ algorithm, and the t:slim X2 3mL (300 units) cartridge. The t:slim X2 pump must be used with a compatible infusion set.

The t:slim X2 pump with Control-IQ technology may be used in combination with a compatible continuous glucose monitor (CGM).

The t:connect™ mobile app can also be used with the System as a method of viewing pump information and limited control of the pump through your smartphone. This functionality is limited to compatible smartphone operating systems and pump software versions.

The Dexcom G6 CGM is compatible with the t:slim X2 insulin pump with Control-IQ technology. The Dexcom G6 transmitter may be referred to as the “transmitter.” The Dexcom G6 sensor may be referred to as the “sensor.” Together, the Dexcom G6 transmitter

and Dexcom G6 sensor may be referred to as the “CGM.”

The pump delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The disposable cartridge is filled with up to 300 units of U-100 insulin and attached to the pump. The cartridge is replaced every 48–72 hours.

The Control-IQ automated insulin dosing feature is an algorithm embedded in the t:slim X2 pump software. This feature enables the t:slim X2 pump to automatically adjust the delivery of insulin based on CGM sensor readings; however, the feature is not a substitute for your own active diabetes management, including giving a bolus for meals. Control-IQ technology utilizes the CGM sensor readings and other data to calculate a predicted glucose value 30 minutes into the future. For more information on how Control-IQ technology is activated, see Chapter 30 Introduction to Control-IQ Technology.

The pump can be used for basal and bolus insulin delivery with or without a CGM. If a CGM is not used, sensor

glucose readings will not be sent to the pump display and you will not be able to use Control-IQ technology.

The sensor is a disposable device that is inserted under the skin to continuously monitor glucose levels. The transmitter connects to the sensor pod and wirelessly sends readings to the pump, which acts as a receiver for the therapeutic CGM, every 5 minutes. The pump shows sensor glucose readings, a trend graph, as well as the direction and rate of change arrows.

The sensor measures glucose in the interstitial fluid under the skin—not in blood, and sensor readings are not identical to readings from a blood glucose (BG) meter.

The t:connect mobile app enables you to connect a smartphone to the pump using *Bluetooth*® wireless technology to display your pump information and perform some pump functions on the smartphone as well as display pump notifications. The t:connect mobile app can transmit pump and therapy data from the pump to the cloud as long as your smartphone is connected to the internet. Download the t:connect

mobile app from Google Play™ or from the App Store® and visit support.tandemdiabetes.com for installation instructions.

NOTE

For an up-to-date list of supported smartphones, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

PRECAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

1.4 About this User Guide

This user guide covers important information on how to operate your System. It provides step-by-step instructions to help you properly program, manage, and care for the System. It also provides important warnings and precautions on proper operation and technical information to ensure your safety.

The user guide is organized into sections. Section 1 provides important

information you need to know before you start using the System. Section 2 covers instructions for using the t:slim X2 pump and using the t:connect mobile app with the pump. Section 3 covers instructions for using CGM with your pump. Section 4 covers instructions for using Control-IQ technology on your pump. Section 5 provides information on the technical specifications of your pump.

The pump screens used in this user guide demonstrate how to use features, and are examples only. They should not be considered suggestions for your individual needs.

For customers in the United States, product information, including electronic versions of the user guide, t:connect Getting Started Guide, t:connect user guides, and a CGM training tutorial, are available at tandemdiabetes.com. Product information for users outside the United States can be provided by your local Tandem distributor.

1.5 Indications for Use

The t:slim X2 insulin pump with interoperable technology (the Pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

The Pump is intended for single patient, home use and requires a prescription.

The Pump is indicated for use in persons two years of age and greater.

Control-IQ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when

CHAPTER 1 • Introduction

the glucose value is predicted to exceed a predefined threshold.

Control-IQ technology is intended for the management of Type 1 diabetes mellitus in persons two years of age and greater.

Control-IQ technology is intended for single patient use and requires a prescription.

1.6 Compatible Insulins

The t:slim X2 insulin pump with Control-IQ technology is designed for use with rapid acting insulin analogs that have been tested and found to be safe for use in the pump:

- NovoLog/NovoRapid U-100 insulin
- Humalog U-100 insulin

NovoLog/NovoRapid is compatible with the system for use up to 72 hours (3 days). Humalog is compatible with the system for use up to 48 hours (2 days).

If you have questions about using other insulins, contact your healthcare provider. Always consult your

healthcare provider and refer to the insulin labeling prior to use.

1.7 Compatible iCGMs

Compatible CGMs include the following iCGMs:

- Dexcom G6 CGM

For information about Dexcom G6 CGM product specifications and performance characteristics, visit the manufacturer's website for applicable product instructions.

The Dexcom G6 sensors and transmitters are sold and shipped separately by Dexcom.

NOTE

The Dexcom G6 CGM currently allows pairing with one medical device at a time (either the t:slim X2 pump or the Dexcom receiver), but you can still use the Dexcom G6 CGM app and your t:slim X2 pump simultaneously using the same transmitter ID.

NOTE

The Mobile Connection setting on your Pump does not relate to the Bluetooth connection

between your CGM and Pump. For connecting a CGM to your Pump, see Section 21.1 About Bluetooth Technology. For connecting your Pump to the t:connect mobile app, see Section 4.3 Connecting to a Smartphone.

NOTE

Product instructions for the Dexcom G6 CGM System includes important information on how to use the Dexcom G6 CGM information (including sensor glucose readings, trend graph, trend arrow, alarm/alerts) to make treatment decisions. Ensure that you have reviewed this information and discussed it with your healthcare provider, who can guide you in correctly using your Dexcom G6 CGM information when making treatment decisions.

1.8 Important User Information

Review all instructions in this user guide before using the System.

If you are not able to use the System according to the instructions in this user guide and other applicable user guides, you may be putting your health and safety at risk.

If you are new to using CGM, continue using your BG meter until you are familiar with CGM usage.

If you are currently using the pump without Dexcom G6 CGM, or if you are currently using Dexcom G6 CGM, it is still very important that you review all instructions in this user guide before using the combined System.

Pay special attention to Warnings and Precautions in this user guide. Warnings and Precautions are identified with a  or  symbol.

If you still have questions after reading this user guide, contact Customer Technical Support 24 hours a day, 7 days a week.

1.9 Important Pediatric User Information

The following recommendations are meant to help younger users and their caregivers program, manage, and care for the System.

Younger children may inadvertently press or tap the pump or the t:connect

mobile app, leading to unintentional delivery of insulin.

It is the responsibility of the healthcare provider and caregiver to determine if the user is appropriate for treatment with this device and the t:connect mobile app.

We recommend reviewing the Quick Bolus and Security PIN capabilities of the pump and determining how they best fit with your care plan. These features are detailed in Chapters 8 Manual Bolus and 5 Getting Started.

Inadvertent dislodgement of the infusion site may occur more frequently with children so consider securing the infusion site and tubing.

WARNING

Control-IQ technology should not be used by people who use less than 5 units of insulin per day and should not be used in patients who weigh less than 20 pounds (9 kilograms), which are the minimum inputs required to initiate Control-IQ technology and for it to operate safely.

WARNING

The t:slim X2 insulin pump with Control-IQ technology should not be used in children under the age of two years old.

WARNING

DO NOT allow small children (either pump users or non-users) to ingest small parts, such as the rubber USB port cover and cartridge components. Small parts could pose a choking hazard. If ingested or swallowed, these small component pieces may cause internal injury or infection.

WARNING

The pump includes parts (such as the USB cable and infusion set tubing) that could pose a strangulation or asphyxiation hazard. Always use the appropriate length of infusion set tubing and arrange cables and tubing to minimize the risk of strangulation. **ENSURE** that these parts are stored in a secure place when not in use.

WARNING

For patients who do not self-manage their disease, the Security PIN function should **ALWAYS** be on when the pump is not being used by a caregiver. The Security PIN function is intended to prevent inadvertent screen taps or button presses that may lead to insulin delivery

CHAPTER 1 • Introduction

or changes in the pump settings. These changes can potentially lead to hypoglycemia (low BG) or hyperglycemia (high BG) events. See Section 5.13 Turn Security PIN On or Off for details on how to turn the Security PIN function on.

⚠ WARNING

For patients whose insulin administration is managed by a caregiver, **ALWAYS** turn off the Quick Bolus feature to avoid inadvertent bolus delivery. If the Security PIN is turned on, the Quick Bolus feature is automatically disabled. Inadvertent screen taps, button presses, or tampering with the insulin pump could result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events. See Section 5.13 Turn Security PIN On or Off for details on how to turn the Security PIN function off.

1.10 Emergency Kit

You should always have an appropriate emergency kit with you. At the very least, this kit should include an insulin syringe and vial of insulin or a prefilled insulin pen as a backup for emergency situations. Talk with your healthcare

provider regarding what items this kit should include.

Some examples of what to include in your everyday emergency kit are:

- BG testing supplies: meter, strips, control solution, lancets, meter batteries
- Fast-acting carbohydrate to treat low BG
- Extra snack for longer coverage than fast-acting carbohydrate
- Glucagon emergency kit
- Rapid-acting insulin and syringes or a prefilled insulin pen and pen needles
- Infusion sets (minimum of 2)
- Insulin pump cartridges (minimum of 2)
- Infusion site preparation products (antiseptic wipes, skin adhesive)
- Diabetes identification card or jewelry

2 t:slim X2 Insulin Pump Features

CHAPTER 2

Important Safety Information

CHAPTER 2 • Important Safety Information

The following includes important safety information related to your t:slim X2™ pump and its components. The information presented in this chapter does not represent all warnings and precautions related to the System. Pay attention to other warnings and precautions listed throughout this user guide as they relate to special circumstances, features, or users.

2.1 t:slim X2 Insulin Pump Warnings

▲ WARNING

DO NOT start to use your pump or the t:connect™ mobile app before reading the user guide. Failure to follow the instructions in this user guide can result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events. If you have questions or need further clarification on your pump use, ask your healthcare provider or call Customer Technical Support.

▲ WARNING

DO NOT start to use your pump before you have been appropriately trained on its use by a certified trainer or through the training materials available online if you are updating your pump.

Consult with your healthcare provider for your individual training needs for the pump. Failure to complete the necessary training on your pump could result in serious injury or death.

▲ WARNING

ONLY use U-100 Humalog or U-100 NovoLog with your pump. Only U-100 Humalog and U-100 NovoLog have been tested and found to be compatible for use in the pump. Use of insulin with greater or lesser concentration can result in an over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT put any other drugs or medications inside your pump cartridge. The pump is designed only for continuous subcutaneous insulin infusion (CSII) using U-100 Humalog or U-100 NovoLog insulin. Use of other drugs or medications can damage the pump and result in injury if infused.

▲ WARNING

DO NOT use manual injections or inhaled insulins while using the pump. Using insulin not provided by the pump can cause the system to over deliver insulin, which can lead to severe hypoglycemia (low BG) events.

▲ WARNING

The pump is not intended for anyone unable or unwilling to:

- » Test blood glucose (BG) levels as recommended by a healthcare provider
- » Demonstrate adequate carbohydrate counting skills
- » Maintain sufficient diabetes self-care skills
- » See healthcare provider(s) regularly

The user must also have adequate vision and/or hearing in order to recognize all functions of the pump, including alerts, alarms, and reminders.

▲ WARNING

DO NOT start to use your pump before consulting with your healthcare provider to determine which features are most appropriate for you. Only your healthcare provider can determine and help you adjust your Basal Rate(s), Carb Ratio(s), Correction Factor(s), Target BG, and duration of insulin action. In addition, only your healthcare provider can determine your CGM settings and how you should use your sensor trend information to help you manage your diabetes. Incorrect settings can result in over delivery or under delivery of

insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

ALWAYS be prepared to inject insulin with an alternative method if delivery is interrupted for any reason. Your pump is designed to deliver insulin reliably, but because it uses only rapid-acting insulin, you will not have long-acting insulin in your body. Failure to have an alternative method of insulin delivery can lead to very high BG or Diabetic Ketoacidosis (DKA).

▲ WARNING

ONLY use cartridges and infusion sets with matching connectors and follow their instructions for use. Failure to do so may result in over delivery or under delivery of insulin and may cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT place your infusion set on any scars, lumps, moles, stretch marks or tattoos. Placing your infusion set in these areas can cause swelling, irritation or infection. This can affect insulin absorption and cause high or low BG.

▲ WARNING

ALWAYS carefully follow the instructions for use accompanying your infusion set for proper insertion and infusion site care, as failure to do so could result in over delivery or under delivery of insulin or infection.

▲ WARNING

NEVER fill your tubing while your infusion set is connected to your body. Always ensure that the infusion set is disconnected from your body before filling the tubing. Failure to disconnect your infusion set from your body before filling the tubing can result in over delivery of insulin. This can cause hypoglycemia (low BG) events.

▲ WARNING

NEVER reuse cartridges or use cartridges other than those manufactured by Tandem Diabetes Care. Use of cartridges not manufactured by Tandem Diabetes Care or reuse of cartridges may result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

ALWAYS twist the tubing connector between the cartridge tubing and the infusion set tubing an extra quarter of a turn to ensure a secure connection. A loose connection can cause

insulin to leak, resulting in under delivery of insulin. If the connection comes loose, disconnect the infusion set from your body before tightening. This can cause hyperglycemia (high BG).

▲ WARNING

DO NOT disconnect the tubing connector between the cartridge tubing and the infusion set tubing. If the connection comes loose, disconnect the infusion set from your body before tightening. Failure to disconnect before tightening can result in over delivery of insulin. This can cause hypoglycemia (low BG).

▲ WARNING

DO NOT remove or add insulin from a filled cartridge after loading onto the pump. This will result in an inaccurate display of the insulin level on the *Home* screen and you could run out of insulin before the pump detects an empty cartridge. This can cause very high BG, or Diabetic Ketoacidosis (DKA).

▲ WARNING

DO NOT deliver a bolus until you have reviewed the calculated bolus amount. If you deliver an insulin amount that is too high or too low, this could cause hypoglycemia (low BG) or hyperglycemia (high BG) events. You can always

CHAPTER 2 • Important Safety Information

adjust the insulin units up or down before you decide to deliver your bolus.

⚠ WARNING

ALWAYS use the USB cable provided with your t:slim X2 insulin pump to minimize the risk of fires or burns.

⚠ WARNING

DO NOT allow small children (either pump users or non-users) to ingest small parts, such as the rubber USB port cover and cartridge components. Small parts could pose a choking hazard. If ingested or swallowed, these small component pieces may cause internal injury or infection.

⚠ WARNING

The pump includes parts (such as the USB cable and infusion set tubing) that could pose a strangulation or asphyxiation hazard. **ALWAYS** use the appropriate length of infusion set tubing and arrange cables and tubing to minimize the risk of strangulation. **ENSURE** that these parts are stored in a secure place when not in use.

⚠ WARNING

For patients who do not self-manage their disease, the Security PIN function should **ALWAYS** be on when the pump is not being

used by a caregiver. The Security PIN function is intended to prevent inadvertent screen taps or button presses that may lead to insulin delivery or changes in the pump settings. These changes can potentially lead to hypoglycemic or hyperglycemic events.

⚠ WARNING

For patients whose insulin administration is managed by a caregiver, **ALWAYS** turn off the Quick Bolus feature to avoid inadvertent bolus delivery. If the Security PIN is turned on, the Quick Bolus feature is automatically disabled. Inadvertent screen taps, button presses, or tampering with the insulin pump could result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

DO NOT change your infusion set before bedtime or if you will not be able to test your BG 1–2 hours after the new infusion set is placed. It is important to confirm that the infusion set is inserted correctly and delivering insulin. It is also important to respond quickly to any problems with the insertion to ensure continued insulin delivery.

⚠ WARNING

Use of accessories, cables, adapters, and chargers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches to any part of the t:slim X2 pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ WARNING

Some skin care products such as lotions, sunscreens, and insect repellents can cause cracks in the plastic used to manufacture the pump and cartridge. **DO NOT** allow these

products to come in contact with the pump or cartridge. **ALWAYS** remove your pump before applying these products and **ALWAYS** wash your hands before handling your pump or cartridge after using such products. **ALWAYS** change your cartridge if it becomes exposed to such products and immediately clean your pump. Failure to do so may result in damage to the pump and cartridge and in some cases over or under delivery of insulin.

2.2 Magnetic Resonance Imaging Safety

⚠ WARNING

The System is magnetic resonance (MR) unsafe. You must take off your pump, transmitter, and sensor and leave them outside the procedure room.

2.3 Radiology and Medical Procedures and Your t:connect X2 System

Please review your smartphone manufacturer's instructions before using the t:connect mobile app during any of the procedures listed below.

⚠ WARNING

ALWAYS notify the provider/technician about your diabetes and your pump. If you need to discontinue use of the pump for medical procedures, follow your healthcare provider's instructions to replace missed insulin when you reconnect to the pump. Check your BG before disconnecting from the pump and again when you reconnect and treat high BG levels as recommended by your healthcare provider.

⚠ WARNING

DO NOT expose your pump, transmitter, or sensor to:

- » X-ray
- » Computed Tomography (CT) scan
- » Positron Emission Tomography (PET) scan
- » Other exposure to radiation

⚠ WARNING

There is no need to disconnect for electrocardiograms (EKGs) or colonoscopies. If you have questions, contact Customer Technical Support.

⚠ WARNING

DO NOT use the pump if you have a condition which, in the opinion of your healthcare

provider, would put you at risk. Examples of individuals who should not use the pump include those with uncontrolled thyroid disease, renal failure (e.g. dialysis or eGFR <30), hemophilia, or another major bleeding disorder, or unstable cardiovascular disease.

⚠ WARNING

DO NOT expose your pump, transmitter, or sensor to:

- » Pacemaker/Automatic Implantable Cardioverter Defibrillator (AICD) placement or reprogramming
- » Cardiac Catheterization
- » Nuclear Stress Test

You must take off your pump, transmitter, and sensor and leave them outside the procedure room if you are going to have any of the above medical procedures.

⚠ WARNING

There are other procedures where you should proceed with caution:

- » **Laser Surgery** – Your System can usually be worn during the procedure. However, some lasers can create

CHAPTER 2 • Important Safety Information

interference and cause the System to alarm.

- » **General Anesthesia** – Depending on the equipment being used, you may or may not need to remove your System. Be sure to ask your healthcare provider.

2.4 t:connect Mobile App Warnings

⚠ WARNING

DO NOT start to use the bolus feature of the t:connect mobile app before you have been appropriately trained on its use. Failure to follow the instructions in this user guide and in-app help on the bolus feature of the t:connect mobile app could result in delay of therapy. If the information displayed to you in your t:connect mobile app does not match your signs and symptoms, **ALWAYS** refer to the t:slim X2 insulin pump before making any treatment decisions.

⚠ WARNING

DO NOT use a smartphone that has been jailbroken or rooted, or with Android developer mode on. Data may become vulnerable if you install the t:connect mobile app on a smartphone that has been jailbroken or rooted, or uses an unreleased or pre-released operating

system. Only download the t:connect mobile app on Google Play™ or from the App Store®. See Chapter 4 Getting to Know Your t:connect Mobile App for t:connect mobile app installation.

⚠ WARNING

Any time you request any bolus, you have 10 seconds to cancel the bolus after requesting it to completely avoid insulin delivery. Both the pump and the t:connect mobile app will say “requesting bolus” during this time as long as your pump and the t:connect mobile app are connected. You can cancel the bolus from either the pump or the app regardless of how you requested it.

⚠ WARNING

ALWAYS rely on your pump to make therapy decisions when using a smartphone that is incompatible with the Bolus Delivery feature.

⚠ WARNING

Use of accessories, cables, adapters, and chargers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches to any part of the t:slim X2 pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

2.5 t:slim X2 Insulin Pump Precautions

⚠ PRECAUTION

DO NOT open or attempt to repair your insulin pump. The pump is a sealed device that should be opened and repaired only by Tandem Diabetes Care. Modification could result in a safety hazard. If your pump seal is broken, the pump is no longer watertight and the warranty is voided.

⚠ PRECAUTION

CHANGE your infusion set every 48 hours if using Humalog insulin; every 72 hours if using NovoLog insulin. Wash your hands with anti-bacterial soap before handling the infusion set and thoroughly clean the insertion site on your body to avoid infection. Contact your healthcare provider if you have symptoms of infection at your insulin infusion site.

⚠ PRECAUTION

ALWAYS remove all air bubbles from the pump before beginning insulin delivery. Ensure there are no air bubbles when drawing insulin into the filling syringe, hold the pump with the white fill port pointed up when filling the tubing, and ensure that there are no air bubbles in the tubing when filling. Air in the cartridge and tubing takes space where insulin should be and can affect insulin delivery.

⚠ PRECAUTION

CHECK your infusion site daily for proper placement and leaks. **REPLACE** your infusion set if you notice leaks around the site. Improperly placed sites or leaks around the infusion site can result in under delivery of insulin.

⚠ PRECAUTION

CHECK your infusion set tubing daily for any leaks, air bubbles, or kinks. Air in the tubing, leaks in the tubing, or kinked tubing may restrict or stop insulin delivery and result in under delivery of insulin.

⚠ PRECAUTION

CHECK the tubing connection between your cartridge tubing and infusion set tubing daily to ensure it is tight and secure. Leaks around the

tubing connection can result in under delivery of insulin.

⚠ PRECAUTION

ALWAYS check that your cartridge has enough insulin to last through the night before going to bed. If you are sleeping, you could fail to hear the Empty Cartridge Alarm and miss part of your basal insulin delivery.

⚠ PRECAUTION

CHECK your pump's personal settings regularly to ensure they are correct. Incorrect settings can result in over delivery or under delivery of insulin. Consult with your healthcare provider as needed.

⚠ PRECAUTION

ALWAYS make sure that the correct time and date are set on your insulin pump. Not having the correct time and date setting may affect safe insulin delivery. When editing time, always check that the AM/PM setting is accurate, if applicable. AM is to be used from midnight until 11:59 AM. PM is to be used from noon until 11:59 PM.

⚠ PRECAUTION

CONFIRM that the screen display turns on, you can hear audible beeps, feel the pump vibrate,

and see the green LED light blinking around the edge of the **Screen On/Quick Bolus** button when you connect a power source to the USB port. These features are used to notify you about alerts, alarms, and other conditions that require your attention. If these features are not working, discontinue use of the pump and contact Customer Technical Support.

⚠ PRECAUTION

CHECK your pump regularly for potential alarm conditions that may display. It is important to be aware of conditions that may affect insulin delivery and require your attention so you can respond as soon as possible.

⚠ PRECAUTION

DO NOT use the vibrate feature for alerts and alarms during sleep unless otherwise directed by your healthcare provider. Having the volume for alerts and alarms set to high will help ensure that you don't miss an alert or alarm.

⚠ PRECAUTION

ALWAYS look at the screen to confirm correct programming of the bolus amount when you first use the Quick Bolus feature. Looking at the screen will ensure that you are correctly using the beep/vibration commands to program the intended bolus amount.

CHAPTER 2 • Important Safety Information

⚠ PRECAUTION

DO NOT use your pump if you think it might be damaged due to dropping it or hitting it against a hard surface. Check that the pump is working properly by plugging a power source into the USB port and confirming that the display turns on, you hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the **Screen On/Quick Bolus** button. If you are unsure about potential damage, discontinue use of the pump and contact Customer Technical Support.

⚠ PRECAUTION

AVOID exposure of your pump to temperatures below 41°F (5°C) or above 99°F (37°C). Insulin can freeze at low temperatures or degrade at high temperatures. Insulin that has been exposed to conditions outside of the manufacturer's recommended ranges can affect the safety and performance of the pump.

⚠ PRECAUTION

AVOID submerging your pump in fluid beyond a depth of 3 feet (0.91 m) or for more than 30 minutes (IP27 rating). If your pump has been exposed to fluid beyond these limits, check for any signs of fluid entry. If there are signs of fluid entry, discontinue use of the pump and contact Customer Technical Support.

⚠ PRECAUTION

AVOID areas where there may be flammable anesthetics or explosive gases. The pump is not suitable for use in these areas and there is a risk of explosion. Remove your pump if you need to enter these areas.

⚠ PRECAUTION

MAKE SURE to not move further than the length of the USB cable when you are connected to the pump and to a charging source. Moving further than the length of the USB cable may cause the cannula to be pulled out of the infusion site. For this reason it is recommended not to charge the pump while sleeping.

⚠ PRECAUTION

DISCONNECT your infusion set from your body while on high-speed/high gravity amusement park thrill rides. Rapid changes in altitude or gravity can affect insulin delivery and cause injury.

⚠ PRECAUTION

DISCONNECT your infusion set from your body before flying in an aircraft without cabin pressurization or in planes used for aerobatics or combat simulation (pressurized or not). Rapid changes in altitude or gravity can affect insulin delivery and cause injury.

⚠ PRECAUTION

CONSULT your healthcare provider about lifestyle changes such as weight gain or loss, and starting or stopping exercise. Your insulin needs may change in response to lifestyle changes. Your Basal Rate(s) and other settings may need adjustment.

⚠ PRECAUTION

CHECK your BG using a BG meter following a gradual elevation change of up to each 1,000 feet (305 meters), such as when snow skiing or driving on a mountain road. Delivery accuracy can vary up to 15% until 3 units of total insulin have been delivered or elevation has changed by more than 1,000 feet (305 meters). Changes in delivery accuracy can affect insulin delivery and cause injury.

⚠ PRECAUTION

ALWAYS check with your healthcare provider for specific guidelines if you want or need to disconnect from the pump for any reason. Depending on the length of time and reason you are disconnecting, you may need to replace missed basal and/or bolus insulin. Check your BG before disconnecting from the pump and again when you reconnect, and treat high BG levels as recommended by your healthcare provider.

⚠ PRECAUTION

ENSURE that your personal insulin delivery settings are programmed into the pump before use if you receive a warranty replacement pump. Failure to enter your insulin delivery settings could result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events. Consult your healthcare provider as needed.

⚠ PRECAUTION

ALWAYS dispose of used components such as cartridges, syringes, needles, infusion sets, and CGM sensors following local regulations. Needles should be disposed in an appropriate sharps container. Do not attempt to recap needles. Wash your hands thoroughly after handling used components.

⚠ PRECAUTION

If you choose to use a pump case or other accessories not provided by Tandem, **DO NOT** cover the six vent holes on the back of the pump. Covering the vent holes could affect insulin delivery.

2.6 t:connect Mobile App Precautions**⚠ PRECAUTION**

ALWAYS turn Zoom Mode off when using the t:connect mobile app. If your smartphone has Zoom Mode turned on, you should rely on your pump for all therapy decisions.

⚠ PRECAUTION

If you start a manual bolus request on the pump, you must complete it on the pump. You cannot request a bolus from the t:connect mobile app while a bolus request is active on the pump.

⚠ PRECAUTION

Pump notifications cannot be cleared from your t:connect mobile app. Pump Alerts, Alarms, and Notifications can be viewed on your smartphone, but must be cleared on the t:slim X2 pump.

⚠ PRECAUTION

The t:connect mobile app receives data from the connected pump via a secure Bluetooth wireless technology connection. If the Bluetooth connection between the pump and the t:connect mobile app is lost, the t:connect mobile app will not display current insulin pump information and

cannot be used to request a bolus. To help maintain the wireless connection between the insulin pump and the t:connect mobile app, it is recommended the smartphone running the t:connect mobile app is within five feet of the compatible insulin pump.

⚠ PRECAUTION

ALWAYS ensure your pump has established a Bluetooth wireless connection with your smartphone before you use the t:connect mobile app. Confirm that the information displayed to you matches your signs and symptoms.

⚠ PRECAUTION

Use of the t:connect mobile app together with your insulin pump may impact the battery life of your pump due to the wireless data transmission between the devices.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. If you close or force stop your t:connect mobile app, it will not be running in the background.

CHAPTER 2 • Important Safety Information

⚠ PRECAUTION

DO NOT ignore symptoms of high and low glucose. If your t:connect mobile app readings do not match your symptoms, check your pump display and confirm that your pump has established a Bluetooth connection with your smartphone.

⚠ PRECAUTION

ALWAYS rely on your pump for therapy decisions if:

- » Your smartphone is incompatible with the Bolus Delivery feature of the t:connect mobile app
- » Your smartphone is lost or damaged
- » Your smartphone loses Bluetooth connectivity with your pump

⚠ PRECAUTION

DO NOT update your smartphone operating system prior to confirming that it is compatible with the Bolus Delivery plus Display and Data Upload feature of the t:connect mobile app. If you update to an incompatible operating system version, you will lose the ability to request, stop, or cancel a bolus from the t:connect mobile app.

⚠ PRECAUTION

DISCONTINUE use of the t:connect mobile app if your smartphone is damaged, or if a significant portion of its display is damaged or does not illuminate.

⚠ PRECAUTION

The t:connect mobile app is not intended to replace self-monitoring practices as advised by a physician.

⚠ PRECAUTION

The t:connect mobile app is not intended for use by anyone unable to use a smartphone proficiently. Users must have adequate vision and/or hearing in order to use the t:connect mobile app.

⚠ PRECAUTION

Use of mobile devices not complying with either IEC 60950-1, IEC 62368-1, or an equivalent standard may increase the risk of electrical hazards.

Supported mobile devices and the charging equipment provided by their manufacturers are compliant with appropriate electrical safety standards (IEC 60950-1, IEC 62368-1, or equivalent). For more information on supported devices, please visit

tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

2.7 Tandem Cybersecurity Preventative Measures

Medical devices, like other computer systems, can be vulnerable to cybersecurity risks, potentially impacting the safety and effectiveness of the device. Incorrect use of the t:slim X2 insulin pump or your failure to follow the instructions, precautions, and warnings in this user guide may result in an inoperable pump or expose your t:slim X2 insulin pump to cybersecurity risks.

- Keep your pump, smartphone, and t:connect mobile app in your control or on your person at all times.
- Always disconnect your pump from the computer and USB cable when not using it to upload pump data or perform software updates with the Tandem Device Updater.
- Do not share your pump's serial number or t:connect mobile app

pairing code with any untrusted individual. Do not write these numbers down anywhere they can be accessed by an untrusted individual.

- Do not connect to or allow any third-party devices to pair with your pump that are not included as part of the Tandem system. See 1.3 System Description for a full system description.
- Do not use any software or third-party applications which have not been authorized by Tandem as being safe for use with your pump.
- Only attempt to perform software updates using the authorized Tandem Device Updater.

Contact Tandem's Customer Technical Support if you suspect your pump may have been compromised by any cybersecurity interference or vulnerability.

2.8 Potential Benefits From Using Your Pump

- The pump provides an automated way to deliver basal and bolus insulin. Delivery can be fine-tuned based on up to six customizable Personal Profiles, each with up to 16 time-based settings for Basal Rate, Carb Ratio, Correction Factor, and Target BG. In addition, the temp rate feature allows you to program a temporary Basal Rate change for up to 72 hours.
- The pump gives you the option of delivering a bolus all at once, or delivering a percentage over an extended period of time without navigating to different menus. You can also program a bolus more discreetly using the Quick Bolus feature, which can be used without looking at the pump, and can be programmed in increments of either units of insulin or grams of carbohydrate.
- From the *Bolus* screen, the “calculator within a calculator” feature allows you to enter multiple

carbohydrate values and add them together. The insulin pump's bolus calculator will recommend a bolus based on the entire amount of carbohydrates entered, which can help eliminate guesswork.

- The pump keeps track of the amount of active insulin from food and correction boluses (IOB). When programming additional food or correction boluses, the pump will subtract the amount of IOB from the recommended bolus if your BG is below the target set in your active Personal Profile. This can help prevent insulin stacking, which can lead to hypoglycemia (low BG).
- You can program a number of reminders that will prompt you to retest your BG after a low or high BG is entered, as well as a “Missed Meal Bolus Reminder” which will alert you if a bolus isn't entered during a specified period of time. If activated, these can help reduce the likelihood that you will forget to check your BG or bolus for meals.
- You have the ability to view a variety of data right on your screen,

CHAPTER 2 • Important Safety Information

including the time and amount of your last bolus, your total insulin delivery by day, as well as broken into basal, food bolus, and correction bolus.

2.9 Possible Risks From Using Your Pump

As with any medical device, there are risks associated with using your pump. Many of the risks are common to insulin therapy in general, but there are additional risks associated with continuous insulin infusion and continuous glucose monitoring. Reading your user guide and following the instructions for use are critical for the safe operation of your System. Consult your healthcare provider about how these risks may impact you.

Inserting and wearing an infusion set might cause infection, bleeding, pain or skin irritations (redness, swelling, bruising, itching, scarring, or skin discoloration).

There is a remote chance that an infusion set cannula fragment could remain under your skin if the cannula

breaks while you are wearing it. If you think a cannula has broken under your skin, contact your healthcare provider and call Customer Technical Support.

Other risks associated with infusion sets include occlusions and air bubbles in the tubing or dislodged cannula, which can affect insulin delivery. If your BG does not decrease after initiating a bolus, or you have other unexplained high BG, it is recommended that you check your infusion set for an occlusion or air bubbles, and verify that the cannula has not dislodged. If the condition persists, call Customer Technical Support or seek medical attention as required.

Risks that could result from pump failure include the following:

- possible hypoglycemia (low BG) from over-delivery of insulin due to a hardware defect or software anomaly.
- hyperglycemia (high BG) and ketosis possibly leading to Diabetic Ketoacidosis (DKA) due to pump failure resulting in cessation of insulin delivery due to either a

hardware defect, software anomaly, or infusion set failure. Having a backup method of insulin delivery greatly reduces your risk of severe hyperglycemia or DKA.

2.10 Working with your Healthcare Provider

Any clinical language presented in this user guide is based on the assumption that you have been educated by your healthcare provider on certain terms and how they apply to you in your diabetes management. Your healthcare provider can help you establish diabetes management guidelines that best fit your lifestyle and needs.

Consult your healthcare provider before using the pump to determine which features are most appropriate for you. Only your healthcare provider can determine and help you adjust your Basal Rate(s), insulin-to-carbohydrate ratio(s), Correction Factor(s), Target BG, and duration of insulin action. In addition, only your healthcare provider can determine your CGM settings and how you should use your sensor trend

information to help you manage your diabetes.

2.1.1 Verification of Proper Functionality

Pump Functionality

A power supply (AC adapter with micro-USB connector) is provided with your pump. Before using your pump, ensure that the following occur when you connect a power supply into the USB port of your pump:

- You hear an audible alert
- You see the green light illuminate from the edge around the **Screen On/Quick Bolus** button
- You feel a vibratory alert
- You see a charge symbol (lightning bolt) on the battery level indicator

In addition, before using your pump, ensure the following:

- Press the **Screen On/Quick Bolus** button to turn the screen on so that you can see the display

- When the display screen is on, the touchscreen responds to your finger tap

⚠ PRECAUTION

CONFIRM that the pump screen display turns on, you can hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the **Screen On/Quick Bolus** button when you connect a power source to the USB port. These features are used to notify you about alerts, alarms, and other conditions that require your attention. If these features are not working, discontinue use of your pump and contact Customer Technical Support.

t:connect Mobile App Functionality

Before using the t:connect mobile app, when you connect a smartphone to your pump, ensure the data displayed on your t:connect mobile app matches the data displayed on your pump screen.

⚠ PRECAUTION

ALWAYS ensure your pump has established a Bluetooth wireless connection with your smartphone before you use the t:connect mobile app. Confirm that the information displayed to you matches your signs and symptoms.

This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 3

Getting to Know Your t:slim X2 Insulin Pump

CHAPTER 3 • Getting to Know Your t:slim X2 Insulin Pump

3.1 What your t:slim X2 Pump Package Includes

Your pump package should include the following items:

1. t:slim X2™ insulin pump
2. pump case
3. t:slim X2 Insulin Pump with Control-IQ™ Technology User Guide
4. USB cable
5. wall power USB adapter
6. cartridge removal tool

If any of these items are missing, contact your local customer support.

If you use a CGM, the Dexcom G6 sensors and transmitters are sold and shipped separately.

Your pump is shipped with a clear screen protector. Do not remove the screen protector.

Your pump comes with a protective cover in the place where the cartridge is normally inserted. This cover must be removed and replaced with a cartridge prior to initiating insulin delivery.

The t:slim X2 3 mL cartridge with t:lock™ connector consists of the reservoir chamber and a micro-delivery chamber for the delivery of very small amounts of insulin. A variety of compatible infusion sets with the t:lock connector are available from Tandem Diabetes Care, Inc. The t:lock connector allows a secure connection between the cartridge and the infusion set. Use only t:slim X2 cartridges and compatible infusion sets with t:lock connectors manufactured for Tandem Diabetes Care, Inc.

Your pump also includes consumable components that may require replacement during the life of your pump, including:

- pump case(s)/clip(s)
- screen protector
- USB rubber door
- USB cable

Supply Reordering

To order cartridges, infusion sets, supplies, accessories, screen protectors, please contact your local customer support or your usual supplier of diabetes products.

3.2 Pump Terminology**Basal**

Basal is a slow continuous delivery of insulin, which keeps glucose levels stable between meals and during sleep. It is measured in units per hour (units/hr).

BG

BG is the abbreviation for blood glucose, which is the level of glucose in the blood, measured in mg/dL.

BG Target

BG target is a specific BG or glucose value goal, an exact number, not a range. When a glucose value is entered in the pump, the calculated insulin bolus will be adjusted up or down as needed to attain this target.

Bolus

A bolus is a quick dose of insulin that is usually delivered to cover food eaten or correct high glucose. With the pump it can be delivered as a Standard, a Correction, an Extended, or a Quick Bolus.

Cannula

The cannula is the part of the infusion set that is inserted under the skin through which insulin is delivered.

Carb

Carb or Carbohydrate refers to sugars and starches that the body breaks down into glucose and uses as an energy source, measured in grams.

Carb Ratio

The carb ratio is the number of grams of carbohydrate that 1 unit of insulin will cover. Also known as insulin-to-carbohydrate ratio.

Correction Bolus

A correction bolus is given to correct high glucose.

Correction Factor

A correction factor is the amount of glucose that is lowered by 1 unit of

insulin. Also known as the Insulin Sensitivity Factor (ISF).

Extended Bolus

An extended bolus is a bolus that is delivered over a period of time. It is commonly used to cover food that takes longer to digest. When administering an extended bolus with your pump, enter the DELIVER NOW portion to dose a percentage of insulin immediately and the remaining percentage over a period time.

Grams

Grams are the measurement for a carbohydrate.

Insulin Duration

Insulin duration is the amount of time that insulin is active and available in the body after a bolus has been delivered. This also relates to the calculation for Insulin on Board (IOB).

Insulin On Board (IOB)

IOB is the insulin that is still active (has the ability to continue to lower the glucose) in the body after a bolus has been delivered.

Load

Load refers to the process of removing, filling, and replacing a new cartridge and infusion set.

Personal Profile

A personal profile is a personalized group of settings that defines the delivery of basal and bolus insulin within specific time segments throughout a 24 hour period.

Quick Bolus

Quick bolus (using the **Screen On/Quick Bolus** button) is a way to deliver a bolus by following beep/vibration commands without navigating through or viewing the pump screen.

Temp Rate

Temp rate is an abbreviation for a temporary basal rate. It is used to increase or decrease the current basal rate for a short period of time to accommodate special situations. 100% is the same basal rate as programmed. 120% means 20% more and 80% means 20% less than the programmed basal rate.

CHAPTER 3 • Getting to Know Your t:slim X2 Insulin Pump

Units

Units are the measurement for insulin.

USB Cable

USB is the abbreviation for Universal Serial Bus. The USB cable connects into the pump's micro USB port.

WARNING

ALWAYS use the USB cable provided with your t:slim X2 insulin pump to minimize the risk of fires or burns.

3.3 Explanation of Insulin X2 Insulin Pump Icons

The following icons may appear on your pump screen:

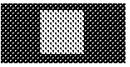
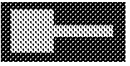
Pump Icon Definitions

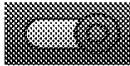
Symbol	Definition
	The amount of charge left in the pump battery.
	A system reminder, alert, error, or alarm is active.
	All insulin deliveries are stopped.
	Basal insulin is programmed and being delivered.
	Bluetooth wireless technology
	Accept. Tap to continue to the next screen or to answer yes to a message on the pump screen.
	Save. Tap to save settings on the screen.
	Delete. Tap to delete characters or digits on a keypad.
	New. Tap to add a new item.

Symbol	Definition
	The amount of insulin remaining in the cartridge.
	A temporary basal rate is active.
	A basal rate of 0 u/hr is active.
	A temporary basal rate of 0 u/hr is active.
	A bolus is being delivered.
	Cancel. Tap to cancel the current operation.
	Decline. Tap to exit the screen or answer no to a message on the pump screen.
	Back. Tap to navigate to the previous screen.
	Total. Tap to total values on a keypad.

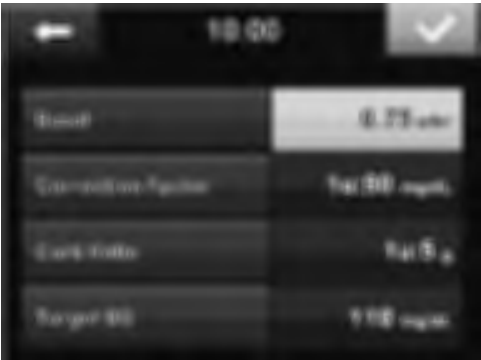
CHAPTER 3 • Getting to Know Your Insulin Pump

Pump Icon Definitions (Continued)

Symbol	Definition
	Space. Tap to enter a space on the character keypad.
	OK. Tap to confirm the current instruction or setting on the screen.
	A food and/or correction bolus was delivered. This icon only appears when a CGM sensor session is active.
	An extended bolus was delivered. The square represents the DELIVER NOW portion of the bolus, and the line represents the DELIVERY LATER portion of the bolus. This icon only appears when a CGM sensor session is active.

Symbol	Definition
	Security PIN has been enabled. See Section 5.13 Turn Security PIN On or Off.
	The associated setting is turned on.
	The associated setting is turned off.

3.4 Explanation of Pump Colors

	Red LED 1 red blink every 30 seconds indicates a malfunction or alarm condition.
	Yellow LED 1 yellow blink every 30 seconds indicates an alert or reminder condition.
	Green LED • 1 green blink every 30 seconds indicates the pump is functioning normally. • 3 green blinks every 30 seconds indicate the pump is charging.
	Orange Highlight When editing settings, changes are highlighted in orange for review before saving.

CHAPTER 3 • Getting to Know Your t:slim X2 Insulin Pump

3.5 Pump Back Side

1. **t:slim X2 Cartridge:** A single-use disposable cartridge can hold up to 300 units (3.0 mL) of insulin.
2. **Vent Holes:** Vent holes help the pump function correctly. It is important that these vents remain uncovered.

PRECAUTION

If you choose to use a pump case or other accessories not provided by Tandem, **DO NOT** cover the six vent holes on the back of the pump. Covering the vent holes could affect insulin delivery.



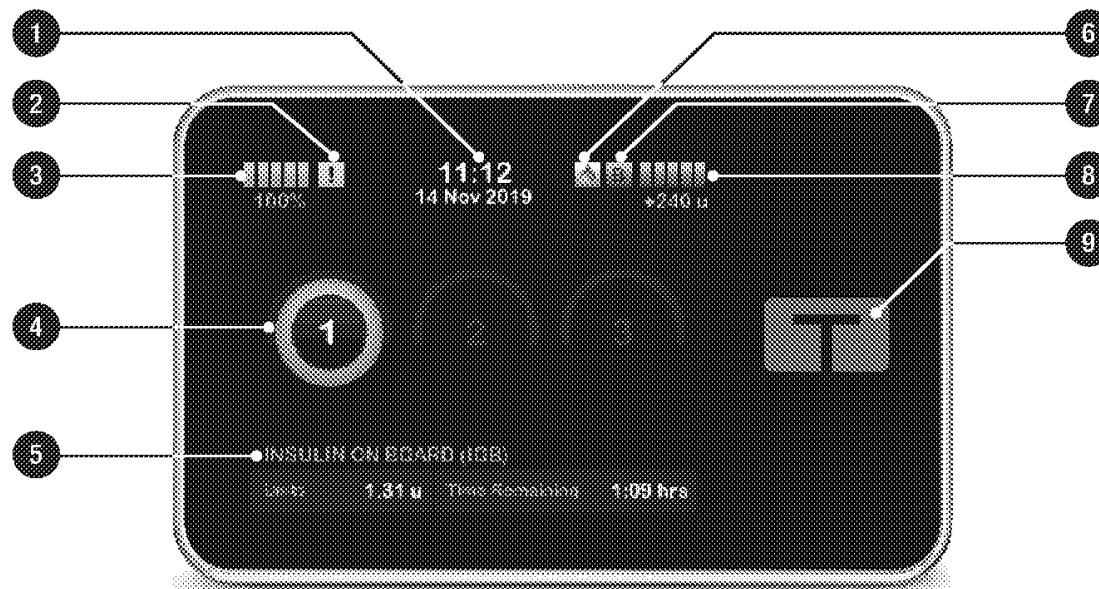
CHAPTER 3 • Getting to Know Your Tandem T2 Insulin Pump

3.6 Lock Screen

The *Lock* screen appears anytime you turn on the screen. You must tap 1–2–3 in sequential order to unlock the pump.

1. **Time and Date Display:** Displays the current time and date.
2. **Alert Icon:** Indicates a reminder, alert or alarm is active behind the *Lock* screen.
3. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
4. **1–2–3:** Unlocks pump screen.
5. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.
6. **Active Bolus Icon:** Indicates a bolus is active.
7. **Status:** Displays current system settings and insulin delivery status.
8. **Insulin Level:** Displays the current amount of insulin in the cartridge.
9. **Tandem Logo:** Returns to the *Home* screen.

CHAPTER 3 • Getting to Know Your tulin X2 Insulin Pump

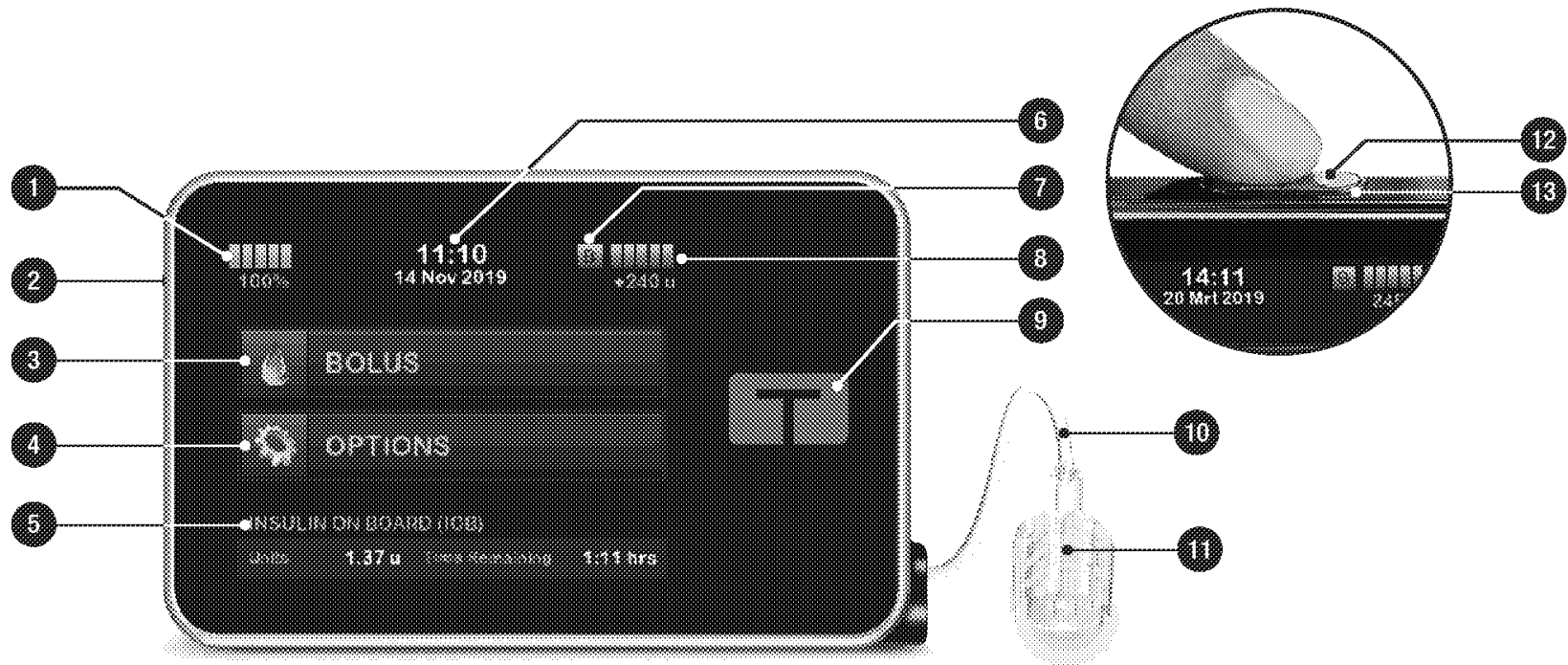


CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.7 Home Screen

1. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
2. **USB Port:** Port to charge your pump battery. Close the cover when not in use.
3. **Bolus:** Program and deliver a bolus.
4. **Options:** Stop/Resume insulin delivery, manage pump and CGM settings, start/stop activities, load a cartridge, and view history.
5. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.
6. **Time and Date Display:** Displays the current time and date.
7. **Status:** Displays current system settings and insulin delivery status.
8. **Insulin Level:** Displays the current amount of insulin in the cartridge.
9. **Tandem Logo:** Returns to the *Home* screen.
10. **Cartridge Tubing:** Tubing that is attached to the cartridge.
11. **Tubing Connector:** Connects the cartridge tubing to the infusion set tubing.
12. **Screen On/Quick Bolus button:** Turns the pump screen on/off or programs a Quick Bolus (if activated).
13. **LED Indicator:** Illuminates when connected to a power supply and indicates proper functionality.

CHAPTER 3 • Getting to Know Your tulin X2 Insulin Pump



CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.8 Current Status Screen

The *Current Status* screen can be accessed from the *Lock* screen and the *Home* screen by tapping the insulin level symbol. It is for display only; no changes can be made from this screen.

1. : Returns to the *Home* screen.
2. **Profile**: Displays current active Personal Profile.
3. **Basal Rate**: Displays current basal rate being delivered in units/hr. If a temp rate is active, this row will change to display current temp rate being delivered in units/hr.
4. **Last Bolus**: Displays amount, date and time of last bolus.
5. **Control-IQ Status**: Displays Control-IQ technology status.
6. **Up/Down Arrow**: Indicates there is more information.
7. **Correction Factor**: Displays current correction factor used to calculate a bolus.
8. **Carb Ratio**: Displays current carb ratio used to calculate a bolus.
9. **Target BG**: Displays current BG target used to calculate a bolus.
10. **Insulin Duration**: Displays current insulin duration setting used to calculate insulin on board.
11. **Last Calibration**: Displays date and time of last calibration.
12. **Time Sensor Started**: Displays date and time of last time sensor started.
13. **Transmitter Battery**: Displays CGM transmitter battery status.
14. **Mobile Connection**: Displays whether the mobile connection is turned on or off, whether a smartphone is paired with the pump, and if so whether the smartphone is actively connected to the pump.

CHAPTER 3 • Getting to Know Your tslim X2 Insulin Pump



CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.9 Bolus Screen

The Bolus screen will default to use units of insulin in calculating a bolus. You may change this setting in your Personal Profile to use grams of carbohydrate instead. Both screens are shown on the next page as examples.

1. : Returns to the *Home* screen.
2. **Insulin:** Enter units of insulin. You may change this setting to use grams of carb. See Section 6.2 Creating a New Profile for details on how to set the Increment Type.
3. **Units:** Displays total units calculated. Tap to enter a bolus request or change (override) a calculated bolus.
4. **View Calculation:** Displays how the insulin dose was calculated using the current settings.
5. **Glucose:** Enter BG or sensor glucose level. This value is populated automatically if each of the following conditions are true:

- Control-IQ technology is turned on and available
- A CGM session is active
- A CGM value is present
- A CGM trend arrow is available on the *CGM Home* screen

NOTE

For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's product instructions. You can also see Section 25.3 Rate of Change Arrows.

You can choose to use this value or enter another value from an alternate testing method.

6. : Moves to next step.
7. **Carbs:** Enter grams of carbohydrate. You may change this setting to use units of insulin. See Section 6.2 Creating a New Profile for details on how to set the Increment Type.

Using Units



Using Grams

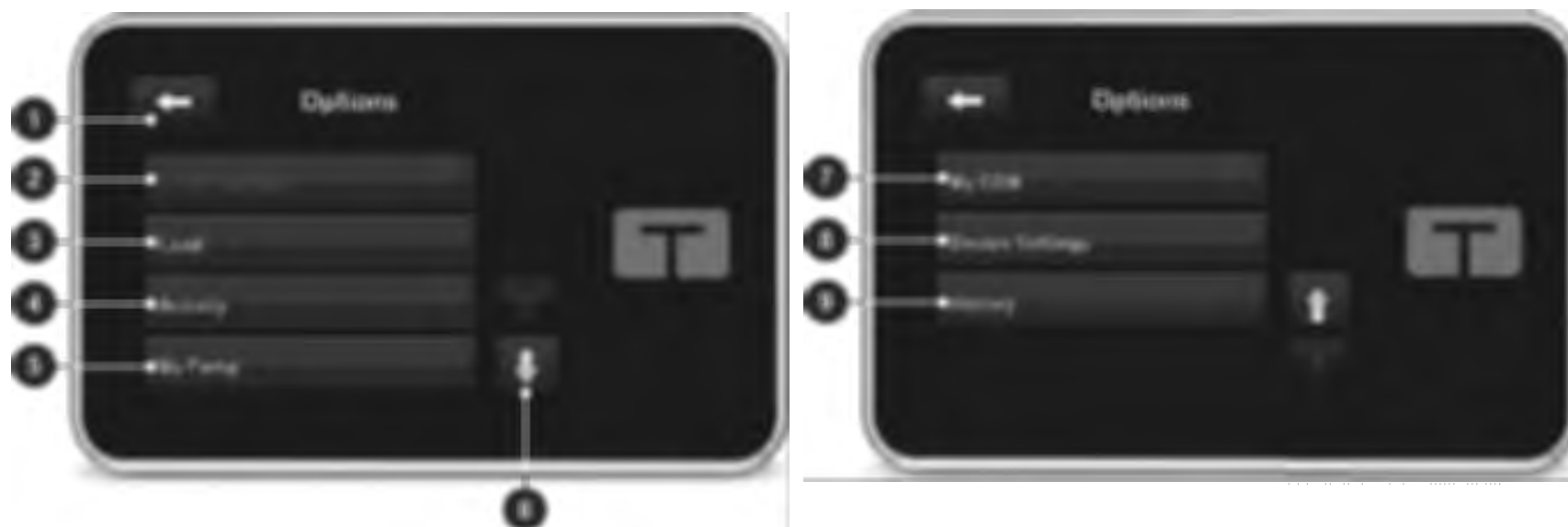


CHAPTER 3 • Getting to Know Your Insulin X2 Insulin Pump

3.10 Options Screen

1. : Returns to the *Home* screen.
2. **Stop Insulin:** Stops insulin delivery. If insulin delivery is stopped, RESUME INSULIN will be displayed.
3. **Load:** Change Cartridge, Fill Tubing, Fill Cannula, and Site Reminder.
4. **Activity:** Programs on Exercise, Sleep, and temporary Basal Rates.
5. **My Pump:** Personal Profiles, Control-IQ, Alerts & Reminders, and Pump Info.
6. **Up/Down Arrow:** Indicates there is more information.
7. **My CGM:** Start/Stop Sensor, Calibrate CGM, CGM Alerts, Transmitter ID, and CGM Info.
8. **Device Settings:** Display settings, Bluetooth settings, Time and Date, Sound Volume, and Security PIN.
9. **History:** Displays historical log of pump and CGM events.

CHAPTER 3 • Getting to Know Your tslim X2 Insulin Pump



CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.11 My Pump Screen

1. : Returns to the *Options* screen.
2. **Personal Profiles:** A group of settings that define basal and bolus delivery.
3. **Control-IQ:** Turn on/off Control-IQ technology and enter required values.
4. **Alerts & Reminders:** Customize Pump Reminders and Pump Alerts.
5. **Pump Info:** Displays pump serial number, local customer support service contact information website, and other technical information.



CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.12 Device Settings Screen

1. : Returns to the *Options* screen.
2. **Display Settings:** Customize the Screen Timeout settings.
3. **Bluetooth Settings:** Turn on/off mobile connection.
4. **Time and Date:** Edit the time and date that will be displayed on the pump.
5. **Sound Volume:** Customize the sound volume for pump alarms, pump alerts, reminders, keypad, bolus, quick bolus, fill tubing, and CGM alerts.
6. **Security PIN:** Turn on/off the Security PIN.

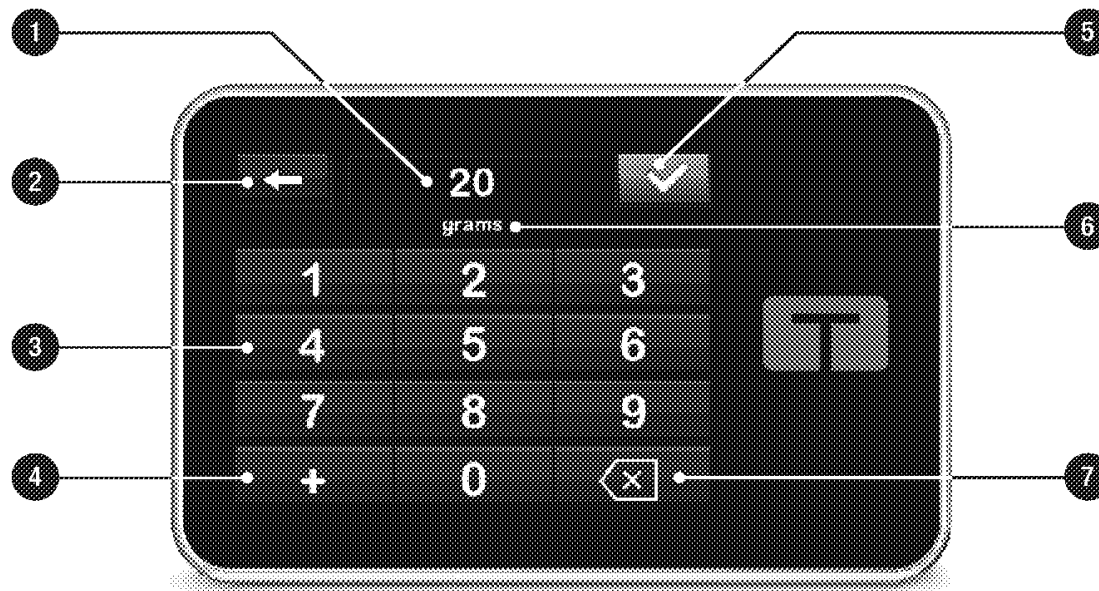
CHAPTER 3 • Getting to Know Your tslim X2 Insulin Pump



CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.13 Number Keypad Screen

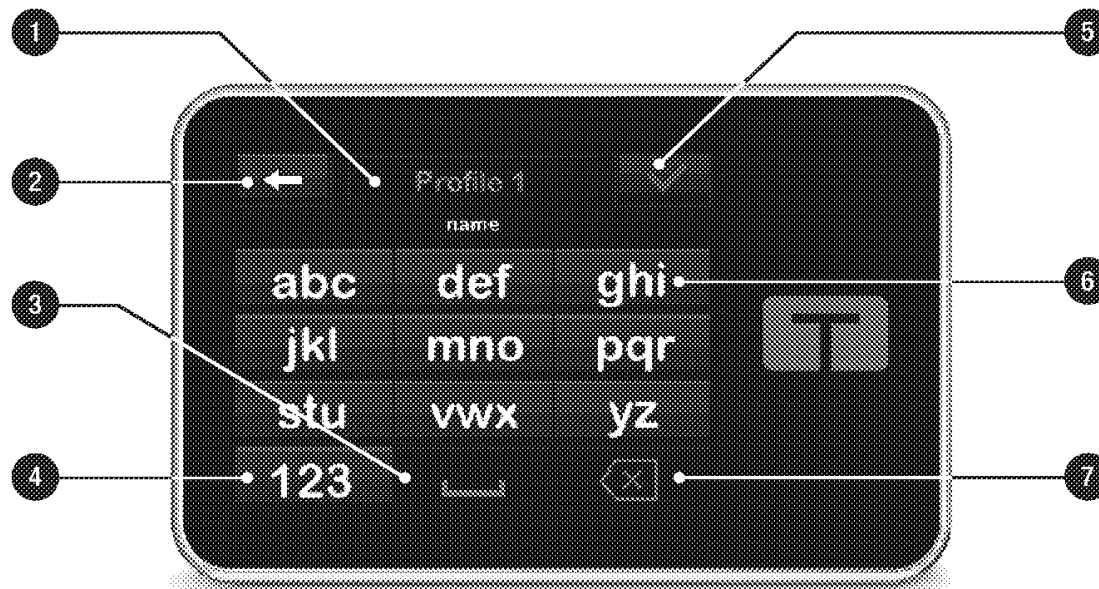
1. **Value Entered.**
2. : Returns to previous screen.
3. **Keypad Numbers.**
4. : Allows numbers to be added on the gram screen. If in units, this displays as a decimal point.
5. : Completes task and saves information entered.
6. **Units/Grams:** Unit of measure associated with the value entered.
7. : Deletes last number entered.



CHAPTER 3 • Getting to Know Your Insulin X2 Insulin Pump

3.14 Letter Keypad Screen

1. **Name of Profile.**
2. : Returns to previous screen.
3. : Enters a space.
4. **123:** Changes keypad mode from letters (ABC) to numbers (123).
5. : Saves entered information.
6. **Letters:** Tap once for first letter displayed, 2 quick taps for middle letter, and 3 quick taps for third letter.
7. : Deletes last letter or number entered.



This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 4

Getting to Know Your t:connect Mobile App

CHAPTER 4 • Getting to Know Your t:connect Mobile App

4.1 Overview

The t:connect™ mobile app is a companion app for the t:slim X2™ insulin pump. Before you begin, ensure your smartphone and the t:connect mobile app are compatible, and turn off smartphone automatic operating system (OS) updates. The feature set available within the t:connect mobile app is dependent on your pump software version as well as your smartphone model and operating system. Available feature sets are:

- **Display and Data Upload:** This feature set provides a secondary display of your pump and continuous glucose monitoring (CGM) information, including display of your pump alerts and alarms, and enables wireless uploading of pump and CGM data to the Tandem cloud.
- **Bolus Delivery plus Display and Data Upload:** In addition to the Display and Data Upload features, the bolus delivery feature allows you to use the t:connect mobile app to

request a bolus, stop a bolus, and cancel a bolus.

To download the t:connect mobile app, go to Google Play™ or the App Store®. For installation instructions, visit support.tandemdiabetes.com.

 NOTE

For an up-to-date list of supported smartphones, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

For more information on the setup and configuration of your smartphone to work with the t:connect mobile app, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

In certain situations, the features of the t:connect mobile app may be restricted, including when using an incompatible smartphone or pump.

 WARNING

ALWAYS rely on your pump to make therapy decisions when using a smartphone that is incompatible with the Bolus Delivery feature.

 PRECAUTION

ALWAYS rely on your pump for therapy decisions when:

- » Your smartphone is incompatible with the Bolus Delivery feature of the t:connect mobile app
- » Your smartphone is lost or damaged
- » Your smartphone loses Bluetooth connectivity with your pump

 PRECAUTION

Pump notifications cannot be cleared from your t:connect mobile app. Pump Alerts, Alarms, and Notifications can be viewed on your smartphone, but must be cleared on the t:slim X2 pump.

 PRECAUTION

DO NOT update your smartphone operating system prior to confirming that it is compatible with the Bolus Delivery plus Display and Data Upload feature of the t:connect mobile app. If you update to an incompatible operating system

version, you will lose the ability to request or control a bolus from the t:connect mobile app.

⚠ PRECAUTION

Discontinue use of the t:connect mobile app if your smartphone is damaged, or if a significant portion of its display is damaged or does not illuminate.

4.2 Install the t:connect Mobile App

⚠ WARNING

DO NOT use a smartphone that has been jailbroken or rooted, or with Android developer mode on. Data may become vulnerable if you install the t:connect mobile app on a smartphone that has been jailbroken or rooted, or uses an unreleased or pre-released operating system. Only download the t:connect mobile app on Google Play™ or from the App Store®.

⚠ PRECAUTION

ALWAYS turn Zoom Mode off when using the t:connect mobile app. If your smartphone has Zoom Mode turned on, you should rely on your pump for all therapy decisions.

Supported mobile devices are compliant with appropriate electrical

safety standards (IEC 60950-1, IEC 62368-1, or equivalent).

⚠ PRECAUTION

Use of mobile devices not complying with either IEC 60950-1, IEC 62368-1, or an equivalent standard may increase the risk of electrical hazards.

Supported mobile devices and the charging equipment provided by their manufacturers are compliant with appropriate electrical safety standards (IEC 60950-1, IEC 62368-1, or equivalent). For more information on supported devices, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

📌 NOTE

The t:connect mobile app must run in the background in order to receive and transmit data to and from your pump, as well as to the Tandem cloud. When you connect the t:connect mobile app to the pump, you must disable battery optimization on your smartphone to ensure the t:connect mobile app can receive alerts and alarms. It is recommended to follow your smartphone manufacturer's instructions for charging.

Enable smartphone security (e.g., screen lock, passcode, face recognition) before using the t:connect mobile app to administer a bolus. Never share your security PIN/password or authorize any other person to access your smartphone via their biometric information to avoid unintentional changes in your delivery of insulin.

After you download the t:connect mobile app, locate it on your smartphone and open it. The sign-in screen appears.

- You should allow all permission requests from the t:connect mobile app to ensure you receive all notifications from your pump. (See Section 4.4 Set Mobile Notifications to configure your notification settings.)
- For Android users, to use Bluetooth, the t:connect mobile app may ask for access to your device location; tap **Allow**.

If you have an existing t:connect account, log in using your username and password.

CHAPTER 4 • Getting to Know Your t:connect Mobile App

If you are a new user:

1. Tap **Get Started**.
2. Enter your account information, including name, account type, and login information.

NOTE

For personal accounts, you must be at least 13 years old in accordance with the Children's Online Privacy Protection Act (COPPA), which prohibits collecting information from people under the age of 13 without parental consent. If you are taking care of or acting on behalf of someone younger than 13, select a parent, guardian, or caretaker account.

3. The *Your glucose targets and limits* screen appears. You can set your High Glucose value, your Target Glucose Range values, and your Low Glucose value for display on your reports. The ADA-recommended values are 181, 70-180, and 69 respectively.

NOTE

We encourage you to discuss these values with your healthcare provider before setting

them. You can leave the fields blank during account set-up and enter them later. Setting or changing these values will not change any settings in the pump itself.

Update the t:connect Mobile App

When updates to the t:connect mobile app are available, do not uninstall the app. When you download and install an

update, your t:connect mobile app will still be connected to your t:connect account, the smartphone will still be paired with your pump, and your app settings will remain the same.

If you uninstall the t:connect mobile app, when you re-install the t:connect mobile app, you will be asked to log in using your credentials. Once you are logged in, your t:connect mobile app settings will be restored from the last time you synchronized with the Tandem cloud.

Updating Your Smartphone

Before you manually update your phone operating system, confirm that the t:connect mobile app is compatible with the new operating system. For more information about managing automatic updates, tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

⚠ PRECAUTION

DO NOT update your smartphone operating system prior to confirming that it is compatible with the Bolus Delivery plus Display and Data Upload feature of the t:connect mobile app. If you update to an incompatible operating system

version, you will lose the ability to request or control a bolus from the t:connect mobile app. For more information, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

4.3 Connecting to a Smartphone

You can connect one compatible smartphone to the pump to display pump information and perform some pump functions on that smartphone using the t:connect mobile app.

NOTE

This Mobile Connection setting is not related to your CGM Bluetooth connection. For CGM Bluetooth information, see Section 21.1 About Bluetooth Technology.

When you connect the t:connect mobile app to the pump, you must disable battery optimization on your smartphone to ensure the t:connect mobile app can receive alerts and alarms. It is recommended to follow your smartphone manufacturer's instructions for charging.

NOTE

For more information on the setup and configuration of your smartphone to work with the t:connect mobile app, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

Pair a Smartphone

NOTE

Always use the t:connect mobile app to pair your pump with your smartphone. Do not attempt to use your smartphone's Bluetooth menu.

NOTE

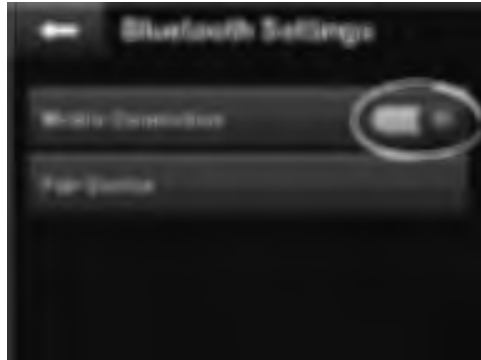
We strongly suggest that you upload pump data to the t:connect web application using the USB cable provided with your pump before you complete the pairing process to ensure all your pump data is uploaded as quickly as possible to the Tandem cloud. The first time you upload data to the Tandem cloud could take many hours over a slow internet connection on your smartphone.

Pair the t:connect mobile app with your pump as follows:

1. From your smartphone, open the t:connect mobile app.
 - » If you have an existing t:connect account, log in using your credentials.
 - » If you are a new user, create an account as shown in Section 4.1 Overview.
- ✓ The t:connect mobile app will prompt you to begin the pairing process.
2. From your pump's *Home* screen:
 - a. Tap **OPTIONS**.
 - b. Tap the **Down Arrow**.
 - c. Tap **Device Settings**.
 - d. Tap **Bluetooth Settings**.
 - e. Tap the on/off toggle next to **Mobile Connection** and tap .

CHAPTER 4 • Getting to Know Your t:connect Mobile App

to confirm. **Pair Device** is now displayed.



3. From the t:connect mobile app on your smartphone:
 - a. Tap **Begin** in the t:connect mobile app. A confirmation prompt will appear.
 - b. Choose the appropriate pump serial number on the *Select your pump* screen and tap **Next**.

NOTE

If you don't know your pump serial number, check your *Pump Info* screen as shown in Section 10.1 t:slim X2 Pump Info.

4. From your pump's *Bluetooth Settings* screen, tap **Pair Device**.
5. Your pump will display a *Mobile App notification* screen. Tap  to generate your device pairing code.

- ✓ Your pump will display a unique pairing code.

NOTE

The code is case sensitive and is only valid for 5 minutes - if more than 5 minutes have passed, tap **Pair Device** again to generate a new code.

NOTE

DO NOT tap **OK** on your pump. Tapping **OK** before completing pairing will cancel the pairing process.

6. From your smartphone, enter the pairing code generated in Step 5 into the t:connect mobile app and tap **Pair with pump**.
- ✓ Your pump will display a confirmation screen.

7. From your smartphone, tap **Sync pump data** in the t:connect mobile app to proceed with your normal pump use. The t:connect mobile app will display your dashboard and begin displaying pump data.

NOTE

If your smartphone does not pair with your pump, check your smartphone's Bluetooth settings, then retry steps 1 - 7. Note that if your smartphone asks you to allow it to communicate with an external device, you should accept.

8. From your pump, tap  to close the *PAIRING CODE* screen. If the pump has successfully paired with your smartphone, the *DEVICE PAIRED* screen is displayed.

Your t:connect mobile app will remain synchronized with your pump as long as a Bluetooth connection is established. The t:connect mobile app uploads your pump's data into the Tandem cloud approximately once per hour whenever it is connected to wi-fi or cellular data, depending on your data use settings. This allows you and your healthcare provider easy access to your

data via the t:connect web application without requiring access to your pump or connection cables.

PRECAUTION

ALWAYS ensure your pump has established a Bluetooth wireless connection with your smartphone before you use the t:connect mobile app. Confirm that the information displayed to you matches your signs and symptoms.

Unpair a Smartphone

You can disconnect a smartphone from a pump:

- If you replace your smartphone, you must unpair your previously paired smartphone from your pump before you can pair your new smartphone.
- If you replace your pump, you must unpair your old pump from your smartphone before you can pair your new pump.

Unpair a smartphone from your pump as follows:

1. From the t:connect mobile app:
 - a. Tap **Settings** on the *Navigation* bar.

- b. Tap **Paired Pump**.
- c. Tap **Unpair pump**. A confirmation prompt will appear.
- d. Tap **Unpair**. The t:connect mobile app displays a banner confirming that your pump has been unpaired and returns you to the pairing screen.

2. From your pump's *Home* screen, disable your pump's Mobile Connection toggle:

- a. Tap **Options**.
- b. Tap **Device Settings**.
- c. Tap **Bluetooth Settings**.
- d. Tap the on/off toggle next to Mobile Connection and tap  to confirm. **Pair Device** will disappear.

3. From your smartphone, remove your pump from your smartphone's Bluetooth device list.

If your pump is malfunctioning, or you otherwise don't have access to your pump (e.g., the pump has been lost or returned to Tandem), use your t:connect mobile app to unpair your smartphone from your pump as follows:

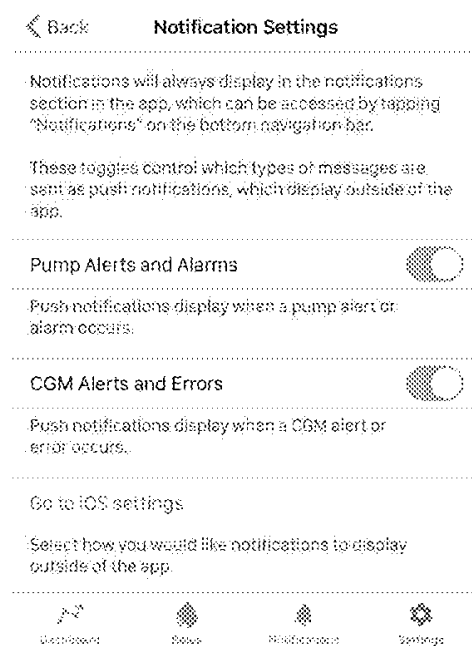
1. Tap **Settings** on the *Navigation* bar.
2. Tap **Paired Pump**.
3. Tap **Unpair pump**. A confirmation prompt will appear.
4. Tap **Unpair**. The t:connect mobile app displays a banner confirming that your pump has been unpaired and returns you to the pairing screen.

Once you have unpaired your smartphone from your pump, you can pair a different combination of smartphone and pump as described in *Pair a Smartphone*.

CHAPTER 4 • Getting to Know Your t:connect Mobile App

4.4 Set Mobile Notifications

The t:connect mobile app can display notifications generated by your pump or sent from the Tandem cloud, including pump alerts, alarms, and reminders. Tap **Settings** on the *Navigation* bar, then tap **Notification Settings** to toggle push notifications as desired. The following example shows possible push notification settings.



To ensure you receive notifications on the t:connect mobile app, confirm the smartphone sound mode is not set to mute, and enable the following settings:

- t:connect mobile app notifications
- Bluetooth

Check your smartphone settings to ensure your t:connect mobile app can connect to the internet.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. For more information, see Section 4.3 *Connecting to a Smartphone*, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

📌 NOTE

Check your smartphone's operating system push notification settings as well as those in the t:connect mobile app to ensure your pump and CGM alerts and alarms are set to your preference.

4.5 Mobile Connection Security

Only one smartphone and t:connect mobile app may pair with your pump. When pairing your pump to a t:connect mobile app, a unique code will be generated and used to secure communications between the pump and smartphone. All transmissions between the pump and smartphone are encrypted. The pump is designed to deny any unauthorized or unrecognized connections.

The pump is designed to check the integrity of all commands and data received from the t:connect mobile app. If the pump receives unexpected commands or data from the t:connect mobile app, the pump will ignore it and continue to operate as intended.

4.6 Lost Pump Connection

When your smartphone is more than five feet from the pump or experiencing Bluetooth connection issues, the t:connect mobile app will not display pump data until you restore the connection between your smartphone and the pump.

⚠ PRECAUTION

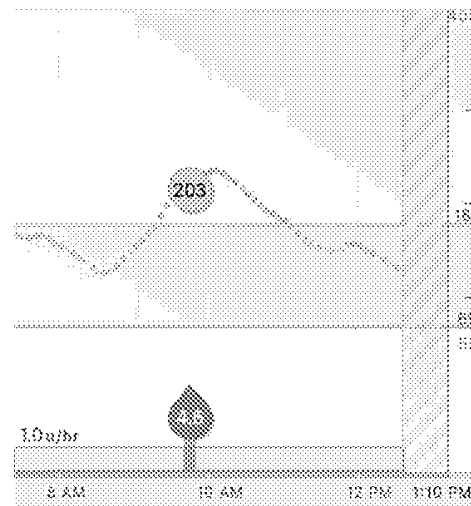
ALWAYS ensure your pump has established a Bluetooth wireless connection with your smartphone before you use the t:connect mobile app. Confirm that the information displayed to you matches your signs and symptoms.

The *Pump Connection Lost* notification banner replaces the current pump

status until you re-establish the Bluetooth connection.



Pump connection lost 30 min ago
You can use your pump until the connection is restored. Turn on Bluetooth in your phone's settings.

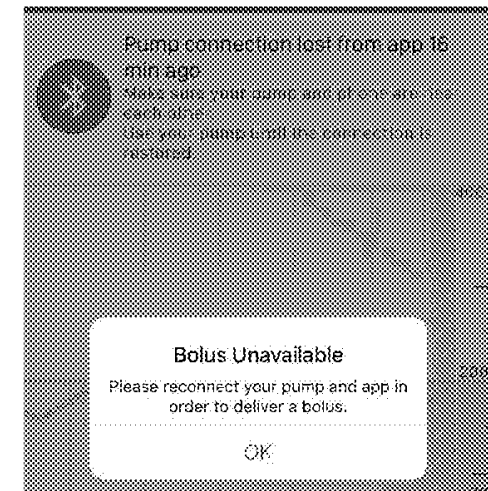


You will also see a gray shaded area on the graph since no data can be displayed when the connection is lost. When the connection is lost, use the pump to administer therapy while troubleshooting the loss of connection.

⚠ PRECAUTION

DO NOT ignore symptoms of high and low glucose. If your t:connect mobile app readings do not match your symptoms, check your pump display and confirm that your pump has established a Bluetooth connection with your smartphone.

If your smartphone and the pump are not connected, tapping **Bolus** on the navigation bar generates a *Bolus Unavailable* alert as shown in the following example.



CHAPTER 4 • Getting to Know Your t:connect Mobile App

Reconnect Bluetooth

When you see the *Pump Connection Lost* notification banner:

- Make sure that your pump and smartphone are within five feet of one another and without any obstruction between the two (including body parts).
- Confirm that Bluetooth technology is enabled on your smartphone.

If the connection is not restored within five minutes, reset the connection between your smartphone and your pump:

1. Force quit or close the t:connect mobile app.
2. Open the t:connect mobile app.
3. If your connection is lost again, disable your smartphone's Bluetooth connection.
4. Enable your smartphone's Bluetooth connection.

5. If your connection is lost again, sign out of your t:connect account.
6. Pair your smartphone with your pump as described in Section 4.3 *Connecting to a Smartphone*.

If the connection is lost again, discontinue use of the t:connect mobile app and contact Customer Technical Support.

4.7 Restart the t:connect Mobile App

If you have persistent issues with the t:connect mobile app, force stop or close the t:connect mobile app to end the current session.

For iOS devices:

1. Double-tap the Home button, or swipe up from the bottom of the screen and hold.
2. Find the t:connect mobile app and swipe up to close.
3. Reopen the t:connect mobile app.

For Android devices:

1. Open your smartphone's Settings menu.
2. Open your smartphone's application manager.
3. Tap **t:connect**. You may need to scroll down your list of applications to locate it among your apps.
4. Tap **Force Stop**.
5. Reopen the t:connect mobile app.

⚠ PRECAUTION

ALWAYS keep your t:connect mobile app running in the background so that pump alerts, alarms, and notifications can be displayed on your smartphone. These notifications are only received when the t:connect mobile app is either active or open in the background. If you close or force stop your t:connect mobile app, it will not be running in the background.

If the issue persists, try re-pairing the pump:

1. From the t:connect mobile app, tap **Settings**.

2. Tap Paired Pump.
3. Tap Unpair Pump.
4. Repeat the pairing process as shown in Section 4.3 Connecting to a Smartphone.

CHAPTER 4 • Getting to Know Your t:connect Mobile App

4.8 t:connect Mobile App Dashboard

1. **Pump Battery Level:** Displays the level of pump battery power remaining. When the pump is connected for charging, the charging icon (lightning bolt) will display.
2. **Most Recent 5-Minute Glucose Reading and Trend Arrow.**
3. **BG Entry:** Your BG value at the moment you entered it into your bolus calculator.
4. **Graph of Most Recent Glucose Readings:** Displays CGM sensor readings for the last 24 hours. You may swipe left and right to see all 24-hours in the graph. This graph also includes blood glucose (BG) readings entered into the bolus calculator.
5. **Delivered Bolus:** The amount of bolus insulin actually delivered for a given bolus event.
6. **Delivered Basal:** The amount of insulin delivered as basal for the past 24-hour period. This includes changes in insulin delivery related to use of Control-IQ™ technology.
7. **Status:** Displays current system settings and insulin delivery status. Swipe up to scroll down in the t:connect mobile app and see complete Status information.
8. **Navigation Bar:** Displays icons representing each mobile app page. The icon for the active t:connect mobile app page is highlighted blue.
9. **Insulin Level:** Displays the current amount of insulin in the cartridge. You can also tap the Insulin Level icon to automatically scroll down and see complete Status information.
10. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.
11. **Dashboard:** Displays pump status bar, current glucose reading, IOB status, CGM graph, time in range information, and current status.
12. **Bolus:** Navigate to the *Bolus* screen to program and deliver a bolus (only available with compatible devices).
13. **Notifications:** Displays active pump alerts, alarms, reminders, and malfunctions. See Section 4.4 Set Mobile Notifications for more information.
14. **Settings:** Navigate to the settings screen, including Glucose Thresholds for Display, App Notification Settings, Data Control settings, Tandem account information, pump pairing and unpairing, About, and Help.

CHAPTER 4 • Getting to Know Your t:connect Mobile App



CHAPTER 4 • Getting to Know Your t:connect Mobile App

4.9 t:connect Mobile App Bolus Screen

1. **Cancel:** Exit the *Bolus* screen and return to the Dashboard.
2. **Units:** Displays total units calculated. Tap to enter a bolus request or change (override) a calculated bolus.
3. **Insulin:** Enter units of insulin. You may change this setting on the pump to use grams of carbohydrate. See Section 8.9 Quick Bolus for more information.
4. **Delivery Calculation:** The amount of bolus insulin actually delivered for a given bolus event, including a breakdown of calculated Correction bolus, input Food bolus, and Insulin On Board (IOB) automatically.
5. **Next:** Accept changes input on the Bolus screen and proceed to the Bolus confirmation screen.
6. **Glucose:** Enter BG or sensor glucose level. This value is

populated automatically if each of the following are true:

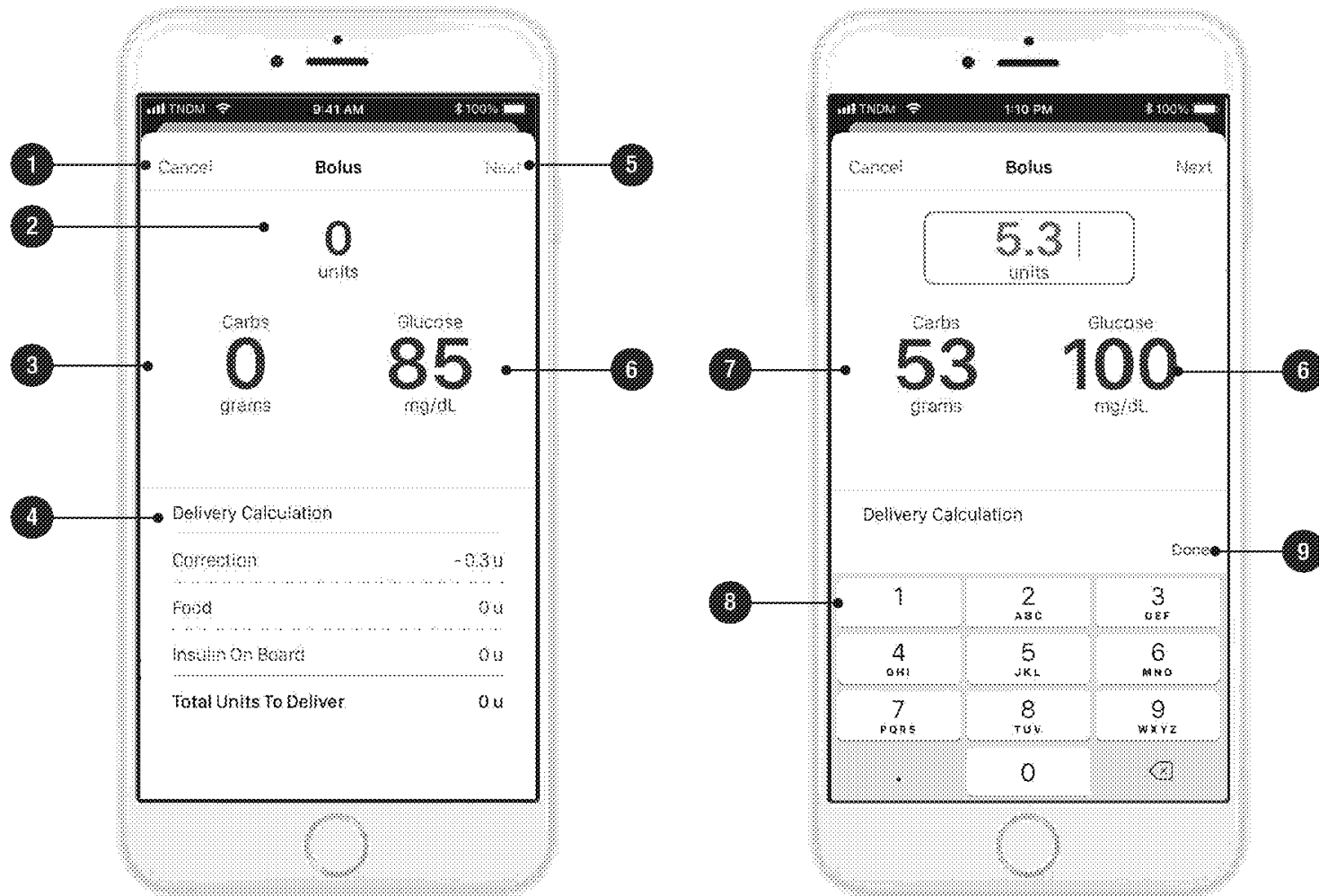
- Control-IQ technology is turned on and available
- A CGM session is active
- A CGM value is present
- A CGM trend arrow is available on the CGM Home screen

 NOTE

For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's user guide. You can also see Section 25.3 Rate of Change Arrows.

7. **Carbs:** Enter grams of carbohydrate. You may change this setting on the pump to use units of insulin. See Section 8.9 Quick Bolus for more information.
8. **Keypad Numbers.**
9. **Done:** Completes task and saves information entered.

CHAPTER 4 • Getting to Know Your t:connect Mobile App



CHAPTER 4 • Getting to Know Your t:connect Mobile App

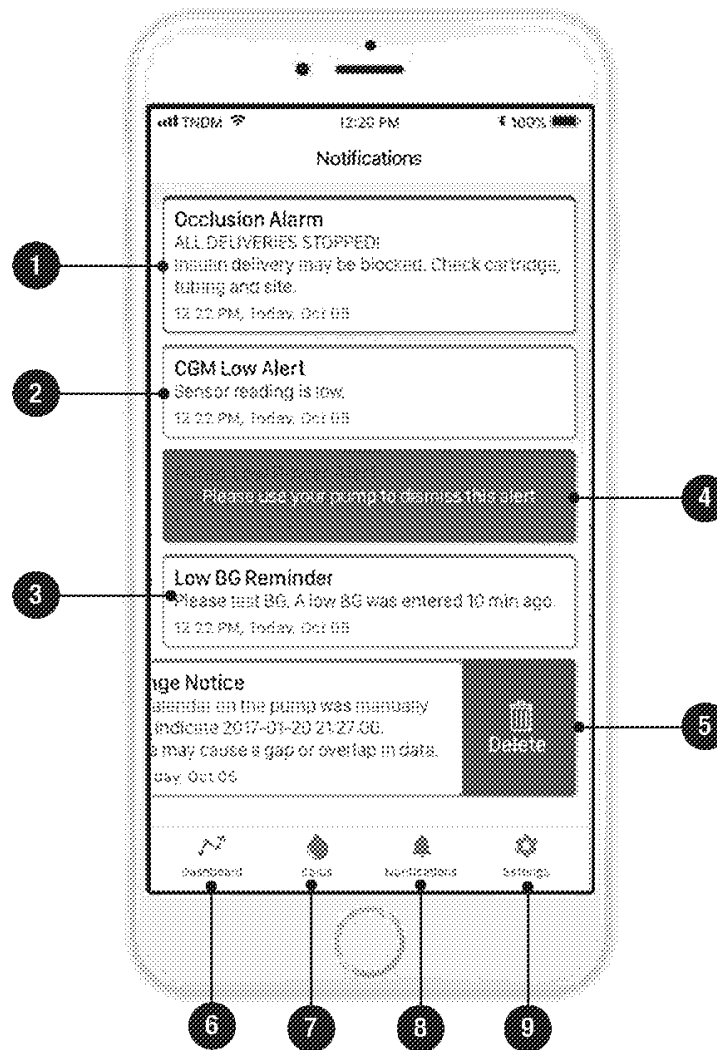
4.18 t:connect Mobile App
Notifications Screen

⚠ PRECAUTION

Pump notifications cannot be cleared from your t:connect mobile app. Pump Alerts, Alarms, and Notifications can be viewed on your smartphone, but must be cleared on the t:slim X2 pump.

1. **Alarm:** Displays a pump alarm. Alarms are outlined in red in the t:connect mobile app.
2. **Alert:** Displays a pump alert. Alerts are outlined in yellow in the t:connect mobile app.
3. **Reminder:** Displays a pump reminder. Reminders are outlined in blue in the t:connect mobile app.
4. **Dismiss:** Appears if you slide an alert notification (yellow outline) with your finger to the left. Tap this icon to dismiss the alert.
5. **Delete:** Appears if you slide a reminder or informational notification (blue outline) with your finger to the left. Tap this icon to delete the reminder or informational message.
6. **Dashboard:** Displays pump status bar, current glucose reading, IOB status, CGM graph, time in range information, and current status.
7. **Bolus:** Navigate to the *Bolus* screen to program and deliver a bolus (only available with compatible devices).
8. **Notifications:** Displays active pump alerts, alarms, reminders, and malfunctions. See Section 4.4 Set Mobile Notifications for more information.
9. **Settings:** Navigate to the settings screen, including Glucose Thresholds for Display, App Notification Settings, Data Control settings, Tandem account information, pump pairing and unpairing, About, and Help.

CHAPTER 4 • Getting to Know Your t:connect Mobile App

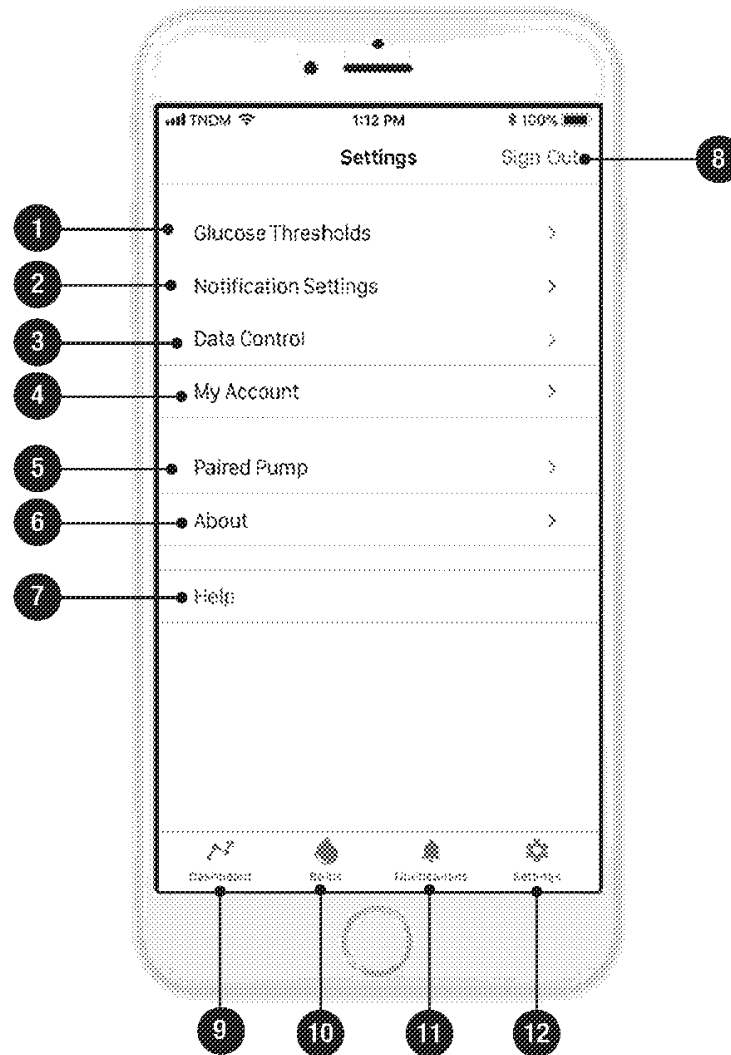


CHAPTER 4 • Getting to Know Your t:connect Mobile App

4.11 t:connect Mobile App Settings

1. **Glucose Thresholds:** Customize the way your data appears on your Dashboard and in the t:connect web application, including high glucose limit, target glucose range, low glucose limit, and how often your cartridge and infusion set should be change.
 2. **Notification Settings:** Set which events trigger notifications (e.g., pump alerts and alarms, CGM alerts and errors).
 3. **Data Control:** Directly access smartphone operating system settings relevant to the t:connect mobile app (e.g., whether to allow cellular data use to upload data).
 4. **My Account:** Edit account information. Any changes to your t:connect account made via the t:connect mobile app also apply to the t:connect web application.
 5. **Paired Pump:** Pair a pump with your smartphone, or unpair a pump from your smartphone.
-  **NOTE**
Always use the t:connect mobile app to pair your pump with your smartphone. Do not attempt to use your smartphone's Bluetooth menu.
6. **About:** Access Tandem contact information, corporate policies, and legal notices.
 7. **Help:** Access in-app help information, including FAQs, the pump user guide, an Icons and Graphics Glossary, and an App Guide that includes information on smartphone compatibility, setting up your smartphone, and troubleshooting information.
 8. **Sign Out:** Sign out of the t:connect mobile app. Tapping **Sign Out** generates a confirmation prompt.
 9. **Dashboard:** Displays pump status bar, current glucose reading, IOB status, CGM graph, time in range information, and current status.
 10. **Bolus:** Navigate to the *Bolus* screen to program and deliver a bolus (only available with compatible devices).
 11. **Notifications:** Displays active pump alerts, alarms, reminders, and malfunctions. See Section 4.4 Set Mobile Notifications for more information.
 12. **Settings:** Navigate to the settings screen, including Glucose Thresholds for Display, App Notification Settings, Data Control settings, Tandem account information, pump pairing and unpairing, About, and Help.

CHAPTER 4 • Getting to Know Your t:connect Mobile App



This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 5

Getting Started

CHAPTER 5 • Getting Started

5.1 Charging the t:slim X2 Pump

The pump is powered by an internal lithium polymer rechargeable battery. A full charge will typically last between 4 and 7 days, depending on your use of CGM and the t:connect™ mobile app. If you utilize both CGM and the t:connect mobile app, your battery is designed to last up to 4 days. Please be aware that the battery life on a single charge can vary considerably depending on individual usage, including insulin delivered, display-on time, and frequency of reminders, alerts, and alarms.

Accessories for charging from wall outlets, as well as from a computer USB port, are included with the pump. Use only the accessories provided to charge your pump. If you lose any of the accessories, or need a replacement, contact Customer Technical Support.

⚠ WARNING

ALWAYS use the USB cable provided with your t:slim X2™ insulin pump to minimize the risk of fires or burns.

The battery level indicator is displayed in the upper left portion of the *Home* screen. The charge amount will increase or decrease by 5% at a time (for example, you will see 100%, 95%, 90%, 85%). When the charge amount is less than 5%, it will begin decreasing 1% at a time (for example, you will see 4%, 3%, 2%, 1%).

When you first receive your pump, you will need to connect it to a charging source before it can be used. Charge the pump until the battery level indicator on the upper left portion of the *Home* screen reads 100% (initial charge can take up to 2.5 hours).

Tandem Diabetes Care recommends that you periodically check the battery level indicator, charge the pump for a short period of time every day (10 to 15 minutes), and avoid frequent full discharges.

■ NOTE

If the battery is fully discharged, the screen may not power on immediately when connected to a charging source. The LED around the **Screen On/Quick Bolus** button will blink green until there is enough charge to power on the touchscreen.

The pump continues to operate normally while charging. You do not need to disconnect from the pump while charging.

⚠ PRECAUTION

MAKE SURE to not move further than the length of the USB cable when you are connected to the pump and to a charging source. Moving further than the length of the USB cable may cause the cannula to be pulled out of the infusion site. For this reason it is recommended not to charge the pump while sleeping.

If you choose to disconnect from the pump while charging, check with your healthcare provider for specific guidelines. Depending on the length of time you are disconnected, you may need to replace missed basal and/or bolus insulin. Check your BG before disconnecting from the pump and again when you reconnect.

To charge the pump from an AC power outlet:

1. Plug the included USB cable into the AC power adapter.
2. Plug the AC power adapter into a grounded AC power outlet.

3. Plug the other end of the cable into the micro USB port on the pump.

To charge the pump using an optional car power USB adapter:

⚠ WARNING

When using an optional car power USB adapter, the charger must be connected to an isolated, battery powered 12 Volt system, such as an automobile. Connecting the DC vehicle adapter charger to 12 Volt DC that is generated by a power supply connected to alternating current (AC) mains is prohibited.

1. Plug the USB cable into the car power USB adapter.
2. Plug the car power USB adapter into a grounded auxiliary power outlet.
3. Plug the other end of the cable into the micro USB port on the pump.

To charge the pump using a USB port on a computer:

Ensure that the computer complies with the IEC 60950-1 (or equivalent) safety standard.

1. Plug the included USB cable into your computer.
2. Plug the other end of the cable into the micro USB port on the pump.

📌 NOTE

Before using a computer to charge the pump, it is recommended that a driver be installed on the computer by downloading the t:connect uploader software from our website at tandemdiabetes.com. This will also allow communication between the pump, the computer, and the t:connect web application.

Depending on your computer, charging time will vary. The pump will display a CONNECTION ERROR ALERT message if it is not charging properly.

When you charge the pump, you will notice the following:

- The screen illuminates
- An audible alert
- The LED (edge around the Screen On/Quick Bolus button) blinks green
- A vibrating alert

- A charge symbol (lightning bolt) on the battery level indicator appears

⚠ PRECAUTION

CONFIRM that the screen display turns on, you can hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the Screen On/Quick Bolus button when you connect a power source to the USB port. These features are used to notify you about alerts, alarms, and other conditions that require your attention. If these features are not working, discontinue use of the t:slim X2™ pump and contact Customer Technical Support.

5.2 Turning the Pump On

Plug in your pump to a charging source. The pump will make an audible noise when it has turned on and is ready for use.

5.3 Using the Touchscreen

To turn on your pump screen, first press the Screen On/Quick Bolus button, then use the pad of your finger to quickly and lightly tap on the screen. Do not use your fingernail or other

CHAPTER 5 • Getting Started

object to interact with the screen. It will not activate the screen or its functions.

Your pump is designed to give you quick and easy access to the functions that you will use in your day-to-day diabetes management whether basic or advanced.

The pump has several safety features to prevent unintentional interaction with the touchscreen. The screen must be unlocked by tapping 1–2–3 in sequence. On all screens, if three non-active areas of the touchscreen are tapped before an active area is tapped, the screen will turn off to prevent accidental screen interactions. There is also a Security PIN feature that can be set up to prevent unintentional access (see Section 5.13 Turn Security PIN On or Off).

NOTE

When using the pump, tap the **Tandem logo** to return to the *Home* screen or tap  to return to the previous screen.

5.4 Turning the t:slim X2 Pump Screen On

To turn on your pump screen, press the **Screen On/Quick Bolus** button, located on the top of the pump, once.

- ✓ The *Lock* screen will be displayed.

5.5 Turning the Pump Screen Off

To turn the pump screen off, press and release the **Screen On/Quick Bolus** button. This turns off the screen, but not the pump.

NOTE

Turn off the pump screen by pressing the **Screen On/Quick Bolus** button before placing the pump back in its case or any pocket/clothing. Always position the pump screen away from the skin when worn under clothing.

The pump continues to function normally when the screen is not on.

5.6 Turning the Pump Off

To turn the pump off completely, plug the pump into a power source and hold the **Screen On/Quick Bolus** button down for 30 seconds.

5.7 Unlocking the t:slim X2 Pump Screen

The *Lock* screen appears anytime you turn on the screen, and after a bolus or temp rate is requested. To unlock the screen:

1. Press **Screen On/Quick Bolus** button.
2. Tap 1.
3. Tap 2.
4. Tap 3.

- ✓ The pump screen is now unlocked. The last screen that was viewed will be displayed.

You must tap 1–2–3 in sequential order to unlock the pump. If you do not tap

1–2–3 in sequential order, the pump will force you to restart the unlock sequence from the beginning.

If the Security PIN feature is enabled, you will need to enter your PIN after unlocking the screen.

5.8 Edit Time

After powering up your pump for the first time, set the current time and date. Refer back to this section if you need to edit the time for either traveling in a different time zone or adjusting for Daylight Savings Time.

⚠ PRECAUTION

ALWAYS make sure that the correct time and date are set on your pump. Not having the correct time and date setting may affect safe insulin delivery. When editing time, always check that the AM/PM setting is accurate, if applicable. AM is to be used from midnight until 11:59 AM. PM is to be used from noon until 11:59 PM.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.

3. Tap **Device Settings**.
4. Tap **Time and Date**.
5. Tap **Edit Time**.
6. Tap **Time**.
7. Using the on-screen keypad, enter the hour and minutes. Verify and tap .
8. Tap **Time of Day** to set AM or PM, or tap the **24-hour Time** on/off toggle setting to on.
9. Verify the correct time is set and tap .

Any edits to Time or Date will not be saved until you tap .

5.9 Edit Date

1. From the *Time and Date* screen tap **Edit Date**.
2. Tap **Day**.

3. Using the on-screen keypad enter the current day. Verify and tap .
4. Tap **Month**.
5. Find and tap the current month displayed on the right. Use **Up/Down Arrow** to view months not displayed.
6. Tap **Year**.
7. Using the on-screen keypad enter the current year. Verify and tap .
8. Verify the correct date is set and tap .

Tap the **Tandem logo** to return to the *Home* screen.

5.10 Basal Limit

The Basal Limit setting allows you to set a limit to the Basal Rate that is set in the Personal Profiles, as well as the amount of insulin that will be delivered when using a Temp Rate.

CHAPTER 5 • Getting Started

You are unable to set any Basal Rates or temp Basal Rates that exceed the Basal Limit. You can set your Basal Limit from 0.2 to 15 units per hour. Work with your healthcare provider to set the proper Basal Limit.

NOTE

If you are setting your Basal Limit after you have set any of your Personal Profiles, you cannot set your Basal Limit lower than any of your existing Basal Rates.

The default Basal Limit is 3 units per hour. If you are updating your pump from a version that did not previously have the Basal Limit setting, the Basal Limit will be set to a value two times the highest Basal Rate setting in your pump.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap **Pump Settings**.

5. Tap **Basal Limit**.



6. Using the on-screen keypad, enter a Basal Limit amount that is between 0.2 – 15 units.
 7. Tap .
 8. Review the Basal Limit value and tap .
 9. Confirm settings and tap .
- ✓ A *SETTING SAVED* screen is temporarily displayed.

5.11 Display Settings

The display settings for your t:slim X2 pump includes Screen Timeout.

You can set the Screen Timeout to the length of time you want the screen to stay on before it automatically turns off. The default for the Screen Timeout is 30 seconds. The options are 15, 30, 60, and 120 seconds.

You can always turn the screen off before it automatically times out by pressing the **Screen On/Quick Bolus** button.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Device Settings**.
4. Tap **Display Settings**.
5. Tap **Screen Timeout**.
6. Select preferred time and tap .

7. Tap the **Tandem** logo to return to the *Home* screen.

5.12 Sound Volume

The Sound Volume is preset to high. Sound Volume can be personalized for Alarms, Alerts, Reminders, Keypad, Bolus, Quick Bolus, and Fill Tubing. Options for Sound Volume include high, medium, low, and vibrate.

⚠ PRECAUTION

DO NOT use the vibrate feature for alerts and alarms during sleep unless otherwise directed by your healthcare provider. Having the volume for alerts and alarms set to high will help ensure that you don't miss an alert or alarm.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Device Settings**.
4. Tap **Sound Volume**.
5. Tap desired option. Use **Up/Down Arrow** to view additional options.

6. Select preferred volume.
7. Continue to make changes for all Sound Volume options by repeating steps 5 and 6.
8. Tap  when all changes are complete.
9. Tap the **Tandem** logo to return to the *Home* screen.

5.13 Turn Security PIN On or Off

The Security PIN is preset to off. With the Security PIN turned on, you cannot unlock and use the pump without entering the Security PIN. To turn on the Security PIN, follow these steps.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Device Settings**.
4. Tap the **Down Arrow**.
5. Tap **Security PIN**.

6. Tap **Security PIN** to toggle the feature on.
7. Tap  to create your Security PIN.
8. Using the keypad, enter a number between four and six digits. A PIN may not begin with the number zero.
9. Tap .
10. Tap  to verify your Security PIN.
11. Use the keypad to repeat and verify the new Security PIN.
12. Tap .
- ✓ A *PIN CREATED* screen is displayed.
13. Tap  to turn the Security PIN on.
14. Tap .

It is possible to change your Security PIN or override an old Security PIN if you forget your Security PIN.

CHAPTER 5 • Getting Started

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the Down Arrow.
3. Tap **Device Settings**.
4. Tap the Down Arrow.
5. Tap **Security PIN**.
6. Tap **Change Security PIN**.
7. Tap .
8. Using the keypad, enter the current Security PIN. If you forget your Security PIN, use the override code **314159**.
 - » The override PIN can be used as many times as needed and never resets or changes to another PIN. It can be used to unlock the pump when the Security PIN feature is on. If desired, you may use this as a valid Security PIN.
9. Tap .
10. Tap  to enter a new Security PIN.

11. Use the keypad to enter a new Security PIN.
12. Tap .
13. Tap  to verify your new Security PIN.
14. Use the keypad to repeat and verify the new Security PIN.
15. Tap .
- ✓ A *PIN UPDATED* screen is displayed.
16. Tap .

pair or unpair your smartphone and your pump.

NOTE

Do not turn the mobile connection on if you are not using or do not have access to the t:connect mobile app. Turning the mobile connection on may impact pump battery life.

5.14 Mobile Connection

You can connect one compatible smartphone to the pump to display pump information and perform some pump functions on that smartphone using the t:connect mobile app. See Section 4.3 Connecting to a Smartphone for detailed instructions to

2 t:slim X2 Insulin Pump Features

CHAPTER 6

Insulin Delivery Settings

CHAPTER 6 • Insulin Delivery Settings

6.1 Personal Profiles Overview

⚠ WARNING

DO NOT start to use your pump before consulting with your healthcare provider to determine which features are most appropriate for you. Only your healthcare provider can determine and help you adjust your Basal Rate(s), Carb Ratio(s), Correction Factor(s), Target BG, and duration of insulin action. In addition, only your healthcare provider can determine your CGM settings and how you should use your sensor trend information to help you manage your diabetes. Incorrect settings can result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

A Personal Profile is a group of settings that define basal and bolus delivery within specific time segments throughout a 24-hour period. Each profile can be personalized with a name. Within a Personal Profile the following can be set:

- **Timed Settings:** Basal Rate, Correction Factor, Carb Ratio and Target BG.

- **Bolus Settings:** Insulin Duration and Carbohydrates setting (on/off).

NOTE

In order to turn on Control-IQ™ technology, the Timed Settings must be complete for every time segment, and the Carbohydrates setting must be turned on in the Bolus Settings.

The t:slim X2™ pump uses the settings in your active profile to calculate the delivery of basal insulin, food boluses and correction boluses based on your Target BG. If you only define a Basal Rate in Timed Settings, your pump will only be able to deliver basal insulin and standard and extended boluses. Your pump will not calculate correction boluses.

Up to six different Personal Profiles can be created and up to 16 different time segments can be set in each Personal Profile. Having several Personal Profiles provides more flexibility for your body and lifestyle. For example, you could have “Weekday” and “Weekend” profiles if you have different insulin delivery needs on weekdays and weekends, based on schedule, food intake, activity, etc.

NOTE

Some of the Personal Profile settings are overridden when Control-IQ technology is turned on. See Chapter 30 Introduction to Control-IQ Technology.

6.2 Creating a New Profile

Creating Personal Profiles

You can create up to six Personal Profiles; however, only one can be active at a time. In the *Personal Profiles* screen, the active profile is positioned at the top of the list and is marked as ON. When you create a Personal Profile, you can set any or all of the following Timed Settings:

- Basal Rate (your Basal Rate in units/ hr)
- Correction Factor (amount 1 unit of insulin lowers BG)
- Carb Ratio (grams of carbohydrate covered by 1 unit of insulin)
- Target BG (your ideal BG level, measured in mg/dL)

Although you do not need to define every setting, some pump features require certain settings to be defined and activated. When you are creating a new profile, your pump prompts you to set up any required settings before you can continue.

The ranges you can set for Timed Settings are:

- Basal (range: 0 and 0.1 to 15 units/hr)

NOTE

The Basal Rate may not exceed the Basal Limit set in Pump Settings (Section 5.10 Basal Limit). If you are setting your Basal Limit after you have set any of your Personal Profiles, you cannot set your Basal Limit lower than any of your existing Basal Rates.

NOTE

If Control-IQ technology is on and the pump has not received a CGM reading for 20 minutes, the system will automatically revert to your programmed basal rate. Examples of CGM readings not being received include when the pump and CGM are out of range, during the sensor startup

period, when a sensor session ends, or when there is a transmitter or sensor error.

WARNING

Control-IQ technology reverts to your programmed basal rate when the pump has not received a CGM reading for 20 minutes. For example, when the pump and CGM are out of range, during the sensor startup period, when a sensor session ends, or when there is a transmitter or sensor error.

- Correction Factor (range: 1 unit:1 mg/dL to 1 unit:600 mg/dL)
- Carb Ratio (range: 1 unit:1 gram to 1 unit:300 grams)

Below a Carb Ratio of 1:10, increments can be entered in 0.1 gram. For example a Carb Ratio of 1:8.2 can be programmed.

- Target BG (range: 70 mg/dL to 250 mg/dL)

In addition, you can set any or all of the following Bolus Settings:

- Insulin Duration (how long a bolus lowers your BG)

- Carbs (ON indicates entering grams of Carb; OFF indicates entering units of insulin)

NOTE

Changing the Carbs setting on the pump changes the bolus calculators on both the pump and the t:connect™ mobile app.

The default settings and ranges for Bolus Settings are as follows:

- Insulin Duration (default: 5 hrs; range: 2 to 8 hrs)

NOTE

When using Control-IQ technology, the insulin duration is set to five hours and cannot be changed. This duration is used for all bolus deliveries as well as for basal adjustments made by Control-IQ technology.

- Carbs (default: dependent on pump history)

NOTE

If you received a new pump with Control-IQ technology, the default setting will be on. If you updated your pump, the default setting will be the same as what you set up on your pump previously. Check to ensure that the

CHAPTER 6 • Insulin Delivery Settings

Carbs setting is on in order to use Control-IQ technology.

Insulin Duration and Insulin on Board (IOB)

Your pump remembers how much insulin your pump has delivered from boluses. It does this by relying on the insulin duration. The insulin duration reflects the amount of time that insulin is actively lowering your BG.

While the insulin duration setting reflects how long insulin from previous boluses lowers your BG, the IOB feature reflects how much insulin is remaining in your body from previous boluses. IOB is always displayed on the *Home* screen and is used in bolus delivery calculations when applicable. When a glucose value is entered during bolus programming, your pump will consider any active IOB and adjusts the calculated bolus if necessary.

The insulin duration time is displayed on the *Home* screen when Control-IQ technology is not enabled.

Consult your healthcare provider to accurately set your insulin duration.

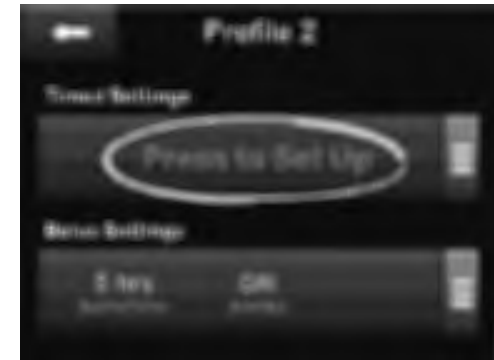
If you have Control-IQ technology enabled, IOB includes all basal delivered above and below the programmed Basal Rate, in addition to all bolus insulin delivered. The insulin duration time is not displayed on the *Home* screen.

Insulin duration is set to 5 hours when Control-IQ technology is enabled and cannot be changed.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap  to create a new profile.
5. Using the on-screen keypad, enter a profile name (up to 16 characters) and tap .

To use the letter keypad, tap once for first letter displayed, two quick taps for middle letter; and three quick taps for the third letter.

6. Tap **Press to Set Up** to begin setting insulin delivery settings.



8.3 Programming a New Personal Profile

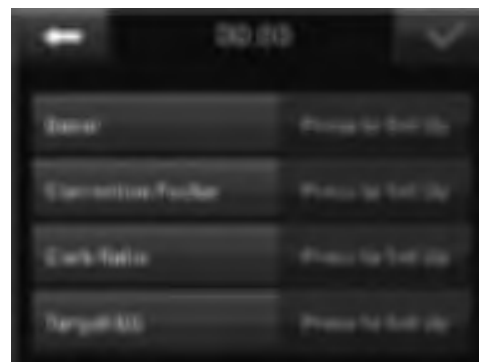
Once the Personal Profile has been created, the settings must be programmed. The first time segment will start at midnight.

- You must program a Basal Rate in order to have a Personal Profile that you can activate.
- You must have Carbs turned on, and you must set a Basal Rate, Correction Factor, Carb Ratio, and Target BG in order to turn Control-IQ technology on.
- Be sure to tap  after entering or changing a value.

PRECAUTION

ALWAYS confirm that the decimal point placement is correct when entering your Personal Profile information. Incorrect decimal point placement can prevent you from getting the proper insulin amount that your healthcare provider has prescribed for you.

Timed Settings



1. Once the new profile has been created, tap **Basal**.
2. Using the on-screen keypad, enter your Basal Rate and tap .

NOTE

If you have previously set a Basal Limit in the Pump Settings, then the Basal Rate entered here must be lower than the Basal Limit entered in the Pump Settings.

3. Tap **Correction Factor**.
4. Using the on-screen keypad, enter your Correction Factor (the mg/dL that 1 unit of insulin will lower BG) and tap .

5. Tap **Carb Ratio**.
6. Using the on-screen keypad, enter your insulin-to-carbohydrate ratio (the grams of carbohydrate to be covered by 1 unit of insulin) and tap .
7. Tap **Target BG**.
8. Using the on-screen keypad, enter your Target BG and tap .

NOTE

Once Control-IQ technology is turned on, the default Target BG is set to 110 mg/dL. For details about target ranges and how Control-IQ technology works, see Chapter 30 Introduction to Control-IQ Technology.

9. Review entered values and tap .
10. Confirm Settings.
 - Tap  if entered data is correct.
 - Tap  to make changes.

CHAPTER 6 • Insulin Delivery Settings

11. Tap  to set the Bolus Settings, or tap  to create additional time segments.



Adding More Time Segments

When adding more time segments, any settings that you entered in the previous time segment are copied and appear in the new segment. This allows you to simply adjust only the specific settings you want, rather than have to enter them all over again.

1. On the *Add Segment* screen, tap **Start Time**.
2. Using the on-screen keypad, enter the time (hour and minutes) that you want the segment to begin, and tap .

3. On the *Add Segment* screen, tap **Time of Day** to select AM or PM, if applicable.

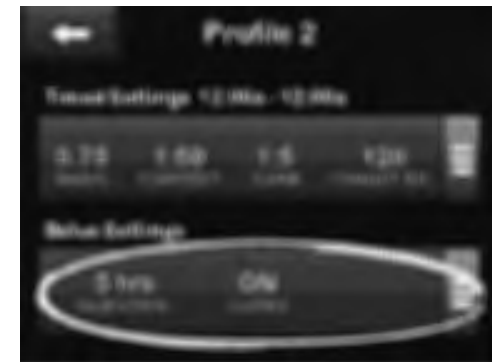
✓ Once a time segment is set beyond 12:00 PM, the default will change to PM.

4. Tap .
5. Repeat steps 1 to 10 from Section 6.2 Creating a New Profile above for each segment you want to create (up to 16).

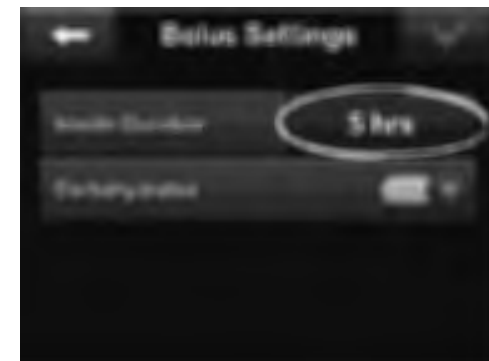
To find time segments in the list that are not displayed on the first screen, tap the **Down Arrow**.

Bolus Settings

1. Tap the **Bolus Settings** panel.



2. Tap **Insulin Duration**.



3. Using the on-screen keypad, enter the desired time for the duration of insulin action (2–8 hrs) and tap .

4. Review entered values and tap .

5. Confirm Settings.

- Tap  if entered data is correct.
- Tap  to make changes.

6. Tap the **Tandem** logo to return to the *Home* screen.

Adding More Personal Profiles

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap .
5. Name the new profile and repeat steps for Timed Settings and Bolus Settings.

NOTE

The Carbohydrates option is turned on by default, but a ratio will still need to be

defined. The Carbohydrates option must be used if Control-IQ technology is enabled.

6.4 Editing or Reviewing an Existing Profile

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to edit or review.
5. Tap **Edit**.

NOTE

To review settings but bypass editing the settings, skip the remaining steps in this section. You can tap  to navigate to the Personal Profiles list or tap the **Tandem** logo to return to the *Home* screen.

6. Tap **Timed Settings** panel.
7. Tap the desired time segment to edit.

8. Tap **Basal**, **Correction Factor**, **Carb Ratio** or **Target BG** to make changes as needed and use the on-screen keypad to enter changes. Tap .

9. View recent changes and tap .

10. Confirm Settings.

- Tap  if entered data is correct.
- Tap  to make changes.

11. Edit other time segments within the Timed Settings by tapping on them and using the same steps described above.

12. Tap  after editing all of the time segments.

13. Tap the **Bolus Settings** panel to change Insulin Duration Carbohydrates as needed. Use the on-screen keypad to enter desired changes. Tap .

14. Confirm Settings.

CHAPTER 6 • Insulin Delivery Settings

- Tap  if entered data is correct.
 - Tap  and make changes.
15. Tap the **Tandem logo** to return to the *Home* screen.

NOTE

To add a time segment, tap  and enter the desired start time.

NOTE

To delete a time segment, tap on the X to the left of the time segment and tap  to confirm.

6.5 Duplicating an Existing Profile

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to duplicate.
5. Tap **Duplicate**.

6. Confirm profile to duplicate by tapping .
 7. Using the on-screen keypad, enter the name (up to 16 characters) for the new profile and tap .
- ✓ *Profile Duplicated* screen is displayed.
 - ✓ A new Personal Profile will be created with the same settings as the profile copied.
8. Tap the **Timed Settings** or **Bolus Settings** panel to make changes to the new profile.

6.6 Activating an Existing Profile

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to be activated.

- The **Activate** and **Delete** options are disabled for the active profile because the profile is already activated. You cannot delete a profile until you have activated another profile.
- If you have only one profile defined, you do not need to activate it (that profile is automatically activated).

5. Tap **Activate**.

- ✓ A screen to confirm the activation request is displayed.

6. Tap .

- ✓ *Profile Activated* screen is displayed.

6.7 Renaming an Existing Profile

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.

4. Tap the name of the Personal Profile to be renamed.
5. Tap **Down Arrow**, and then **Rename**.
6. Using the on-screen keypad, rename the profile name (up to 16 characters) and tap .
7. Tap the **Tandem** logo to return to the *Home* screen.

6.8 Deleting an Existing Profile

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to be deleted.

NOTE

The active Personal Profile cannot be deleted.

5. Tap **Delete**.

6. Tap .

✓ *Profile Deleted* screen is displayed.

7. Tap the **Tandem** logo to return to the *Home* screen.

6.9 Starting a Temporary Basal Rate

A Temp Rate is used to increase or decrease (by percentage) the current Basal Rate for a period of time. This feature can be helpful for situations such as exercise or illness.

When you enter the *Temp Rate* screen, the default values are 100% (current Basal Rate) and a Duration of 0:15 min. The Temp Rate can be set from a minimum of 0% of current Basal Rate to a maximum of 250% of current Basal Rate in increments of 1%.

Duration can be set from a minimum of 15 minutes to a maximum of 72 hours in increments of 1 minute.

If you program a Temp Rate greater than 0% but less than the minimum allowable Basal Rate of 0.1 units/hr,

you will be notified that the selected rate is too low and that it will be set to the minimum allowable rate for delivery.

If you program a Temp Rate more than the maximum allowable Basal Rate of 15 units/hr, or more than your Basal Limit set up in the Pump Settings, you will be notified that the selected rate is too high and that it will be reduced so that it does not exceed the maximum allowable rate for delivery.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap **Temp Rate**.
4. Tap **Temp Rate** again.
5. Using the on-screen keypad enter desired percentage. The current rate is 100%. An increase is greater than 100% and decrease is less than 100%.
6. Tap .

CHAPTER 6 • Insulin Delivery Settings

7. Tap **Duration**. Using the on-screen keypad enter desired length of time for Temp Rate. Tap .

You can always tap **View Units** to see the actual units to be delivered.

8. Verify settings and tap .

- ✓ The *TEMP RATE STARTED* screen is temporarily displayed.

- ✓ The *Lock* screen will be displayed with the icon indicating a Temp Rate is active.

- An T in an orange box means a Temp Rate is active.
- A T in a red box means a Temp Rate of 0 u/hr is active.

NOTE

If a Temp Rate is active when you stop insulin, including when you change a cartridge or infusion set, the Temp Rate timer will remain active. The Temp Rate will be resumed when insulin delivery is resumed as long as there is time remaining on the Temp Rate Timer.

6.10 Stopping a Temp Rate

To stop an active temp rate:

1. From the *Home* screen, tap **OPTIONS**.
 2. Tap **Activity**.
 3. On the *Activity* screen, tap  on the right side of Temp Rate.
 4. On the confirmation screen, tap .
- ✓ The *TEMP RATE STOPPED* screen appears before returning to the *Activity* screen.

2 t:slim X2 Insulin Pump Features

CHAPTER 7

Infusion Site Care and Loading Cartridge

CHAPTER 7 • Infusion Site Care and Loading Cartridge

7.1 Infusion Site Selection and Care**⚠ WARNING**

ALWAYS use only cartridges and insulin infusion sets with matching connectors and follow their instructions for use. Failure to do so may result in over delivery or under delivery of insulin and may cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

ALWAYS carefully follow the instructions for use accompanying your infusion set for proper insertion and infusion site care, as failure to do so could result in over delivery or under delivery of insulin or infection.

⚠ WARNING

DO NOT place your infusion set on any scars, lumps, moles, stretch marks or tattoos. Placing your infusion set in these areas can cause swelling, irritation or infection. This can affect insulin absorption and cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

DO NOT change your infusion set before bedtime or if you will not be able to test your BG

1–2 hours after the new infusion set is placed. It is important to confirm that the infusion set is inserted correctly and delivering insulin. It is also important to respond quickly to any problems with the insertion to ensure continued insulin delivery.

⚠ PRECAUTION

CHECK your infusion site daily for proper placement and leaks. **REPLACE** your infusion set if you notice leaks around the site, or if you suspect your infusion set cannula may have become dislodged. Improperly placed sites or leaks around the infusion site can result in under delivery of insulin.

General Guidelines**Site Selection**

- Your infusion set can be worn anywhere on your body that you would normally inject insulin. Absorption varies from site to site. Discuss options with your healthcare provider.
- The most commonly used sites are the abdomen, upper buttocks, hips, upper arms, and upper legs.

- The abdomen is the most popular site because of access to fatty tissue. If using the abdominal area, **AVOID**:

- Areas that would constrict the site such as the belt line, waistline, or where you would normally bend.
- Areas 2 inches (5 cm) around your belly button.
- **AVOID** sites with any scars, moles, stretch marks, or tattoos.
- **AVOID** site areas within 3 inches (7.6 cm) of your CGM sensor site.

Site Rotation**⚠ PRECAUTION**

CHANGE your infusion set every 48 hours if using Humalog insulin; every 72 hours if using NovoLog insulin. Wash your hands with anti-bacterial soap before handling the infusion set and thoroughly clean the insertion site on your body to avoid infection. Contact your healthcare provider if you have symptoms of infection at your insulin infusion site.

- The infusion set must be replaced and rotated every 48 hours if using

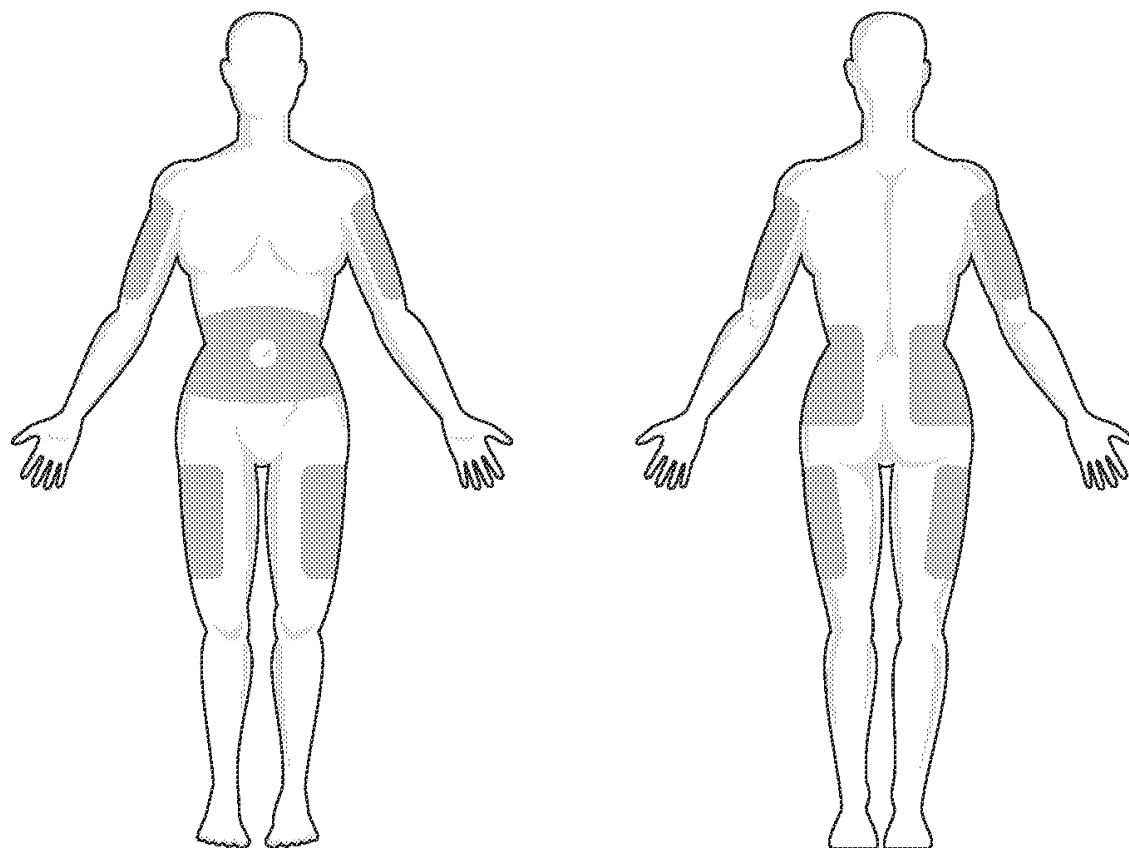
Humalog insulin; every 72 hours if using NovoLog insulin, or more often if needed.

- With experience, you will find areas that not only provide better absorption, but are more comfortable. Keep in mind, using the same areas may cause scarring or lumps which can affect insulin absorption.
- Consult your healthcare provider to establish a rotation schedule that best fits your needs.

Keep it Clean

- When changing your infusion set, use clean techniques to avoid an infection.
- Wash your hands, use antiseptic wipes or infusion site preparation products, and keep the area clean.
- Site preparation products that have both an antiseptic and an adhesive are encouraged.

Areas of Body for Infusion Set Insertion



CHAPTER 7 • Infusion Site Care and Loading Cartridge

7.2 Cartridge Instructions for Use

For complete cartridge labeling, consult the cartridge instructions for use included in the t:slim™ cartridge box.

7.3 Filling and Loading a t:slim X2 Cartridge

This section describes how to fill the cartridge with insulin and load the cartridge into your t:slim X2™ pump. The single-use disposable cartridge can hold up to 300 units (3.0 mL) of insulin.

⚠ WARNING

ONLY use U-100 Humalog or U-100 NovoLog with your pump. Only U-100 Humalog and U-100 NovoLog have been tested and found to be compatible for use in the pump. Use of insulin with greater or lesser concentration can result in an over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

ALWAYS use cartridges manufactured by Tandem Diabetes Care. Use of any other cartridge brand may result in over delivery or under delivery of insulin. This can cause

hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

DO NOT reuse cartridges. Reuse of cartridges may result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

Before you begin, make sure you have the following items:

- 1 unopened cartridge
- 3.0 mL syringe and fill needle
- vial of U-100 Humalog or U-100 NovoLog insulin
- alcohol prep swab
- 1 new infusion set
- infusion set instructions for use

📌 NOTE

The pump will beep or vibrate, depending on your pump settings, while the tubing is filling with insulin. To change the Fill Tubing sound setting, see Section 5.12 Sound Volume.

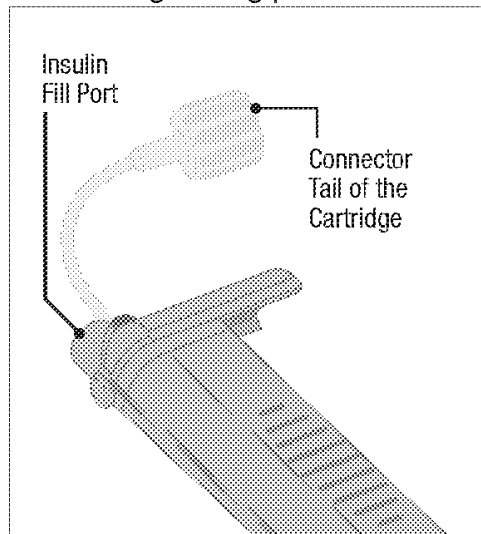
📌 NOTE

DO NOT remove the used cartridge from the pump during the load process until prompted on the pump screen.

📌 NOTE

Control-IQ™ technology will continue to make calculations based on CGM values while the cartridge is being filled. Since there is no insulin delivered during the cartridge fill process, there will be no actual Basal Rate adjustments until the cartridge is filled and loaded back onto the pump. Control-IQ technology will then immediately begin to operate normally.

The illustration identifies the connector and insulin fill port used in the cartridge filling process.



⚠ PRECAUTION

CHANGE your cartridge every 48–72 hours as recommended by your healthcare provider. Wash your hands with anti-bacterial soap before handling the infusion set and thoroughly clean the insertion site on your body to avoid infection. Contact your healthcare provider if you have symptoms of infection at your insulin infusion site.

Instructions for Drawing Insulin from Vial into Syringe

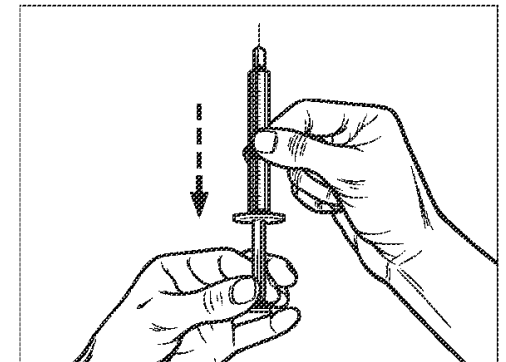
⚠ PRECAUTION

ALWAYS remove all air bubbles from the cartridge before beginning insulin delivery. Ensure there are no air bubbles when drawing insulin into the filling syringe, hold the pump with the white fill port pointed up when filling the tubing, and ensure that there are no air bubbles in the tubing when filling. Air in the system takes space where insulin should be and can affect insulin delivery.

The fill estimate displayed on the pump is the amount of insulin available for delivery. It does not include insulin needed to fill the tubing (up to 30 units) and a small amount of insulin that is not available for delivery. When filling the syringe, add approximately 45 units to the amount of insulin you want available for delivery.

- For example, the pump requires a minimum of 50 units available for delivery after fill tubing has been completed. Fill the syringe with approximately 95 units to have enough to fill your tubing and still have 50 units available for delivery.

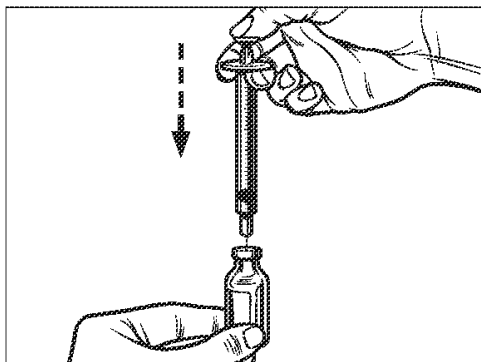
1. Inspect the needle and syringe package for any signs of damage. Discard any damaged product.
2. Wash your hands thoroughly.
3. Wipe the rubber septum of the insulin vial with an alcohol swab.
4. Remove the needle and syringe from their packaging. Securely twist needle onto syringe. Safely remove protective cap from needle by pulling outward.
5. Draw air into syringe up to the amount of insulin desired.



6. With insulin vial upright, insert needle into vial. Inject air from

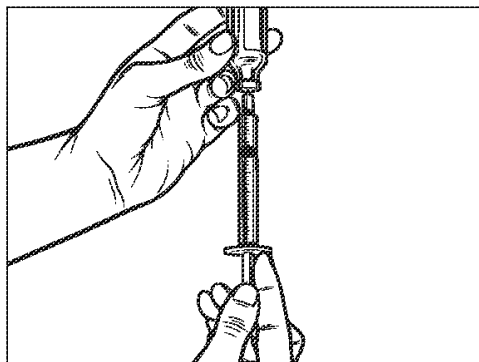
CHAPTER 7 • Insulin Site Care and Loading Cartridge

syringe into vial. Maintain pressure on syringe plunger.

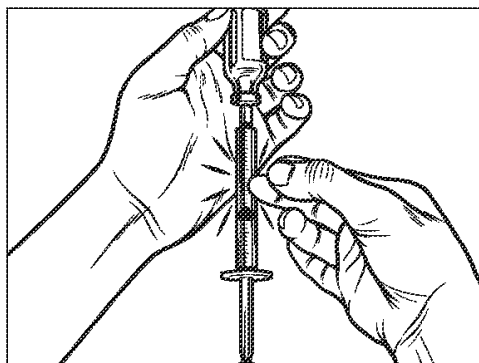


7. With needle still inserted into vial, turn vial and syringe upside down. Release syringe plunger. Insulin will begin to flow from the vial into the syringe.

8. Slowly pull back the plunger to the desired amount of insulin.



9. While the filling needle is still in the vial and upside down, tap the syringe so that any air bubbles rise to the top. Then slowly push the plunger upwards, forcing any air bubbles back into the vial.

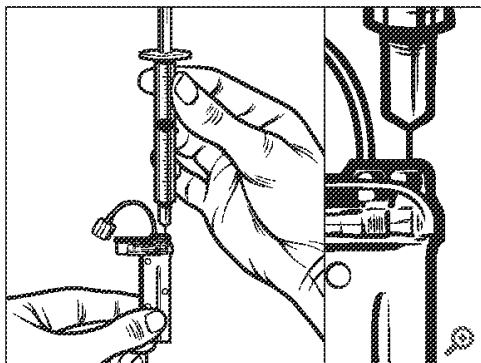


10. Check the syringe for air bubbles and do one of the following:

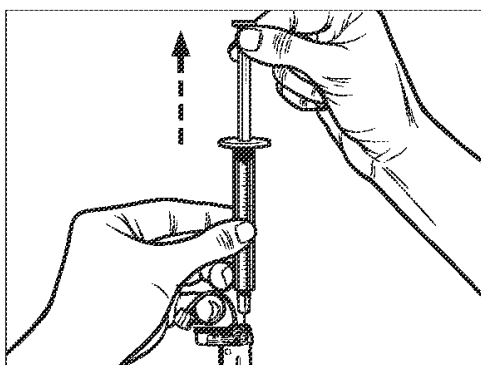
- If there are air bubbles present, repeat step 9.
- If no air bubbles are present, remove the filling needle from the vial.

Instructions for Filling the Cartridge

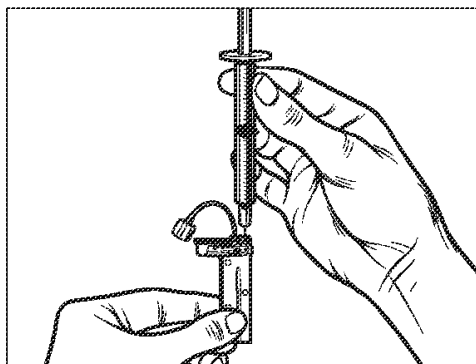
1. Inspect the cartridge package for any signs of damage. Discard any damaged product.
2. Open the package and remove the cartridge.
3. Hold the cartridge upright and gently insert the needle into the white insulin fill port on the cartridge. The needle is not intended to go all the way in, so do not force it.



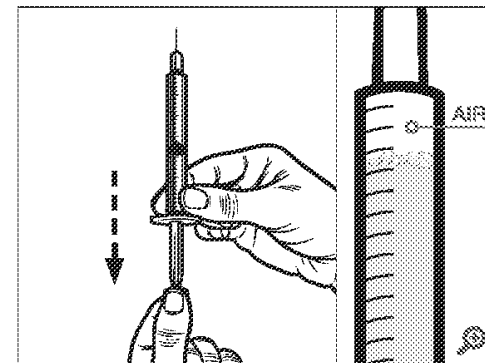
4. Keeping the syringe vertically aligned with the cartridge, and the needle inside the fill port, pull back on the plunger until it is fully retracted. This will remove any residual air from the cartridge. Bubbles will rise toward the plunger.



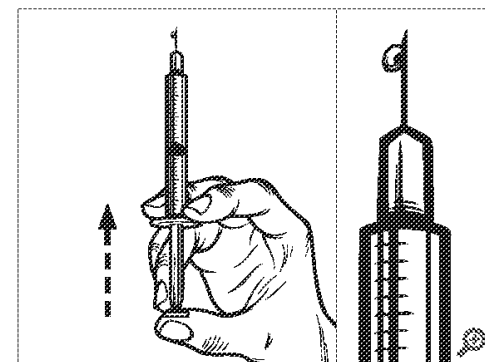
5. Make sure the needle is still in the fill port and release the plunger. Pressure will pull the plunger to its neutral position but it will NOT push any air back inside the cartridge.



6. Withdraw the needle from the fill port.
7. Turn the syringe upright and pull down on the plunger. Flick the barrel to make sure that any air bubbles rise to the top.



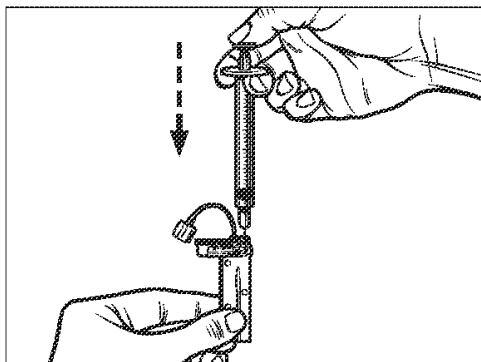
8. Gently press on the plunger to remove air bubbles until insulin fills the needle hub and you see a drop of insulin at the tip of the needle.



9. Re-insert the needle in the fill port and slowly fill the cartridge with insulin. It is normal to feel some

CHAPTER 7 • Infusion Site Care and Loading Cartridge

back pressure as you slowly press on the plunger.



10. Maintain pressure on the plunger while you remove the needle from the cartridge. Check the cartridge for leaks. If you detect insulin leaking, discard the cartridge and repeat entire process with a new cartridge.
11. Always dispose of used needles, syringes, cartridges, and infusion sets following local regulations.

Instructions on How to Install a Cartridge

If this is the very first time you are loading the cartridge, remove the

shipping canister (which is not for human use) from the back of the pump.

1. From the *Home* screen, tap **OPTIONS**.

2. Tap **Load**.

During the load sequence, the **Tandem** logo is disabled. Tapping it will not return to the *Home* screen.

3. Tap **Change Cartridge**.

4. A screen will display to notify you that all insulin deliveries will be stopped. Tap  to continue.

NOTE

This screen will not be displayed if this is the first time loading a new cartridge and you have not started actively pumping.

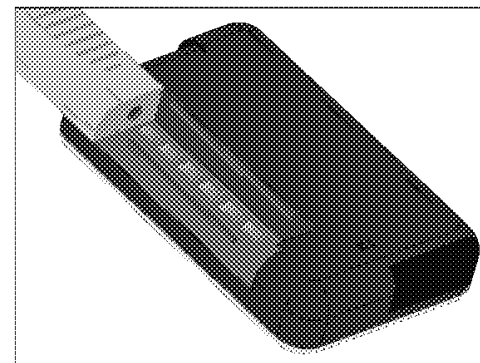
5. Disconnect the infusion set from your body and tap  to continue.

- ✓ *Preparing for Cartridge* screen is displayed.

6. Remove the used cartridge. If needed, place the cartridge removal

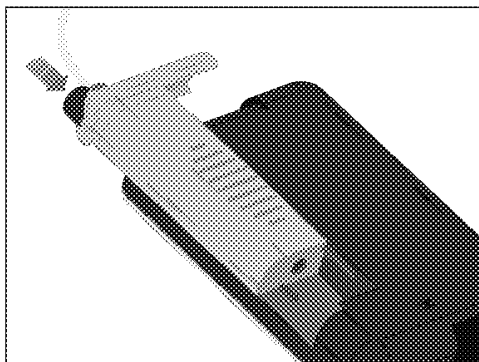
tool or the edge of a coin in the slot at the bottom of the cartridge and twist to aid in the removal of the cartridge.

7. Place the bottom of the cartridge at the end of the pump. Make sure cartridge is lined up to both guide tracks.



8. Push on the circular fill port next to the cartridge tubing to slide the

cartridge onto the pump. Tap the UNLOCK icon when completed.



9. Tap  to continue.

- ✓ *Detecting Cartridge* screen is displayed.
- ✓ After completing the cartridge change, the pump will automatically prompt you to fill the tubing.

10. Tap  to fill the tubing.

⚠ WARNING

DO NOT remove or add insulin from a filled cartridge after loading onto the pump. This will result in an inaccurate display of the insulin level on the *Home* screen and you could run out of insulin before the pump detects an empty

cartridge. This can cause very high BG, or Diabetic Ketoacidosis (DKA).

7.4 Filling Tubing

Filling the Infusion Set Tubing with Insulin

⚠ WARNING

NEVER fill your tubing while your infusion set is connected to your body. Always ensure that the infusion set is disconnected from your body before filling the tubing. Failure to disconnect your infusion set from your body before filling the tubing can result in over delivery of insulin. This can cause hypoglycemia (low BG) events.

This section describes how to fill the infusion set tubing with insulin after you change the cartridge. If you just completed step 10 from the previous section, skip to step 4.

■ NOTE

The pump will beep or vibrate, depending on your pump settings, while the tubing is filling with insulin. To change the Fill Tubing sound setting, see Section 5.12 Sound Volume.

To fill the tubing without changing the cartridge, from the *Home* screen tap **OPTIONS**, tap **Load**, tap **Fill Tubing** and then follow the instructions.

- Tap **NEW** if you installed a new cartridge.
- Tap **FILL** if you did not install a new cartridge and want to continue with filling the tubing.

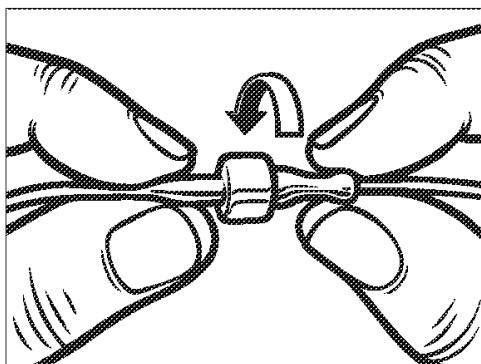
⚠ PRECAUTION

CHECK your infusion set tubing daily for any leaks, air bubbles, or kinks. Air in the tubing, leaks in the tubing, or kinked tubing may restrict or stop insulin delivery and result in under delivery of insulin.

1. Verify that the infusion set is disconnected from your body.
2. Ensure that the new infusion set package is not damaged, and remove the sterile tubing from the package. If the package is damaged or opened, discard properly and use another tubing set. Be careful to keep the tubing connector away from unclean areas.

CHAPTER 7 • Insulin Site Care and Loading Cartridge

3. Attach the infusion set tubing to the tubing connector on the cartridge tubing. Twist clockwise until finger tight and then twist another quarter of a turn to ensure a secure connection.

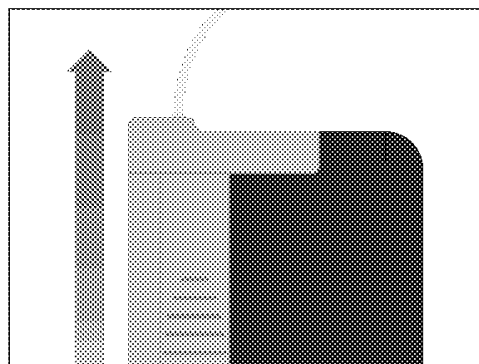


⚠ WARNING

ALWAYS twist the tubing connector between the cartridge tubing and the infusion set tubing an extra quarter of a turn to ensure a secure connection. A loose connection can cause insulin to leak, resulting in under delivery of insulin. This can cause hyperglycemia (high BG) events.

4. Hold the pump vertically to ensure any air in the cartridge will be dispelled first. Tap **START**. The pump will beep and vibrate regularly

while the tubing is being filled, depending on your Sound Volume settings.



- ✓ *Starting Fill* screen is displayed.

The following are approximate amounts of insulin to fill different tubing lengths:

- 10–15 units for 23 inch (60 cm) tubing
- 15–20 units for 32 inch (80 cm) tubing
- 20–25 units for 43 inch (110 cm) tubing

5. Tap **STOP** after 3 drops of insulin are seen at the end of the infusion set tubing.

- ✓ *Stopping Fill* screen is displayed.

- ✓ *Detecting Insulin* screen is displayed.

6. Verify that drops are seen and tap **DONE**.

- If you do not see drops, tap **FILL**. The *Fill Tubing* screen appears, repeat steps 4 and 5 until you see 3 drops of insulin at the end of the tubing.
- The tubing may be filled with a maximum of 30 units of insulin during each fill cycle. If you do not tap **STOP**, a notification screen will appear letting you know that the maximum amount has been filled. Do one of the following:
 - a. If you are finished filling the tubing, tap **DONE**.
 - b. If you want to fill the tubing with more than 30 units, tap **FILL** to

go back to the *Fill Tubing* screen.

- ✓ *Fill Tubing is complete* screen is temporarily displayed.

NOTE

After tubing fill is complete, when the pump returns to the *Home* screen, an estimate of how much insulin is in the cartridge is displayed in the upper right portion of the screen. You will see one of the following on the screen:

- + 40 u More than 40 units detected in the cartridge
- + 60 u More than 60 units detected in the cartridge
- + 120 u More than 120 units detected in the cartridge
- + 180 u More than 180 units detected in the cartridge
- + 240 u More than 240 units detected in the cartridge

After 10 units are delivered, an actual number of units remaining in the cartridge will be displayed on the *Home* screen.

The amount of insulin remaining displayed on the *Home* screen will decrease 5 units at a time (for example, you will see 140, 135, 130, 125). When less than 40 units remain, it will begin decreasing 1 unit at a time (for example, you will see 40, 39, 38, 37) until there is 1 unit remaining.

- ✓ A screen will display to instruct you to insert a new infusion set and connect to the filled tubing.

7.5 Filling Cannula

Filling the Infusion Set Cannula with Insulin

This section describes how to fill the infusion set cannula with insulin after you fill the tubing.

To fill the cannula without filling the tubing, from the *Home* screen, tap **OPTIONS**, tap **Load**, tap **Fill Cannula** and then follow the instructions below.

If you are using a steel needle infusion set, there is no cannula; skip this section.

To Fill the Cannula:

1. Tap **Fill Cannula**.
2. Insert a new infusion set and connect filled tubing to site, then tap .
3. Tap **Edit Fill Amount**.
 - ✓ The cannula fill amount displayed is based on your last cannula fill amount. Filling stops at this amount.
4. Select amount needed for cannula fill.
 - See your infusion set instructions for use for proper cannula fill amount.
 - If the amount needed is not listed, tap **Other amount** and use the on-screen keypad to enter a value between 0.1 to 1.0 unit.
5. Tap **START**.
 - ✓ The *STARTING FILL* screen is displayed.

CHAPTER 7 • Insulin Site Care and Loading Cartridge

- ✓ After fill is complete, *STOPPING FILL* screen is displayed.

NOTE

You can tap **STOP** at any time during the fill process if you want to stop filling the cannula.

- ✓ The screen will return to the *Load* menu if the Site Reminder is turned off.
6. Tap  to resume insulin if finished. Or tap **Site Reminder** to set reminder. If Site Reminder is on, the pump will automatically display the *Site Reminder* screen (see the next section).

7.6 Setting Site Reminder

This section describes how to set the Site Reminder after you fill the cannula.

To set the Site Reminder without filling the cannula, from the *Home* screen, tap **OPTIONS**, tap **Load**, tap **Site Reminder** then follow the instructions below.

1. Tap  if correct. Tap **Edit Reminder** if settings need to be changed.
 2. Tap **Remind Me In** and select the number of days (1–3).
- ✓ The default for the Site Reminder is set for 3 days
3. Tap **Remind Me At**. Use the on-screen keypad to enter time and tap .
 4. Tap **Time of Day** to change AM or PM, if applicable. Tap .
 5. Verify Site Reminder is set correctly and tap .
- ✓ *Setting Saved* screen is displayed.
 - ✓ *Load* screen is displayed.
6. Tap .
- ✓ A reminder to test BG in 1 to 2 hours will display.
7. Tap .

NOTE

If this is the first time using your pump and a Personal Profile has not been defined, a screen will notify you that a profile must be activated to resume insulin. Tap **CLOSE**.

- ✓ *RESUMING INSULIN* screen is temporarily displayed.

NOTE

Control-IQ technology will continue to operate while changing a cartridge. If you complete a cartridge change and resume insulin while Control-IQ technology is adjusting insulin, insulin will resume until the next five minute CGM reading. At this time the pump will resume normal operation.

2 t:slim X2 Insulin Pump Features

CHAPTER 8

Manual Bolus

CHAPTER 8

8.1 Manual Bolus Overview**⚠ WARNING**

DO NOT deliver a bolus until you have reviewed the calculated bolus amount. If you deliver an insulin amount that is too high or too low, this could cause hypoglycemia (low BG) or hyperglycemia (high BG) events. You can change the amount of insulin before you deliver your bolus.

⚠ WARNING

Delivering large boluses, or delivering multiple boluses back to back may cause hypoglycemia (low BG) events. Pay attention to IOB and the bolus calculator recommended dose before delivering large or multiple boluses.

⚠ WARNING

If you do not see a reduction in BG after initiating a bolus, it is recommended that you check your infusion set for an occlusion, air bubbles, or for leaks or cannula dislodgement. If the condition persists, call Customer Technical Support or seek medical attention as required.

📌 NOTE

The information in this chapter does NOT apply to boluses delivered automatically by

Control-IQ™ technology. For information about Automatic Bolus Delivery, see Automatic Correction Bolus Delivery in Section 30.2 How Control-IQ Technology Works.

A bolus is a quick dose of insulin that is usually delivered to cover food eaten or to correct high glucose. A bolus can be requested from either the t:slim X2™ insulin pump or the t:connect™ mobile app.

The minimum bolus size is 0.05 units. The maximum bolus size is 25 units. If you attempt to deliver a bolus that is larger than the amount of insulin in the cartridge, a message screen appears indicating that there is not enough insulin to deliver the bolus.

Your t:slim X2 pump offers you the ability to deliver different boluses to cover carbohydrate intake (food bolus) and bring your BG back to target (correction bolus). Food and correction boluses can also be programmed together.

📌 NOTE

If you start a manual bolus request on the pump, you must complete it on the pump. You cannot

request a bolus from the t:connect mobile app while a bolus request is active on the pump.

If Carbs is turned on in your active Personal Profile, you will enter grams of carbohydrate and the bolus will be calculated using your Carb Ratio.

If you are not using Control-IQ technology and Carbs is turned off in your active Personal Profile, you will enter units of insulin to request the bolus.

📌 NOTE

If you deliver a manual bolus, Control-IQ technology will not be able to deliver an automatic correction bolus until 60 minutes after the manual bolus has completed.

Before you use the t:connect™ mobile app to deliver a bolus, ensure your smartphone's security feature (e.g., screen lock, passcode, face recognition) is turned on. Never share your security PIN/password or authorize any other person to access your smartphone via their biometric information to avoid unintentional changes in your delivery of insulin.

NOTE

If your smartphone is not connected to the pump, you can only request a bolus from the pump. For more information on establishing a connection between your smartphone and the pump, see Section 4.3 Connecting to a Smartphone.

PRECAUTION

CHECK your pump's settings regularly to ensure they are correct. Incorrect settings can result in over delivery or under delivery of insulin. Consult your healthcare provider as needed.

8.2 Initiating a Bolus

To request a bolus, tap **BOLUS** on your pump's *Home* screen or tap **Bolus** from the *Navigation* bar in the t:connect mobile app.

WARNING

You have 10 seconds to cancel a bolus after requesting it to completely avoid insulin delivery; both the pump and the t:connect mobile app will say "requesting bolus" during this time. See Section 8.10 Canceling or Stopping a Bolus Using the Pump or Section 8.15 Canceling or Stopping a Bolus Using the t:connect Mobile App for instructions to cancel a bolus.

You can request a bolus using the t:connect mobile app when each of the following conditions are true:

- You have a compatible smartphone (see tandemdiabetes.com/mobilesupport)
- Your smartphone is connected to your pump
- You have a native security feature of your smartphone turned on

See Section 8.11 Bolus Delivery Using the t:connect Mobile App for further instructions to use the t:connect mobile app to request a bolus.

8.3 Correction Bolus Calculation

Once the pump knows your glucose value, it will determine whether to recommend that a correction bolus to be added to any other bolus requested on the *Bolus* screen. The pump can receive your glucose value from manual entry into the pump or the CGM.

When your glucose value is:

- Above Target BG: the insulin for the food bolus and the correction bolus will be added together. If IOB is present, it is subtracted only from the correction portion of the bolus.
- Between 70 mg/dL and Target BG: You will be given an option to reduce the food bolus to account for the lower glucose level. In addition, if IOB is present, it will also be used to reduce the bolus calculation.
- Below 70 mg/dL: The food bolus will be reduced for the low glucose value. In addition, if IOB is present, it will also be used to reduce the bolus calculation.

Always treat hypoglycemia (low BG) with fast-acting carbohydrates according to the instructions of your healthcare provider and then re-test your BG to ensure that the treatment was successful.

CHAPTER 8

Glucose Value Auto-Population with CGM

⚠ PRECAUTION

PAY ATTENTION to the trend information on the *CGM Home* screen, as well as your symptoms, before using CGM values to calculate and deliver a correction bolus. Individual CGM values may not be as accurate as BG meter values.

📌 NOTE

With a CGM that is approved for non-adjunctive use, there is no need to take a fingerstick to make a treatment decision, as long as your symptoms match the CGM readings. The t:slim X2 insulin pump and the t:connect mobile app can automatically use CGM readings in their respective bolus calculators when Control-IQ technology is enabled and there is a valid reading and trend arrow available from the CGM. If your CGM readings don't match your symptoms, it is recommended that you wash your hands thoroughly and use your BG meter to replace the CGM reading in the bolus calculator if the BG meter value matches your symptoms. If you want to align your CGM with your BG meter, you should follow the instructions to calibrate your CGM. Do not take insulin doses too close together, often referred to as stacking insulin. If you have recently given a bolus, you

might wait 60 minutes to see if your readings respond to the bolus.

📌 NOTE

Retrospective analysis of the pivotal study results indicated that there was an increased incidence of CGM values <70 mg/dL five hours after a bolus was delivered when glucose values were auto-populated. See Section 33.10 *Additional Analysis of Sensor Glucose Value Auto-Population with CGM* for more information.

Your glucose value is automatically entered into the GLUCOSE field on the *Bolus* screen when each of the following conditions are true:

- Control-IQ technology is turned on and available
- A CGM session is active
- A CGM value is present
- A CGM trend arrow is available on the CGM Home screen

📌 NOTE

For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's

product instructions. You can also see Section 25.3 *Rate of Change Arrows*.

When the CGM reading is automatically populated into the bolus calculator, only the current CGM reading is used to calculate the correction bolus. The trend arrow is not used in the dose calculation. Speak with your healthcare provider for recommendations on how best to utilize the arrows for your correction bolus dosing.

If your healthcare provider has advised you to use the trend arrow to adjust your correction dose, or if you want to change the glucose value used to calculate your correction dose, you can manually override the glucose value auto-populated from your CGM.

To change the glucose value auto-populated from your CGM you can tap on the GLUCOSE value on the

Bolus screen. The following example shows the *Bolus* screen on the pump.



NOTE

If the glucose value auto-populated from your CGM was above or below your Target BG, your pump will present you with the *Above Target* or *Below Target Correction Bolus* confirmation screen.

Correction Bolus Confirmation Screens

To access the *Correction Bolus* confirmation screen on the pump, tap **BOLUS** from the *CGM Home* screen.

- If your CGM value or trend arrow are not available on the *Home* screen, the *Bolus* screen appears.

- If you have a CGM value and trend arrow, the *Correction Bolus* confirmation screen appears (if appropriate).

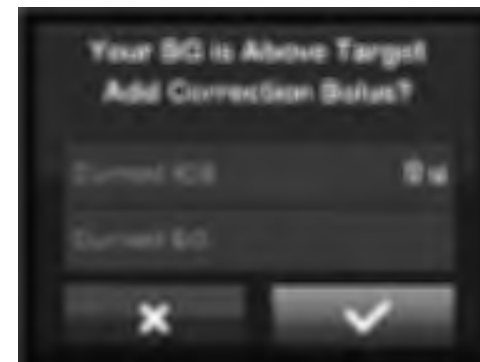
You cannot tap the **Current BG** value on these *Correction Bolus* confirmation screens to change the glucose value auto-populated from your CGM.

Tap either  or  and proceed to the *Bolus* screen to change the glucose value as described above. Once the value is changed, if the manually inputted value is above or below your Target BG, your pump will again present you with the *Above Target* or *Below Target* confirmation screen where you can choose to accept the correction bolus or decline it.

Above Target

If your glucose value is above your Target BG, you can calculate and add a correction bolus to any other bolus you request.

Calculate and add a correction bolus from the pump as follows:



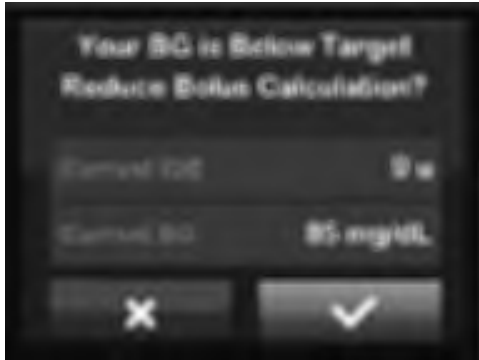
- To accept the correction bolus tap . A correction bolus is calculated and will be added to any food bolus you request on the *Bolus* screen.
- To decline the correction bolus, tap . No correction bolus will be added to any food bolus you request on the *Bolus* screen.

Below Target

If your glucose value is below your Target BG, the pump presents you with the option to calculate and subtract a

CHAPTER 8

correction bolus from any other bolus you request.



Calculate and apply a correction bolus from the pump as follows:

- To accept the correction bolus tap . A correction bolus is calculated and will be subtracted from any food bolus you request on the *Bolus* screen.
- To decline the correction bolus, tap . No correction bolus will be subtracted from any food bolus you request on the *Bolus* screen.

Within Target

If your glucose value is the same value as your Target BG, no *Correction Bolus* screen is displayed.

BG Value Manual Entry

If your glucose value was not auto-populated on the *Bolus* screen based on the conditions needed for that feature, you will need to manually enter your BG value into the pump before confirming bolus delivery. The conditions needed for the auto-populate feature are:

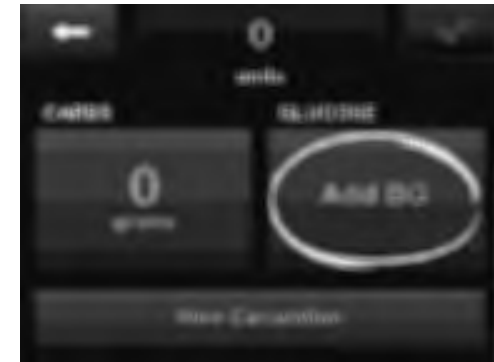
- Control-IQ technology is turned on and available
- A CGM session is active
- A CGM value is present
- A CGM trend arrow is available

NOTE

For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's user guide. You can also see Section 25.3 Rate of Change Arrows.

The *Correction Bolus* confirmation screens are displayed, if appropriate, after you manually enter your BG value on the *Bolus* screen. Manually enter your BG value into the pump as follows:

- From the *Home* screen tap **BOLUS**.
- Tap **Add BG**.



- Using the on-screen keypad, enter your BG value.
- Tap to save the BG value in your pump history.

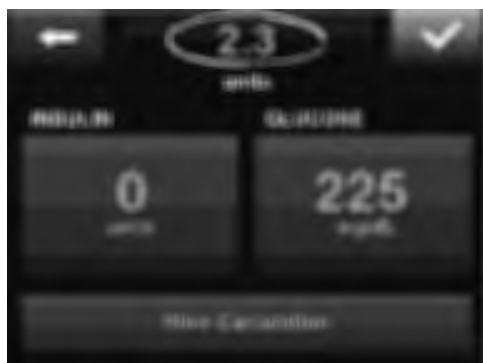
NOTE

This saves the BG value in your pump history whether or not a bolus is delivered.

- Follow the steps in the appropriate Target section above depending on the results of your BG value.

8.4 Bolus Override

You can override the calculated bolus by tapping on the calculated units value and entering the units of insulin you want delivered. The bolus override is always an available option; the following example shows the bolus override on the pump screen.



8.5 Food Bolus Using Units

If you are using Control-IQ technology, skip to Section 8.6 Food Bolus Using Grams. Otherwise, to deliver a food bolus using the pump:

1. From the *Home* screen, tap **BOLUS**.

2. Tap **0 units** on the left side of the screen.
3. Using the on-screen keypad enter units of insulin to be delivered, then tap .

⚠ WARNING

ALWAYS confirm that the decimal point placement is correct when entering bolus information. Incorrect decimal point placement can prevent you from getting the proper amount of insulin that your healthcare provider has prescribed for you.

4. Tap to confirm the units of insulin to be delivered.
 5. Confirm Request.
 - Tap if entered data is correct.
 - Tap to go back to make changes or view calculations.
 6. Tap .
- ✓ The *BOLUS INITIATED* screen is temporarily displayed.

8.6 Food Bolus Using Grams

To deliver a food bolus using the pump:

1. From the *Home* screen, tap **BOLUS**.
2. Tap **0 grams**.
3. Using the on-screen keypad enter grams of carb and tap .
 - To add multiple carb values enter first value, then tap , enter second value, tap . Continue until done.
 - To clear the value entered and start over, tap the back arrow.
4. Check that the grams of carb are entered in the correct location on the screen.
5. Tap to confirm the units of insulin to be delivered.

You can always tap **View Calculation** to display the *Delivery Calculation* screen.

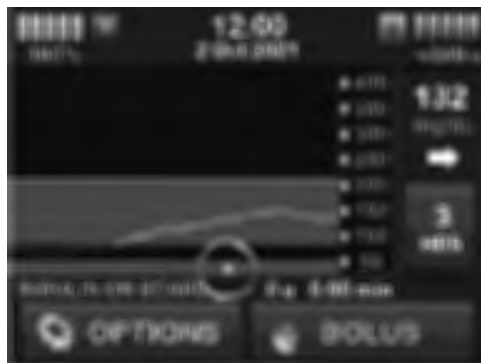
CHAPTER 8

6. Confirm Request.

- Tap  if entered data is correct.
- Tap  to go back to make changes or view calculations.

7. Tap .

- ✓ The *BOLUS INITIATED* screen is temporarily displayed.
- ✓ After the bolus delivery is complete, an icon displays below the CGM graph.

 NOTE

Each bolus icon represents one bolus delivery. Hash marks on the bolus bar denote time increments based on your

graph settings; these hash marks may temporarily obstruct a bolus icon as the graph changes over time.

8.7 Extended Bolus

The Extended Bolus feature allows you to deliver part of the bolus now and part of the bolus slowly over a period of up to 8 hours, or to deliver the whole bolus over an extended period of time. This can be helpful for high fat meals such as pizza or if you have gastroparesis (delayed stomach emptying).

When extending a bolus, any correction bolus amount will always be given in the DELIVER NOW portion. Talk with your healthcare provider to determine if this feature is appropriate for you, as well as for recommendations on the split between now and later and the duration for the later portion.

1. From the *Home* screen, tap **BOLUS**.
2. Tap **0 grams** (or **0 units**).

3. Use the on-screen keypad to enter grams of carb (or units of insulin). Tap .

4. If desired, tap **Add BG**, use the on-screen keypad to enter a glucose value, and tap .

5. Tap  to confirm the units of insulin to be delivered.

You can always tap **View Calculation** to display the *Delivery Calculation* screen.

6. Confirm Request.

- Tap  if entered data is correct.
- Tap  to go back to make changes or view calculations.

7. Tap **EXTENDED** to turn on the extended feature, then tap .

8. Tap **50%** under **DELIVER NOW** to adjust the percentage of the food bolus that is to be delivered immediately.

The percentage value for DELIVER LATER is automatically calculated by the pump. The default is 50% NOW and 50% LATER. The default for DURATION is 2 hours.

9. Use the on-screen keypad to enter the percentage of the bolus to DELIVER NOW and tap .

For the DELIVER NOW portion, the minimum amount is .05 units. If the DELIVER NOW portion is less than .05 units, you will be notified and the DELIVER NOW portion will be set to .05 units.

The DELIVER LATER portion of the extended bolus also has minimum and maximum rates. If you program a DELIVER LATER rate outside of these limits, you are notified and the duration of the DELIVER LATER portion is adjusted.

10. Tap 2 hrs under DURATION.

The default maximum duration for extended bolus delivery is 8 hours.

11. Use the on-screen keypad to adjust the length of time the bolus is to be delivered, then tap .

12. Tap .

You can always tap View Units to display the breakdown of units to be delivered NOW versus LATER.

13. Confirm Request.

- Tap  if entered data is correct.
- Tap  to go back to make changes or view calculations.

14. Tap .

- ✓ The *BOLUS INITIATED* screen is temporarily displayed.

- ✓ After the bolus delivery is complete, an icon displays below the CGM graph.



Only one extended bolus can be active at any given time. However, if the DELIVER LATER portion of an extended bolus is active, you can request another standard bolus.

8.8 Max Bolus

The Max Bolus setting allows you to set a limit to the maximum insulin delivery amount for a single bolus.

The default setting for Max Bolus is 10 units, but can be set to any value between 1 to 25 units. To adjust the Max Bolus setting, follow these steps.

CHAPTER 8

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap **Pump Settings**.
5. Tap **Max Bolus**.



6. Using the on-screen keypad, enter the desired amount for maximum bolus (1–25 units) and tap .

NOTE

If you set the max bolus to 25 units and a bolus larger than 25 units is calculated using your Carb Ratio or Correction Factor, after the bolus is delivered a reminder

screen will appear. The option of delivering the remaining amount of the bolus up to an additional 25 units will be given (see Section 13.9 Max Bolus Alerts). You must confirm delivery of this additional amount from your pump.

8.9 Quick Bolus

The Quick Bolus function enables you to deliver a bolus by simply pressing a button, if enabled. It is a way to deliver a bolus by following beep/vibration commands without navigating through or viewing the pump screen.

Quick Bolus can be set to correspond to either units of insulin or grams of carbohydrate. When Control-IQ technology is enabled, it will use the Quick Bolus as a correction bolus if configured as units of insulin, or as a food bolus if configured as grams of carbohydrate. Control-IQ technology uses the information about carbohydrate intake to optimize insulin delivery after eating.

Configure Quick Bolus

The default for the Quick Bolus function is off. Quick Bolus can be set to either units of insulin or grams of carbohydrate. The increment options are 0.5, 1.0, 2.0, and 5.0 units; or 2, 5, 10 and 15 grams.

NOTE

It is recommended to use grams of carbohydrate in a bolus delivery whenever using Control-IQ technology.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap **Pump Settings**.
5. Tap **Quick Bolus**.
6. Tap **Increment Type**.
7. Tap **units of insulin or grams of carbohydrate** to select. Tap .
8. Tap **Increment Amount**.

9. Select the preferred increment amount.

NOTE

The increment amount is added with each press of the **Screen On/Quick Bolus** button when delivering a quick bolus.

10. Review entered values and tap .

11. Confirm Settings.

- Tap  if entered data is correct.
- Tap  to go back to make changes.

12. Tap the **Tandem** logo to return to the *Home* screen.

Deliver a Quick Bolus

If the Quick Bolus function is turned on, you can deliver a bolus by pressing the **Screen On/Quick Bolus** button to deliver your bolus. Quick boluses are delivered as standard boluses (there is no glucose value entry or extended bolus).

PRECAUTION

ALWAYS check the pump screen to confirm correct programming of the bolus amount when you first use the Quick Bolus feature. Checking the screen will ensure that you are correctly using the beep/vibration commands to program the intended bolus amount.

1. Press and hold the **Screen On/Quick Bolus** button. The *Quick Bolus* screen will appear. Listen for two beeps (if sound volume is set to beep) or feel for vibrations (if sound volume is set to vibrate).
2. Press the **Screen On/Quick Bolus** button for each increment until desired amount is reached. The pump will beep/vibrate for each button press.
3. Wait for the pump to beep/vibrate once for each increment pressed to confirm desired amount.
4. After the pump beeps/vibrates, press and hold the **Screen On/Quick Bolus** button for several seconds to deliver the bolus.

NOTE

If you want to cancel the bolus and return to the *Home* screen, tap  on the *Quick Bolus* screen.

If more than 10 seconds have passed with no input, the bolus is canceled and never delivered. In this case, the Incomplete Bolus Alert will be displayed on your pump and (if applicable) on your smartphone via the t:connect mobile app.

You cannot exceed the Max Bolus setting defined in your Pump Settings when using the Quick Bolus feature. Once you reach the Max Bolus amount, a different tone will sound to notify you (if Quick Bolus is set to vibrate, the pump will stop vibrating in response to additional button presses to notify you). Look at the screen to confirm the bolus amount.

You cannot exceed 20 button presses when using the Quick Bolus feature. Once you reach 20 button presses, a different tone will sound to notify you (if Quick Bolus is

CHAPTER 8

set to vibrate, the pump will stop vibrating in response to additional button presses to notify you). Look at the screen to confirm the bolus amount.

If you hear a different tone at any point during programming or the pump stops vibrating in response to button presses, check the screen to confirm the bolus amount. If the *Quick Bolus* screen does not display the correct bolus amount, use the touchscreen to enter bolus information.

- ✓ The *BOLUS INITIATED* screen is temporarily displayed.

NOTE

If Control-IQ technology is on and has adjusted insulin delivery during a Quick Bolus, the remaining Quick Bolus insulin will be delivered.

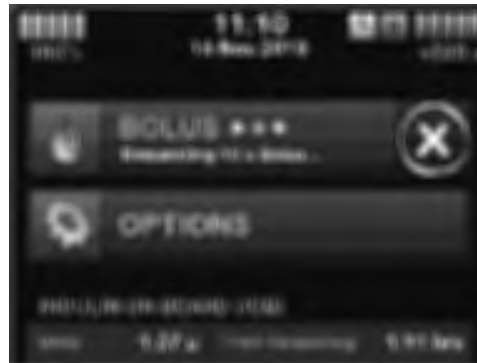
8.10 Canceling or Stopping a Bolus Using the Pump

You have 10 seconds to cancel a bolus after requesting it to completely avoid

insulin delivery; the pump will say “requesting bolus” during this time.

To cancel a bolus request from the pump:

1. Tap 1–2–3 to access the *Home* screen.
2. Tap  to cancel the bolus.



- ✓ **BOLUS** will remain inactive while the bolus is being canceled.

NOTE

Once canceled, **BOLUS** will become active again on the Home screen.

To stop a bolus after delivery has started:

1. Tap 1–2–3 to access the *Home* screen.
2. Tap  to stop delivery.
3. Tap .
- ✓ The *BOLUS STOPPED* screen is displayed and the units delivered are calculated.
- ✓ Units requested and delivered are shown.
4. Tap .

8.11 Bolus Delivery Using the t:connect Mobile App

Before you use the t:connect mobile app to deliver a bolus, enable your smartphone security feature (e.g., screen lock, passcode, face recognition). Never share your security PIN/password or authorize any other person to access your smartphone via

their biometric information to avoid unintentional delivery of insulin.

NOTE

If your smartphone is not compatible with the Bolus Delivery feature set of the t:connect mobile app, you cannot use the t:connect mobile app to request, cancel, or stop a bolus. For an up-to-date list of supported smartphones, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen.

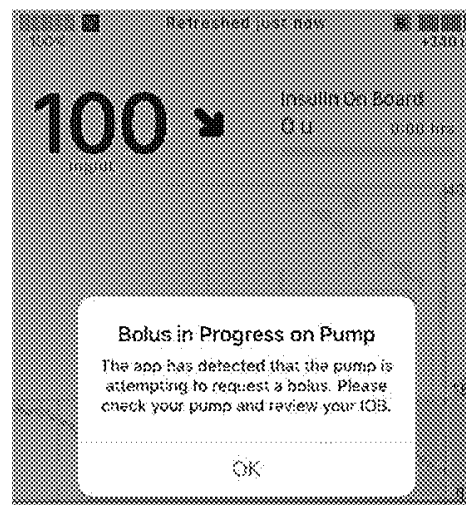
You can use the t:connect mobile app to deliver the following boluses:

- Correction bolus (see Section 8.12 Correction Bolus Using the t:connect Mobile App)
- Override bolus (see Section 8.13 Bolus Override Using the t:connect Mobile App)
- Food bolus using either units of insulin or grams of carbohydrate (see Section 8.14 Food Bolus Using the t:connect Mobile App)

You must use your pump for the following features:

- Extended Bolus (see Section 8.7 Extended Bolus)
- Max Bolus setting (see Section 8.8 Max Bolus)
- Quick Bolus (see Section 8.9 Quick Bolus)

If you request any bolus from the pump, you must complete it on the pump. If you attempt to request a bolus from the t:connect mobile app while a bolus request is active on the pump, the t:connect mobile app will generate the *Bolus in Progress on Pump* notification and prevent you from starting a bolus.



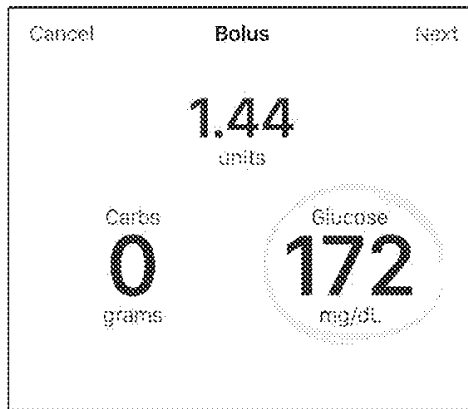
8.12 Correction Bolus Using the t:connect Mobile App

Once the t:connect mobile app knows your glucose value, it will determine whether to recommend that a correction bolus to be added to any other bolus requested on the *Bolus* screen. The t:connect mobile app can receive your glucose value from manual entry into the t:connect mobile app or auto-populate from the CGM. See *Glucose Value Auto-Population with CGM* for more information about automatically populated glucose values.

To change the glucose value auto-populated from your CGM you can tap on the GLUCOSE value on the *Bolus* screen. The following example

CHAPTER 8

shows the *Bolus* screen in the t:connect mobile app.



Correction Bolus Confirmation Screens

To access the Correction Bolus confirmation screen on the t:connect mobile app and enable the Correction Bolus toggle, tap Bolus on the Navigation bar.

- If your CGM value or trend arrow are not available on the Home screen, the Correction Bolus confirmation screen appears after you enter your glucose value into the t:connect mobile app as described above.

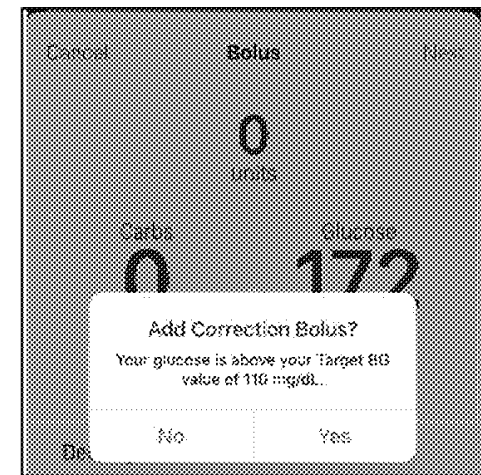
- If you have a CGM value and trend arrow, the Correction Bolus confirmation screen appears when you tap Bolus (if appropriate).

Above Target

If your BG or sensor glucose value is above your Target BG, you can calculate and add a correction bolus to any other bolus you request.

Calculate and add a correction bolus from the t:connect mobile app as follows:

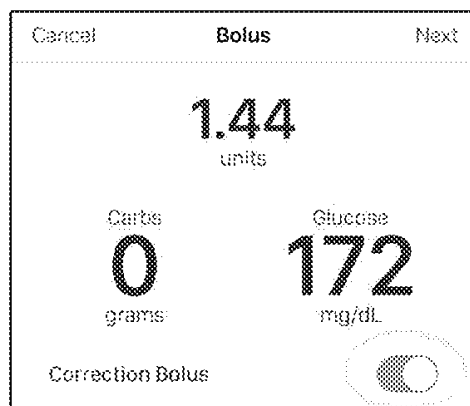
- To accept the correction bolus, tap **Yes** on the *Correction Bolus* confirmation screen.



- To decline the correction bolus, tap **No** on the *Correction Bolus* confirmation screen.

If you tap **Yes**, the Correction Bolus toggle will be turned on. You can later decline the correction bolus by tapping

the Correction Bolus toggle to the OFF position.

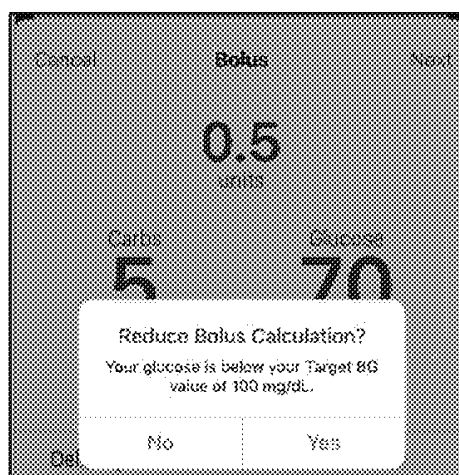


Below Target

If your BG or sensor glucose value is below your Target BG, the t:connect mobile app presents you with the option to subtract a correction bolus from any other bolus you request; any values the t:connect mobile app delivery calculation shows in red are subtracted from the calculated bolus amount.

Calculate and add a correction bolus from the t:connect mobile app as follows:

- To accept the correction bolus, tap **Yes** on the *Correction Bolus* confirmation screen.



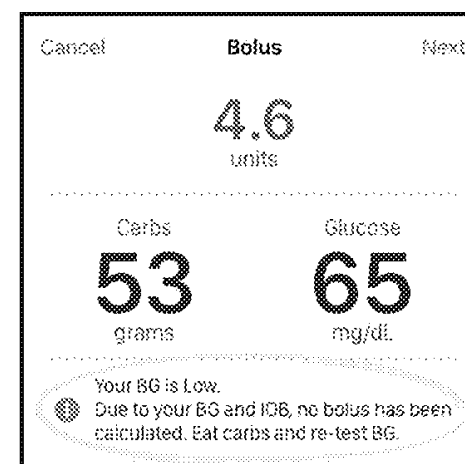
- To decline the correction bolus, tap **No** on the *Correction Bolus* confirmation screen.

If you tap **Yes**, the Correction Bolus toggle will be turned on. You can later decline the correction bolus by tapping the Correction Bolus toggle to the OFF position.

NOTE

If your blood glucose is below 70 mg/dL, the food bolus will be reduced to automatically correct for the low glucose value. In this case,

the Correction toggle will be unavailable, and the t:connect mobile app will display the Low BG Alert in its place.



Within Target

If your BG or sensor glucose value is the same value as your Target BG, no correction bolus will be included in the bolus calculation.

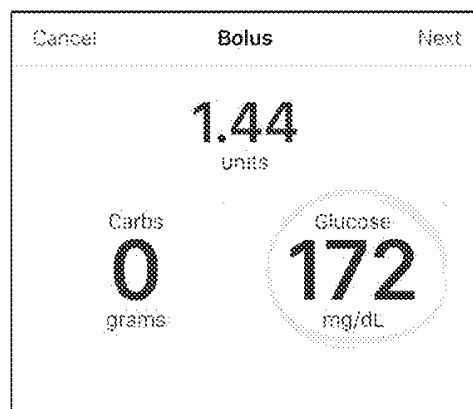
BG Value Manual Entry Using the t:connect Mobile App

Manually enter your BG value into the t:connect mobile app as follows:

- From the navigation bar, tap **Bolus**.

CHAPTER 8

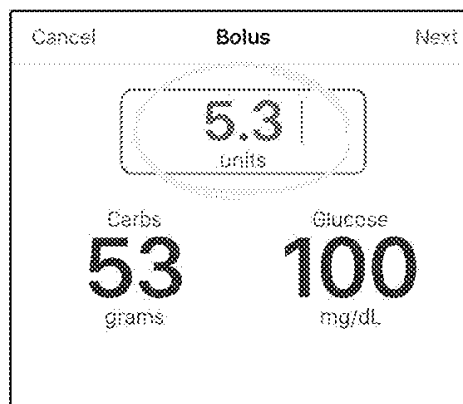
2. Tap Add Glucose.



3. Use the on-screen number keypad to enter your BG value.
4. Tap **Done** (iOS) or **✓** (Android) on the number keypad to save your BG value in your pump history and close the number keypad.
5. Follow the steps in the appropriate Target section above depending on the results of your BG value.

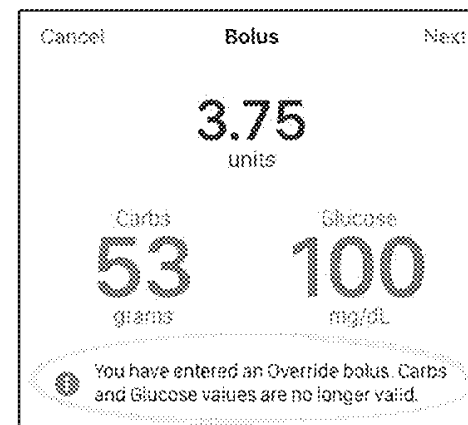
8.13 Bolus Override Using the t:connect Mobile App

You can override the calculated bolus by tapping on the calculated units value and entering the units of insulin you want delivered. The bolus override is always an available option; the following example shows the bolus override in the t:connect mobile app.



If you use the t:connect mobile app to set the override bolus value, the Bolus Override Alert will appear as an

informational message on the *Bolus* screen.



8.14 Food Bolus Using the t:connect Mobile App

To deliver a food bolus using the t:connect mobile app:

1. Tap the **Bolus** icon on the *Navigation* bar.
2. Tap **0 grams** or **0 units** on the left side of the screen, depending on the settings in your active Personal Profile.

3. Use the number keypad to enter units of insulin or grams of carb to be delivered.
4. Tap **Done** (iOS) or  (Android) on the number keypad to close the keypad.
- ✓ The total bolus amount at the top of the screen updates (if applicable).
5. Tap **Next** (iOS) or  (Android) to confirm the units of insulin to be delivered.
- ✓ The *Confirm Bolus* screen is temporarily displayed.
6. Confirm request:
 - Tap **Next** (iOS) or  (Android) if entered data is correct.
 - Tap **Back** (iOS) or **X** (Android) to go back to make changes or view calculations.
7. Tap the **Deliver Bolus** icon.
8. The t:connect mobile app will generate a confirmation prompt;

use your smartphone's security feature to confirm the bolus request or tap **Cancel** to return to the *Bolus* screen.

- ✓ The t:connect mobile app returns you to the dashboard.
- 9. A bolus bar appears above the navigation bar until the entire bolus has been delivered, including a cancel/stop button as well as the bolus type and amount requested.

8.15 Canceling or Stopping a Bolus Using the t:connect Mobile App

⚠ WARNING

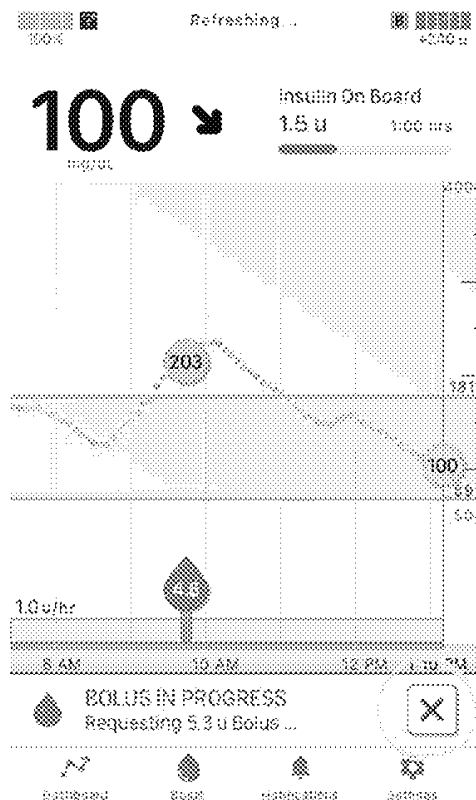
Any time you request a bolus, you have 10 seconds to cancel the bolus after requesting it to completely avoid insulin delivery. Both the pump and the t:connect mobile app will say "requesting bolus" during this time as long as your pump and the t:connect mobile app are connected. You can cancel the bolus from either the pump or the app regardless of how you requested it.

You may cancel or stop any bolus via the t:connect mobile app as long as the t:connect mobile app has a Bluetooth connection to the pump, regardless of whether you initiated the bolus from the pump or the t:connect mobile app.

To cancel a bolus request from the t:connect mobile app:

CHAPTER 8

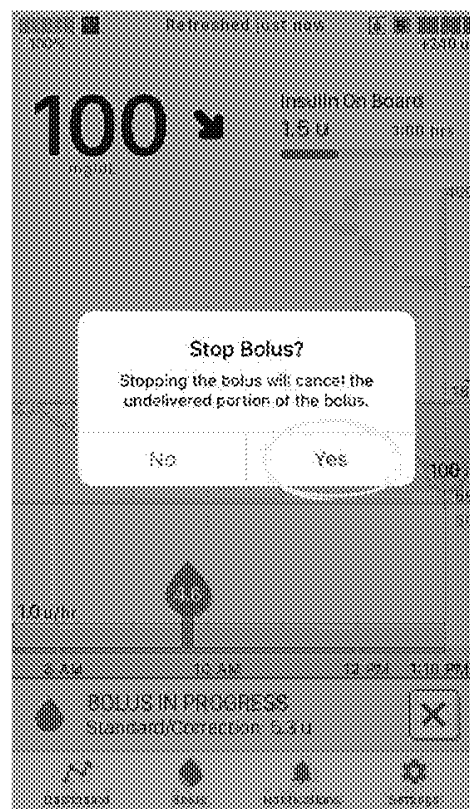
1. Tap  to cancel delivery.



NOTE

The  is always available in the t:connect mobile app as part of the bolus bar during bolus delivery; you don't need to visit the *Bolus* screen to cancel a bolus.

2. Tap **Yes** in the confirmation prompt to cancel the bolus.



- ✓ The Bolus Stopped Alert appears and lists the units delivered as 0.

To stop a bolus after delivery has started:

1. Tap  on the t:connect mobile app bolus bar to stop delivery.
 2. Tap **Yes** on the t:connect mobile app confirmation prompt.
- ✓ The *BOLUS STOPPED* screen is displayed and the units delivered are calculated.
 - ✓ Units requested and delivered are shown.
3. Tap  on the t:connect mobile app informational message.

8.16 Pump Connection Lost

Connection Lost During Bolus Request

If your smartphone becomes disconnected from the pump while you are requesting a bolus before you confirm bolus delivery, the t:connect mobile app generates a Pump Connection Lost Alert. When you

receive this notification, tap **OK** to return to the dashboard.

- No bolus will be delivered. Use the pump to deliver this bolus.
- Check your smartphone's Bluetooth connection and Bluetooth settings.
- You cannot use the t:connect mobile app to request a bolus until you have restored your smartphone's connection to the pump.

Connection Lost During Bolus Delivery

If your smartphone becomes disconnected from the pump while the pump is delivering a bolus, the t:connect mobile app generates a Pump Connection Lost Alert. When you receive this notification, the t:connect mobile app will return you to the dashboard.

- Your pump will still deliver the remainder of the bolus unless you use the pump to stop the bolus.

- You must re-establish the connection between your smartphone and the pump before you use the t:connect mobile app to deliver another bolus. See Section 4.3 Connecting to a Smartphone.

⚠ PRECAUTION

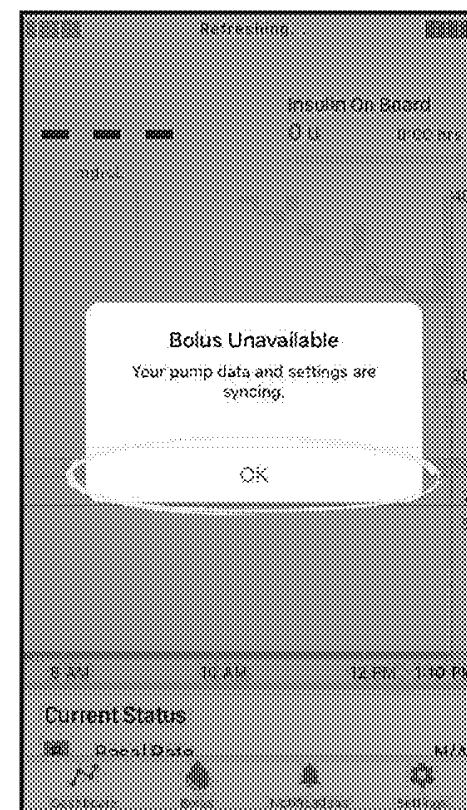
DO NOT ignore symptoms of high and low glucose. If your t:connect mobile app readings do not match your symptoms, check your pump display and confirm that your pump has established a Bluetooth connection with your smartphone.

📌 NOTE

This Mobile Connection setting is not related to your CGM Bluetooth connection. For CGM Bluetooth information, see Section 21.1 About Bluetooth Technology.

Even if the t:connect mobile app has established a connection with the pump, you cannot use the t:connect mobile app to request a bolus until it has received your bolus settings from the pump. If you tap **Bolus** during this time to request a bolus, the t:connect mobile app will generate a Bolus Unavailable Alert as shown in the

following example; tap **OK** to return to the dashboard.



This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 9

Starting, Stopping, or Resuming Insulin

CHAPTER 8 • Starting, Stopping, or Resuming Insulin

9.1 Starting Insulin Delivery

Insulin delivery starts once you have a Personal Profile configured and activated. See Chapter 6 Insulin Delivery Settings for instructions on creating, configuring, and activating a Personal Profile.

9.2 Stopping Insulin Delivery

You can stop all insulin delivery at any time. When you stop all insulin delivery, any active bolus and any active temp rate are immediately stopped. No insulin delivery can take place while your pump is stopped. The pump will present a Resume Pump Alarm to remind you to manually resume insulin after a certain period of time. The default setting for this alarm is 15 minutes.

1. From the *Home* screen, tap **OPTIONS**.
 2. Tap **STOP INSULIN**.
- ✓ A confirmation screen displays.

3. To change the Resume Pump Alarm setting, skip to Step 4. Otherwise, tap  to accept the default setting.
- ✓ The *All Deliveries Stopped* screen appears before returning to the *Home* screen showing the status ALL DELIVERIES STOPPED. A red exclamation mark icon also appears to the right of the time and date.
4. To change the Resume Pump Alarm setting, tap the panel in the middle of the screen.



5. Select the radio button that corresponds with the time you would like the Resume Pump Alarm to display.

- ✓ The pump returns to the confirmation screen.
 - ✓ The pump will save the new alarm time, and will use this setting the next time insulin is manually suspended, unless the pump has been reset, in which case the default setting will be used.
6. Tap .
 - ✓ The *All Deliveries Stopped* screen appears before returning to the *Home* screen showing the status ALL DELIVERIES STOPPED. A red exclamation mark icon also appears to the right of the time and date.

NOTE

If you manually stop insulin delivery, you must manually resume insulin delivery. Control-IQ™ technology does not automatically resume insulin if you stop it manually.

9.3 Resuming Insulin Delivery

If pump screen is not on, press **Screen On/Quick Bolus** button once to turn on your t:slim X2™ pump screen.

1. Tap 1–2–3.
 2. Tap .
- ✓ The *RESUMING INSULIN* screen is temporarily displayed.

– OR –

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **RESUME INSULIN**.
3. Tap .

The *RESUMING INSULIN* screen is temporarily displayed.

9.4 Disconnecting When Using Control-IQ Technology

When you need to disconnect your pump from your body, stop insulin delivery. Stopping insulin delivery tells the system that you are not actively delivering insulin, which also stops Control-IQ technology so that it does not continue to calculate insulin delivery adjustments.

This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 10

t:slim X2 Insulin Pump Information and History

CHAPTER 10 • t:slim X2 Insulin Pump Information and History

10.1 t:slim X2 Pump Info

Your t:slim X2™ pump allows access to information about your pump. In the *Pump Info* screen you have access to items such as your pump Serial Number, Customer Technical Support contact information, website, and software/hardware versions.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Pump Info**.
4. Scroll through the Pump Info using the **Up/Down Arrows**.
5. Tap the **Tandem logo** to return to the *Home* screen.

10.2 t:slim X2 Pump History

Pump History displays a historical log of pump events. At least 90 days of data can be viewed in History. When the maximum number of events is reached,

the oldest events are removed from the history log and replaced with the most recent events. The following can be viewed in Pump History:

Delivery Summary, Total Daily Dose, Bolus, Basal, Load, BG, Alerts and Alarms, Control-IQ, and Complete.

Delivery Summary breaks down total insulin delivery by basal and bolus types into units and percentages. It can be viewed by the selected time period of: Today, 7 Day, 14 Day and 30 Day Average.

Total Daily Dose breaks down basal and bolus delivery into units and percentages for each individual day. You can scroll through each individual day to see your total insulin delivery.

The Bolus, Basal, Load, BG, and Alerts and Alarms are categorized by date. The event details in each report are listed by time.

The Complete section includes all information from each section as well as any changes to settings.

The letter “D” (D: Alert) before an Alert or Alarm indicates the time it was

declared. The letter “C” (C: Alert) indicates the time it was cleared.

Bolus history shows the bolus request, the bolus start time, and the bolus completion time.

- The letters “PB” indicate a bolus requested, canceled, or stopped via the pump.
- The letters “RB” indicate a bolus requested, canceled, or stopped via the t:connect mobile app.

The Control-IQ history shows the historical log of the Control-IQ™ technology status, including when the feature is enabled or disabled, when Basal Rate changes were made, and when Control-IQ technology boluses were delivered. The rate of insulin delivery may change as frequently as every five minutes.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **History**.

4. Tap **Pump History**.
5. Tap desired option.
6. Tap the **Tandem** logo to return to the *Home* screen.

To find the *Help* and *About* screens, from your t:connect mobile app, tap **Settings**.

NOTE

You must access these logs on the pump; the t:connect™ mobile app does not display the pump history logs.

10.3 t:connect Mobile App Info

The t:connect mobile app allows access to information about the t:connect mobile app.

- The *Help* screen gives you access to items such as an in-app guide to t:connect mobile app configuration and use, a list of frequently asked questions, and Customer Technical Support contact information.
- The *About* screen gives you access to items such as the t:connect mobile app instructions for use, legal information, and t:connect mobile app software version.

This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 11

t:slim X2 Insulin Pump Reminders

CHAPTER 11 • Insulin K2 Insulin Pump Reminders

Your pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check your BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

If multiple Reminders, Alerts, and Alarms happen at the same time, Alarms will be displayed first, Alerts will be displayed second, and Reminders will be displayed third. Each must be confirmed separately until all have been acknowledged.

Information in this section will help you learn how to respond to Reminders.

Reminders notify you with a single sequence of three notes or a single vibration depending on the volume/vibrate setting in Sound Volume. They repeat every 10 minutes

until acknowledged. Reminders do not escalate.

11.1 Low BG Reminder

The Low BG Reminder prompts you to re-test your BG after a low glucose value is read. When turning this reminder on, you need to set a low glucose value that triggers the reminder, as well as how much time should pass before the reminder occurs.

The default for this reminder is preset to off. If on, the defaults are Remind Me Below 70 mg/dL, and Remind Me After 15 min, but you can set these values from 70 to 120 mg/dL and 10 to 20 min.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **Low BG**.

6. Low BG is set to on; to turn off, tap **Low BG**.

- a. Tap **Remind Me Below** and using the on-screen keypad, enter a Low BG value (from 70 to 120 mg/dL) that you want to trigger the reminder, then tap .
- b. Tap **Remind Me After** and using the on-screen keypad, enter the time (from 10 to 20 min), then tap .
- c. Tap  when all changes are complete.
- d. Tap the **Tandem logo** to return to the *Home* screen.

To Respond to the Low BG Reminder

To clear the reminder, tap  and then check your glucose.

11.2 High BG Reminder

The High BG Reminder prompts you to re-test your BG after a high glucose

value is read. When you turn this reminder on, you need to set a high glucose value that triggers the reminder, as well as how much time should pass before the reminder occurs.

The default for this reminder is preset to off. If on, the defaults are Remind Me Above 200 mg/dL, and Remind Me After 120 min, but you can set these values from 150 to 300 mg/dL and 1 to 3 hours.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **High BG**.
6. High BG is set to on; to turn off, tap **High BG**.
 - a. Tap **Remind Me Above** and using the on-screen keypad, enter a High BG value (from 150

to 300 mg/dL) that you want to trigger the reminder, then tap



- b. Tap **Remind Me After** and using the on-screen keypad, enter the time (from 1 to 3 hours), then tap
- c. Tap when all changes are complete.

7. Tap the **Tandem** logo to return to the *Home* screen.

To Respond to the High BG Reminder

To clear the reminder tap and then check your glucose.

11.3 After Bolus BG Reminder

The After Bolus BG Reminder prompts you to test your BG at a selected time after bolus delivery. When turning this reminder on, you need to set how much time should pass before the reminder occurs. The default is 1 hour and 30 minutes. It can be set from 1 to 3 hours.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **After Bolus BG**.
6. After Bolus BG is set to on; to turn off, tap **After Bolus BG**.
7. Tap **Remind Me After** and using the on-screen keypad, enter the time (from 1 to 3 hours) that you want to trigger the reminder, then tap .
8. Tap when all changes are complete.
9. Tap the **Tandem** logo to return to the *Home* screen.

To Respond to the After Bolus BG Reminder

To clear the reminder tap and then check BG using your BG meter.

CHAPTER 11 • Using X2 Insulin Pump Reminders

11.4 Missed Meal Bolus Reminder

The Missed Meal Bolus Reminder lets you know if a bolus was not delivered during a specified time period. Four separate reminders are available. When programming this reminder you need to select the Days, the Start Time, and End Time for each reminder.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **Missed Meal Bolus**.
6. On the Missed Meal Bolus screen, tap which reminder you want to set (Reminder 1 to 4) and do the following:
 - a. Tap **Reminder 1** (or 2, 3, 4).
 - b. Reminder 1 is set to on; to turn off, tap **Reminder 1**.

- c. Tap **Selected Days** and tap the day(s) you want the reminder to be on, then tap .
 - d. Tap **Start Time**, tap **Time** and using the on-screen keypad enter the start time, then tap .
 - e. Tap **Time of Day** to select AM or PM, if applicable, then tap .
 - f. Tap **End Time**, tap **Time** and using the on-screen keypad enter the end time, then tap .
 - g. Tap **Time of Day** to select AM or PM, if applicable, then tap .
 - h. Tap  when all changes are complete.
7. Tap the **Tandem logo** to return to the *Home* screen.

To Respond to the Missed Meal Bolus Reminder

To clear the reminder tap  and deliver a bolus if necessary.

11.5 Site Reminder

The Site Reminder prompts you to change your infusion set. The default for this reminder is preset to off. If on, the reminder can be set for 1 – 3 days and at a time of day selected by you.

For detailed information on the Site Reminder feature, see Section 7.6 *Setting Site Reminder*.

To Respond to the Site Reminder

To clear the reminder tap  and change your infusion set.

2 t:slim X2 Insulin Pump Features

CHAPTER 12

User Settable Alerts and Alarms

CHAPTER 12 • User-Settable Alerts and Alarms

12.1 Low Insulin Alert

Your t:slim X2™ pump keeps track of how much insulin remains in the cartridge and alerts you when it is low. The default for this alert is preset to 20 units. You can set this alert setting anywhere between 10 and 40 units. When the insulin amount reaches the set value, the Low Insulin Alert beeps/vibrates and appears on the screen. After the alert is cleared, the low insulin indicator (a single red bar on the insulin level display on the *Home* screen appears).

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Alerts**.
5. Tap **Low Insulin**.
6. Using the on-screen keypad, enter the number of units (from 10 to 40 units) that you want the Low Insulin

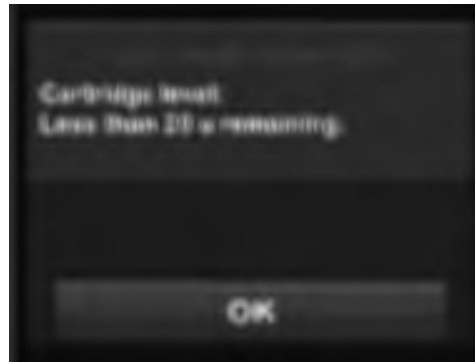
Alert value to be set to, and tap



7. Tap when all changes are complete.

To Respond to the Low Insulin Alert

To clear the alert, tap .

**12.2 Auto-Off Alarm**

Your pump can stop insulin delivery and alert you or whoever is with you if there has been no interaction with the pump within a specified period of time, particularly if you do not wear a CGM or use Control-IQ™ technology.

The default for this alarm is preset to 12 hours. You can set it anywhere between 5 and 24 hours, or off. This alarm notifies you that there has been no interaction with the pump in the specified number of hours and the pump will shut down after 60 seconds.

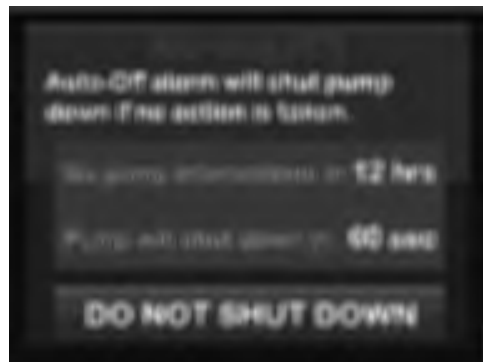
When the number of hours since you have pressed the **Screen On/Quick Bolus** button and tapped any interactive screen option or delivered a Quick Bolus passes the set value, the Auto-Off Alarm beeps and appears on the screen, and insulin delivery stops.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Alerts**.
5. Tap **Auto-Off**.
6. Tap **Auto-Off**. A confirmation screen will appear.
 - Tap to continue.

- Tap  to go back.
- 7. Verify Auto-Off is set to on, then tap **Time**.
- 8. Using the on-screen keypad, enter the number of hours (from 5 – 24 hours) that you want the Auto-Off Alarm to be triggered, and tap .
- 9. Tap , then tap  when all changes are complete.
- 10. Tap the Tandem logo to return to the *Home* screen.

To Respond to Auto-Off Warning

Tap **DO NOT SHUT DOWN**.

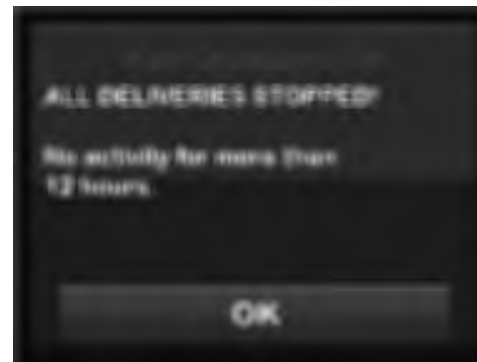


- ✓ The warning clears and the pump returns to normal operation.

If you do not clear the warning within the 60-second countdown period, the Auto-Off Alarm occurs, accompanied by an audible alarm. This alarm notifies you that your pump has stopped delivering insulin.

Auto-Off Alarm Screen

Tap .



- ✓ The *Home* screen appears, indicating a status of All Deliveries Stopped.

You must resume delivery to continue therapy, see Section 9.3 Resuming Insulin Delivery.

12.3 Max Basal Alert

Your pump allows you to set a limit to the Basal Rate that the pump will not allow you to exceed during a Temp Rate.

Once the Basal Limit in the Pump Settings has been set up (see Section 5.10 Basal Limit), you will receive an alert if the following scenarios occur.

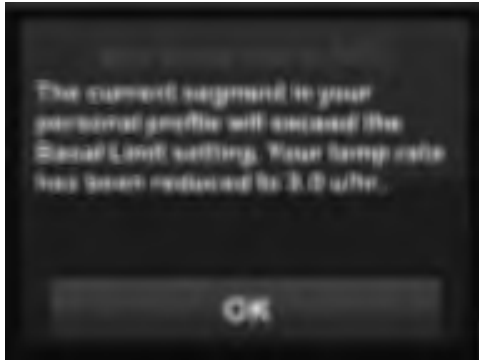
1. A Temp Rate was requested that exceeds the Basal Limit.
2. A Temp Rate is in progress, and a new Personal Profile time segment has begun, causing the Temp Rate to exceed the Basal Limit.

To Respond to Max Basal Alert

Tap  to accept the reduced Temp Rate. The reduced Temp Rate value is

CHAPTER 12 • User Settable Alarms and Alarms

the same Basal Limit value that was set up in Personal Profiles.



2 t:slim X2 Insulin Pump Features

CHAPTER 13

t:slim X2 Insulin Pump Alerts

CHAPTER 13 • t:slim X2 Insulin Pump Alerts

Your pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check you BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

If multiple Reminders, Alerts, and Alarms happen at the same time, Alarms will be displayed first, Alerts will be displayed second, and Reminders will be displayed third. Each must be confirmed separately until all have been confirmed.

Information in this section will help you learn how to respond to Alerts.

Alerts notify you with 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume. They repeat regularly

until acknowledged. Alerts do not escalate.

The t:connect™ mobile app also can provide messages, alerts, and alarms from your t:slim X2™ pump as push notifications on your smartphone. These push notifications will be identical to your pump's display unless otherwise noted in this chapter.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. For more information about connecting your pump and smartphone, see Section 4.3 Connecting to a Smartphone, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

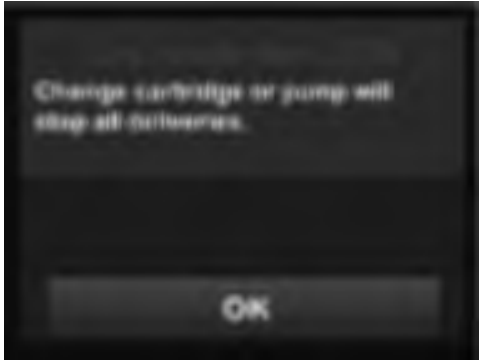
📌 NOTE

There is an additional list of alerts and errors related to CGM use in Chapter 26 CGM Alerts and Errors.

📌 NOTE

There is an additional list of alerts related to Control-IQ™ technology use in Chapter 32 Control-IQ Technology Alerts.

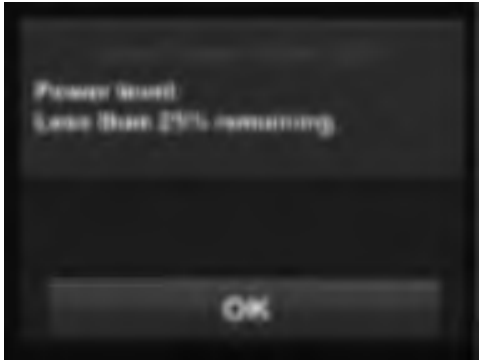
13.1 Low Insulin Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	5 units or less of insulin remain in the cartridge.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Change your cartridge as soon as possible to avoid the EMPTY CARTRIDGE ALARM and running out of insulin.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.2 Low Power Alerts

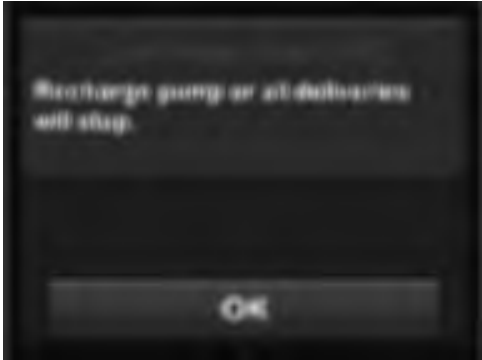
Low Power Alert 1

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Less than 25% of battery power remains.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Charge your pump as soon as possible to avoid the second LOW POWER ALERT.

NOTE

Once the LOW POWER ALERT occurs, the low-power indicator (a single red bar on the battery level display on the *Home* and *Lock* screens) appears.

Low Power Alert 2

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Less than 5% of battery power remains. Insulin delivery will continue for 30 minutes and then the pump will power off and insulin delivery will stop.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Charge your pump immediately to avoid the LOW POWER ALARM and pump power off.

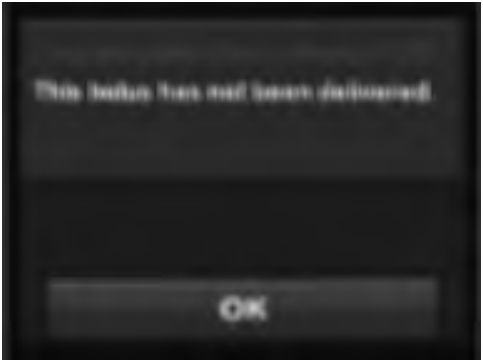
 NOTE

Once the LOW POWER ALERT occurs, the low-power indicator (a single red bar on the battery level display on the *Home* and *Lock* screens) appears.

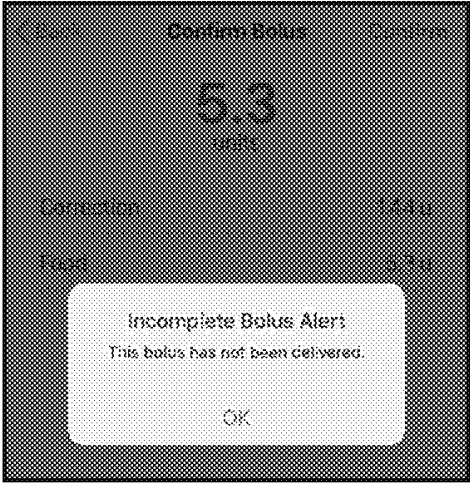
CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.3 Incomplete Bolus Alert

Incomplete Bolus Alert – Pump Screen

Screen	Explanation	
What will I see on the screen? 	What does it mean?	You started a bolus request but did not complete the request within 90 seconds.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap . The <i>Bolus</i> screen will appear. Continue with your bolus request.

Incomplete Bolus Alert – t:connect Mobile App

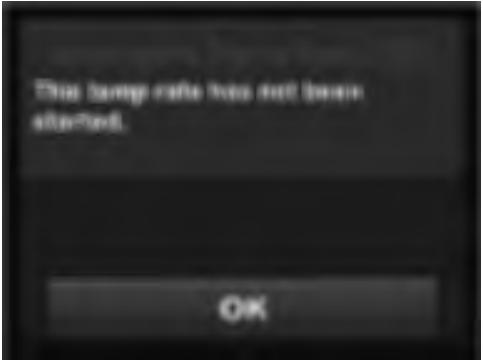
Screen	Explanation	
What will I see in the t:connect mobile app*? 	What does it mean?	You started a bolus request but did not complete the request within 90 seconds.
	How will the t:connect mobile app notify me?	• If the t:connect mobile app is open and on the <i>Bolus</i> screen, an informational message appears. • If you receive the Incomplete Bolus Alert due to interaction with other smartphone features (e.g., answering a call, using another app) or other screens in the t:connect mobile app, you will receive the alert as a notification banner.
	Will the t:connect mobile app re-notify me?	No, the alert remains on the t:connect mobile app screen until you tap OK.
	How should I respond?	Tap OK on the informational message in the t:connect mobile app. The <i>Bolus</i> screen will appear. Continue with your bolus request.

NOTE

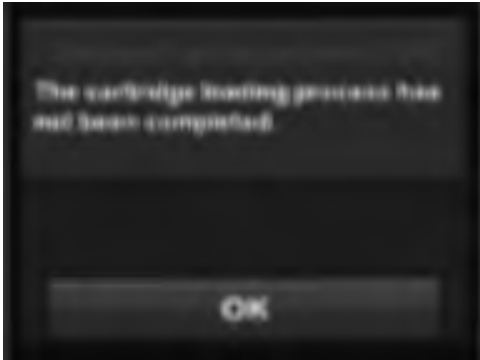
The Incomplete Bolus Alert is the only alert in this chapter that appears differently on the pump. All other pump alerts are identical in the t:connect mobile app.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.4 Incomplete Temp Rate Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	You started to set up a temp rate but did not complete the request within 90 seconds.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	1. Tap . The <i>Temp Rate</i> screen will appear. Continue setting up your temp rate. 2. Tap  if you do not want to continue setting up your temp rate.

13.5 Incomplete Load Sequence Alerts**Incomplete Cartridge Change Alert**

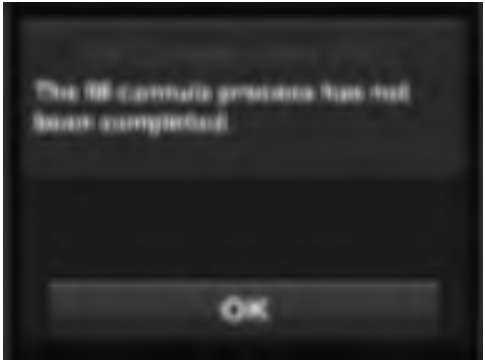
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You selected Change Cartridge from the <i>Load</i> menu but did not complete the process within 3 minutes.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Complete the cartridge change process.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

Incomplete Fill Tubing Alert

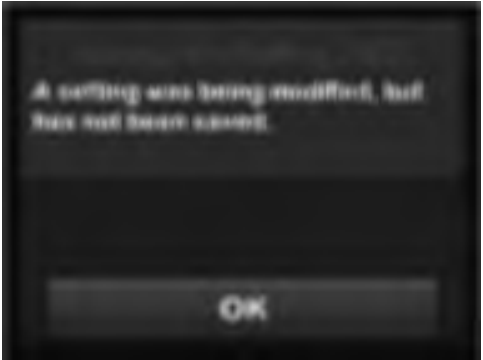
Screen	Explanation	
What will I see on the Screen? 	What does it mean?	You selected Fill Tubing from the <i>Load</i> menu but did not complete the process within 3 minutes.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap . Complete the fill tubing process.

Incomplete Fill Cannula Alert

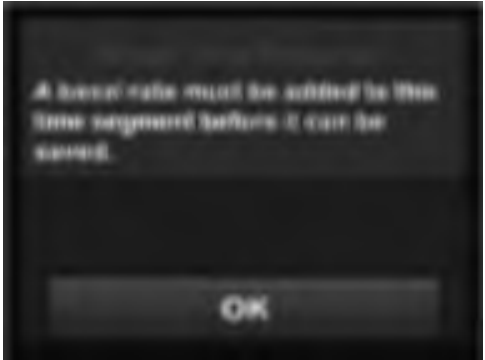
Screen	Explanation	
What will I see on the Screen? 	What does it mean?	You selected Fill Cannula from the <i>Load</i> menu but did not complete the process within 3 minutes.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Complete the cannula fill process.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.6 Incomplete Setting Alert

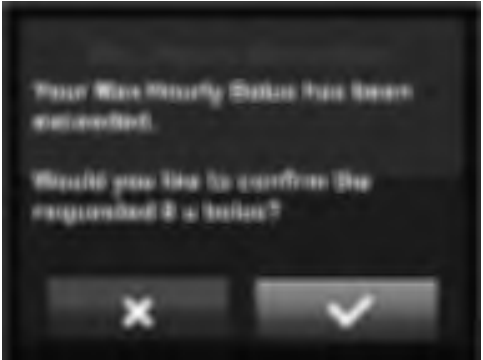
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You started to set up a new Personal Profile or Control-IQ technology setting but did not save or complete the programming within 5 minutes.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap . Complete programming the Personal Profile or Control-IQ technology setting.

13.7 Basal Rate Required Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	You did not enter a Basal Rate in a time segment in Personal Profiles. A Basal Rate must be entered in each time segment (rate can be 0 u/hr).
	How will the System notify me?	Prompt screen only.
	Will the System re-notify me?	No, a Basal Rate must be entered to save the time segment.
	How should I respond?	Tap . Enter a Basal Rate in the time segment.

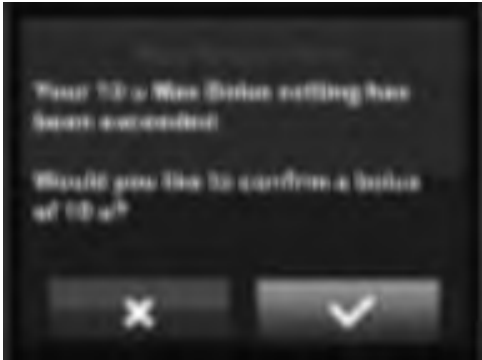
CHAPTER 13 • Insulin X2 Insulin Pump Alerts

13.8 Max Hourly Bolus Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	In the previous 60 minutes, you requested total bolus delivery that is more than 1.5 times your Max Bolus setting.
	How will the System notify me?	Prompt screen only.
	Will the System re-notify me?	No, you must tap  or  to deliver the bolus.
	How should I respond?	• Tap  to return to the <i>Bolus</i> screen and adjust the bolus delivery amount. • Tap  to confirm the bolus.

13.9 Max Bolus Alerts

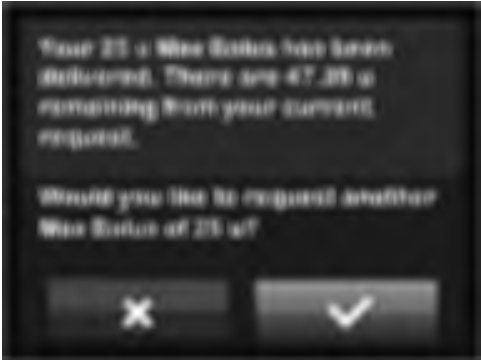
Max Bolus Alert 1

Screen	Explanation	
What will I see on the screen? 	What does it mean?	You requested a bolus larger than the Max Bolus setting in your active Personal Profile.
	How will the System notify me?	Prompt screen only.
	Will the System re-notify me?	No, you must tap  or  to deliver the bolus.
	How should I respond?	• Tap  to return to the <i>Bolus</i> screen and adjust the bolus delivery amount. • Tap  to deliver the amount of your Max Bolus setting.

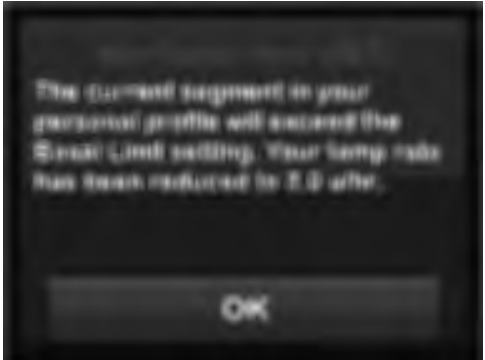
CHAPTER 13 • Insulin X2 Insulin Pump Alerts

Max Bolus Alert 2

The following applies only if you have Carbs turned on in your active Personal Profile and your Max Bolus amount is set to 25 units.

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your Max Bolus is set to 25 units and you requested a bolus larger than 25 units.
	How will the System notify me?	Prompt screen only.
	Will the System re-notify me?	No, you must tap  or  to deliver the remaining amount of the bolus request.
	How should I respond?	Before responding to this Alert, always consider whether your bolus insulin needs have changed since you requested the original bolus. • Tap  to deliver the remaining amount of the bolus request. A confirmation screen will appear. • Tap  if you do not want to deliver the remaining amount of the bolus request.

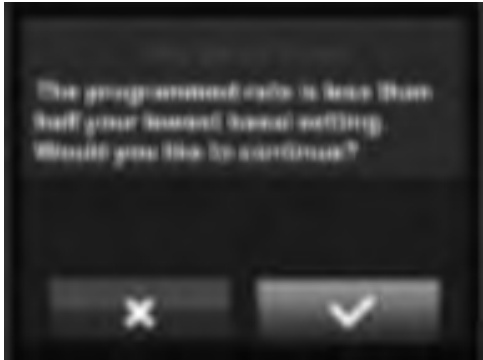
13.10 Max Basal Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	An active Temp Rate exceeds your Basal Limit setting due to a new timed segment activation within Personal Profiles. This alert will only display once your timed segment changes.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibration setting selected in Sound Volume.
	Will the System re-notify me?	No, you must tap  to move forward.
	How should I respond?	Tap  to accept the reduced Temp Rate. The reduced Temp Rate value is the same Basal Limit value that was set up in Personal Profiles.

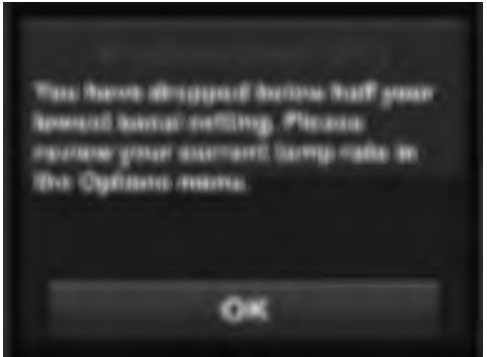
CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.11 Min Basal Alerts

Min Basal Alert 1

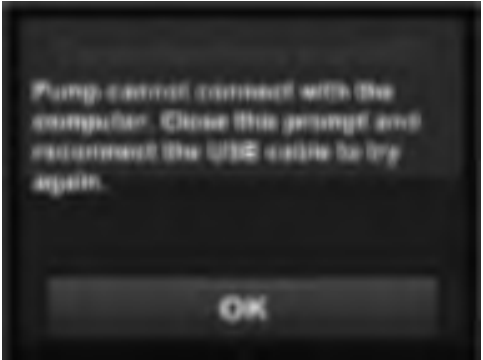
Screen	Explanation	
What will I see on the screen? 	What does it mean?	When entering a Basal Rate or requesting a temp rate, you requested a Basal Rate less than half of the lowest basal rate defined in your Personal Profile.
	How will the System notify me?	Prompt screen only.
	Will the System re-notify me?	No, you must tap  or  to move forward.
	How should I respond?	• Tap  to return to the previous screen to adjust the amount. • Tap  to dismiss the alert and continue with the request.

Min Basal Alert 2

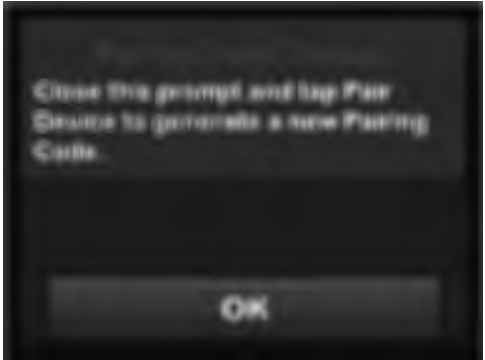
Screen	Explanation	
What will I see on the screen? 	What does it mean?	An active temp rate dropped below half of your lowest basal setting defined in your Personal Profile.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  and review your current temp rate in the <i>Activity</i> menu.

CHAPTER 13 • Insulin X2 Insulin Pump Alerts

13.12 Connection Error Alert

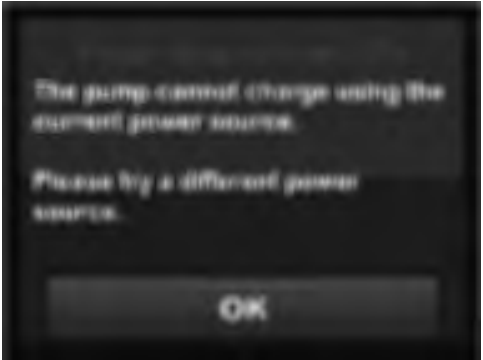
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You connected pump to a computer with the USB cable to charge it or upload data to the t:connect web application and a connection could not be made.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap . Disconnect and reconnect the USB cable to try again.

13.13 Pairing Code Timeout

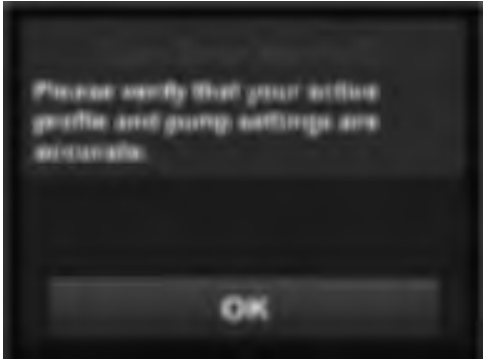
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You attempted to connect a smartphone to the pump, but the pairing process took too long (more than 5 minutes) and was unsuccessful.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	No.
	How should I respond?	Tap . Try to pair the smartphone again.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.14 Power Source Alert

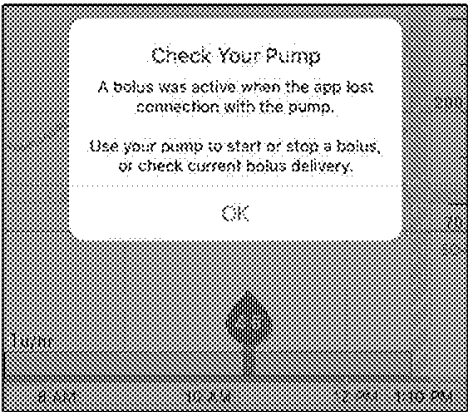
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You connected your pump to a power source that does not have enough power to charge the pump.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Connect the pump to a different power source to charge.

13.15 Data Error Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump encountered a condition that could potentially result in a loss of data.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Check your Personal Profiles and pump settings to verify that they are accurate. See Section 6.4 Editing or Reviewing an Existing Profile.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.16 Pump Connection Lost Alert - t:connect Mobile App

Screen	Explanation	
What will I see in the t:connect mobile app? 	What does it mean?	You started a bolus request in the t:connect mobile app, but your smartphone became disconnected from your pump before or during bolus delivery.
	How will the t:connect mobile app notify me?	• If the t:connect mobile app is open and on the <i>Bolus</i> screen, an informational message appears. • If bolus delivery is in progress, you will receive the alert as a notification banner.
	Will the t:connect mobile app re-notify me?	No, the alert remains on the t:connect mobile app screen until you tap OK.
	How should I respond?	Tap OK to return to the dashboard. • If bolus delivery is in progress, your pump will still deliver the remainder of the bolus unless you use your pump to stop the bolus. • You cannot use the t:connect mobile app to request another bolus until you have restored your smartphone's connection to the pump.

NOTE

The Pump Connection Lost Alert is the only alert in this chapter that appears in the t:connect mobile app but not on the pump.

2 t:slim X2 Insulin Pump Features

CHAPTER 14

t:slim X2 Insulin Pump Alarms

CHAPTER 14 • t:slim X2 Insulin Pump Alarms

⚠ PRECAUTION

CHECK your pump regularly for potential alarm conditions that may display. It is important to be aware of conditions that may affect insulin delivery and require your attention so you can respond as soon as possible.

Your t:slim X2™ pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check your BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

If multiple Reminders, Alerts, and Alarms happen at the same time, Alarms will be displayed first, Alerts will be displayed second, and Reminders will be displayed third. Each must be confirmed separately until all have been confirmed.

Information in this section will help you learn how to respond to Alarms.

Alarms notify you with 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume. If not acknowledged, alarms escalate to highest volume and vibe. Alarms repeat regularly until the condition that caused the alarm is corrected.

The t:connect™ mobile app also can provide messages, alerts, and alarms from your t:slim X2 pump as push notifications on your smartphone. These push notifications will be identical to your pump's display unless otherwise noted in this chapter.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. For more information about connecting your pump and smartphone, see Section 4.3 Connecting to a Smartphone, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

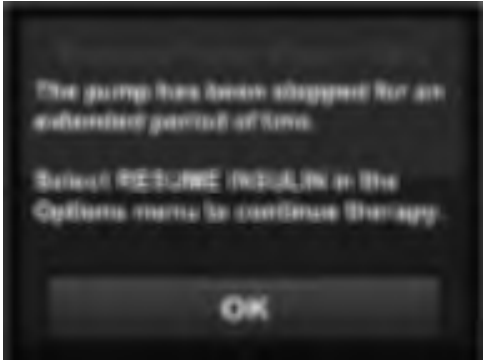
📌 NOTE

There is a list of alerts and errors related to CGM use in Chapter 26 CGM Alerts and Errors.

📌 NOTE

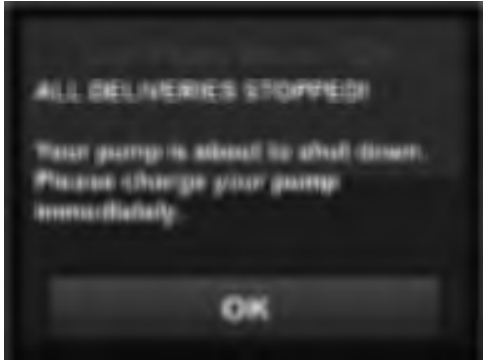
There is a list of alerts related to Control-IQ™ technology use in Chapter 32 Control-IQ Technology Alerts.

14.1 Resume Pump Alarm

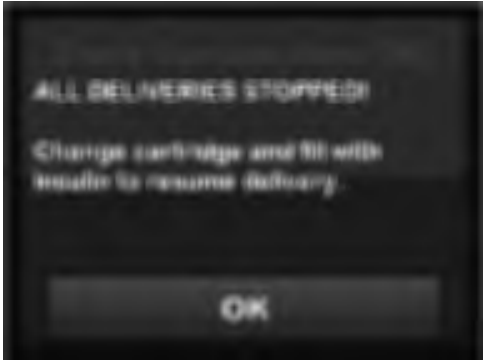
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You selected STOP INSULIN in the <i>Options</i> menu and insulin delivery has been stopped for more than 15 minutes.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes. • If not acknowledged by tapping , the System will re-notify you every 3 minutes at highest volume and vibrate. • If acknowledged by tapping , the System will re-notify you in 15 minutes.
	How should I respond?	To resume insulin, from the <i>Options</i> menu, tap RESUME INSULIN and tap  to confirm.

CHAPTER 14 • Insulin K2 Insulin Pump Alarms

14.2 Low Power Alarm

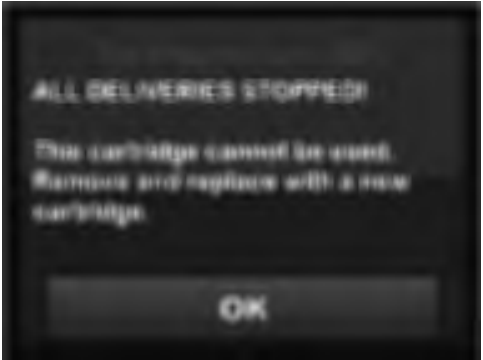
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected a power level of 1% or less remaining and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until no power remains and the pump shuts down.
	How should I respond?	Tap  . Charge your pump immediately to resume insulin delivery.

14.3 Empty Cartridge Alarm

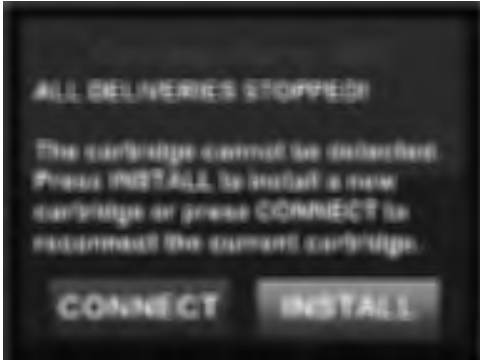
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected that the cartridge is empty and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you change the cartridge.
	How should I respond?	Tap  . Change your cartridge immediately by tapping OPTIONS from the <i>Home</i> screen, then Load and follow the instructions in Section 7.3 Filling and Loading a <i>t:slim</i> X2 Cartridge.

CHAPTER 14 • t:slim X2 Insulin Pump Alarms

14.4 Cartridge Error Alarm

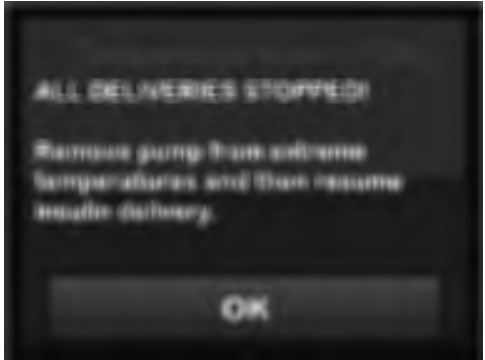
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected that the cartridge could not be used and all deliveries have stopped. This can be caused by cartridge defect, not following the proper procedure to load the cartridge, or over filling the cartridge (with more than 300 units of insulin).
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you change the cartridge.
	How should I respond?	Tap . Change your cartridge immediately by tapping OPTIONS from the <i>Home</i> screen, then Load and follow the instructions in Section 7.3 Filling and Loading a t:slim X2 Cartridge.

14.5 Cartridge Removal Alarm

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected that the cartridge has been removed and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you reconnect the current cartridge or change the cartridge.
	How should I respond?	Tap CONNECT to reattach the current cartridge. Tap INSTALL to load a new cartridge.

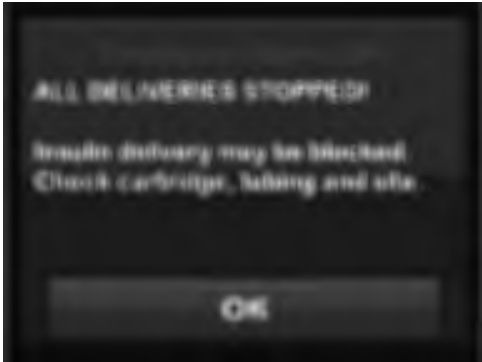
CHAPTER 14 • Insulin K2 Insulin Pump Alarms

14.6 Temperature Alarm

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected an internal temperature below 35°F (2°C) or above 113°F (45°C) or a battery temperature below 35°F (2°C) or above 125°F (52°C) and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until a temperature in the operating range is detected.
	How should I respond?	Tap . Remove the pump from the extreme temperature and then resume insulin delivery.

14.7 Occlusion Alarms

Occlusion Alarm 1

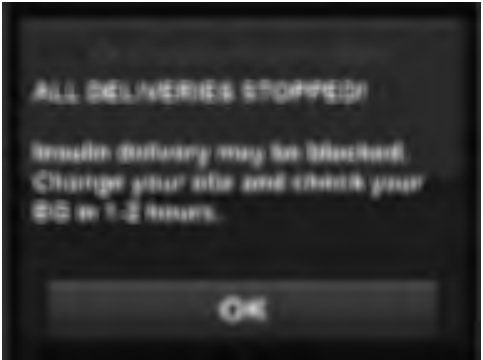
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected that insulin delivery is blocked and all deliveries have stopped. See Section 34.4 t:slim X2 Pump Performance Characteristics for more information on how long it can take the system to detect an occlusion.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you resume insulin delivery.
	How should I respond?	Tap  . Check the cartridge, tubing, and infusion site for any sign of damage or blockage and correct the condition. To resume insulin, from the <i>Options</i> menu, tap RESUME INSULIN and tap  to confirm.

NOTE

If the occlusion alarm occurs during bolus delivery, after tapping , a screen will appear letting you know how much of the requested bolus was delivered before the occlusion alarm. When the occlusion is cleared, some or all of the previously requested insulin volume may be delivered. Test your BG at the time of alarm and follow your healthcare provider's instructions for managing potential or confirmed occlusions.

CHAPTER 14 • Insulin X2 Insulin Pump Alarms

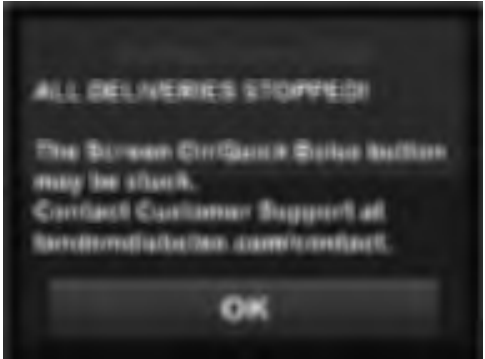
Occlusion Alarm 2

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected a second occlusion alarm shortly after the first occlusion alarm and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you resume insulin delivery.
	How should I respond?	Tap . Change the cartridge, tubing, and infusion site to ensure proper delivery of insulin. Resume insulin after changing the cartridge, tubing, and infusion site.

■ NOTE

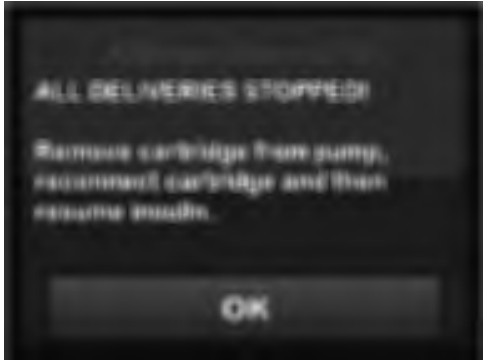
If the second occlusion alarm occurs during bolus delivery, after tapping , a screen will appear letting you know that the amount of bolus delivery could not be determined and was not added to your IOB.

14.8 Screen On/Quick Bolus Button Alarm

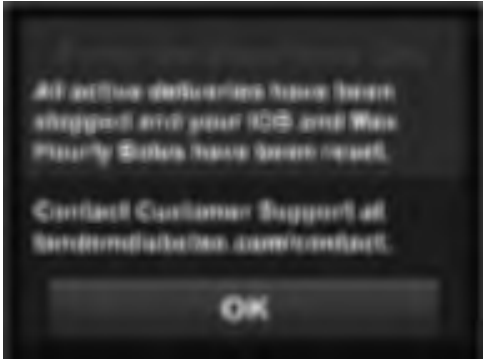
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The Screen On/Quick Bolus button (on the top of your pump) is stuck or not functioning properly and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until the condition is corrected.
	How should I respond?	Tap  . Contact Customer Technical Support.

CHAPTER 14 • Insulin K2 Insulin Pump Alarms

14.9 Altitude Alarm

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected a pressure difference between inside the cartridge and the surrounding air within the validated operating range of -1,300 feet to 10,000 feet (-396 meters to 3,048 meters) and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until the condition is corrected.
	How should I respond?	Tap  . Remove the cartridge from the pump (this will allow the cartridge to fully vent) and then reconnect the cartridge.

14.10 Reset Alarm

Screen	Explanation	
	What does it mean?	Your pump experienced a reset and all deliveries have been stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you tap  .
	How should I respond?	Tap  . Contact Customer Technical Support.

This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 15

t:slim X2 Insulin Pump Malfunction

CHAPTER 15 • Insulin X2 Insulin Pump Malfunction

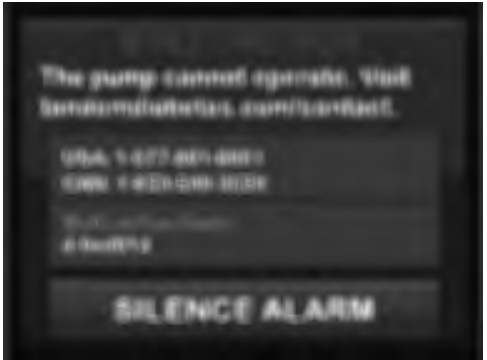
15.1 Malfunction

If your pump detects a system error, the *MALFUNCTION* screen appears and all deliveries are stopped. Contact Customer Technical Support.

Malfunctions notify you with 3 sequences of 3 notes at highest volume and 3 vibrations. They repeat at regular intervals until acknowledged by tapping **SILENCE ALARM**.

⚠ PRECAUTION

ALWAYS check with your healthcare provider for specific guidelines if you want or need to disconnect from the pump for any reason. Depending on the length of time and reason you are disconnecting, you may need to replace missed basal and/or bolus insulin. Check your BG before disconnecting from the pump and again when you reconnect, and treat high and low BG levels as recommended by your healthcare provider.

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected a system error and all deliveries have been stopped.
	How will the System notify me?	3 sequences of 3 notes at highest volume and 3 vibrations.
	Will the System re-notify me?	Yes, every 3 minutes until you acknowledge the malfunction by tapping SILENCE ALARM .
	How should I respond?	• Write down the Malfunction Code number that appears on the screen. • Tap SILENCE ALARM. The <i>MALFUNCTION</i> screen will remain on the pump even though the alarm is silenced. • Contact Customer Technical Support and provide the Malfunction Code number that you wrote down.

This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 16

Taking Care of Your Pump

CHAPTER 16 • Taking Care of Your Pump

16.1 Overview

This section provides information on caring for and maintaining your pump.

Cleaning Your Pump

When cleaning your pump, use a damp lint-free cloth. Do not use household or industrial cleaners, solvents, bleach, scouring pads, chemicals, or sharp instruments. Never submerge the pump in water or use any other liquid to clean it. Do not place the pump in the dishwasher or use hot water to clean it. If needed, use only a very mild detergent, such as a bit of liquid soap with warm water. When drying your pump, use a soft towel; never place your pump in a microwave oven or baking oven to dry it.

Maintaining Your Pump

The pump requires no preventative maintenance.

Inspecting Your Pump for Damage**▲ PRECAUTION**

DO NOT use your pump if you think it might be damaged due to dropping it or hitting it against a hard surface. Check that the pump is working properly by plugging a power source into the USB port and confirming that the display turns on, you hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the **Screen On/Quick Bolus** button. If you are unsure about potential damage, discontinue use of the pump and contact Customer Technical Support.

If you drop your pump or it has been hit against something hard, ensure that it is still working properly. Check that the touchscreen is working and clear, and that the cartridge and infusion set are properly in place. Check for leaks around the cartridge and at the tubing connector to the infusion set. Immediately contact Customer Technical Support if you notice any cracks, chips, or other damage.

Storing Your Pump

If you need to stop using your pump for a long period of time, you can place the

pump in storage mode. To place the pump in storage mode, connect the pump to a power source and then press and hold down the **Screen On/Quick Bolus** button for 30 seconds. The pump will beep 3 times before going into storage mode. Disconnect the pump from the power source.

Keep the pump protected when not in use. Store at temperatures between -4°F (-20°C) and 140°F (60°C) and at relative humidity levels between 20% and 90%.

To bring the pump out of storage mode, simply connect the pump to a power source.

Disposing of System Components

Consult Customer Technical Support for instructions for disposal of devices containing electronic waste such as your pump. Follow local regulations for disposal of potentially biohazardous materials such as used cartridges, needles, syringes, infusion sets, and sensors.

2 t:slim X2 Insulin Pump Features

CHAPTER 17

Lifestyle Issues and Travel

CHAPTER 17 • Lifestyle Issues and Travel

17.1 Overview

While the convenience and flexibility of the pump allow most users to participate in a variety of activities, some lifestyle changes may be required. Additionally, your insulin needs may change in response to lifestyle changes.

⚠ PRECAUTION

CONSULT your healthcare provider about lifestyle changes such as weight gain or loss, and starting or stopping exercise. Your insulin needs may change in response to lifestyle changes. Your Basal Rate(s) and other settings may need adjustment.

Physical Activity

The pump can be worn during most forms of exercise, such as running, cycling, hiking, and resistance training. During exercise, the pump can be worn in the provided case, your pocket, or other third-party “sport cases.” When choosing third-party pump cases or stickers, do not cover the six vent holes on the back of the pump.

⚠ PRECAUTION

If you choose to use a pump case or other accessories not provided by Tandem, **DO NOT** cover the six vent holes on the back of the pump. Covering the vent holes could affect insulin delivery.

For activities where contact is a concern, such as baseball, hockey, martial arts, or basketball, you can disconnect from your pump for short periods of time. If planning to disconnect from your pump, discuss a plan with your healthcare provider to compensate for any basal insulin delivery you miss while disconnected, and be sure to continue to check your BG levels. Even if you disconnect your tubing from your infusion site, the pump should continue to receive data from the transmitter as long as it is within the 20-foot (6-meter) range without obstruction.

Aquatic Activities**⚠ PRECAUTION**

AVOID submerging your pump in fluid beyond a depth of 3 feet (0.91 meters) or for more than 30 minutes (IP27 rating). If your pump has been exposed to fluid beyond these limits, check for

any signs of fluid entry. If there are signs of fluid entry, discontinue use of the pump and contact Customer Technical Support.

Your pump is watertight to a depth of 3 feet (0.91 meters) for up to 30 minutes (IP27 rating), but it is not waterproof. Your pump should not be worn while swimming, scuba diving, surfing, or during any other activities that could submerge the pump for an extended period of time. Your pump should not be worn in hot tubs or saunas.

Extreme Altitudes

Some activities, such as hiking, skiing or snowboarding, could expose your pump to extreme altitudes. The pump has been tested at altitudes up to 10,000 feet (3,048 meters) at standard operating temperatures.

Extreme Temperatures

You should avoid activities which could expose your pump to temperatures below 41°F (5°C) or above 98.6°F (37°C), as insulin can freeze at low temperatures or degrade at high temperatures.

Other Activities Which Require Removing Your Pump

⚠ PRECAUTION

If you remove your pump for 30 minutes or longer, it is recommended that you suspend insulin delivery. If insulin is not suspended, Control-IQ™ technology will continue to operate while the pump is removed, and will continue to dose insulin.

There are other activities, such as bathing and intimacy, when it may be more convenient for you to remove your pump. It is safe to do so for short periods of time. If planning to disconnect from your pump, discuss a plan with your healthcare provider for compensating for any basal delivery you miss while disconnected, and be sure to check your BG levels frequently. Missing basal delivery could cause your BG to rise.

Travel

The flexibility afforded by an insulin pump can simplify some aspects of travel, but it still requires planning. Be sure to order your pump supplies before your trip so that you have

enough supplies with you while you're away from home. In addition to pump supplies, you should also always bring the following items:

- The items listed in the Emergency Kit described in Section 1.10 Emergency Kit.
- A prescription for both rapid-acting and long-acting insulin of the type recommended by your healthcare provider in case you need to take insulin by injection.
- A letter from your healthcare provider explaining the medical need for your insulin pump and other supplies.

Traveling by Air

⚠ PRECAUTION

DO NOT expose your pump to X-ray screening used for carry-on and checked luggage. Newer full body scanners used in airport security screening are also a form of X-ray and your pump should not be exposed to them. Notify the security agent that your pump cannot be exposed to X-ray machines and request an alternate means of screening.

Your pump has been designed to withstand common electromagnetic interference including airport metal detectors.

The pump is safe for use on commercial airlines. The pump is a Medical Portable Electronic Device (M-PED). The system complies with radiated emissions requirements defined in RTCA/DO-160G, Section 21, Category M. Any M-PED which meet the requirements of this standard in all modes of operation may be used on board aircraft without the need for further testing by the operator.

Pack your pump supplies in your carry-on luggage. **DO NOT** pack your supplies in checked luggage as it could get delayed or lost.

If traveling, contact Customer Technical Support prior to your trip to obtain a travel loaner pump in case your pump malfunctions outside of Tandem's replacement area.

If you enable Airplane mode on your smartphone, you must maintain an active Bluetooth connection between your smartphone and your pump to use

CHAPTER 17 • Lifestyle Issues and Travel

the t:connect™ mobile app. You can always use your pump to deliver a bolus if you cannot connect your smartphone and pump. Please check with your airline carrier and smartphone manufacturer instructions prior to traveling to determine conditions for using Bluetooth.

⚠ WARNING

ALWAYS use your t:slim X2™ insulin pump for therapy decisions if your Bluetooth connection between your smartphone and pump is disabled.

📌 NOTE

The t:connect mobile app requires an active Bluetooth connection to connect with your pump. If you turn on Airplane mode, make sure you keep Bluetooth enabled to connect to your pump.

3 CGM Features

CHAPTER 18

Important Safety Information When Using the t:slim X2 Insulin Pump with Dexcom G6 CGM

CHAPTER 18 • Important Safety Information When Using the t:slim X2 Insulin Pump with Dexcom G6 CGM

The following includes important safety information related to your CGM and its components. The information presented in this chapter does not represent all warnings and precautions related to the CGM. Visit Dexcom's website for applicable product instructions that also present warnings and precautions.

18.1 Warnings

Using Dexcom G6 with Your t:slim X2™ Insulin Pump

▲ WARNING

DO NOT ignore symptoms of high and low glucose. If your sensor glucose alerts and readings do not match your symptoms, measure your BG with a BG meter even if your sensor is not reading in the high or low range.

▲ WARNING

DO NOT ignore sensor wire fractures. Sensors may fracture on rare occasions. If a sensor wire breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation (redness, swelling, or pain) at the insertion site. If you experience a

broken sensor wire, please report this to Customer Technical Support.

▲ WARNING

DO NOT use Dexcom G6 CGM in pregnant women or persons on dialysis. The System is not approved for use in pregnant women or persons on dialysis and has not been evaluated in these populations. Sensor glucose readings may be inaccurate in these populations and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT use Dexcom G6 CGM in critically ill patients. It is not known how different conditions or medications common to the critically ill population may affect the performance of the System. Sensor glucose readings may be inaccurate in critically ill patients, and solely relying on the sensor glucose alerts and readings for treatment decisions could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT insert the sensor in sites other than the abdomen (belly) or upper buttocks (for ages 2–17 only). Other sites have not been studied and are not approved. Use in other sites might cause

sensor glucose readings to be inaccurate and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT expect CGM alerts until after the 2-hour startup. You will **NOT** get any sensor glucose readings or alerts until after the 2-hour startup ends. During this time you might miss severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT use your transmitter if it is damaged/cracked. This could create an electrical safety hazard or malfunction, which might cause electrical shocks.

▲ WARNING

STORE the Dexcom G6 CGM sensor at temperatures between 36°F (2.2°C) to 86°F (30°C) for the length of the sensor's shelf life. You may store the sensor in the refrigerator if it is within this temperature range. The sensor should not be stored in a freezer. Storing the sensor improperly might cause the sensor glucose readings to be inaccurate, and you might miss severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

CHAPTER 18 • Important Safety Information When Using the t:slim X2 Insulin Pump with Dexcom G6 CGM

⚠ WARNING

DO NOT allow young children to hold the sensor, transmitter or transmitter kit box without adult supervision. The sensor and transmitter include small parts that may pose a choking hazard.

⚠ WARNING

If a sensor session is ended, either automatically or manually, you will not receive any CGM alerts. In order to receive CGM alerts, a sensor session must be started and transmitting sensor values to the pump based on a sensor code or sensor calibration.

18.2 Precautions**Using Dexcom G6 CGM with Your t:slim X2 Insulin Pump****⚠ PRECAUTION**

DO NOT open the sensor package until you have washed your hands with soap and water, and let them dry. You may contaminate the insertion site and suffer an infection if you have dirty hands while inserting the sensor.

⚠ PRECAUTION

DO NOT insert the sensor until you have cleaned the skin with a topical antimicrobial solution, such as isopropyl alcohol, and allowed the skin to dry. Inserting into unclean skin might lead to infection. Do not insert the sensor until the cleaned area is dry so the sensor adhesive will stick better.

⚠ PRECAUTION

AVOID using the same spot repeatedly for sensor insertion. Rotate your sensor placement sites, and do not use the same site for two sensor sessions in a row. Using the same site might cause scarring or skin irritation.

⚠ PRECAUTION

AVOID inserting the sensor in areas that are likely to be bumped, pushed or compressed, or areas of skin with scarring, tattoos, or irritation as these are not ideal sites to measure glucose. Insertion in those areas might affect accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

AVOID injecting insulin or placing an infusion set within 3 inches (7.6 cm) of the sensor. The insulin might affect sensor accuracy and could

result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

DO NOT use the sensor if its sterile package has been damaged or opened. Using an unsterile sensor might cause infection.

⚠ PRECAUTION

PAY ATTENTION to the trend information on your *CGM Home* screen, as well as your symptoms, before using CGM values to calculate and deliver a correction bolus. Individual CGM values may not be as accurate as BG meter values.

⚠ PRECAUTION

To calibrate the Dexcom G6 CGM, **ALWAYS** enter the exact BG value that your BG meter displays within 5 minutes of a carefully performed BG measurement. Do not enter sensor glucose readings for calibration. Entering incorrect BG values, BG values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

CHAPTER 18 • Important Safety Information When Using the Trisim X2 Insulin Pump with Dexcom G6 CGM

⚠ PRECAUTION

DO NOT calibrate if your BG is changing at a significant rate, typically more than 2 mg/dL per minute. Do not calibrate when your receiver screen is showing the rising or falling single arrow or double arrow, which indicates that your BG is rapidly rising or falling. Calibrating during significant rise or fall of BG may affect sensor accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

The Dexcom G6 CGM accuracy may be affected when your sensor glucose is changing at a significant rate (i.e., 2 to 3 mg/dL/min or more than 3 mg/dL each minute), such as during exercise or after a meal.

⚠ PRECAUTION

AVOID separating the transmitter and pump by more than 20 feet (6 meters). The transmission range from the transmitter to the pump is up to 20 feet (6 meters) without obstruction. Wireless communication does not work well through water so the range is reduced if you are in a pool, bathtub, or on a water bed, etc. To ensure communication, it is suggested that you face your pump screen out and away from the body, and wear the pump on the same side of the

body that you wear your CGM. Types of obstruction differ and have not been tested. If your transmitter and pump are farther than 20 feet (6 meters) apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

DO NOT use alternative BG site testing (blood from your palm or forearm, etc.) for calibration. Alternative site BG values may be different than those taken from a fingerstick BG value and may not represent the timeliest BG value. Use a BG value taken only from a fingerstick for calibration. Alternative site BG values might affect sensor accuracy and result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

ENSURE that your transmitter ID is programmed into the pump before you use the System if you receive a warranty replacement pump. The pump cannot communicate with the transmitter unless the transmitter ID is entered. If the pump and transmitter are not communicating, you will not receive sensor glucose readings and you

might miss severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

DO NOT discard your transmitter. It is reusable. The same transmitter is used for each session until you have reached the end of the transmitter battery life.

⚠ PRECAUTION

The Dexcom G6 sensor is not compatible with older versions of transmitters or receivers. Do not mix transmitters, receivers, and sensors from different generations.

⚠ PRECAUTION

Taking medications with acetaminophen while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

⚠ PRECAUTION

Hydroxyurea is a medication used in the treatment of diseases including cancer and sickle cell anemia. It is known to interfere with glucose readings from the Dexcom sensor. The use of hydroxyurea will result in sensor glucose readings that are higher than actual glucose

CHAPTER 18 • Important Safety Information When Using the t:slim X2 Insulin Pump with Dexcom G6 CGM

levels. The level of inaccuracy in sensor glucose readings is based on the amount of hydroxyurea in the body. Relying on sensor glucose values while taking hydroxyurea could result in missed hypoglycemia alerts or errors in diabetes management, such as giving a higher dose of insulin than necessary to correct falsely high sensor glucose values. It can also result in errors when reviewing, analyzing and interpreting historical patterns for assessing glucose control. **DO NOT** use the Dexcom CGM readings to make diabetes treatment decisions or assess glucose control when taking hydroxyurea. Use your BG meter and consult with your healthcare provider about alternative glucose monitoring approaches.

18.3 Potential Benefits From Using the t:slim X2 Insulin Pump with CGM

When paired with Dexcom G6 transmitter and sensor, your pump can receive CGM readings every 5 minutes, which are displayed as a trend graph on the *CGM Home* screen. You can also program your pump to alert you when your CGM readings are above or below a given level, or are rising or falling quickly. Unlike the readings from

a standard BG meter, CGM readings allow you to view trends in real time, as well as capture information when you would otherwise be unable to check your blood sugar, such as while you are asleep. This information can be useful for you and your healthcare provider when considering changes to your therapy. In addition, the programmable alerts can help you to spot potential low or high BG sooner than you would using a only a BG meter.

- In some studies, CGM was shown to increase time in the target glucose range. Subjects in these studies had better diabetes control (lowered A1C values, reduced glycemic variability and time spent in low and high BG ranges)^{1, 2, 3} which can help reduce diabetes related complications.^{4, 5} These benefits can be seen especially with using real-time CGM at least six days per week² and were sustained over time.⁶ In some cases, patients perceived an increase in their quality of life and peace of mind when using real-time CGM as well as reporting a high satisfaction with CGM.⁷

¹ Garg S, Zisser H, Schwartz S, et al. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. *Diabetes Care*. 2006; 29(1):44-50.

² JDRF CGM Study Group. Continuous glucose monitoring and intensive treatment of type 1 diabetes. *NEJM*. 2008; 359:1464-76.

³ Battelino T, Phillip M, Bratina N, et al. Effect of continuous glucose monitoring of hypoglycemia in type 1 diabetes. *Diabetes Care* 2011; 34(4):795-800.

⁴ The Diabetes Control and Complications Research Group. The effect of intensive treatment of diabetes on the development and progression of long- term complications of insulin-dependent diabetes mellitus. *NEJM*. 1993; 329:997-1036.

⁵ Ohkubo Y, Kishikawa H, Araki E, et al. Intensive insulin therapy prevents progression of diabetic microvascular complications in Japanese patients with non-insulin dependent diabetes mellitus: a randomized prospective

CHAPTER 18 • Important Safety Information When Using the tslim X2 Insulin Pump with Dexcom G6 CGM

6-year study. *Diabetes Res Clin Pract.* 1995; 28(2):103-117.

⁶ JDRF CGM Study Group. Sustained benefit of continuous glucose monitoring on A1c, glucose profiles, and hypoglycemia in adults with type 1 diabetes. *Diabetes Care* 2009; 32(11):2047-2049.

⁷ JDRF CGM Study Group. Quality-of-Life measures in children and adults with type 1 diabetes. *Diabetes Care* 2010; 33(10):2175-2177.

18.4 Possible Risks From Using the tslim X2 Insulin Pump with CGM

Inserting the sensor and wearing the adhesive patch might cause infection, bleeding, pain and skin irritations (redness, swelling, bruising, itching, scarring, or skin discoloration).

There is a remote chance that a sensor wire fragment could remain under your skin if the sensor wire breaks while you are wearing it. If you think a sensor wire has broken under your skin, contact your healthcare provider and call Customer Technical Support.

Other risks associated with CGM use include the following:

- You will not get sensor glucose alerts when the alert function is turned off, your transmitter and pump are out of range, or when your pump is not showing sensor glucose readings. You might not notice alerts if you are unable to hear them or feel the vibration.
- There are a number of risks as a result of the fact that the Dexcom G6 CGM takes readings from fluid below the skin (interstitial fluid) instead of blood. There are differences in how glucose is measured in the blood compared to how it is measured in interstitial fluid, and glucose is absorbed into the interstitial fluid slower than it is absorbed into the blood, which can cause CGM readings to lag behind readings from a BG meter.

3 CGM Features

CHAPTER 19

Getting to Know Your CGM System

CHAPTER 19 • Getting to Know Your CGM System

19.1 CGM Terminology**Alternate Site BG Testing**

Alternate site BG testing is when you take a BG value on your BG meter using a blood sample from an area on your body other than your fingertip. Do not use alternate site testing to calibrate your sensor.

Applicator

The applicator is a disposable piece that comes attached to the sensor pod and inserts the sensor under the skin. There is a needle inside the applicator that is removed after you insert the sensor.

Calibration

Calibration is when you enter BG values from a BG meter into the System. Calibrations may be needed for your System to show continuous glucose readings and trend information.

CGM

Continuous glucose monitoring.

CGM Reading

A CGM reading is a sensor glucose reading shown on your pump. This

reading is in mg/dL units and is updated every 5 minutes.

HypoRepeat

HypoRepeat is an optional CGM auditory and vibration alert setting that keeps repeating the fixed low alert every 5 seconds until your sensor glucose value rises above 55 mg/dL or you confirm it. This alert can be helpful if you want extra awareness for severe lows.

mg/dL

Milligrams per deciliter. The standard unit of measure for sensor glucose readings.

Receiver

When the Dexcom G6 CGM is used with the pump to display CGM readings, the insulin pump replaces the receiver for the therapeutic CGM. A smartphone with the Dexcom app may be used in addition to the pump to receive sensor readings.

Rise and Fall (Rate of Change) Alerts

Rise and fall alerts occur based on how much and how fast your glucose levels rise or fall.

RF

RF is the abbreviation for radio frequency. RF transmission is used to send glucose information from the transmitter to the pump.

Sensor

The sensor is the part that of the CGM includes an applicator and wire. The applicator inserts the wire under your skin, and the wire measures glucose levels in your tissue fluid.

Sensor Glucose Data Gaps

Glucose data gaps occur when your System is unable to provide a sensor glucose reading.

Sensor Glucose Trends

Glucose trends let you see the pattern of your glucose levels. The trend graph shows where your glucose levels have been during the time shown on the screen and where your glucose levels are now.

Sensor Pod

The sensor pod is the small plastic base of the sensor attached to your skin that holds the transmitter in place.

Startup Period

The startup period is the 2-hour period after you tell the System you inserted a new sensor. Sensor glucose readings are not provided during this time.

Transmitter

The transmitter is the part of the CGM that snaps into the sensor pod and wirelessly sends glucose information to your pump.

Transmitter ID

The transmitter ID is a series of numbers and/or letters that you enter into your pump to let it connect and communicate with the transmitter.

Trend (Rate of Change) Arrows

Trend arrows show how fast your glucose levels are changing. There are seven different arrows that show when your glucose direction and speed change.

CHAPTER 18 • Getting to Know Your CGM System

19.2 Explanation of CGM Pump Icons

The following CGM icons may appear on your pump screen:

CGM Icon Definitions

Symbol	Meaning
	Unknown sensor reading.
	CGM sensor session is active, but the transmitter and pump are out of range.
	The CGM sensor has failed.
	The CGM sensor session has ended.
	Wait 15 minutes calibration error.
	Startup calibration is required (2 BG values).
	Additional startup calibration is required.
	CGM calibration is required.

Symbol	Meaning
	Transmitter error.
	CGM sensor session is active, and the transmitter is communicating with the pump.
	CGM sensor session is active, but the transmitter is not communicating with the pump.
	Sensor startup 0–30 minutes.
	Sensor startup 31–60 minutes.
	Sensor startup 61–90 minutes.
	Sensor startup 91–119 minutes.

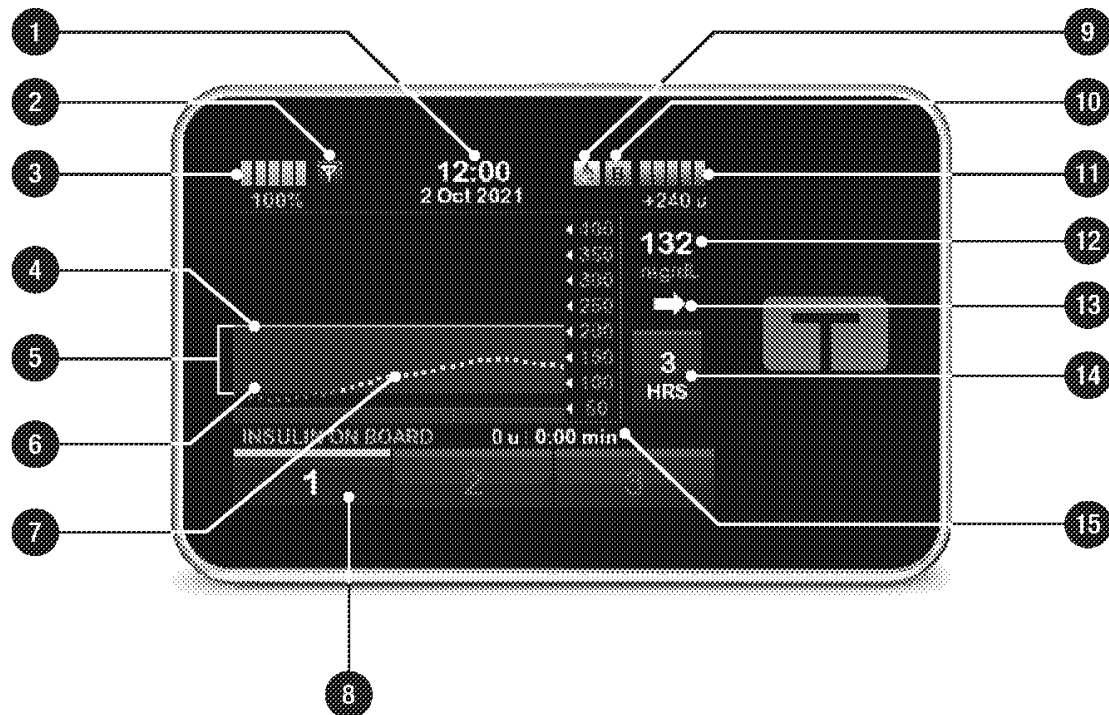
This Page is Intentionally Left Blank

CHAPTER 19 • Getting to Know Your CGM System

19.3 CGM Lock Screen

The *CGM Lock* screen appears anytime you turn on the screen and you are using your pump with a CGM.

1. **Time and Date Display:** Displays the current time and date.
2. **Antenna:** Indicates communication status between pump and transmitter.
3. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
4. **High Glucose Alert Setting.**
5. **Sensor Glucose Target Range.**
6. **Low Glucose Alert Setting.**
7. **Graph of Most Recent Sensor Glucose Readings.**
8. **1–2–3:** Unlocks pump screen.
9. **Active Bolus Icon:** Indicates a bolus is being delivered.
10. **Status:** Displays current system settings and insulin delivery status.
11. **Insulin Level:** Displays the current amount of insulin in the cartridge.
12. **Most Recent 5-Minute Sensor Glucose Reading.**
13. **Trend Arrow:** Indicates direction and rate of change.
14. **Trend Graph Time (HRS):** 1, 3, 6, 12 and 24 hour views available.
15. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.



CHAPTER 19 • Getting to Know Your CGM System

19.4 CGM Home Screen

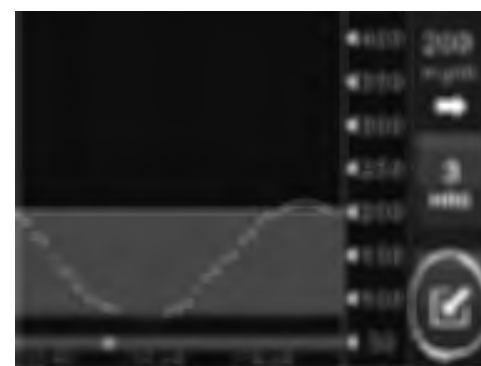
1. **Time and Date Display:** Displays the current time and date.
2. **Antenna:** Indicates communication status between pump and transmitter.
3. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
4. **High Glucose Alert Setting.**
5. **Sensor Glucose Target Range.**
6. **Low Glucose Alert Setting.**
7. **Graph of Most Recent Sensor Glucose Readings.**
8. **Options:** Stop/Resume insulin delivery, manage pump and CGM settings, start/stop activities, load a cartridge, and view history.
9. **Bolus icon:** Denotes a bolus delivery. Each bolus icon represents one bolus delivery even if the icon is temporarily obstructed by the hash marks on the bolus bar as the graph changes over time.
10. **Bolus:** Program and deliver a bolus.
11. **Status:** Displays current system settings and insulin delivery status.
12. **Insulin Level:** Displays the current amount of insulin in the cartridge.
13. **Most Recent 5-Minute Sensor Glucose Reading.**
14. **Trend Arrow:** Indicates direction and rate of change.
15. **Trend Graph Time (HRS):** 1, 3, 6, 12 and 24 hour views available.
16. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.

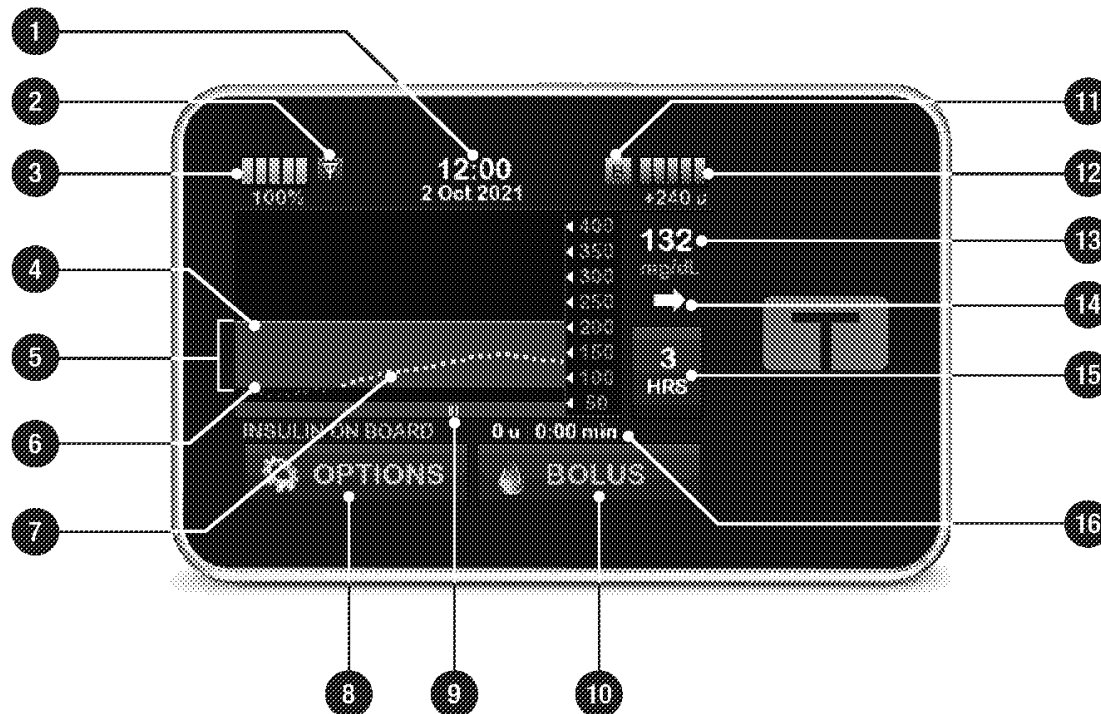
To view CGM information on the full screen:

From the *CGM Home* screen tap anywhere on the CGM trend graph.



Tap the “minimize” icon to return to the *CGM Home* screen.





CHAPTER 19 • Getting to Know Your CGM System

19.5 My CGM Screen

1. **Start Sensor:** Starts a CGM session. If sensor is active, STOP SENSOR will be displayed.
2. **Calibrate CGM:** Enter a calibration BG value. Only active when sensor session is active.
3. **CGM Alerts:** Customize CGM Alerts.
4. **Transmitter ID:** Enter the transmitter ID.
5. **CGM Info:** View the CGM information.



This Page is Intentionally Left Blank

3 CGM Features

CHAPTER 20

CGM Overview

CHAPTER 20 • CGM Overview

20.1 CGM System Overview

This section of the user guide covers instructions for using a CGM with your t:slim X2™ pump. Use of a CGM is optional, but in order to use Control-IQ™ technology, CGM is required. When used, CGM allows readings from your sensor to be displayed on your pump screen. To make treatment decisions during a new sensor startup period, you will also need a commercially available BG meter to use with your System.

As an example, a compatible CGM is the Dexcom G6 CGM System, which consists of a sensor, transmitter, and a receiver.

The Dexcom G6 sensor is a disposable device that is inserted under the skin to continuously monitor glucose levels from interstitial fluid (the fluid under your skin). The Dexcom G6 transmitter connects to the sensor using Bluetooth wireless technology communication and sends readings to the pump display every 5 minutes. The pump display shows sensor glucose readings, a trend graph, and the direction and

rate of change arrows. For information about inserting a Dexcom G6 CGM sensor, placing a Dexcom G6 transmitter, and Dexcom G6 product specifications, visit the manufacturer's website for applicable product instructions and training information.

You can also program your pump to alert you when your CGM readings are above or below a given level, or are rising or falling quickly. If CGM readings become 55 mg/dL or lower, the CGM Fixed Low Alert will sound. This alert is not customizable.

20.2 Device Connection Overview

The Dexcom G6 CGM only allows pairing with one medical device at a time (either the t:slim X2 pump or the Dexcom receiver), but you can still use the Dexcom G6 CGM app and your pump simultaneously using the same transmitter ID. The Dexcom G6 CGM does not connect directly to the t:connect™ mobile app. CGM readings in the t:connect mobile app are provided through the t:slim X2 insulin pump connection.

You can also use both the Dexcom G6 mobile app and t:connect mobile app at the same time. The Dexcom G6 mobile app can be used to start and stop sensor sessions as well as connect with the other Dexcom compatible services. The Dexcom G6 CGM does not connect directly to the t:connect mobile app; CGM readings in the t:connect mobile app are provided via the t:slim X2 pump connection.

Unlike the readings from a standard BG meter, CGM readings allow you to view trends in real time, as well as capture information when you would otherwise be unable to check your BG, such as while you are asleep. This information can be useful for you and your healthcare provider when considering changes to your therapy. In addition, the programmable alerts can help you to spot potential low or high glucose sooner than you would using a only a BG meter.

20.3 Receiver (t:slim X2 Insulin Pump) Overview

To review the icons and controls displayed on the *Home* screen with CGM enabled, see Section 19.4 CGM Home Screen.

20.4 Transmitter Overview

This section provides information about CGM devices that have a separate transmitter. The information contained in this section is specific to the Dexcom G6 CGM and is provided as an example. For information about the Dexcom G6 transmitter, visit the manufacturer's website for applicable product instructions.

Snapping into the transmitter holder, the transmitter wirelessly sends sensor glucose information to your pump. If you have a new transmitter, only open the package when you are ready to use it.

Even if you disconnect your tubing from your infusion site, the pump should continue to receive data from the

transmitter as long as it is within the 20-foot (6 meter) range without obstruction.

If your transmitter is damaged or cracked, do not use it. Immediately contact Customer Technical Support if you notice any cracks or other damage. Do not use the sensor if its sterile package has been damaged or opened.

Transmitter features:

- Reusable
 - Do not discard after sensor session.
 - Only for you, don't share a transmitter.
- Water resistant
- Can transmit data to your pump for up to 20 feet (6 meters). Range is less if you are in or under water.
- Battery lasts approximately 90 days. Pump or smart device prompts you when battery is running low.

- Serial number is on the back
- M-PED designation
 - Emission levels meet IATA standards.
 - May be used on board aircraft without any further testing by the operator.

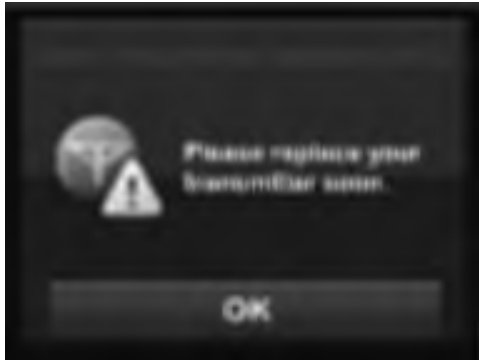
⚠ PRECAUTION

DO keep your transmitter and pump within 20 feet (6 meters) with no obstacles (like walls or metal) between them. Otherwise, they may not be able to communicate. If water is between your transmitter and the pump (for example, if you're showering or swimming) keep them closer to each other. The range is reduced because Bluetooth technology doesn't work as well through water. To ensure communication, it is suggested that you face your pump screen out and away from the body, and wear the pump on the same side of the body that you wear your CGM.

The transmitter battery will last 90 days. Once you see the Low Transmitter Battery Alert, replace the transmitter as soon as possible. Your transmitter

CHAPTER 20 • CGM Overview

battery may drain as quickly as 7 days after this alert occurs.



submerged for up to 8 feet (2.4 meters) and up to 24 hours. Underwater use will affect the ability to communicate with the pump, so the range will be much less than during normal use. Extended contact with water could weaken the adhesive used by your infusion sets and Dexcom CGM sensors and cause them to fall off prematurely.

20.5 Sensor Overview

This section provides information about CGM devices that have a separate sensor. The information contained in this section is specific to the Dexcom G6 CGM and is provided as an example. For information about the Dexcom G6 sensor, visit the manufacturer's website for applicable product instructions.

The Dexcom G6 sensor is water resistant when showering, bathing or swimming if the transmitter is fully snapped in. The sensor has been tested to be water resistant when

3 CGM Features

CHAPTER 21

CGM Settings

CHAPTER 21 • CGM Settings

21.1 About Bluetooth Technology

Bluetooth Low Energy technology is a type of wireless communication used in cell phones and many other devices. Your t:slim X2™ pump uses Bluetooth wireless technology communication to wirelessly pair together with other devices, such as a CGM or smartphone running the t:connect™ mobile app. This allows the pump to wirelessly communicate with paired devices securely and only with each other.

21.2 Disconnecting from the Dexcom Receiver

The Dexcom G6 CGM only allows pairing with one medical device at a time. Ensure your transmitter is not connected to the receiver before pairing with the pump by doing the following:

Before entering your CGM transmitter ID into the pump, turn off the Dexcom G6 receiver and wait 15 minutes. This allows the Dexcom G6 transmitter to forget the connection currently in place with the Dexcom G6 receiver.

NOTE

It is not enough to Stop the Sensor Session on your Dexcom receiver prior to pairing to the pump. The receiver power must be completely off in order to avoid connection problems.

You may still use a smartphone with the Dexcom G6 CGM app and your pump simultaneously with the same transmitter ID.

21.3 Setting CGM Volume

You can set the sound pattern and volume for CGM alerts and prompts to meet your individual needs. Reminders, alerts, and alarms for pump functions are separate from alerts and errors for CGM functions and do not follow the same pattern and volume.

To set your sound volume, see Section 5.12 Sound Volume.

CGM Volume options:**Vibrate**

You can set your CGM to alert you with vibration rather than sound. The only exception to this is the Fixed Low Alert at 55 mg/dL, which alerts you as a

vibration first, followed by beeps 5 minutes later if not confirmed.

Soft

When you want your alert to be less noticeable. This sets all alerts and alarms to lower volume beeps.

Normal

The default profile when you receive your pump. This sets all alerts and alarms to higher volume beeps.

HypoRepeat

Very similar to normal profile, but it continuously repeats the Fixed Low Alert every 5 seconds until your sensor glucose reading rises above 55 mg/dL or the alert is confirmed. This can be helpful if you want extra alerts for severe low sensor glucose readings.

The CGM volume setting that you choose applies to all CGM alerts, errors, and prompts which have their own unique sound pattern, tone and volume. This allows you to identify each alert and error and its meaning.

The Fixed Low Alert at 55 mg/dL cannot be turned off or changed.

The Soft, Normal, and HypoRepeat options have the following sequence:

- The first alert is vibrate only.
- If the alert is not confirmed in 5 minutes, the system vibrates and beeps.
- If the alert is not confirmed in 5 more minutes, the system vibrates and beeps louder. This continues at the same volume every 5 minutes until confirmed.
- If the alert is confirmed and your sensor glucose readings continue to be at or below 55 mg/dL your system repeats the alert sequence in 30 minutes (HypoRepeat option only).

CHAPTER 21 • CGM Settings

Sound Option Descriptions

CGM Volume	Vibrate	Soft	Normal	HypoRepeat
High Alert	2 long vibrates	2 long vibrates + 2 low beeps	2 long vibrates + 2 medium beeps	2 long vibrates + 2 medium beeps
Low Alert	3 short vibrates	3 short vibrates + 3 low beeps	3 short vibrates + 3 medium beeps	3 short vibrates + 3 medium beeps
Rise Alert	2 long vibrates	2 long vibrates + 2 low beeps	2 long vibrates + 2 medium beeps	2 long vibrates + 2 medium beeps
Fall Alert	3 short vibrates	3 short vibrates + 3 low beeps	3 short vibrates + 3 medium beeps	3 short vibrates + 3 medium beeps
Out of Range Alert	1 long vibrate	1 long vibrate + 1 low beep	1 long vibrate + 1 medium beep	1 long vibrate + 1 medium beep
Fixed Low Alert	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps + pause + repeat sequence
All Other Alerts	1 long vibrate	1 long vibrate + 1 low beep	1 long vibrate + 1 medium beep	1 long vibrate + 1 medium beep

To Select Your CGM Volume:

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Device Settings**.
4. Tap **Sound Volume**.
5. Tap the **Down Arrow**.
6. Tap **CGM Alerts**.
7. Tap **Vibrate**, **Soft**, **Normal** or **HypoRepeat** to select.
- ✓ Once a value is selected, the pump will return to the previous screen.
8. Tap .

- Hardware Revision
- BLE Hardware ID
- Software Number

You can view this information at any time.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap the **Down Arrow**.
5. Tap **CGM Info**.

21.4 CGM Info

CGM Info contains important information about your device. The following can be found in CGM Info:

- Firmware Revision

This Page is Intentionally Left Blank

3 CGM Features

CHAPTER 22

Setting CGM Alerts

CHAPTER 22 • Setting CGM Alerts

Setting Your CGM Alerts

You can create personal settings for how and when you want the System to tell you what is happening.

 NOTE

The following applies to setting CGM alerts on the pump. If you are using a CGM app, any alerts that have been set up in the app are not automatically transferred to the pump and must be set up separately.

The High and Low Alerts tell you when your sensor glucose readings are outside your target glucose range.

Rise and Fall (rate of change) Alerts let you know when your glucose levels are changing fast.

The System also has a 55 mg/dL Fixed Low Alert that cannot be changed or turned off. This safety feature tells you your sensor glucose level may be dangerously low.

The Out of Range Alert notifies you when the transmitter and pump are not communicating. Keep the transmitter and the pump within 20 feet (6 meters) of each other without obstruction.

When the transmitter and the pump are too far apart, you will not get sensor glucose readings or alerts.

High and Low Glucose Alerts

You can personalize the High and Low Alerts which tell you when your sensor glucose readings are outside of your target sensor glucose range. When you have both your High and Low Alerts turned on, a gray zone on your trend graph shows your target range. The default for the High Alert is on, 200 mg/dL. The default for the Low Alert is on, 80 mg/dL. Consult with your healthcare provider before setting the High and Low Glucose Alert setting.

22.1 Setting Your High Glucose Alert and Repeat Feature

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap **CGM Alerts**.

5. Tap **High and Low**.

6. To Set the High Alert, tap **High Alert**.

7. Tap **Alert Me Above**.

The default setting for the High Alert is 200 mg/dL.

 NOTE

To turn off the High Alert, tap the on/off toggle.

8. Using the on-screen keypad, enter the value above which you want to be notified. It can be set between 120 and 400 mg/dL in 1 mg/dL increments.

9. Tap .

The repeat feature allows you to set a time for the High Alert to sound again and display on your pump as long as your sensor glucose reading remains above the High Alert value. The default value is: Never (the alert will not sound again). You can set the repeat feature to sound again every 15 minutes, 30 minutes, 1

hour, 2 hours, 3 hours, 4 hours, or 5 hours when your sensor glucose reading remains above the High Alert value.

To Set Up the Repeat Feature:

10. Tap **Repeat**.

11. To select the repeat time, tap the time you want the alert to sound again. For instance, if you select 1 hr, the alert will sound every hour as long as your sensor glucose reading remains above the High Alert value.

Use the up and down arrows to view all Repeat options.

✓ Once a value is selected, the pump will return to the previous screen.

12. Tap .

22.2 Setting Your Low Glucose Alert and Repeat Feature

1. From the *Home* screen, tap **OPTIONS**.

2. Tap the **Down Arrow**.

3. Tap **My CGM**.

4. Tap **CGM Alerts**.

5. Tap **High and Low**.

6. To Set the Low Alert, tap **Low Alert**.

7. Tap **Alert Me Below**.

The default setting for the Low Alert is 80 mg/dL.

NOTE

To turn off the Low Alert, tap the on/off toggle.

8. Using the on-screen keypad, enter the value below which you want to be notified. It can be set between 60 and 100 mg/dL in 1 mg/dL increments.

9. Tap .

The repeat feature allows you to set a time for the Low Alert to sound again and display on your pump as long as your sensor glucose reading

remains below the Low Alert value. The default value is: Never (the alert will not sound again). You can set the repeat feature to sound again every 15 minutes, 30 minutes, 1 hour, 2 hours, 3 hours, 4 hours, or 5 hours when your sensor glucose reading remains below the Low Alert value.

To Set Up the Repeat Feature:

10. Tap **Repeat**.

11. To select the repeat time, tap the time you want the alert to sound again. For instance, if you select 1 hr, the alert will sound every hour as long as your sensor glucose reading remains below the Low Alert Value.

Use the up and down arrows to view all repeat options.

✓ Once a value is selected, the pump will return to the previous screen.

12. Tap .

CHAPTER 22 • Setting CGM Alerts

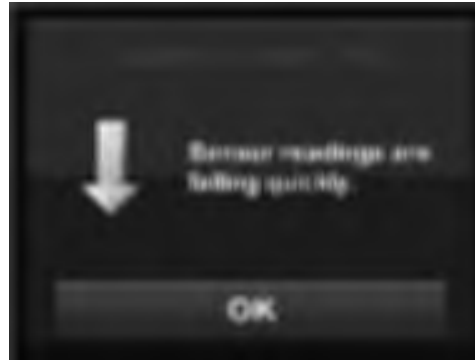
22.3 Rate Alerts

Rate alerts tell you when your glucose levels are rising (Rise Alert) or falling (Fall Alert) and by how much. You can choose to be alerted when your sensor glucose reading is rising or falling 2 mg/dL or more per minute, or 3 mg/dL or more per minute. The default value for both the Fall Alert and the Rise Alert is off. When turned on, the default is 3 mg/dL. Consult with your healthcare provider before setting the Rise and Fall Alerts.

Examples

If you set your Fall Alert to 2 mg/dL per minute and your sensor glucose readings fall at this rate or faster, the CGM Fall Alert with one arrow pointing down shows. The pump vibrates or

beeps according to your CGM volume selection.



If you set your Rise Alert to 3 mg/dL per minute and your sensor glucose readings rise at this rate or faster, the CGM Rise Alert with two arrows pointing up shows. The pump vibrates or beeps according to your CGM volume selection.



22.4 Setting Your Rise Alert

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap **CGM Alerts**.
5. Tap **Rise and Fall**.
6. Tap **Rise Alert**.
7. To select the default of 3 mg/dL/min, tap

To change your selection, tap **Rate**.

NOTE

To turn off the Rise Alert, tap the on/off toggle.

8. Tap **2 mg/dL/min** to select.
- ✓ Once a value is selected, the pump will return to the previous screen.
9. Tap

22.5 Setting Your Fall Alert

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap **CGM Alerts**.
5. Tap **Rise and Fall**.
6. Tap **Fall Alert**.
7. To select the default of 3 mg/dL/min, tap .

To change your selection, tap **Rate**.

NOTE

To turn off the Fall Alert, tap the on/off toggle.

8. Tap **2 mg/dL/min** to select.
- ✓ Once a value is selected, the pump will return to the previous screen.
9. Tap .

22.6 Setting Your Out of Range Alert

The range from the transmitter to the pump is up to 20 feet (6 meters) without obstruction.

The Out of Range Alert lets you know when your transmitter and pump are not communicating with each other. This alert is on by default.

PRECAUTION

We recommend that you keep the CGM Out of Range Alert turned on to notify you if your CGM is disconnected from your pump whenever you are not actively monitoring your pump status. Your CGM is providing the data that Control-IQ™ technology requires to make predictions to automate insulin dosing.

Keep the transmitter and the pump within 20 feet (6 meters) of each other without obstruction. To ensure communication, it is suggested that you face your pump screen out and away from the body, and wear the pump on the same side of the body that you wear your CGM. When the transmitter and pump are not communicating, you will not get sensor glucose readings or

alerts. The default value is on and will alert after 20 minutes.

The Out Of Range symbol appears on the pump *Home* screen and on the *Out of Range Alert* screen (if turned on) when the transmitter and pump are not communicating. The amount of time out of range also shows on the alert screen. It will continue to re-alert until the transmitter and pump are back in range.

NOTE

Control-IQ technology will continue to operate for the first 15 minutes that the transmitter and pump are out of range. Once the Out of Range condition is present for 20 minutes, Control-IQ technology will stop operation until the two devices are within range.

To Set Your Out of Range Alert:

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap **CGM Alerts**.

CHAPTER 22 • Setting CGM Alerts

5. Tap **Out of Range**.

The default is set to on and the time is set to 20 minutes.

6. To change the time, tap **Alert After**.

7. Using the on-screen keypad, enter the time after which you want to be alerted (between 20 minutes and 3 hours and 20 minutes) then tap



8. Tap .

3 CGM Features

CHAPTER 23

Starting or Stopping a CGM Sensor Session

CHAPTER 23 • Starting or Stopping a CGM Sensor Session

23.1 Enter Your Transmitter ID

To activate the Bluetooth wireless technology communication, you need to enter the unique transmitter ID into your pump. Once the transmitter ID has been entered into your pump, the two devices can be paired, allowing your sensor glucose readings to be displayed on your pump.

If you need to replace your transmitter, you will need to enter the new transmitter ID into your pump. If you need to replace your pump, you will need to re-enter the transmitter ID into your pump.

1. Remove the transmitter from its packaging.

▲ WARNING

DO NOT use your transmitter if it is damaged/cracked. This could create an electrical safety hazard or malfunction, which might cause electrical shocks.

2. From the *Home* screen, tap **OPTIONS**.

3. Tap the Down Arrow.

4. Tap **My CGM**.

5. Tap **Transmitter ID**.

6. Using the on-screen keypad, enter the unique transmitter ID.

The transmitter ID can be found on the back of your transmitter or on the transmitter box.

The letters I, O, V, and Z are not used in transmitter IDs and should not be entered. If one of these letters is entered, you will be notified that an invalid ID was entered and prompted to enter a valid ID.

7. Tap .

8. To make sure that the correct transmitter ID is entered, you will be prompted to enter it a second time.

9. Repeat step 6 above, then tap .

If the transmitter IDs you entered do not match you will be prompted to start the process again.

- ✓ Once matching values have been entered, you will be returned to the *My CGM* screen and the transmitter ID you entered will be highlighted in orange.

23.2 Start the Sensor

To start a CGM session, follow the steps below.

1. From the *Home* screen, tap **OPTIONS**.

2. Tap the Down Arrow.

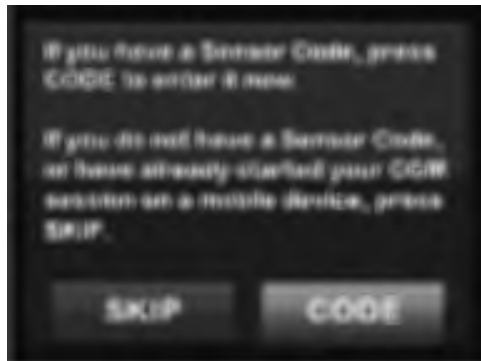
3. Tap **My CGM**.

4. Tap **START SENSOR**.

- ✓ Once you start a sensor session, the **START SENSOR** option is replaced with **STOP SENSOR**.

The following screen displays prompting you to either enter the sensor code, or to skip this step. If you choose to enter the sensor code, you will not be prompted to calibrate for the duration of the sen-

sensor session. For information about Dexcom G6 CGM sensor codes, visit the manufacturer's website for applicable user guides.



Tap **CODE** to enter the 4-digit sensor code. If you don't have a code, or if you have already started a sensor session with the Dexcom G6 CGM app, you can tap **SKIP**.

If you don't enter a code into the t:slim X2™ pump, you will need to calibrate your sensor every 24 hours. A prompt to calibrate will be displayed on the pump.

5. Tap  to confirm.

- ✓ The *SENSOR STARTED* screen will appear to let you know your sensor startup has begun.
 - ✓ Your pump will return to the *CGM Home* screen with the 3 hour trend graph and the sensor startup countdown symbol displayed.
6. Check your pump *CGM Home* screen 10 minutes after starting your sensor session to make sure your pump and transmitter are communicating. The antenna symbol should be to the right of the battery indicator and should be white.
 7. If you see the out of range symbol below the insulin level indicator, and the antenna symbol is grayed out, follow these troubleshooting tips:
 - a. Make sure your pump and transmitter are within 20 feet (6 meters) of each other without obstruction. Re-check in 10 minutes to see if the out of range symbol is still active.

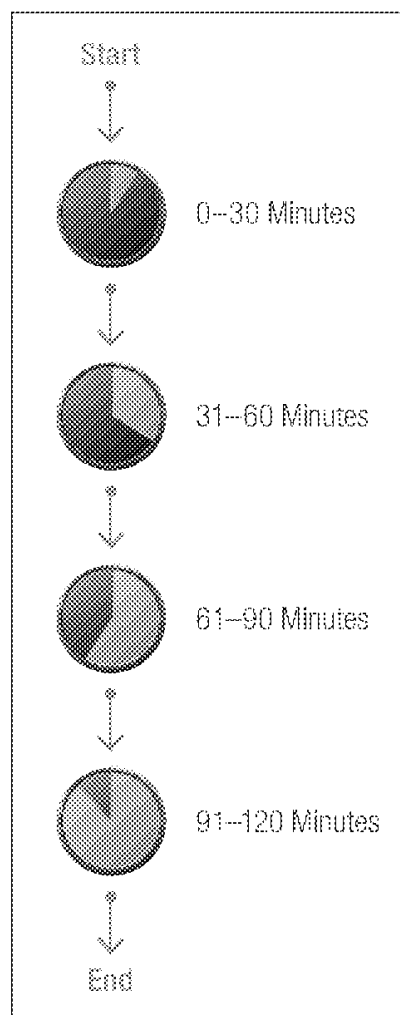
- b. If the pump and transmitter are still not communicating, check the *My CGM* screen to make sure the correct transmitter ID is entered.
- c. If the correct transmitter ID is entered and the pump and transmitter are still not communicating, contact Customer Technical Support.

CHAPTER 23 • Starting or Stopping a CGM Sensor Session

23.3 Sensor Startup Period

As an example, the Dexcom G6 sensor needs a 2-hour startup period to adjust to being under your skin. You will not get sensor glucose readings or alerts until the 2-hour startup period ends. For information about Dexcom G6 CGM sensor startup periods, visit the manufacturer's website for applicable product instructions.

During the startup period, the *CGM Home* screen on your pump shows a 2-hour countdown symbol in the upper right portion of the screen. The countdown symbol fills in over time to show that you are getting closer to the active sensor session..

Sensor Startup Period Timeline**⚠ WARNING**

Continue to use a BG meter and test strips in order to make treatment decisions during the 2-hour startup period.

📌 NOTE

During the sensor startup period, Control-IQ technology will not affect the Basal Rates or deliver automatic correction boluses. The sensor must be actively providing readings for Control-IQ technology to operate.

Examples

For example, if you started your sensor session 20 minutes ago, you would see this countdown symbol on the *CGM Home* screen.



If you started your sensor session 90 minutes ago, you would see this countdown symbol on the *CGM Home* screen.



At the end of the 2-hour startup period, the countdown symbol will be replaced with the current CGM reading.



Follow the instructions in the next chapter to calibrate your sensor. Skip the calibration instructions if you entered a sensor code. You may enter a calibration into the System at any time, even if you have already entered sensor code. Pay attention to your symptoms, and if they do not match the current CGM readings, you may choose to enter a calibration.

Ending Your Sensor Session

When the sensor session ends, you will need to replace the sensor and start a new sensor session. In some cases your sensor session may end early. You may also choose to end the sensor session early. However, if you end a sensor session early, you cannot re-start the session with that same sensor. A new sensor must be used.

NOTE

DO NOT throw away the transmitter at the end of a sensor session. Continue use of the transmitter until the pump notifies you that the transmitter battery is about to expire. Wipe the outside of the transmitter with isopropyl alcohol between sensor sessions.

Sensor glucose alerts and alarms do not work after the sensor session ends. Once the sensor session has ended, CGM readings are not available. If you are using Control-IQ technology, it becomes inactive when a CGM sensor session is ended.

23.4 Automatic Sensor Shut-Off

Your t:slim X2 pump tells you how much time you have left until your sensor session is complete. The *SENSOR EXPIRING SOON* screen shows at 6 hours remaining, 2 hours remaining, and 30 minutes remaining before your session ends. You will continue to receive sensor glucose readings after each reminder.

When you see the *SENSOR EXPIRING SOON* screen:

1. Tap **OK** to return to the previous screen.
- ✓ The *SENSOR EXPIRING SOON* screen will show again when there are 2 hours remaining, and when there are 30 minutes remaining.

CHAPTER 23 • Starting or Stopping a CGM Sensor Session

- ✓ After the final 30 minutes, the *REPLACE SENSOR* screen is displayed.
- 2. Tap .
- ✓ The *CGM Home* screen will appear with the Replace Sensor icon in the place where sensor glucose readings normally show.

New sensor glucose readings do not show on your pump after your sensor session ends. You must remove your sensor and insert a new sensor.

23.5 Ending a Sensor Session Before Automatic Shut-Off

You can end your sensor session at any time before the automatic sensor shutoff. To end your sensor session early:

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.

4. Tap **STOP SENSOR**.

5. Tap  to confirm.

- ✓ The *SENSOR STOPPED* screen is temporarily displayed.
- ✓ The *CGM Home* screen will appear with the Replace Sensor icon in the place where sensor glucose readings normally show.

New sensor glucose readings do not show on your pump after your sensor session ends. You must remove your sensor and insert a new sensor.

23.6 Removing the Sensor and Transmitter

⚠ WARNING

DO NOT ignore broken or detached sensor wires. A sensor wire could remain under your skin. If a sensor wire breaks off under your skin and you can't see it, don't try to remove it. Contact your healthcare provider. Also seek professional medical help if you have symptoms of infection or inflammation (redness, swelling, or pain) at the insertion site. If you experience a

broken sensor, please report this to Customer Technical Support.

For information about removing the Dexcom G6 sensor and Dexcom G6 transmitter, visit the manufacturer's website for applicable product instructions.

3 CGM Features

CHAPTER 24

Calibrating Your CGM System

CHAPTER 24 • Calibrating Your CGM System

24.1 Calibration Overview

If you did not enter a CGM sensor code when starting a sensor session, you will be prompted to calibrate at the following intervals:

- 2-hour startup: 2 calibrations 2 hours after you start your sensor session
- 12-hour update: 12 hours after the 2 hour start up calibration
- 24-hour update: 24 hours after the 2 hour start up calibration
- Every 24 hours: every 24 hours after the 24-hour update
- When notified

On the first day of your sensor session, you must enter four BG values into your pump to calibrate. You must enter one BG value to calibrate every 24 hours after your first startup calibration. The pump will remind you when the System needs these calibrations. In addition, you may be prompted to enter additional BG values to calibrate as needed.

⚠ PRECAUTION

DO NOT calibrate when your trend arrow is up, double-up, down, or double-down because your BG is changing at more than 2 mg/dL per minute.

When calibrating, you must enter your BG values into the pump by hand. You can use any commercially available BG meter. You must calibrate with accurate BG meter values to get accurate sensor glucose readings.

Follow these important instructions when obtaining BG values for calibration:

- BG values used for calibration must be between 40 to 400 mg/dL and must have been taken within the past 5 minutes.
- Your sensor cannot be calibrated if the glucose value from your BG meter is less than 20 mg/dL or greater than 600 mg/dL. For safety reasons, it is recommended that you treat your BG value before calibrating.
- Make sure a sensor glucose reading shows in the upper right

portion of the *CGM Home* screen before calibrating.

- Make sure the antenna symbol is visible to the right of the battery indicator on the *CGM Home* screen and is active (white, not greyed out) before calibrating.
- Always use the same BG meter to calibrate that you routinely use to measure your BG. Do not switch your BG meter in the middle of a sensor session. BG meter and strip accuracy vary between BG meter brands.
- The accuracy of the BG meter used for calibration may affect the accuracy of sensor glucose readings. Follow your BG meter manufacturer's instructions for BG testing.

24.2 Startup Calibration

If you did not enter a sensor code when starting the sensor session, the system will prompt you to calibrate to provide accurate information.

NOTE

The instructions in this section do not apply if you entered the sensor code when you started the sensor session.

Two hours after you start the sensor session, the *CALIBRATE CGM* screen will appear, letting you know that two separate BG values from your BG meter must be entered. You will not see sensor glucose readings until the pump accepts the BG values.

1. From the *CALIBRATE CGM* screen, Tap .
- ✓ The *CGM Home* screen will appear with two blood drops in the upper right portion of the screen. The two blood drops will stay on the screen until you enter two separate BG values to calibrate.
2. Wash and dry your hands, make sure your BG test strips have been stored properly and are not expired, and make sure your BG meter is properly coded (if required).
3. Take a BG measurement using your BG meter. Carefully apply the blood

sample to the test strip following your BG meter manufacturer's instructions.

⚠ PRECAUTION

DO use fingertips to calibrate from your BG meter. Blood from other places may be less accurate and not as timely.

4. Tap **OPTIONS**.
5. Tap the **Down Arrow**.
6. Tap **My CGM**.
7. Tap **Calibrate CGM**.
8. Using the on-screen keypad, enter the BG value from your BG meter.

⚠ PRECAUTION

To calibrate the System, **DO** enter the exact BG value displayed on your BG meter within 5 minutes of a carefully performed BG meter. Do not enter the sensor glucose readings for calibration. Entering incorrect BG values, BG values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe

hypoglycemia (low BG) or hyperglycemia (high BG) events.

9. Tap .
10. Tap  to confirm the calibration.

Tap  if the BG value does not exactly match the reading from your BG meter. The on-screen keypad will reappear. Enter the exact reading from your BG meter.
- ✓ The *CALIBRATION ACCEPTED* screen will appear.
- ✓ The *My CGM* screen will appear.
11. Tap **Calibrate CGM** to enter your second BG value.

✓ The on-screen keypad will appear.
12. Wash and dry your hands, make sure your BG test strips have been stored properly and are not expired, and make sure your BG meter is properly coded (if required).
13. Take a BG measurement using your BG meter. Carefully apply the blood

CHAPTER 24 • Calibrating Your CGM System

sample to the test strip following your BG meter manufacturer's instructions.

14. Follow steps 8–10 to enter your second BG value.

24.3 Calibration BG Value and Correction Bolus

Your t:slim X2™ pump uses the BG value entered for calibration to determine if a correction bolus is needed, or to provide other important information about your insulin on board and BG.

- If you enter a calibration value that is above your Target BG in Personal Profiles, the *Above Target Correction Bolus* confirmation screen will appear. To add a correction bolus, tap . Follow the instructions in Section 8.3 *Correction Bolus Calculation* to deliver a correction bolus.
- If you enter a calibration value that is below your Target BG in Personal Profiles, a message screen will indicate “Your BG is Below Target”,

and other important information will appear on the screen.

- If you enter your Target BG as a calibration value, the pump will return to the *CGM Home* screen.

24.4 Reasons You May Need to Calibrate

You may need to calibrate if your symptoms do not match the glucose values provided by your CGM.

If you see the *CALIBRATION ERROR* screen, you will be prompted to enter a BG value to calibrate in either 15 minutes or 1 hour, depending on the error.

NOTE

Although it is not required, and you will not be prompted to calibrate, you may enter a calibration into the System at any time, even if you have already entered a sensor code. Pay attention to your symptoms, and if they do not match the current CGM readings, you may choose to enter a calibration.

3 CGM Features

CHAPTER 25

Viewing CGM Data on Your t:slim X2 Insulin Pump

CHAPTER 25 • Viewing CGM Data on Your Lilliput X2 Insulin Pump

25.1 Overview

⚠ WARNING

DO NOT ignore how you feel. If your sensor glucose alerts and readings do not match what you're feeling, use your BG meter to make diabetes treatment decisions or, if needed, seek immediate medical attention.

The pump screens in this section illustrate the screen when Control-IQ™ technology is off. For information about CGM screens when Control-IQ technology is on, see Section 31.9 Control-IQ Technology Information on Your Screen.

During an active sensor session, CGM readings are sent to your pump every 5 minutes. This section teaches you how to view your sensor glucose readings and trend information. The trend graph provides additional information that your BG meter does not. It shows your current sensor glucose value, the direction it is changing and how fast it is changing. The trend graph can also show you where your sensor glucose has been over time.

Your BG meter measures glucose in your blood. Your sensor measures glucose from interstitial fluid (the fluid under your skin). Because glucose from different fluids is measured, readings from your BG meter and sensor may not match.

The greatest benefit you get from using continuous glucose monitoring will come from trending information. It is important that you focus on the trends and rate of change on your receiver or pump rather than the exact sensor glucose reading.

Press the **Screen On/Quick Bolus** button to turn the screen on. If a CGM session is active, you will see the *CGM Home* screen with the 3 hour trend graph displayed.



- The current time and date are shown at the top of the screen in the middle.
- Each “dot” on the trend graph is a sensor glucose reading reported every 5 minutes.
- Your High Alert setting shows as an orange line across the trend graph.
- Your Low Alert setting shows as a red line across the trend graph.
- The gray zone highlights your target sensor glucose range, between your High and Low Alert settings.
- Sensor glucose readings are shown in milligrams per deciliter (mg/dL).
- If your sensor glucose reading is between your High and Low Alert settings, it is shown in white.
- If your sensor glucose reading is above your High Alert setting, it is shown in orange.
- If your sensor glucose reading is below your Low Alert setting, it is shown in red.

- If your sensor glucose reading is 55 mg/dL or lower, it is shown in red, regardless of the Low Alert setting.
- The dots on the trend graph display as different colors based on your High and Low Alert settings: white if between High and Low Alert settings, orange if above High Alert setting, red if below Low Alert setting.

25.2 CGM Trend Graphs

You can view your past sensor glucose trend information on your *CGM Home* screen.

1, 3, 6, 12, and 24 hour trend views can be seen. The 3 hour Trend Graph is the default view and will be shown on the *CGM Home* screen even if a different trend graph was shown when the screen turned off.

Your trend graph shows a flat line or dots at 50 or 400 mg/dL when your glucose is outside this range.

To view different Trend Graph times, tap on the Trend Graph Time (HRS) to cycle through the options.

3 Hour Trend Graph (default view) shows you your current sensor glucose reading along with the last 3 hours of sensor glucose readings.



6 Hour Trend Graph shows you your current sensor glucose reading along with the last 6 hours of sensor glucose readings.



12 Hour Trend Graph shows you your current sensor glucose reading along with the last 12 hours of sensor glucose readings.

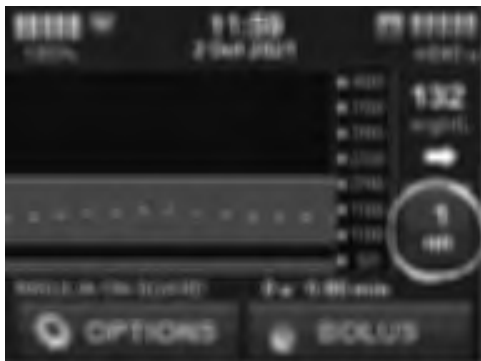


24 Hour Trend Graph shows you your current sensor glucose reading along with the last 24 hours of sensor glucose readings.



CHAPTER 25 • Viewing CGM Data on Your Insulin Pump

1 Hour Trend Graph shows you your current sensor glucose reading along with the last 1 hour of sensor glucose readings.



LOW shows when your most recent sensor glucose reading is less than 40 mg/dL.



HIGH shows when your most recent sensor glucose reading is greater than 400 mg/dL.



25.3 Rate of Change Arrows

Your rate of change arrows add detail about the direction and speed of sensor glucose change over the last 15–20 minutes.

The trend arrows show below your current sensor glucose reading.



Do not overreact to the rate of change arrows. Consider recent insulin dosing, activity, food intake, your overall trend graph and your BG value before taking action.

If there are missed communications between the sensor and your pump during the last 15–20 minutes due to being out of range or due to an error condition, an arrow may not display. If the trend arrow is missing, and you are concerned that your BG level may be rising or falling, take a BG measurement using your BG meter.

The table below shows the different trend arrows your receiver or pump displays:

Trend Arrow Definitions

	Constant: Your sensor glucose is steady (not increasing/decreasing more than 1 mg/dL each minute). Your sensor glucose could increase or decrease by up to 15 mg/dL in 15 minutes.		Slowly falling: Your sensor glucose is falling 1–2 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease up to 30 mg/dL in 15 minutes.
	Slowly rising: Your sensor glucose is rising 1–2 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase up to 30 mg/dL in 15 minutes.		Falling: Your sensor glucose is falling 2–3 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease up to 45 mg/dL in 15 minutes.
	Rising: Your sensor glucose is rising 2–3 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase up to 45 mg/dL in 15 minutes.		Rapidly falling: Your sensor glucose is falling more than 3 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease more than 45 mg/dL in 15 minutes.
	Rapidly rising: Your sensor glucose is rising more than 3 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase more than 45 mg/dL in 15 minutes.	No Arrow	No rate of change information: The System cannot calculate how fast your sensor glucose is rising or falling at this time.

CHAPTER 25 • Viewing CGM Data on Your Lilliput X2 Insulin Pump

25.4 CGM History

CGM History displays the historical log of CGM events. At least 90 days of data can be viewed in History. When the maximum number of events is reached, the oldest events are removed from the history log and replaced with the most recent events. The following history sections can be viewed:

- Sessions and Calibrations
- Alerts and Errors
- Complete

Each section above is organized by date. If there are no events associated with a date, the day will not be shown in the list.

The Sessions and Calibrations section includes the start time and date for each Sensor Session, the stop time and date for each Sensor Session, and all calibration BG values entered.

The Alerts and Errors section includes the date and time for all Alerts and Errors that occurred. The letter “D” (D: Alert) before an Alert or Alarm indicates

the time it was declared. The letter “C” (C: Alert) indicates the time it was cleared.

The Complete section includes all information from the Sessions and Calibrations and Alerts and Errors sections as well as any changes to settings.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **History**.
4. Tap **CGM History**.
5. Tap section you want to view. Each section is organized by date. Tap the date to view events from that day. Use the **Down Arrow** to scroll to more dates.

25.5 Missed Readings

If your pump misses CGM readings for a period of time, you will see three dashes where the CGM reading typically displays on the *CGM Home*

screen and on the *CGM Lock* screen. The system will automatically attempt to backfill missing data points up to 6 hours in the past when connectivity is restored and readings begin to appear. If the sensor glucose number or trend arrow is missing, and you are concerned that your BG level may be rising or falling, take a BG measurement using your BG meter.

NOTE

Control-IQ technology will continue to operate for the first 15 minutes after CGM readings become unavailable. If connectivity is not restored after 20 minutes, Control-IQ technology will stop operation until CGM readings are available. While Control-IQ technology is not operating, your pump will continue to deliver insulin according to your Personal Profile settings. Once CGM readings are available, Control-IQ technology will automatically resume. For more information, see Chapter 30 *Introduction to Control-IQ Technology*.

3 CGM Features

CHAPTER 26

CGM Alerts and Errors

CHAPTER 26 • CGM Alerts and Errors

Information in this section will help you learn how to respond to CGM alerts and errors. It applies only to the CGM portion of your System. CGM alerts and errors do not follow the same pattern of vibration and beeps as insulin delivery reminders, alerts, and alarms.

The t:connect™ mobile app also can provide messages, alerts, and alarms from your t:slim X2™ pump as push notifications on your smartphone. These push notifications will be identical to your pump's display unless otherwise noted in this chapter.

PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. For more information about connecting your pump and smartphone, see Section 4.3 Connecting to a Smartphone, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

For information on insulin delivery reminders, alerts, and alarms, see

Chapters 13 t:slim X2 Insulin Pump Alerts, 14 t:slim X2 Insulin Pump Alarms, and 15 t:slim X2 Insulin Pump Malfunction.

For information on Control-IQ™ technology alerts, see Chapter 32 Control-IQ Technology Alerts.

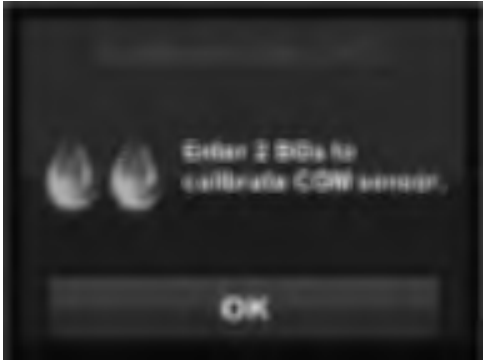
WARNING

If a sensor session is ended, either automatically or manually, Control-IQ technology is unavailable and will not adjust insulin. In order for Control-IQ technology to be enabled, a sensor session must be started and transmitting sensor values to the pump based on a sensor code or sensor calibration.

PRECAUTION

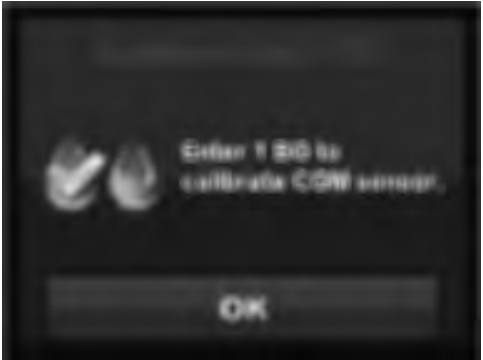
You must customize the CGM alert settings on your t:slim X2 pump and the Dexcom G6 CGM app separately. The alert settings apply to the smartphone and pump separately.

26.1 Startup Calibration Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	2-hour CGM startup period is complete. This will only appear if you did not enter a sensor code.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the System re-notify me?	Yes, every 15 minutes until you calibrate.
	How should I respond?	Tap  and enter 2 separate BG values to calibrate the system and start your CGM session.

CHAPTER 26 • CGM Alerts and Errors

26.2 Second Startup Calibration Alert

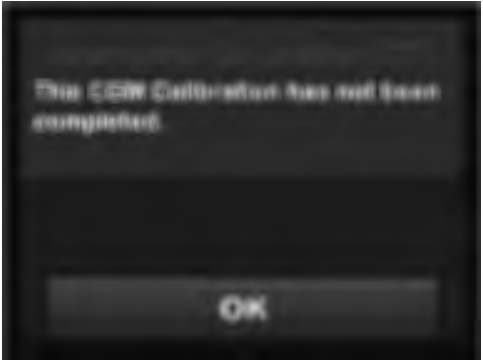
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The System needs an additional BG value to complete startup calibration. This will only appear if you did not enter a sensor code.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the System re-notify me?	Yes, every 15 minutes until second calibration is entered.
	How should I respond?	Tap  and enter a BG value to calibrate the System and start your CGM session.

26.3 12 Hour Calibration Alert

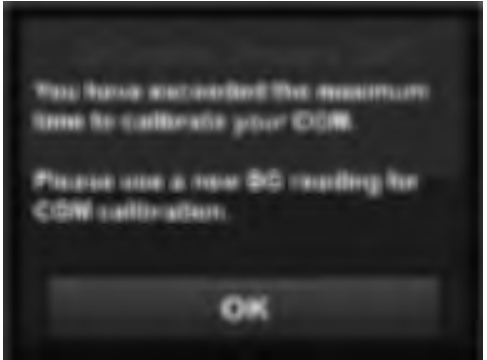
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The System needs a BG value to calibrate. This will only appear if you did not enter a sensor code.
	How will the System notify me?	On screen only with no vibration or beep.
	Will the System re-notify me?	Yes, every 15 minutes.
	How should I respond?	Tap  and enter a BG value to calibrate the system.

CHAPTER 26 • CGM Alerts and Errors

26.4 Incomplete Calibration

Screen	Explanation	
What will I see on the screen? 	What does it mean?	If you start to enter a calibration value using the keypad and do not complete the entry within 90 seconds, this screen appears.
	How will the System notify me?	2 beeps or vibrations depending on Sound Volume selected.
	Will the System re-notify me?	Yes, every 5 minutes until confirmed.
	How should I respond?	Tap  and complete your calibration by entering the value using the on-screen keypad.

26.5 Calibration Timeout

Screen	Explanation	
What will I see on the screen? 	What does it mean?	If you start to enter a calibration value using the keypad and do not complete the entry within 5 minutes, this screen appears.
	How will the System notify me?	2 beeps or vibrations depending on Sound Volume selected.
	Will the System re-notify me?	Yes, every 5 minutes until confirmed.
	How should I respond?	Tap  and obtain a new BG value using your BG meter. Enter the value using the on-screen keypad to calibrate the System.

CHAPTER 26 • CGM Alerts and Errors

26.6 Wait 15 Minute Calibration Error Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The sensor cannot calibrate.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the System re-notify me?	No.
	How should I respond?	Tap  to confirm. Wait 15 minutes then enter 1 more BG value. Wait 15 more minutes. If error screen still appears, enter 1 more BG value. Wait 15 minutes. If no sensor glucose readings appear, the sensor needs to be replaced.

26.7 Calibration Required Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The System needs a BG value to calibrate. Sensor glucose readings will not be displayed at this time.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the System re-notify me?	Yes, every 15 minutes.
	How should I respond?	Tap  and enter a BG value to calibrate the System.

CHAPTER 26 • CGM Alerts and Errors

26.8 CGM High Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your most recent sensor glucose reading is at or above the High Alert setting.
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes until confirmed or your sensor glucose value drops below the Alert level.
	Will the System re-notify me?	Only if you have turned on the Repeat feature.
	How should I respond?	Tap  to confirm.

26.9 CGM Low Alert

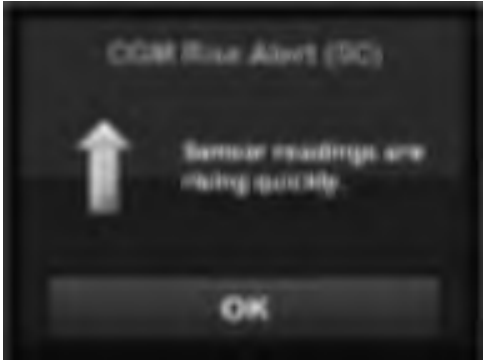
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your most recent sensor glucose reading is at or below the Low Alert setting.
	How will the System notify me?	3 vibrations, then 3 vibrations/beeps every 5 minutes until confirmed or your sensor glucose value goes above the Alert level.
	Will the System re-notify me?	Only if you have turned on the Repeat feature.
	How should I respond?	Tap  to confirm.

CHAPTER 26 • CGM Alerts and Errors

26.10 CGM Fixed Low Alert

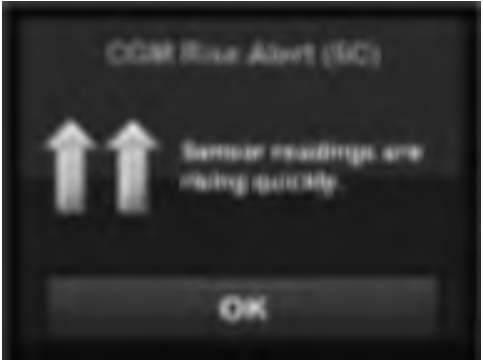
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your most recent sensor glucose reading is at or below 55 mg/dL.
	How will the System notify me?	4 Vibrations, then 4 vibrations/beeps every 5 minutes until confirmed or your sensor glucose value goes above 55 mg/dL.
	Will the System re-notify me?	Yes, 30 minutes after each confirmation until your sensor glucose value goes above 55 mg/dL.
	How should I respond?	Tap  to confirm.

26.11 CGM Rise Alert

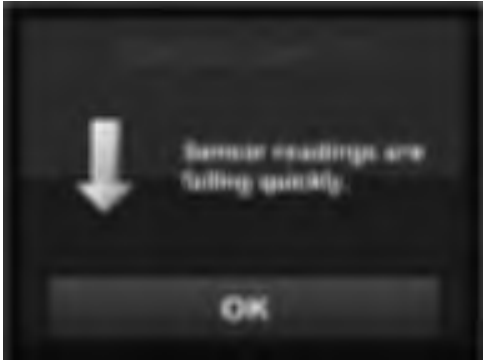
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your sensor glucose levels are rising at 2 mg/dL per minute or faster (at least 30 mg/dL in 15 minutes).
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes or until confirmed.
	Will the System re-notify me?	No.
	How should I respond?	Tap  to confirm.

CHAPTER 26 • CGM Alerts and Errors

26.12 CGM Rapid Rise Alert

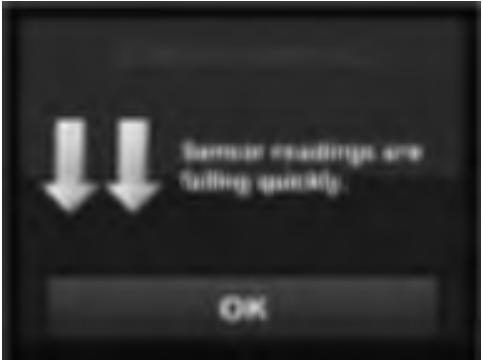
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your sensor glucose levels are rising at 3 mg/dL per minute or faster (at least 45 mg/dL in 15 minutes).
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes or until confirmed.
	Will the System re-notify me?	No.
	How should I respond?	Tap  to confirm.

26.13 CGM Fail Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your sensor glucose levels are falling at 2 mg/dL per minute or faster (at least 30 mg/dL in 15 minutes).
	How will the System notify me?	3 vibrations, then 3 vibrations/beeps every 5 minutes or until confirmed.
	Will the System re-notify me?	No.
	How should I respond?	Tap  to confirm.

CHAPTER 26 • CGM Alerts and Errors

26.14 CGM Rapid Fall Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your sensor glucose levels are falling at 3 mg/dL per minute or faster (at least 45 mg/dL in 15 minutes).
	How will the System notify me?	3 vibrations, then 3 vibrations/beeps every 5 minutes or until confirmed.
	Will the System re-notify me?	No.
	How should I respond?	Tap  to confirm.

26.15 Unknown Sensor Glucose Reading

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The sensor is sending sensor glucose readings that the System does not understand. You will not receive sensor glucose readings.
	How will the System notify me?	On screen only with no vibration or beep.
	Will the System re-notify me?	The 3 dashes will remain on the screen until a new sensor glucose reading is received and displayed in their place. If no sensor glucose readings are received after 20 minutes, the CGM Unavailable Alert will trigger. See Section 26.20 CGM Unavailable.
	How should I respond?	Wait 30 minutes for more information from the system. Do not enter BG values for calibration. The system will not use BG values for calibration when “- - -” appears on the screen.

CHAPTER 26 • CGM Alerts and Errors

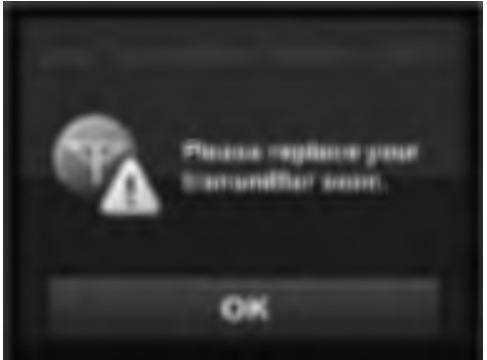
26.16 Out of Range Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The transmitter and pump are not communicating. The pump will not receive sensor glucose readings, and Control-IQ technology is not able to predict sensor glucose levels or adjust insulin delivery.
	How will the System notify me?	1 vibrate, then vibration/beep every 5 minutes until the transmitter and pump are back in range.
	Will the System re-notify me?	Yes, if the transmitter and pump remain out of range.
	How should I respond?	Tap  to confirm and move the transmitter and pump closer together, or remove the obstruction between them.

⚠ WARNING

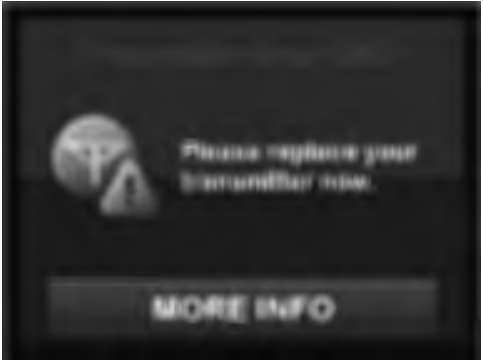
Control-IQ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate settings in your active Personal Profile.

26.17 Low Transmitter Battery Alert

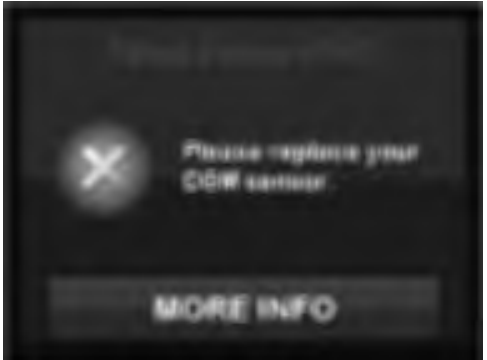
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Transmitter battery is low.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the System re-notify me?	Yes, the alarm will notify you when there are 21, 14, and 7 days of transmitter battery life remaining.
	How should I respond?	Tap  to confirm. Replace the transmitter as soon as possible.

CHAPTER 26 • CGM Alerts and Errors

26.18 Transmitter Error

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The transmitter has failed and the CGM session has stopped.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes.
	Will the System re-notify me?	No.
	How should I respond?	Tap MORE INFO. A screen notifying you that your CGM session has stopped but insulin delivery continues will appear. Replace the transmitter immediately.

26.19 Failed Sensor Error

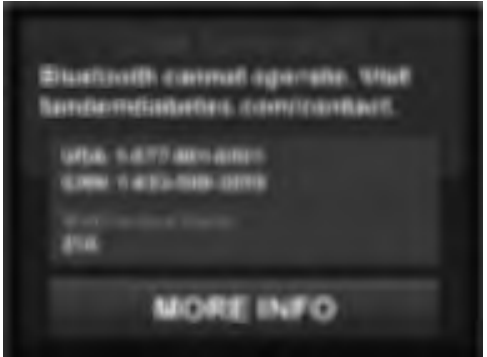
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The sensor is not working properly and the CGM session has stopped.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes.
	Will the System re-notify me?	No.
	How should I respond?	Tap MORE INFO. A screen notifying you that your CGM session has stopped but insulin delivery continues will appear. Replace the sensor and begin a new CGM session.

CHAPTER 26 • CGM Alerts and Errors

26.20 CGM Unavailable

Screen	Explanation	
What will I see on the screen?	What does it mean?	Your CGM session has been stopped for more than 20 minutes and the CGM can no longer be used.
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes or until confirmed.
	Will the System re-notify me?	Yes, every 20 minutes until the CGM session is available. If the condition persists for 3 hours, the Failed Sensor alert will be displayed. See Section 26.19 Failed Sensor Error.
	How should I respond?	Tap  and contact Customer Technical Support.

26.21 CGM System Error

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your CGM System is not working properly; the CGM session has stopped and the CGM can no longer be used.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes.
	Will the System re-notify me?	No.
	How should I respond?	Tap MORE INFO . A screen notifying you that your CGM System cannot operate but insulin delivery continues will appear. Call Customer Technical Support.

This Page is Intentionally Left Blank

3 CGM Features

CHAPTER 27

CGM Troubleshooting

CHAPTER 27 • CGM Troubleshooting

This chapter provides helpful tips and instructions to help you fix issues you may have while using the CGM portion of your System.

If the troubleshooting steps in this chapter do not fix your issue, contact Customer Technical Support.

The following tips are specific to troubleshooting the Dexcom G6 CGM connected to your pump. For more information about Dexcom G6 CGM troubleshooting, visit the manufacturer's website for applicable product instructions.

27.1 CGM Pairing Troubleshooting

Possible issue:

Difficulty pairing your Dexcom G6 CGM with your t:slim X2™ insulin pump.

Troubleshooting tip:

The Dexcom G6 CGM only allows pairing with one medical device at a time. Ensure your CGM is not connected to the Dexcom receiver before pairing with the pump. You may still use a smartphone with the Dexcom

G6 CGM app and your t:slim X2 insulin pump simultaneously with the same transmitter ID. See Section 21.2 Disconnecting from the Dexcom Receiver.

27.2 Calibration Troubleshooting

To ensure proper calibration of your CGM, follow these important tips.

Before you take a BG value for calibration, wash your hands, make sure your BG test strips have been stored properly and are not expired, and make sure that your meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions that came with your BG meter or test strips.

Do not calibrate if you see the Out of Range symbol in the place where your sensor glucose readings are normally shown on the screen.

Do not calibrate if you see “- - -” in the place where your sensor glucose readings are normally shown on the screen.

Do not calibrate if your BG value is below 20 mg/dL or above 600 mg/dL.

27.3 Unknown Sensor Reading Troubleshooting

When your CGM cannot provide a sensor glucose reading “- - -” shows in the place where your sensor glucose is normally shown on the screen. This means that the System does not understand the sensor signal temporarily.

Often the System can correct the problem and continue providing sensor glucose readings. If it has been at least 3 hours since your last sensor glucose reading, contact Customer Technical Support.

Do not enter any BG values for calibration when you see “- - -” on your screen. The System will not use a BG value for calibration when this symbol is on your screen.

If you see “- - -” often during a sensor session, follow the troubleshooting tips below before inserting another sensor.

- Make sure your sensor is not expired.
- Make sure your sensor pod is not dislodged or peeling up.
- Make sure your transmitter is snapped in completely.
- Make sure nothing is rubbing the sensor pod (e.g., clothing, seat belts, etc.).
- Make sure to select a good insertion site.
- Make sure your insertion site is clean and dry before sensor insertion.
- Wipe the bottom of the transmitter with a damp cloth or isopropyl alcohol wipe. Place the transmitter on a clean, dry cloth and air dry for 2–3 minutes.

27.4 Out of Range/No Antenna Troubleshooting

⚠ WARNING

Control-IQ™ technology can only adjust insulin delivery when your CGM is in range. If you go

out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate settings in your active Personal Profile

⚠ PRECAUTION

AVOID separating the transmitter and the pump by more than 20 feet (6 meters). The transmission range from the transmitter to the pump is up to 20 feet (6 meters) without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and pump are farther than 20 feet (6 meters) apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

If you see the Out of Range icon on your screen in the place where your sensor glucose reading normally shows, then your t:slim X2 pump is not communicating with your transmitter and sensor glucose readings will not show on your screen. Each time you start a new sensor session, wait 10 minutes for your t:slim X2 pump to start communicating with your transmitter.

When a sensor session is active, you may sometimes experience loss of communication for 10 minutes at a time. This is normal.

If you see the Out of Range icon for more than 10 minutes, move your t:slim X2 pump and CGM transmitter closer together and remove any obstructions. Wait 10 minutes and communication should be restored.

You must enter your transmitter ID correctly into your pump to receive sensor glucose readings (see Section 23.1 Enter Your Transmitter ID). Make sure you have removed your sensor and stopped your sensor session before checking or changing your transmitter ID. You cannot change your transmitter ID during a sensor session.

If you are still having trouble getting sensor glucose readings, contact Customer Technical Support.

27.5 Failed Sensor Troubleshooting

The System may detect issues with your sensor where it cannot determine your glucose reading. The sensor

CHAPTER 27 • CGM Troubleshooting

session ends and the *FAILED SENSOR* screen shows on your t:slim X2 pump. If you see this screen, it means your CGM session has ended.

- Remove your sensor and insert a new sensor.
- To help improve future sensor performance, follow the troubleshooting tips below.
- Make sure your sensor is not expired.
- Make sure your sensor pod is not dislodged or peeling up.
- Make sure your transmitter is snapped in completely.
- Make sure nothing is rubbing the sensor pod (e.g., clothing, seat belts, etc.).
- Make sure you have selected a good insertion site.

27.6 Sensor Inaccuracies

Inaccuracies are usually related to your sensor only and not to your transmitter or pump. Your sensor glucose readings

are meant to be used for trending purposes only. The sensor measures glucose in the fluid under the skin—not in blood, and sensor glucose readings are not identical to readings from your BG meter.

⚠ PRECAUTION

To calibrate the System, **DO** enter the exact BG value that your BG meter displays within 5 minutes of a carefully performed BG measurement. Do not enter sensor glucose values for calibration. Entering incorrect BG values, BG values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

If the difference between your sensor glucose reading and BG value is greater than 20% of the BG value for sensor readings >80 mg/dL or greater than 20 mg/dL for sensor readings <80 mg/dL, wash your hands and take another BG measurement. If the difference between this second BG measurement and the sensor is still greater than 20% for sensor readings >80 mg/dL or greater than 20 mg/dL for sensor readings <80 mg/dL,

recalibrate your sensor using the second BG value. The sensor glucose reading will correct over the next 15 minutes. If you see differences between your sensor glucose readings and BG values outside of this acceptable range, follow the troubleshooting tips below before inserting another sensor:

- Make sure your sensor is not expired.
- Make sure you do not calibrate when “- -” or the Out of Range icon are on the screen.
- Do not use alternative BG site testing (blood from your palm or forearm, etc.) for calibration as alternative site readings may be different than those from a BG value. Use a BG value only from your fingers for calibration.
- Use only BG values between 20–600 mg/dL for calibration. If one or more of your values is outside of this range, the receiver will not calibrate.
- Use the same BG meter you routinely use to measure your BG to

calibrate. Do not switch your BG meter in the middle of a sensor session. BG meter and strip accuracy vary between BG meter brands.

- Before taking a BG measurement for calibration, wash your hands, make sure your BG test strips have been stored properly and are not expired, and make sure that your BG meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions provided with your BG meter or test strips.
- Make sure you are using your BG meter following the manufacturer's instructions to get accurate BG values for calibration.

This Page is Intentionally Left Blank

4 Control-IQ Technology Features

CHAPTER 28

Control-IQ Technology Important Safety Information

CHAPTER 28 • Control-IQ Technology Important Safety Information

The following includes important safety information related to Control-IQ™ technology. The information presented in this chapter does not represent all warnings and precautions related to the System. Pay attention to other warnings and precautions listed throughout this user guide as they relate to special circumstances, features, or users.

28.1 Control-IQ Warnings

▲ WARNING

Control-IQ technology has not been evaluated in pregnant women or persons on dialysis. Sensor glucose readings may be inaccurate in these populations and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

Control-IQ technology has not been evaluated in critically ill patients. It is not known how different conditions or medications common to the critically ill population may affect the performance of the Control-IQ technology. Sensor glucose readings may be inaccurate in critically ill patients, and solely relying on the sensor glucose alerts and readings for treatment

decisions could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

Control-IQ technology should not be used by people who use less than 5 units of insulin per day and should not be used by people who weigh less than 20 pounds (9 kilograms), which are the minimum inputs required to initiate Control-IQ technology and for it to operate safely.

▲ WARNING

The t:slim X2™ insulin pump with Control-IQ technology should not be used in children under the age of two years old.

▲ WARNING

Control-IQ technology reverts to your programmed basal rate when the pump has not received a CGM reading for 20 minutes. For example, when the pump and CGM are out of range, during the sensor startup period, when a sensor session ends, or when there is a transmitter or sensor error.

▲ WARNING

If a sensor session is ended, either automatically or manually, Control-IQ technology is

unavailable and will not adjust insulin. In order for Control-IQ technology to be enabled, a sensor session must be started and transmitting sensor values to the pump based on a sensor code or sensor calibration.

▲ WARNING

DO NOT use manual injections or inhaled insulins while using Control-IQ technology. Using insulin not provided by the pump while using closed loop therapy can cause the system to over deliver insulin, which can lead to severe hypoglycemia (low BG) events.

▲ WARNING

DO NOT use Control-IQ technology if you are taking hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anemia. The use of hydroxyurea will result in sensor glucose readings that are higher than actual glucose levels. The level of inaccuracy in sensor glucose readings is based on the amount of hydroxyurea in the body. Control-IQ technology relies on sensor glucose readings to adjust insulin, provide automatic correction boluses, and provide high and low glucose alerts. If Control-IQ technology receives sensor readings that are higher than actual glucose levels, it could result in missed hypoglycemia alerts and errors in diabetes

management, such as delivery of excess basal insulin and correction boluses, including automatic correction boluses. Hydroxyurea can also result in errors when reviewing, analyzing and interpreting historical patterns for assessing glucose control. Use your BG meter and consult with your healthcare provider about alternative glucose monitoring approaches.

28.2 Control-IQ Precautions

⚠ PRECAUTION

If you remove your pump for 30 minutes or longer, it is recommended that you suspend insulin delivery. If insulin is not suspended, Control-IQ technology will continue to operate while the pump is removed, and will continue to dose insulin.

⚠ PRECAUTION

We recommend that you keep the CGM Out of Range Alert turned on to notify you if your CGM is disconnected from your pump whenever you are not actively monitoring your pump status. Your CGM is providing the data that Control-IQ technology requires to make predictions to automate insulin dosing.

This Page is Intentionally Left Blank

4 Control-IQ Technology Features

CHAPTER 29

Getting to Know Control-IQ Technology

CHAPTER 29 • Getting to Know Control-IQ Technology

29.1 Responsible Use of Control-IQ Technology

Systems like the t:slim X2™ insulin pump with Control-IQ™ technology are not substitutes for the active management of diabetes, including manually bolusing for meals. There are common scenarios in which automated systems cannot prevent a hypoglycemic event. Control-IQ technology relies on current CGM sensor readings to function and will not be able to predict sensor glucose values and suspend insulin delivery if a patient's CGM is not functioning properly or their pump is unable to receive the CGM signal. Patients should be instructed to always use the components of the pump system (pump, cartridges, CGM, and infusion sets) according to the applicable instructions for use and check them regularly to make sure they are functioning as expected. Patients should always pay attention to their sensor glucose values, actively monitor and manage BG, and treat accordingly.

29.2 Explanation of Control-IQ Technology Icons

If you have a CGM session active and are using Control-IQ technology, you may see the following additional icons on your pump screen:

Control-IQ Technology Icon Definitions

Symbol	Meaning
	Control-IQ technology is enabled but not actively increasing or decreasing basal insulin delivery.
	Control-IQ technology is increasing basal insulin delivery.
	Control-IQ technology is decreasing basal insulin delivery.
	Control-IQ technology has stopped basal insulin delivery.
	Control-IQ technology is delivering an automatic correction bolus.
	The Sleep Activity is enabled.
	Control-IQ technology delivered an automatic correction bolus.

Symbol	Meaning
	Basal insulin is programmed and being delivered.
	Control-IQ technology is increasing basal insulin delivery.
	Control-IQ technology is decreasing basal insulin delivery.
	Basal insulin delivery is stopped and a Basal Rate of 0 u/hr is active.
	Control-IQ technology is delivering an automatic correction bolus.
	The Exercise Activity is enabled.

CHAPTER 29 • Getting to Know Control-IQ Technology

29.3 Control-IQ Lock Screen

The *Control-IQ Lock* screen appears any time you turn on the screen and you are using your pump with a CGM and Control-IQ technology enabled.

The *Control-IQ Lock* screen is the same as the *CGM Lock* screen, with the following additions. See Section 19.3 CGM Lock Screen.

1. **Control-IQ Technology Status:** Indicates the status of Control-IQ technology.
2. **CGM Graph Shading:** Red shading indicates Control-IQ technology is, or was, delivering 0 units of insulin for the period indicated.



CHAPTER 29 • Getting to Know Control-IQ Technology

29.4 Control-IQ Home Screen

The *Home* screen with Control-IQ technology enabled is identical to the *CGM Home* screen, with the following additions. See Section 19.4 CGM Home Screen.

1. **Control-IQ Technology Status:**
Indicates the status of Control-IQ technology.
2. **Control-IQ Activity Status:**
Indicates an Activity is enabled.
3. **CGM Graph Shading:** Red shading indicates Control-IQ technology is, or was, delivering 0 units of insulin for the period indicated.



CHAPTER 29 • Getting to Know Control-IQ Technology

29.5 Control-IQ Screen

1. **Control-IQ Technology on/off:**
Turns on, or off, Control-IQ technology.
2. **Weight:** Displays your current weight. This value is manually entered in on the numerical keypad.

NOTE

Your weight should be representative of what you weigh when you start Control-IQ technology. Weight can be updated when you visit your healthcare provider. The minimum value for weight is 20 pounds (9 kilograms). The maximum value for weight is 440 pounds (200 kilograms).

3. **Total Daily Insulin:** Displays your current total daily insulin value in units. This value is manually entered in on the numerical keypad.

NOTE

If you don't know your Total Daily Insulin (TDI), speak with your healthcare provider to get this value. The minimum value for TDI is 5 units. The maximum value for TDI is 200 units.



This Page is Intentionally Left Blank

4 Control-IQ Technology Features

CHAPTER 30

Introduction to Control-IQ Technology

CHAPTER 30 • Introduction to Control-IQ Technology

30.1 Control-IQ Technology Overview

Control-IQ™ technology is a feature of the t:slim X2™ pump that automatically adjusts insulin dosing in response to readings from a CGM. The pump can be used with or without Control-IQ technology enabled. The following sections describe how Control-IQ technology works and how it responds to CGM values while you are awake, sleeping, and exercising.

⚠ PRECAUTION

You must continue to take boluses to cover food eaten or to correct a high sensor glucose value. Read all Control-IQ technology instructions before activating Control-IQ technology.

📌 NOTE

The target CGM ranges used by Control-IQ technology are not customizable.

📌 NOTE

The Insulin On Board (IOB) Time Remaining, which indicates how long the total units of insulin from food and correction boluses will be active in the body, is not displayed when Control-IQ technology is enabled due to the

variability of insulin delivery when automatically responding to CGM values. The IOB units will always be displayed on the *Home* and *Lock* screens.

30.2 How Control-IQ Technology Works**⚠ WARNING**

Control-IQ technology is not a substitute for understanding and being ready at any time to take over manual control of your current or future diabetes therapy.

⚠ WARNING

Control-IQ technology is not designed to prevent all hypoglycemia (low BG) or hyperglycemia (high BG).

⚠ WARNING

Control-IQ technology adjusts the delivery of insulin, but does not treat low BG. Always pay attention to your symptoms, manage your BG level, and treat according to the recommendations of your healthcare provider.

⚠ WARNING

Do not use Control-IQ technology unless recommended by your healthcare provider.

⚠ WARNING

Do not use Control-IQ technology until you have received training.

⚠ WARNING

Control-IQ technology relies on current CGM sensor readings and will not be able to accurately predict BG levels and adjust insulin delivery if for any reason your CGM is not functioning properly, or does not transmit three of the last four sensor values to your pump.

⚠ PRECAUTION

We recommend that you enable the High Glucose Alert and the Low Glucose Alert when using Control-IQ technology so that you will be notified if sensor glucose readings are outside of your target range, and you can treat high or low BG according to your healthcare provider's recommendations.

Control-IQ technology responds to the actual CGM readings as well as predicts CGM values 30 minutes in the future. Insulin delivery is automatically adjusted based on the predicted CGM value, your active Personal Profile, and whether or not a Control-IQ technology Activity is enabled.

NOTE

Control-IQ technology activity types are not automatically enabled, and must be set up as a scheduled occurrence or turned on as needed. For more information, see sections 31.5 Schedule Sleep, 31.7 Manually Start or Stop Sleep, and 31.8 Manually Start or Stop Exercise.

Control-IQ technology adjusts insulin delivery in several ways to help keep your actual glucose value within the target range. It will decrease or suspend insulin delivery when predicted sensor glucose values are below a preset treatment value, increase insulin delivery when predicted sensor glucose values are above a preset treatment value, and automatically deliver a correction bolus once per hour, as needed. The automatic correction bolus is based on a predicted sensor glucose value. There are maximum insulin delivery limits based on your Personal Profile settings. These different insulin delivery actions are described below. Each of the insulin delivery adjustments occurs in different ways depending on whether you are using the Sleep Activity, using the Exercise Activity, or neither. For more detail on how insulin adjustments are

made for different activities see Sections Control-IQ Technology With No Activity Enabled, Control-IQ Technology During Sleep, and Control-IQ Technology During Exercise Activity in this chapter.

Personal Profile Basal Rate Delivery

When the predicted CGM value is within the treatment value range (112.5 mg/dL – 160 mg/dL), the pump will deliver insulin at the rate determined by the active Personal Profile settings.

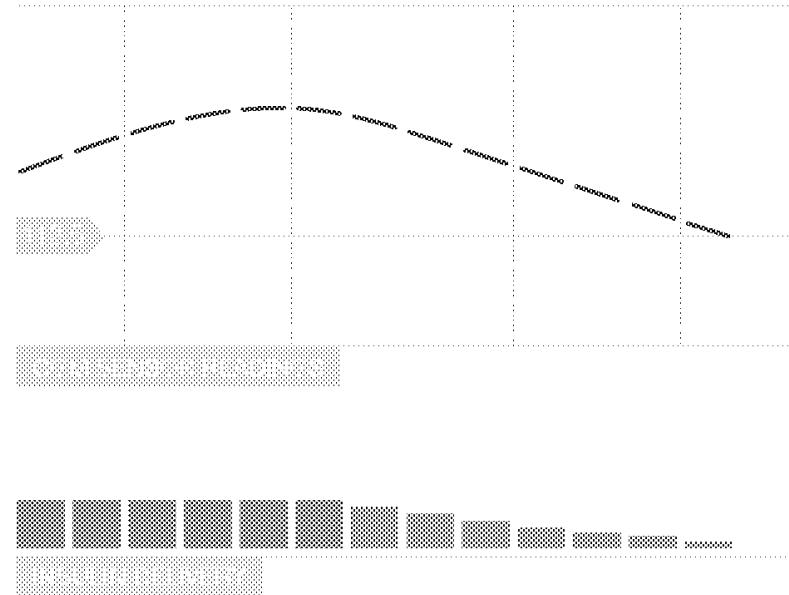
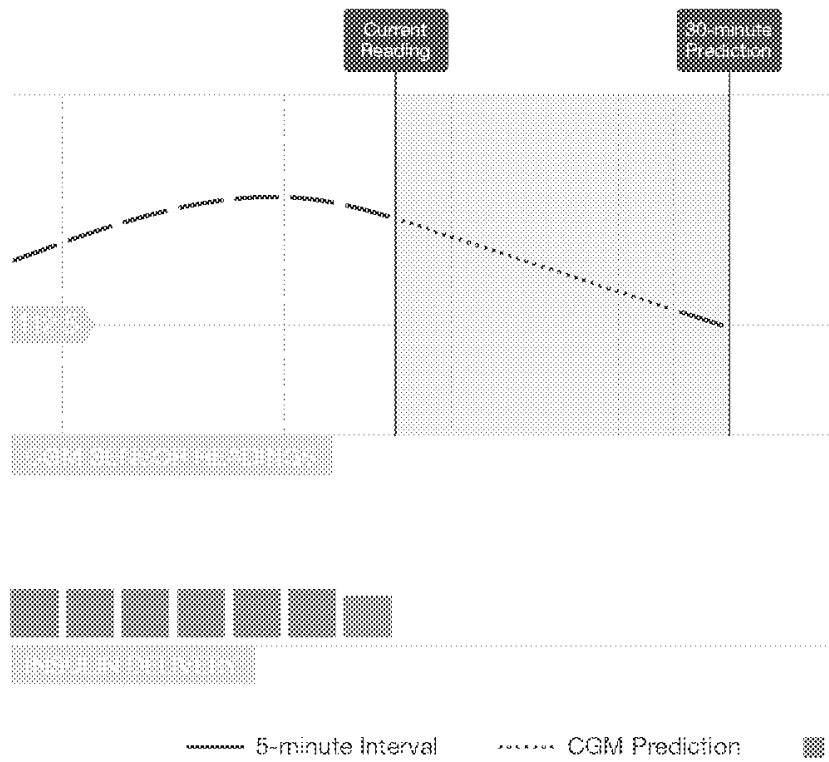
All Personal Profile settings must be completed in order to use Control-IQ technology. See Chapter 6 Insulin Delivery Settings for more information about Personal Profiles.

Decreased Insulin Delivery

When Control-IQ technology predicts that your sensor glucose value will be at or below a preset treatment value (112.5 mg/dL) 30 minutes in the future, the rate of insulin delivery will start decreasing to attempt to keep the actual sensor glucose values within the target range. The following diagrams depict how the system uses 30 minute

predictions to gradually decrease insulin delivery compared to the personal profile Basal Rate. The diagram on the left depicts the prediction, the diagram on the right depicts how the insulin and CGM readings might look if the CGM graph continued on the trend.

CHAPTER 35 • Introduction to Control-IQ Technology



NOTE

Diagrams are for illustrative purposes only and are not intended to reflect actual results.

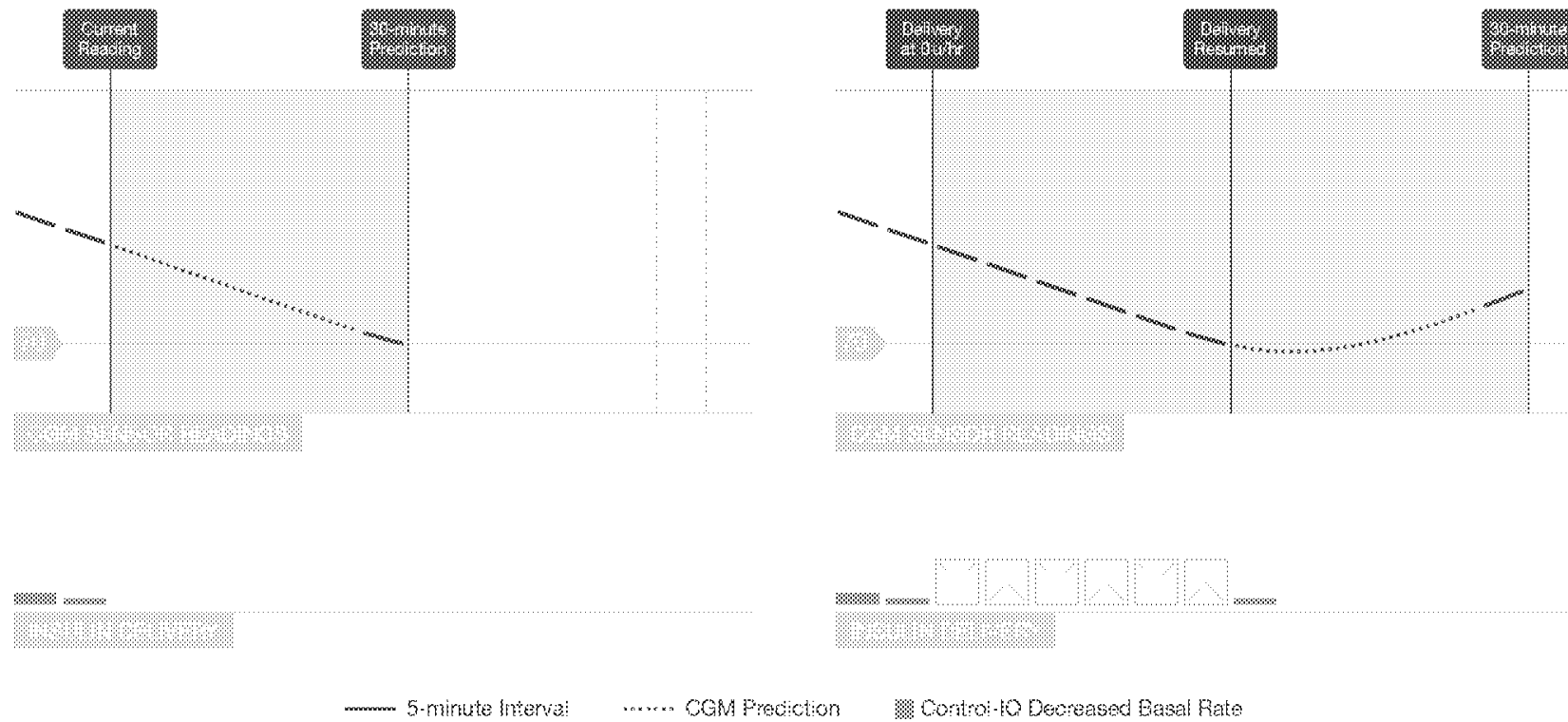
Insulin Decreased or Delivering 0 Units per Hour

Control-IQ technology can reduce the basal delivery to a percent of the Basal Rate in addition to completely suspending. When Control-IQ technology predicts that your sensor glucose value will be lower than a preset treatment value (70 mg/dL) 30 minutes in the future, insulin delivery will decrease and may set the Basal Rate at 0 units per hour if necessary to attempt to keep the actual sensor glucose values within the target range. Manual boluses can still be delivered when Control-IQ technology is decreasing or suspending insulin. The following diagrams depict an illustration of when Control-IQ technology might set the insulin delivery rate to 0 units per hour, and when it will resume at a decreased rate after the 30 minute prediction is above the target sensor glucose value.

■ NOTE

When Control-IQ technology sets the Basal Rate to 0 units per hour, bolus deliveries will continue. This includes starting a new bolus and any remaining bolus from an extended bolus delivery.

CHAPTER 35 • Introduction to Control-IQ Technology



NOTE

Diagrams are for illustrative purposes only and are not intended to reflect actual results.

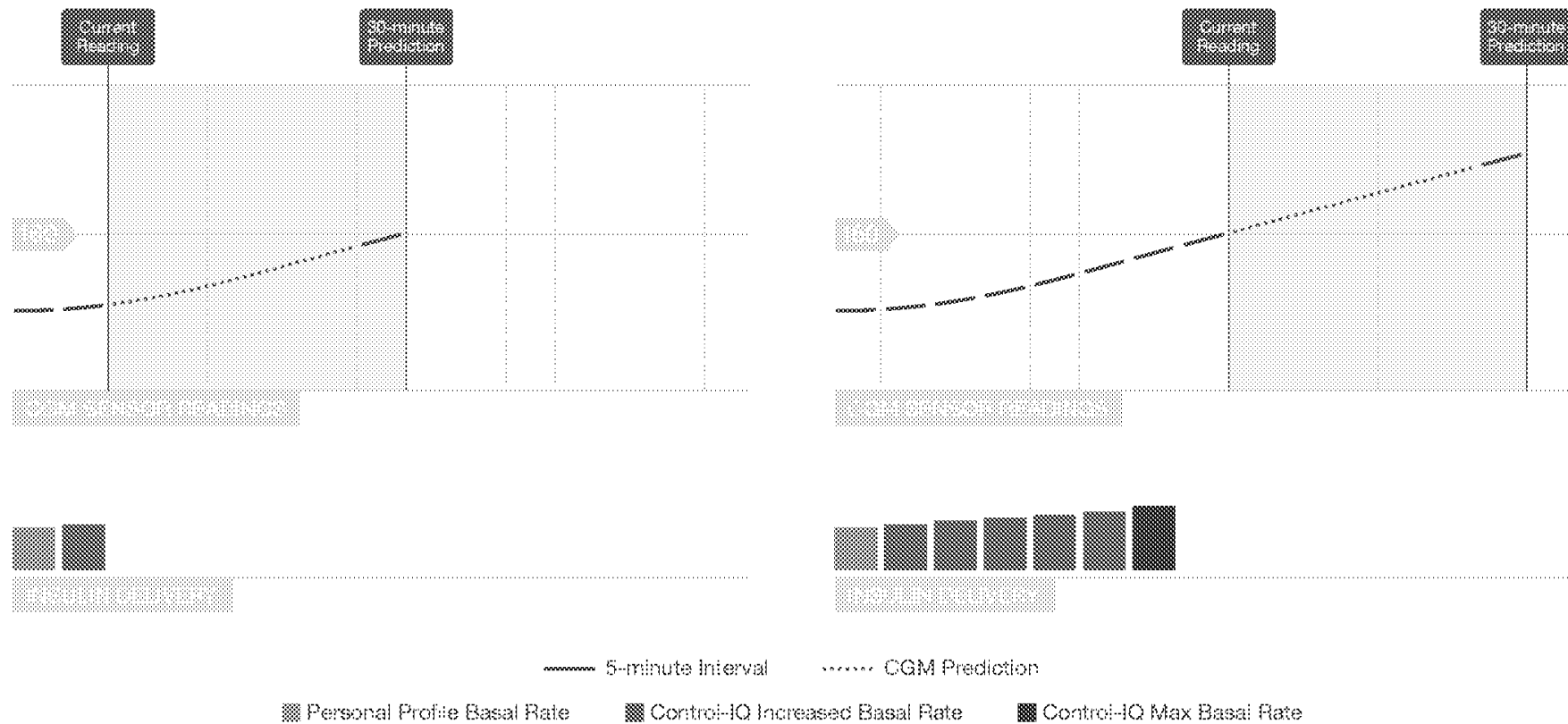
Increasing Insulin Delivery

When Control-IQ technology predicts that your sensor glucose value will be at or above a preset treatment value (160 mg/dL) 30 minutes in the future, the rate of insulin delivery will start increasing to attempt to keep the actual CGM values within the target CGM range. The following diagrams depict when Control-IQ technology might be increasing and delivering at the maximum increased Basal Rate.

Maximum Insulin Delivery

When Control-IQ technology predicts that your sensor glucose value will be above a preset treatment value (160 mg/dL) 30 minutes in the future, but the maximum rate of insulin delivery has been reached, Control-IQ technology stops increasing the insulin delivery rate. The maximum insulin delivery rate is a calculated value that is dependent on an individual's Correction Factor setting (found in the active Personal Profile), the Total Daily Insulin estimated by Control-IQ technology based on actual total daily insulin values, and the current insulin on board (IOB).

CHAPTER 35 • Introduction to Control-IQ Technology



NOTE

Diagrams are for illustrative purposes only and are not intended to reflect actual results.

Automatic Correction Bolus Delivery

When Control-IQ technology predicts that your CGM value will be at or above a preset treatment value (180 mg/dL) 30 minutes in the future, and when Control-IQ technology is either Increasing Insulin Delivery or delivering Maximum Insulin Delivery, the pump will automatically deliver correction boluses to attempt to achieve the target range.

The automatic correction bolus will deliver a total correction bolus calculated based on the Personal Profile Correction Factor and predicted CGM reading. The target sensor glucose for the automatic correction bolus is 110 mg/dL. Automatic correction bolus delivery occurs at most once every 60 minutes, and will not be delivered within 60 minutes of the start, cancellation, or completion of an automatic bolus or manual bolus. For an extended bolus, this 60 minutes does not start until after the DELIVER NOW duration has completed. The percentage and duration between boluses is designed to avoid insulin stacking that may cause unsafe reductions in sensor glucose values.

NOTE

Each automatic correction bolus delivery can be manually canceled or stopped during the delivery in the same way that a Manual Bolus can be stopped. See Section 8.10 Canceling or Stopping a Bolus Using the Pump and Section 8.15 Canceling or Stopping a Bolus Using the t:connect Mobile App.

NOTE

The maximum amount of insulin that an automatic correction bolus will deliver is 6 units. This value cannot be increased, but you may choose to deliver a manual bolus after the automatic correction bolus delivery is complete.

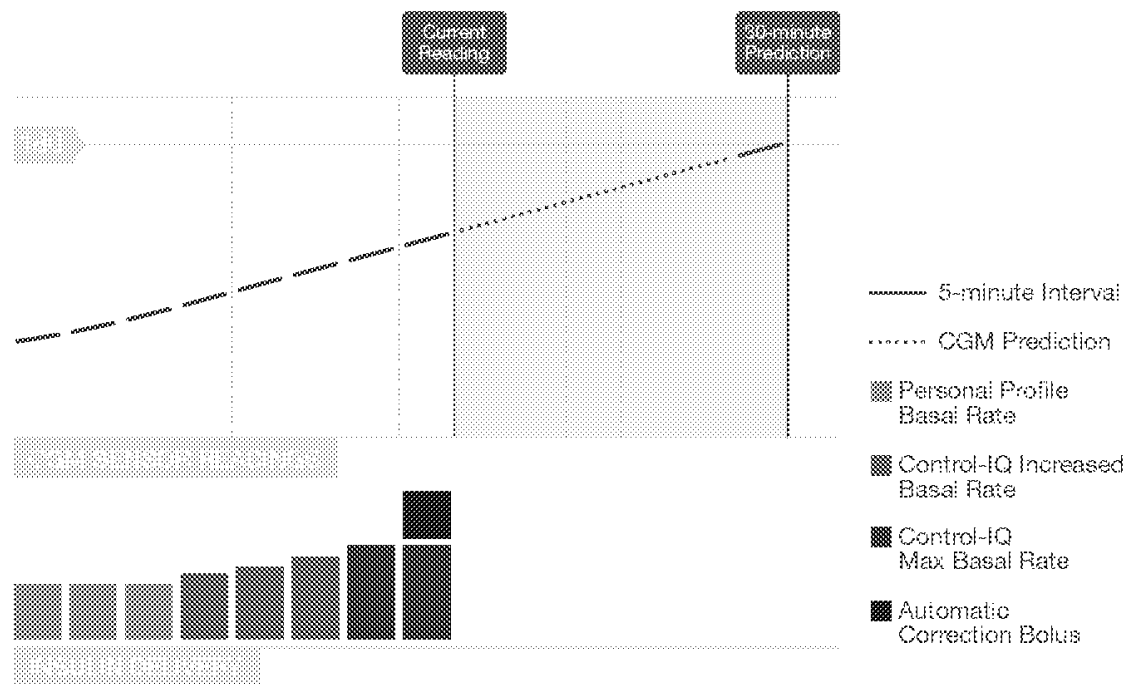
PRECAUTION

The pump does not activate sound or vibration to indicate when an automatic correction bolus delivery has started. The following pump screens indicate that an automatic correction

bolus is being delivered and that an automatic correction bolus was delivered, respectively.



CHAPTER 35 • Introduction to Control-IQ Technology



NOTE

Diagrams are for illustrative purposes only and are not intended to reflect actual results.

30.3 Control-IQ Technology and Activity

When Control-IQ technology is turned on you can choose to activate Sleep or Exercise to help the System adjust the automated insulin dosing settings as described in previous sections.

If you have not started either Sleep or Exercise, the System will use the settings described in the following section.

Control-IQ Technology With No Activity Enabled

The CGM range targeted by Control-IQ technology with no Activity enabled is 112.5–160 mg/dL. This range is wider than the Sleep and Exercise ranges to account for the variability of factors that affect CGM values while people are awake and not exercising.

Decreasing Insulin With No Activity Enabled

Insulin is decreased when Control-IQ technology predicts a CGM reading of ≤ 112.5 mg/dL 30 minutes in the future.

Suspended Insulin With No Activity Enabled

Insulin is set to 0 units/hour when Control-IQ technology predicts a CGM reading ≤ 70 mg/dL 30 minutes in the future.

Increasing Insulin With No Activity Enabled

Insulin is increased when Control-IQ technology predicts a CGM reading of ≥ 160 mg/dL 30 minutes in the future.

Automatic Correction Bolus With No Activity

When no Activity is enabled, Control-IQ technology will deliver automatic correction boluses as described in the Automatic Correction Bolus Delivery section of this chapter.

Control-IQ Technology During Sleep

The Control-IQ technology Sleep Activity range is targeted during scheduled sleep times and when the Sleep Activity is manually started (until it is stopped). See Chapter 31 Configuring and Using Control-IQ Technology and see Section Enable a Sleep Schedule for instructions on setting the hours you plan to sleep and

Section Manually Start Sleep for starting the Sleep Activity manually in that chapter.

The CGM range targeted by Control-IQ technology during the Sleep Activity is 112.5 mg/dL–120 mg/dL. This range is smaller than the target range with no Activity enabled since there are fewer variables that affect CGM values while you are sleeping. During the Sleep Activity, Control-IQ technology will not deliver automatic boluses.

Decreasing Insulin During Sleep Activity

Insulin is decreased when Control-IQ technology predicts a CGM reading of ≤ 112.5 mg/dL 30 minutes in the future.

Suspended Insulin During Sleep Activity

Insulin is set to 0 units/hour when Control-IQ technology predicts a CGM reading ≤ 70 mg/dL 30 minutes in the future.

Increasing Insulin During Sleep Activity

Insulin is increased when Control-IQ technology predicts a CGM reading of ≥ 120 mg/dL 30 minutes in the future.

CHAPTER 30 • Introduction to Control-IQ Technology

Automatic Correction Bolus During Sleep Activity

Automatic correction boluses will not be delivered while Sleep is enabled.

When Control-IQ technology switches back to the settings with no Activity enabled, whether according to scheduled wake time or due to manually stopping Sleep, the transition from the targeted sleep CGM range to targeted settings with no Activity enabled CGM range occurs slowly and can take 30-60 minutes. This helps ensure that actual CGM values transition gradually.

Control-IQ Technology During Exercise Activity

During the Exercise Activity, Control-IQ technology uses the target CGM range 140 mg/dL–160 mg/dL. This target range is smaller and higher than the target range with no Activity enabled to accommodate the likely natural drop in glucose following exercise.

If the Exercise Activity is on when a Sleep Schedule is due to begin, the Sleep Schedule does not start. In this

scenario you must manually start Sleep once you turn Exercise off.

Decreasing Insulin During Exercise Activity

Insulin is decreased when Control-IQ technology predicts a CGM reading of ≤ 140 mg/dL 30 minutes in the future.

Suspended Insulin During Exercise Activity

Insulin is set to 0 units/hour when Control-IQ technology predicts a CGM reading ≤ 80 mg/dL 30 minutes in the future.

Increasing Insulin During Exercise Activity

Insulin is increased when Control-IQ technology predicts a CGM reading of ≥ 160 mg/dL 30 minutes in the future.

Automatic Correction Bolus During Exercise Activity

When the Exercise Activity is enabled, Control-IQ technology will deliver automatic correction boluses as described in the Automatic Correction Bolus Delivery section of this chapter.

See Chapter 31 Configuring and Using Control-IQ Technology for instructions on starting or stopping Exercise.

For a summary of all treatment values and how they are different for each Activity, see the diagram on the next page.

			 Control-IQ	 Sleep Activity	 Exercise Activity
  Delivers	Delivers an automatic correction bolus if sensor glucose is predicted to be above ____ mg/dL.		180	---	180
  Increases	Increases basal insulin delivery if sensor glucose is predicted to be above ____ mg/dL.		160	120	160
  Maintains	Maintains active Personal Profile settings when sensor glucose is between ____ - ____ mg/dL.		112.5 - 160	112.5 - 120	140 - 160
  Decreases	Decreases basal insulin delivery if sensor glucose is predicted to be below ____ mg/dL.		112.5	112.5	140
  Stops	Stops basal insulin delivery if sensor glucose is predicted to be below ____ mg/dL.		70	70	80

This Page is Intentionally Left Blank

4 Control-IQ Technology Features

CHAPTER 31

Configuring and Using Control-IQ Technology

CHAPTER 31 • Configuring and Using Control-IQ Technology

31.1 Required Settings**Required Personal Profile Settings**

In order to use Control-IQ™ technology, the following Personal Profile settings must be configured. See Chapter 6 Insulin Delivery Settings for instructions about setting these values.

- Basal Rate
- Correction Factor
- Carb Ratio
- Target BG
- Carbohydrates turned on in Bolus Settings

Required Control-IQ Technology Pump Settings

In addition to the required Personal Profile settings, there are two values specific to Control-IQ technology that must be set. These are:

- Weight
- Total Daily Insulin

Recommended Control-IQ Technology Pump Settings

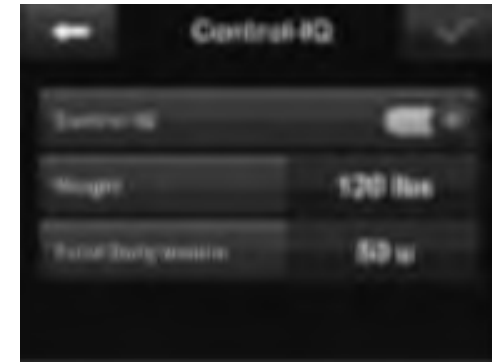
Although Sleep can be started and stopped manually, it is recommended that you schedule sleep. This chapter explains how to do both. The following settings are required to schedule sleep:

- Selected Days
- Start Time
- End Time

31.2 Set Weight

Control-IQ technology cannot be turned on unless Weight is entered. The Weight value may be updated when you visit your healthcare provider.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Control-IQ**.
 - ✓ The *Control-IQ* screen is displayed.



4. Tap **Weight**.
5. Tap **Pounds** or **Kilograms** to set the unit of weight.
6. Tap .
7. Enter the weight value on the numeric keypad. Weight can be set from a minimum of 20 pounds (9 kilograms) to a maximum of 440 pounds (200 kilograms).
8. Tap .
9. If you are done with the Control-IQ settings, tap .
 - ✓ The **SETTING SAVED** screen is temporarily displayed.

31.3 Set Total Daily Insulin

Control-IQ technology cannot be turned on unless Total Daily Insulin is entered. The Total Daily Insulin value is used by Control-IQ technology to calculate the maximum insulin delivery rate and to maintain a safe and effective increase in insulin dose.

The Total Daily Insulin value may be updated when you visit your healthcare provider.

NOTE

Once you have used Control-IQ technology, it will maintain and use the actual total insulin delivered, including the adjustments made to basal and all types of boluses while using the System. It is important to update the Total Daily Insulin setting in the *Control-IQ* screen when you visit your healthcare provider. This value is used for the 2-hour maximum insulin alert.

An estimate of Total Daily Insulin should be entered. Include all types of insulin (basal and bolus) delivered in a 24-hour period. Consult your healthcare provider if you need assistance estimating your insulin requirements.

Enter your Total Daily Insulin Value

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Control-IQ**.
4. Tap **Total Daily Insulin**.
5. Use the numeric keypad to enter the total units of insulin typically required in a 24-hour period. Total Daily Insulin can be set from a minimum of 5 units to a maximum of 200 units.
6. Tap .
7. If you are done with the Control-IQ settings, tap .
- ✓ The **SETTING SAVED** screen is temporarily displayed.
8. When you are done setting up Control-IQ, tap the **Tandem logo** to return to the *CGM Home* screen.

31.4 Turn Control-IQ Technology On or Off

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Control-IQ**.
4. To turn Control-IQ on, tap the toggle next to **Control-IQ**.
5. To turn Control-IQ off, tap the toggle next to **Control-IQ**.
 - Tap  to confirm and turn Control-IQ off.
 - Tap  to leave Control-IQ on.

31.5 Schedule Sleep

Control-IQ technology operates differently during Sleep than with no Activity enabled. Sleep can be scheduled to turn on and off automatically, or it can be turned on and off manually. This section covers how to set Sleep to turn on and off

CHAPTER 31 • Configuring and Using Control-IQ Technology

automatically. For detailed information about how to use Control-IQ technology, see Chapter 30 Introduction to Control-IQ Technology.

You can configure two different Sleep Schedules to account for changes in lifestyle, such as a weekday sleep schedule and a weekend sleep schedule.

NOTE

If you manually start Sleep before a Sleep Schedule begins, it does not impact the scheduled wake time. For example, if your Sleep Schedule is set from 10pm to 6am (22:00 to 6:00), and you start Sleep manually at 9pm (21:00), Sleep will end at 6am (6:00) as scheduled; unless manually stopped.

NOTE

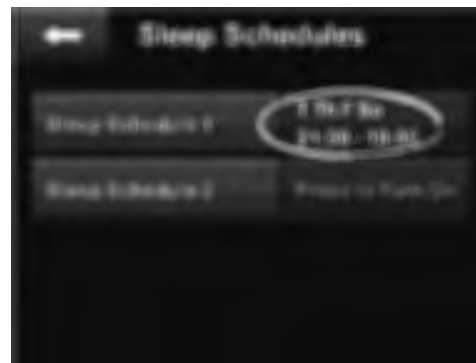
Exercise and Sleep may not be enabled at the same time. If Exercise is active at the time a Sleep Schedule begins, the Sleep Schedule will not enable. However, once Exercise is disabled, the Sleep Schedule will start automatically.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.

3. Tap **Sleep Schedules**.

4. Select which Sleep Schedule to configure.

- If no Sleep Schedules are configured, tap **Sleep Schedule 1**.
- If you are editing an existing schedule, tap the schedule summary that displays to the right of the sleep schedule you want to edit.

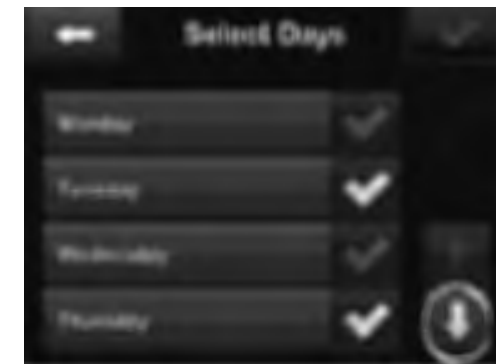


5. On the Sleep Schedule screen, tap **Selected Days**. The default is the current day of the week only, according to the day of the week set on the pump.

6. On the Select Days screen, tap the **checkmark** to the right of each day of the week that you want included in the Sleep Schedule.

When a checkmark is green, the corresponding day of the week is active. To deactivate a day, tap the associated checkmark again so that it turns gray.

Tap the **Down Arrow** to see more days of the week.



7. When you are finished selecting the days, tap .

NOTE

If no days are selected when you tap , the schedule is set to off and the remaining

sleep schedule settings are not displayed. The remaining instructions do not apply to an incomplete schedule.

8. Tap **Start Time**.
9. Tap **Time**. The numbered keypad is displayed.
10. Enter the time you would like the Sleep Schedule to start by entering the number(s) for the hour followed by the minutes. For example, tap 9 3 0 to set the time to 9:30 or 2 1 0 0 to set the time to 21:00.
11. Tap . You are returned to the *Start Time* screen.
12. Tap **AM** or **PM** to set the Time of Day, if applicable.
13. Tap . You are returned to the *Sleep Schedule 1* screen.
14. Tap **End Time**.
15. Tap **Time**. The numbered keypad is displayed.

16. Enter the time you would like the Sleep Schedule to end and tap . You are returned to the *End Time* screen.

17. Tap **AM** or **PM** to set the Time of Day, if applicable.
18. Tap . The *Sleep Schedule 1* screen is displayed.
19. Tap  to save the schedule.
- ✓ The SETTING SAVED screen is temporarily displayed, followed by the *Sleep Schedules* screen.
20. When you are done configuring sleep, tap  to return to the *Activity* screen or tap the **Tandem** logo to return to the *Home* screen.

31.6 Enable or Disable a Sleep Schedule

Once a Sleep Schedule is configured, it is enabled by default when it is saved. If you have multiple Sleep Schedules configured, you can change the

enabled Sleep Schedule or turn them off completely.

Enable a Sleep Schedule

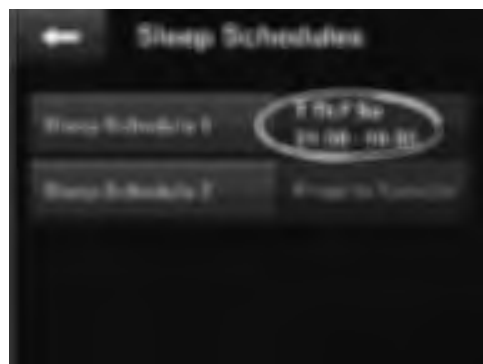
1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap **Sleep Schedules**.
4. Tap the schedule summary next to the name of the Sleep Schedule you want to enable. (If no sleep schedules are configured, see Section 31.5 Schedule Sleep.)
5. Tap the toggle next to the schedule name.
6. Tap .

Disable a Sleep Schedule

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap **Sleep Schedules**.

CHAPTER 31 • Configuring and Using Control-IQ Technology

Tap the schedule summary next to the Sleep Schedule you want to disable.



4. Tap the toggle.

5. Tap .

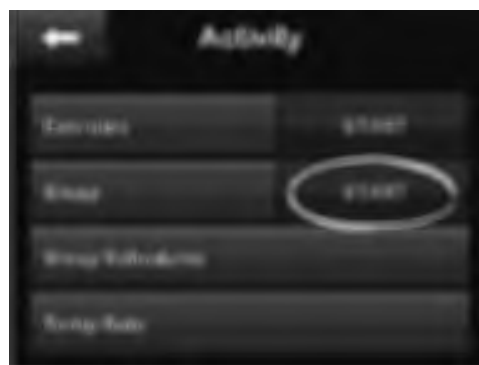
31.7 Manually Start or Stop Sleep

In addition to scheduling sleep, Sleep can be manually started and/or stopped.

Sleep time determines when Control-IQ technology, if enabled, switches to Sleep activity. Control-IQ technology must be on and a CGM session must be active to start Sleep.

Manually Start Sleep

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap the **START** text next to **Sleep**.

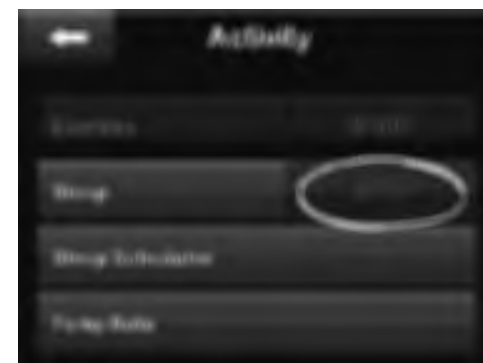


- ✓ A SLEEP STARTED screen is temporarily displayed. The Sleep icon is displayed on the *Home* screen.

Manually Stop Sleep

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.

3. Tap the **STOP** text next to **Sleep**.



- ✓ A SLEEP STOPPED message is temporarily displayed. The Sleep icon is removed from the *Home* screen.

31.8 Manually Start or Stop Exercise

Start Exercise

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap the **START** text next to **Exercise**.

- ✓ An EXERCISE STARTED message is temporarily displayed. The Exercise icon is displayed on the *Home* screen.

Stop Exercise

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap the **STOP** text next to **Exercise**.

- ✓ An EXERCISE STOPPED message is temporarily displayed. The Exercise icon is removed from the *Home* screen.

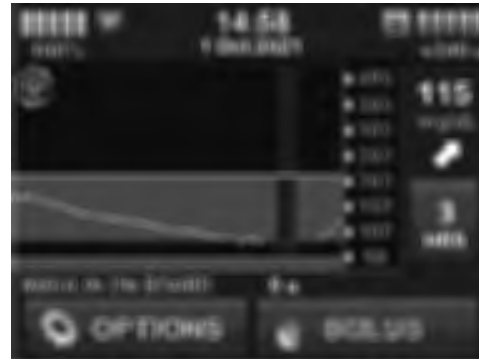
31.9 Control-IQ Technology Information on Your Screen

Control-IQ Technology Status Icon

When Control-IQ technology is on, the CGM Trend Graph displays a diamond icon in the top left corner. This icon uses different colors to communicate information about how Control-IQ technology is operating. Each different

color and its meaning can be found in Section 29.2 Explanation of Control-IQ Technology Icons.

When Control-IQ technology is on but not active (i.e. insulin is being delivered normally), the diamond icon is gray as depicted below. Regardless of the color, the icon always appears in the same place.



Exercise and Sleep Icons

When Exercise or Sleep is turned on, the respective icon displays in the same place on the screen, since they can never be active at the same time. The following image shows the sleep icon

active on the CGM Trend Graph screen.



When Exercise is on, the Exercise icon is displayed in the same location.

Basal Status Icons

There are several basal status icons that display in different colors, each of which communicates information about how Control-IQ technology is operating. Each different color and its meaning can be found in Section 29.2 Explanation of Control-IQ Technology Icons.

CHAPTER 31 • Configuring and Using Control-IQ Technology

The following image highlights where the basal status icons display.



Automatic Correction Bolus Status Icon

When Control-IQ technology is on and delivering an automatic correction bolus, an icon displays to the left of the basal status icon. (The manual bolus icon displays in the same place on the screen; see the Section 3.3 Explanation of t:slim X2 Insulin Pump Icons for the manual bolus icon image.) The following image shows the location of the bolus icon.

NOTE

The text **BOLUS** followed by 3 ellipses displays below the CGM graph. The **Control-IQ** text

appearing below **BOLUS** indicates that there is an automatic correction bolus delivered by Control-IQ technology. The amount of the bolus is also displayed.



CGM Trend Graph Insulin Delivery Suspended

Portions of the CGM Trend Graph that display a red band in the background indicate the times when Control-IQ technology was delivering 0 units/hour.

Each dot on the CGM graph represents a five-minute increment.



4 Control-IQ Technology Features

CHAPTER 32

Control-IQ Technology Alerts

CHAPTER 32 • Control-IQ Technology Alerts

Information in this section will help you learn how to respond to Control-IQ™ technology alerts and errors. It applies only to the Control-IQ technology within your System. The Control-IQ technology alerts follow the same pattern as other pump alerts according to your Sound Volume selection.

The t:connect™ mobile app also can provide messages, alerts, and alarms from your t:slim X2™ pump as push notifications on your smartphone. These push notifications will be identical to your pump's display unless otherwise noted in this chapter.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. For more information about connecting your pump and smartphone, see Section 4.3 Connecting to a Smartphone, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

For information on insulin delivery reminders, alerts, and alarms see Chapters 13 t:slim X2 Insulin Pump Alerts, 14 t:slim X2 Insulin Pump Alarms, and 15 t:slim X2 Insulin Pump Malfunction.

For information on CGM Alerts and Errors, see Chapter 26 CGM Alerts and Errors.

32.1 Out of Range Alert – Control-IQ Technology Disabled

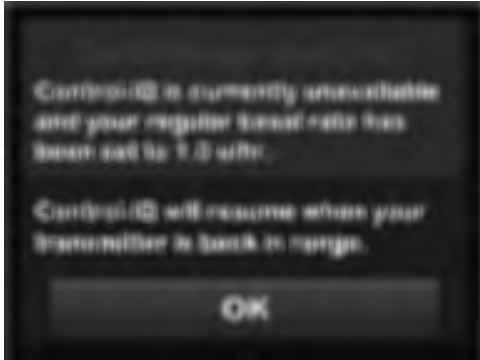
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The transmitter and pump are not communicating. The pump will not receive sensor glucose readings, and Control-IQ technology is not able to predict sensor glucose levels or adjust insulin delivery.
	How will the System notify me?	1 vibrate, then vibration/beep every 5 minutes until the transmitter and pump are back in range.
	Will the System re-notify me?	Yes, if the transmitter and pump remain out of range.
	How should I respond?	Tap  to confirm and move the transmitter and pump closer together, or remove the obstruction between them.

⚠ WARNING

Control-IQ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate settings in your active Personal Profile.

CHAPTER 32 • Control-IQ Technology Alerts

32.2 Out of Range Alert – Control-IQ Technology Enabled

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Control-IQ technology is turned on, but the transmitter and pump are not communicating. The pump will not receive sensor glucose readings. Control-IQ technology will continue to adjust basal rates and deliver automatic correction boluses for the first 20 minutes that the transmitter and pump are out of range. Control-IQ technology will resume automated insulin dosing once the transmitter and pump are back within range.
	How will the System notify me?	1 vibrate, then vibration/beep every 5 minutes until the transmitter and pump are back in range.
	Will the System re-notify me?	Yes, if the transmitter and pump remain out of range.
	How should I respond?	Tap  to confirm and move the transmitter and pump closer together, or remove the obstruction between them.

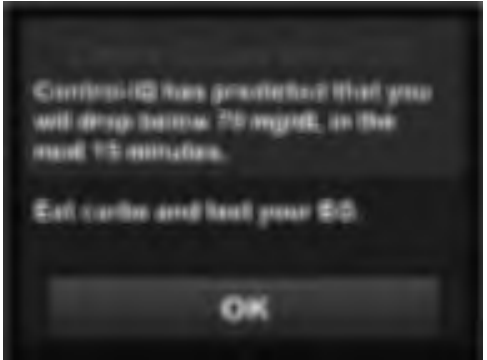
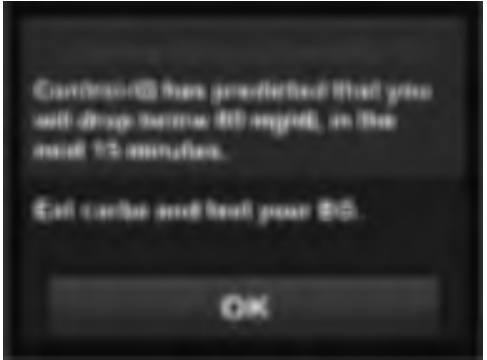
⚠ WARNING

Control-IQ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate settings in your active Personal Profile.

📌 NOTE

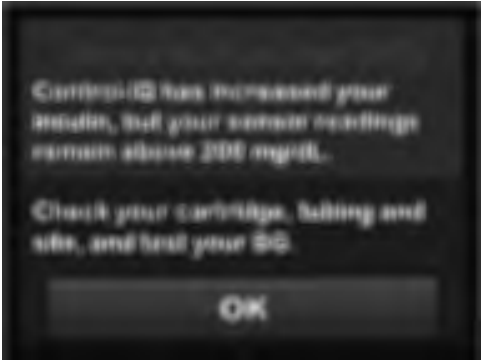
It is recommended that you keep the Out of Range Alert turned on and set to 20 minutes. If your pump and CGM are not connected for 20 minutes, Control-IQ technology will not work. Control-IQ technology will begin working immediately when the transmitter and pump are back within range.

32.3 Control-IQ Technology Low Alert

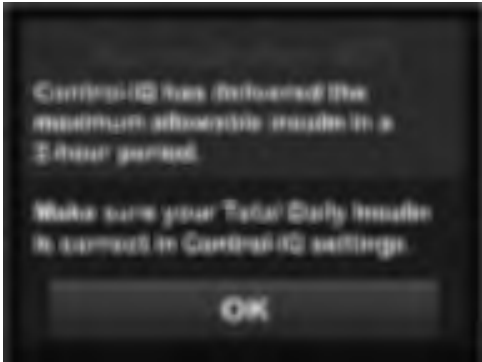
Screen	Explanation	
What will I see on the screen?  	What does it mean?	Control-IQ Low Alert has predicted that your sensor glucose reading will drop below 70 mg/dL, or below 80 mg/dL if Exercise is enabled, in the next 15 minutes.
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes until acknowledged.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Eat carbs and test your BG. Tap  to close the alert screen.

CHAPTER 32 • Control-IQ Technology Alerts

32.4 Control-IQ High Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Control-IQ technology has three hours of CGM data available and has increased insulin delivery, but detects a sensor glucose reading above 200 mg/dL and does not predict that the sensor glucose reading will decrease in the next 30 minutes.
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes until acknowledged.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged, and then every 2 hours if the issue still persists.
	How should I respond?	Check your cartridge, tubing, and site, and test your BG. Treat your high sensor glucose as necessary. Tap  to close the alert screen.

32.5 Max Insulin Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The pump has delivered the maximum allowable 2 hour insulin amount based on your Total Daily Insulin setting. You see this alert when Control-IQ technology has delivered 50% of your Total Daily Insulin (through basal and/or bolus deliveries) over the previous rolling 2 hour window, and detects this condition for 20 minutes in a row. Control-IQ technology will suspend insulin delivery for a minimum of 5 minutes, and then resume insulin delivery once the condition is no longer detected.
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes until acknowledged.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  .

This Page is Intentionally Left Blank

4 Control-IQ Technology Features

CHAPTER 33

Overview of Control-IQ Technology Clinical Studies

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.1 Introduction

The following data represents the clinical performance of the t:slim X2™ insulin pump with Control-IQ™ technology in multiple studies.

The first pivotal study (DCLP3) included participants ≥ 14 years old. A second pivotal study (DCLP5) included participants 6 years to 13 years old. A third pivotal study (PEDAP) included participants 2 years to < 6 years old. These three studies used the original version of Control-IQ technology (Control-IQ 1.0) and were all randomized control trials (RCTs).

Two more pivotal trials were subsequently performed. The PEDAP trial was extended for a 3-month extension phase where all participants used the study device. High insulin use was evaluated in the Higher-IQ trial, a single arm study. These two studies used an updated version of Control-IQ technology (Control-IQ 1.5).

All participants in all of these studies used the Dexcom G6 CGM.

Control-IQ technology has not been evaluated in children under 2 years of age. The safety and/or effectiveness of Control-IQ technology in children under 2 years of age is unknown.

33.2 Software Version History

Control-IQ 1.5 introduced changes to allow for a wider range of weight and total daily insulin (TDI) input. Other changes were implemented and are outlined in the table below.

Parameter	Control-IQ 1.0	Control-IQ 1.5
Minimum Total Daily Insulin Entry	10 units	5 units
Maximum Total Daily Insulin Entry	100 units	200 units
Minimum Weight Entry	55 pounds	20 pounds
Maximum Weight Entry	308 pounds	440 pounds
Correction Factor Range Accepted by Algorithm	1:10 to 1:200	1:10 to 1:600
Maximum Extended Bolus Duration	2 hours	8 hours
Temporary Basal Rates with Closed-Loop Active	No	Yes
Basal Rate Clipping*	Yes	No
<i>*Limited to 3 units/hour when delivering programmed basal rate</i>		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.3 The DCLP3 Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 6 months under normal conditions in adults and adolescents 14 years of age or older. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to the use of sensor augmented pump (SAP) therapy alone (the control arm), labeled as Control-IQ and SAP in the tables in this section.

168 participants were randomly assigned to use Control-IQ technology or SAP for the study in a 2:1 ratio. The Control-IQ technology arm included 112 participants and the SAP arm included 56 participants. All 168 participants completed the trial.

Baseline characteristics of study participants are provided in this section. The study population consisted of patients with a clinical diagnosis of type 1 diabetes, 14 to 71 years of age, treated with insulin via an insulin pump or injections for at least one year.

Females known to be pregnant were not included.

The summary statistics presented for the DCLP3 describe the primary outcome measure of the sensor glucose time in range between 70-180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study is not designed to determine difference in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm used the original Control-IQ algorithm (Control-IQ 1.0).

The primary outcome sensor time in range 70-180 mg/dL showed a mean adjusted difference 11% improvement with Control-IQ technology use compared to the control arm.

There was one episode of Diabetic Ketoacidosis (DKA), caused by infusion site failure in the Control-IQ arm. There were no severe hypoglycemic events in the DCLP3 with Control-IQ technology use. No other serious adverse events related to the device were reported.

DCLP3: Baseline Characteristics including Demographics at Enrollment (N=168)

Characteristic		Control-IQ (n=112)	SAP (n=56)
Age (years)			
	Mean $\pm$ SD	33 $\pm$ 16	33 $\pm$ 17
	Range	14 to 71	14 to 63
	<18 years	31 (28%)	17 (30%)
	$\geq$ 18 years	81 (72%)	39 (70%)
Sex – Female n (%)		54 (48%)	30 (54%)
Race / Ethnicity*			
	White non-Hispanic	94 (86%)	53 (95%)
	Black / African American	4 (4%)	0 (0%)
	Asian	3 (3%)	2 (4%)
	Native Hawaiian / Other Pacific Islander	1 (<1%)	0 (0%)
	More than one race	7 (6%)	1 (2%)
Income [†]			
	<\$50,000	10 (11%)	2 (4%)
	\$50,000 – <\$100,000	24 (27%)	18 (36%)
	$\geq$ \$100,000	55 (62%)	30 (60%)
Education [‡]			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

DCLP3: Baseline Characteristics including Demographics at Enrollment (N=168) (Continued)

Characteristic		Control-IQ (n=112)	SAP (n=56)
	≤High School Diploma	3 (3%)	6 (11%)
	Associates Degree or Some College	13 (12%)	7 (13%)
	Bachelor's Degree	51 (46%)	21 (38%)
	Master's Degree	32 (28%)	17 (30%)
	Doctoral or Professional Degree	13 (12%)	5 (9%)
Health Insurance [§]			
	Private	102 (94%)	50 (91%)
	CHP or another government / Medicaid	5 (5%)	5 (9%)
	None	2 (2%)	0 (0%)
*Three subjects in the Control-IQ technology arm did not provide race information. †Twenty-three subjects in the Control-IQ technology arm and 6 in SAP arm did not provide income information. ‡Highest level completed by the subject, or the primary caregiver if the participant was <18 years old. One subject in the Control-IQ technology arm did not provide education information. §Three subjects in the Control-IQ technology arm and one in the SAP arm did not provide insurance information.			

Adverse Effects

The following tables provide a full list of adverse events that occurred during the main part of the DCLP3 study:

DCLP3: Types of Adverse Events by Treatment Arm (N=168)

		Number of Events	
		Control-IQ (n=112)	SAP (n=56)
Total Number of Adverse Events		13	3
Adverse Events Related to Study Device			
	Ketosis (Infusion Site Failure)	3	0
	Hyperglycemia (Infusion Site Failure)	4	2
	Hyperglycemia (Defected Cartridge)	1	0
	Diabetic Ketoacidosis (Infusion Set Failure)	1	0
Adverse Effects Not Related to a Study Device			
	Hyperglycemia (User Error)	3	0
	Hyperglycemia (Respiratory Infection)	0	1
	Coronary Bypass Surgery	1	0
	Otitis Externa	1	0
	Concussion	1	0

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Adverse Effects

The following table provides a list of only hyperglycemia or ketosis events during the DCLP3 study:

DCLP3: Hyperglycemia/Ketosis Events by Treatment Arm (N=168)

	Number of Events	
	Control-IQ (n=112)	SAP (n=56)
Ketosis (Infusion Site Failure)	3	0
Hyperglycemia (Infusion Site Failure)	4	2
Hyperglycemia (Defected Cartridge)	1	0
Diabetic Ketoacidosis (Infusion Set Failure)	1	0
Hyperglycemia (User Error)*	3	0
Hyperglycemia (Respiratory Infection)	0	1
<i>*Discontinued pump, forgot to replace</i>		

Intervention Compliance

The following table provides an overview of how often the t:slimX2 insulin pump with Control-IQ technology was used in the Control-IQ arm:

DCLP3: Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over the 6-Month Period (n=112)

	Average Pump Use*	Average Time Control-IQ Available**
Weeks 1–4	100%	91%
Weeks 5–8	99%	91%
Weeks 9–12	100%	91%
Weeks 12–16	99%	91%
Weeks 17–20	99%	91%
Weeks 21–End	99%	82%
Overall	99%	89%
*The denominator is the total possible time within the 6-month study period. **Control-IQ Available is calculated as the percent of time when Control-IQ technology was available and operating normally during the 6-month study period.		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Primary Analysis

The primary outcome of the DCLP3 was to compare the CGM sensor values in range between 70 - 180 mg/dL between the Control-IQ technology and the SAP arms. The data represent the overall system performance 24-hours per day.

DCLP3: Comparison of CGM Values Between Control-IQ and SAP Users (N=168)

Characteristic	Control-IQ	SAP	Difference Between Study Arm and Control Arm
Average Sensor Glucose (std dev)	156 mg/dL (19 mg/dL)	170 mg/dL (25 mg/dL)	-14 mg/dL
Average % 70–180 mg/dL (std dev)	71.4% (11.7%)	59.2% (14.6%)	+11%
Average % >180 mg/dL (std dev)	27% (12%)	38.5% (15.2%)	-10%
Average % <70 mg/dL (std dev)	1.59% (1.15%)	2.25% (1.46%)	-0.88%
Average % <54 mg/dL (std dev)	0.29% (0.29%)	0.35% (0.32%)	-0.10%

The following table describes the average time participants in both the Control-IQ technology arm and the SAP arm spent with sensor glucose levels between 70 - 180 mg/dL by month at baseline and during the study period:

DCLP3: Percentage of Time in Range per Study Arm by Month (N=168)

Month	Control-IQ	SAP
Baseline	61%	59%
Month 1	73%	62%
Month 2	72%	60%
Month 3	71%	60%
Month 4	72%	58%
Month 5	71%	58%
Month 6	70%	58%

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Secondary Analysis

The following table shows secondary analysis comparing the percent of time that participants spent at the indicated sensor glucose levels during the daytime and nighttime for the DCLP3:

DCLP3: Secondary Analysis by Time of Day (N=168)

Characteristic	Unit of Measure	Daytime		Nighttime	
		Control-IQ	SAP	Control-IQ	SAP
Overall Sensor Glucose Control	Average Sensor Glucose (std dev)	158 mg/dL (20 mg/dL)	170 mg/dL (26 mg/dL)	150 mg/dL (18 mg/dL)	170 mg/dL (27 mg/dL)
	Average % Sensor Glucose 70 – 180 mg/dL (std dev)	69.8% (12.4%)	59.4% (14.6%)	76.1% (12.4%)	58.5% (16.2%)

The following table compares the percent of time spent between 70 - 180 mg/dL across the different baseline HbA1c values observed in the DCLP3 study in both treatment arms:

Percentage of Time in Range per Study Arm by Baseline HbA1c (N=168)

Baseline HbA1c	Time in Range	
	Control-IQ	SAP
≤6.5	85%	78%
6.6–7.0	76%	69%
7.1–7.5	71%	49%
7.6–8.0	69%	56%
≥8.1	60%	47%

The following table compares the average HbA1c values for all DCLP3 participants at baseline, after 13 weeks, and after 26 weeks. There was a relative difference of -0.33% between the Control-IQ arm and the SAP arm:

Comparison of HbA1c Values (N=168)

Time Period	Control-IQ	SAP
Baseline	7.40	7.40
After 13 Weeks	7.02	7.36
After 26 Weeks	7.06	7.39

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

The following table compares the change in HbA1c values for participants over the course of the DCLP3:

DCLP3: Change in HbA1c Values from Randomization to 26 Weeks (N=168)

			Number of Subjects (% of Subjects) with Change in HbA1c									
			Decrease >1%		Decrease 0 to 1%		No Change		Increase 0 to 1%		Increase >1%	
			n	%	n	%	n	%	n	%	n	%
Baseline Central Lab HbA1c		n										
5% ≤ HbA1c < 6%	Treatment	8	0	0%	1	13%	0	0%	7	88%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%
6% ≤ HbA1c < 7%	Treatment	30	0	0%	18	60%	3	10%	9	30%	0	0%
	Control	19	0	0%	10	53%	0	0%	9	47%	0	0%
7% ≤ HbA1c < 8%	Treatment	45	4	9%	33	73%	2	4%	5	11%	1	2%
	Control	22	0	0%	11	50%	1	5%	8	36%	2	9%
8% ≤ HbA1c < 9%	Treatment	22	5	23%	15	68%	1	5%	1	5%	0	0%
	Control	13	0	0%	8	62%	0	0%	4	31%	1	8%
9% ≤ HbA1c < 10%	Treatment	4	1	25%	2	50%	0	0%	1	25%	0	0%
	Control	1	0	0%	0	0%	0	0%	1	100%	0	0%
HbA1c ≥ 10%	Treatment	2	2	100%	0	0%	0	0%	0	0%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%

DCLP3: Change in HbA1c Values from Randomization to 26 Weeks (N=168) (Continued)

			Number of Subjects (% of Subjects) with Change in HbA1c									
Overall	Treatment	111	12	11%	69	62%	6	5%	23	21%	1	<1%
	Control	55	0	0%	29	53%	1	2%	22	40%	3	5%

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.4 The DCLP5 Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in children age 6 to 13 years of age. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to the use of SAP therapy alone (the control group).

The study design was very similar to DCLP3. In DCLP5, participants (N=101) were randomly assigned to Control-IQ or SAP in a 3:1 ratio. In this study, the Control-IQ arm included 78 participants. Like the DCLP3, this study population had a clinical diagnosis of type 1 diabetes. Unlike the DCLP3, the DCLP5 had participants 6 to 13 years of age. They were treated with insulin via an insulin pump or injections for at least one year. They weighed ≥ 25 kilograms and ≤ 140 kilograms and took at least 10 units of insulin a day. Females known to be pregnant were not included. Participants were required to be living with at least one parent or guardian knowledgeable about

diabetes and managing diabetes-related emergencies and willing to participate in all training sessions.

No participants were enrolled in the DCLP5 study who had inpatient psychiatric treatment in the past 6 months, the presence of a known adrenal disorder, untreated thyroid disease, cystic fibrosis, severe infectious process not anticipated to resolve prior to study procedures (e.g. meningitis, pneumonia, osteomyelitis), any skin condition in the area of insertion that prevents safe sensor or pump placement (e.g. bad sunburn, pre-existing dermatitis, intertrigo, psoriasis, extensive scarring, cellulitis), abnormal liver function tests (transaminase >3 times the upper limit of normal), or abnormal renal function test results (estimated glomerular filtration rate [GFR] <60 mL/minute/1.7m²). Participants were also excluded for use of any medication, any carcinogenic disease, or other significant medical disorder if that injury, medication, or disease in the judgment of the investigator would affect the completion of the protocol.

The summary statistics presented for the DCLP5 describe the primary outcome measure of the sensor glucose time in range between 70-180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study is not designed to determine difference in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm use the original Control-IQ algorithm (Control-IQ 1.0).

There were no episodes of DKA in the DCLP5. There were no severe hypoglycemic events in the DCLP5 with Control-IQ technology use. No other serious adverse events related to the device were reported.

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
Age (years)			
	6 – 9	21 (27%)	8 (35%)
	10 – 13	57 (73%)	15 (65%)
	Median (IQR)	11 (9, 12)	10 (8, 13)
	Range	6 to 13	6 to 13
Sex – Female n (%)		38 (49%)	12 (52%)
Race / Ethnicity			
	White non-Hispanic	64 (82%)	18 (78%)
	Hispanic or Latino	6 (8%)	2 (9%)
	Black / African American	0 (0%)	0 (0%)
	Asian	1 (1%)	1 (4%)
	More than one race	7 (9%)	2 (9%)
Annual Household Income			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101) (Continued)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
	<\$25,000	0 (0%)	0 (0%)
	\$25,000 – <\$35,000	2 (3%)	0 (0%)
	\$35,000 – <\$50,000	1 (1%)	2 (10%)
	\$50,000 – <\$75,000	5 (7%)	0 (0%)
	\$75,000 – <\$100,000	13 (18%)	4 (19%)
	\$100,000 – <\$200,000	27 (36%)	8 (38%)
	≥\$200,000	26 (35%)	7 (33%)
Parent Education			
	≤High School Diploma	2 (3%)	0 (0%)
	Associates Degree or Some College	5 (6%)	1 (4%)
	Bachelor's Degree	32 (41%)	9 (39%)
	Master's Degree	34 (44%)	11 (48%)
	Doctoral or Professional Degree	5 (6%)	2 (9%)
Health Insurance			

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101) (Continued)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
	Private	70 (90%)	21 (91%)
	CHP or another government / Medicaid	6 (8%)	1 (4%)
	Military	2 (3%)	1 (4%)
	Other	0 (0%)	0 (0%)
	None	0 (0%)	0 (0%)
*Missing data (CLC/SAP): annual household income 4 (5%)/2 (9%), total daily insulin 1 (1%)/0 (0%). All other variables have no missing data.			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Adverse Effects

The following tables provide a full list of adverse events that occurred during the main part of the DCLP5 study:

DCLP5: Types of Adverse Events by Treatment Arm (N=101)

		Number of Events	
		Control-IQ (n=78)	SAP (n=23)
Total Number of Adverse Events		16	3
Adverse Events Related to Study Device			
	Ketosis (Infusion Site Failure)	8	0
	Abscess at Sensor Site (CGM Sensor)	0	2
	Hyperglycemia (Defected Cartridge)	1	0
Adverse Effects Not Related to a Study Device			
	Hypoglycemia (User Error)	1	0
	Ketosis (User Error)	2	1
	Ketosis (Gastroenteritis)	1	0
	Hyperglycemia (User Error)	2	0
	Accidental Over-Delivery of Insulin (User Error)*	1	0
*One subject primed tubing while connected to body. This was a serious adverse event, requiring treatment in the emergency room for hypoglycemia prevention.			

The following table provides a list of only hyperglycemia or ketosis events during the DCLP5 study:

DCLP5: Hyperglycemia/Ketosis Events by Treatment Arm (N=101)

	Number of Events	
	Control-IQ (n=78)	SAP (n=23)
Ketosis (Infusion Site Failure)	8	0
Hyperglycemia (Defected Cartridge)	1	0
Ketosis (User Error)*	2	1
Ketosis (Gastroenteritis)	1	0
Hyperglycemia (User Error) [†]	2	0
<i>*Improper cartridge fill</i> <i>[†]Failed to recharge pump battery</i>		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used in the Control-IQ arm:

DCLP5: Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over the 4-Month Period (n=78)

	Average Time Control-IQ Available*
Weeks 1–4	93.4%
Weeks 5–8	93.8%
Weeks 9–12	94.1%
Weeks 13–End	94.4%
Overall	92.8%
*Control-IQ Available is calculated as the percent of time when Control-IQ technology was available and operating normally during the 4-month study period.	

Primary Analysis

The primary outcome of the DCLP5 was to compare the CGM sensor values in range between 70 - 180 mg/dL between the Control-IQ technology arms and the SAP arms. The data represent the overall system performance 24 hours per day.

DCLP5: Comparison of CGM Values Between Control-IQ and SAP Users (N=101)

Characteristic	Control-IQ	SAP	Difference Between Study Arm and Control Arm
Average Sensor Glucose (std dev)	162 mg/dL (18 mg/dL)	179 mg/dL (26 mg/dL)	-17 mg/dL
Average % 70–180 mg/dL (std dev)	67% (10%)	55% (13%)	+11%
Average % >180 mg/dL (std dev)	31% (10%)	43% (14%)	-10%
Average % <70 mg/dL (std dev)	1.8% (1.38%)	2.1% (1.18%)	-0.40%
Average % <54 mg/dL (std dev)	0.34% (0.35%)	0.38% (0.35%)	-0.07%

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

The following table describes the average time participants in both the Control-IQ technology arm and the SAP arm spent with sensor glucose levels between 70 - 180 mg/dL by month at baseline and during the study period.

DCLP5: Percentage of Time in Range per Study Arm by Month (N=101)

Month	Control-IQ	SAP
Baseline	53%	51%
Month 1	68%	56%
Month 2	68%	54%
Month 3	67%	56%
Month 4	66%	55%

Secondary Analysis

Secondary analysis comparing the percent of time that participants spent at the indicated sensor glucose levels during the daytime and nighttime for the DCLP5 are shown below:

DCLP5: Secondary Analysis by Time of Day (N=101)

Characteristic	Unit of Measure	Daytime		Nighttime	
		Control-IQ	SAP	Control-IQ	SAP
Overall Sensor Glucose Control	Average Sensor Glucose (std dev)	167 mg/dL (21 mg/dL)	179 mg/dL (27 mg/dL)	146 mg/dL (16 mg/dL)	180 mg/dL (27 mg/dL)
	Average % Sensor Glucose 70 – 180 mg/dL (std dev)	63% (11%)	56% (14%)	80% (9%)	54% (16%)

The following table compares the change in HbA1c values for participants over the course of the DCLP5:

DCLP5: Change in HbA1c Values from Randomization to 16 Weeks (N=101)

			Number of Subjects (% of Subjects) with Change in HbA1c									
			Decrease >1%		Decrease 0 to 1%		No Change		Increase 0 to 1%		Increase >1%	
			n	%	n	%	n	%	n	%	n	%
Baseline Central Lab HbA1c		n										
5% ≤ HbA1c < 6%	Treatment	3	0	0%	0	0%	2	67%	1	33%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

DCLP5: Change in HbA1c Values from Randomization to 16 Weeks (N=101) (Continued)

			Number of Subjects (% of Subjects) with Change in HbA1c									
6% ≤ HbA1c < 7%	Treatment	18	0	0%	9	50%	1	6%	8	44%	0	0%
	Control	3	0	0%	1	33%	0	0%	2	67%	0	0%
7% ≤ HbA1c < 8%	Treatment	28	3	11%	20	71%	0	0%	5	18%	0	0%
	Control	8	0	0%	5	63%	0	0%	2	25%	1	13%
8% ≤ HbA1c < 9%	Treatment	20	11	55%	9	45%	0	0%	0	0%	0	0%
	Control	10	0	0%	7	70%	0	0%	3	30%	0	0%
9% ≤ HbA1c < 10%	Treatment	7	5	71%	1	14%	0	0%	1	14%	0	0%
	Control	1	0	0%	1	100%	0	0%	0	0%	0	0%
HbA1c ≥ 10%	Treatment	1	0	0%	1	100%	0	0%	0	0%	0	0%
	Control	1	0	0%	1	100%	0	0%	0	0%	0	0%
Overall	Treatment	77	19	25%	40	52%	3	4%	15	19%	0	0%
	Control	23	0	0%	15	65%	0	0%	7	30%	1	4%

33.5 The PEDAP Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 4 months under normal conditions in preschoolers 2 to <6 years of age. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to Standard Care (SC, the control group), which included SAP therapy and multiple daily injection (MDI) therapy.

The study design was otherwise very similar to DCLP3 and DCLP5. In PEDAP, participants (N=102) were randomly assigned to Control-IQ or SC in a 2:1 ratio.

In this study, the Control-IQ arm included 69 participants, and the SC arm included 34 participants. The study population was similar to the DCLP5 in that the participants had a clinical diagnosis of type 1 diabetes, but they were younger, 2 to 5 years of age. They were treated with insulin via an insulin pump or injections for at least 6 months. They weighed at least 20

pounds (9 kilograms) and took at least 5 unites of insulin per day.

Participants were required to be living with at least one parent or guardian knowledgeable about diabetes and managing diabetes-related emergencies and willing to participate in all training sessions. No participants were enrolled in the PEDAP study who had a history of adrenal insufficiency, untreated thyroid disease, use of oral or injectable steroids within the last 8 weeks, history of chronic renal disease or currently on hemodialysis, hemophilia or any other bleeding disorder, history of >1 severe hypoglycemic event with seizure or loss of consciousness in the last 3 months, history of >1 DKA event in the last 6 months not related to illness, infusion set failure, or initial diagnosis, known ongoing adhesive intolerance, or condition, which in the opinion of the investigator or designee, would put the participant or study at risk. Concurrent use of any non-insulin glucose lowering agent (including GLP-1 agonists, Symlin, DPP-4 inhibitors, and sulfonylureas) was not allowed.

The summary statistics presented for the PEDAP describe the primary outcome measure of the sensor glucose time in range between 70 - 180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study was not designed to determine differences in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow lower weight and total daily insulin dose entry.

The primary outcome sensor time in range 70 - 180 mg/dL showed a mean adjusted difference 12.4% improvement with Control-IQ technology use of the SAP arm, very

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

similar to that seen in the DCLP3 and DCLP5.

There was one episode of DKA, caused by infusion site failure, in the PEDAP Control-IQ arm. There were two cases of severe hypoglycemia in the Control-IQ technology arm and one case in the SC arm. No other serious adverse events related to the device were reported.

Baseline Characteristics

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
Age (years)				
	Mean $\pm$ SD	3.94 $\pm$ 1.24	3.84 (1.23)	4.06 (1.25)
	Range	2.00 to 5.98	2.00 to 5.98	2.02 to 5.90
	2 to <4	47 (46%)	31 (46%)	16 (47%)
	4 to <6	55 (54%)	37 (54%)	18 (53%)
Weight (kg)				
	Mean (SD)	17.7 (4.2)	17.7 (4.7)	17.7 (3.3)
	Range	11.1 to 44.7	11.1 to 44.7	11.8 to 23.9
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase				
	Median (IQR)	0.66 (0.54, 0.79)	0.66 (0.55, 0.77)	0.66 (0.51, 0.80)
	Range	0.26 to 2.12	0.26 to 2.12	0.31 to 1.64
Sex – Female n (%)		52 (51%)	33 (49%)	19 (56%)
Race / Ethnicity				

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102) (Continued)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
	White non-Hispanic	75 (74%)	50 (74%)	25 (74%)
	Black / African American	6 (6%)	4 (6%)	2 (6%)
	Asian	2 (2%)	1 (1%)	1 (3%)
	More than one race	3 (3%)	2 (3%)	1 (3%)
Income*				
	<\$50,000	14 (14%)	8 (12%)	6 (19%)
	\$50,000 – <\$100,000	31 (33%)	19 (30%)	12 (38%)
	≥\$100,000	51 (53%)	37 (57%)	14 (44%)
Parent Education				
	≤High School Diploma	9 (9%)	6 (9%)	3 (9%)
	Technical/Vocational	3 (3%)	2 (3%)	1 (3%)
	Associate Degree	11 (11%)	6 (9%)	5 (15%)
	College Graduate (Bachelor's or higher)	35 (34%)	22 (32%)	13 (38%)
	Advanced Degree (Masters, PhD, MD, etc.)	44 (43%)	32 (47%)	12 (35%)
Health Insurance				

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102) (Continued)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
	Private [‡]	78 (77%)	52 (76%)	26 (79%)
	CHP or another government / Medicaid [†]	22 (24%)	15 (22%)	7 (21%)
	None	1 (<1%)	1 (1%)	0 (0%)
*Missing data (CLC/SC): Health insurance 0/1, annual household income 4/2, BMI percentile 2/0, HbA1c 4/2. All other variables have no missing data. [†]For participants with Private Insurance, 7 participants also had Medicaid, 1 participant also had Medicare, and 1 participant also had other government insurance. [‡]For participants with Medicaid, 1 participant also had other government insurance.				

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Adverse Effects

The following table provides a full list of adverse events that occurred during the main part of the PEDAP study.

PEDAP: Types of Adverse Events by Treatment Arm (N=102)

		Number of Events	
		Control-IQ (n=68)	SC (n=34)
Total Number of Adverse Events		71	14
Severe Hypoglycemic (SH) Events*		2	1
Diabetic Ketoacidosis (DKA) Events [†]		1	0
Other Serious Adverse Events [†] (SAEs)		0	1
Other Adverse Events <i>N Events/N Participants</i>		68/40	12/9
	Hyperglycemia with or without Ketosis Related to Study Device	39/26	0
	Hyperglycemia with or without Ketosis Not Related to Study Device	12/9	8/7
	Hypoglycemia (not severe)	2/2	0/0
	Burn	1/1	0/0

PEDAP: Types of Adverse Events by Treatment Arm (N=102) (Continued)

		Number of Events	
		Control-IQ (n=68)	SC (n=34)
	COVID-19	3/3	0/0
	Fall	1/1	0/0
	Fractured Finger	1/1	0/0
	Gastroenteritis	2/2	2/2
	Hematuria	1/1	0/0
	Medical Device Site Bleeding	1/1	0/0
	Skin Infection	3/2	0/0
	Streptococcal Sore Throat	1/1	0/0
	Upper Respiratory Infection	1/1	0/0
	Vomiting	0/0	2/1
<i>*A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.</i> <i>†DKA events meeting DCCT criteria.</i> <i>‡One participant in the SC group was hospitalized for an asthma flare.</i>			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the PEDAP trial in the intervention arm.

PEDAP Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over 13-week Period (n=68)

	Average Time Control-IQ In Use*
Weeks 1–4	92%
Weeks 5–8	95% (n=67)
Weeks 9–13	95% (n=67)
Overall	94%
*The denominator is the number of days between the beginning of the fourth day after randomization and the end of the day before the 13-week visit, or the end of the day before the last contact date for the participant who dropped out.	

Primary Analysis

The primary outcome of PEDAP was to compare the CGM sensor values in range between 70 - 180 mg/dL between the Control-IQ technology arm and the SC arm. The data represent the overall system performance 24 hours per day.

PEDAP: Percent Time in Range: Primary Endpoint Tested for Superiority (N=101)

Time and Change	Control-IQ (n=67)	SC (n=34)
Baseline	57% (18)	55% (15)
13 Weeks	69% (11) (n=68)	56% (13)
Change from Baseline mean (SD)	12.5% (11.8)	1.0% (6.6)
13 week Adjusted Group Difference (95% CI) [p-value]	12.4% (9.5, 15.3) [<0.001]	

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Secondary Analysis

Change in HbA1c values to baseline subgroups follows:

PEDAP: Change in HbA1c Values to Baseline Subgroups (Treatment n=59, Control n=31)

		N	Baseline mean (SD)	Change from Baseline Mean (SD)
Baseline HbA1c				
<7.0%	Treatment	21	6.4 (0.5)	-0.08 (0.33)
	Control	8	6.5 (0.3)	-0.18 (0.37)
7% ≤ HbA1c < 8%	Treatment	19	7.5 (0.3)	-0.51 (0.34)
	Control	8	7.4 (0.2)	-0.01 (0.36)
HbA1c ≥ 8%	Treatment	19	8.9 (0.9)	-1.22 (0.81)
	Control	15	8.5 (0.4)	-0.31 (0.40)
Overall	Treatment	59	8.9 (0.9)	-1.22 (0.81)
	Control	15	8.5 (0.4)	-0.31 (0.40)

33.6 The PEDAP Extension Phase

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in preschoolers 2 to <6 years of age. The PEDAP extension phase allowed participants in the preceding PEDAP RCT to continue in the trial for an additional 13 weeks during an Extension Phase (N=96), with all participants using Control-IQ use for 3 more months. A subset of participants also performed meal and exercise challenges during the study.

Participants used either Closed-Loop Control (CLC) for the RCT and the extension phase of the study (CLC-CLC), or used Standard Care (SC) for the RCT arm of the study, then switched to CLC during the extension phase (SC-CLC).

Participants in the CLC-CLC arm (N=63, those who continued with Control-IQ) were compared to the SC-CLC group (who were in the standard care arm for the RCT, who

then switched to Control-IQ for the extension, N=33).

The summary statistics presented for the PEDAP Extension Phase describe key CGM outcomes, as well as analysis of secondary endpoints.

All participants in the PEDAP extension phase used the updated Control-IQ algorithm (Control-IQ 1.5).

Key CGM outcomes showed, in the CLC-CLC group, time in range 70 - 180 mg/dL increased from 57% at PEDAP RCT baseline to 70% at the end of the 13-week RCT, and this was sustained during the Extension Phase at 70%, with no significant change comparing the CLC use in the RCT phase to CLC use in the Extension Phase.

In the SC-CLC group, time in range 70 - 180 mg/dL was 55% at the PEDAP RCT baseline, 56% during the RCT, and 68% during the Extension Phase. Comparing standard care from the RCT with use of CLC in the extension, the mean difference in time in range 70 -180 mg/dL was 11.8%.

There were two cases of severe hypoglycemia in the 63 participants in the CLC-CLC group (3%) unrelated to the study device, and no cases among the 33 participants in the SC-CLC group. No cases of DKA were reported. No other serious adverse events related to the device were reported.

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Baseline Characteristics

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
Age at Beginning of Extension Phase (years)				
	Mean (SD)	4.17 (1.23)	4.10 (1.23)	4.32 (1.23)
	Range	2.30 to 6.33	2.33 to 6.33	2.35 to 6.22
	2 to <4	44 (46%)	29 (46%)	15 (45%)
	4 to <6	44 (46%)	31 (49%)	13 (39%)
	6 to <7	8 (8%)	3 (5%)	5 (15%)
Sex – Female n (%)		51 (53%)	32 (51%)	19 (58%)
Weight (kg)				
	Mean (SD)	18.5 (4.4)	18.7 (4.9)	18.2 (3.3)
	Range	12.2 to 47.2	12.7 to 47.2	12.2 to 24.4
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase				
	Median (IQR)	0.69 (0.59, 0.82)	0.69 (0.59, 0.80)	0.69 (0.55, 0.94)
	Range	0.42 to 1.70	0.42 to 1.70	0.44 to 1.38
Race / Ethnicity				

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96) (Continued)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
	White non-Hispanic	81 (84%)	53 (85%)	28 (85%)
	Black / African American	5 (5%)	3 (5%)	2 (6%)
	Asian	2 (2%)	1 (2%)	1 (3%)
	More than one race	8 (8%)	6 (10%)	2 (6%)
Hispanic Ethnicity		14 (15%)	9 (14%)	5 (15%)
Income at RCT Baseline*				
	<\$50,000	13 (14%)	7 (11%)	6 (19%)
	\$50,000 to \$100,000	31 (34%)	19 (33%)	12 (39%)
	>\$100,000	46 (51%)	33 (56%)	13 (42%)
Parent Education at RCT Baseline				
	High School graduate/diploma/GED	7 (7%)	4 (6%)	3 (9%)
	Technical/Vocational	3 (3%)	2 (3%)	1 (3%)
	Associate Degree	11 (11%)	6 (10%)	5 (15%)
	College Graduate (Bachelor's or equivalent)	34 (35%)	22 (35%)	12 (36%)
	Advanced Degree (Masters, PhD, MD, etc.)	41 (43%)	29 (46%)	12 (36%)
Health Insurance at RCT Baseline*				

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96) (Continued)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
	Private [‡]	74 (78%)	49 (78%)	25 (78%)
	Medicare / Medicaid [†]	13 (14%)	9 (14%)	4 (12%)
	Other Government Insurance	8 (8%)	5 (8%)	3 (9%)
*Missing data (CLC-CLC/SC-CLC): Health insurance 0/1, annual household income 4/2. All other variables have no missing data. [†].For participants with Private Insurance, 6 participants also had Medicaid, 1 participant also had Medicare, and 1 participant also had other government insurance. [‡].For participants with Medicaid, 1 participant also had other government insurance.				

Adverse Effects

The following table provides a full list of adverse events that occurred during the PEDAP extension phase. There were no DKA events:

Summary of Adverse Events During PEDAP Extension Phase (N=96)

		Number of Events	
		CLC-CLC (n=63)	SC-CLC (n=33)
Total Number of Adverse Events		46	29
Severe Hypoglycemic (SH) Events* <i>N Events/N Participants</i>		2/2	0/0
Other Serious Adverse Events [†] (SAEs) <i>N Events/N Participants</i>		1/1	0/0
Other Adverse Events <i>N Events/N Participants</i>		43/34	29/16
	Hyperglycemia with or without Ketosis Related to Study Device	20/18	8/8
	Hyperglycemia with or without Ketosis Not Related to Study Device	10/8	12/4
	Hypoglycemia (not severe)	1/1	0/0
	Allergy NOS	1/1	0/0

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Summary of Adverse Events During PEDAP Extension Phase (N=96) (Continued)

		Number of Events	
		CLC-CLC (n=63)	SC-CLC (n=33)
	Cellulitis	0/0	1/1
	COVID-19	3/3	0/0
	Fever	0/0	1/1
	Gastroenteritis	2/2	2/2
	Head Injury	0/0	1/1
	Influenza	1/1	0/0
	Laceration	0/0	1/1
	Pneumonia	1/1	0/0
	Skin Infection	1/1	2/2
	Upper Respiratory Infection	1/1	0/0
	Viral Syndrome	1/1	0/0
	Vomiting	1/1	1/1
*A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions. † One participant in the CLC-CLC group was hospitalized for muscle pain			

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the PEDAP extension phase. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ 1.5).

PEDAP Extension Phase Median Percentage of Time of Closed-Loop System Use

	CLC-CLC	SC-CLC
Weeks 1–13*	94% (n=63)	NA (n=33)
Weeks 14–17	96% (n=63)	96% (n=33)
Weeks 18–21	96% (n=62)	96% (n=32)
Weeks 22–26	96% (n=61)	96% (n=31)
Weeks 14–26**	96% (n=63)	95% (n=33)
<i>*The denominator for Weeks 1–13 is the number of days between the beginning of the fourth day after the randomization and the end of the day before the 13-week visit.</i> <i>**Denominator for Weeks 14–26 is the number of days between the beginning of the fourth day after the Extension Training visit and the end of the day before the 26-week visit, or the end of the day before the last contact date for the participants who dropped out.</i>		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Key CGM Outcomes

Time in range 70 - 180 mg/dL for all phases of the trial is shown below. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ 1.5).

PEDAP Extension Phase: Percent Time in Range 70 - 180 mg/dL: Primary Endpoint Tested for Superiority (N=96)

Time and Change	CLC-CLC (n=63)	SC-CLC (n=33)
RCT Baseline	57% (18) n=62	55% (15)
Weeks 1-13	70% (11)	56% (13)
Weeks 14-26	70% (11)	68% (9)
26 week Adjusted Group Difference (95% CI) [p-value]*	0.1% (-1.2, 1.4) [0.86]	
*The point estimate and 95% confidence interval for the difference were calculated from a direct likelihood model. This model adjusted for the RCT baseline value of the metric, age, prior CGM and pump use, and site as a random effect. P-values and confidence intervals were adjusted to control the false discovery rate.		

Secondary Analysis

The following table shows secondary analysis of HbA1c outcomes. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ 1.5):

PEDAP Extension Phase: HbA1c Outcomes*

		N	Baseline mean (SD)
Baseline HbA1c			
RCT Baseline	CLC-CLC	59	7.6 (1.2)
	SC-CLC	32	7.7 (0.9)
Week 13	CLC-CLC	58	7.0 (0.7)
	SC-CLC	32	7.5 (0.9)
Week 26	CLC-CLC	55	7.1 (0.8)
	SC-CLC	28	7.2 (0.7)
*CLC-CLC group used closed-loop control for both the RCT and the extension phase. SC-CLC used standard care for the RCT and closed-loop control for the extension phase.			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.7 The Higher-IQ Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in adults with high insulin needs.

The Higher-IQ study enrolled adults (N=34) with type 1 diabetes using at least one basal rate greater than 3 units/hour, in a single arm, prospective study of Control-IQ technology use for 13 weeks. All participants also performed meal and exercise challenges during the study.

Participants were at least 18 years of age, had type 1 diabetes for at least 1 year, were users of an insulin pump for at least 3 months, had a hemoglobin A1c 10.5% and had a weight $\leq$ 440 pounds.

Baseline characteristics of study participants are provided below. Participants with more than 1 episode of severe hypoglycemia or DKA in the last 6 months were not included. Females known to be pregnant were not included. Participants with

hemophilia or any other bleeding disorder, history of adrenal insufficiency, untreated thyroid disease, chronic kidney disease which could affect CGM accuracy, history of gastroparesis, or a condition, which in the opinion of the investigator or designee, would put the participant or study at risk were not included.

Treatment with sulfonylureas, meglitinides, or Symlin was not permitted. Participants taking GLP-1 receptor agonists, DPP-4 inhibitors, and/or SGLT-2 inhibitors were allowed to continue these medications if they were on a stable dose for the last 3 months,

The summary statistics presented for Higher-IQ describe key CGM outcomes, as well as analysis of change in HbA1c.

All participants in the Higher-IQ study used the updated Control-IQ algorithm (Control-IQ 1.5).

Key CGM outcomes showed time in range 70 - 180 mg/dL was 64.75% overall, with time in hypoglycemia of 1.04%.

HbA1c decreased from 7.69% at baseline to 6.87% after 13 weeks of Control-IQ use, a decrease of 0.82%.

There were no DKA or severe hypoglycemia events in the study. No other serious adverse events related to the device were reported.

Higher-IQ Baseline Characteristics Including Demographics at Enrollment (N=34)

Characteristic		Single Arm Study (N=34)		
Age (years)				
	Mean (SD)	39.9 (11.9)		
	Range	20 to 66		
Sex – Female n (%)		41.2%		
Weight (kg)				
	Mean (SD)	114.8 (17.4)		
	Range	85.1 to 169.3		
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase				
	Median (IQR)	0.69 (0.59, 0.82)	0.69 (0.59, 0.80)	0.69 (0.55, 0.94)
	Range	0.42 to 1.70	0.42 to 1.70	0.44 to 1.38
Race / Ethnicity				
	White non-Hispanic	34 (100%)		
	Black / African American	2 (5.9%)		
	Native Hawaiian or Other Pacific Islander	1 (2.9%)		
Hispanic Ethnicity		3 (8.8%)		
Highest Level of Education				

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Higher-IQ Baseline Characteristics Including Demographics at Enrollment (N=34)

Characteristic		Single Arm Study (N=34)
	Less than high school	1 (2.9%)
	High School graduate/diploma/GED	4 (11.8%)
	Some college but no degree	8 (23.5%)
	Associate Degree	3 (8.8%)
	College Graduate (Bachelor's or equivalent)	13 (38.2%)
	Advanced Degree (Masters, PhD, MD, etc.)	5 (14.7%)

Adverse Effects

The following table provides a full list of adverse events that occurred during the Higher-IQ study:

Higher-IQ – All Adverse Events (N=34)

		Number of Events
		All Participants Used Control-IQ
Total Number of Adverse Events		38
Severe Hypoglycemic (SH) Events*		0
Diabetic Ketoacidosis (DKA) Events [†]		0
Other Serious Adverse Events [‡] (SAEs)		1
Other Adverse Events <i>N Events/N Participants</i>		37/18
	Hyperglycemia with or without Ketosis Related to Study Device	1/1
	Hyperglycemia with or without Ketosis Not Related to Study Device	0/0
	Bronchitis	1/1
	Chronic Kidney Disease	1/1
	Cough	1/1
	COVID-19	2/2
	Dyslipidemia	1/1
	Hypertension	1/1
	Influenza	3/3

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Higher-IQ – All Adverse Events (N=34) (Continued)

		Number of Events
		All Participants Used Control-IQ
	Ligament Sprain	1/1
	Migraine	1/1
	Myalgia	1/1
	Nausea/Vomiting	2/2
	Oropharyngeal Pain	1/1
	Otitis Externa	1/1
	Otitis Media	2/2
	Pharyngitis Streptococcal	1/1
	Skin Abrasion	1/1
	Sleep Apnea Syndrome	1/1
	Stiff Person Syndrome	1/1
	Tooth Abscess	1/1
	Tooth Fracture	1/1
	Tympanic Membrane Perforation	1/1
	Upper Respiratory Tract Infection	10/7

Higher-IQ – All Adverse Events (N=34) (Continued)

	Number of Events
	All Participants Used Control-IQ
<i>*A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.</i> <i>†DKA events meeting DCCT criteria.</i> <i>‡One participant was hospitalized for new onset atrial fibrillation.</i>	

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the Higher-IQ trial:

Higher-IQ Intervention Adherence over the 13-week Study Period (N=34)

	Sensor Use (%)	Closed-Loop System Use (%)
Mean (SD)	97.9%	93%

Key CGM Outcomes

Key CGM outcomes are shown below, for overall, daytime, and overnight:

Higher-IQ: Percentage of Time in Glycemic Ranges (N=34)

CGM Time in Range Mean % (SD)	Overall	Daytime	Overnight
BG 70-180mg/dL	64.75% (10.75)	63.47% (10.89)	68.47% (14.81)
BG >180mg/dL	34.21% (11.05)	35.62% (11.25)	30.09% (15.01)
BG ≥250mg/dL	10.45% (6.78)	10.74% (6.29)	9.58% (10.39)
BG 70-140mg/dL	37.87% (10.75)	36.96% (10.81)	40.55% (14.43)
BG <54mg/dL	0.20% (0.22)	0.15% (0.17)	0.35% (0.42)
BG <70 mg/dL	1.04% (0.98)	0.90% (0.90)	1.44% (1.48)

Secondary Analysis

Higher-IQ: Change in Central Lab HbA1c at 13 Weeks (N=34)

	Baseline	13 Weeks	Change from Baseline	P Value
HbA1c (%) Mean (SD)	7.69 (1.08)	6.87 (0.57)	-0.82 (0.73)	p<0.001

This Page is Intentionally Left Blank

5 Technical Specifications and Warranty

CHAPTER 34

Technical Specifications

CHAPTER 34 • Technical Specifications

34.1 Overview

This section provides tables of technical specifications, performance characteristics, options, settings, and electromagnetic compliance information for the t:slim X2™ pump. The specifications in this section meet the international standards set forth in IEC 60601-1 and IEC 60601-2-24.

34.2 t:slim X2 Pump Specifications**t:slim X2 Pump Specifications**

Specification Type	Specification Details
Classification	External PSU: Class II, Infusion Pump. Internally-powered equipment, Type BF applied part. The risk of ignition of flammable anesthetics and explosive gases by the pump is remote. While this risk is remote, it is not recommended to operate the t:slim X2 pump in the presence of flammable anesthetics or explosive gases.
Size	3.13" x 2.0" x 0.6" (L x W x H) - (7.95 cm x 5.08 cm x 1.52 cm)
Weight (with full disposable)	3.95 ounces (112 grams)
Operating Conditions	Temperature: 41°F (5°C) to 98.6°F (37°C) Humidity: 20% to 90% RH non-condensing
Storage Conditions	Temperature: -4°F (-20°C) to 140°F (60°C) Humidity: 20% to 90% RH non-condensing
Atmospheric Pressure	-1,300 feet to 10,000 feet (-396 meters to 3,048 meters)
Moisture Protection	IP27: Watertight to a depth of 3 feet (0.91 meters) for up to 30 minutes
Cartridge Volume	3.0 mL or 300 units
Cannula Fill Amount	0.1 to 1.0 units of insulin

t:slim X2 Pump Specifications (Continued)

Specification Type	Specification Details
Insulin Concentration	U-100
Alarm Type	Visual, audible, and vibratory
Basal Delivery Accuracy at all Flow Rates (tested per IEC 60601-2-24)	$\pm 5\%$ The pump is designed to vent automatically when there is a pressure difference between inside the cartridge and the surrounding air. In certain conditions, such as a gradual elevation change of 1,000 feet (305 meters), the pump may not vent immediately and delivery accuracy can vary up to 15% until 3 units have been delivered or elevation changes by more than 1,000 feet (305 meters).
Bolus Delivery Accuracy at all Volumes (tested per IEC 60601-2-24)	$\pm 5\%$
Patient Protection from Air Infusion	The pump provides subcutaneous delivery into interstitial tissue and does not deliver intravenous injections. Clear tubing aids in detecting air.
Maximum Infusion Pressure Generated and Occlusion Alarm Threshold	30 PSI
Frequency of Basal Delivery	5 minutes for all Basal Rates
Retention Time of Electronic Memory when Internal System Battery is Fully Discharged (including Alarm Settings and Alarm History)	Greater than 30 days
Infusion Set used for Testing	Unomedical Comfort Infusion Set
Typical Operating Time when System is Operating at Intermediate Rate	During normal use, the intermediate rate is 2 units/hr; battery charge can be reasonably expected to last between 4 and 7 days, depending on your use of CGM and the t:connect™ mobile app features from a fully charged state to a totally discharged state

CHAPTER 34 • Technical Specifications

t:slim X2 Pump Specifications (Continued)

Specification Type	Specification Details
Handling of Over-Infusion or Under-Infusion	The method of delivery isolates the insulin chamber from the patient and the software performs frequent monitoring of system status. Multiple software monitors provide redundant protection against unsafe conditions. Over-infusion is mitigated by monitoring glucose, (whether via CGM, BG meter, or both), layering of redundancies and confirmations, and numerous other safeguard alarms. Users are required to review and confirm the details of all bolus deliveries, Basal Rates, and temp rates to ensure certainty before initiating a delivery. In addition, once bolus deliveries are confirmed, the user is given 5 seconds to cancel the delivery before it is started. An optional Auto-Off alarm triggers when the user has not interacted with the pump's user interface for a predefined period of time. Under-infusion is mitigated by occlusion detection and BG monitoring as BG entries are recorded. Users are prompted to treat high BG conditions with a correction bolus.
Bolus Volume at Release of Occlusion (2 units per hour Basal)	Less than 3 units with Unomedical Comfort (110cm) Infusion Set
Residual Insulin Remaining in the Cartridge (unusable)	Approximately 15 units
Minimum Audible Alarm Volume	45 dBA at 1 meter

 NOTE

Accuracies stated in this table are valid for all Tandem Diabetes Care, Inc. branded infusion sets including: AutoSoft™ 90, AutoSoft™ XC, AutoSoft™ 30, VariSoft™, and TruSteel™ branded infusion sets.

USB Charging/Download Cable Specifications

Specification Type	Specification Detail
Tandem P/N	004113
Length	6 feet (2 meters)
Type	USB A to USB Micro B

Power Supply/Charger, AC, Wall Mount, USB Specifications

Specification Type	Specification Detail
Tandem P/N	007866
Input	100 to 240 Volts AC, 50/60 Hz
Output Voltage	5 Volts DC
Max Output Power	5 Watts
Output Connector	USB type A

Computer, USB Connector, Specifications

Specification Type	Specification Detail
Output Voltage	5 Volts DC
Output Connector	USB type A
Safety Standard Compliance	60950-1 or 60601-1 or equivalent

CHAPTER 34 • Technical Specifications

Requirements for Charging from a Computer

The t:slim X2 pump is designed to be connected to a host computer for battery charging and data transfer. The following minimum characteristics are required of the host computer:

- USB 1.1 port (or later)
- Computer compliant with 60950-1 or equivalent safety standard

Connecting the pump to a host computer that is attached to other equipment could result in previously unidentified risks to the patient, operator, or a third party. The user should identify, analyze, evaluate, and control these risks.

Subsequent changes to the host computer could introduce new risks and require additional analysis. These changes can include but are not limited to changing the configuration of the computer, connecting additional items to the computer, disconnecting items from the computer, and updating or upgrading equipment connected to the computer.

▲ WARNING

ALWAYS use the USB cable provided with your t:slim X2 insulin pump to minimize the risk of fires or burns.

34.3 t:slim X2 Pump Options and Settings**t:slim X2 Pump Options and Settings**

Option/Setting Type	Option/Setting Detail
Time	May be set to 12-hour or 24-hour clock (default is 12-hour clock)
Basal Rate Setting Range	0.1 – 15 units/hr
Insulin Delivery Profiles (Basal and Bolus)	6
Basal Rate Segments	16 per delivery profile
Basal Rate Increment	0.001 at programmed rates equal to or greater than 0.1 units/hr
Temp Basal Rate	15 minutes to 72 hours with 1 minute resolution with a range of 0% to 250%
Bolus Setup	Can deliver based on carb input (grams) or insulin input (units). The range for carbs is 1 to 999 grams, the range for insulin is 0.05 to 25 units
Insulin-to-Carb (IC) Ratio	16 time segments per 24-hour period; Ratio: 1 unit of insulin per x grams of carb; 1:1 to 1:300 (can be set by 0.1 below 10)
BG Target Value	16 time segments. 70 to 250 mg/dL in 1 mg/dL increments
Correction Factor	16 time segments; Ratio: 1 unit of insulin reduces BG x mg/dL; 1:1 to 1:600 (1 mg/dL increments)
Duration of Insulin Action	1 time segment; 2 to 8 hours in 1-minute increments (default is 5 hrs)
Bolus Increment	0.01 at volumes greater than 0.05 units
Quick Bolus Increments	When set to units of insulin: 0.5, 1, 2, 5 units (default is 0.5 units); or when set to grams of carb: 2, 5, 10, 15 grams (default is 2 g)

CHAPTER 34 • Technical Specifications

t:slim X2 Pump Options and Settings (Continued)

Option/Setting Type	Option/Setting Detail
Maximum Extended Bolus Time	8 hours
Maximum Bolus Size	25 units
Maximum Automatic Bolus Size	6 units
Low Cartridge Volume Indicator	Status indicator visible on <i>Home</i> screen; Low Insulin Alert is user adjustable from 10 to 40 units (default is 20 units).
Auto-Off Alarm	On or Off (default is on); user-adjustable (5 to 24 hours; default is 12 hours, which you can change when option is set to on).
History Storage	At least 90 days of data
Language	Dependent on region of use. May be set to English, Czech, Danish, Dutch, Finnish, French, German, Italian, Norwegian, Portuguese, Spanish, or Swedish (default is English).
Security PIN	Protects from unintentional access, and blocks access to quick bolus when enabled (default is off).
Screen Lock	Protects from unintentional screen interactions.
Site Reminder	Prompts user to change infusion set. Can be set for 1 to 3 days at a time selected by user (default is off).
Missed Meal Bolus Reminder	Prompts user if a bolus has not occurred during the period of time the reminder is set for. 4 reminders available (default is off).
After Bolus Reminder	Prompts user to test BG at a selected time period after a bolus has been delivered. Can be set between 1 to 3 hours (default is off).
High BG Reminder	Prompts user to retest BG after a High BG has been entered. User selects High BG value and time for reminder. (default is off).

t:slim X2 Pump Options and Settings (Continued)

Option/Setting Type	Option/Setting Detail
Low BG Reminder	Prompts user to retest BG after a Low BG has been entered. User selects Low BG value and time for reminder. (default is off).

34.4 t:slim X2 Pump Performance Characteristics

The t:slim X2 insulin pump delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The following accuracy data was collected on both types of delivery in laboratory studies performed by Tandem.

Basal Delivery

To assess basal delivery accuracy, 32 t:slim X2 pumps were tested by delivering at low, medium, and high Basal Rates (0.1, 2.0, and 15 U/hr). Sixteen of the pumps were new, and 16 had been aged to simulate four years of regular use. For both aged and unaged pumps, eight pumps were tested with a new cartridge, and eight with a cartridge which underwent two years of real time aging. Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid at various time points was used to assess pumping accuracy.

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for low, medium, and high Basal Rate settings for all pumps tested. For the medium and high basal rates, accuracy is reported from the time basal delivery started with no warm-up period. For the minimum Basal Rate, accuracy is reported after a 1-hour warm-up period. For each time period, the tables show the volume of insulin requested in the first row and the volume that was delivered as measured by the scale in the second row.

Low Basal Rate Delivery Performance (0.1 U/hr)

Basal Duration (Number of Units Delivered with 0.1 U/hr Setting)	1 hour (0.1 U)	6 hours (0.6 U)	12 hours (1.2 U)
Amount Delivered [min, max]	0.12 U [0.09, 0.16]	0.67 U [0.56, 0.76]	1.24 U [1.04, 1.48]

Medium Basal Rate Delivery Performance (2.0 U/hr)

Basal Duration (Number of Units Delivered with 2 U/hr Setting)	1 hour (2 U)	6 hours (12 U)	12 hours (24 U)
Amount Delivered [min, max]	2.1 U [2.1, 2.2]	12.4 U [12.0, 12.8]	24.3 U [22.0, 24.9]

High Basal Rate Delivery Performance (15 U/hr)

Basal Duration (Number of Units Delivered with 15 U/hr Setting)	1 hour (15 U)	6 hours (90 U)	12 hours (180 U)
Amount Delivered [min, max]	15.4 U [14.7, 15.7]	90.4 U [86.6, 93.0]	181 U [175.0, 187.0]

Bolus Delivery

To assess bolus delivery accuracy, 32 t:slim X2 pumps were tested by delivering consecutive low, medium, and high bolus volumes (0.05, 2.5, and 25 units). Sixteen of the pumps were new, and 16 had been aged to simulate four years of regular use. For both aged and unaged pumps, eight pumps were tested with a new cartridge, and eight with a cartridge which underwent two years of real time aging. Water was used as a substitute for insulin for this testing. The water was pumped into a container on a scale, and the weight of the liquid at various time points was used to assess pumping accuracy.

Delivered bolus volumes were compared to the requested bolus volume delivery for minimum, intermediate, and maximum bolus volumes. The tables below show average, minimum and maximum bolus sizes observed as well as the number of boluses which were observed to be within the specified range of each target bolus volume.

CHAPTER 34 • Technical Specifications

Summary of Bolus Delivery Performance (n=32 pumps)

Individual Bolus Accuracy Performance	Target Bolus Size [Units]	Mean Bolus Size [Units]	Min Bolus Size [Units]	Max Bolus Size [Units]
Min Bolus Delivery Performance (n=800 boluses)	0.050	0.050	0.000	0.114
Intermediate Bolus Delivery Performance (n=800 boluses)	2.50	2.46	0.00	2.70
Max Bolus Delivery Performance (n=256 boluses)	25.00	25.03	22.43	25.91

Low Bolus Delivery Performance (0.05U) (n=800 boluses)

	Units of Insulin Delivered After a 0.05 U Bolus Request									
	<0.0125 (<25%)	0.0125– 0.0375 (25–75%)	0.0375– 0.045 (75–90%)	0.045– 0.0475 (90–95%)	0.0475– 0.0525 (95–105%)	0.0525– 0.055 (105–110%)	0.055– 0.0625 (110–125%)	0.0625– 0.0875 (125–175%)	0.0875– 0.125 (175–250%)	>0.125 (>250%)
Number and Percent of Boluses Within Range	21/800 (2.6%)	79/800 (9.9%)	63/800 (7.9%)	34/800 (4.3%)	272/800 (34.0%)	180/800 (22.5%)	105/800 (13.1%)	29/800 (3.6%)	17/800 (2.1%)	0/800 (0.0%)

Intermediate Bolus Delivery Performance (2.5U) (n=800 boluses)

	Units of Insulin Delivered After a 2.5 U Bolus Request									
	<0.625 (<25%)	0.625– 1.875 (25–75%)	1.875– 2.25 (75–90%)	2.25– 2.375 (90–95%)	2.375– 2.625 (95–105%)	2.625– 2.75 (105–110%)	2.75– 3.125 (110–125%)	3.125– 4.375 (125–175%)	4.375– 6.25 (175–250%)	>6.25 (>250%)
Number and Percent of Boluses Within Range	9/800 (1.1%)	14/800 (1.8%)	11/800 (1.4%)	8/800 (1.0%)	753/800 (94.1%)	5/800 (0.6%)	0/800 (0.0%)	0/800 (0.0%)	0/800 (0.0%)	0/800 (0.0%)

High Bolus Delivery Performance (25U) (n=256 boluses)

	Units of Insulin Delivered After a 25 U Bolus Request									
	<6.25 (<25%)	6.25– 18.75 (25–75%)	18.75– 22.5 (75–90%)	22.5– 23.75 (90–95%)	23.75– 26.25 (95–105%)	26.25– 27.5 (105–110%)	27.5– 31.25 (110–125%)	31.25– 43.75 (125–175%)	43.75– 62.5 (175–250%)	>62.5 (>250%)
Number and Percent of Boluses Within Range	0/256 (0.0%)	0/256 (0.0%)	1/256 (0.4%)	3/256 (1.2%)	252/256 (98.4%)	0/256 (0.0%)	0/256 (0.0%)	0/256 (0.0%)	0/256 (0.0%)	0/256 (0.0%)

CHAPTER 34 • Technical Specifications

Rate of Delivery

Characteristic	Value
25 Unit Bolus Delivery Speed	2.97 Units/min Typical
2.5 Unit Bolus Delivery Speed	1.43 Units/min Typical
20 Unit Prime	9.88 Units/min Typical

Bolus Duration

Characteristic	Value
25 Unit Bolus Duration	8 minutes 26 seconds Typical
2.5 Unit Bolus Duration	1 minute 45 seconds Typical

Time to Occlusion Alarm*

Operating Rate	Typical	Maximum
Bolus (3 units or Greater)	1 minute 2 seconds	3 Minutes
Basal (2 units/hr)	1 Hour 4 Minutes	2 Hours
Basal (0.1 units/hr)	19 Hours 43 Minutes	36 Hours
*The time to occlusion alarm is based on insulin volume not delivered. During an occlusion event, boluses of less than 3 units may not trigger an occlusion alarm if no basal insulin is being delivered. The bolus amount will reduce the time to occlusion depending on the Basal Rate.		

34.5 Electromagnetic Compatibility

The information contained in this section is specific to the System. This information provides reasonable assurance of normal operation, but does not guarantee such under all conditions. If the System must be used in close proximity with other electrical equipment, the System should be observed in this environment to verify normal operation. Special precautions for electromagnetic compatibility must be taken when using medical electrical equipment. The System must be placed into service with adherence to the EMC information provided here.

▲ WARNING

Use of accessories, cables, adapters, and chargers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

▲ WARNING

ALWAYS use the USB cable provided with your t:slim X2 insulin pump to minimize the risk of fires or burns.

For IEC 60601-1 testing, Essential Performance for the System is defined as follows:

- The System will not over deliver a clinically significant amount of insulin.
- The System will not under deliver a clinically significant amount of insulin without notification to the user.
- The System will not deliver a clinically significant amount of insulin after occlusion release.
- The System will not discontinue reporting CGM data without notification to the user.

This section contains the following tables of information:

- Wireless Co-existence and Data Security
- Electromagnetic Emissions
- Electromagnetic Immunity
- Wireless Technology

34.6 Wireless Co-existence and Data Security

The System is designed to work safely and effectively in the presence of wireless devices typically found at home, work, retail stores, and places of leisure where daily activities occur.

▲ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches to any part of the t:slim X2 pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The System is designed to send and accept Bluetooth wireless technology communication. Communication is not established until you enter the appropriate credentials into your pump.

The System and system components are designed to ensure data security and patient confidentiality using a series of cybersecurity measures, including device authentication, message encryption, and message validation.

CHAPTER 34 • Technical Specifications

34.7 t:connect Mobile App Security

The smartphone's biometric security or other native authentication prevents unauthorized access. Never share your security PIN/password or authorize any other person to access your smartphone via their biometric information to avoid unintentional changes in your delivery of insulin.

⚠ WARNING

DO NOT use a smartphone that has been jailbroken or rooted, or with Android developer mode on. Data may become vulnerable if you install the t:connect mobile app on a smartphone that has been jailbroken or rooted, or uses an unreleased or pre-release operating system. Only download the t:connect mobile app on Google Play™ or from the App Store®. See Section 4.3 Connecting to a Smartphone for t:connect mobile app installation.

If the app becomes corrupted or compromised, uninstall the t:connect mobile app and follow the instructions in Section 4.3 Connecting to a Smartphone to regain a known configuration of the t:connect mobile app.

Once supported, Tandem intends to support a particular smartphone and OS combination for at least one year. When the mobile app is no longer compatible with a particular smartphone or OS, no further security updates will be provided.

■ NOTE

For an up-to-date list of supported mobile devices and operating systems, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

Please report any cybersecurity incident or vulnerability to Tandem Customer Technical Support as soon as you discover it.

34.8 Electromagnetic Emissions

The System is intended for use in the electromagnetic environment specified below. Always make sure that the System is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions, CISPR 11	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions, CISPR 11	Class B	The System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions, IEC 61000-3-2	N/A	
Voltage Fluctuations/Flicker Emissions, IEC 61000-3-3	N/A	

CHAPTER 34 • Technical Specifications

34.9 Electromagnetic Immunity

The System is intended for use in home healthcare electromagnetic environments.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air
Electrical Fast Transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines (100 kHz repetition frequency)	± 2 kV for power supply lines ± 1 kV for input/output lines (100 kHz repetition frequency)
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level
Proximity Field from Wireless Transmitters	385 MHz: 27 V/m @ 18 Hz Pulse modulation 450 MHz: 28 V/m @ FM modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz Pulse modulation 810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz Pulse modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz Pulse Modulation 2450 MHz: 28 V/m @ 217 Hz Pulse modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz Pulse modulation	385 MHz: 27 V/m @ 18 Hz Pulse modulation 450 MHz: 28 V/m @ FM modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz Pulse modulation 810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz Pulse modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz Pulse Modulation 2450 MHz: 28 V/m @ 217 Hz Pulse modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz Pulse modulation
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	70% UR (30% dip in Ur) for 25 cycles 0% Ur (100% dip in Ur) for 1 cycle at 0 degrees 0% Ur (100% dip in Ur) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% Ur (100% dip in Ur) for 250 cycles	70% UR (30% dip in Ur) for 25 cycles 0% Ur (100% dip in Ur) for 1 cycle at 0 degrees 0% Ur (100% dip in Ur) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% Ur (100% dip in Ur) for 250 cycles
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	400 A/m (IEC 60601-2-24)

CHAPTER 34 • Technical Specifications

34.10 Quality of Wireless Service

The manufacturer defines the quality of service of the System as the percent of readings successfully received by the pump, where the CGM transmitter and pump attempt to communicate every 5 minutes. One of the System's essential performance requirements states that the System will not discontinue reporting data and/or information from the CGM to the user without notification.

The System notifies the user of a missed reading, or when the transmitter and pump are out of range of one another in several ways. The first is when a dot is missed on the CGM Trend Graph which will occur within five minutes of the previous reading. The second indication occurs after 10 minutes when the Out of Range Icon is displayed on the *CGM Home* screen. The third is a user settable alert that will notify the user when the transmitter and pump are out of range of one another. Setting this alert is defined in Section 22.6 Setting Your Out of Range Alert.

The System performance requirements state that 90% of readings will be successfully transferred to the pump display while the transmitter and pump are within 20 feet (6 meters) of each other, and no more than 12 consecutive readings (1 hour) will be missed.

For proper use of the t:connect mobile app, the pump and smartphone require successful wireless communication every 5 minutes. The quality of wireless service between the pump and smartphone hosting the t:connect mobile application is assured within 20 feet, unless there is wireless interference caused by other devices in the 2.4 GHz band. This interference may impact the smartphone's ability to maintain this quality of service. To improve the quality of service in the presence of other devices operating in the 2.4 GHz band, decrease the distance between the smartphone and the pump. If connectivity is lost, the t:connect mobile application will provide notification; use your Pump until connectivity improves.

34.11 Wireless Technology

The t:slim X2 insulin pump utilizes wireless technology with the following characteristics:

Wireless Technology Specifications

Specification Type	Specification Detail
Wireless Technology	Bluetooth Low Energy (BLE) version 5.0
Tx/Rx Frequency Range	2.360 to 2.500 GHz
Bandwidth (per channel)	2 MHz
Radiated Output Power (maximum)	+8 dBm
Modulation	Gaussian Frequency-Shift Keying
Data Rate	2 Mbps
Data Communication Range (maximum)	20 feet

CHAPTER 34 • Technical Specifications

34.12 FCC Notice Concerning Interference

The transmitter covered by this user guide has been certified under FCC ID: PH29433.

Although the transmitter has been approved by the United States Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from the transmitter will be free from interference.

Compliance Statement (Part 15.19)

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Warning (Part 15.21)

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC Interference Statement (Part 15.105 (b))

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This portable transmitter with its antenna complies with FCC/IC RF exposure limits for general population/uncontrolled exposure.

34.13 Warranty Information**Warranty****t:slim X2 Insulin Pump**

This warranty is valid only in the United States.

Tandem Diabetes Care, Inc. ("Tandem") warrants the t:slim X2 insulin pump against defects in materials and workmanship, under normal use, for the period of 4 years from the original date of shipment of the pump to the

original end use purchaser (the “Warranty Period”). For any defective t:slim X2 pump covered by the foregoing warranty, Tandem will, at its discretion, repair the pump or replace it with a new or refurbished t:slim X2 pump, subject to the conditions and exclusions stated herein. Repair or replacement of a t:slim X2 pump will not extend the original 4 year warranty, which will continue to apply. If your t:slim X2 pump is replaced, then you must return your original pump to Tandem in accordance with Tandem’s instructions. In the event the defective t:slim X2 pump is not returned, then this warranty shall be void and you will not be entitled to future pump replacement or repairs.

The warranty is valid only if the t:slim X2 pump is used in accordance with Tandem’s instructions for use and this user guide and will not apply if:

- damage results from changes or modifications made to the t:slim X2 insulin pump by the user or third persons after the date of manufacture;

- damage results from service or repairs performed to any part of the t:slim X2 pump by any person or entity other than Tandem;
- the t:slim X2 pump seal is broken;
- a non-Tandem cartridge is used with the t:slim X2 pump;
- damage consists of scratches and wear to surfaces and other externally exposed parts due to wear and tear;
- damage results from an event or accident beyond the control of Tandem; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse.

From time-to-time Tandem may offer software updates for your t:slim X2 pump to help to ensure the up-to-date functionality of your pump or software that are intended to add new features to your t:slim X2 pump. Tandem reserves the right to offer those

updates, if any, in its sole discretion either at no charge or for an additional fee to be determined at a future date. To the extent that an update is offered at no charge, it is considered to be included in the original cost of your pump. Any future software updates will be subject to your acceptance of other terms and conditions that may be applicable at that time, including additional terms that may modify or limit the terms of this Warranty.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the t:slim X2 pump covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate.

This warranty only applies to the t:slim X2 pump and does not apply to other products or accessories. This warranty is valid only in the United States. No employee of Tandem or any other party is authorized to make any warranty in addition to those made in this Warranty.

The remedies provided for in this warranty are the exclusive remedies available for any warranty claims.

CHAPTER 34 • Technical Specifications

Neither Tandem nor its suppliers or distributors shall be liable for losses, liabilities, claims or damages of any kind or nature whatsoever, including, without limitation, any indirect, incidental, consequential, or special damages of any kind caused by or arising out of a defect in the product. All other warranties, express or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

Warranty

t:slim X2 3mL Cartridges

This warranty is valid only in the United States.

Tandem Diabetes Care, Inc. ("Tandem") warrants its cartridge against defects in materials and workmanship for one use during the period of 3 days after the individual cartridge sterile packaging has been opened, not to exceed 6 months from date of shipment of the cartridge to the end user (the "Warranty Period"). During the Warranty Period, Tandem will replace any defective cartridge, subject to the conditions and exclusions stated herein.

The warranty is valid only if the cartridges are used in accordance with the accompanying instructions for use and user guide and will not apply if:

- the cartridge has been used for more than a single-time use by a single end-user;
- damage results during the improper opening of the sterile package not in conformance with the procedures outlined in the associated instructions for use;
- the sterile package is compromised while in the control of the user by any means other than purposeful opening by the user at the time of intended product use;
- damage results from changes or modifications made to the cartridge by the user or third persons after the date of manufacture;
- damage results from service or repairs performed to any part of the cartridge by any person or entity other than Tandem;

- damage is caused by use of the cartridge with any non-Tandem insulin pump;
- damage results from an event or accident beyond the control of Tandem; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty does not apply to insulin pumps and other accessories. This warranty is valid only in the United States. No employee of Tandem or any other party is authorized to make any warranty in addition to those made in this Warranty.

The remedies provided for in this warranty are the exclusive remedies available for any warranty claims.

Neither Tandem nor its suppliers or distributors shall be liable for losses, liabilities, claims or damages of any kind or nature whatsoever, including, without limitation, any indirect, incidental, consequential, or special damages of any kind caused by or arising out of a defect in the product. All other warranties, express or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

Warranty t:lock™ Infusion Sets

This warranty is valid only in the United States.

Tandem Diabetes Care, Inc. ("Tandem") warrants its infusion sets against defects in materials and workmanship for one use during the period of 3 days after the individual infusion set sterile packaging has been opened, not to exceed 6 months from date of shipment of the infusion set to the end user (the "Warranty Period"). During the Warranty Period, Tandem will replace any defective infusion set, subject to the conditions and exclusions stated herein.

The warranty is valid only if the infusion sets are used in accordance with the accompanying instructions for use and user guide provided with your insulin pump and will not apply if:

- the infusion set has been used for more than a single-time use by a single end-user;
- the sterile package is compromised while in the control of the user by any means other than purposeful opening by the user at the time of intended product use;
- damage results during the improper opening of the sterile package not in conformance with the procedures outlined in the accompanying instructions for use;
- damage results from changes or modifications made to the infusion set by the user or third persons after the date of manufacture;
- damage results from service or repairs performed to any part of the infusion set by any person or entity other than Tandem;

- damage is caused by use of the t:lock infusion set with any non-Tandem insulin pump;
- damage results from an event or accident beyond the control of Tandem; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty does not apply to insulin pumps and other accessories. No employee of Tandem or any other party, including without limitation any authorized distributor, is authorized to make any warranty in addition to those made in this warranty.

The remedies provided for in this warranty are the exclusive remedies available for any warranty claims.

CHAPTER 34 • Technical Specifications

Neither Tandem nor its suppliers or distributors shall be liable for losses, liabilities, claims or damages of any kind or nature whatsoever, including, without limitation, any indirect, incidental, consequential, or special damages of any kind caused by or arising out of a defect in the product. All other warranties, express or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

CGM Warranty

Tandem Diabetes Care does not sell CGM sensors or transmitters and therefore provides no warranty for CGM sensors or transmitters used with the t:slim X2 insulin pump. For more information about CGM warranty information, visit the manufacturer's website.

34.14 Returned Goods Policy

The following represents the returned goods policy applicable only to customers in the United States.

Any insulin pump product ("Pump") that was originally purchased from Tandem

Diabetes Care, Inc. ("Tandem") or one of its authorized distributors within the United States may be returned to Tandem only for the following reasons: (1) during the applicable Warranty Period, if the customer experiences an issue with the Pump that is covered by the Warranty, then Tandem will repair or replace the Pump as provided under the Warranty above, or (2) during the ninety (90) day period after the shipment of the Pump, if the customer discovers that the Pump is not suited for the customer based on a valid, good faith medical reason which has been confirmed by the customer's physician, then Tandem or the authorized distributor will accept the return of the Pump and provide a refund to the customer and/or its insurance company for the amount actually paid for the Pump. Tandem will not accept or be obligated to accept for return any Pump for any other reason. To assure prompt handling when returning a Pump, the customer must first obtain a returned materials authorization (RMA) number from Tandem's or its authorized distributor's Customer Service Department. This RMA number must be clearly written on the outer box. If

Tandem provides a label, the label must be attached or taped to the outer box. If no label is provided, Tandem recommends shipping via insured ground service with a tracking number. Tandem is not responsible for lost or damaged packages.

To obtain an RMA number and shipping address, please contact Tandem Customer Technical Support. Returns pre-authorized by Tandem's authorized distributors should be sent to the distributor authorizing the return, unless other instructions are provided. Returns made without the RMA number will be returned to the customer, freight collect. This policy is subject to applicable law.

34.15 t:slim X2 Insulin Pump Event Data (Black Box)

Your t:slim X2 pump's event data is monitored and logged on the pump. The information stored on the pump may be obtained and used by Customer Technical Support and other internal Tandem personnel in accordance with our Privacy Notice for troubleshooting purposes when a

pump is uploaded to a data management application that supports use of the t:slim X2 pump, or if the pump is returned. Others who may assert a legal right to know, or who obtain your consent to know such information may also have access to read and use this data. Our Privacy Notice is available on our website and through our other applications. The Privacy Notice is available at tandemdiabetes.com/privacy/privacy-policy.

34.16 Product List

For a complete product list, please contact Customer Technical Support.

Insulin Delivery

- t:slim X2 insulin pump with Control-IQ technology
- t:case (pump cover with clip)
- t:slim X2 user guide
- USB cable
- USB charger with power plugs

- cartridge removal tool

Consumables

- cartridge
- t:slim X2 cartridge (t:lock™ connector) with filling syringe and needle
- infusion set (all with t:lock connector)

Infusion sets are available in different cannula sizes, tubing lengths, insertion angles, and may come with or without an insertion device. Some infusion sets have a soft cannula and others have a steel needle.

Contact your local customer support service for available sizes and lengths of the following infusion sets with t:lock connectors:

- AutoSoft 90 infusion set
- AutoSoft 30 infusion set
- VariSoft infusion set
- TruSteel infusion set

Optional Accessories/Replacement Parts

- t:case pump cover (black, blue, pink, purple, turquoise, olive)
- t:holster
- t:slim USB charging cable
- t:slim USB charger
- power plug for t:slim USB charger
- cartridge removal tool
- t:slim screen protector
- USB rubber door

INDEX

A

AC power adapter	88
Accessories	88
Active Bolus Icon	48, 212
After Bolus BG Reminder	147
Air Bubbles	
Check Tubing	113
Removing Before Delivery	109
Airport Security	199
Alarms	177
Altitude Alarm	188
Auto-Off Alarm	150
Cartridge Error Alarm	182
Cartridge Removal Alarm	183
Empty Cartridge Alarm	181
Low Power Alarm	180
Occlusion Alarms	185, 186
Reset Alarm	189
Resume Pump Alarm	179
Screen On/Quick Bolus Button Alarm	187
Temperature Alarm	184
Alerts	153

Alert Icon, Where to Find	48
Alerts & Reminders	58
Basal Rate Required Alert	165
CGM	229, 251
CGM Rise and Fall	232
CGM, 12 Hour Calibration Alert	255
CGM, Calibrate CGM Alert	259
CGM, Calibration Error Alert	258
CGM, Calibration Timeout Alert	257
CGM, Failed Sensor	271
CGM, Fall Alert	265, 266
CGM, High Alert	260
CGM, Incomplete Calibration Alert	256
CGM, Low Alert	261, 262
CGM, Low Transmitter Battery Alert	269
CGM, Out of Range Alert	268, 319, 320
CGM, Rise Alert	263, 264
CGM, Second Startup Calibration Alert	254
CGM, Startup Calibration Alert	253
CGM, System Error	273
CGM, Transmitter Error	270
CGM, Unavailable	272
Connection Error Alert	172
Control-IQ Technology	317
Control-IQ Technology, High Alert	322
Control-IQ Technology, Low Alert	321

Control-IQ Technology, Max Insulin Alert	323
Data Error Alert	175
High Glucose Alert, Set	230
Incomplete Bolus Alert	158
Incomplete Cartridge Change Alert	161
Incomplete Fill Cannula Alert	163
Incomplete Fill Tubing Alert	162
Incomplete Load Sequence Alerts	161
Incomplete Personal Profile Alert	164
Incomplete Setting Alert	164
Incomplete Temp Rate Alert	160
Low Glucose Alert, Set	231
Low Insulin Alert	150, 155
Low Power Alerts	156, 157
Max Bolus Alerts	167, 168
Max Hourly Bolus Alert	166
Min Basal Alerts	170, 171
Out of Range Alert, Set	233
Power Source Alert	174
Alternate Site BG Testing	208
Altitude	198
Altitude Alarm	188
Aquatic Activities, Pump	198
Arrows	
CGM Trends	249
Up/Down Arrows	56

Auto-Off Alarm	150

B

Basal	40
Basal Rate Required Alert	165
Current Basal Rate	52
Delivery Accuracy	381
Frequency of Delivery	381
in Personal Profiles	99
Set a Temp Rate	103
Stop a Temp Rate	104
Temp Basal Rate	41
Timed Settings	97
Basal Rate Required Alert	165
Battery	88
Battery Level	48, 50
Battery, Charge	89
BG	40
High BG Reminder	146
Low BG Reminder	146
Target BG	40, 96
Target BG in Personal Profiles	99
BG Reminder	147
Bluetooth	224

Bolus	41, 117
Active Bolus Icon	48, 212
After Bolus BG Reminder	147
Bolus Overview	118
Bolus Screen	54
Cancel a Bolus	128, 133
Correction Bolus	41
Delivery Accuracy	381
Extended Bolus	41, 124
Food Bolus Using Grams	123
Food Bolus Using Units	123
in Personal Profiles	100
Quick Bolus	41
Stop a Bolus	128, 133
Timed Settings	97

C

Calculation	54
Calibrate CGM Alert	259
Calibration Alert, 12 Hour	255
Calibration Error Alert	258
Calibration Timeout Alert	257
Cancel a Bolus	128, 133
Cannula	41

Cannula, Fill Cannula	115
Carb Ratio	41
Current Status	52
in Personal Profiles	99
Timed Settings	97
Carbohydrate	41
Carbohydrates	
Carbs, in Personal Profiles	97
Food Bolus Using Grams	123
Food Bolus, on Bolus Screen	54
Carbs	41
Carbs, on Bolus Screen	54
Caring for Your Pump	195
Cartridge	108
Cartridge Tubing	50
Change Cartridge	112
Fill Cartridge	110
Load Cartridge	108, 112
Load the Cartridge	41
Cartridge Error Alarm	182
Cartridge Removal Alarm	183
Cartridge, Warranty	402
CGM	
12 Hour Calibration Alert	255
Alerts and Errors	251

Automatic Sensor Shut-Off	239	History, View	250
Calibrate Blood Glucose Value	244	Incomplete Calibration Alert	256
Calibrate CGM Alert	259	Low BG Alert Default	231
Calibrating Your CGM	241	Low BG Alert Repeat	231
Calibration Error Alert	258	Low Glucose Alert, Set	231
Calibration Overview	242	Low Transmitter Battery Alert	269
Calibration Prompts	210	My CGM Screen	216
Calibration Timeout Alert	257	Out of Range Alert	268, 319, 320
CGM Fall Alert	265, 266	Out of Range Alert, Set	233
CGM High Alert	260	Out of Range/No Antenna, Troubleshooting	277
CGM Info	227	Pair Your CGM	224, 236
CGM Low Alert	261, 262	Rate of Change Arrows	248
CGM Rise Alert	263, 264	Receiver	221
CGM Settings	224	Rise and Fall Alerts	232
CGM System Error	273	Second Startup Calibration Alert	254
CGM Unavailable	272	Sensor Inaccuracies, Troubleshooting	278
Default Volume	224	Sensor Startup Period	238
End a Sensor Session	240	Set Correction Bolus	244
Enter Transmitter ID	224, 236	Set Volume	224
Failed Sensor	271	Start Calibration	242
Failed Sensor, Troubleshooting	277	Start or Stop a CGM Sensor	235
Glucose Trend Arrows	248	Startup Calibration Alert	253
Glucose Trend Graphs	247	Status Symbols	210
High BG Alert Default	230	System Overview	220
High BG Alert Repeat	230	Transmitter Error	270
High Glucose Alert, Set	230	Transmitter ID	236

Troubleshooting	275	Calculate Total Daily Insulin	311
Unknown Sensor Reading	267	During Exercise	306
Unknown Sensor Reading, Troubleshooting	276	During Sleep	305
View Data on Pump, Overview	246	High Alert	322
CGM Fall Alert	265, 266	Home Screen	290
CGM High Alert	260	How it Works	296
CGM ID	236	Increasing Insulin Delivery	301
CGM Low Alert	261, 262	Information on Your Screen	315
CGM Rise Alert	263, 264	Insulin Decreased	297
CGM Safety Information	202	Insulin Suspended	299
CGM System Error	273	Low Alert	321
CGM Unavailable	272	Manually Start or Stop Sleep	314
Charge		Max Insulin Alert	323
AC Power Outlet	88	Maximum Insulin Delivery	301
Car Adapter	89	No Activity Enabled	305
Computer	89	Overview	296
Charge the Pump	88	Personal Profile Basal Rate Delivery	297
Cleaning Your System	196	Required Settings	310
Colors		Responsible Use	286
Explanation of Pump Colors	45	Schedule Sleep	311
Computer Charging Specifications	384	Set Weight	310
Connection Error Alert	172	Start or Stop Exercise	314
Contents, of Pump Package	40	Total Daily Insulin	292
Control-IQ Technology		Turn On or Off	311
Automatic Correction Bolus Delivery	303	Weight	292
		Control-IQ Technology Safety Information	282

Correction Bolus	41
Correction Factor	41, 97
in Personal Profiles	99
Timed Settings	97
Current Status Screen	52

D

Data Error Alert	175
Data, View CGM Overview	246
Date	
Date and Time Display	48
Edit Date	91
Default	
Auto-Off Alarm	150
Basal Temp Rate	103
CGM Default Volume	224
CGM Fall Alert	232
CGM Out of Range Alert	233
CGM Rise Alert	232
Extended Bolus	124
High BG Reminder	147
High Glucose Alert	230
Low BG Reminder	146
Low Glucose Alert	231

Low Insulin Alert	150
Quick Bolus	126
Screen Timeout	92
Site Reminder	148

Delete Personal Profile	103
Delivery Summary	142
Device Settings	60, 92
Disconnect When Filling	113
Display Settings	92
Disposing of System Components	196

E

Edit	
Edit Date	91
Edit Time	91
Site Reminder	116
Electromagnetic Compatibility	393
Electromagnetic Emissions	395
Electromagnetic Immunity	396
Empty Cartridge Alarm	181
End CGM Sensor Session	240
Extended Bolus	41, 124
Default	124

F

Failed Sensor Error	271
Fall Alert, Set	233
Fill	
Fill Cannula	115
Fill Cartridge	110
Fill Port	109, 110
Fill Tubing	113

G

Glucose Rate of Change Arrows	248
Glucose Trend Graphs	247
Grams	
Food Bolus, on Bolus Screen	54
Food Bolus, using	123

H

Healthcare Provider	36
High Alert	
Control-IQ Technology	322
High BG Reminder	146

History

CGM History	250
Control-IQ Technology History	142
Pump History	142
Home Screen	50
Home Screen, CGM	214
Home Screen, Control-IQ Technology	290

I

Icons

Explanation of Icons	43, 210, 287
Incomplete Bolus Alert	158
Incomplete Calibration Alert	256
Incomplete Cartridge Change Alert	161
Incomplete Fill Cannula Alert	163
Incomplete Fill Tubing Alert	162
Incomplete Load Sequence Alerts	161
Incomplete Setting Alert	164
Incomplete Temp Rate Alert	160
Infusion Set Risks	36, 106
Infusion Site Care	106
Infusion Site Care, Pediatric	23
Insulin	

Insulin Duration	97
Insulin Level Display	48, 115
Insulin On Board (IOB)	41, 48
Insulin On Board (IOB) Display	48
Resume Insulin Delivery	138
Stop Insulin Delivery	138, 139
Insulin Duration, in Personal Profiles	97
Insulin on Board (IOB), in Personal Profiles	98
Interference, FCC Notice	400

K

Keypad	62, 64
Letter Keypad	64
Number Keypad	62

L

LED	45
LED, location on Home Screen	50
Lifestyle Issues	197
Load Cartridge	108, 112
Low BG Reminder	146
Low Insulin Alert	150, 155

Low Power Alarm	180
Low Power Alerts	156, 157
Low Transmitter Battery Alert	269

M

Maintaining Your Pump	195
Malfunction	192
Manual Bolus	118
Max Basal Alert	151
Max Bolus	125
Max Bolus Alerts	167, 168
Max Hourly Bolus Alert	166
Max Insulin Alert	
Control-IQ Technology	323
Min Basal Alerts	170, 171
Missed Meal Bolus Reminder	148
My Pump Screen	58

O

Occlusion Alarms	185, 186
Options Screen	56
Out of Range Alert	268, 319, 320

Overview

CGM Overview	220

P**Pediatric**

Infusion Site Care	23
Security PIN	23

Personal Profiles

Activate a Profile	102
Add Profiles	101
Copy an Existing	102
Create a New Profile	96
Delete a Profile	103
Edit or View	101
Personal Profiles Overview	96
Program a Personal Profile	99
Rename a Profile	102

Power Adapter, AC	88

Power Source Alert	174

Pump History	142

Pump History, Delivery Summary	142

Pump Info	142

Pump Info, Serial Number	142

Pump Package Contents	40

Pump Performance, Specifications	388

Pump Settings, Specifications	385

Pump Specifications	380

Q

Quick Bolus	41, 126
Pediatric	23

R

Receiver, CGM	221

Reminders	145

After Bolus BG	147

Alerts & Reminders	58

High BG	146

Low BG	146

Missed Meal Bolus	148

Site Reminder	116, 148

Reset Alarm	189

Resume Insulin Delivery	138

Resume Pump Alarm	179

Returned Goods Policy	404

Rise Alert, Set	232

Risks from Using the Pump	36
Risks from Using the System	206

S

Safety Information

CGM	201
Control-IQ Technology	281
Pump	25

Screen On/Quick Bolus Button Alarm	187

Screen Protector	40

Screen Timeout, set	92

Screens

Bolus Screen	54
CGM Home Screen	214
CGM Lock Screen	212
Control-IQ Technology	292
Control-IQ Technology Home Screen	290
Control-IQ Technology Lock Screen	288
Current Status Screen	52
Device Settings	60
Home Screen	50
Letter Keypad Screen	64
Lock Screen	48
My CGM Screen	216

My Pump Screen	58
Number Keypad Screen	62
Options Screen	56
Unlock	90
Second Startup Calibration Alert, CGM	254
Security PIN	93
Pediatric	23
Sensor	
Applicator	208
Automatic Shut-Off	239
Failed Sensor, Troubleshooting	277
Out of Range Alert	268, 319, 320
Out of Range/No Antenna, Troubleshooting	277
Troubleshooting	275
Troubleshooting Sensor Reading	276
Unknown Reading	267
Sensor Startup Period	238
Sensor, Start a Session	236
Sensor, Start Calibration	242
Serial Number	18, 142
Set CGM Volume	224
Settings, Pump Setting Specifications	385
Site Reminder	
Set Site Reminder	148
Site Reminder, Set	116

Sound 93**Specifications**

Computer Charging	384
Electromagnetic Compatibility	393
Electromagnetic Emissions	395
Electromagnetic Immunity	396
Pump	380
Pump Performance	388
Water Resistance	380
Startup Calibration Alert	253
Stop a Bolus	128, 133
Stop a Temp Rate	104
Stop CGM Sensor Session	240
Stop Insulin Delivery	138, 139
Storing Your System	196
Supply Reordering	40

T

Tandem Logo	50, 90
Target BG	40
in Personal Profiles	96, 99
Timed Settings	97
Technical Specifications	379
Temp Rate	

Stop a Temp Rate	104
Temp Rate, Set a Temp Basal Rate	103
Temperature Alarm	184
Temperature, Extreme	198
Time	
Date and Time Display	48
Edit Time	91
Time Segments	96
Time Segments, in Personal Profiles	99
Time Segments	
add to Personal Profile	100
Timed Settings	97
in Personal Profiles	99
Transmitter	
Safety Lock	208
Transmitter Error	270
Transmitter ID	236
Travel	199
Traveling, by Air	199
Trend Graphs, Glucose Trends, Arrows	247
Troubleshooting CGM	275
Tubing	
Cartridge Tubing	50
Fill Tubing	113
Tubing Connector	50, 109, 114

U

Units	42
Food Bolus, on Bolus Screen	54
Food Bolus, Using Units	123
Units, on Bolus Screen	54
Unknown Sensor Reading	267
Unlock the Screen	90
USB	
USB Adapter	89
USB Cable	40, 89
USB Port	50, 89

V

View Calculation	54
Volume	93

W

Warranty	
Cartridges	402
Pump Warranty	400
Water Resistance, Pump	198

Watertight, Pump	198

PATENTS AND TRADEMARKS

Covered by one or more patents. For a list of patents, see tandemdiabetes.com/legal/intellectual-property.

Tandem Diabetes Care, the Tandem Diabetes Care logo, t:connect, t:slim X2, and Control-IQ are either registered trademarks or trademarks of Tandem Diabetes Care, Inc., in the U.S. and/or other countries. t:lock, t:slim X2, AutoSoft, TruSteel, and VariSoft are trademarks of Tandem Diabetes Care, Inc. Dexcom and Dexcom G6 are either registered trademarks or trademarks of Dexcom, Inc. in the United States and/or other countries. The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Tandem Diabetes Care, Inc. is under license. All other third party marks are the property of their respective owners.

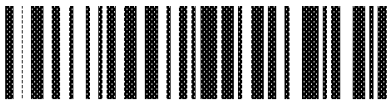




UNITED STATES:
(877) 801-6901
tandemdiabetes.com

CANADA:
(833) 509-3598
tandemdiabetes.ca

OTHER COUNTRIES:
tandemdiabetes.com/contact



1012260_B
AW-1012259_B
2023-OCT-26

© 2023 Tandem Diabetes Care, Inc. All rights reserved.



September 11, 2023

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SUBJECT: Tandem response to interactive questions regarding 510(k)s K232380 and K232382. Received via email, dated September 6, 2023

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Sincerely,

(b)(6)

Christin Dunn
Senior Regulatory Affairs Specialist





Human Factors (HF) Consult Memo

Consult Number: CON2320291
Document Number: K232380
Applicant: Tandem Diabetes Care, Inc.
Trade Name: T:slim X2 Insulin Pump with Interoperable Technology – Control IQ
Consult Type: 510(k)
Requestor: Suvajyoti Guha; Suvajyoti.Guha@fda.hhs.gov
Requestor Home: CDRH/OSEL/DAM
Requested Consultant: Anthony Maiorana; Anthony.Maiorana@fda.hhs.gov
Gatekeeper / Consultant: Tania Reina; Tania.Reina@fda.hhs.gov
Consultant Home: CDRH/OPEQ/OHTVII/DCTD/DDDB
Date Requested: 08/16/2023
Due Date: 09/12/2023

(b)(5)



**U.S. FOOD & DRUG
ADMINISTRATION**

(b)(5)

For each of the specific issues identified in the recommended requests to the applicant above, I provided a statement of basis for the request(s); and either cited as part of it an available, applicable, and relevant final rule, statute, final guidance, or FDA-recognized consensus standard or confirmed to the best of my ability that there is no final rule, statute, final guidance, or FDA-recognized consensus standard available, applicable, and relevant to the request(s).

Reviewer Sign-Off

Anthony Maiorana -S
2023.09.11 11:57:10 -04'00'

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Hi Christina and Lan,

(b)(4)

Thanks, and please let us know if you have any follow up questions on these two feedbacks.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image007.png@01DA0E4B.038E89A0]<<http://www.fda.gov/>>

[cid:image008.jpg@01DA0E4B.038E89A0]<<https://www.facebook.com/FDA>>

[cid:image009.jpg@01DA0E4B.038E89A0] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_1x9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJPtOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA>

[cid:image010.jpg@01DA0E4B.038E89A0]

<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image011.jpg@01DA0E4B.038E89A0]
<http://secure-web.cisco.com/1c6NVqVSfV2kjznn-U1A0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdH-QoytaqVxWfZhoJkuVQM_G5MsbRPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgiMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCyl14AJqcO7Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image012.jpg@01DA0E4B.038E89A0]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cE1u4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

Hi Suvajyoti,

I'm confirming receipt of the additional questions.

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Wednesday, September 6, 2023 6:34 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov

Subject: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Can you please respond to the following interactive questions by COB Sep 11, 2023 -

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, W062 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image001.png@01D9E0C1.EC33D4B0]<<http://www.fda.gov/>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

[cid:image002.jpg@01D9E0C1.EC33D4B0] <<https://www.facebook.com/FDA>>
[cid:image003.jpg@01D9E0C1.EC33D4B0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D9E0C1.EC33D4B0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>
[cid:image005.jpg@01D9E0C1.EC33D4B0] <<http://www.flickr.com/photos/fdaphotos/>>
[cid:image006.jpg@01D9E0C1.EC33D4B0]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Thanks Christin.

We have received the information.

Thanks again and have a nice weekend.

Suvajyoti Guha

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Friday, August 11, 2023 4:19 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232380@docs.fda.gov; k232382@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>

Subject: [EXTERNAL] RE: K232380 and K232382 - Lead Reviewer and RTA items

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello Suvajyoti,

Pleasure to meet you and I look forward to working with you.

Please see my responses below:

K232380

(b)(4)

K232382

(b)(4)

Thank you,



Christin Dunn

Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different
12400 High Bluff Drive, San Diego CA 92130
tandemdiabetes.com

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Friday, August 11, 2023 12:41 PM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; k232382@docs.fda.gov

Subject: K232380 and K232382 - Lead Reviewer and RTA items

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

I am the lead reviewer for K232380 and K232382. Can you please provide your responses to the following questions by 3 PM Eastern Time Monday August 14 --

K232380

(b)(4)

K232382

(b)(4)

Thanks, and looking forward to working with you on both submissions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).



Hi Suvajyoti,

Please see final IFU and 510(k) summaries for K232380 and K232382 attached.

Thank you,
Christin

From: Christin Dunn
Sent: Friday, October 27, 2023 10:05 AM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Thank you, Suvajyoti!

Yes, that time is reasonable.

Have a great weekend,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Friday, October 27, 2023 8:56 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Thanks Christin. Thanks for the heads up on the delay.

Given the time zone difference, it would be appreciated if you can send it by 3 PM Eastern time on Oct 30, 2023. Would that be reasonable?

Thanks,
Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | QHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10963 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>
Sent: Friday, October 27, 2023 11:52 AM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Would it be possible for us to send you the labeling documents and 510(k) summaries by COB Monday, October 30th?

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Thursday, October 26, 2023 12:33 PM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov

Subject: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.
i Christin,

Can you please send your finalized and complete Labeling documents and 510k summaries for the pump (k232380) and Control IQ (k232382)?

It would be great if you can send it by COB **Oct 27, 2023**.

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer
Division of Applied Mechanics (**DAM**)
Office of Science and Engineering Laboratories (**OSEL**)
Center for Devices and Radiological Health (**CDRH**)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993
✉: Suvajyoti.Guha@fda.hhs.gov
☎: 301.796.9573



• • • • •

Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>





October 20, 2023

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SUBJECT: Tandem response to interactive questions regarding 510(k)s K232380 and K232382.
Received via email, dated October 16, 2023

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Sincerely,

(b)(6)

Christin Dunn
Senior Regulatory Affairs Specialist

Attachments

- Attachment 1 - AW-1012259_Clean_Chapter 33 Overview of Control-IQ Technology Clinical Studies_16Oct2023



Attachment 1

AW-1012259_Clean_Chapter 33 Overview of Control-IQ Technology Clinical Studies_16Oct2023



4 Control-IQ Technology Features

CHAPTER 33

Overview of Control-IQ Technology Clinical Studies

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.1 Introduction

The following data represents the clinical performance of the t:slim X2™ insulin pump with Control-IQ™ technology in multiple studies.

The first pivotal study (DCLP3) included participants ≥ 14 years old. A second pivotal study (DCLP5) included participants 6 years to 13 years old. A third pivotal study (PEDAP) included participants 2 years to < 6 years old. These three studies used the original version of Control-IQ technology (Control-IQ 1.0) and were all randomized control trials (RCTs).

Two more pivotal trials were subsequently performed. The PEDAP trial was extended for a 3-month extension phase where all participants used the study device. High insulin use was evaluated in the Higher-IQ trial, a single arm study. These two studies used an updated version of Control-IQ technology (Control-IQ 1.5).

All participants in all of these studies used the Dexcom G6 CGM.

Control-IQ technology has not been evaluated in children under 2 years of age. The safety and/or effectiveness of Control-IQ technology in children under 2 years of age is unknown.

33.2 Software Version History

Control-IQ 1.5 introduced changes to allow for a wider range of weight and total daily insulin (TDI) input. Other changes were implemented and are outlined in the table below.

Parameter	Control-IQ 1.0	Control-IQ 1.5
Minimum Total Daily Insulin Entry	10 units	5 units
Maximum Total Daily Insulin Entry	100 units	200 units
Minimum Weight Entry	55 pounds	20 pounds
Maximum Weight Entry	308 pounds	440 pounds
Correction Factor Range Accepted by Algorithm	1:10 to 1:200	1:10 to 1:600
Maximum Extended Bolus Duration	2 hours	8 hours
Temporary Basal Rates with Closed-Loop Active	No	Yes
Basal Rate Clipping*	Yes	No

**Limited to 3 units/hour when delivering programmed basal rate)*

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.3 The DCLP 3 Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 6 months under normal conditions in adults and adolescents 14 years of age or older. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to the use of sensor augmented pump (SAP) therapy alone (the control arm), labeled as Control-IQ and SAP in the tables in this section.

168 participants were randomly assigned to use Control-IQ technology or SAP for the study in a 2:1 ratio. The Control-IQ technology arm included 112 participants and the SAP arm included 56 participants. All 168 participants completed the trial.

Baseline characteristics of study participants are provided in this section. The study population consisted of patients with a clinical diagnosis of type 1 diabetes, 14 to 71 years of age, treated with insulin via an insulin pump or injections for at least one year.

Females known to be pregnant were not included.

The summary statistics presented for the DCLP3 describe the primary outcome measure of the sensor glucose time in range between 70-180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study is not designed to determine difference in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm used the original Control-IQ algorithm (Control-IQ 1.0).

The primary outcome sensor time in range 70-180 mg/dL showed a mean adjusted difference 11% improvement with Control-IQ technology use compared to the control arm.

There was one episode of Diabetic Ketoacidosis (DKA), caused by infusion site failure in the Control-IQ arm. There were no severe hypoglycemic events in the DCLP3 with Control-IQ technology use. No other serious adverse events related to the device were reported.

DCLP3: Baseline Characteristics including Demographics at Enrollment (N=168)

Characteristic		Control-IQ (n=112)	SAP (n=56)
Age (years)			
	Mean $\pm$ SD	33 $\pm$ 16	33 $\pm$ 17
	Range	14 to 71	14 to 63
	<18 years	31 (28%)	17 (30%)
	$\geq$ 18 years	81 (72%)	39 (70%)
Sex – Female n (%)		54 (48%)	30 (54%)
Race / Ethnicity*			
	White non-Hispanic	94 (86%)	53 (95%)
	Black / African American	4 (4%)	0 (0%)
	Asian	3 (3%)	2 (4%)
	Native Hawaiian / Other Pacific Islander	1 (<1%)	0 (0%)
	More than one race	7 (6%)	1 (2%)
Income [†]			
	<\$50,000	10 (11%)	2 (4%)
	\$50,000 – <\$100,000	24 (27%)	18 (36%)
	$\geq$ \$100,000	55 (62%)	30 (60%)
Education [‡]			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

DCLP3: Baseline Characteristics including Demographics at Enrollment (N=168) (Continued)

Characteristic		Control-IQ (n=112)	SAP (n=56)
	≤High School Diploma	3 (3%)	6 (11%)
	Associates Degree or Some College	13 (12%)	7 (13%)
	Bachelor's Degree	51 (46%)	21 (38%)
	Master's Degree	32 (28%)	17 (30%)
	Doctoral or Professional Degree	13 (12%)	5 (9%)
Health Insurance [§]			
	Private	102 (94%)	50 (91%)
	CHP or another government / Medicaid	5 (5%)	5 (9%)
	None	2 (2%)	0 (0%)
*Three subjects in the Control-IQ technology arm did not provide race information. †Twenty-three subjects in the Control-IQ technology arm and 6 in SAP arm did not provide income information. ‡Highest level completed by the subject, or the primary caregiver if the participant was <18 years old. One subject in the Control-IQ technology arm did not provide education information. §Three subjects in the Control-IQ technology arm and one in the SAP arm did not provide insurance information.			

Adverse Effects

The following tables provide a full list of adverse events that occurred during the main part of the DCLP3 study:

DCLP3: Types of Adverse Events by Treatment Arm (N=168)

		Number of Events	
		Control-IQ (n=112)	SAP (n=56)
Total Number of Adverse Events		13	3
Adverse Events Related to Study Device			
	Ketosis (Infusion Site Failure)	3	0
	Hyperglycemia (Infusion Site Failure)	4	2
	Hyperglycemia (Defected Cartridge)	1	0
	Diabetic Ketoacidosis (Infusion Set Failure)	1	0
Adverse Effects Not Related to a Study Device			
	Hyperglycemia (User Error)	3	0
	Hyperglycemia (Respiratory Infection)	0	1
	Coronary Bypass Surgery	1	0
	Otitis Externa	1	0
	Concussion	1	0

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Adverse Effects

The following table provides a list of only hyperglycemia or ketosis events during the DCLP3 study:

DCLP3: Hyperglycemia/Ketosis Events by Treatment Arm (N=168)

	Number of Events	
	Control-IQ (n=112)	SAP (n=56)
Ketosis (Infusion Site Failure)	3	0
Hyperglycemia (Infusion Site Failure)	4	2
Hyperglycemia (Defected Cartridge)	1	0
Diabetic Ketoacidosis (Infusion Set Failure)	1	0
Hyperglycemia (User Error)*	3	0
Hyperglycemia (Respiratory Infection)	0	1
<i>*Discontinued pump, forgot to replace</i>		

Intervention Compliance

The following table provides an overview of how often the t:slimX2 insulin pump with Control-IQ technology was used in the Control-IQ arm:

DCLP3: Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over the 6-Month Period (n=112)

	Average Pump Use*	Average Time Control-IQ Available**
Weeks 1–4	100%	91%
Weeks 5–8	99%	91%
Weeks 9–12	100%	91%
Weeks 12–16	99%	91%
Weeks 17–20	99%	91%
Weeks 21–End	99%	82%
Overall	99%	89%
<i>*The denominator is the total possible time within the 6-month study period.</i> <i>**Control-IQ Available is calculated as the percent of time when Control-IQ technology was available and operating normally during the 6-month study period.</i>		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Primary Analysis

The primary outcome of the DCLP3 was to compare the CGM sensor values in range between 70 - 180 mg/dL between the Control-IQ technology and the SAP arms. The data represent the overall system performance 24-hours per day.

DCLP3: Comparison of CGM Values Between Control-IQ and SAP Users (N=168)

Characteristic	Control-IQ	SAP	Difference Between Study Arm and Control Arm
Average Sensor Glucose (std dev)	156 mg/dL (19 mg/dL)	170 mg/dL (25 mg/dL)	-14 mg/dL
Average % 70–180 mg/dL (std dev)	71.4% (11.7%)	59.2% (14.6%)	+11%
Average % >180 mg/dL (std dev)	27% (12%)	38.5% (15.2%)	-10%
Average % <70 mg/dL (std dev)	1.59% (1.15%)	2.25% (1.46%)	-0.88%
Average % <54 mg/dL (std dev)	0.29% (0.29%)	0.35% (0.32%)	-0.10%

The following table describes the average time participants in both the Control-IQ technology arm and the SAP arm spent with sensor glucose levels between 70 - 180 mg/dL by month at baseline and during the study period:

DCLP3: Percentage of Time in Range per Study Arm by Month (N=168)

Month	Control-IQ	SAP
Baseline	61%	59%
Month 1	73%	62%
Month 2	72%	60%
Month 3	71%	60%
Month 4	72%	58%
Month 5	71%	58%
Month 6	70%	58%

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Secondary Analysis

The following table shows secondary analysis comparing the percent of time that participants spent at the indicated sensor glucose levels during the daytime and nighttime for the DCLP3:

DCLP3: Secondary Analysis by Time of Day (N=168)

Characteristic	Unit of Measure	Daytime		Nighttime	
		Control-IQ	SAP	Control-IQ	SAP
Overall Sensor Glucose Control	Average Sensor Glucose (std dev)	158 mg/dL (20 mg/dL)	170 mg/dL (26 mg/dL)	150 mg/dL (18 mg/dL)	170 mg/dL (27 mg/dL)
	Average % Sensor Glucose 70 – 180 mg/dL (std dev)	69.8% (12.4%)	59.4% (14.6%)	76.1% (12.4%)	58.5% (16.2%)

The following table compares the percent of time spent between 70 - 180 mg/dL across the different baseline HbA1c values observed in the DCLP3 study in both treatment arms:

Percentage of Time in Range per Study Arm by Baseline HbA1c (N=168)

Baseline HbA1c	Time in Range	
	Control-IQ	SAP
≤6.5	85%	78%
6.6–7.0	76%	69%
7.1–7.5	71%	49%
7.6–8.0	69%	56%
≥8.1	60%	47%

The following table compares the average HbA1c values for all DCLP3 participants at baseline, after 13 weeks, and after 26 weeks. There was a relative difference of -0.33% between the Control-IQ arm and the SAP arm:

Comparison of HbA1c Values (N=168)

Time Period	Control-IQ	SAP
Baseline	7.40	7.40
After 13 Weeks	7.02	7.36
After 26 Weeks	7.06	7.39

CHAPTER 33 • Overview of Control-IG Technology Clinical Studies

The following table compares the change in HbA1c values for participants over the course of the DCLP3:

DCLP3: Change in HbA1c Values from Randomization to 26 Weeks (N=168)

			Number of Subjects (% of Subjects) with Change in HbA1c									
			Decrease >1%		Decrease 0 to 1%		No Change		Increase 0 to 1%		Increase >1%	
			n	%	n	%	n	%	n	%	n	%
Baseline Central Lab HbA1c		n										
5% ≤ HbA1c < 6%	Treatment	8	0	0%	1	13%	0	0%	7	88%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%
6% ≤ HbA1c < 7%	Treatment	30	0	0%	18	60%	3	10%	9	30%	0	0%
	Control	19	0	0%	10	53%	0	0%	9	47%	0	0%
7% ≤ HbA1c < 8%	Treatment	45	4	9%	33	73%	2	4%	5	11%	1	2%
	Control	22	0	0%	11	50%	1	5%	8	36%	2	9%
8% ≤ HbA1c < 9%	Treatment	22	5	23%	15	68%	1	5%	1	5%	0	0%
	Control	13	0	0%	8	62%	0	0%	4	31%	1	8%
9% ≤ HbA1c < 10%	Treatment	4	1	25%	2	50%	0	0%	1	25%	0	0%
	Control	1	0	0%	0	0%	0	0%	1	100%	0	0%
HbA1c ≥ 10%	Treatment	2	2	100%	0	0%	0	0%	0	0%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%

DCLP3: Change in HbA1c Values from Randomization to 26 Weeks (N=168) (Continued)

			Number of Subjects (% of Subjects) with Change in HbA1c									
Overall	Treatment	111	12	11%	69	62%	6	5%	23	21%	1	<1%
	Control	55	0	0%	29	53%	1	2%	22	40%	3	5%

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.4 The DCLP5 Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in children age 6 to 13 years of age. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to the use of SAP therapy alone (the control group).

The study design was very similar to DCLP3. In DCLP5, participants (N=101) were randomly assigned to Control-IQ or SAP in a 3:1 ratio. In this study, the Control-IQ arm included 78 participants. Like the DCLP3, this study population had a clinical diagnosis of type 1 diabetes. Unlike the DCLP3, the DCLP5 had participants 6 to 13 years of age. They were treated with insulin via an insulin pump or injections for at least one year. They weighed ≥ 25 kilograms and ≤ 140 kilograms and took at least 10 units of insulin a day. Females known to be pregnant were not included. Participants were required to be living with at least one parent or guardian knowledgeable about

diabetes and managing diabetes-related emergencies and willing to participate in all training sessions.

No participants were enrolled in the DCLP5 study who had inpatient psychiatric treatment in the past 6 months, the presence of a known adrenal disorder, untreated thyroid disease, cystic fibrosis, severe infectious process not anticipated to resolve prior to study procedures (e.g. meningitis, pneumonia, osteomyelitis), any skin condition in the area of insertion that prevents safe sensor or pump placement (e.g. bad sunburn, pre-existing dermatitis, intertrigo, psoriasis, extensive scarring, cellulitis), abnormal liver function tests (transaminase >3 times the upper limit of normal), or abnormal renal function test results (estimated glomerular filtration rate [GFR] <60 mL/minute/1.7m²). Participants were also excluded for use of any medication, any carcinogenic disease, or other significant medical disorder if that injury, medication, or disease in the judgment of the investigator would affect the completion of the protocol.

The summary statistics presented for the DCLP5 describe the primary outcome measure of the sensor glucose time in range between 70-180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study is not designed to determine difference in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm use the original Control-IQ algorithm (Control-IQ 1.0).

There were no episodes of DKA in the DCLP5. There were no severe hypoglycemic events in the DCLP5 with Control-IQ technology use. No other serious adverse events related to the device were reported.

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
Age (years)			
	6 – 9	21 (27%)	8 (35%)
	10 – 13	57 (73%)	15 (65%)
	Median (IQR)	11 (9, 12)	10 (8, 13)
	Range	6 to 13	6 to 13
Sex – Female n (%)		38 (49%)	12 (52%)
Race / Ethnicity			
	White non-Hispanic	64 (82%)	18 (78%)
	Hispanic or Latino	6 (8%)	2 (9%)
	Black / African American	0 (0%)	0 (0%)
	Asian	1 (1%)	1 (4%)
	More than one race	7 (9%)	2 (9%)
Annual Household Income			
	<\$25,000	0 (0%)	0 (0%)
	\$25,000 – <\$35,000	2 (3%)	0 (0%)
	\$35,000 – <\$50,000	1 (1%)	2 (10%)
	\$50,000 – <\$75,000	5 (7%)	0 (0%)

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101) (Continued)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
	\$75,000 – <\$100,000	13 (18%)	4 (19%)
	\$100,000 – <\$200,000	27 (36%)	8 (38%)
	≥\$200,000	26 (35%)	7 (33%)
Parent Education			
	≤High School Diploma	2 (3%)	0 (0%)
	Associates Degree or Some College	5 (6%)	1 (4%)
	Bachelor's Degree	32 (41%)	9 (39%)
	Master's Degree	34 (44%)	11 (48%)
	Doctoral or Professional Degree	5 (6%)	2 (9%)
Health Insurance			
	Private	70 (90%)	21 (91%)
	CHP or another government / Medicaid	6 (8%)	1 (4%)
	Military	2 (3%)	1 (4%)
	Other	0 (0%)	0 (0%)
	None	0 (0%)	0 (0%)
*Missing data (CLC/SAP): annual household income 4 (5%)/2 (9%), total daily insulin 1 (1%)/0 (0%). All other variables have no missing data.			

Adverse Effects

The following tables provide a full list of adverse events that occurred during the main part of the DCLP5 study:

DCLP5: Types of Adverse Events by Treatment Arm (N=101)

		Number of Events	
		Control-IQ (n=78)	SAP (n=23)
Total Number of Adverse Events		16	3
Adverse Events Related to Study Device			
	Ketosis (Infusion Site Failure)	8	0
	Abscess at Sensor Site (CGM Sensor)	0	2
	Hyperglycemia (Defected Cartridge)	1	0
Adverse Effects Not Related to a Study Device			
	Hypoglycemia (User Error)	1	0
	Ketosis (User Error)	2	1
	Ketosis (Gastroenteritis)	1	0
	Hyperglycemia (User Error)	2	0
	Accidental Over-Delivery of Insulin (User Error)*	1	0
*One subject primed tubing while connected to body. This was a serious adverse event, requiring treatment in the emergency room for hypoglycemia prevention.			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

The following table provides a list of only hyperglycemia or ketosis events during the DCLP5 study:

DCLP5: Hyperglycemia/Ketosis Events by Treatment Arm (N=101)

	Number of Events	
	Control-IQ (n=78)	SAP (n=23)
Ketosis (Infusion Site Failure)	8	0
Hyperglycemia (Defected Cartridge)	1	0
Ketosis (User Error)*	2	1
Ketosis (Gastroenteritis)	1	0
Hyperglycemia (User Error) [†]	2	0
<i>*Improper cartridge fill</i> <i>[†]Failed to recharge pump battery</i>		

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used in the Control-IQ arm:

DCLP5: Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over the 4-Month Period (n=78)

	Average Time Control-IQ Available*
Weeks 1–4	93.4%
Weeks 5–8	93.8%
Weeks 9–12	94.1%
Weeks 13–End	94.4%
Overall	92.8%
<i>*Control-IQ Available is calculated as the percent of time when Control-IQ technology was available and operating normally during the 4-month study period.</i>	

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Primary Analysis

The primary outcome of the DCLP5 was to compare the CGM sensor values in range between 70 - 180 mg/dL between the Control-IQ technology arms and the SAP arms. The data represent the overall system performance 24 hours per day.

DCLP5: Comparison of CGM Values Between Control-IQ and SAP Users (N=101)

Characteristic	Control-IQ	SAP	Difference Between Study Arm and Control Arm
Average Sensor Glucose (std dev)	162 mg/dL (18 mg/dL)	179 mg/dL (26 mg/dL)	-17 mg/dL
Average % 70–180 mg/dL (std dev)	67% (10%)	55% (13%)	+11%
Average % >180 mg/dL (std dev)	31% (10%)	43% (14%)	-10%
Average % <70 mg/dL (std dev)	1.8% (1.38%)	2.1% (1.18%)	-0.40%
Average % <54 mg/dL (std dev)	0.34% (0.35%)	0.38% (0.35%)	-0.07%

The following table describes the average time participants in both the Control-IQ technology arm and the SAP arm spent with sensor glucose levels between 70 - 180 mg/dL by month at baseline and during the study period.

DCLP5: Percentage of Time in Range per Study Arm by Month (N=101)

Month	Control-IQ	SAP
Baseline	53%	51%
Month 1	68%	56%
Month 2	68%	54%
Month 3	67%	56%

DCLP5: Percentage of Time in Range per Study Arm by Month (N=101) (Continued)

Month	Control-IQ	SAP
Month 4	66%	55%

Secondary Analysis

Secondary analysis comparing the percent of time that participants spent at the indicated sensor glucose levels during the daytime and nighttime for the DCLP5 are shown below:

DCLP5: Secondary Analysis by Time of Day (N=101)

Characteristic	Unit of Measure	Daytime		Nighttime	
		Control-IQ	SAP	Control-IQ	SAP
Overall Sensor Glucose Control	Average Sensor Glucose (std dev)	167 mg/dL (21 mg/dL)	179 mg/dL (27 mg/dL)	146 mg/dL (16 mg/dL)	180 mg/dL (27 mg/dL)
	Average % Sensor Glucose 70 – 180 mg/dL (std dev)	63% (11%)	56% (14%)	80% (9%)	54% (16%)

CHAPTER 33 • Overview of Continuous Glucose Monitoring Technology Clinical Studies

The following table compares the change in HbA1c values for participants over the course of the DCLP5:

DCLP5: Change in HbA1c Values from Randomization to 16 Weeks (N=101)

			Number of Subjects (% of Subjects) with Change in HbA1c									
			Decrease >1%		Decrease 0 to 1%		No Change		Increase 0 to 1%		Increase >1%	
			n	%	n	%	n	%	n	%	n	%
Baseline Central Lab HbA1c		n										
5% ≤ HbA1c < 6%	Treatment	3	0	0%	0	0%	2	67%	1	33%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%
6% ≤ HbA1c < 7%	Treatment	18	0	0%	9	50%	1	6%	8	44%	0	0%
	Control	3	0	0%	1	33%	0	0%	2	67%	0	0%
7% ≤ HbA1c < 8%	Treatment	28	3	11%	20	71%	0	0%	5	18%	0	0%
	Control	8	0	0%	5	63%	0	0%	2	25%	1	13%
8% ≤ HbA1c < 9%	Treatment	20	11	55%	9	45%	0	0%	0	0%	0	0%
	Control	10	0	0%	7	70%	0	0%	3	30%	0	0%
9% ≤ HbA1c < 10%	Treatment	7	5	71%	1	14%	0	0%	1	14%	0	0%
	Control	1	0	0%	1	100%	0	0%	0	0%	0	0%
HbA1c ≥ 10%	Treatment	1	0	0%	1	100%	0	0%	0	0%	0	0%
	Control	1	0	0%	1	100%	0	0%	0	0%	0	0%

DCLP5: Change in HbA1c Values from Randomization to 16 Weeks (N=101) (Continued)

			Number of Subjects (% of Subjects) with Change in HbA1c									
Overall	Treatment	77	19	25%	40	52%	3	4%	15	19%	0	0%
	Control	23	0	0%	15	65%	0	0%	7	30%	1	4%

33.5 The PEDAP Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 4 months under normal conditions in preschoolers 2 to <6 years of age. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to Standard Care (SC, the control group), which included SAP therapy and multiple daily injection (MDI) therapy.

The study design was otherwise very similar to DCLP3 and DCLP5. In PEDAP, participants (N=102) were randomly assigned to Control-IQ or SC in a 2:1 ratio.

In this study, the Control-IQ arm included 69 participants, and the SC arm included 34 participants. The study population was similar to the DCLP5 in that the participants had a clinical diagnosis of type 1 diabetes, but they were younger, 2 to 5 years of age. They were treated with insulin via an insulin pump or injections for at least 6 months. They weighed at least 20

pounds (9 kilograms) and took at least 5 unites of insulin per day.

Participants were required to be living with at least one parent or guardian knowledgeable about diabetes and managing diabetes-related emergencies and willing to participate in all training sessions. No participants were enrolled in the PEDAP study who had a history of adrenal insufficiency, untreated thyroid disease, use of oral or injectable steroids within the last 8 weeks, history of chronic renal disease or currently on hemodialysis, hemophilia or any other bleeding disorder, history of >1 severe hypoglycemic event with seizure or loss of consciousness in the last 3 months, history of >1 DKA event in the last 6 months not related to illness, infusion set failure, or initial diagnosis, known ongoing adhesive intolerance, or condition, which in the opinion of the investigator or designee, would put the participant or study at risk. Concurrent use of any non-insulin glucose lowering agent (including GLP-1 agonists, Symlin, DPP-4 inhibitors, and sulfonylureas) was not allowed.

The summary statistics presented for the PEDAP describe the primary outcome measure of the sensor glucose time in range between 70 - 180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study was not designed to determine differences in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow lower weight and total daily insulin dose entry.

The primary outcome sensor time in range 70 - 180 mg/dL showed a mean adjusted difference 12.4% improvement with Control-IQ technology use of the SAP arm, very

similar to that seen in the DCLP3 and DCLP5.

There was one episode of DKA, caused by infusion site failure, in the PEDAP Control-IQ arm. There were two cases of severe hypoglycemia in the Control-IQ technology arm and one case in the SC arm. No other serious adverse events related to the device were reported.

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Baseline Characteristics

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
Age (years)				
	Mean $\pm$ SD	3.94 $\pm$ 1.24	3.84 (1.23)	4.06 (1.25)
	Range	2.00 to 5.98	2.00 to 5.98	2.02 to 5.90
	2 to <4	47 (46%)	31 (46%)	16 (47%)
	4 to <6	55 (54%)	37 (54%)	18 (53%)
Weight (kg)				
	Mean (SD)	17.7 (4.2)	17.7 (4.7)	17.7 (3.3)
	Range	11.1 to 44.7	11.1 to 44.7	11.8 to 23.9
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase				
	Median (IQR)	0.66 (0.54, 0.79)	0.66 (0.55, 0.77)	0.66 (0.51, 0.80)
	Range	0.26 to 2.12	0.26 to 2.12	0.31 to 1.64
Sex – Female n (%)		52 (51%)	33 (49%)	19 (56%)
Race / Ethnicity				

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102) (Continued)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
	White non-Hispanic	75 (74%)	50 (74%)	25 (74%)
	Black / African American	6 (6%)	4 (6%)	2 (6%)
	Asian	2 (2%)	1 (1%)	1 (3%)
	More than one race	3 (3%)	2 (3%)	1 (3%)
Income*				
	<\$50,000	14 (14%)	8 (12%)	6 (19%)
	\$50,000 – <\$100,000	31 (33%)	19 (30%)	12 (38%)
	≥\$100,000	51 (53%)	37 (57%)	14 (44%)
Parent Education				
	≤High School Diploma	9 (9%)	6 (9%)	3 (9%)
	Technical/Vocational	3 (3%)	2 (3%)	1 (3%)
	Associate Degree	11 (11%)	6 (9%)	5 (15%)
	College Graduate (Bachelor's or higher)	35 (34%)	22 (32%)	13 (38%)
	Advanced Degree (Masters, PhD, MD, etc.)	44 (43%)	32 (47%)	12 (35%)
Health Insurance				

CHAPTER 32 • Overview of Control IQ Technology Clinical Studies

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102) (Continued)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
	Private [‡]	78 (77%)	52 (76%)	26 (79%)
	CHP or another government / Medicaid [†]	22 (24%)	15 (22%)	7 (21%)
	None	1 (<1%)	1 (1%)	0 (0%)
*Missing data (CLC/SC): Health insurance 0/1, annual household income 4/2, BMI percentile 2/0, HbA1c 4/2. All other variables have no missing data. [†]For participants with Private Insurance, 7 participants also had Medicaid, 1 participant also had Medicare, and 1 participant also had other government insurance. [‡]For participants with Medicaid, 1 participant also had other government insurance.				

Adverse Effects

The following table provides a full list of adverse events that occurred during the main part of the PEDAP study.

PEDAP: Types of Adverse Events by Treatment Arm (N=102)

		Number of Events	
		Control-IQ (n=68)	SC (n=34)
Total Number of Adverse Events		71	14
Severe Hypoglycemic (SH) Events*		2	1
Diabetic Ketoacidosis (DKA) Events [†]		1	0
Other Serious Adverse Events [‡] (SAEs)		0	1
Other Adverse Events <i>N Events/N Participants</i>		68/40	12/9
	Hyperglycemia with or without Ketosis Related to Study Device	39/26	0
	Hyperglycemia with or without Ketosis Not Related to Study Device	12/9	8/7
	Hypoglycemia (not severe)	2/2	0/0
	Burn	1/1	0/0
	COVID-19	3/3	0/0
	Fall	1/1	0/0
	Fractured Finger	1/1	0/0
	Gastroenteritis	2/2	2/2
	Hematuria	1/1	0/0

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

PEDAP: Types of Adverse Events by Treatment Arm (N=102) (Continued)

		Number of Events	
		Control-IQ (n=68)	SC (n=34)
	Medical Device Site Bleeding	1/1	0/0
	Skin Infection	3/2	0/0
	Streptococcal Sore Throat	1/1	0/0
	Upper Respiratory Infection	1/1	0/0
	Vomiting	0/0	2/1
<i>*A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.</i> [†]<i>DKA events meeting DCCT criteria.</i> [‡]<i>One participant in the SC group was hospitalized for an asthma flare.</i>			

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the PEDAP trial in the intervention arm.

PEDAP Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over 13-week Period (n=68)

	Average Time Control-IQ In Use*
Weeks 1–4	92%
Weeks 5–8	95% (n=67)
Weeks 9–13	95% (n=67)
Overall	94%
<i>*The denominator is the number of days between the beginning of the fourth day after randomization and the end of the day before the 13-week visit, or the end of the day before the last contact date for the participant who dropped out.</i>	

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Primary Analysis

The primary outcome of PEDAP was to compare the CGM sensor values in range between 70 - 180 mg/dL between the Control-IQ technology arm and the SC arm. The data represent the overall system performance 24 hours per day.

PEDAP: Percent Time in Range: Primary Endpoint Tested for Superiority (N=101)

Time and Change	Control-IQ (n=67)	SC (n=34)
Baseline	57% (18)	55% (15)
13 Weeks	69% (11) (n=68)	56% (13)
Change from Baseline mean (SD)	12.5% (11.8)	1.0% (6.6)
13 week Adjusted Group Difference (95% CI) [p-value]	12.4% (9.5, 15.3) [<0.001]	

Secondary Analysis

Change in HbA1c values to baseline subgroups follows:

PEDAP: Change in HbA1c Values to Baseline Subgroups (Treatment n=59, Control n=31)

		N	Baseline mean (SD)	Change from Baseline Mean (SD)
Baseline HbA1c				
<7.0%	Treatment	21	6.4 (0.5)	-0.08 (0.33)
	Control	8	6.5 (0.3)	-0.18 (0.37)
7% ≤ HbA1c < 8%	Treatment	19	7.5 (0.3)	-0.51 (0.34)
	Control	8	7.4 (0.2)	-0.01 (0.36)
HbA1c ≥ 8%	Treatment	19	8.9 (0.9)	-1.22 (0.81)
	Control	15	8.5 (0.4)	-0.31 (0.40)
Overall	Treatment	59	8.9 (0.9)	-1.22 (0.81)
	Control	15	8.5 (0.4)	-0.31 (0.40)

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.6 The PEDAP Extension Phase

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in preschoolers 2 to <6 years of age. The PEDAP extension phase allowed participants in the preceding PEDAP RCT to continue in the trial for an additional 13 weeks during an Extension Phase (N=96), with all participants using Control-IQ use for 3 more months. A subset of participants also performed meal and exercise challenges during the study.

Participants used either Closed-Loop Control (CLC) for the RCT and the extension phase of the study (CLC-CLC), or used Standard Care (SC) for the RCT arm of the study, then switched to CLC during the extension phase (SC-CLC).

Participants in the CLC-CLC arm (N=63, those who continued with Control-IQ) were compared to the SC-CLC group (who were in the standard care arm for the RCT, who

then switched to Control-IQ for the extension, N=33).

The summary statistics presented for the PEDAP Extension Phase describe key CGM outcomes, as well as analysis of secondary endpoints.

All participants in the PEDAP extension phase used the updated Control-IQ algorithm (Control-IQ 1.5).

Key CGM outcomes showed, in the CLC-CLC group, time in range 70 - 180 mg/dL increased from 57% at PEDAP RCT baseline to 70% at the end of the 13-week RCT, and this was sustained during the Extension Phase at 70%, with no significant change comparing the CLC use in the RCT phase to CLC use in the Extension Phase.

In the SC-CLC group, time in range 70 - 180 mg/dL was 55% at the PEDAP RCT baseline, 56% during the RCT, and 68% during the Extension Phase. Comparing standard care from the RCT with use of CLC in the extension, the mean difference in time in range 70 -180 mg/dL was 11.8%.

There were two cases of severe hypoglycemia in the 63 participants in the CLC-CLC group (3%) unrelated to the study device, and no cases among the 33 participants in the SC-CLC group. No cases of DKA were reported. No other serious adverse events related to the device were reported.

Baseline Characteristics

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
Age at Beginning of Extension Phase (years)				
	Mean (SD)	4.17 (1.23)	4.10 (1.23)	4.32 (1.23)
	Range	2.30 to 6.33	2.33 to 6.33	2.35 to 6.22
	2 to <4	44 (46%)	29 (46%)	15 (45%)
	4 to <6	44 (46%)	31 (49%)	13 (39%)
	6 to <7	8 (8%)	3 (5%)	5 (15%)
Sex – Female n (%)		51 (53%)	32 (51%)	19 (58%)
Weight (kg)				
	Mean (SD)	18.5 (4.4)	18.7 (4.9)	18.2 (3.3)
	Range	12.2 to 47.2	12.7 to 47.2	12.2 to 24.4
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase				
	Median (IQR)	0.69 (0.59, 0.82)	0.69 (0.59, 0.80)	0.69 (0.55, 0.94)
	Range	0.42 to 1.70	0.42 to 1.70	0.44 to 1.38
Race / Ethnicity				

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96) (Continued)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
	White non-Hispanic	81 (84%)	53 (85%)	28 (85%)
	Black / African American	5 (5%)	3 (5%)	2 (6%)
	Asian	2 (2%)	1 (2%)	1 (3%)
	More than one race	8 (8%)	6 (10%)	2 (6%)
Hispanic Ethnicity		14 (15%)	9 (14%)	5 (15%)
Income at RCT Baseline*				
	<\$50,000	13 (14%)	7 (11%)	6 (19%)
	\$50,000 to \$100,000	31 (34%)	19 (33%)	12 (39%)
	>\$100,000	46 (51%)	33 (56%)	13 (42%)
Parent Education at RCT Baseline				
	High School graduate/diploma/GED	7 (7%)	4 (6%)	3 (9%)
	Technical/Vocational	3 (3%)	2 (3%)	1 (3%)
	Associate Degree	11 (11%)	6 (10%)	5 (15%)
	College Graduate (Bachelor's or equivalent)	34 (35%)	22 (35%)	12 (36%)
	Advanced Degree (Masters, PhD, MD, etc.)	41 (43%)	29 (46%)	12 (36%)
Health Insurance at RCT Baseline*				

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96) (Continued)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
	Private [‡]	74 (78%)	49 (78%)	25 (78%)
	Medicare / Medicaid [†]	13 (14%)	9 (14%)	4 (12%)
	Other Government Insurance	8 (8%)	5 (8%)	3 (9%)
<i>*Missing data (CLC-CLC/SC-CLC): Health insurance 0/1, annual household income 4/2. All other variables have no missing data.</i> <i>[†].For participants with Private Insurance, 6 participants also had Medicaid, 1 participant also had Medicare, and 1 participant also had other government insurance.</i> <i>[‡].For participants with Medicaid, 1 participant also had other government insurance.</i>				

CHAPTER 33 • Overview of Control-IG Technology Clinical Studies

Adverse Effects

The following table provides a full list of adverse events that occurred during the PEDAP extension phase. There were no DKA events:

Summary of Adverse Events During PEDAP Extension Phase (N=96)

		Number of Events	
		CLC-CLC (n=63)	SC-CLC (n=33)
Total Number of Adverse Events		46	29
Severe Hypoglycemic (SH) Events* <i>N Events/N Participants</i>		2/2	0/0
Other Serious Adverse Events [†] (SAEs) <i>N Events/N Participants</i>		1/1	0/0
Other Adverse Events <i>N Events/N Participants</i>		43/34	29/16
	Hyperglycemia with or without Ketosis Related to Study Device	20/18	8/8
	Hyperglycemia with or without Ketosis Not Related to Study Device	10/8	12/4
	Hypoglycemia (not severe)	1/1	0/0
	Allergy NOS	1/1	0/0
	Cellulitis	0/0	1/1
	COVID-19	3/3	0/0
	Fever	0/0	1/1
	Gastroenteritis	2/2	2/2
	Head Injury	0/0	1/1

Summary of Adverse Events During PEDAP Extension Phase (N=96) (Continued)

		Number of Events	
		CLC-CLC (n=63)	SC-CLC (n=33)
	Influenza	1/1	0/0
	Laceration	0/0	1/1
	Pneumonia	1/1	0/0
	Skin Infection	1/1	2/2
	Upper Respiratory Infection	1/1	0/0
	Viral Syndrome	1/1	0/0
	Vomiting	1/1	1/1
<i>*A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.</i> <i>†One participant in the CLC-CLC group was hospitalized for muscle pain</i>			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the PEDAP extension phase. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ 1.5).

PEDAP Extension Phase Median Percentage of Time of Closed-Loop System Use

	CLC-CLC	SC-CLC
Weeks 1–13*	94% (n=63)	NA (n=33)
Weeks 14–17	96% (n=63)	96% (n=33)
Weeks 18–21	96% (n=62)	96% (n=32)
Weeks 22–26	96% (n=61)	96% (n=31)
Weeks 14–26**	96% (n=63)	95% (n=33)
*The denominator for Weeks 1–13 is the number of days between the beginning of the fourth day after the randomization and the end of the day before the 13-week visit. **Denominator for Weeks 14–26 is the number of days between the beginning of the fourth day after the Extension Training visit and the end of the day before the 26-week visit, or the end of the day before the last contact date for the participants who dropped out.		

Key CGM Outcomes

Time in range 70 - 180 mg/dL for all phases of the trial is shown below. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ 1.5).

PEDAP Extension Phase: Percent Time in Range 70 - 180 mg/dL: Primary Endpoint Tested for Superiority (N=96)

Time and Change	CLC-CLC (n=63)	SC-CLC (n=33)
RCT Baseline	57% (18) n=62	55% (15)
Weeks 1-13	70% (11)	56% (13)
Weeks 14-26	70% (11)	68% (9)
26 week Adjusted Group Difference (95% CI) [p-value]*	0.1% (-1.2, 1.4) [0.86]	
*The point estimate and 95% confidence interval for the difference were calculated from a direct likelihood model. This model adjusted for the RCT baseline value of the metric, age, prior CGM and pump use, and site as a random effect. P-values and confidence intervals were adjusted to control the false discovery rate.		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Secondary Analysis

The following table shows secondary analysis of HbA1c outcomes. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ 1.5):

PEDAP Extension Phase: HbA1c Outcomes*

		N	Baseline mean (SD)
Baseline HbA1c			
RCT Baseline	CLC-CLC	59	7.6 (1.2)
	SC-CLC	32	7.7 (0.9)
Week 13	CLC-CLC	58	7.0 (0.7)
	SC-CLC	32	7.5 (0.9)
Week 26	CLC-CLC	55	7.1 (0.8)
	SC-CLC	28	7.2 (0.7)
*CLC-CLC group used closed-loop control for both the RCT and the extension phase. SC-CLC used standard care for the RCT and closed-loop control for the extension phase.			

33.7 The Higher-IQ Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in adults with high insulin needs.

The Higher-IQ study enrolled adults (N=34) with type 1 diabetes using at least one basal rate greater than 3 units/hour, in a single arm, prospective study of Control-IQ technology use for 13 weeks. All participants also performed meal and exercise challenges during the study.

Participants were at least 18 years of age, had type 1 diabetes for at least 1 year, were users of an insulin pump for at least 3 months, had a hemoglobin A1c 10.5% and had a weight ≤ 440 pounds.

Baseline characteristics of study participants are provided below. Participants with more than 1 episode of severe hypoglycemia or DKA in the last 6 months were not included. Females known to be pregnant were not included. Participants with

hemophilia or any other bleeding disorder, history of adrenal insufficiency, untreated thyroid disease, chronic kidney disease which could affect CGM accuracy, history of gastroparesis, or a condition, which in the opinion of the investigator or designee, would put the participant or study at risk were not included.

Treatment with sulfonylureas, meglitinides, or Symlin was not permitted. Participants taking GLP-1 receptor agonists, DPP-4 inhibitors, and/or SGLT-2 inhibitors were allowed to continue these medications if they were on a stable dose for the last 3 months,

The summary statistics presented for Higher-IQ describe key CGM outcomes, as well as analysis of change in HbA1c.

All participants in the Higher-IQ study used the updates Control-IQ algorithm (Control-IQ 1.5).

Key CGM outcomes showed time in range 70 - 180 mg/dL was 64.75% overall, with time in hypoglycemia of 1.04%.

HbA1c decreased from 7.69% at baseline to 6.87% after 13 weeks of Control-IQ use, a decrease of 0.82%.

There were no DKA or severe hypoglycemia events in the study. No other serious adverse events related to the device were reported.

CHAPTER 32 • Overview of Control-IQ Technology Clinical Studies

Higher-IQ Baseline Characteristics Including Demographics at Enrollment (N=34)

Characteristic		Single Arm Study (N=34)
Age (years)		
	Mean (SD)	39.9 (11.9)
	Range	20 to 66
Sex – Female n (%)		41.2%
Weight (kg)		
	Mean (SD)	114.8 (17.4)
	Range	85.1 to 169.3
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase		
	Median (IQR)	1.2 (0.4)
	Range	0.5 to 2.0
Race / Ethnicity		
	White non-Hispanic	34 (100%)
	Black / African American	2 (5.9%)
	Native Hawaiian or Other Pacific Islander	1 (2.9%)
Hispanic Ethnicity		3 (8.8%)
Highest Level of Education		

Higher-IQ Baseline Characteristics Including Demographics at Enrollment (N=34)

Characteristic		Single Arm Study (N=34)
	Less than high school	1 (2.9%)
	High School graduate/diploma/GED	4 (11.8%)
	Some college but no degree	8 (23.5%)
	Associate Degree	3 (8.8%)
	College Graduate (Bachelor's or equivalent)	13 (38.2%)
	Advanced Degree (Masters, PhD, MD, etc.)	5 (14.7%)

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Adverse Effects

The following table provides a full list of adverse events that occurred during the Higher-IQ study:

Higher-IQ – All Adverse Events (N=34)

		Number of Events
		All Participants Used Control-IQ
Total Number of Adverse Events		38
Severe Hypoglycemic (SH) Events*		0
Diabetic Ketoacidosis (DKA) Events [†]		0
Other Serious Adverse Events [‡] (SAEs)		1
Other Adverse Events <i>N Events/N Participants</i>		37/18
	Hyperglycemia with or without Ketosis Related to Study Device	1/1
	Hyperglycemia with or without Ketosis Not Related to Study Device	0/0
	Bronchitis	1/1
	Chronic Kidney Disease	1/1
	Cough	1/1
	COVID-19	2/2
	Dyslipidemia	1/1
	Hypertension	1/1
	Influenza	3/3
	Ligament Sprain	1/1
	Migraine	1/1

Higher-IQ – All Adverse Events (N=34) (Continued)

		Number of Events
		All Participants Used Control-IQ
	Myalgia	1/1
	Nausea/Vomiting	2/2
	Oropharyngeal Pain	1/1
	Otitis Externa	1/1
	Otitis Media	2/2
	Pharyngitis Streptococcal	1/1
	Skin Abrasion	1/1
	Sleep Apnea Syndrome	1/1
	Stiff Person Syndrome	1/1
	Tooth Abscess	1/1
	Tooth Fracture	1/1
	Tympanic Membrane Perforation	1/1
	Upper Respiratory Tract Infection	10/7
*A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions. †DKA events meeting DCCT criteria. ‡One participant was hospitalized for new onset atrial fibrillation.		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the Higher-IQ trial:

Higher-IQ Intervention Adherence over the 13-week Study Period (N=34)

	Sensor Use (%)	Closed-Loop System Use (%)
Mean (SD)	7.9%	93%

Key CGM Outcomes

Key CGM outcomes are shown below, for overall, daytime, and overnight:

Higher-IQ: Percentage of Time in Glycemic Ranges (N=34)

CGM Time in Range Mean % (SD)	Overall	Daytime	Overnight
BG 70-180mg/dL	64.75% (10.75)	63.47% (10.89)	68.47% (14.81)
BG >180mg/dL	34.21% (11.05)	35.62% (11.25)	30.09% (15.01)
BG ≥250mg/dL	10.45% (6.78)	10.74% (6.29)	9.58% (10.39)
BG 70-140mg/dL	37.87% (10.75)	36.96% (10.81)	40.55% (14.43)
BG <54mg/dL	0.20% (0.22)	0.15% (0.17)	0.35% (0.42)
BG <70 mg/dL	1.04% (0.98)	0.90% (0.90)	1.44% (1.48)

Secondary Analysis

Higher-IQ: Change in Central Lab HbA1c at 13 Weeks (N=34)

	Baseline	13 Weeks	Change from Baseline	P Value
HbA1c (%) Mean (SD)	7.69 (1.08)	6.87 (0.57)	-0.82 (0.73)	p<0.001



September 28, 2023

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SUBJECT: Tandem response to interactive questions regarding 510(k) K232382. Received via email, dated September 20, 2023

(b)(4)

(b)(4)



(b)(4)

Sincerely,

(b)(6)

Christin Dunn
Senior Regulatory Affairs Specialist



Attachments

- Attachment 1 – AW-1012259_Redline_Chapter 33 Overview of Control-IQ Technology Clinical Studies
- Attachment 2 – AW-1012259_Clean_Chapter 33 Overview of Control-IQ Technology Clinical Studies



Attachment 1

AW-1012259_Redline_Chapter 33 Overview of Control-IQ Technology Clinical Studies



(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Attachment 2

AW-1012259_Clean_Chapter 33 Overview of Control-IQ Technology Clinical Studies



(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Hi Suvajyoti,

Please see our responses to your questions attached.

(b)(4)

I will be out of office next Monday and Tuesday (October 23rd & 24th), please send any inquiries to Lan Herrington (cc'ed).

Thank you and have a great weekend,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Monday, October 16, 2023 9:55 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; k232382@docs.fda.gov

Subject: k232380 and k232382 - Tandem - Control IQ 1.5

(b)(4)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

Please see the following interactive items. Can you please provide your response and update (b)(4) documents by COB Oct 20, 2023?

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics (DAM)

Office of Science and Engineering Laboratories (OSEL)

Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

✉: Suvajyoti.Guha@fda.hhs.gov

☎: 301.796.9573



x x x x x





August 22, 2023

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SUBJECT: Tandem Response to interactive request #5 regarding 510(k) K232382. Received via email, dated August 18, 2023.

(b)(4)

Sincerely,

(b)(6)

Christin Dunn

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Hello Suvajyoti,

Please see our response to Question #5 attached.

Best Regards,

Christin

From: Christin Dunn

Sent: Friday, August 18, 2023 8:23 AM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Maiorana, Anthony <Anthony.Maiorana@fda.hhs.gov>; Balsam, Joshua <Joshua.Balsam@fda.hhs.gov>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; Lan Herrington <LHerrington@tandemdiabetes.com>

Subject: RE: K232380 and K232382 - miscellaneous interactive questions

Hi Suvajyoti,

I'm confirming receipt of your questions.

We will reach out to you if we have any questions.

Thank you,

[signature_225592142]

Christin Dunn

Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different

12400 High Bluff Drive, San Diego CA 92130

tandemdiabetes.com<<https://tandemdiabetes.com/>>

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Friday, August 18, 2023 6:59 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>; k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Maiorana, Anthony <Anthony.Maiorana@fda.hhs.gov<mailto:Anthony.Maiorana@fda.hhs.gov>>; Balsam, Joshua <Joshua.Balsam@fda.hhs.gov<mailto:Joshua.Balsam@fda.hhs.gov>>

Subject: K232380 and K232382 - miscellaneous interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Can you please respond to the following interactive questions? For 1-4 below I request that you provide your responses by COB August 25, 2023.

For response 5 below, I request that you provide your response by COB August 22, 2023 and cc our Human Factors SME Dr. Anthony Maiorana.

(b)(4)

(b)(4)

If you have any follow up questions for me related to the above, please direct them to me by 4 PM today eastern time as I will be on leave for part of next week.

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image002.png@01D9D509.5A1BBED0]<<http://www.fda.gov/>>

[cid:image003.jpg@01D9D509.5A1BBED0]<<https://www.facebook.com/FDA>>

[cid:image004.jpg@01D9D509.5A1BBED0] <<https://secure->

web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-
MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJW
vO9_SYvb8-IGlf0t1w_ADo-
yDsJptOn1rp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2
F%2Ftwitter.com%2FUS_FDA> [cid:image005.jpg@01D9D509.5A1BBED0]
<http://www.youtube.com/user/USFoodandDrugAdmin> [cid:image006.jpg@01D9D509.5A1BBED0]
<http://secure-web.cisco.com/1c6NVqVSfV2kjjznn-
U1A0J4oUTrapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdh-
QoytaqVxWfZhoJkuVQM_G5MsbRPgvSCB5PGeVwtpbhJUixavwE97sYwVt8Mo6d8v_N86E9R-
gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCy114AJqc07Gx7nhZg/http
%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image007.jpg@01D9D509.5A1BBED0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback
regarding the customer service you have received (click here<https://secure-
web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-
cE1u4gzEtucxrYj-MwioKnRxnEXGvvX1Gb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-
P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A
%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

Hi Christin and Lan,

Thanks for providing the responses.

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Friday, October 20, 2023 4:43 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; k232382@docs.fda.gov

Subject: [EXTERNAL] RE: k232380 and k232382 - Tandem - Control IQ 1.5 - (b)(4)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our responses to your questions attached.

(b)(4)

I will be out of office next Monday and Tuesday (October 23rd & 24th), please send any inquiries to Lan Herrington (cc'ed).

Thank you and have a great weekend,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Monday, October 16, 2023 9:55 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; k232382@docs.fda.gov

Subject: k232380 and k232382 - Tandem - Control IQ 1.5 - (b)(4)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

I Christin,

Please see the following interactive items. Can you please provide your response and update (b)(4) documents by COB Oct 20, 2023?

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer
Division of Applied Mechanics (DAM)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993
✉: Suvajyoti.Guha@fda.hhs.gov
☎: 301.796.9573



• ◀ ▶ ✕ ✖ ✗

Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



Hi Christin,

Attached are some edits for the 510k summary for the pump;

(b)(4)

(b)(4)

Can you please provide updated version before COB today?

Thanks and please let me know if you have any questions.

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics (DAM)

Office of Science and Engineering Laboratories (OSEL)

Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

✉: Suvajyoti.Guha@fda.hhs.gov

☎: 301.796.9573



Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

4 Control-IQ Technology Features

CHAPTER 33

Overview of Control-IQ Technology Clinical Studies

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.1 Introduction

The following data represents the clinical performance of the t:slim X2™ insulin pump with Control-IQ™ technology in multiple studies.

The first pivotal study (DCLP3) included participants ≥ 14 years old. A second pivotal study (DCLP5) included participants 6 years to 13 years old. A third pivotal study (PEDAP) included participants 2 years to < 6 years old. These three studies used the original version of Control-IQ technology (Control-IQ 1.0) and were all randomized control trials (RCTs).

Two more pivotal trials were subsequently performed. The PEDAP trial was extended for a 3-month extension phase where all participants used the study device. High insulin use was evaluated in the Higher-IQ trial, a single arm study. These two studies used an updated version of Control-IQ technology (Control-IQ 1.5).

All participants in all of these studies used the Dexcom G6 CGM.

Control-IQ technology has not been evaluated in children under 2 years of age. The safety and/or effectiveness of Control-IQ technology in children under 2 years of age is unknown.

33.2 Software Version History

Control-IQ 1.5 introduced changes to allow for a wider range of weight and total daily insulin (TDI) input. Other changes were implemented and are outlined in the table below.

Parameter	Control-IQ 1.0	Control-IQ 1.5
Minimum Total Daily Insulin Entry	10 units	5 units
Maximum Total Daily Insulin Entry	100 units	200 units
Minimum Weight Entry	55 pounds	20 pounds
Maximum Weight Entry	308 pounds	440 pounds
Correction Factor Range Accepted by Algorithm	1:10 to 1:200	1:10 to 1:600
Maximum Extended Bolus Duration	2 hours	8 hours
Temporary Basal Rates with Closed-Loop Active	No	Yes
Basal Rate Clipping*	Yes	No

**Limited to 3 units/hour when delivering programmed basal rate)*

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.3 The DCLP 3 Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 6 months under normal conditions in adults and adolescents 14 years of age or older. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to the use of sensor augmented pump (SAP) therapy alone (the control arm), labeled as Control-IQ and SAP in the tables in this section.

168 participants were randomly assigned to use Control-IQ technology or SAP for the study in a 2:1 ratio. The Control-IQ technology arm included 112 participants and the SAP arm included 56 participants. All 168 participants completed the trial.

Baseline characteristics of study participants are provided in this section. The study population consisted of patients with a clinical diagnosis of type 1 diabetes, 14 to 71 years of age, treated with insulin via an insulin pump or injections for at least one year.

Females known to be pregnant were not included.

The summary statistics presented for the DCLP3 describe the primary outcome measure of the sensor glucose time in range between 70-180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study is not designed to determine difference in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm used the original Control-IQ algorithm (Control-IQ 1.0).

The primary outcome sensor time in range 70-180 mg/dL showed a mean adjusted difference 11% improvement with Control-IQ technology use compared to the control arm.

There was one episode of Diabetic Ketoacidosis (DKA), caused by infusion site failure in the Control-IQ arm. There were no severe hypoglycemic events in the DCLP3 with Control-IQ technology use. No other serious adverse events related to the device were reported.

DCLP3: Baseline Characteristics including Demographics at Enrollment (N=168)

Characteristic		Control-IQ (n=112)	SAP (n=56)
Age (years)			
	Mean $\pm$ SD	33 $\pm$ 16	33 $\pm$ 17
	Range	14 to 71	14 to 63
	<18 years	31 (28%)	17 (30%)
	$\geq$ 18 years	81 (72%)	39 (70%)
Sex – Female n (%)		54 (48%)	30 (54%)
Race / Ethnicity*			
	White non-Hispanic	94 (86%)	53 (95%)
	Black / African American	4 (4%)	0 (0%)
	Asian	3 (3%)	2 (4%)
	Native Hawaiian / Other Pacific Islander	1 (<1%)	0 (0%)
	More than one race	7 (6%)	1 (2%)
Income [†]			
	<\$50,000	10 (11%)	2 (4%)
	\$50,000 – <\$100,000	24 (27%)	18 (36%)
	$\geq$ \$100,000	55 (62%)	30 (60%)
Education [‡]			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

DCLP3: Baseline Characteristics including Demographics at Enrollment (N=168) (Continued)

Characteristic		Control-IQ (n=112)	SAP (n=56)
	≤High School Diploma	3 (3%)	6 (11%)
	Associates Degree or Some College	13 (12%)	7 (13%)
	Bachelor's Degree	51 (46%)	21 (38%)
	Master's Degree	32 (28%)	17 (30%)
	Doctoral or Professional Degree	13 (12%)	5 (9%)
Health Insurance [§]			
	Private	102 (94%)	50 (91%)
	CHP or another government / Medicaid	5 (5%)	5 (9%)
	None	2 (2%)	0 (0%)
*Three subjects in the Control-IQ technology arm did not provide race information. †Twenty-three subjects in the Control-IQ technology arm and 6 in SAP arm did not provide income information. ‡Highest level completed by the subject, or the primary caregiver if the participant was <18 years old. One subject in the Control-IQ technology arm did not provide education information. §Three subjects in the Control-IQ technology arm and one in the SAP arm did not provide insurance information.			

Adverse Effects

The following tables provide a full list of adverse events that occurred during the main part of the DCLP3 study:

DCLP3: Types of Adverse Events by Treatment Arm (N=168)

		Number of Events	
		Control-IQ (n=112)	SAP (n=56)
Total Number of Adverse Events		13	3
Adverse Events Related to Study Device			
	Ketosis (Infusion Site Failure)	3	0
	Hyperglycemia (Infusion Site Failure)	4	2
	Hyperglycemia (Defected Cartridge)	1	0
	Diabetic Ketoacidosis (Infusion Set Failure)	1	0
Adverse Effects Not Related to a Study Device			
	Hyperglycemia (User Error)	3	0
	Hyperglycemia (Respiratory Infection)	0	1
	Coronary Bypass Surgery	1	0
	Otitis Externa	1	0
	Concussion	1	0

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Adverse Effects

The following table provides a list of only hyperglycemia or ketosis events during the DCLP3 study:

DCLP3: Hyperglycemia/Ketosis Events by Treatment Arm (N=168)

	Number of Events	
	Control-IQ (n=112)	SAP (n=56)
Ketosis (Infusion Site Failure)	3	0
Hyperglycemia (Infusion Site Failure)	4	2
Hyperglycemia (Defected Cartridge)	1	0
Diabetic Ketoacidosis (Infusion Set Failure)	1	0
Hyperglycemia (User Error)*	3	0
Hyperglycemia (Respiratory Infection)	0	1
<i>*Discontinued pump, forgot to replace</i>		

Intervention Compliance

The following table provides an overview of how often the t:slimX2 insulin pump with Control-IQ technology was used in the Control-IQ arm:

DCLP3: Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over the 6-Month Period (n=112)

	Average Pump Use*	Average Time Control-IQ Available**
Weeks 1–4	100%	91%
Weeks 5–8	99%	91%
Weeks 9–12	100%	91%
Weeks 12–16	99%	91%
Weeks 17–20	99%	91%
Weeks 21–End	99%	82%
Overall	99%	89%
<i>*The denominator is the total possible time within the 6-month study period.</i> <i>**Control-IQ Available is calculated as the percent of time when Control-IQ technology was available and operating normally during the 6-month study period.</i>		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Primary Analysis

The primary outcome of the DCLP3 was to compare the CGM sensor values in range between 70 - 180 mg/dL between the Control-IQ technology and the SAP arms. The data represent the overall system performance 24-hours per day.

DCLP3: Comparison of CGM Values Between Control-IQ and SAP Users (N=168)

Characteristic	Control-IQ	SAP	Difference Between Study Arm and Control Arm
Average Sensor Glucose (std dev)	156 mg/dL (19 mg/dL)	170 mg/dL (25 mg/dL)	-14 mg/dL
Average % 70–180 mg/dL (std dev)	71.4% (11.7%)	59.2% (14.6%)	+11%
Average % >180 mg/dL (std dev)	27% (12%)	38.5% (15.2%)	-10%
Average % <70 mg/dL (std dev)	1.59% (1.15%)	2.25% (1.46%)	-0.88%
Average % <54 mg/dL (std dev)	0.29% (0.29%)	0.35% (0.32%)	-0.10%

The following table describes the average time participants in both the Control-IQ technology arm and the SAP arm spent with sensor glucose levels between 70 - 180 mg/dL by month at baseline and during the study period:

DCLP3: Percentage of Time in Range per Study Arm by Month (N=168)

Month	Control-IQ	SAP
Baseline	61%	59%
Month 1	73%	62%
Month 2	72%	60%
Month 3	71%	60%
Month 4	72%	58%
Month 5	71%	58%
Month 6	70%	58%

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Secondary Analysis

The following table shows secondary analysis comparing the percent of time that participants spent at the indicated sensor glucose levels during the daytime and nighttime for the DCLP3:

DCLP3: Secondary Analysis by Time of Day (N=168)

Characteristic	Unit of Measure	Daytime		Nighttime	
		Control-IQ	SAP	Control-IQ	SAP
Overall Sensor Glucose Control	Average Sensor Glucose (std dev)	158 mg/dL (20 mg/dL)	170 mg/dL (26 mg/dL)	150 mg/dL (18 mg/dL)	170 mg/dL (27 mg/dL)
	Average % Sensor Glucose 70 – 180 mg/dL (std dev)	69.8% (12.4%)	59.4% (14.6%)	76.1% (12.4%)	58.5% (16.2%)

The following table compares the percent of time spent between 70 - 180 mg/dL across the different baseline HbA1c values observed in the DCLP3 study in both treatment arms:

Percentage of Time in Range per Study Arm by Baseline HbA1c (N=168)

Baseline HbA1c	Time in Range	
	Control-IQ	SAP
≤6.5	85%	78%
6.6–7.0	76%	69%
7.1–7.5	71%	49%
7.6–8.0	69%	56%
≥8.1	60%	47%

The following table compares the average HbA1c values for all DCLP3 participants at baseline, after 13 weeks, and after 26 weeks. There was a relative difference of -0.33% between the Control-IQ arm and the SAP arm:

Comparison of HbA1c Values (N=168)

Time Period	Control-IQ	SAP
Baseline	7.40	7.40
After 13 Weeks	7.02	7.36
After 26 Weeks	7.06	7.39

CHAPTER 33 • Overview of Control-IG Technology Clinical Studies

The following table compares the change in HbA1c values for participants over the course of the DCLP3:

DCLP3: Change in HbA1c Values from Randomization to 26 Weeks (N=168)

			Number of Subjects (% of Subjects) with Change in HbA1c									
			Decrease >1%		Decrease 0 to 1%		No Change		Increase 0 to 1%		Increase >1%	
			n	%	n	%	n	%	n	%	n	%
Baseline Central Lab HbA1c		n										
5% ≤ HbA1c < 6%	Treatment	8	0	0%	1	13%	0	0%	7	88%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%
6% ≤ HbA1c < 7%	Treatment	30	0	0%	18	60%	3	10%	9	30%	0	0%
	Control	19	0	0%	10	53%	0	0%	9	47%	0	0%
7% ≤ HbA1c < 8%	Treatment	45	4	9%	33	73%	2	4%	5	11%	1	2%
	Control	22	0	0%	11	50%	1	5%	8	36%	2	9%
8% ≤ HbA1c < 9%	Treatment	22	5	23%	15	68%	1	5%	1	5%	0	0%
	Control	13	0	0%	8	62%	0	0%	4	31%	1	8%
9% ≤ HbA1c < 10%	Treatment	4	1	25%	2	50%	0	0%	1	25%	0	0%
	Control	1	0	0%	0	0%	0	0%	1	100%	0	0%
HbA1c ≥ 10%	Treatment	2	2	100%	0	0%	0	0%	0	0%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%

DCLP3: Change in HbA1c Values from Randomization to 26 Weeks (N=168) (Continued)

			Number of Subjects (% of Subjects) with Change in HbA1c									
Overall	Treatment	111	12	11%	69	62%	6	5%	23	21%	1	<1%
	Control	55	0	0%	29	53%	1	2%	22	40%	3	5%

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.4 The DCLP5 Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in children age 6 to 13 years of age. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to the use of SAP therapy alone (the control group).

The study design was very similar to DCLP3. In DCLP5, participants (N=101) were randomly assigned to Control-IQ or SAP in a 3:1 ratio. In this study, the Control-IQ arm included 78 participants. Like the DCLP3, this study population had a clinical diagnosis of type 1 diabetes. Unlike the DCLP3, the DCLP5 had participants 6 to 13 years of age. They were treated with insulin via an insulin pump or injections for at least one year. They weighed ≥ 25 kilograms and ≤ 140 kilograms and took at least 10 units of insulin a day. Females known to be pregnant were not included. Participants were required to be living with at least one parent or guardian knowledgeable about

diabetes and managing diabetes-related emergencies and willing to participate in all training sessions.

No participants were enrolled in the DCLP5 study who had inpatient psychiatric treatment in the past 6 months, the presence of a known adrenal disorder, untreated thyroid disease, cystic fibrosis, severe infectious process not anticipated to resolve prior to study procedures (e.g. meningitis, pneumonia, osteomyelitis), any skin condition in the area of insertion that prevents safe sensor or pump placement (e.g. bad sunburn, pre-existing dermatitis, intertrigo, psoriasis, extensive scarring, cellulitis), abnormal liver function tests (transaminase >3 times the upper limit of normal), or abnormal renal function test results (estimated glomerular filtration rate [GFR] <60 mL/minute/1.7m²). Participants were also excluded for use of any medication, any carcinogenic disease, or other significant medical disorder if that injury, medication, or disease in the judgment of the investigator would affect the completion of the protocol.

The summary statistics presented for the DCLP5 describe the primary outcome measure of the sensor glucose time in range between 70-180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study is not designed to determine difference in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm use the original Control-IQ algorithm (Control-IQ 1.0).

There were no episodes of DKA in the DCLP5. There were no severe hypoglycemic events in the DCLP5 with Control-IQ technology use. No other serious adverse events related to the device were reported.

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
Age (years)			
	6 – 9	21 (27%)	8 (35%)
	10 – 13	57 (73%)	15 (65%)
	Median (IQR)	11 (9, 12)	10 (8, 13)
	Range	6 to 13	6 to 13
Sex – Female n (%)		38 (49%)	12 (52%)
Race / Ethnicity			
	White non-Hispanic	64 (82%)	18 (78%)
	Hispanic or Latino	6 (8%)	2 (9%)
	Black / African American	0 (0%)	0 (0%)
	Asian	1 (1%)	1 (4%)
	More than one race	7 (9%)	2 (9%)
Annual Household Income			
	<\$25,000	0 (0%)	0 (0%)
	\$25,000 – <\$35,000	2 (3%)	0 (0%)
	\$35,000 – <\$50,000	1 (1%)	2 (10%)
	\$50,000 – <\$75,000	5 (7%)	0 (0%)

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101) (Continued)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
	\$75,000 – <\$100,000	13 (18%)	4 (19%)
	\$100,000 – <\$200,000	27 (36%)	8 (38%)
	≥\$200,000	26 (35%)	7 (33%)
Parent Education			
	≤High School Diploma	2 (3%)	0 (0%)
	Associates Degree or Some College	5 (6%)	1 (4%)
	Bachelor's Degree	32 (41%)	9 (39%)
	Master's Degree	34 (44%)	11 (48%)
	Doctoral or Professional Degree	5 (6%)	2 (9%)
Health Insurance			
	Private	70 (90%)	21 (91%)
	CHP or another government / Medicaid	6 (8%)	1 (4%)
	Military	2 (3%)	1 (4%)
	Other	0 (0%)	0 (0%)
	None	0 (0%)	0 (0%)
*Missing data (CLC/SAP): annual household income 4 (5%)/2 (9%), total daily insulin 1 (1%)/0 (0%). All other variables have no missing data.			

Adverse Effects

The following tables provide a full list of adverse events that occurred during the main part of the DCLP5 study:

DCLP5: Types of Adverse Events by Treatment Arm (N=101)

		Number of Events	
		Control-IQ (n=78)	SAP (n=23)
Total Number of Adverse Events		16	3
Adverse Events Related to Study Device			
	Ketosis (Infusion Site Failure)	8	0
	Abscess at Sensor Site (CGM Sensor)	0	2
	Hyperglycemia (Defected Cartridge)	1	0
Adverse Effects Not Related to a Study Device			
	Hypoglycemia (User Error)	1	0
	Ketosis (User Error)	2	1
	Ketosis (Gastroenteritis)	1	0
	Hyperglycemia (User Error)	2	0
	Accidental Over-Delivery of Insulin (User Error)*	1	0
*One subject primed tubing while connected to body. This was a serious adverse event, requiring treatment in the emergency room for hypoglycemia prevention.			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

The following table provides a list of only hyperglycemia or ketosis events during the DCLP5 study:

DCLP5: Hyperglycemia/Ketosis Events by Treatment Arm (N=101)

	Number of Events	
	Control-IQ (n=78)	SAP (n=23)
Ketosis (Infusion Site Failure)	8	0
Hyperglycemia (Defected Cartridge)	1	0
Ketosis (User Error)*	2	1
Ketosis (Gastroenteritis)	1	0
Hyperglycemia (User Error) [†]	2	0
<i>*Improper cartridge fill</i> <i>[†]Failed to recharge pump battery</i>		

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used in the Control-IQ arm:

DCLP5: Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over the 4-Month Period (n=78)

	Average Time Control-IQ Available*
Weeks 1–4	93.4%
Weeks 5–8	93.8%
Weeks 9–12	94.1%
Weeks 13–End	94.4%
Overall	92.8%
<i>*Control-IQ Available is calculated as the percent of time when Control-IQ technology was available and operating normally during the 4-month study period.</i>	

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Primary Analysis

The primary outcome of the DCLP5 was to compare the CGM sensor values in range between 70 - 180 mg/dL between the Control-IQ technology arms and the SAP arms. The data represent the overall system performance 24 hours per day.

DCLP5: Comparison of CGM Values Between Control-IQ and SAP Users (N=101)

Characteristic	Control-IQ	SAP	Difference Between Study Arm and Control Arm
Average Sensor Glucose (std dev)	162 mg/dL (18 mg/dL)	179 mg/dL (26 mg/dL)	-17 mg/dL
Average % 70–180 mg/dL (std dev)	67% (10%)	55% (13%)	+11%
Average % >180 mg/dL (std dev)	31% (10%)	43% (14%)	-10%
Average % <70 mg/dL (std dev)	1.8% (1.38%)	2.1% (1.18%)	-0.40%
Average % <54 mg/dL (std dev)	0.34% (0.35%)	0.38% (0.35%)	-0.07%

The following table describes the average time participants in both the Control-IQ technology arm and the SAP arm spent with sensor glucose levels between 70 - 180 mg/dL by month at baseline and during the study period.

DCLP5: Percentage of Time in Range per Study Arm by Month (N=101)

Month	Control-IQ	SAP
Baseline	53%	51%
Month 1	68%	56%
Month 2	68%	54%
Month 3	67%	56%

DCLP5: Percentage of Time in Range per Study Arm by Month (N=101) (Continued)

Month	Control-IQ	SAP
Month 4	66%	55%

Secondary Analysis

Secondary analysis comparing the percent of time that participants spent at the indicated sensor glucose levels during the daytime and nighttime for the DCLP5 are shown below:

DCLP5: Secondary Analysis by Time of Day (N=101)

Characteristic	Unit of Measure	Daytime		Nighttime	
		Control-IQ	SAP	Control-IQ	SAP
Overall Sensor Glucose Control	Average Sensor Glucose (std dev)	167 mg/dL (21 mg/dL)	179 mg/dL (27 mg/dL)	146 mg/dL (16 mg/dL)	180 mg/dL (27 mg/dL)
	Average % Sensor Glucose 70 – 180 mg/dL (std dev)	63% (11%)	56% (14%)	80% (9%)	54% (16%)

CHAPTER 33 • Overview of Continuous Glucose Monitoring Technology Clinical Studies

The following table compares the change in HbA1c values for participants over the course of the DCLP5:

DCLP5: Change in HbA1c Values from Randomization to 16 Weeks (N=101)

			Number of Subjects (% of Subjects) with Change in HbA1c									
			Decrease >1%		Decrease 0 to 1%		No Change		Increase 0 to 1%		Increase >1%	
			n	%	n	%	n	%	n	%	n	%
Baseline Central Lab HbA1c		n										
5% ≤ HbA1c < 6%	Treatment	3	0	0%	0	0%	2	67%	1	33%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%
6% ≤ HbA1c < 7%	Treatment	18	0	0%	9	50%	1	6%	8	44%	0	0%
	Control	3	0	0%	1	33%	0	0%	2	67%	0	0%
7% ≤ HbA1c < 8%	Treatment	28	3	11%	20	71%	0	0%	5	18%	0	0%
	Control	8	0	0%	5	63%	0	0%	2	25%	1	13%
8% ≤ HbA1c < 9%	Treatment	20	11	55%	9	45%	0	0%	0	0%	0	0%
	Control	10	0	0%	7	70%	0	0%	3	30%	0	0%
9% ≤ HbA1c < 10%	Treatment	7	5	71%	1	14%	0	0%	1	14%	0	0%
	Control	1	0	0%	1	100%	0	0%	0	0%	0	0%
HbA1c ≥ 10%	Treatment	1	0	0%	1	100%	0	0%	0	0%	0	0%
	Control	1	0	0%	1	100%	0	0%	0	0%	0	0%

DCLP5: Change in HbA1c Values from Randomization to 16 Weeks (N=101) (Continued)

			Number of Subjects (% of Subjects) with Change in HbA1c									
Overall	Treatment	77	19	25%	40	52%	3	4%	15	19%	0	0%
	Control	23	0	0%	15	65%	0	0%	7	30%	1	4%

33.5 The PEDAP Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 4 months under normal conditions in preschoolers 2 to <6 years of age. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to Standard Care (SC, the control group), which included SAP therapy and multiple daily injection (MDI) therapy.

The study design was otherwise very similar to DCLP3 and DCLP5. In PEDAP, participants (N=102) were randomly assigned to Control-IQ or SC in a 2:1 ratio.

In this study, the Control-IQ arm included 69 participants, and the SC arm included 34 participants. The study population was similar to the DCLP5 in that the participants had a clinical diagnosis of type 1 diabetes, but they were younger, 2 to 5 years of age. They were treated with insulin via an insulin pump or injections for at least 6 months. They weighed at least 20

pounds (9 kilograms) and took at least 5 unites of insulin per day.

Participants were required to be living with at least one parent or guardian knowledgeable about diabetes and managing diabetes-related emergencies and willing to participate in all training sessions. No participants were enrolled in the PEDAP study who had a history of adrenal insufficiency, untreated thyroid disease, use of oral or injectable steroids within the last 8 weeks, history of chronic renal disease or currently on hemodialysis, hemophilia or any other bleeding disorder, history of >1 severe hypoglycemic event with seizure or loss of consciousness in the last 3 months, history of >1 DKA event in the last 6 months not related to illness, infusion set failure, or initial diagnosis, known ongoing adhesive intolerance, or condition, which in the opinion of the investigator or designee, would put the participant or study at risk. Concurrent use of any non-insulin glucose lowering agent (including GLP-1 agonists, Symlin, DPP-4 inhibitors, and sulfonylureas) was not allowed.

The summary statistics presented for the PEDAP describe the primary outcome measure of the sensor glucose time in range between 70 - 180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study was not designed to determine differences in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow lower weight and total daily insulin dose entry.

The primary outcome sensor time in range 70 - 180 mg/dL showed a mean adjusted difference 12.4% improvement with Control-IQ technology use of the SAP arm, very

similar to that seen in the DCLP3 and DCLP5.

There was one episode of DKA, caused by infusion site failure, in the PEDAP Control-IQ arm. There were two cases of severe hypoglycemia in the Control-IQ technology arm and one case in the SC arm. No other serious adverse events related to the device were reported.

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Baseline Characteristics

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
Age (years)				
	Mean $\pm$ SD	3.94 $\pm$ 1.24	3.84 (1.23)	4.06 (1.25)
	Range	2.00 to 5.98	2.00 to 5.98	2.02 to 5.90
	2 to <4	47 (46%)	31 (46%)	16 (47%)
	4 to <6	55 (54%)	37 (54%)	18 (53%)
Weight (kg)				
	Mean (SD)	17.7 (4.2)	17.7 (4.7)	17.7 (3.3)
	Range	11.1 to 44.7	11.1 to 44.7	11.8 to 23.9
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase				
	Median (IQR)	0.66 (0.54, 0.79)	0.66 (0.55, 0.77)	0.66 (0.51, 0.80)
	Range	0.26 to 2.12	0.26 to 2.12	0.31 to 1.64
Sex – Female n (%)		52 (51%)	33 (49%)	19 (56%)
Race / Ethnicity				

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102) (Continued)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
	White non-Hispanic	75 (74%)	50 (74%)	25 (74%)
	Black / African American	6 (6%)	4 (6%)	2 (6%)
	Asian	2 (2%)	1 (1%)	1 (3%)
	More than one race	3 (3%)	2 (3%)	1 (3%)
Income*				
	<\$50,000	14 (14%)	8 (12%)	6 (19%)
	\$50,000 – <\$100,000	31 (33%)	19 (30%)	12 (38%)
	≥\$100,000	51 (53%)	37 (57%)	14 (44%)
Parent Education				
	≤High School Diploma	9 (9%)	6 (9%)	3 (9%)
	Technical/Vocational	3 (3%)	2 (3%)	1 (3%)
	Associate Degree	11 (11%)	6 (9%)	5 (15%)
	College Graduate (Bachelor's or higher)	35 (34%)	22 (32%)	13 (38%)
	Advanced Degree (Masters, PhD, MD, etc.)	44 (43%)	32 (47%)	12 (35%)
Health Insurance				

CHAPTER 32 • Overview of Control IQ Technology Clinical Studies

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102) (Continued)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
	Private [‡]	78 (77%)	52 (76%)	26 (79%)
	CHP or another government / Medicaid [†]	22 (24%)	15 (22%)	7 (21%)
	None	1 (<1%)	1 (1%)	0 (0%)
<i>*Missing data (CLC/SC): Health insurance 0/1, annual household income 4/2, BMI percentile 2/0, HbA1c 4/2. All other variables have no missing data.</i> <i>[†]For participants with Private Insurance, 7 participants also had Medicaid, 1 participant also had Medicare, and 1 participant also had other government insurance.</i> <i>[‡]For participants with Medicaid, 1 participant also had other government insurance.</i>				

Adverse Effects

The following table provides a full list of adverse events that occurred during the main part of the PEDAP study.

PEDAP: Types of Adverse Events by Treatment Arm (N=102)

		Number of Events	
		Control-IQ (n=68)	SC (n=34)
Total Number of Adverse Events		71	14
Severe Hypoglycemic (SH) Events*		2	1
Diabetic Ketoacidosis (DKA) Events [†]		1	0
Other Serious Adverse Events [‡] (SAEs)		0	1
Other Adverse Events <i>N Events/N Participants</i>		68/40	12/9
	Hyperglycemia with or without Ketosis Related to Study Device	39/26	0
	Hyperglycemia with or without Ketosis Not Related to Study Device	12/9	8/7
	Hypoglycemia (not severe)	2/2	0/0
	Burn	1/1	0/0
	COVID-19	3/3	0/0
	Fall	1/1	0/0
	Fractured Finger	1/1	0/0
	Gastroenteritis	2/2	2/2
	Hematuria	1/1	0/0

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

PEDAP: Types of Adverse Events by Treatment Arm (N=102) (Continued)

		Number of Events	
		Control-IQ (n=68)	SC (n=34)
	Medical Device Site Bleeding	1/1	0/0
	Skin Infection	3/2	0/0
	Streptococcal Sore Throat	1/1	0/0
	Upper Respiratory Infection	1/1	0/0
	Vomiting	0/0	2/1
<i>*A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.</i> <i>†DKA events meeting DCCT criteria.</i> <i>‡One participant in the SC group was hospitalized for an asthma flare.</i>			

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the PEDAP trial in the intervention arm.

PEDAP Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over 13-week Period (n=68)

	Average Time Control-IQ In Use*
Weeks 1–4	92%
Weeks 5–8	95% (n=67)
Weeks 9–13	95% (n=67)
Overall	94%
<i>*The denominator is the number of days between the beginning of the fourth day after randomization and the end of the day before the 13-week visit, or the end of the day before the last contact date for the participant who dropped out.</i>	

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Primary Analysis

The primary outcome of PEDAP was to compare the CGM sensor values in range between 70 - 180 mg/dL between the Control-IQ technology arm and the SC arm. The data represent the overall system performance 24 hours per day.

PEDAP: Percent Time in Range: Primary Endpoint Tested for Superiority (N=101)

Time and Change	Control-IQ (n=67)	SC (n=34)
Baseline	57% (18)	55% (15)
13 Weeks	69% (11) (n=68)	56% (13)
Change from Baseline mean (SD)	12.5% (11.8)	1.0% (6.6)
13 week Adjusted Group Difference (95% CI) [p-value]	12.4% (9.5, 15.3) [<0.001]	

Secondary Analysis

Change in HbA1c values to baseline subgroups follows:

PEDAP: Change in HbA1c Values to Baseline Subgroups (Treatment n=59, Control n=31)

		N	Baseline mean (SD)	Change from Baseline Mean (SD)
Baseline HbA1c				
<7.0%	Treatment	21	6.4 (0.5)	-0.08 (0.33)
	Control	8	6.5 (0.3)	-0.18 (0.37)
7% ≤ HbA1c < 8%	Treatment	19	7.5 (0.3)	-0.51 (0.34)
	Control	8	7.4 (0.2)	-0.01 (0.36)
HbA1c ≥ 8%	Treatment	19	8.9 (0.9)	-1.22 (0.81)
	Control	15	8.5 (0.4)	-0.31 (0.40)
Overall	Treatment	59	8.9 (0.9)	-1.22 (0.81)
	Control	15	8.5 (0.4)	-0.31 (0.40)

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.6 The PEDAP Extension Phase

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in preschoolers 2 to <6 years of age. The PEDAP extension phase allowed participants in the preceding PEDAP RCT to continue in the trial for an additional 13 weeks during an Extension Phase (N=96), with all participants using Control-IQ use for 3 more months. A subset of participants also performed meal and exercise challenges during the study.

Participants used either Closed-Loop Control (CLC) for the RCT and the extension phase of the study (CLC-CLC), or used Standard Care (SC) for the RCT arm of the study, then switched to CLC during the extension phase (SC-CLC).

Participants in the CLC-CLC arm (N=63, those who continued with Control-IQ) were compared to the SC-CLC group (who were in the standard care arm for the RCT, who

then switched to Control-IQ for the extension, N=33).

The summary statistics presented for the PEDAP Extension Phase describe key CGM outcomes, as well as analysis of secondary endpoints.

All participants in the PEDAP extension phase used the updated Control-IQ algorithm (Control-IQ 1.5).

Key CGM outcomes showed, in the CLC-CLC group, time in range 70 - 180 mg/dL increased from 57% at PEDAP RCT baseline to 70% at the end of the 13-week RCT, and this was sustained during the Extension Phase at 70%, with no significant change comparing the CLC use in the RCT phase to CLC use in the Extension Phase.

In the SC-CLC group, time in range 70 - 180 mg/dL was 55% at the PEDAP RCT baseline, 56% during the RCT, and 68% during the Extension Phase. Comparing standard care from the RCT with use of CLC in the extension, the mean difference in time in range 70 -180 mg/dL was 11.8%.

There were two cases of severe hypoglycemia in the 63 participants in the CLC-CLC group (3%) unrelated to the study device, and no cases among the 33 participants in the SC-CLC group. No cases of DKA were reported. No other serious adverse events related to the device were reported.

Baseline Characteristics

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
Age at Beginning of Extension Phase (years)				
	Mean (SD)	4.17 (1.23)	4.10 (1.23)	4.32 (1.23)
	Range	2.30 to 6.33	2.33 to 6.33	2.35 to 6.22
	2 to <4	44 (46%)	29 (46%)	15 (45%)
	4 to <6	44 (46%)	31 (49%)	13 (39%)
	6 to <7	8 (8%)	3 (5%)	5 (15%)
Sex – Female n (%)		51 (53%)	32 (51%)	19 (58%)
Weight (kg)				
	Mean (SD)	18.5 (4.4)	18.7 (4.9)	18.2 (3.3)
	Range	12.2 to 47.2	12.7 to 47.2	12.2 to 24.4
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase				
	Median (IQR)	0.69 (0.59, 0.82)	0.69 (0.59, 0.80)	0.69 (0.55, 0.94)
	Range	0.42 to 1.70	0.42 to 1.70	0.44 to 1.38
Race / Ethnicity				

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96) (Continued)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
	White non-Hispanic	81 (84%)	53 (85%)	28 (85%)
	Black / African American	5 (5%)	3 (5%)	2 (6%)
	Asian	2 (2%)	1 (2%)	1 (3%)
	More than one race	8 (8%)	6 (10%)	2 (6%)
Hispanic Ethnicity		14 (15%)	9 (14%)	5 (15%)
Income at RCT Baseline*				
	<\$50,000	13 (14%)	7 (11%)	6 (19%)
	\$50,000 to \$100,000	31 (34%)	19 (33%)	12 (39%)
	>\$100,000	46 (51%)	33 (56%)	13 (42%)
Parent Education at RCT Baseline				
	High School graduate/diploma/GED	7 (7%)	4 (6%)	3 (9%)
	Technical/Vocational	3 (3%)	2 (3%)	1 (3%)
	Associate Degree	11 (11%)	6 (10%)	5 (15%)
	College Graduate (Bachelor's or equivalent)	34 (35%)	22 (35%)	12 (36%)
	Advanced Degree (Masters, PhD, MD, etc.)	41 (43%)	29 (46%)	12 (36%)
Health Insurance at RCT Baseline*				

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96) (Continued)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
	Private [‡]	74 (78%)	49 (78%)	25 (78%)
	Medicare / Medicaid [†]	13 (14%)	9 (14%)	4 (12%)
	Other Government Insurance	8 (8%)	5 (8%)	3 (9%)
<i>*Missing data (CLC-CLC/SC-CLC): Health insurance 0/1, annual household income 4/2. All other variables have no missing data.</i> <i>[†].For participants with Private Insurance, 6 participants also had Medicaid, 1 participant also had Medicare, and 1 participant also had other government insurance.</i> <i>[‡].For participants with Medicaid, 1 participant also had other government insurance.</i>				

CHAPTER 33 • Overview of Control-IG Technology Clinical Studies

Adverse Effects

The following table provides a full list of adverse events that occurred during the PEDAP extension phase. There were no DKA events:

Summary of Adverse Events During PEDAP Extension Phase (N=96)

		Number of Events	
		CLC-CLC (n=63)	SC-CLC (n=33)
Total Number of Adverse Events		46	29
Severe Hypoglycemic (SH) Events* <i>N Events/N Participants</i>		2/2	0/0
Other Serious Adverse Events [†] (SAEs) <i>N Events/N Participants</i>		1/1	0/0
Other Adverse Events <i>N Events/N Participants</i>		43/34	29/16
	Hyperglycemia with or without Ketosis Related to Study Device	20/18	8/8
	Hyperglycemia with or without Ketosis Not Related to Study Device	10/8	12/4
	Hypoglycemia (not severe)	1/1	0/0
	Allergy NOS	1/1	0/0
	Cellulitis	0/0	1/1
	COVID-19	3/3	0/0
	Fever	0/0	1/1
	Gastroenteritis	2/2	2/2
	Head Injury	0/0	1/1

Summary of Adverse Events During PEDAP Extension Phase (N=96) (Continued)

		Number of Events	
		CLC-CLC (n=63)	SC-CLC (n=33)
	Influenza	1/1	0/0
	Laceration	0/0	1/1
	Pneumonia	1/1	0/0
	Skin Infection	1/1	2/2
	Upper Respiratory Infection	1/1	0/0
	Viral Syndrome	1/1	0/0
	Vomiting	1/1	1/1
<i>*A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.</i> <i>†One participant in the CLC-CLC group was hospitalized for muscle pain</i>			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the PEDAP extension phase. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ 1.5).

PEDAP Extension Phase Median Percentage of Time of Closed-Loop System Use

	CLC-CLC	SC-CLC
Weeks 1–13*	94% (n=63)	NA (n=33)
Weeks 14–17	96% (n=63)	96% (n=33)
Weeks 18–21	96% (n=62)	96% (n=32)
Weeks 22–26	96% (n=61)	96% (n=31)
Weeks 14–26**	96% (n=63)	95% (n=33)
*The denominator for Weeks 1–13 is the number of days between the beginning of the fourth day after the randomization and the end of the day before the 13-week visit. **Denominator for Weeks 14–26 is the number of days between the beginning of the fourth day after the Extension Training visit and the end of the day before the 26-week visit, or the end of the day before the last contact date for the participants who dropped out.		

Key CGM Outcomes

Time in range 70 - 180 mg/dL for all phases of the trial is shown below. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ 1.5).

PEDAP Extension Phase: Percent Time in Range 70 - 180 mg/dL: Primary Endpoint Tested for Superiority (N=96)

Time and Change	CLC-CLC (n=63)	SC-CLC (n=33)
RCT Baseline	57% (18) n=62	55% (15)
Weeks 1-13	70% (11)	56% (13)
Weeks 14-26	70% (11)	68% (9)
26 week Adjusted Group Difference (95% CI) [p-value]*	0.1% (-1.2, 1.4) [0.86]	
*The point estimate and 95% confidence interval for the difference were calculated from a direct likelihood model. This model adjusted for the RCT baseline value of the metric, age, prior CGM and pump use, and site as a random effect. P-values and confidence intervals were adjusted to control the false discovery rate.		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Secondary Analysis

The following table shows secondary analysis of HbA1c outcomes. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ 1.5):

PEDAP Extension Phase: HbA1c Outcomes*

		N	Baseline mean (SD)
Baseline HbA1c			
RCT Baseline	CLC-CLC	59	7.6 (1.2)
	SC-CLC	32	7.7 (0.9)
Week 13	CLC-CLC	58	7.0 (0.7)
	SC-CLC	32	7.5 (0.9)
Week 26	CLC-CLC	55	7.1 (0.8)
	SC-CLC	28	7.2 (0.7)
*CLC-CLC group used closed-loop control for both the RCT and the extension phase. SC-CLC used standard care for the RCT and closed-loop control for the extension phase.			

33.7 The Higher-IQ Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in adults with high insulin needs.

The Higher-IQ study enrolled adults (N=34) with type 1 diabetes using at least one basal rate greater than 3 units/hour, in a single arm, prospective study of Control-IQ technology use for 13 weeks. All participants also performed meal and exercise challenges during the study.

Participants were at least 18 years of age, had type 1 diabetes for at least 1 year, were users of an insulin pump for at least 3 months, had a hemoglobin A1c 10.5% and had a weight $\leq$ 440 pounds.

Baseline characteristics of study participants are provided below. Participants with more than 1 episode of severe hypoglycemia or DKA in the last 6 months were not included. Females known to be pregnant were not included. Participants with

hemophilia or any other bleeding disorder, history of adrenal insufficiency, untreated thyroid disease, chronic kidney disease which could affect CGM accuracy, history of gastroparesis, or a condition, which in the opinion of the investigator or designee, would put the participant or study at risk were not included.

Treatment with sulfonylureas, meglitinides, or Symlin was not permitted. Participants taking GLP-1 receptor agonists, DPP-4 inhibitors, and/or SGLT-2 inhibitors were allowed to continue these medications if they were on a stable dose for the last 3 months,

The summary statistics presented for Higher-IQ describe key CGM outcomes, as well as analysis of change in HbA1c.

All participants in the Higher-IQ study used the updated Control-IQ algorithm (Control-IQ 1.5).

Key CGM outcomes showed time in range 70 - 180 mg/dL was 64.75% overall, with time in hypoglycemia of 1.04%.

HbA1c decreased from 7.69% at baseline to 6.87% after 13 weeks of Control-IQ use, a decrease of 0.82%.

There were no DKA or severe hypoglycemia events in the study. No other serious adverse events related to the device were reported.

CHAPTER 32 • Overview of Control-IQ Technology Clinical Studies

Higher-IQ Baseline Characteristics Including Demographics at Enrollment (N=34)

Characteristic		Single Arm Study (N=34)
Age (years)		
	Mean (SD)	39.9 (11.9)
	Range	20 to 66
Sex – Female n (%)		41.2%
Weight (kg)		
	Mean (SD)	114.8 (17.4)
	Range	85.1 to 169.3
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase		
	Median (IQR)	1.2 (0.4)
	Range	0.5 to 2.0
Race / Ethnicity		
	White non-Hispanic	34 (100%)
	Black / African American	2 (5.9%)
	Native Hawaiian or Other Pacific Islander	1 (2.9%)
Hispanic Ethnicity		3 (8.8%)
Highest Level of Education		

Higher-IQ Baseline Characteristics Including Demographics at Enrollment (N=34)

Characteristic		Single Arm Study (N=34)
	Less than high school	1 (2.9%)
	High School graduate/diploma/GED	4 (11.8%)
	Some college but no degree	8 (23.5%)
	Associate Degree	3 (8.8%)
	College Graduate (Bachelor's or equivalent)	13 (38.2%)
	Advanced Degree (Masters, PhD, MD, etc.)	5 (14.7%)

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Adverse Effects

The following table provides a full list of adverse events that occurred during the Higher-IQ study:

Higher-IQ – All Adverse Events (N=34)

		Number of Events
		All Participants Used Control-IQ
Total Number of Adverse Events		38
Severe Hypoglycemic (SH) Events*		0
Diabetic Ketoacidosis (DKA) Events [†]		0
Other Serious Adverse Events [‡] (SAEs)		1
Other Adverse Events <i>N Events/N Participants</i>		37/18
	Hyperglycemia with or without Ketosis Related to Study Device	1/1
	Hyperglycemia with or without Ketosis Not Related to Study Device	0/0
	Bronchitis	1/1
	Chronic Kidney Disease	1/1
	Cough	1/1
	COVID-19	2/2
	Dyslipidemia	1/1
	Hypertension	1/1
	Influenza	3/3
	Ligament Sprain	1/1
	Migraine	1/1

Higher-IQ – All Adverse Events (N=34) (Continued)

		Number of Events
		All Participants Used Control-IQ
	Myalgia	1/1
	Nausea/Vomiting	2/2
	Oropharyngeal Pain	1/1
	Otitis Externa	1/1
	Otitis Media	2/2
	Pharyngitis Streptococcal	1/1
	Skin Abrasion	1/1
	Sleep Apnea Syndrome	1/1
	Stiff Person Syndrome	1/1
	Tooth Abscess	1/1
	Tooth Fracture	1/1
	Tympanic Membrane Perforation	1/1
	Upper Respiratory Tract Infection	10/7
<i>*A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.</i> <i>†DKA events meeting DCCT criteria.</i> <i>‡One participant was hospitalized for new onset atrial fibrillation.</i>		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the Higher-IQ trial:

Higher-IQ Intervention Adherence over the 13-week Study Period (N=34)

	Sensor Use (%)	Closed-Loop System Use (%)
Mean (SD)	97.9%	93%

Key CGM Outcomes

Key CGM outcomes are shown below, for overall, daytime, and overnight:

Higher-IQ: Percentage of Time in Glycemic Ranges (N=34)

CGM Time in Range Mean % (SD)	Overall	Daytime	Overnight
BG 70-180mg/dL	64.75% (10.75)	63.47% (10.89)	68.47% (14.81)
BG >180mg/dL	34.21% (11.05)	35.62% (11.25)	30.09% (15.01)
BG ≥250mg/dL	10.45% (6.78)	10.74% (6.29)	9.58% (10.39)
BG 70-140mg/dL	37.87% (10.75)	36.96% (10.81)	40.55% (14.43)
BG <54mg/dL	0.20% (0.22)	0.15% (0.17)	0.35% (0.42)
BG <70 mg/dL	1.04% (0.98)	0.90% (0.90)	1.44% (1.48)

Secondary Analysis

Higher-IQ: Change in Central Lab HbA1c at 13 Weeks (N=34)

	Baseline	13 Weeks	Change from Baseline	P Value
HbA1c (%) Mean (SD)	7.69 (1.08)	6.87 (0.57)	-0.82 (0.73)	p<0.001

Hi Christin,

Please see the following interactive items. Can you please provide your response and updated labeling documents by COB Oct 20, 2023?

(b)(4)

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, W062 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image001.png@01DA002F.F0D84860]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA002F.F0D84860]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA002F.F0D84860] <https://twitter.com/US_FDA>

[cid:image004.jpg@01DA002F.F0D84860] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01DA002F.F0D84860] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01DA002F.F0D84860]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Thanks Christin. Thanks for the heads up on the delay.

Given the time zone difference, it would be appreciated if you can send it by 3 PM Eastern time on Oct 30, 2023. Would that be reasonable?

Thanks,
Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2223 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>
Sent: Friday, October 27, 2023 11:52 AM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Would it be possible for us to send you the labeling documents and 510(k) summaries by COB Monday, October 30th?

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Thursday, October 26, 2023 12:33 PM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov
Subject: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

I Christin,

Can you please send your finalized and complete Labeling documents and 510k summaries for the pump (k232380) and Control IQ (k232382)?

It would be great if you can send it by COB Oct 27, 2023.

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer
Division of Applied Mechanics (DAM)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993
✉: Suvajyoti.Guha@fda.hhs.gov
☎: 301.796.9573



Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



Thanks Christin.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Tuesday, September 12, 2023 2:02 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: RE: [EXTERNAL] RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our response below:

(b)(4)

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Tuesday, September 12, 2023 7:42 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: RE: [EXTERNAL] RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>
Sent: Monday, September 11, 2023 2:32 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: [EXTERNAL] RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our response to the additional questions sent on September 6th.

Thank you,
Christin

From: Christin Dunn
Sent: Wednesday, September 6, 2023 12:59 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov
Subject: RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Hi Suvajyoti,

I'm confirming receipt of the additional questions.

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Wednesday, September 6, 2023 6:34 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov
Subject: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

Can you please respond to the following interactive questions by COB Sep 11, 2023 –

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer
Division of Applied Mechanics (DAM)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993
✉: Suvajyoti.Guha@fda.hhs.gov
☎: 301.796.9573



Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



Hi Suvajyoti,

We have received FDA's decision to proceed forward with interactive review for K232380 and K232382.

Can you please let us know when we can expect to receive additional questions?

Thank You and Best Regards,



Christin Dunn
Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different
12400 High Bluff Drive, San Diego CA 92130
tandemdiabetes.com

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.



U.S. FOOD & DRUG
ADMINISTRATION

Food and Drug Administration
Office Location
Business Address
Phone Number

Premarket Notification 510(k) Review

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Hi Suvajyoti,

Please see final IFU and 510(k) summaries for K232380 and K232382 attached.

Thank you,

Christin

From: Christin Dunn

Sent: Friday, October 27, 2023 10:05 AM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Thank you, Suvajyoti!

Yes, that time is reasonable.

Have a great weekend,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Friday, October 27, 2023 8:56 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>; k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington <LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Thanks Christin. Thanks for the heads up on the delay.

Given the time zone difference, it would be appreciated if you can send it by 3 PM Eastern time on Oct 30, 2023. Would that be reasonable?

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01DA0B27.074A2260]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA0B27.074A2260] <https://www.facebook.com/FDA>
[cid:image003.jpg@01DA0B27.074A2260] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJpTOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image004.jpg@01DA0B27.074A2260]
<http://www.youtube.com/user/USFoodandDrugAdmin> [cid:image005.jpg@01DA0B27.074A2260]
<http://secure-web.cisco.com/1c6NVqVSfV2kjjnn-U1A0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdh-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCYll4AJqcO7Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image006.jpg@01DA0B27.074A2260]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvX1Gb7eTpSkXQ1VK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdhrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Sent: Friday, October 27, 2023 11:52 AM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington
<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Would it be possible for us to send you the labeling documents and 510(k) summaries by COB Monday, October 30th?

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Thursday, October 26, 2023 12:33 PM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>

Subject: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Can you please send your finalized and complete Labeling documents and 510k summaries for the pump (k232380) and Control IQ (k232382)?

It would be great if you can send it by COB Oct 27, 2023.

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, W062 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image007.png@01DA0B27.074A2260]<<http://www.fda.gov/>>

[cid:image008.jpg@01DA0B27.074A2260]<<https://www.facebook.com/FDA>>

[cid:image009.jpg@01DA0B27.074A2260] <https://twitter.com/US_FDA>

[cid:image010.jpg@01DA0B27.074A2260] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image011.jpg@01DA0B27.074A2260] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image012.jpg@01DA0B27.074A2260]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Thank you. We have received your response.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image007.png@01D9E4BD.5ACE1F30]<<http://www.fda.gov/>>

[cid:image008.jpg@01D9E4BD.5ACE1F30]<<https://www.facebook.com/FDA>>

[cid:image009.jpg@01D9E4BD.5ACE1F30] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNNlccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJptOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAxr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image010.jpg@01D9E4BD.5ACE1F30]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image011.jpg@01D9E4BD.5ACE1F30]
<http://secure-web.cisco.com/1c6NVqVSfV2kjznn-U1A0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdh-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCyl14AJqcO7Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image012.jpg@01D9E4BD.5ACE1F30]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Monday, September 11, 2023 2:32 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: [EXTERNAL] RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our response to the additional questions sent on September 6th.

Thank you,

Christin

From: Christin Dunn

Sent: Wednesday, September 6, 2023 12:59 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>

Subject: RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Hi Suvajyoti,

I'm confirming receipt of the additional questions.

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Wednesday, September 6, 2023 6:34 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>

Subject: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Can you please respond to the following interactive questions by COB Sep 11, 2023 -

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health
(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image013.png@01D9E4BD.5ACE1F30]<<http://www.fda.gov/>>

[cid:image014.jpg@01D9E4BD.5ACE1F30]<<https://www.facebook.com/FDA>>

[cid:image015.jpg@01D9E4BD.5ACE1F30] <https://twitter.com/US_FDA>

[cid:image016.jpg@01D9E4BD.5ACE1F30] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image017.jpg@01D9E4BD.5ACE1F30] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image018.jpg@01D9E4BD.5ACE1F30]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Received. Thanks Christin.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01DA0B79.7BCD9570]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA0B79.7BCD9570]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA0B79.7BCD9570] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsPtOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image004.jpg@01DA0B79.7BCD9570]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image005.jpg@01DA0B79.7BCD9570]
<http://secure-web.cisco.com/1c6NVqVSfv2kjjznn-U1A0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdh-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLomGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCyll4AJqcO7Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image006.jpg@01DA0B79.7BCD9570]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdhrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Monday, October 30, 2023 8:48 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; David Berger <DBerger@tandemdiabetes.com>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

My apologies, please see IFU and 510(k) summaries as 3 separate files attached.

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>>

Sent: Monday, October 30, 2023 5:14 PM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington
<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ -
Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when
responding, opening attachments, or clicking links.

Hi Christin,

My apologies. Usually, in our final stages of finalization, we need these documents as
separate attachments. Can you resend the following as separate documents?

1. Finalized label - user guide (one since it's the same one for both submissions
k232380 and k232382)
2. 510k summary for k232380
3. 510k summary for k232382

I can generate the IFU form on my end, so that won't be necessary.

I tried to print them separately as three PDFs but could not, probably because its
protected on your end? Below is the error I keep getting. If you can send the above
request first thing tomorrow morning (10/31) that would be much appreciated.

[cid:image007.png@01DA0B79.7BCD9570]

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01DA0B79.7BCD9570]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA0B79.7BCD9570]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA0B79.7BCD9570] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8T07yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJpTOn1rp90Xo0UwJUyB1bVEkc2HcBqPoCs9g9N_NFMoHDXAr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image004.jpg@01DA0B79.7BCD9570]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image005.jpg@01DA0B79.7BCD9570]
<https://secure-web.cisco.com/1c6NVqVSfv2kjznn-UlA0J4oUTRapVCu10_n_AyTYEq2nEyp_lnxIiz0fkdh-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEXYi07VdBOzWewttCYH7Gm0I2nqxYQoCYll4AJqc07Gx7nhZg/http>

%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image006.jpg@01DA0B79.7BCD9570]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/ldVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRrxrnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Sent: Monday, October 30, 2023 2:50 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington
<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see final IFU and 510(k) summaries for K232380 and K232382 attached.

Thank you,

Christin

From: Christin Dunn

Sent: Friday, October 27, 2023 10:05 AM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington
<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Thank you, Suvajyoti!

Yes, that time is reasonable.

Have a great weekend,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Friday, October 27, 2023 8:56 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington

<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Thanks Christin. Thanks for the heads up on the delay.

Given the time zone difference, it would be appreciated if you can send it by 3 PM Eastern time on Oct 30, 2023. Would that be reasonable?

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01DA0B79.7BCD9570]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA0B79.7BCD9570]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA0B79.7BCD9570] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8T07yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJpTOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image004.jpg@01DA0B79.7BCD9570]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image005.jpg@01DA0B79.7BCD9570]
<http://secure-web.cisco.com/1c6NVqVSfV2kjjzn-U1A0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkDH-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCyll4AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image006.jpg@01DA0B79.7BCD9570]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAKeqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdhrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Sent: Friday, October 27, 2023 11:52 AM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington
<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Would it be possible for us to send you the labeling documents and 510(k) summaries by COB Monday, October 30th?

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Thursday, October 26, 2023 12:33 PM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;

k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>

Subject: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Can you please send your finalized and complete Labeling documents and 510k summaries for the pump (k232380) and Control IQ (k232382)?

It would be great if you can send it by COB Oct 27, 2023.

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, W062 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>

?: 301.796.9573

[cid:image008.png@01DA0B79.7BCD9570]<<http://www.fda.gov/>>

[cid:image009.jpg@01DA0B79.7BCD9570]<<https://www.facebook.com/FDA>>

[cid:image010.jpg@01DA0B79.7BCD9570] <https://twitter.com/US_FDA>

[cid:image011.jpg@01DA0B79.7BCD9570] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image012.jpg@01DA0B79.7BCD9570] <<http://www.flickr.com/photos/fdapictures/>>

[cid:image013.jpg@01DA0B79.7BCD9570]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



Food and Drug Administration
Office Location
Business Address
Phone Number

Premarket Notification 510(k) Review

Post-Review Reminders

☐ For SE Decisions: Upload SE Letter, and PDFs of IFU form and 510(k) Summary (if included) in DocMan.

To add reminders, type the reminder in the text field to the left then press the Tab key.

Date: November 1, 2023			
Reviewer: Suvajyoti Guha			
510(k)# K232380 Subject: Traditional			
Applicant: Tandem Diabetes Care, Inc.		Device Trade Name: t:slim X2 Insulin Pump with Interoperable Technology (with t:connect Mobile App)	
Contact Name: Christin Dunn		Contact Title: Senior Regulatory Affairs Specialist	
Correspondent Firm: Tandem Diabetes Care, Inc.		Phone: (858) 401-1641 Email: cdunn@tandemdiabetes.com	
Received Date: August 8, 2023		Due Date: November 6, 2023	
Pro Code(s): QFG Class: II Reg #: 880.5730		Reg Name: Alternate Controller Enabled Infusion Pump	
Predicate Devices:			
Submission #	Pro Code	Device Trade Name	Applicant
K203234	QFG	t:slim X2 Insulin Pump with Interoperable Technology (with t:connect mobile app)	Tandem Diabetes Care, Inc.

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)



U.S. FOOD & DRUG
ADMINISTRATION

Build Correspondence

Convert to PDF

Tandem Diabetes Care, Inc.
Christin Dunn
Senior Regulatory Affairs Specialist
12400 High Bluff Drive
San Diego, California 92130

Re: K232380

Trade/Device Name: t:slim X2 Insulin Pump with Interoperable Technology

Regulation Number: 21 CFR 880.5730

Regulation Name: Alternate Controller Enabled Infusion Pump

Regulatory Class: Class II

Product Code: QFG

Dated: August 4, 2023

Received: August 8, 2023

Dear Christin Dunn:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Hi Christin,

Please see the following interactive items. Can you please provide your response and updated (b)(4) documents by COB Oct 20, 2023?

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer
Division of Applied Mechanics (DAM)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993
✉: Suvajyoti.Guha@fda.hhs.gov
☎: 301.796.9573



x > x x v

Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Hi Suvajyoti,

Please see our response to the three (b)(4) questions attached.

Best Regards,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Thursday, September 21, 2023 9:06 AM

To: Lan Herrington <LHerrington@tandemdiabetes.com>; Christin Dunn
<CDunn@tandemdiabetes.com>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov

Subject: K232382 - Tandem - Control IQ 1.5 - (b)(4)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi,

(b)(4)

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01D9F21E.591EED40]<<http://www.fda.gov/>>

[cid:image002.jpg@01D9F21E.591EED40]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01D9F21E.591EED40] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf81gYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_1x9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDs_jPtOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image004.jpg@01D9F21E.591EED40]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image005.jpg@01D9F21E.591EED40]
<http://secure-web.cisco.com/1c6NVqVSfv2kjznn-U1A0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdH-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgiMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBoRwewttCYH7Gm0I2nqxYQoCyll4AJqcO7Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image006.jpg@01D9F21E.591EED40]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvX1Gb7eTpSkXQ1VK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-P64NYh2n8dNKlev2arzrrrUMGgDJPDQ06jlP_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).



TANDEM
Diabetes Care

510(K) SUMMARY

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Thanks Lan. We have received your response.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01DA05C5.CC903530]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA05C5.CC903530]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA05C5.CC903530] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_Syvb8-IGlf0t1w_ADo-yDsJpTOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAxR6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image004.jpg@01DA05C5.CC903530]

[cid:image005.jpg@01DA05C5.CC903530]

<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image005.jpg@01DA05C5.CC903530]

<http://secure-web.cisco.com/1c6NVqVSfV2kjznn-UlA0J4oUTRapVCu10_n_AyTYEq2nEyp_lnxIiz0fkdh-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgiMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCyll4AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image006.jpg@01DA05C5.CC903530]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-P64NYh2n8dNKlev2arzrrrUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdhrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Lan Herrington <LHerrington@tandemdiabetes.com>
Sent: Monday, October 23, 2023 3:26 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232380@docs.fda.gov; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; k232382@docs.fda.gov; Christin Dunn <CDunn@tandemdiabetes.com>
Subject: [EXTERNAL] RE: k232380 and k232382 - Tandem - Control IQ 1.5 - (b)(4)

(b)(4)

(b)(4)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello Suvajyoti,

(b)(4)

(b)(4)

Thanks.

Lan

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Monday, October 23, 2023 11:23 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington
<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>;
k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>

Subject: RE: k232380 and k232382 - Tandem - Control IQ 1.5 - (b)(4)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin and Lan,

Thanks for providing the responses.

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01DA05C5.CC903530]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA05C5.CC903530]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA05C5.CC903530] <<https://secure->

web.cisco.com/1WRRqguZ08h8HWOWMxJVQ1slo6cm-
MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJW
vO9_SYvb8-IGlf0t1w_ADo-
yDsJptOn1rp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2
F%2Ftwitter.com%2FUS_FDA> [cid:image004.jpg@01DA05C5.CC903530]
<http://www.youtube.com/user/USFoodandDrugAdmin> [cid:image005.jpg@01DA05C5.CC903530]
<http://secure-web.cisco.com/1c6NVqVSfV2kjznn-
U1A0J4oUTrapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdH-
QoytaqVxWfZhoJkuVQM_G5MsbRPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-
gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBoRwewttCYH7Gm0I2nqxYQoCYl14AJqc07Gx7nhZg/http
%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image006.jpg@01DA05C5.CC903530]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback
regarding the customer service you have received (click here<https://secure-
web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-
cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-
P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A
%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Sent: Friday, October 20, 2023 4:43 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington
<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>;
k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>

Subject: [EXTERNAL] RE: k232380 and k232382 - Tandem - Control IQ 1.5 - (b)(4)
(b)(4)

CAUTION: This email originated from outside of the organization. Do not click links or
open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our responses to your questions attached.

(b)(4)

I will be out of office next Monday and Tuesday (October 23rd & 24th), please send any
inquiries to Lan Herrington (cc'ed).

Thank you and have a great weekend,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Monday, October 16, 2023 9:55 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>;
k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>

Subject: k232380 and k232382 - Tandem - Control IQ 1.5 - (b)(4)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Please see the following interactive items. Can you please provide your response and updated (b)(4) documents by COB Oct 20, 2023?

(b)(4)

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image007.png@01DA05C5.CC903530]<<http://www.fda.gov/>>

[cid:image008.jpg@01DA05C5.CC903530]<<https://www.facebook.com/FDA>>

[cid:image009.jpg@01DA05C5.CC903530] <https://twitter.com/US_FDA>

[cid:image010.jpg@01DA05C5.CC903530] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image011.jpg@01DA05C5.CC903530] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image012.jpg@01DA05C5.CC903530]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here

<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Hi Suvajyoti,

We have received FDA's decision to proceed forward with interactive review for K232380 and K232382.

Can you please let us know when we can expect to receive additional questions?

Thank You and Best Regards,

[signature_225592142]

Christin Dunn

Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different

12400 High Bluff Drive, San Diego CA 92130

tandemdiabetes.com<<https://tandemdiabetes.com/>>

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

Hi Christin and Lan,

Thanks for providing the responses.

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image007.png@01DA05BC.370361D0]<<http://www.fda.gov/>>

[cid:image008.jpg@01DA05BC.370361D0]<<https://www.facebook.com/FDA>>

[cid:image009.jpg@01DA05BC.370361D0] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJpOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAxr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA>

[cid:image010.jpg@01DA05BC.370361D0] <<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image011.jpg@01DA05BC.370361D0] <http://secure-web.cisco.com/1c6NVqVSfv2kjznn-U1A0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkDH-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLomGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCyl14AJqcO7Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F>

[cid:image012.jpg@01DA05BC.370361D0] <<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RmiAwVZr-cElu4gzEtucxrYj-MwioKnRrxnEXGvvXlGb7eTpSkXQlVK2YAisGWCTEweL2ygi-yMZWf9-0wUmd-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Friday, October 20, 2023 4:43 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; k232382@docs.fda.gov

Subject: [EXTERNAL] RE: k232380 and k232382 - Tandem - Control IQ 1.5 -

(b)(4)

(b)(4)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Please see our responses to your questions attached.

(b)(4)

I will be out of office next Monday and Tuesday (October 23rd & 24th), please send any inquiries to Ian Herrington (cc'ed).

Thank you and have a great weekend,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Monday, October 16, 2023 9:55 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>;
k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>

Subject: k232380 and k232382 - Tandem - Control IQ 1.5 - **(b)(4)**

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Please see the following interactive items. Can you please provide your response and updated **(b)(4)** documents by COB Oct 20, 2023?

(b)(4)

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image013.png@01DA05BC.370361D0]<<http://www.fda.gov/>>

[cid:image014.jpg@01DA05BC.370361D0]<<https://www.facebook.com/FDA>>

[cid:image015.jpg@01DA05BC.370361D0] <https://twitter.com/US_FDA>

[cid:image016.jpg@01DA05BC.370361D0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image017.jpg@01DA05BC.370361D0] <<http://www.flickr.com/photos/fdapotos/>>

[cid:image018.jpg@01DA05BC.370361D0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



August 25, 2023

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SUBJECT: Tandem Response to interactive request regarding 510(k)s K232380 and K232382. Received via email, dated August 18, 2023.

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Sincerely,

(b)(6)

Christin Dunn
Senior Regulatory Affairs Specialist
cdunn@tandemdiabetes.com

Attachments

(b)(4)



Hi Suvajyoti,

Please see our response below:

(b)(4)

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Tuesday, September 12, 2023 7:42 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington
<LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: RE: [EXTERNAL] RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 -
interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when
responding, opening attachments, or clicking links.

Hi Christin,

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01D9E55C.B103ABA0]<<http://www.fda.gov/>>

[cid:image002.jpg@01D9E55C.B103ABA0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01D9E55C.B103ABA0] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJpTOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA>

[cid:image004.jpg@01D9E55C.B103ABA0]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image005.jpg@01D9E55C.B103ABA0]

<http://secure-web.cisco.com/1c6NVqVSfV2kjznn-U1A0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdh-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCy1l4AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image006.jpg@01D9E55C.B103ABA0]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Sent: Monday, September 11, 2023 2:32 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington
<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: [EXTERNAL] RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our response to the additional questions sent on September 6th.

Thank you,

Christin

From: Christin Dunn

Sent: Wednesday, September 6, 2023 12:59 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>

Subject: RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Hi Suvajyoti,

I'm confirming receipt of the additional questions.

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Wednesday, September 6, 2023 6:34 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>

Subject: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Can you please respond to the following interactive questions by COB Sep 11, 2023 -

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>

?: 301.796.9573

[cid:image007.png@01D9E55C.B103ABA0]<<http://www.fda.gov/>>

[cid:image008.jpg@01D9E55C.B103ABA0]<<https://www.facebook.com/FDA>>

[cid:image009.jpg@01D9E55C.B103ABA0] <https://twitter.com/US_FDA>

[cid:image010.jpg@01D9E55C.B103ABA0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image011.jpg@01D9E55C.B103ABA0] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image012.jpg@01D9E55C.B103ABA0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Hi Christin,

Can you please respond to the following interactive questions? For 1-4 below I request that you provide your responses by COB August 25, 2023.

For response 5 below, I request that you provide your response by COB August 22, 2023 and cc our Human Factors SME Dr. Anthony Maiorana.

(b)(4)

(b)(4)

If you have any follow up questions for me related to the above, please direct them to me by 4 PM today eastern time as I will be on leave for part of next week.

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image007.png@01D9D123.6A212D40]<<http://www.fda.gov/>>

[cid:image008.jpg@01D9D123.6A212D40]<<https://www.facebook.com/FDA>>

[cid:image009.jpg@01D9D123.6A212D40] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJtOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2

yDsJtOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2

F%2Ftwitter.com%2FUS_FDA> [cid:image010.jpg@01D9D123.6A212D40]
<http://www.youtube.com/user/USFoodandDrugAdmin> [cid:image011.jpg@01D9D123.6A212D40]
<http://secure-web.cisco.com/1c6NVqVSfV2kjznn-
U1A0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdh-
QoytaqVxWfZhoJkuVQM_G5MsbRPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-
gePHDDPgiMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBorWewttCYH7Gm0I2nqxYQoCYl14AJqcO7Gx7nhZg/http
%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image012.jpg@01D9D123.6A212D40]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06jlP_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).



DECLARATION OF CONFORMITY

a. Name and address of the applicant/sponsor responsible for the DOC

Tandem Diabetes Care, Inc.
12400 High Bluff Drive, San Diego, CA, U.S.A. 92130

b. Product/device identification, including product codes, device marketing name, model number and any other unique product identification data specific to the DOC in question

General Name: interoperable automated glycemic controller
Product Code: QJI
Device Marketing Name: Control-IQ Technology

c. Statement of Conformity

Tandem Diabetes Care, Inc. applied the use of ANSI AAMI IEC 62304:2006/A1:2016 *Medical Device Software - Software Life Cycle Processes [Including Amendment 1 (2016)]* (FDA Recognition Number 13-79)
Tandem hereby declares full conformity to this standard where appropriate.

d. A list of standards for which the DOC applies including, for each standard, the options selected, if any

ANSI/AAMI/IEC 62304:2006 & A1:2016

e. The FDA recognition number for each standard

ANSI AAMI IEC 62304:2006/A1:2016 (FDA Recognition Number 13-79)

f. Date and Place of Issuance

August 7, 2023, Tandem Diabetes Care, Inc.

g. Signature, printed name, and function of the sponsor responsible for the DOC

Carolyn Nguyen, Manager, Quality Engineering, Tandem
Diabetes Care, Inc.

(b)(6)

Carolyn Nguyen

Signature

Printed Name

h. Any limitation on the validity of the DOC (e.g., how long the declaration is valid, what was tested, or concessions made about the testing)



TANDEM
Diabetes Care

outcomes)

This Declaration is valid only for the present Traditional 510(k) submission into which it is incorporated.

Indications for Use

510(k) Number (if known)

k232380

Device Name

t:slim X2 Insulin Pump with Interoperable Technology

Indications for Use (Describe)

The t:slim X2 Insulin Pump with Interoperable Technology (the pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use in individuals 2 years of age and greater.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

(b)(4)

Suvajyoti Guha

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Tuesday, October 31, 2023 1:22 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: [EXTERNAL] RE: k232380 - Tandem - ACE Pump - Edits for 510k summary

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Request received.

(b)(4)

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Tuesday, October 31, 2023 10:18 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>

Subject: k232380 - Tandem - ACE Pump - Edits for 510k summary

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

Attached are some edits for the 510k summary for the pump.

(b)(4)

(b)(4)

Can you please provide updated version before COB today?

Thanks and please let me know if you have any questions.

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics (DAM)

Office of Science and Engineering Laboratories (OSEL)

Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

✉: Suvajyoti.Guha@fda.hhs.gov

☎: 301.796.9573



Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



TANDEM
Diabetes Care

510(K) SUMMARY

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Hi Christina and Lan,

Congratulations on the clearance of the t-slim pump and the Control IQ 1.5

(b)(4)

(b)(4)

(b)(4)

Thanks, and please let us know if you have any follow up questions on these two feedbacks.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

Hi again Christin,

(b)(4)

(b)(4)

Here is our availability for next week –

- Tuesday 2-2:30 PM, 3-4 PM Eastern
- Wednesday 11 AM – 12 noon Eastern, 3:30 – 4:00 PM eastern
- Thursday 1:30 – 3:30 PM Eastern

Can you please let me know your preferred time slot at your earliest convenience, preferably by today/tomorrow?

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics (DAM)

Office of Science and Engineering Laboratories (OSEL)

Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

✉: Suvajyoti.Guha@fda.hhs.gov

☎: 301.796.9573



Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Thank you, Suvajyoti!

Yes, that time is reasonable.

Have a great weekend,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Friday, October 27, 2023 8:56 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Thanks Christin. Thanks for the heads up on the delay.

Given the time zone difference, it would be appreciated if you can send it by 3 PM Eastern time on Oct 30, 2023. Would that be reasonable?

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01DA08BD.104EECE0]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA08BD.104EECE0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA08BD.104EECE0] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQlslo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvo9_SYvb8-IGlf0t1w_ADo-yDsJptOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA>

[cid:image004.jpg@01DA08BD.104EECE0] <https://secure-web.cisco.com/1c6NVqVSfV2kjjznn-UlA0J4oUTRapVCu10_n_AyTYEq2nEyp_lnxIiz0fkdh-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwe97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBorWewttCYH7Gm0I2nqxYQoCyll4AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F>

[cid:image005.jpg@01DA08BD.104EECE0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image006.jpg@01DA08BD.104EECE0] <http://secure-web.cisco.com/1c6NVqVSfV2kjjznn-UlA0J4oUTRapVCu10_n_AyTYEq2nEyp_lnxIiz0fkdh-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwe97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBorWewttCYH7Gm0I2nqxYQoCyll4AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F>

[cid:image007.jpg@01DA08BD.104EECE0] <<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcfDahwMwBML-UZHWKC3RMiAwVZr-cElu4gz2EtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-P64NYh2n8dNKlev2arzrrrUMGgDJPdQ06j1P_IeF_3WlUE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdhrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>
Sent: Friday, October 27, 2023 11:52 AM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>
Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>; k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington <LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>
Subject: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Would it be possible for us to send you the labeling documents and 510(k) summaries by COB Monday, October 30th?

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>
Sent: Thursday, October 26, 2023 12:33 PM
To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>
Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>; k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>
Subject: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Can you please send your finalized and complete Labeling documents and 510k summaries for the pump (k232380) and Control IQ (k232382)?

It would be great if you can send it by COB Oct 27, 2023.

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics
(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories
(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health
(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>

?: 301.796.9573

[cid:image007.png@01DA08BD.104EECE0]<<http://www.fda.gov/>>

[cid:image008.jpg@01DA08BD.104EECE0]<<https://www.facebook.com/FDA>>

[cid:image009.jpg@01DA08BD.104EECE0] <https://twitter.com/US_FDA>

[cid:image010.jpg@01DA08BD.104EECE0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image011.jpg@01DA08BD.104EECE0] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image012.jpg@01DA08BD.104EECE0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Hi Suvajyoti,

Please see our response to questions 1-4 attached.

Have a great weekend!

Best Regards,
Christin

From: Christin Dunn
Sent: Tuesday, August 22, 2023 3:03 PM
To: 'Guha, Suvajyoti' <Suvajyoti.Guha@fda.hhs.gov>
Cc: 'k232382@docs.fda.gov' <k232382@docs.fda.gov>; 'k232380@docs.fda.gov' <k232380@docs.fda.gov>; 'Maiorana, Anthony' <Anthony.Maiorana@fda.hhs.gov>; 'Balsam, Joshua' <Joshua.Balsam@fda.hhs.gov>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; Lan Herrington <LHerrington@tandemdiabetes.com>
Subject: RE: K232380 and K232382 - miscellaneous interactive questions

Hello Suvajyoti,

Please see our response to Question #5 attached.

Best Regards,
Christin

From: Christin Dunn
Sent: Friday, August 18, 2023 8:23 AM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Maiorana, Anthony <Anthony.Maiorana@fda.hhs.gov>; Balsam, Joshua <Joshua.Balsam@fda.hhs.gov>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; Lan Herrington <LHerrington@tandemdiabetes.com>
Subject: RE: K232380 and K232382 - miscellaneous interactive questions

Hi Suvajyoti,

I'm confirming receipt of your questions.

We will reach out to you if we have any questions.

Thank you,



Christin Dunn
Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different
12400 High Bluff Drive, San Diego CA 92130
tandemdiabetes.com

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Friday, August 18, 2023 6:59 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Maiorana, Anthony <Anthony.Maiorana@fda.hhs.gov>; Balsam, Joshua <Joshua.Balsam@fda.hhs.gov>
Subject: K232380 and K232382 - miscellaneous interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

Can you please respond to the following interactive questions? For 1-4 below I request that you provide your responses by COB **August 25, 2023**.

For response 5 below, I request that you provide your response by COB **August 22, 2023** and cc our Human Factors SME Dr. Anthony Maiorana.

Questions? Contact FDA/CDRH/CBER/CDT at CDH1C@FDA.US@fda.hhs.gov or 301-796-8118

(b)(4)

(b)(4)

If you have any follow up questions for me related to the above, please direct them to me by 4 PM today eastern time as I will be on leave for part of next week.

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).



Hi Christin,

Can you please respond to the following interactive questions? For 1-4 below I request that you provide your responses by COB **August 25, 2023**.

For response 5 below, I request that you provide your response by **COB August 22, 2023** and cc our Human Factors SME Dr. Anthony Maiorana.

(b)(4)

If you have any follow up questions for me related to the above, please direct them to me by 4 PM today eastern time as I will be on leave for part of next week.

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10963 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

Received. Thanks!

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Friday, August 25, 2023 2:05 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Maiorana, Anthony <Anthony.Maiorana@fda.hhs.gov>; Balsam, Joshua <Joshua.Balsam@fda.hhs.gov>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; Lan Herrington <LHerrington@tandemdiabetes.com>

Subject: [EXTERNAL] RE: K232380 and K232382 - miscellaneous interactive questions

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our response to questions 1-4 attached.

Have a great weekend!

Best Regards,

Christin

From: Christin Dunn

Sent: Tuesday, August 22, 2023 3:03 PM

To: 'Guha, Suvajyoti' <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: 'k232382@docs.fda.gov' <k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>>; 'k232380@docs.fda.gov' <k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>>; 'Maiorana, Anthony' <Anthony.Maiorana@fda.hhs.gov<mailto:Anthony.Maiorana@fda.hhs.gov>>; 'Balsam, Joshua' <Joshua.Balsam@fda.hhs.gov<mailto:Joshua.Balsam@fda.hhs.gov>>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>; Lan Herrington <LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>

Subject: RE: K232380 and K232382 - miscellaneous interactive questions

Hello Suvajyoti,

Please see our response to Question #5 attached.

Best Regards,

Christin

From: Christin Dunn

Sent: Friday, August 18, 2023 8:23 AM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>; k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Maiorana, Anthony <Anthony.Maiorana@fda.hhs.gov<mailto:Anthony.Maiorana@fda.hhs.gov>>; Balsam, Joshua <Joshua.Balsam@fda.hhs.gov<mailto:Joshua.Balsam@fda.hhs.gov>>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>; Lan Herrington <LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>

Subject: RE: K232380 and K232382 - miscellaneous interactive questions

Hi Suvajyoti,

I'm confirming receipt of your questions.

We will reach out to you if we have any questions.

Thank you,

[signature_225592142]

Christin Dunn

Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different

12400 High Bluff Drive, San Diego CA 92130

tandemdiabetes.com<<https://tandemdiabetes.com/>>

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Friday, August 18, 2023 6:59 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Maiorana, Anthony
<Anthony.Maiorana@fda.hhs.gov<mailto:Anthony.Maiorana@fda.hhs.gov>>; Balsam, Joshua
<Joshua.Balsam@fda.hhs.gov<mailto:Joshua.Balsam@fda.hhs.gov>>

Subject: K232380 and K232382 - miscellaneous interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Can you please respond to the following interactive questions? For 1-4 below I request that you provide your responses by COB August 25, 2023.

For response 5 below, I request that you provide your response by COB August 22, 2023 and cc our Human Factors SME Dr. Anthony Maiorana.

(b)(4)

(b)(4)

(b)(4)

If you have any follow up questions for me related to the above, please direct them to me by 4 PM today eastern time as I will be on leave for part of next week.

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image002.png@01D9D770.E152F6C0]<<http://www.fda.gov/>>

[cid:image003.jpg@01D9D770.E152F6C0]<<https://www.facebook.com/FDA>>

[cid:image004.jpg@01D9D770.E152F6C0] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0tlw_ADo-yDs_jPtOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA>

[cid:image005.jpg@01D9D770.E152F6C0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image006.jpg@01D9D770.E152F6C0] <http://secure-web.cisco.com/1c6NVqVSfV2kjznn-UlA0J4oUTRapVCu10_n_AyTYEq2nEyp_lnxIiz0fkdH-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCYll4AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F>

[cid:image007.jpg@01D9D770.E152F6C0] <<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAKEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3WlUE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

Hi Christin,

My apologies. Usually, in our final stages of finalization, we need these documents as separate attachments. Can you resend the following as separate documents?

1. Finalized label –user guide (one since it's the same one for both submissions k232380 and k232382)
2. 510k summary for k232380
3. 510k summary for k232382

I can generate the IFU form on my end, so that won't be necessary.

I tried to print them separately as three PDFs but could not, probably because its protected on your end? Below is the error I keep getting. If you can send the above request first thing tomorrow morning (10/31) that would be much appreciated.



Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10963 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Monday, October 30, 2023 2:50 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see final IFU and 510(k) summaries for K232380 and K232382 attached.

Thank you,
Christin

From: Christin Dunn

Sent: Friday, October 27, 2023 10:05 AM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Thank you, Suvajyoti!

Yes, that time is reasonable.

Have a great weekend,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Friday, October 27, 2023 8:56 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Thanks Christin. Thanks for the heads up on the delay.

Given the time zone difference, it would be appreciated if you can send it by 3 PM Eastern time on Oct 30, 2023. Would that be reasonable?

Thanks,
Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Friday, October 27, 2023 11:52 AM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Would it be possible for us to send you the labeling documents and 510(k) summaries by COB Monday, October 30th?

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Thursday, October 26, 2023 12:33 PM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov

Subject: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Can you please send your finalized and complete Labeling documents and 510k summaries for the pump (k232380) and Control IQ (k232382)?

It would be great if you can send it by COB Oct 27, 2023.

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics (DAM)

Office of Science and Engineering Laboratories (OSEL)

Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

✉: Suvajyoti.Guha@fda.hhs.gov

☎: 301.796.9573



x > < x o

Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



Hi,

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image007.png@01D9EC84.05C1DE90] <<http://www.fda.gov/>>

[cid:image008.jpg@01D9EC84.05C1DE90] <<https://www.facebook.com/FDA>>

[cid:image009.jpg@01D9EC84.05C1DE90] <<https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm->

MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJW
vO9_SYvb8-IGlf0t1w_ADo-
yDsJPtOnlrp90Xo0UwJUyB1bVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2
F%2Ftwitter.com%2FUS_FDA> [cid:image010.jpg@01D9EC84.05C1DE90]
<http://www.youtube.com/user/USFoodandDrugAdmin> [cid:image011.jpg@01D9EC84.05C1DE90]
<http://secure-web.cisco.com/1c6NVqVSfV2kjjznn-
U1A0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdh-
QoytaqVxWfZhoJkuVQM_G5MsbRPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-
gePHDDPgiMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCy114AJqc07Gx7nhZg/http
%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image012.jpg@01D9EC84.05C1DE90]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback
regarding the customer service you have received (click here<https://secure-
web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-
cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-
P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A
%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K232380

B Applicant

Tandem Diabetes Care, Inc.

C Proprietary and Established Names

t:slim X2 Insulin Pump with Interoperable Technology

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QFG	Class II	21 CFR 880.5730 – Alternate Controller Enabled Infusion Pump	CH - Clinical Chemistry

E Purpose for Submission:

Modification to a cleared device to expand the age indication (from ≥ 6 years old to ≥ 2 years old).

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The t:slim X2 Insulin Pump with Interoperable Technology (the pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use in individuals 2 years of age and greater.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Remove the t:slim X2 Insulin Pump before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The magnetic fields and heat could damage the components of the t:slim X2 insulin pump with interoperable technology. Please review your smart phone manufacturer's instructions before using the t:connect mobile app during any of the procedures listed.

Always ensure the pump has a healthy Bluetooth wireless technology connection with your t:connect mobile app before you use the t:connect mobile app to make treatment decisions. Confirm that the information displayed to you matches your signs and symptoms. If necessary, make sure that your pump and phone are connected and the information displayed matches when making treatment decisions.

For patients who do not self-manage their disease, the Security PIN function should ALWAYS be on when the pump is not being used by a caregiver.

For patients whose insulin administration is managed by a caregiver, ALWAYS turn off the Quick Bolus feature to avoid inadvertent bolus delivery. If the Security PIN is turned on, the Quick Bolus feature is automatically disabled.

III Device Description

The t:slim X2 Insulin Pump with Interoperable Technology is an ambulatory, battery operated, rate programmable infusion pump designed for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The pump consists of an user-operated interface display, an electronic microprocessor software control system including Bluetooth radio and signal processing algorithms that allows the pump to receive continuous glucose monitoring data from an integrated continuous glucose monitoring system. Based on this data, and the thresholds set by users in consultation with healthcare providers, the pump can identify high or low glucose levels, as well as rapidly rising or falling glucose conditions.

The pump also houses an audible speaker and vibrator to provide alarms, alerts and reminders to the user. The insulin cartridge is designed to hold up to 3 mL, or 300 Unites of U-100 insulin. The insulin cartridge is intended to be replaced at least once every three days.

The t:slim X2 system is compatible with interoperable Automated glycemic controllers, such as the Basal-IQ Technology and the Control IQ Technology to aid in diabetes management.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

t:slim X2 Insulin Pump with Interoperable Technology

B Predicate 510(k) Number(s):

K203234

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K232380</u>	<u>K203234</u>
Device Trade Name	t:slim X2 Insulin Pump with Interoperable Technology	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. Intended to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Pump is intended for single patient, home use and requires a prescription.	Same
General Device Characteristic Differences		
Intended User Population	2 years and older with Type 1 diabetes mellitus.	6 years and older with Type 1 diabetes mellitus.

V Standards/Guidance Documents Referenced:

Not applicable.

VI Performance Characteristics:

A. Analytical Performance

The accuracy in basal delivery, bolus delivery and occlusion detection remain unchanged from the predicate.

B. Other Supportive Instrument Performance Characteristics Data

- a) Software: Sponsor made minor changes to the software including modifications to the user interface. Software documentation was reviewed and found to be adequate.
- b) Human Factors: Sponsor leveraged human factors studies previously performed under K203234 for the six years and older age group for their current submission with adequate justification.

VII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

VIII Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

Attachment 1 IFU and 510(k) Summaries

Contents	Pages
AW-1012259_B User Guide, Mobile Bolus, t:slim X2, Control-IQ 7.6 B.5 mgdL, Artwork	2-423
Final 510(k) Summary t:slim X2 K232380	424-429
Final 510(k) Summary Control-IQ K232382	430-436

t:slim X2

Insulin Pump

WITH Control-IQ TECHNOLOGY

User Guide



MG/DL

T:SLIM X2 INSULIN PUMP WITH CONTROL-IQ TECHNOLOGY USER GUIDE

Software Version: Control-IQ 7.6

Congratulations on the purchase of your new t:slim X2™ insulin pump with Control-IQ™ technology.

This user guide is designed to assist you with the features and functions of the t:slim X2 insulin pump with Control-IQ technology. It provides important warnings and cautions on proper operation as well as technical information to ensure your safety. It also provides step-by-step instructions on how to properly program, manage and care for your t:slim X2 insulin pump with Control-IQ technology.

Changes in equipment, software, or procedures occur periodically; information describing these changes will be included in future editions of this user guide.

No part of this publication may be reproduced, stored in a retrieval system, nor transmitted in any form or by any means, electronic or mechanical, without the prior written permission of Tandem Diabetes Care.

Please contact Customer Technical Support to obtain a replacement copy of the user guide that is the correct version for your pump. For contact information in your region see the back cover of this user guide.

Tandem Diabetes Care, Inc.
12400 High Bluff Drive
San Diego, CA 92130 USA
tandemdiabetes.com

WARNINGS:

Control-IQ technology should not be used in anyone under the age of two years old. Control-IQ technology should also not be used in patients who require less than a total daily insulin dose of 5 units per day and should not be used by people who weigh less than 20 pounds (9 kilograms), as those are the required minimum values needed in order for Control-IQ technology to operate safely.

TABLE OF CONTENTS

Section 1: Before You Begin

Chapter 1 • Introduction

1.1	Conventions of This Guide	16
1.2	Explanation of Symbols	18
1.3	System Description	20
1.4	About this User Guide	21
1.5	Indications for Use	21
1.6	Compatible Insulins	22
1.7	Compatible iCGMs	22
1.8	Important User Information	22
1.9	Important Pediatric User Information	23
1.10	Emergency Kit	24

Section 2: t:slim X2 Insulin Pump Features

Chapter 2 • Important Safety Information

2.1	t:slim X2 Insulin Pump Warnings	26
2.2	Magnetic Resonance Imaging Safety	29
2.3	Radiology and Medical Procedures and Your t:slim X2 System	29
2.4	t:connect Mobile App Warnings	30
2.5	t:slim X2 Insulin Pump Precautions	30
2.6	t:connect Mobile App Precautions	33
2.7	Tandem Cybersecurity Preventative Measures	34
2.8	Potential Benefits From Using Your Pump	35

2.9	Possible Risks From Using Your Pump	36
2.10	Working with your Healthcare Provider	36
2.11	Verification of Proper Functionality	37

Chapter 3 • Getting to Know Your t:slim X2 Insulin Pump

3.1	What your t:slim X2 Pump Package Includes	40
3.2	Pump Terminology	40
3.3	Explanation of t:slim X2 Insulin Pump Icons	43
3.4	Explanation of Pump Colors	45
3.5	Pump Back Side	46
3.6	Lock Screen	48
3.7	Home Screen	50
3.8	Current Status Screen	52
3.9	Bolus Screen	54
3.10	Options Screen	56
3.11	My Pump Screen	58
3.12	Device Settings Screen	60
3.13	Number Keypad Screen	62
3.14	Letter Keypad Screen	64

Chapter 4 • Getting to Know Your t:connect Mobile App

4.1	Overview	68
4.2	Install the t:connect Mobile App	69
4.3	Connecting to a Smartphone	71
4.4	Set Mobile Notifications	74
4.5	Mobile Connection Security	74
4.6	Lost Pump Connection	75

4.7	Restart the t:connect Mobile App	76
4.8	t:connect Mobile App Dashboard	78
4.9	t:connect Mobile App Bolus Screen	80
4.10	t:connect Mobile App Notifications Screen	82
4.11	t:connect Mobile App Settings	84

Chapter 5 • Getting Started

5.1	Charging the t:slim X2 Pump	88
5.2	Turning the Pump On	89
5.3	Using the Touchscreen	89
5.4	Turning the t:slim X2 Pump Screen On	90
5.5	Turning the Pump Screen Off	90
5.6	Turning the Pump Off	90
5.7	Unlocking the t:slim X2 Pump Screen	90
5.8	Edit Time	91
5.9	Edit Date	91
5.10	Basal Limit	91
5.11	Display Settings	92
5.12	Sound Volume	93
5.13	Turn Security PIN On or Off	93
5.14	Mobile Connection	94

Chapter 6 • Insulin Delivery Settings

6.1	Personal Profiles Overview	96
6.2	Creating a New Profile	96
6.3	Programming a New Personal Profile	99
6.4	Editing or Reviewing an Existing Profile	101
6.5	Duplicating an Existing Profile	102
6.6	Activating an Existing Profile	102
6.7	Renaming an Existing Profile	102

6.8	Deleting an Existing Profile	103
6.9	Starting a Temporary Basal Rate	103
6.10	Stopping a Temp Rate	104

Chapter 7 • Infusion Site Care and Loading Cartridge

7.1	Infusion Site Selection and Care	106
7.2	Cartridge Instructions for Use	108
7.3	Filling and Loading a t:slim X2 Cartridge	108
7.4	Filling Tubing	113
7.5	Filling Cannula	115
7.6	Setting Site Reminder	116

Chapter 8 • Manual Bolus

8.1	Manual Bolus Overview	118
8.2	Initiating a Bolus	119
8.3	Correction Bolus Calculation	119
8.4	Bolus Override	123
8.5	Food Bolus Using Units	123
8.6	Food Bolus Using Grams	123
8.7	Extended Bolus	124
8.8	Max Bolus	125
8.9	Quick Bolus	126
8.10	Canceling or Stopping a Bolus Using the Pump	128
8.11	Bolus Delivery Using the t:connect Mobile App	128
8.12	Correction Bolus Using the t:connect Mobile App	129
8.13	Bolus Override Using the t:connect Mobile App	132
8.14	Food Bolus Using the t:connect Mobile App	132
8.15	Canceling or Stopping a Bolus Using the t:connect Mobile App	133
8.16	Pump Connection Lost	134

Chapter 9 • Starting, Stopping, or Resuming Insulin

9.1	Starting Insulin Delivery	138
9.2	Stopping Insulin Delivery	138
9.3	Resuming Insulin Delivery	138
9.4	Disconnecting When Using Control-IQ Technology	139

Chapter 10 • t:slim X2 Insulin Pump Information and History

10.1	t:slim X2 Pump Info	142
10.2	t:slim X2 Pump History	142
10.3	t:connect Mobile App Info	143

Chapter 11 • t:slim X2 Insulin Pump Reminders

11.1	Low BG Reminder	146
11.2	High BG Reminder	146
11.3	After Bolus BG Reminder	147
11.4	Missed Meal Bolus Reminder	148
11.5	Site Reminder	148

Chapter 12 • User Settable Alerts and Alarms

12.1	Low Insulin Alert	150
12.2	Auto-Off Alarm	150
12.3	Max Basal Alert	151

Chapter 13 • t:slim X2 Insulin Pump Alerts

13.1	Low Insulin Alert	155
13.2	Low Power Alerts	156
13.3	Incomplete Bolus Alert	158
13.4	Incomplete Temp Rate Alert	160
13.5	Incomplete Load Sequence Alerts	161
13.6	Incomplete Setting Alert	164

13.7	Basal Rate Required Alert	165
13.8	Max Hourly Bolus Alert	166
13.9	Max Bolus Alerts	167
13.10	Max Basal Alert	169
13.11	Min Basal Alerts	170
13.12	Connection Error Alert	172
13.13	Pairing Code Timeout	173
13.14	Power Source Alert	174
13.15	Data Error Alert	175
13.16	Pump Connection Lost Alert - t:connect Mobile App	176

Chapter 14 • t:slim X2 Insulin Pump Alarms

14.1	Resume Pump Alarm	179
14.2	Low Power Alarm	180
14.3	Empty Cartridge Alarm	181
14.4	Cartridge Error Alarm	182
14.5	Cartridge Removal Alarm	183
14.6	Temperature Alarm	184
14.7	Occlusion Alarms	185
14.8	Screen On/Quick Bolus Button Alarm	187
14.9	Altitude Alarm	188
14.10	Reset Alarm	189

Chapter 15 • t:slim X2 Insulin Pump Malfunction

15.1	Malfunction	192

Chapter 16 • Taking Care of Your Pump

16.1	Overview	196

Chapter 17 • Lifestyle Issues and Travel

17.1	Overview	198

Section 3: CGM Features

Chapter 18 • Important Safety Information When Using the t:slim X2 Insulin Pump with Dexcom G6 CGM

18.1	Warnings	202
18.2	Precautions	203
18.3	Potential Benefits From Using the t:slim X2 Insulin Pump with CGM	205
18.4	Possible Risks From Using the t:slim X2 Insulin Pump with CGM	206

Chapter 19 • Getting to Know Your CGM System

19.1	CGM Terminology	208
19.2	Explanation of CGM Pump Icons	210
19.3	CGM Lock Screen	212
19.4	CGM Home Screen	214
19.5	My CGM Screen	216

Chapter 20 • CGM Overview

20.1	CGM System Overview	220
20.2	Device Connection Overview	220
20.3	Receiver (t:slim X2 Insulin Pump) Overview	221
20.4	Transmitter Overview	221
20.5	Sensor Overview	222

Chapter 21 • CGM Settings

21.1	About Bluetooth Technology	224
21.2	Disconnecting from the Dexcom Receiver	224

21.3	Setting CGM Volume	224
21.4	CGM Info	227
Chapter 22 • Setting CGM Alerts		
22.1	Setting Your High Glucose Alert and Repeat Feature	230
22.2	Setting Your Low Glucose Alert and Repeat Feature	231
22.3	Rate Alerts	232
22.4	Setting Your Rise Alert	232
22.5	Setting Your Fall Alert	233
22.6	Setting Your Out of Range Alert	233
Chapter 23 • Starting or Stopping a CGM Sensor Session		
23.1	Enter Your Transmitter ID	236
23.2	Start the Sensor	236
23.3	Sensor Startup Period	238
23.4	Automatic Sensor Shut-Off	239
23.5	Ending a Sensor Session Before Automatic Shut-Off	240
23.6	Removing the Sensor and Transmitter	240
Chapter 24 • Calibrating Your CGM System		
24.1	Calibration Overview	242
24.2	Startup Calibration	242
24.3	Calibration BG Value and Correction Bolus	244
24.4	Reasons You May Need to Calibrate	244
Chapter 25 • Viewing CGM Data on Your t:slim X2 Insulin Pump		
25.1	Overview	246
25.2	CGM Trend Graphs	247
25.3	Rate of Change Arrows	248
25.4	CGM History	250

25.5	Missed Readings	250

Chapter 26 • CGM Alerts and Errors

26.1	Startup Calibration Alert	253
26.2	Second Startup Calibration Alert	254
26.3	12 Hour Calibration Alert	255
26.4	Incomplete Calibration	256
26.5	Calibration Timeout	257
26.6	Wait 15 Minute Calibration Error Alert	258
26.7	Calibration Required Alert	259
26.8	CGM High Alert	260
26.9	CGM Low Alert	261
26.10	CGM Fixed Low Alert	262
26.11	CGM Rise Alert	263
26.12	CGM Rapid Rise Alert	264
26.13	CGM Fall Alert	265
26.14	CGM Rapid Fall Alert	266
26.15	Unknown Sensor Glucose Reading	267
26.16	Out of Range Alert	268
26.17	Low Transmitter Battery Alert	269
26.18	Transmitter Error	270
26.19	Failed Sensor Error	271
26.20	CGM Unavailable	272
26.21	CGM System Error	273

Chapter 27 • CGM Troubleshooting

27.1	CGM Pairing Troubleshooting	276
27.2	Calibration Troubleshooting	276
27.3	Unknown Sensor Reading Troubleshooting	276
27.4	Out of Range/No Antenna Troubleshooting	277

27.5	Failed Sensor Troubleshooting	277
27.6	Sensor Inaccuracies	278

Section 4: Control-IQ Technology Features

Chapter 28 • Control-IQ Technology Important Safety Information

28.1	Control-IQ Warnings	282
28.2	Control-IQ Precautions	283

Chapter 29 • Getting to Know Control-IQ Technology

29.1	Responsible Use of Control-IQ Technology	286
29.2	Explanation of Control-IQ Technology Icons	287
29.3	Control-IQ Lock Screen	288
29.4	Control-IQ Home Screen	290
29.5	Control-IQ Screen	292

Chapter 30 • Introduction to Control-IQ Technology

30.1	Control-IQ Technology Overview	296
30.2	How Control-IQ Technology Works	296
30.3	Control-IQ Technology and Activity	305

Chapter 31 • Configuring and Using Control-IQ Technology

31.1	Required Settings	310
31.2	Set Weight	310
31.3	Set Total Daily Insulin	311
31.4	Turn Control-IQ Technology On or Off	311
31.5	Schedule Sleep	311
31.6	Enable or Disable a Sleep Schedule	313
31.7	Manually Start or Stop Sleep	314

31.8	Manually Start or Stop Exercise	314
31.9	Control-IQ Technology Information on Your Screen	315

Chapter 32 • Control-IQ Technology Alerts

32.1	Out of Range Alert – Control-IQ Technology Disabled	319
32.2	Out of Range Alert – Control-IQ Technology Enabled	320
32.3	Control-IQ Technology Low Alert	321
32.4	Control-IQ High Alert	322
32.5	Max Insulin Alert	323

Chapter 33 • Overview of Control-IQ Technology Clinical Studies

33.1	Introduction	326
33.2	Software Version History	327
33.3	The DCLP3 Trial	328
33.4	The DCLP5 Trial	340
33.5	The PEDAP Trial	351
33.6	The PEDAP Extension Phase	361
33.7	The Higher-IQ Trial	370

Section 5: Technical Specifications and Warranty

Chapter 34 • Technical Specifications

34.1	Overview	380
34.2	t:slim X2 Pump Specifications	380
34.3	t:slim X2 Pump Options and Settings	385
34.4	t:slim X2 Pump Performance Characteristics	388
34.5	Electromagnetic Compatibility	393
34.6	Wireless Co-existence and Data Security	393

34.7	t:connect Mobile App Security	394
34.8	Electromagnetic Emissions	395
34.9	Electromagnetic Immunity	396
34.10	Quality of Wireless Service	398
34.11	Wireless Technology	399
34.12	FCC Notice Concerning Interference	400
34.13	Warranty Information	400
34.14	Returned Goods Policy	404
34.15	t:slim X2 Insulin Pump Event Data (Black Box)	404
34.16	Product List	405

Index

406

This Page is Intentionally Left Blank

1 Before You Begin

CHAPTER 1

Introduction

CHAPTER 1 • Introduction

1.1 Conventions of This Guide

The following are conventions used in this user guide (such as terms, icons, text formatting, and other conventions) along with their explanations.

Formatting Conventions

Convention	Explanation
Bolded Text	Text that is in bold in a sentence or step indicates an on-screen icon or physical button name.
Italic Text	Text that is in italics indicates the name of a screen or menu on the pump display.
Numbered Items	Numbered items are step-by-step instructions for how to perform a specific task.
Blue Text	Calls out a reference to a separate user guide location or website link.

Terminology Definitions

Term	Definition
Touchscreen	The front glass screen of your pump, which displays all programming, operating, and alarm/alert information.
Tap	Quickly and lightly touch the screen with your finger.
Press	Use your finger to depress a physical button (the Screen On/Quick Bolus button is the only physical/hardware button on your pump).
Hold	Keep pressing a button or touching an icon or menu until its function is complete.
Menu	A list of options on your touchscreen that allow you to perform specific tasks.
Icon	An image on your touchscreen that indicates an option or item of information, or a symbol on the back of your pump or its packaging.

Symbol Definitions

Symbol	Definition
	Calls out an important note regarding the use or operation of the system.
	Calls out safety precautions which, if ignored, could result in minor or moderate injury.
	Calls out critical safety information which, if ignored, could result in serious injury or death.
	Indicates how the pump responds to the previous instruction.

CHAPTER 1 • Introduction

1.2 Explanation of Symbols

The following are symbols (and their descriptions), which you may find on your pump, pump supplies and/or their packaging. These symbols tell you about the proper and safe use of the pump. Some of these symbols may not be relevant in your region, and are listed for informational purposes only.

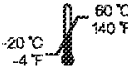
Explanation of t:slim X2 Insulin Pump Symbols

Symbol	Definition
	Caution
	Follow instructions for use
	Consult instructions for use
	For sale by or on the order of a physician only (United States)
	Catalogue number
	Batch code
	International Protection (IP) Code
	Manufacturer

Symbol	Definition
	Type BF Applied Part (patient isolation, not defibrillator protected)
	Non-ionizing Radiation
	Magnetic Resonance (MR) Unsafe; keep away from magnetic resonance imaging (MRI) equipment
	Serial number
	Manufacturer number
	Medical device
	Model number
	Authorized Representative in the European Community

Explanation of t:slim X2 Insulin Pump Symbols (Continued)

Symbol	Definition
	Date of manufacture
	Importer (except United States)
	Direct Current (DC) voltage
	Separate collection for waste electrical and electronic equipment
	Electric Equipment Designed Primarily for Indoor Use
	IEC Class II Equipment
	Use U-100 insulin only
	Wall Power USB Adapter
	Cartridge Removal Tool
	USB Cable

Symbol	Definition
	Indicates the authorized representative in Switzerland
	CE marking of conformity
	Regulatory Compliance Mark
	Humidity limitation
	Temperature limit
	Keep Dry
	Outlet Adapter
	Pump Case
	User Guide

CHAPTER 1 • Introduction

1.3 System Description

The t:slim X2™ insulin pump with Control-IQ™ technology, referred to as the “pump” or the “t:slim X2 pump,” consists of the t:slim X2 insulin pump, the embedded Control-IQ algorithm, and the t:slim X2 3mL (300 units) cartridge. The t:slim X2 pump must be used with a compatible infusion set.

The t:slim X2 pump with Control-IQ technology may be used in combination with a compatible continuous glucose monitor (CGM).

The t:connect™ mobile app can also be used with the System as a method of viewing pump information and limited control of the pump through your smartphone. This functionality is limited to compatible smartphone operating systems and pump software versions.

The Dexcom G6 CGM is compatible with the t:slim X2 insulin pump with Control-IQ technology. The Dexcom G6 transmitter may be referred to as the “transmitter.” The Dexcom G6 sensor may be referred to as the “sensor.” Together, the Dexcom G6 transmitter

and Dexcom G6 sensor may be referred to as the “CGM.”

The pump delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The disposable cartridge is filled with up to 300 units of U-100 insulin and attached to the pump. The cartridge is replaced every 48–72 hours.

The Control-IQ automated insulin dosing feature is an algorithm embedded in the t:slim X2 pump software. This feature enables the t:slim X2 pump to automatically adjust the delivery of insulin based on CGM sensor readings; however, the feature is not a substitute for your own active diabetes management, including giving a bolus for meals. Control-IQ technology utilizes the CGM sensor readings and other data to calculate a predicted glucose value 30 minutes into the future. For more information on how Control-IQ technology is activated, see Chapter 30 Introduction to Control-IQ Technology.

The pump can be used for basal and bolus insulin delivery with or without a CGM. If a CGM is not used, sensor

glucose readings will not be sent to the pump display and you will not be able to use Control-IQ technology.

The sensor is a disposable device that is inserted under the skin to continuously monitor glucose levels. The transmitter connects to the sensor pod and wirelessly sends readings to the pump, which acts as a receiver for the therapeutic CGM, every 5 minutes. The pump shows sensor glucose readings, a trend graph, as well as the direction and rate of change arrows.

The sensor measures glucose in the interstitial fluid under the skin—not in blood, and sensor readings are not identical to readings from a blood glucose (BG) meter.

The t:connect mobile app enables you to connect a smartphone to the pump using *Bluetooth*® wireless technology to display your pump information and perform some pump functions on the smartphone as well as display pump notifications. The t:connect mobile app can transmit pump and therapy data from the pump to the cloud as long as your smartphone is connected to the internet. Download the t:connect

mobile app from Google Play™ or from the App Store® and visit support.tandemdiabetes.com for installation instructions.

NOTE

For an up-to-date list of supported smartphones, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

PRECAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

1.4 About this User Guide

This user guide covers important information on how to operate your System. It provides step-by-step instructions to help you properly program, manage, and care for the System. It also provides important warnings and precautions on proper operation and technical information to ensure your safety.

The user guide is organized into sections. Section 1 provides important

information you need to know before you start using the System. Section 2 covers instructions for using the t:slim X2 pump and using the t:connect mobile app with the pump. Section 3 covers instructions for using CGM with your pump. Section 4 covers instructions for using Control-IQ technology on your pump. Section 5 provides information on the technical specifications of your pump.

The pump screens used in this user guide demonstrate how to use features, and are examples only. They should not be considered suggestions for your individual needs.

For customers in the United States, product information, including electronic versions of the user guide, t:connect Getting Started Guide, t:connect user guides, and a CGM training tutorial, are available at tandemdiabetes.com. Product information for users outside the United States can be provided by your local Tandem distributor.

1.5 Indications for Use

The t:slim X2 insulin pump with interoperable technology (the Pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

The Pump is intended for single patient, home use and requires a prescription.

The Pump is indicated for use in persons two years of age and greater.

Control-IQ technology is intended for use with compatible integrated continuous glucose monitors (iCGM) and alternate controller enabled (ACE) pumps to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when

CHAPTER 1 • Introduction

the glucose value is predicted to exceed a predefined threshold.

Control-IQ technology is intended for the management of Type 1 diabetes mellitus in persons two years of age and greater.

Control-IQ technology is intended for single patient use and requires a prescription.

1.6 Compatible Insulins

The t:slim X2 insulin pump with Control-IQ technology is designed for use with rapid acting insulin analogs that have been tested and found to be safe for use in the pump:

- NovoLog/NovoRapid U-100 insulin
- Humalog U-100 insulin

NovoLog/NovoRapid is compatible with the system for use up to 72 hours (3 days). Humalog is compatible with the system for use up to 48 hours (2 days).

If you have questions about using other insulins, contact your healthcare provider. Always consult your

healthcare provider and refer to the insulin labeling prior to use.

1.7 Compatible iCGMs

Compatible CGMs include the following iCGMs:

- Dexcom G6 CGM

For information about Dexcom G6 CGM product specifications and performance characteristics, visit the manufacturer's website for applicable product instructions.

The Dexcom G6 sensors and transmitters are sold and shipped separately by Dexcom.

NOTE

The Dexcom G6 CGM currently allows pairing with one medical device at a time (either the t:slim X2 pump or the Dexcom receiver), but you can still use the Dexcom G6 CGM app and your t:slim X2 pump simultaneously using the same transmitter ID.

NOTE

The Mobile Connection setting on your Pump does not relate to the Bluetooth connection

between your CGM and Pump. For connecting a CGM to your Pump, see Section 21.1 About Bluetooth Technology. For connecting your Pump to the t:connect mobile app, see Section 4.3 Connecting to a Smartphone.

NOTE

Product instructions for the Dexcom G6 CGM System includes important information on how to use the Dexcom G6 CGM information (including sensor glucose readings, trend graph, trend arrow, alarm/alerts) to make treatment decisions. Ensure that you have reviewed this information and discussed it with your healthcare provider, who can guide you in correctly using your Dexcom G6 CGM information when making treatment decisions.

1.8 Important User Information

Review all instructions in this user guide before using the System.

If you are not able to use the System according to the instructions in this user guide and other applicable user guides, you may be putting your health and safety at risk.

If you are new to using CGM, continue using your BG meter until you are familiar with CGM usage.

If you are currently using the pump without Dexcom G6 CGM, or if you are currently using Dexcom G6 CGM, it is still very important that you review all instructions in this user guide before using the combined System.

Pay special attention to Warnings and Precautions in this user guide. Warnings and Precautions are identified with a  or  symbol.

If you still have questions after reading this user guide, contact Customer Technical Support 24 hours a day, 7 days a week.

1.9 Important Pediatric User Information

The following recommendations are meant to help younger users and their caregivers program, manage, and care for the System.

Younger children may inadvertently press or tap the pump or the t:connect

mobile app, leading to unintentional delivery of insulin.

It is the responsibility of the healthcare provider and caregiver to determine if the user is appropriate for treatment with this device and the t:connect mobile app.

We recommend reviewing the Quick Bolus and Security PIN capabilities of the pump and determining how they best fit with your care plan. These features are detailed in Chapters 8 Manual Bolus and 5 Getting Started.

Inadvertent dislodgement of the infusion site may occur more frequently with children so consider securing the infusion site and tubing.

WARNING

Control-IQ technology should not be used by people who use less than 5 units of insulin per day and should not be used in patients who weigh less than 20 pounds (9 kilograms), which are the minimum inputs required to initiate Control-IQ technology and for it to operate safely.

WARNING

The t:slim X2 insulin pump with Control-IQ technology should not be used in children under the age of two years old.

WARNING

DO NOT allow small children (either pump users or non-users) to ingest small parts, such as the rubber USB port cover and cartridge components. Small parts could pose a choking hazard. If ingested or swallowed, these small component pieces may cause internal injury or infection.

WARNING

The pump includes parts (such as the USB cable and infusion set tubing) that could pose a strangulation or asphyxiation hazard. Always use the appropriate length of infusion set tubing and arrange cables and tubing to minimize the risk of strangulation. **ENSURE** that these parts are stored in a secure place when not in use.

WARNING

For patients who do not self-manage their disease, the Security PIN function should **ALWAYS** be on when the pump is not being used by a caregiver. The Security PIN function is intended to prevent inadvertent screen taps or button presses that may lead to insulin delivery

CHAPTER 1 • Introduction

or changes in the pump settings. These changes can potentially lead to hypoglycemia (low BG) or hyperglycemia (high BG) events. See Section 5.13 Turn Security PIN On or Off for details on how to turn the Security PIN function on.

⚠ WARNING

For patients whose insulin administration is managed by a caregiver, **ALWAYS** turn off the Quick Bolus feature to avoid inadvertent bolus delivery. If the Security PIN is turned on, the Quick Bolus feature is automatically disabled. Inadvertent screen taps, button presses, or tampering with the insulin pump could result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events. See Section 5.13 Turn Security PIN On or Off for details on how to turn the Security PIN function off.

1.10 Emergency Kit

You should always have an appropriate emergency kit with you. At the very least, this kit should include an insulin syringe and vial of insulin or a prefilled insulin pen as a backup for emergency situations. Talk with your healthcare

provider regarding what items this kit should include.

Some examples of what to include in your everyday emergency kit are:

- BG testing supplies: meter, strips, control solution, lancets, meter batteries
- Fast-acting carbohydrate to treat low BG
- Extra snack for longer coverage than fast-acting carbohydrate
- Glucagon emergency kit
- Rapid-acting insulin and syringes or a prefilled insulin pen and pen needles
- Infusion sets (minimum of 2)
- Insulin pump cartridges (minimum of 2)
- Infusion site preparation products (antiseptic wipes, skin adhesive)
- Diabetes identification card or jewelry

2 t:slim X2 Insulin Pump Features

CHAPTER 2

Important Safety Information

CHAPTER 2 • Important Safety Information

The following includes important safety information related to your t:slim X2™ pump and its components. The information presented in this chapter does not represent all warnings and precautions related to the System. Pay attention to other warnings and precautions listed throughout this user guide as they relate to special circumstances, features, or users.

2.1 t:slim X2 Insulin Pump Warnings

▲ WARNING

DO NOT start to use your pump or the t:connect™ mobile app before reading the user guide. Failure to follow the instructions in this user guide can result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events. If you have questions or need further clarification on your pump use, ask your healthcare provider or call Customer Technical Support.

▲ WARNING

DO NOT start to use your pump before you have been appropriately trained on its use by a certified trainer or through the training materials available online if you are updating your pump.

Consult with your healthcare provider for your individual training needs for the pump. Failure to complete the necessary training on your pump could result in serious injury or death.

▲ WARNING

ONLY use U-100 Humalog or U-100 NovoLog with your pump. Only U-100 Humalog and U-100 NovoLog have been tested and found to be compatible for use in the pump. Use of insulin with greater or lesser concentration can result in an over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT put any other drugs or medications inside your pump cartridge. The pump is designed only for continuous subcutaneous insulin infusion (CSII) using U-100 Humalog or U-100 NovoLog insulin. Use of other drugs or medications can damage the pump and result in injury if infused.

▲ WARNING

DO NOT use manual injections or inhaled insulins while using the pump. Using insulin not provided by the pump can cause the system to over deliver insulin, which can lead to severe hypoglycemia (low BG) events.

▲ WARNING

The pump is not intended for anyone unable or unwilling to:

- » Test blood glucose (BG) levels as recommended by a healthcare provider
- » Demonstrate adequate carbohydrate counting skills
- » Maintain sufficient diabetes self-care skills
- » See healthcare provider(s) regularly

The user must also have adequate vision and/or hearing in order to recognize all functions of the pump, including alerts, alarms, and reminders.

▲ WARNING

DO NOT start to use your pump before consulting with your healthcare provider to determine which features are most appropriate for you. Only your healthcare provider can determine and help you adjust your Basal Rate(s), Carb Ratio(s), Correction Factor(s), Target BG, and duration of insulin action. In addition, only your healthcare provider can determine your CGM settings and how you should use your sensor trend information to help you manage your diabetes. Incorrect settings can result in over delivery or under delivery of

insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

ALWAYS be prepared to inject insulin with an alternative method if delivery is interrupted for any reason. Your pump is designed to deliver insulin reliably, but because it uses only rapid-acting insulin, you will not have long-acting insulin in your body. Failure to have an alternative method of insulin delivery can lead to very high BG or Diabetic Ketoacidosis (DKA).

▲ WARNING

ONLY use cartridges and infusion sets with matching connectors and follow their instructions for use. Failure to do so may result in over delivery or under delivery of insulin and may cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT place your infusion set on any scars, lumps, moles, stretch marks or tattoos. Placing your infusion set in these areas can cause swelling, irritation or infection. This can affect insulin absorption and cause high or low BG.

▲ WARNING

ALWAYS carefully follow the instructions for use accompanying your infusion set for proper insertion and infusion site care, as failure to do so could result in over delivery or under delivery of insulin or infection.

▲ WARNING

NEVER fill your tubing while your infusion set is connected to your body. Always ensure that the infusion set is disconnected from your body before filling the tubing. Failure to disconnect your infusion set from your body before filling the tubing can result in over delivery of insulin. This can cause hypoglycemia (low BG) events.

▲ WARNING

NEVER reuse cartridges or use cartridges other than those manufactured by Tandem Diabetes Care. Use of cartridges not manufactured by Tandem Diabetes Care or reuse of cartridges may result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

ALWAYS twist the tubing connector between the cartridge tubing and the infusion set tubing an extra quarter of a turn to ensure a secure connection. A loose connection can cause

insulin to leak, resulting in under delivery of insulin. If the connection comes loose, disconnect the infusion set from your body before tightening. This can cause hyperglycemia (high BG).

▲ WARNING

DO NOT disconnect the tubing connector between the cartridge tubing and the infusion set tubing. If the connection comes loose, disconnect the infusion set from your body before tightening. Failure to disconnect before tightening can result in over delivery of insulin. This can cause hypoglycemia (low BG).

▲ WARNING

DO NOT remove or add insulin from a filled cartridge after loading onto the pump. This will result in an inaccurate display of the insulin level on the *Home* screen and you could run out of insulin before the pump detects an empty cartridge. This can cause very high BG, or Diabetic Ketoacidosis (DKA).

▲ WARNING

DO NOT deliver a bolus until you have reviewed the calculated bolus amount. If you deliver an insulin amount that is too high or too low, this could cause hypoglycemia (low BG) or hyperglycemia (high BG) events. You can always

CHAPTER 2 • Important Safety Information

adjust the insulin units up or down before you decide to deliver your bolus.

▲ WARNING

ALWAYS use the USB cable provided with your t:slim X2 insulin pump to minimize the risk of fires or burns.

▲ WARNING

DO NOT allow small children (either pump users or non-users) to ingest small parts, such as the rubber USB port cover and cartridge components. Small parts could pose a choking hazard. If ingested or swallowed, these small component pieces may cause internal injury or infection.

▲ WARNING

The pump includes parts (such as the USB cable and infusion set tubing) that could pose a strangulation or asphyxiation hazard. **ALWAYS** use the appropriate length of infusion set tubing and arrange cables and tubing to minimize the risk of strangulation. **ENSURE** that these parts are stored in a secure place when not in use.

▲ WARNING

For patients who do not self-manage their disease, the Security PIN function should **ALWAYS** be on when the pump is not being

used by a caregiver. The Security PIN function is intended to prevent inadvertent screen taps or button presses that may lead to insulin delivery or changes in the pump settings. These changes can potentially lead to hypoglycemic or hyperglycemic events.

▲ WARNING

For patients whose insulin administration is managed by a caregiver, **ALWAYS** turn off the Quick Bolus feature to avoid inadvertent bolus delivery. If the Security PIN is turned on, the Quick Bolus feature is automatically disabled. Inadvertent screen taps, button presses, or tampering with the insulin pump could result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT change your infusion set before bedtime or if you will not be able to test your BG 1–2 hours after the new infusion set is placed. It is important to confirm that the infusion set is inserted correctly and delivering insulin. It is also important to respond quickly to any problems with the insertion to ensure continued insulin delivery.

▲ WARNING

Use of accessories, cables, adapters, and chargers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

▲ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches to any part of the t:slim X2 pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

▲ WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

▲ WARNING

Some skin care products such as lotions, sunscreens, and insect repellents can cause cracks in the plastic used to manufacture the pump and cartridge. **DO NOT** allow these

products to come in contact with the pump or cartridge. **ALWAYS** remove your pump before applying these products and **ALWAYS** wash your hands before handling your pump or cartridge after using such products. **ALWAYS** change your cartridge if it becomes exposed to such products and immediately clean your pump. Failure to do so may result in damage to the pump and cartridge and in some cases over or under delivery of insulin.

2.2 Magnetic Resonance Imaging Safety

⚠ WARNING

The System is magnetic resonance (MR) unsafe. You must take off your pump, transmitter, and sensor and leave them outside the procedure room.

2.3 Radiology and Medical Procedures and Your t:connect X2 System

Please review your smartphone manufacturer's instructions before using the t:connect mobile app during any of the procedures listed below.

⚠ WARNING

ALWAYS notify the provider/technician about your diabetes and your pump. If you need to discontinue use of the pump for medical procedures, follow your healthcare provider's instructions to replace missed insulin when you reconnect to the pump. Check your BG before disconnecting from the pump and again when you reconnect and treat high BG levels as recommended by your healthcare provider.

⚠ WARNING

DO NOT expose your pump, transmitter, or sensor to:

- » X-ray
- » Computed Tomography (CT) scan
- » Positron Emission Tomography (PET) scan
- » Other exposure to radiation

⚠ WARNING

There is no need to disconnect for electrocardiograms (EKGs) or colonoscopies. If you have questions, contact Customer Technical Support.

⚠ WARNING

DO NOT use the pump if you have a condition which, in the opinion of your healthcare

provider, would put you at risk. Examples of individuals who should not use the pump include those with uncontrolled thyroid disease, renal failure (e.g. dialysis or eGFR <30), hemophilia, or another major bleeding disorder, or unstable cardiovascular disease.

⚠ WARNING

DO NOT expose your pump, transmitter, or sensor to:

- » Pacemaker/Automatic Implantable Cardioverter Defibrillator (AICD) placement or reprogramming
- » Cardiac Catheterization
- » Nuclear Stress Test

You must take off your pump, transmitter, and sensor and leave them outside the procedure room if you are going to have any of the above medical procedures.

⚠ WARNING

There are other procedures where you should proceed with caution:

- » **Laser Surgery** – Your System can usually be worn during the procedure. However, some lasers can create

CHAPTER 2 • Important Safety Information

interference and cause the System to alarm.

- » **General Anesthesia** – Depending on the equipment being used, you may or may not need to remove your System. Be sure to ask your healthcare provider.

2.4 t:connect Mobile App Warnings

⚠ WARNING

DO NOT start to use the bolus feature of the t:connect mobile app before you have been appropriately trained on its use. Failure to follow the instructions in this user guide and in-app help on the bolus feature of the t:connect mobile app could result in delay of therapy. If the information displayed to you in your t:connect mobile app does not match your signs and symptoms, **ALWAYS** refer to the t:slim X2 insulin pump before making any treatment decisions.

⚠ WARNING

DO NOT use a smartphone that has been jailbroken or rooted, or with Android developer mode on. Data may become vulnerable if you install the t:connect mobile app on a smartphone that has been jailbroken or rooted, or uses an unreleased or pre-released operating

system. Only download the t:connect mobile app on Google Play™ or from the App Store®. See Chapter 4 Getting to Know Your t:connect Mobile App for t:connect mobile app installation.

⚠ WARNING

Any time you request any bolus, you have 10 seconds to cancel the bolus after requesting it to completely avoid insulin delivery. Both the pump and the t:connect mobile app will say “requesting bolus” during this time as long as your pump and the t:connect mobile app are connected. You can cancel the bolus from either the pump or the app regardless of how you requested it.

⚠ WARNING

ALWAYS rely on your pump to make therapy decisions when using a smartphone that is incompatible with the Bolus Delivery feature.

⚠ WARNING

Use of accessories, cables, adapters, and chargers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches to any part of the t:slim X2 pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

2.5 t:slim X2 Insulin Pump Precautions

⚠ PRECAUTION

DO NOT open or attempt to repair your insulin pump. The pump is a sealed device that should be opened and repaired only by Tandem Diabetes Care. Modification could result in a safety hazard. If your pump seal is broken, the pump is no longer watertight and the warranty is voided.

⚠ PRECAUTION

CHANGE your infusion set every 48 hours if using Humalog insulin; every 72 hours if using NovoLog insulin. Wash your hands with anti-bacterial soap before handling the infusion set and thoroughly clean the insertion site on your body to avoid infection. Contact your healthcare provider if you have symptoms of infection at your insulin infusion site.

⚠ PRECAUTION

ALWAYS remove all air bubbles from the pump before beginning insulin delivery. Ensure there are no air bubbles when drawing insulin into the filling syringe, hold the pump with the white fill port pointed up when filling the tubing, and ensure that there are no air bubbles in the tubing when filling. Air in the cartridge and tubing takes space where insulin should be and can affect insulin delivery.

⚠ PRECAUTION

CHECK your infusion site daily for proper placement and leaks. **REPLACE** your infusion set if you notice leaks around the site. Improperly placed sites or leaks around the infusion site can result in under delivery of insulin.

⚠ PRECAUTION

CHECK your infusion set tubing daily for any leaks, air bubbles, or kinks. Air in the tubing, leaks in the tubing, or kinked tubing may restrict or stop insulin delivery and result in under delivery of insulin.

⚠ PRECAUTION

CHECK the tubing connection between your cartridge tubing and infusion set tubing daily to ensure it is tight and secure. Leaks around the

tubing connection can result in under delivery of insulin.

⚠ PRECAUTION

ALWAYS check that your cartridge has enough insulin to last through the night before going to bed. If you are sleeping, you could fail to hear the Empty Cartridge Alarm and miss part of your basal insulin delivery.

⚠ PRECAUTION

CHECK your pump's personal settings regularly to ensure they are correct. Incorrect settings can result in over delivery or under delivery of insulin. Consult with your healthcare provider as needed.

⚠ PRECAUTION

ALWAYS make sure that the correct time and date are set on your insulin pump. Not having the correct time and date setting may affect safe insulin delivery. When editing time, always check that the AM/PM setting is accurate, if applicable. AM is to be used from midnight until 11:59 AM. PM is to be used from noon until 11:59 PM.

⚠ PRECAUTION

CONFIRM that the screen display turns on, you can hear audible beeps, feel the pump vibrate,

and see the green LED light blinking around the edge of the **Screen On/Quick Bolus** button when you connect a power source to the USB port. These features are used to notify you about alerts, alarms, and other conditions that require your attention. If these features are not working, discontinue use of the pump and contact Customer Technical Support.

⚠ PRECAUTION

CHECK your pump regularly for potential alarm conditions that may display. It is important to be aware of conditions that may affect insulin delivery and require your attention so you can respond as soon as possible.

⚠ PRECAUTION

DO NOT use the vibrate feature for alerts and alarms during sleep unless otherwise directed by your healthcare provider. Having the volume for alerts and alarms set to high will help ensure that you don't miss an alert or alarm.

⚠ PRECAUTION

ALWAYS look at the screen to confirm correct programming of the bolus amount when you first use the Quick Bolus feature. Looking at the screen will ensure that you are correctly using the beep/vibration commands to program the intended bolus amount.

CHAPTER 2 • Important Safety Information

⚠ PRECAUTION

DO NOT use your pump if you think it might be damaged due to dropping it or hitting it against a hard surface. Check that the pump is working properly by plugging a power source into the USB port and confirming that the display turns on, you hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the **Screen On/Quick Bolus** button. If you are unsure about potential damage, discontinue use of the pump and contact Customer Technical Support.

⚠ PRECAUTION

AVOID exposure of your pump to temperatures below 41°F (5°C) or above 99°F (37°C). Insulin can freeze at low temperatures or degrade at high temperatures. Insulin that has been exposed to conditions outside of the manufacturer's recommended ranges can affect the safety and performance of the pump.

⚠ PRECAUTION

AVOID submerging your pump in fluid beyond a depth of 3 feet (0.91 m) or for more than 30 minutes (IP27 rating). If your pump has been exposed to fluid beyond these limits, check for any signs of fluid entry. If there are signs of fluid entry, discontinue use of the pump and contact Customer Technical Support.

⚠ PRECAUTION

AVOID areas where there may be flammable anesthetics or explosive gases. The pump is not suitable for use in these areas and there is a risk of explosion. Remove your pump if you need to enter these areas.

⚠ PRECAUTION

MAKE SURE to not move further than the length of the USB cable when you are connected to the pump and to a charging source. Moving further than the length of the USB cable may cause the cannula to be pulled out of the infusion site. For this reason it is recommended not to charge the pump while sleeping.

⚠ PRECAUTION

DISCONNECT your infusion set from your body while on high-speed/high gravity amusement park thrill rides. Rapid changes in altitude or gravity can affect insulin delivery and cause injury.

⚠ PRECAUTION

DISCONNECT your infusion set from your body before flying in an aircraft without cabin pressurization or in planes used for aerobatics or combat simulation (pressurized or not). Rapid changes in altitude or gravity can affect insulin delivery and cause injury.

⚠ PRECAUTION

CONSULT your healthcare provider about lifestyle changes such as weight gain or loss, and starting or stopping exercise. Your insulin needs may change in response to lifestyle changes. Your Basal Rate(s) and other settings may need adjustment.

⚠ PRECAUTION

CHECK your BG using a BG meter following a gradual elevation change of up to each 1,000 feet (305 meters), such as when snow skiing or driving on a mountain road. Delivery accuracy can vary up to 15% until 3 units of total insulin have been delivered or elevation has changed by more than 1,000 feet (305 meters). Changes in delivery accuracy can affect insulin delivery and cause injury.

⚠ PRECAUTION

ALWAYS check with your healthcare provider for specific guidelines if you want or need to disconnect from the pump for any reason. Depending on the length of time and reason you are disconnecting, you may need to replace missed basal and/or bolus insulin. Check your BG before disconnecting from the pump and again when you reconnect, and treat high BG levels as recommended by your healthcare provider.

⚠ PRECAUTION

ENSURE that your personal insulin delivery settings are programmed into the pump before use if you receive a warranty replacement pump. Failure to enter your insulin delivery settings could result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events. Consult your healthcare provider as needed.

⚠ PRECAUTION

ALWAYS dispose of used components such as cartridges, syringes, needles, infusion sets, and CGM sensors following local regulations. Needles should be disposed in an appropriate sharps container. Do not attempt to recap needles. Wash your hands thoroughly after handling used components.

⚠ PRECAUTION

If you choose to use a pump case or other accessories not provided by Tandem, **DO NOT** cover the six vent holes on the back of the pump. Covering the vent holes could affect insulin delivery.

2.6 t:connect Mobile App Precautions**⚠ PRECAUTION**

ALWAYS turn Zoom Mode off when using the t:connect mobile app. If your smartphone has Zoom Mode turned on, you should rely on your pump for all therapy decisions.

⚠ PRECAUTION

If you start a manual bolus request on the pump, you must complete it on the pump. You cannot request a bolus from the t:connect mobile app while a bolus request is active on the pump.

⚠ PRECAUTION

Pump notifications cannot be cleared from your t:connect mobile app. Pump Alerts, Alarms, and Notifications can be viewed on your smartphone, but must be cleared on the t:slim X2 pump.

⚠ PRECAUTION

The t:connect mobile app receives data from the connected pump via a secure Bluetooth wireless technology connection. If the Bluetooth connection between the pump and the t:connect mobile app is lost, the t:connect mobile app will not display current insulin pump information and

cannot be used to request a bolus. To help maintain the wireless connection between the insulin pump and the t:connect mobile app, it is recommended the smartphone running the t:connect mobile app is within five feet of the compatible insulin pump.

⚠ PRECAUTION

ALWAYS ensure your pump has established a Bluetooth wireless connection with your smartphone before you use the t:connect mobile app. Confirm that the information displayed to you matches your signs and symptoms.

⚠ PRECAUTION

Use of the t:connect mobile app together with your insulin pump may impact the battery life of your pump due to the wireless data transmission between the devices.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. If you close or force stop your t:connect mobile app, it will not be running in the background.

CHAPTER 2 • Important Safety Information

⚠ PRECAUTION

DO NOT ignore symptoms of high and low glucose. If your t:connect mobile app readings do not match your symptoms, check your pump display and confirm that your pump has established a Bluetooth connection with your smartphone.

⚠ PRECAUTION

ALWAYS rely on your pump for therapy decisions if:

- » Your smartphone is incompatible with the Bolus Delivery feature of the t:connect mobile app
- » Your smartphone is lost or damaged
- » Your smartphone loses Bluetooth connectivity with your pump

⚠ PRECAUTION

DO NOT update your smartphone operating system prior to confirming that it is compatible with the Bolus Delivery plus Display and Data Upload feature of the t:connect mobile app. If you update to an incompatible operating system version, you will lose the ability to request, stop, or cancel a bolus from the t:connect mobile app.

⚠ PRECAUTION

DISCONTINUE use of the t:connect mobile app if your smartphone is damaged, or if a significant portion of its display is damaged or does not illuminate.

⚠ PRECAUTION

The t:connect mobile app is not intended to replace self-monitoring practices as advised by a physician.

⚠ PRECAUTION

The t:connect mobile app is not intended for use by anyone unable to use a smartphone proficiently. Users must have adequate vision and/or hearing in order to use the t:connect mobile app.

⚠ PRECAUTION

Use of mobile devices not complying with either IEC 60950-1, IEC 62368-1, or an equivalent standard may increase the risk of electrical hazards.

Supported mobile devices and the charging equipment provided by their manufacturers are compliant with appropriate electrical safety standards (IEC 60950-1, IEC 62368-1, or equivalent). For more information on supported devices, please visit

tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

2.7 Tandem Cybersecurity Preventative Measures

Medical devices, like other computer systems, can be vulnerable to cybersecurity risks, potentially impacting the safety and effectiveness of the device. Incorrect use of the t:slim X2 insulin pump or your failure to follow the instructions, precautions, and warnings in this user guide may result in an inoperable pump or expose your t:slim X2 insulin pump to cybersecurity risks.

- Keep your pump, smartphone, and t:connect mobile app in your control or on your person at all times.
- Always disconnect your pump from the computer and USB cable when not using it to upload pump data or perform software updates with the Tandem Device Updater.
- Do not share your pump's serial number or t:connect mobile app

pairing code with any untrusted individual. Do not write these numbers down anywhere they can be accessed by an untrusted individual.

- Do not connect to or allow any third-party devices to pair with your pump that are not included as part of the Tandem system. See 1.3 System Description for a full system description.
- Do not use any software or third-party applications which have not been authorized by Tandem as being safe for use with your pump.
- Only attempt to perform software updates using the authorized Tandem Device Updater.

Contact Tandem's Customer Technical Support if you suspect your pump may have been compromised by any cybersecurity interference or vulnerability.

2.8 Potential Benefits From Using Your Pump

- The pump provides an automated way to deliver basal and bolus insulin. Delivery can be fine-tuned based on up to six customizable Personal Profiles, each with up to 16 time-based settings for Basal Rate, Carb Ratio, Correction Factor, and Target BG. In addition, the temp rate feature allows you to program a temporary Basal Rate change for up to 72 hours.
- The pump gives you the option of delivering a bolus all at once, or delivering a percentage over an extended period of time without navigating to different menus. You can also program a bolus more discreetly using the Quick Bolus feature, which can be used without looking at the pump, and can be programmed in increments of either units of insulin or grams of carbohydrate.
- From the *Bolus* screen, the “calculator within a calculator” feature allows you to enter multiple

carbohydrate values and add them together. The insulin pump's bolus calculator will recommend a bolus based on the entire amount of carbohydrates entered, which can help eliminate guesswork.

- The pump keeps track of the amount of active insulin from food and correction boluses (IOB). When programming additional food or correction boluses, the pump will subtract the amount of IOB from the recommended bolus if your BG is below the target set in your active Personal Profile. This can help prevent insulin stacking, which can lead to hypoglycemia (low BG).
- You can program a number of reminders that will prompt you to retest your BG after a low or high BG is entered, as well as a “Missed Meal Bolus Reminder” which will alert you if a bolus isn't entered during a specified period of time. If activated, these can help reduce the likelihood that you will forget to check your BG or bolus for meals.
- You have the ability to view a variety of data right on your screen,

CHAPTER 2 • Important Safety Information

including the time and amount of your last bolus, your total insulin delivery by day, as well as broken into basal, food bolus, and correction bolus.

2.9 Possible Risks From Using Your Pump

As with any medical device, there are risks associated with using your pump. Many of the risks are common to insulin therapy in general, but there are additional risks associated with continuous insulin infusion and continuous glucose monitoring. Reading your user guide and following the instructions for use are critical for the safe operation of your System. Consult your healthcare provider about how these risks may impact you.

Inserting and wearing an infusion set might cause infection, bleeding, pain or skin irritations (redness, swelling, bruising, itching, scarring, or skin discoloration).

There is a remote chance that an infusion set cannula fragment could remain under your skin if the cannula

breaks while you are wearing it. If you think a cannula has broken under your skin, contact your healthcare provider and call Customer Technical Support.

Other risks associated with infusion sets include occlusions and air bubbles in the tubing or dislodged cannula, which can affect insulin delivery. If your BG does not decrease after initiating a bolus, or you have other unexplained high BG, it is recommended that you check your infusion set for an occlusion or air bubbles, and verify that the cannula has not dislodged. If the condition persists, call Customer Technical Support or seek medical attention as required.

Risks that could result from pump failure include the following:

- possible hypoglycemia (low BG) from over-delivery of insulin due to a hardware defect or software anomaly.
- hyperglycemia (high BG) and ketosis possibly leading to Diabetic Ketoacidosis (DKA) due to pump failure resulting in cessation of insulin delivery due to either a

hardware defect, software anomaly, or infusion set failure. Having a backup method of insulin delivery greatly reduces your risk of severe hyperglycemia or DKA.

2.10 Working with your Healthcare Provider

Any clinical language presented in this user guide is based on the assumption that you have been educated by your healthcare provider on certain terms and how they apply to you in your diabetes management. Your healthcare provider can help you establish diabetes management guidelines that best fit your lifestyle and needs.

Consult your healthcare provider before using the pump to determine which features are most appropriate for you. Only your healthcare provider can determine and help you adjust your Basal Rate(s), insulin-to-carbohydrate ratio(s), Correction Factor(s), Target BG, and duration of insulin action. In addition, only your healthcare provider can determine your CGM settings and how you should use your sensor trend

information to help you manage your diabetes.

2.1.1 Verification of Proper Functionality

Pump Functionality

A power supply (AC adapter with micro-USB connector) is provided with your pump. Before using your pump, ensure that the following occur when you connect a power supply into the USB port of your pump:

- You hear an audible alert
- You see the green light illuminate from the edge around the **Screen On/Quick Bolus** button
- You feel a vibratory alert
- You see a charge symbol (lightning bolt) on the battery level indicator

In addition, before using your pump, ensure the following:

- Press the **Screen On/Quick Bolus** button to turn the screen on so that you can see the display

- When the display screen is on, the touchscreen responds to your finger tap

⚠ PRECAUTION

CONFIRM that the pump screen display turns on, you can hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the **Screen On/Quick Bolus** button when you connect a power source to the USB port. These features are used to notify you about alerts, alarms, and other conditions that require your attention. If these features are not working, discontinue use of your pump and contact Customer Technical Support.

t:connect Mobile App Functionality

Before using the t:connect mobile app, when you connect a smartphone to your pump, ensure the data displayed on your t:connect mobile app matches the data displayed on your pump screen.

⚠ PRECAUTION

ALWAYS ensure your pump has established a Bluetooth wireless connection with your smartphone before you use the t:connect mobile app. Confirm that the information displayed to you matches your signs and symptoms.

This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 3

Getting to Know Your t:slim X2 Insulin Pump

CHAPTER 3 • Getting to Know Your t:slim X2 Insulin Pump

3.1 What your t:slim X2 Pump Package Includes

Your pump package should include the following items:

1. t:slim X2™ insulin pump
2. pump case
3. t:slim X2 Insulin Pump with Control-IQ™ Technology User Guide
4. USB cable
5. wall power USB adapter
6. cartridge removal tool

If any of these items are missing, contact your local customer support.

If you use a CGM, the Dexcom G6 sensors and transmitters are sold and shipped separately.

Your pump is shipped with a clear screen protector. Do not remove the screen protector.

Your pump comes with a protective cover in the place where the cartridge is normally inserted. This cover must be removed and replaced with a cartridge prior to initiating insulin delivery.

The t:slim X2 3 mL cartridge with t:lock™ connector consists of the reservoir chamber and a micro-delivery chamber for the delivery of very small amounts of insulin. A variety of compatible infusion sets with the t:lock connector are available from Tandem Diabetes Care, Inc. The t:lock connector allows a secure connection between the cartridge and the infusion set. Use only t:slim X2 cartridges and compatible infusion sets with t:lock connectors manufactured for Tandem Diabetes Care, Inc.

Your pump also includes consumable components that may require replacement during the life of your pump, including:

- pump case(s)/clip(s)
- screen protector
- USB rubber door
- USB cable

Supply Reordering

To order cartridges, infusion sets, supplies, accessories, screen protectors, please contact your local customer support or your usual supplier of diabetes products.

3.2 Pump Terminology**Basal**

Basal is a slow continuous delivery of insulin, which keeps glucose levels stable between meals and during sleep. It is measured in units per hour (units/hr).

BG

BG is the abbreviation for blood glucose, which is the level of glucose in the blood, measured in mg/dL.

BG Target

BG target is a specific BG or glucose value goal, an exact number, not a range. When a glucose value is entered in the pump, the calculated insulin bolus will be adjusted up or down as needed to attain this target.

Bolus

A bolus is a quick dose of insulin that is usually delivered to cover food eaten or correct high glucose. With the pump it can be delivered as a Standard, a Correction, an Extended, or a Quick Bolus.

Cannula

The cannula is the part of the infusion set that is inserted under the skin through which insulin is delivered.

Carb

Carb or Carbohydrate refers to sugars and starches that the body breaks down into glucose and uses as an energy source, measured in grams.

Carb Ratio

The carb ratio is the number of grams of carbohydrate that 1 unit of insulin will cover. Also known as insulin-to-carbohydrate ratio.

Correction Bolus

A correction bolus is given to correct high glucose.

Correction Factor

A correction factor is the amount of glucose that is lowered by 1 unit of

insulin. Also known as the Insulin Sensitivity Factor (ISF).

Extended Bolus

An extended bolus is a bolus that is delivered over a period of time. It is commonly used to cover food that takes longer to digest. When administering an extended bolus with your pump, enter the DELIVER NOW portion to dose a percentage of insulin immediately and the remaining percentage over a period time.

Grams

Grams are the measurement for a carbohydrate.

Insulin Duration

Insulin duration is the amount of time that insulin is active and available in the body after a bolus has been delivered. This also relates to the calculation for Insulin on Board (IOB).

Insulin On Board (IOB)

IOB is the insulin that is still active (has the ability to continue to lower the glucose) in the body after a bolus has been delivered.

Load

Load refers to the process of removing, filling, and replacing a new cartridge and infusion set.

Personal Profile

A personal profile is a personalized group of settings that defines the delivery of basal and bolus insulin within specific time segments throughout a 24 hour period.

Quick Bolus

Quick bolus (using the **Screen On/Quick Bolus** button) is a way to deliver a bolus by following beep/vibration commands without navigating through or viewing the pump screen.

Temp Rate

Temp rate is an abbreviation for a temporary basal rate. It is used to increase or decrease the current basal rate for a short period of time to accommodate special situations. 100% is the same basal rate as programmed. 120% means 20% more and 80% means 20% less than the programmed basal rate.

CHAPTER 3 • Getting to Know Your t:slim X2 Insulin Pump

Units

Units are the measurement for insulin.

USB Cable

USB is the abbreviation for Universal Serial Bus. The USB cable connects into the pump's micro USB port.

WARNING

ALWAYS use the USB cable provided with your t:slim X2 insulin pump to minimize the risk of fires or burns.

3.3 Explanation of Insulin X2 Insulin Pump Icons

The following icons may appear on your pump screen:

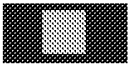
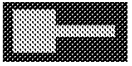
Pump Icon Definitions

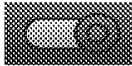
Symbol	Definition
	The amount of charge left in the pump battery.
	A system reminder, alert, error, or alarm is active.
	All insulin deliveries are stopped.
	Basal insulin is programmed and being delivered.
	Bluetooth wireless technology
	Accept. Tap to continue to the next screen or to answer yes to a message on the pump screen.
	Save. Tap to save settings on the screen.
	Delete. Tap to delete characters or digits on a keypad.
	New. Tap to add a new item.

Symbol	Definition
	The amount of insulin remaining in the cartridge.
	A temporary basal rate is active.
	A basal rate of 0 u/hr is active.
	A temporary basal rate of 0 u/hr is active.
	A bolus is being delivered.
	Cancel. Tap to cancel the current operation.
	Decline. Tap to exit the screen or answer no to a message on the pump screen.
	Back. Tap to navigate to the previous screen.
	Total. Tap to total values on a keypad.

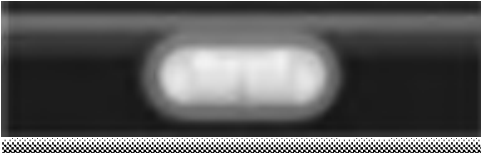
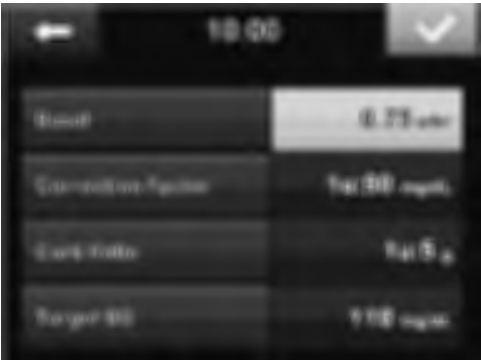
CHAPTER 3 • Getting to Know Your Insulin Pump

Pump Icon Definitions (Continued)

Symbol	Definition
	Space. Tap to enter a space on the character keypad.
	OK. Tap to confirm the current instruction or setting on the screen.
	A food and/or correction bolus was delivered. This icon only appears when a CGM sensor session is active.
	An extended bolus was delivered. The square represents the DELIVER NOW portion of the bolus, and the line represents the DELIVERY LATER portion of the bolus. This icon only appears when a CGM sensor session is active.

Symbol	Definition
	Security PIN has been enabled. See Section 5.13 Turn Security PIN On or Off.
	The associated setting is turned on.
	The associated setting is turned off.

3.4 Explanation of Pump Colors

	Red LED 1 red blink every 30 seconds indicates a malfunction or alarm condition.
	Yellow LED 1 yellow blink every 30 seconds indicates an alert or reminder condition.
	Green LED • 1 green blink every 30 seconds indicates the pump is functioning normally. • 3 green blinks every 30 seconds indicate the pump is charging.
	Orange Highlight When editing settings, changes are highlighted in orange for review before saving.

CHAPTER 3 • Getting to Know Your t:slim X2 Insulin Pump

3.5 Pump Back Side

1. **t:slim X2 Cartridge:** A single-use disposable cartridge can hold up to 300 units (3.0 mL) of insulin.
2. **Vent Holes:** Vent holes help the pump function correctly. It is important that these vents remain uncovered.

PRECAUTION

If you choose to use a pump case or other accessories not provided by Tandem, **DO NOT** cover the six vent holes on the back of the pump. Covering the vent holes could affect insulin delivery.



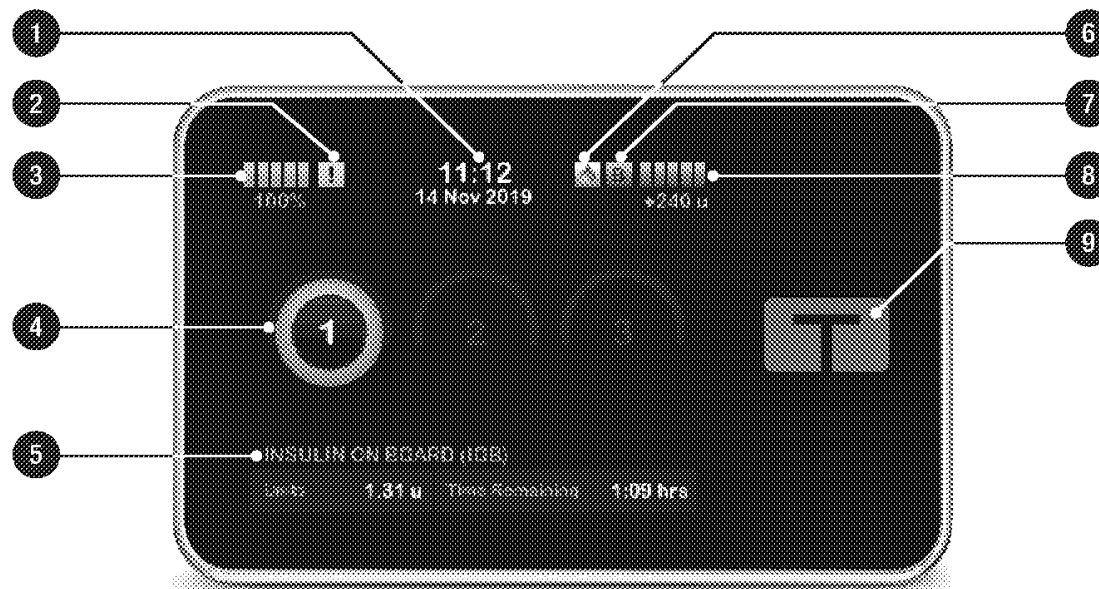
CHAPTER 3 • Getting to Know Your Tandem T2 Insulin Pump

3.6 Lock Screen

The *Lock* screen appears anytime you turn on the screen. You must tap 1–2–3 in sequential order to unlock the pump.

1. **Time and Date Display:** Displays the current time and date.
2. **Alert Icon:** Indicates a reminder, alert or alarm is active behind the *Lock* screen.
3. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
4. **1–2–3:** Unlocks pump screen.
5. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.
6. **Active Bolus Icon:** Indicates a bolus is active.
7. **Status:** Displays current system settings and insulin delivery status.
8. **Insulin Level:** Displays the current amount of insulin in the cartridge.
9. **Tandem Logo:** Returns to the *Home* screen.

CHAPTER 3 • Getting to Know Your tslim X2 Insulin Pump

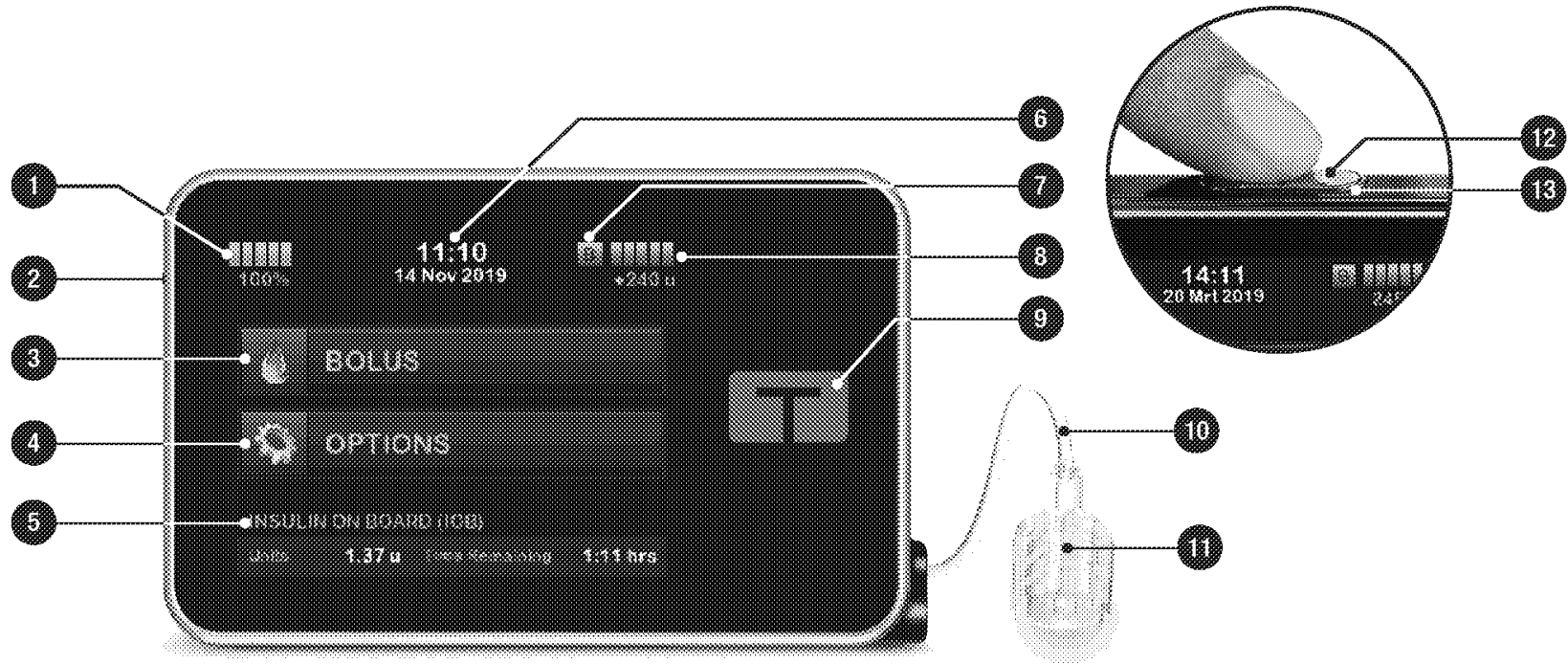


CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.7 Home Screen

1. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
2. **USB Port:** Port to charge your pump battery. Close the cover when not in use.
3. **Bolus:** Program and deliver a bolus.
4. **Options:** Stop/Resume insulin delivery, manage pump and CGM settings, start/stop activities, load a cartridge, and view history.
5. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.
6. **Time and Date Display:** Displays the current time and date.
7. **Status:** Displays current system settings and insulin delivery status.
8. **Insulin Level:** Displays the current amount of insulin in the cartridge.
9. **Tandem Logo:** Returns to the *Home* screen.
10. **Cartridge Tubing:** Tubing that is attached to the cartridge.
11. **Tubing Connector:** Connects the cartridge tubing to the infusion set tubing.
12. **Screen On/Quick Bolus button:** Turns the pump screen on/off or programs a Quick Bolus (if activated).
13. **LED Indicator:** Illuminates when connected to a power supply and indicates proper functionality.

CHAPTER 3 • Getting to Know Your tulin X2 Insulin Pump



CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.8 Current Status Screen

The *Current Status* screen can be accessed from the *Lock* screen and the *Home* screen by tapping the insulin level symbol. It is for display only; no changes can be made from this screen.

1. : Returns to the *Home* screen.
2. **Profile**: Displays current active Personal Profile.
3. **Basal Rate**: Displays current basal rate being delivered in units/hr. If a temp rate is active, this row will change to display current temp rate being delivered in units/hr.
4. **Last Bolus**: Displays amount, date and time of last bolus.
5. **Control-IQ Status**: Displays Control-IQ technology status.
6. **Up/Down Arrow**: Indicates there is more information.
7. **Correction Factor**: Displays current correction factor used to calculate a bolus.
8. **Carb Ratio**: Displays current carb ratio used to calculate a bolus.
9. **Target BG**: Displays current BG target used to calculate a bolus.
10. **Insulin Duration**: Displays current insulin duration setting used to calculate insulin on board.
11. **Last Calibration**: Displays date and time of last calibration.
12. **Time Sensor Started**: Displays date and time of last time sensor started.
13. **Transmitter Battery**: Displays CGM transmitter battery status.
14. **Mobile Connection**: Displays whether the mobile connection is turned on or off, whether a smartphone is paired with the pump, and if so whether the smartphone is actively connected to the pump.

CHAPTER 3 • Getting to Know Your tslim X2 Insulin Pump



CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.9 Bolus Screen

The Bolus screen will default to use units of insulin in calculating a bolus. You may change this setting in your Personal Profile to use grams of carbohydrate instead. Both screens are shown on the next page as examples.

1. : Returns to the *Home* screen.
2. **Insulin:** Enter units of insulin. You may change this setting to use grams of carb. See Section 6.2 Creating a New Profile for details on how to set the Increment Type.
3. **Units:** Displays total units calculated. Tap to enter a bolus request or change (override) a calculated bolus.
4. **View Calculation:** Displays how the insulin dose was calculated using the current settings.
5. **Glucose:** Enter BG or sensor glucose level. This value is populated automatically if each of the following conditions are true:

- Control-IQ technology is turned on and available
- A CGM session is active
- A CGM value is present
- A CGM trend arrow is available on the *CGM Home* screen

NOTE

For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's product instructions. You can also see Section 25.3 Rate of Change Arrows.

You can choose to use this value or enter another value from an alternate testing method.

6. : Moves to next step.
7. **Carbs:** Enter grams of carbohydrate. You may change this setting to use units of insulin. See Section 6.2 Creating a New Profile for details on how to set the Increment Type.

Using Units



Using Grams

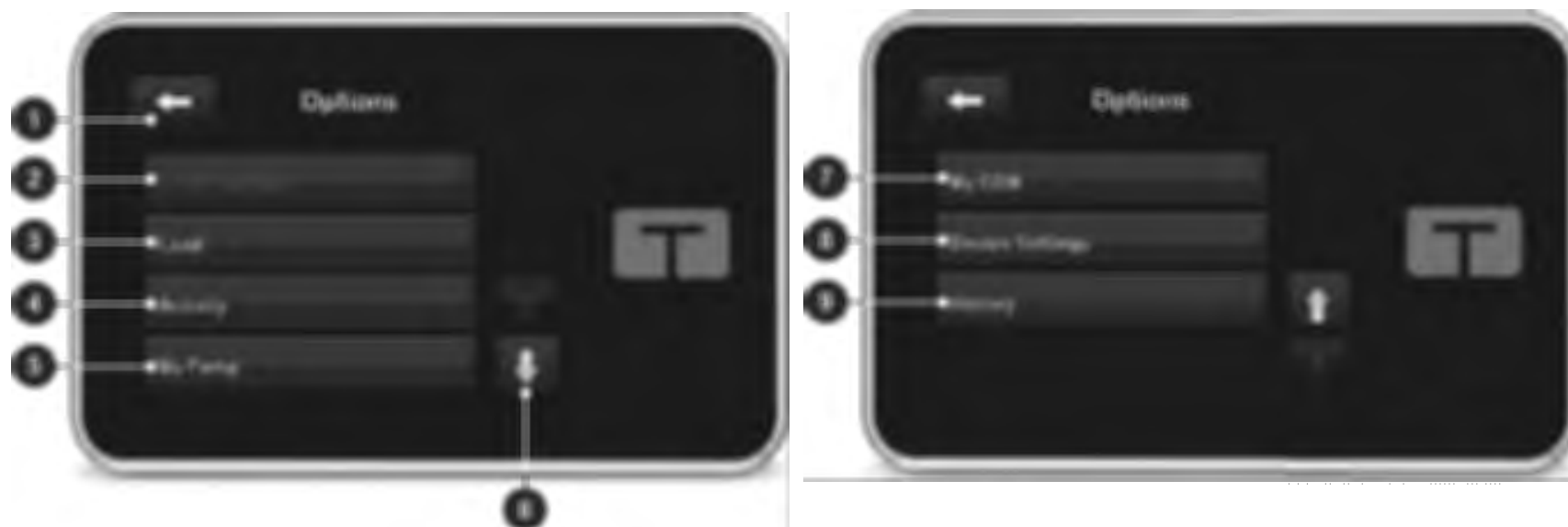


CHAPTER 3 • Getting to Know Your Insulin X2 Insulin Pump

3.10 Options Screen

1. : Returns to the *Home* screen.
2. **Stop Insulin:** Stops insulin delivery. If insulin delivery is stopped, RESUME INSULIN will be displayed.
3. **Load:** Change Cartridge, Fill Tubing, Fill Cannula, and Site Reminder.
4. **Activity:** Programs on Exercise, Sleep, and temporary Basal Rates.
5. **My Pump:** Personal Profiles, Control-IQ, Alerts & Reminders, and Pump Info.
6. **Up/Down Arrow:** Indicates there is more information.
7. **My CGM:** Start/Stop Sensor, Calibrate CGM, CGM Alerts, Transmitter ID, and CGM Info.
8. **Device Settings:** Display settings, Bluetooth settings, Time and Date, Sound Volume, and Security PIN.
9. **History:** Displays historical log of pump and CGM events.

CHAPTER 3 • Getting to Know Your tslim X2 Insulin Pump



CHAPTER 3 • Getting to Know Your Insulin X2 Insulin Pump

3.11 My Pump Screen

1. : Returns to the *Options* screen.
2. **Personal Profiles:** A group of settings that define basal and bolus delivery.
3. **Control-IQ:** Turn on/off Control-IQ technology and enter required values.
4. **Alerts & Reminders:** Customize Pump Reminders and Pump Alerts.
5. **Pump Info:** Displays pump serial number, local customer support service contact information website, and other technical information.



CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.12 Device Settings Screen

1. : Returns to the *Options* screen.
2. **Display Settings:** Customize the Screen Timeout settings.
3. **Bluetooth Settings:** Turn on/off mobile connection.
4. **Time and Date:** Edit the time and date that will be displayed on the pump.
5. **Sound Volume:** Customize the sound volume for pump alarms, pump alerts, reminders, keypad, bolus, quick bolus, fill tubing, and CGM alerts.
6. **Security PIN:** Turn on/off the Security PIN.

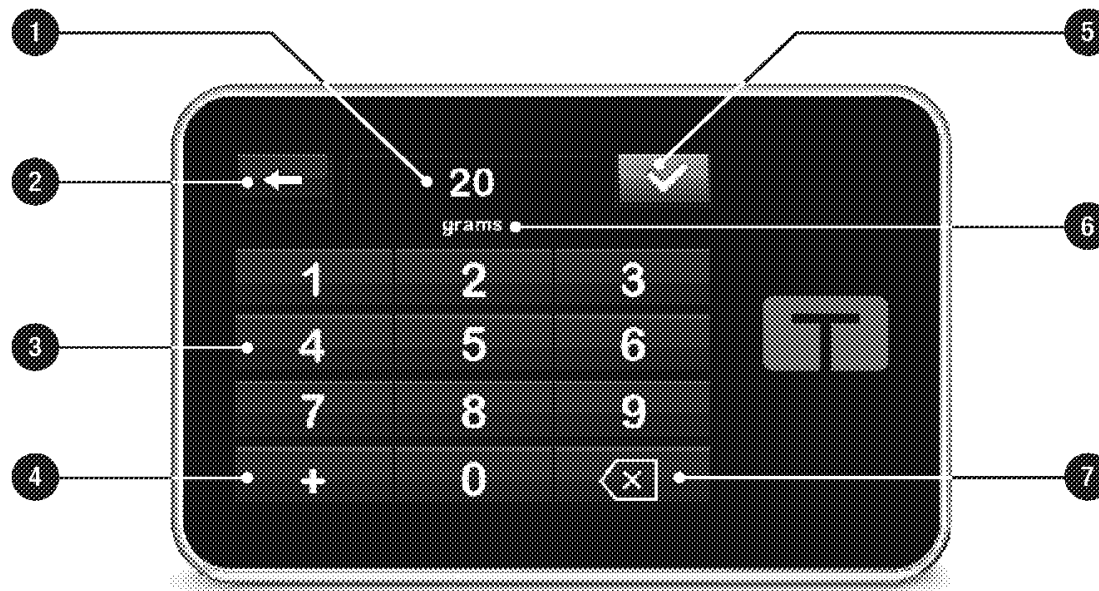
CHAPTER 3 • Getting to Know Your tslim X2 Insulin Pump



CHAPTER 3 • Getting to Know Your Insulin J12 Insulin Pump

3.13 Number Keypad Screen

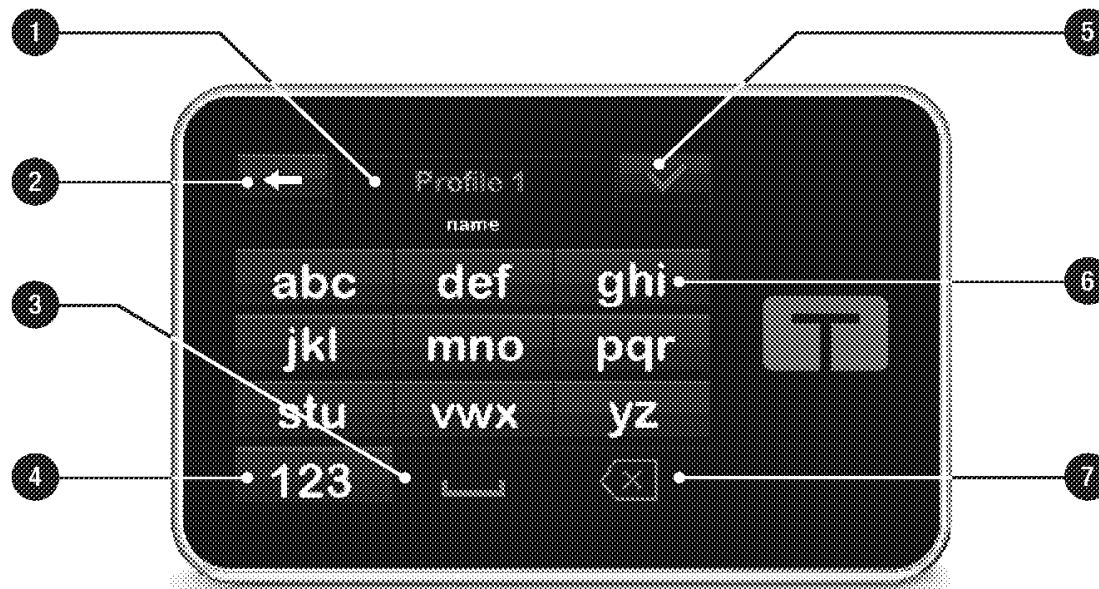
1. **Value Entered.**
2. : Returns to previous screen.
3. **Keypad Numbers.**
4. : Allows numbers to be added on the gram screen. If in units, this displays as a decimal point.
5. : Completes task and saves information entered.
6. **Units/Grams:** Unit of measure associated with the value entered.
7. : Deletes last number entered.



CHAPTER 3 • Getting to Know Your Insulin X2 Insulin Pump

3.14 Letter Keypad Screen

1. **Name of Profile.**
2. : Returns to previous screen.
3. : Enters a space.
4. **123:** Changes keypad mode from letters (ABC) to numbers (123).
5. : Saves entered information.
6. **Letters:** Tap once for first letter displayed, 2 quick taps for middle letter, and 3 quick taps for third letter.
7. : Deletes last letter or number entered.



This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 4

Getting to Know Your t:connect Mobile App

CHAPTER 4 • Getting to Know Your t:connect Mobile App

4.1 Overview

The t:connect™ mobile app is a companion app for the t:slim X2™ insulin pump. Before you begin, ensure your smartphone and the t:connect mobile app are compatible, and turn off smartphone automatic operating system (OS) updates. The feature set available within the t:connect mobile app is dependent on your pump software version as well as your smartphone model and operating system. Available feature sets are:

- **Display and Data Upload:** This feature set provides a secondary display of your pump and continuous glucose monitoring (CGM) information, including display of your pump alerts and alarms, and enables wireless uploading of pump and CGM data to the Tandem cloud.
- **Bolus Delivery plus Display and Data Upload:** In addition to the Display and Data Upload features, the bolus delivery feature allows you to use the t:connect mobile app to

request a bolus, stop a bolus, and cancel a bolus.

To download the t:connect mobile app, go to Google Play™ or the App Store®. For installation instructions, visit support.tandemdiabetes.com.

 NOTE

For an up-to-date list of supported smartphones, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

For more information on the setup and configuration of your smartphone to work with the t:connect mobile app, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

In certain situations, the features of the t:connect mobile app may be restricted, including when using an incompatible smartphone or pump.

 WARNING

ALWAYS rely on your pump to make therapy decisions when using a smartphone that is incompatible with the Bolus Delivery feature.

 PRECAUTION

ALWAYS rely on your pump for therapy decisions when:

- » Your smartphone is incompatible with the Bolus Delivery feature of the t:connect mobile app
- » Your smartphone is lost or damaged
- » Your smartphone loses Bluetooth connectivity with your pump

 PRECAUTION

Pump notifications cannot be cleared from your t:connect mobile app. Pump Alerts, Alarms, and Notifications can be viewed on your smartphone, but must be cleared on the t:slim X2 pump.

 PRECAUTION

DO NOT update your smartphone operating system prior to confirming that it is compatible with the Bolus Delivery plus Display and Data Upload feature of the t:connect mobile app. If you update to an incompatible operating system

version, you will lose the ability to request or control a bolus from the t:connect mobile app.

⚠ PRECAUTION

Discontinue use of the t:connect mobile app if your smartphone is damaged, or if a significant portion of its display is damaged or does not illuminate.

4.2 Install the t:connect Mobile App

⚠ WARNING

DO NOT use a smartphone that has been jailbroken or rooted, or with Android developer mode on. Data may become vulnerable if you install the t:connect mobile app on a smartphone that has been jailbroken or rooted, or uses an unreleased or pre-released operating system. Only download the t:connect mobile app on Google Play™ or from the App Store®.

⚠ PRECAUTION

ALWAYS turn Zoom Mode off when using the t:connect mobile app. If your smartphone has Zoom Mode turned on, you should rely on your pump for all therapy decisions.

Supported mobile devices are compliant with appropriate electrical

safety standards (IEC 60950-1, IEC 62368-1, or equivalent).

⚠ PRECAUTION

Use of mobile devices not complying with either IEC 60950-1, IEC 62368-1, or an equivalent standard may increase the risk of electrical hazards.

Supported mobile devices and the charging equipment provided by their manufacturers are compliant with appropriate electrical safety standards (IEC 60950-1, IEC 62368-1, or equivalent). For more information on supported devices, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

📌 NOTE

The t:connect mobile app must run in the background in order to receive and transmit data to and from your pump, as well as to the Tandem cloud. When you connect the t:connect mobile app to the pump, you must disable battery optimization on your smartphone to ensure the t:connect mobile app can receive alerts and alarms. It is recommended to follow your smartphone manufacturer's instructions for charging.

Enable smartphone security (e.g., screen lock, passcode, face recognition) before using the t:connect mobile app to administer a bolus. Never share your security PIN/password or authorize any other person to access your smartphone via their biometric information to avoid unintentional changes in your delivery of insulin.

After you download the t:connect mobile app, locate it on your smartphone and open it. The sign-in screen appears.

- You should allow all permission requests from the t:connect mobile app to ensure you receive all notifications from your pump. (See Section 4.4 Set Mobile Notifications to configure your notification settings.)
- For Android users, to use Bluetooth, the t:connect mobile app may ask for access to your device location; tap **Allow**.

If you have an existing t:connect account, log in using your username and password.

CHAPTER 4 • Getting to Know Your t:connect Mobile App

If you are a new user:

1. Tap **Get Started**.
2. Enter your account information, including name, account type, and login information.

NOTE

For personal accounts, you must be at least 13 years old in accordance with the Children's Online Privacy Protection Act (COPPA), which prohibits collecting information from people under the age of 13 without parental consent. If you are taking care of or acting on behalf of someone younger than 13, select a parent, guardian, or caretaker account.

3. The *Your glucose targets and limits* screen appears. You can set your High Glucose value, your Target Glucose Range values, and your Low Glucose value for display on your reports. The ADA-recommended values are 181, 70-180, and 69 respectively.

NOTE

We encourage you to discuss these values with your healthcare provider before setting

them. You can leave the fields blank during account set-up and enter them later. Setting or changing these values will not change any settings in the pump itself.

Update the t:connect Mobile App

When updates to the t:connect mobile app are available, do not uninstall the app. When you download and install an

update, your t:connect mobile app will still be connected to your t:connect account, the smartphone will still be paired with your pump, and your app settings will remain the same.

If you uninstall the t:connect mobile app, when you re-install the t:connect mobile app, you will be asked to log in using your credentials. Once you are logged in, your t:connect mobile app settings will be restored from the last time you synchronized with the Tandem cloud.

Updating Your Smartphone

Before you manually update your phone operating system, confirm that the t:connect mobile app is compatible with the new operating system. For more information about managing automatic updates, tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

⚠ PRECAUTION

DO NOT update your smartphone operating system prior to confirming that it is compatible with the Bolus Delivery plus Display and Data Upload feature of the t:connect mobile app. If you update to an incompatible operating system

version, you will lose the ability to request or control a bolus from the t:connect mobile app. For more information, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

4.3 Connecting to a Smartphone

You can connect one compatible smartphone to the pump to display pump information and perform some pump functions on that smartphone using the t:connect mobile app.

NOTE

This Mobile Connection setting is not related to your CGM Bluetooth connection. For CGM Bluetooth information, see Section 21.1 About Bluetooth Technology.

When you connect the t:connect mobile app to the pump, you must disable battery optimization on your smartphone to ensure the t:connect mobile app can receive alerts and alarms. It is recommended to follow your smartphone manufacturer's instructions for charging.

NOTE

For more information on the setup and configuration of your smartphone to work with the t:connect mobile app, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

Pair a Smartphone

NOTE

Always use the t:connect mobile app to pair your pump with your smartphone. Do not attempt to use your smartphone's Bluetooth menu.

NOTE

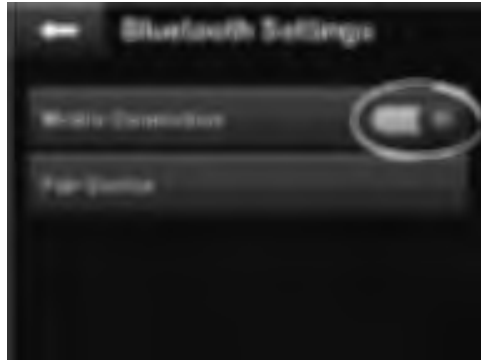
We strongly suggest that you upload pump data to the t:connect web application using the USB cable provided with your pump before you complete the pairing process to ensure all your pump data is uploaded as quickly as possible to the Tandem cloud. The first time you upload data to the Tandem cloud could take many hours over a slow internet connection on your smartphone.

Pair the t:connect mobile app with your pump as follows:

1. From your smartphone, open the t:connect mobile app.
 - » If you have an existing t:connect account, log in using your credentials.
 - » If you are a new user, create an account as shown in Section 4.1 Overview.
- ✓ The t:connect mobile app will prompt you to begin the pairing process.
2. From your pump's *Home* screen:
 - a. Tap **OPTIONS**.
 - b. Tap the **Down Arrow**.
 - c. Tap **Device Settings**.
 - d. Tap **Bluetooth Settings**.
 - e. Tap the on/off toggle next to **Mobile Connection** and tap .

CHAPTER 4 • Getting to Know Your t:connect Mobile App

to confirm. **Pair Device** is now displayed.



3. From the t:connect mobile app on your smartphone:
 - a. Tap **Begin** in the t:connect mobile app. A confirmation prompt will appear.
 - b. Choose the appropriate pump serial number on the *Select your pump* screen and tap **Next**.

NOTE

If you don't know your pump serial number, check your *Pump Info* screen as shown in Section 10.1 t:slim X2 Pump Info.

4. From your pump's *Bluetooth Settings* screen, tap **Pair Device**.
5. Your pump will display a *Mobile App notification* screen. Tap  to generate your device pairing code.

- ✓ Your pump will display a unique pairing code.

NOTE

The code is case sensitive and is only valid for 5 minutes - if more than 5 minutes have passed, tap **Pair Device** again to generate a new code.

NOTE

DO NOT tap **OK** on your pump. Tapping **OK** before completing pairing will cancel the pairing process.

6. From your smartphone, enter the pairing code generated in Step 5 into the t:connect mobile app and tap **Pair with pump**.
- ✓ Your pump will display a confirmation screen.

7. From your smartphone, tap **Sync pump data** in the t:connect mobile app to proceed with your normal pump use. The t:connect mobile app will display your dashboard and begin displaying pump data.

NOTE

If your smartphone does not pair with your pump, check your smartphone's Bluetooth settings, then retry steps 1 - 7. Note that if your smartphone asks you to allow it to communicate with an external device, you should accept.

8. From your pump, tap  to close the *PAIRING CODE* screen. If the pump has successfully paired with your smartphone, the *DEVICE PAIRED* screen is displayed.

Your t:connect mobile app will remain synchronized with your pump as long as a Bluetooth connection is established. The t:connect mobile app uploads your pump's data into the Tandem cloud approximately once per hour whenever it is connected to wi-fi or cellular data, depending on your data use settings. This allows you and your healthcare provider easy access to your

data via the t:connect web application without requiring access to your pump or connection cables.

PRECAUTION

ALWAYS ensure your pump has established a Bluetooth wireless connection with your smartphone before you use the t:connect mobile app. Confirm that the information displayed to you matches your signs and symptoms.

Unpair a Smartphone

You can disconnect a smartphone from a pump:

- If you replace your smartphone, you must unpair your previously paired smartphone from your pump before you can pair your new smartphone.
- If you replace your pump, you must unpair your old pump from your smartphone before you can pair your new pump.

Unpair a smartphone from your pump as follows:

1. From the t:connect mobile app:
 - a. Tap **Settings** on the *Navigation* bar.

- b. Tap **Paired Pump**.
- c. Tap **Unpair pump**. A confirmation prompt will appear.
- d. Tap **Unpair**. The t:connect mobile app displays a banner confirming that your pump has been unpaired and returns you to the pairing screen.

2. From your pump's *Home* screen, disable your pump's Mobile Connection toggle:
 - a. Tap **Options**.
 - b. Tap **Device Settings**.
 - c. Tap **Bluetooth Settings**.
 - d. Tap the on/off toggle next to Mobile Connection and tap  to confirm. **Pair Device** will disappear.
3. From your smartphone, remove your pump from your smartphone's Bluetooth device list.

If your pump is malfunctioning, or you otherwise don't have access to your pump (e.g., the pump has been lost or returned to Tandem), use your t:connect mobile app to unpair your smartphone from your pump as follows:

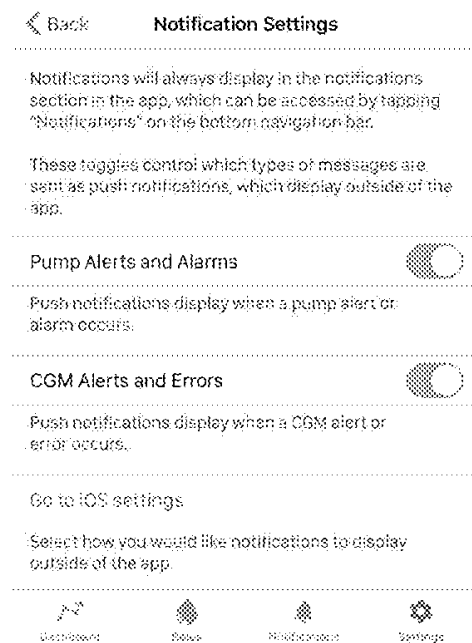
1. Tap **Settings** on the *Navigation* bar.
2. Tap **Paired Pump**.
3. Tap **Unpair pump**. A confirmation prompt will appear.
4. Tap **Unpair**. The t:connect mobile app displays a banner confirming that your pump has been unpaired and returns you to the pairing screen.

Once you have unpaired your smartphone from your pump, you can pair a different combination of smartphone and pump as described in *Pair a Smartphone*.

CHAPTER 4 • Getting to Know Your t:connect Mobile App

4.4 Set Mobile Notifications

The t:connect mobile app can display notifications generated by your pump or sent from the Tandem cloud, including pump alerts, alarms, and reminders. Tap **Settings** on the *Navigation* bar, then tap **Notification Settings** to toggle push notifications as desired. The following example shows possible push notification settings.



To ensure you receive notifications on the t:connect mobile app, confirm the smartphone sound mode is not set to mute, and enable the following settings:

- t:connect mobile app notifications
- Bluetooth

Check your smartphone settings to ensure your t:connect mobile app can connect to the internet.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. For more information, see Section 4.3 *Connecting to a Smartphone*, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

📌 NOTE

Check your smartphone's operating system push notification settings as well as those in the t:connect mobile app to ensure your pump and CGM alerts and alarms are set to your preference.

4.5 Mobile Connection Security

Only one smartphone and t:connect mobile app may pair with your pump. When pairing your pump to a t:connect mobile app, a unique code will be generated and used to secure communications between the pump and smartphone. All transmissions between the pump and smartphone are encrypted. The pump is designed to deny any unauthorized or unrecognized connections.

The pump is designed to check the integrity of all commands and data received from the t:connect mobile app. If the pump receives unexpected commands or data from the t:connect mobile app, the pump will ignore it and continue to operate as intended.

4.6 Lost Pump Connection

When your smartphone is more than five feet from the pump or experiencing Bluetooth connection issues, the t:connect mobile app will not display pump data until you restore the connection between your smartphone and the pump.

⚠ PRECAUTION

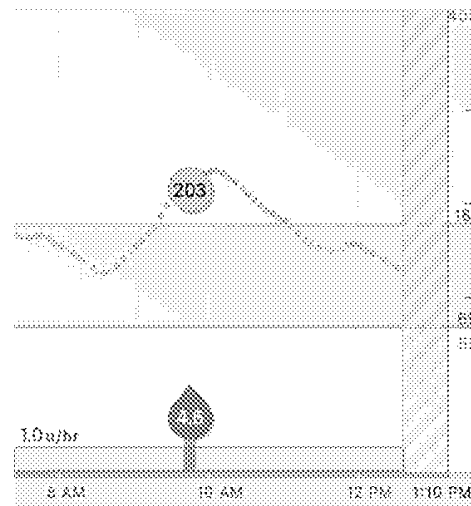
ALWAYS ensure your pump has established a Bluetooth wireless connection with your smartphone before you use the t:connect mobile app. Confirm that the information displayed to you matches your signs and symptoms.

The *Pump Connection Lost* notification banner replaces the current pump

status until you re-establish the Bluetooth connection.



Pump connection lost 30 min ago
You can use your pump until the connection is restored. Turn on Bluetooth in your phone's settings.

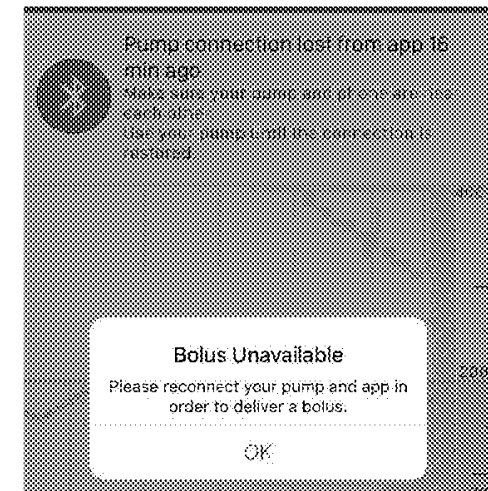


You will also see a gray shaded area on the graph since no data can be displayed when the connection is lost. When the connection is lost, use the pump to administer therapy while troubleshooting the loss of connection.

⚠ PRECAUTION

DO NOT ignore symptoms of high and low glucose. If your t:connect mobile app readings do not match your symptoms, check your pump display and confirm that your pump has established a Bluetooth connection with your smartphone.

If your smartphone and the pump are not connected, tapping **Bolus** on the navigation bar generates a *Bolus Unavailable* alert as shown in the following example.



CHAPTER 4 • Getting to Know Your t:connect Mobile App

Reconnect Bluetooth

When you see the *Pump Connection Lost* notification banner:

- Make sure that your pump and smartphone are within five feet of one another and without any obstruction between the two (including body parts).
- Confirm that Bluetooth technology is enabled on your smartphone.

If the connection is not restored within five minutes, reset the connection between your smartphone and your pump:

1. Force quit or close the t:connect mobile app.
2. Open the t:connect mobile app.
3. If your connection is lost again, disable your smartphone's Bluetooth connection.
4. Enable your smartphone's Bluetooth connection.

5. If your connection is lost again, sign out of your t:connect account.
6. Pair your smartphone with your pump as described in Section 4.3 *Connecting to a Smartphone*.

If the connection is lost again, discontinue use of the t:connect mobile app and contact Customer Technical Support.

4.7 Restart the t:connect Mobile App

If you have persistent issues with the t:connect mobile app, force stop or close the t:connect mobile app to end the current session.

For iOS devices:

1. Double-tap the Home button, or swipe up from the bottom of the screen and hold.
2. Find the t:connect mobile app and swipe up to close.
3. Reopen the t:connect mobile app.

For Android devices:

1. Open your smartphone's Settings menu.
2. Open your smartphone's application manager.
3. Tap **t:connect**. You may need to scroll down your list of applications to locate it among your apps.
4. Tap **Force Stop**.
5. Reopen the t:connect mobile app.

⚠ PRECAUTION

ALWAYS keep your t:connect mobile app running in the background so that pump alerts, alarms, and notifications can be displayed on your smartphone. These notifications are only received when the t:connect mobile app is either active or open in the background. If you close or force stop your t:connect mobile app, it will not be running in the background.

If the issue persists, try re-pairing the pump:

1. From the t:connect mobile app, tap **Settings**.

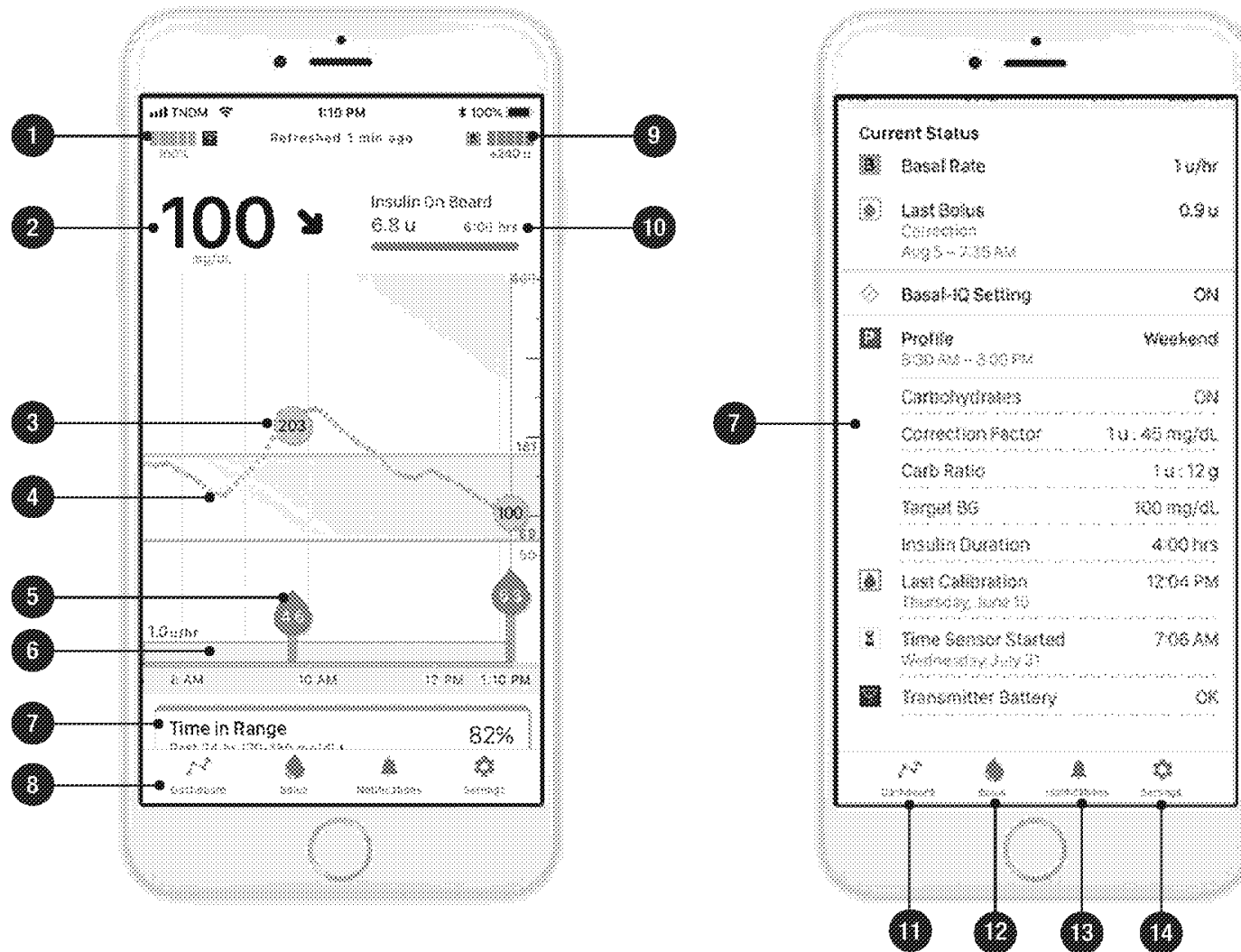
2. Tap Paired Pump.
3. Tap Unpair Pump.
4. Repeat the pairing process as shown in Section 4.3 Connecting to a Smartphone.

CHAPTER 4 • Getting to Know Your t:connect Mobile App

4.8 t:connect Mobile App Dashboard

1. **Pump Battery Level:** Displays the level of pump battery power remaining. When the pump is connected for charging, the charging icon (lightning bolt) will display.
2. **Most Recent 5-Minute Glucose Reading and Trend Arrow.**
3. **BG Entry:** Your BG value at the moment you entered it into your bolus calculator.
4. **Graph of Most Recent Glucose Readings:** Displays CGM sensor readings for the last 24 hours. You may swipe left and right to see all 24-hours in the graph. This graph also includes blood glucose (BG) readings entered into the bolus calculator.
5. **Delivered Bolus:** The amount of bolus insulin actually delivered for a given bolus event.
6. **Delivered Basal:** The amount of insulin delivered as basal for the past 24-hour period. This includes changes in insulin delivery related to use of Control-IQ™ technology.
7. **Status:** Displays current system settings and insulin delivery status. Swipe up to scroll down in the t:connect mobile app and see complete Status information.
8. **Navigation Bar:** Displays icons representing each mobile app page. The icon for the active t:connect mobile app page is highlighted blue.
9. **Insulin Level:** Displays the current amount of insulin in the cartridge. You can also tap the Insulin Level icon to automatically scroll down and see complete Status information.
10. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.
11. **Dashboard:** Displays pump status bar, current glucose reading, IOB status, CGM graph, time in range information, and current status.
12. **Bolus:** Navigate to the *Bolus* screen to program and deliver a bolus (only available with compatible devices).
13. **Notifications:** Displays active pump alerts, alarms, reminders, and malfunctions. See Section 4.4 Set Mobile Notifications for more information.
14. **Settings:** Navigate to the settings screen, including Glucose Thresholds for Display, App Notification Settings, Data Control settings, Tandem account information, pump pairing and unpairing, About, and Help.

CHAPTER 4 • Getting to Know Your t:connect Mobile App



CHAPTER 4 • Getting to Know Your t:connect Mobile App

4.9 t:connect Mobile App Bolus Screen

1. **Cancel:** Exit the *Bolus* screen and return to the Dashboard.
2. **Units:** Displays total units calculated. Tap to enter a bolus request or change (override) a calculated bolus.
3. **Insulin:** Enter units of insulin. You may change this setting on the pump to use grams of carbohydrate. See Section 8.9 Quick Bolus for more information.
4. **Delivery Calculation:** The amount of bolus insulin actually delivered for a given bolus event, including a breakdown of calculated Correction bolus, input Food bolus, and Insulin On Board (IOB) automatically.
5. **Next:** Accept changes input on the Bolus screen and proceed to the Bolus confirmation screen.
6. **Glucose:** Enter BG or sensor glucose level. This value is

populated automatically if each of the following are true:

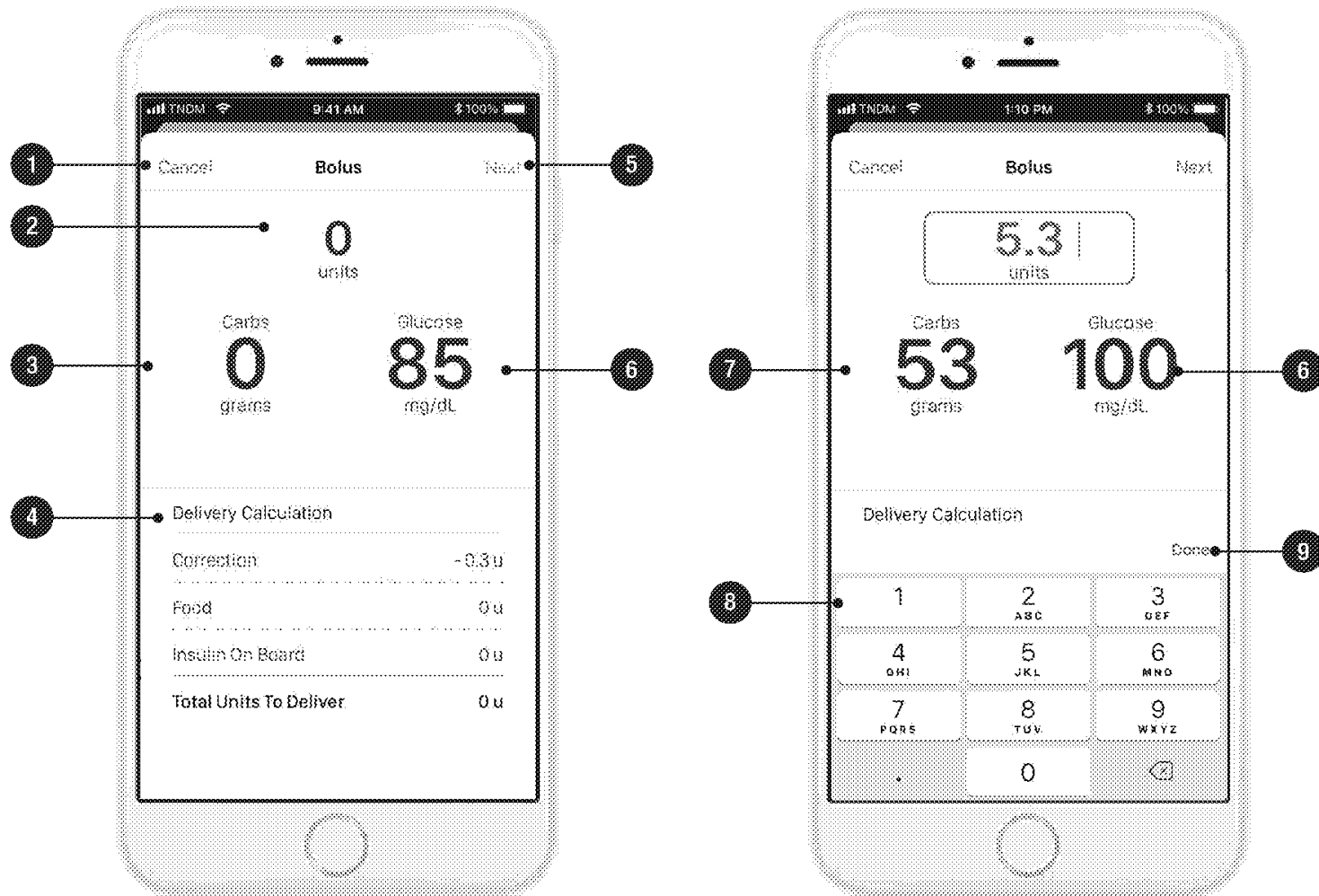
- Control-IQ technology is turned on and available
- A CGM session is active
- A CGM value is present
- A CGM trend arrow is available on the CGM Home screen

 NOTE

For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's user guide. You can also see Section 25.3 Rate of Change Arrows.

7. **Carbs:** Enter grams of carbohydrate. You may change this setting on the pump to use units of insulin. See Section 8.9 Quick Bolus for more information.
8. **Keypad Numbers.**
9. **Done:** Completes task and saves information entered.

CHAPTER 4 • Getting to Know Your t:connect Mobile App



CHAPTER 4 • Getting to Know Your t:connect Mobile App

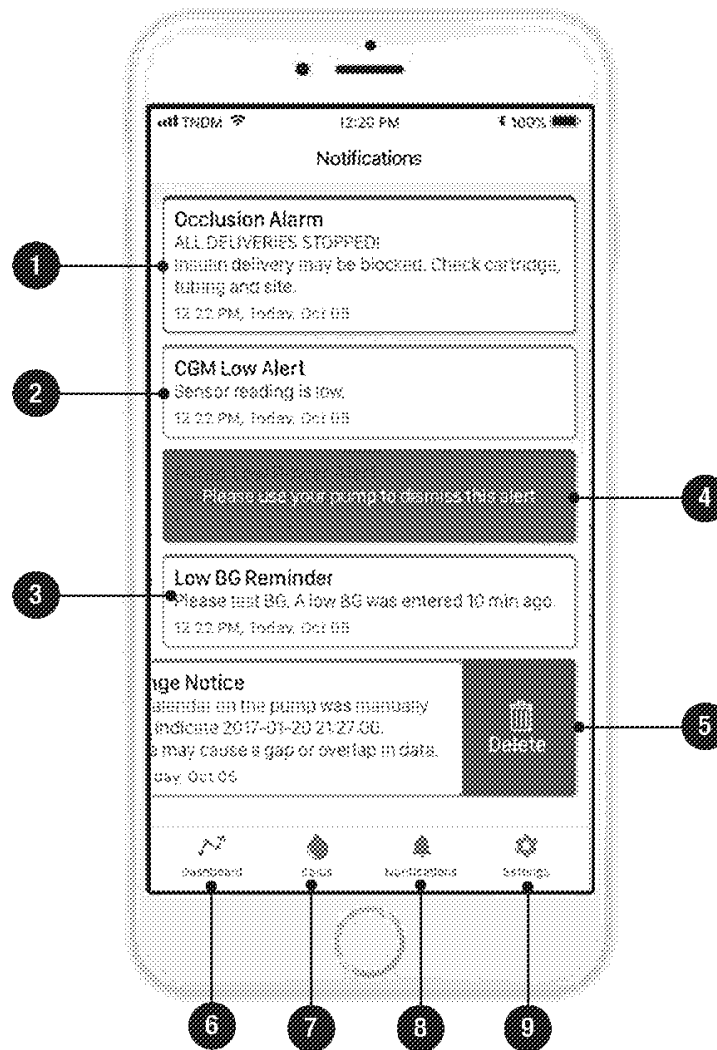
4.18 t:connect Mobile App
Notifications Screen

⚠ PRECAUTION

Pump notifications cannot be cleared from your t:connect mobile app. Pump Alerts, Alarms, and Notifications can be viewed on your smartphone, but must be cleared on the t:slim X2 pump.

1. **Alarm:** Displays a pump alarm. Alarms are outlined in red in the t:connect mobile app.
2. **Alert:** Displays a pump alert. Alerts are outlined in yellow in the t:connect mobile app.
3. **Reminder:** Displays a pump reminder. Reminders are outlined in blue in the t:connect mobile app.
4. **Dismiss:** Appears if you slide an alert notification (yellow outline) with your finger to the left. Tap this icon to dismiss the alert.
5. **Delete:** Appears if you slide a reminder or informational notification (blue outline) with your finger to the left. Tap this icon to delete the reminder or informational message.
6. **Dashboard:** Displays pump status bar, current glucose reading, IOB status, CGM graph, time in range information, and current status.
7. **Bolus:** Navigate to the *Bolus* screen to program and deliver a bolus (only available with compatible devices).
8. **Notifications:** Displays active pump alerts, alarms, reminders, and malfunctions. See Section 4.4 Set Mobile Notifications for more information.
9. **Settings:** Navigate to the settings screen, including Glucose Thresholds for Display, App Notification Settings, Data Control settings, Tandem account information, pump pairing and unpairing, About, and Help.

CHAPTER 4 • Getting to Know Your t:connect Mobile App

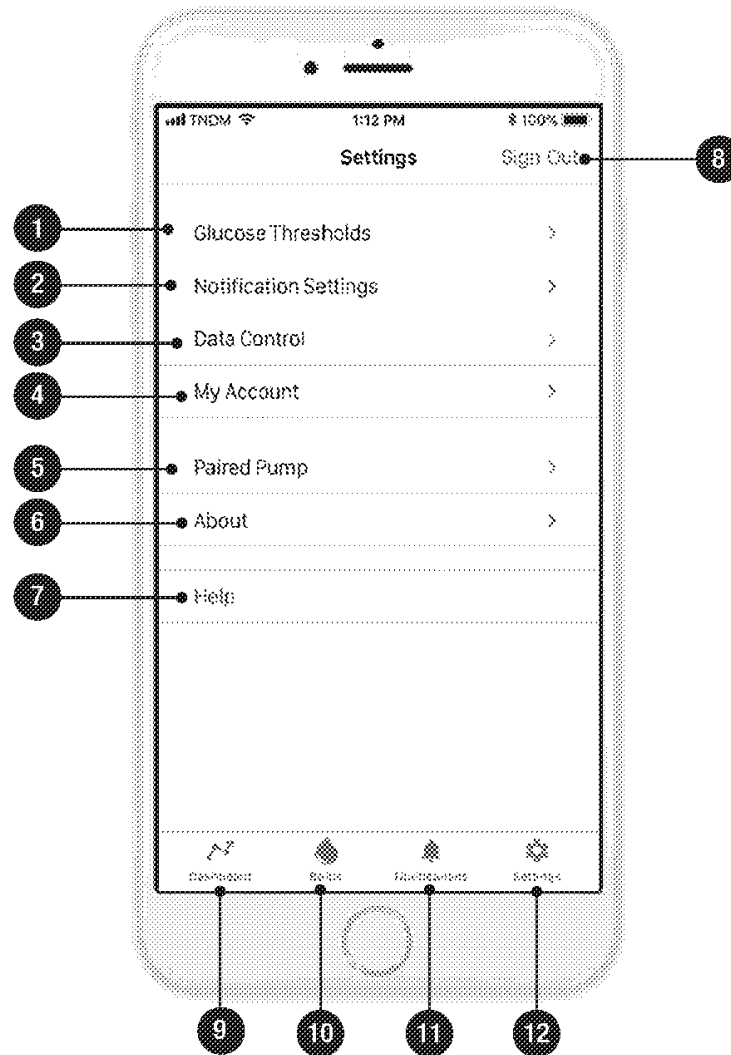


CHAPTER 4 • Getting to Know Your t:connect Mobile App

4.11 t:connect Mobile App Settings

1. **Glucose Thresholds:** Customize the way your data appears on your Dashboard and in the t:connect web application, including high glucose limit, target glucose range, low glucose limit, and how often your cartridge and infusion set should be change.
 2. **Notification Settings:** Set which events trigger notifications (e.g., pump alerts and alarms, CGM alerts and errors).
 3. **Data Control:** Directly access smartphone operating system settings relevant to the t:connect mobile app (e.g., whether to allow cellular data use to upload data).
 4. **My Account:** Edit account information. Any changes to your t:connect account made via the t:connect mobile app also apply to the t:connect web application.
 5. **Paired Pump:** Pair a pump with your smartphone, or unpair a pump from your smartphone.
-  **NOTE**
Always use the t:connect mobile app to pair your pump with your smartphone. Do not attempt to use your smartphone's Bluetooth menu.
6. **About:** Access Tandem contact information, corporate policies, and legal notices.
 7. **Help:** Access in-app help information, including FAQs, the pump user guide, an Icons and Graphics Glossary, and an App Guide that includes information on smartphone compatibility, setting up your smartphone, and troubleshooting information.
 8. **Sign Out:** Sign out of the t:connect mobile app. Tapping **Sign Out** generates a confirmation prompt.
 9. **Dashboard:** Displays pump status bar, current glucose reading, IOB status, CGM graph, time in range information, and current status.
 10. **Bolus:** Navigate to the *Bolus* screen to program and deliver a bolus (only available with compatible devices).
 11. **Notifications:** Displays active pump alerts, alarms, reminders, and malfunctions. See Section 4.4 Set Mobile Notifications for more information.
 12. **Settings:** Navigate to the settings screen, including Glucose Thresholds for Display, App Notification Settings, Data Control settings, Tandem account information, pump pairing and unpairing, About, and Help.

CHAPTER 4 • Getting to Know Your t:connect Mobile App



This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 5

Getting Started

CHAPTER 5 • Getting Started

5.1 Charging the t:slim X2 Pump

The pump is powered by an internal lithium polymer rechargeable battery. A full charge will typically last between 4 and 7 days, depending on your use of CGM and the t:connect™ mobile app. If you utilize both CGM and the t:connect mobile app, your battery is designed to last up to 4 days. Please be aware that the battery life on a single charge can vary considerably depending on individual usage, including insulin delivered, display-on time, and frequency of reminders, alerts, and alarms.

Accessories for charging from wall outlets, as well as from a computer USB port, are included with the pump. Use only the accessories provided to charge your pump. If you lose any of the accessories, or need a replacement, contact Customer Technical Support.

⚠ WARNING

ALWAYS use the USB cable provided with your t:slim X2™ insulin pump to minimize the risk of fires or burns.

The battery level indicator is displayed in the upper left portion of the *Home* screen. The charge amount will increase or decrease by 5% at a time (for example, you will see 100%, 95%, 90%, 85%). When the charge amount is less than 5%, it will begin decreasing 1% at a time (for example, you will see 4%, 3%, 2%, 1%).

When you first receive your pump, you will need to connect it to a charging source before it can be used. Charge the pump until the battery level indicator on the upper left portion of the *Home* screen reads 100% (initial charge can take up to 2.5 hours).

Tandem Diabetes Care recommends that you periodically check the battery level indicator, charge the pump for a short period of time every day (10 to 15 minutes), and avoid frequent full discharges.

■ NOTE

If the battery is fully discharged, the screen may not power on immediately when connected to a charging source. The LED around the **Screen On/Quick Bolus** button will blink green until there is enough charge to power on the touchscreen.

The pump continues to operate normally while charging. You do not need to disconnect from the pump while charging.

⚠ PRECAUTION

MAKE SURE to not move further than the length of the USB cable when you are connected to the pump and to a charging source. Moving further than the length of the USB cable may cause the cannula to be pulled out of the infusion site. For this reason it is recommended not to charge the pump while sleeping.

If you choose to disconnect from the pump while charging, check with your healthcare provider for specific guidelines. Depending on the length of time you are disconnected, you may need to replace missed basal and/or bolus insulin. Check your BG before disconnecting from the pump and again when you reconnect.

To charge the pump from an AC power outlet:

1. Plug the included USB cable into the AC power adapter.
2. Plug the AC power adapter into a grounded AC power outlet.

3. Plug the other end of the cable into the micro USB port on the pump.

To charge the pump using an optional car power USB adapter:

⚠ WARNING

When using an optional car power USB adapter, the charger must be connected to an isolated, battery powered 12 Volt system, such as an automobile. Connecting the DC vehicle adapter charger to 12 Volt DC that is generated by a power supply connected to alternating current (AC) mains is prohibited.

1. Plug the USB cable into the car power USB adapter.
2. Plug the car power USB adapter into a grounded auxiliary power outlet.
3. Plug the other end of the cable into the micro USB port on the pump.

To charge the pump using a USB port on a computer:

Ensure that the computer complies with the IEC 60950-1 (or equivalent) safety standard.

1. Plug the included USB cable into your computer.
2. Plug the other end of the cable into the micro USB port on the pump.

📌 NOTE

Before using a computer to charge the pump, it is recommended that a driver be installed on the computer by downloading the t:connect uploader software from our website at tandemdiabetes.com. This will also allow communication between the pump, the computer, and the t:connect web application.

Depending on your computer, charging time will vary. The pump will display a CONNECTION ERROR ALERT message if it is not charging properly.

When you charge the pump, you will notice the following:

- The screen illuminates
- An audible alert
- The LED (edge around the Screen On/Quick Bolus button) blinks green
- A vibrating alert

- A charge symbol (lightning bolt) on the battery level indicator appears

⚠ PRECAUTION

CONFIRM that the screen display turns on, you can hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the Screen On/Quick Bolus button when you connect a power source to the USB port. These features are used to notify you about alerts, alarms, and other conditions that require your attention. If these features are not working, discontinue use of the t:slim X2™ pump and contact Customer Technical Support.

5.2 Turning the Pump On

Plug in your pump to a charging source. The pump will make an audible noise when it has turned on and is ready for use.

5.3 Using the Touchscreen

To turn on your pump screen, first press the Screen On/Quick Bolus button, then use the pad of your finger to quickly and lightly tap on the screen. Do not use your fingernail or other

CHAPTER 5 • Getting Started

object to interact with the screen. It will not activate the screen or its functions.

Your pump is designed to give you quick and easy access to the functions that you will use in your day-to-day diabetes management whether basic or advanced.

The pump has several safety features to prevent unintentional interaction with the touchscreen. The screen must be unlocked by tapping 1–2–3 in sequence. On all screens, if three non-active areas of the touchscreen are tapped before an active area is tapped, the screen will turn off to prevent accidental screen interactions. There is also a Security PIN feature that can be set up to prevent unintentional access (see Section 5.13 Turn Security PIN On or Off).

NOTE

When using the pump, tap the **Tandem logo** to return to the *Home* screen or tap  to return to the previous screen.

5.4 Turning the t:slim X2 Pump Screen On

To turn on your pump screen, press the **Screen On/Quick Bolus** button, located on the top of the pump, once.

- ✓ The *Lock* screen will be displayed.

5.5 Turning the Pump Screen Off

To turn the pump screen off, press and release the **Screen On/Quick Bolus** button. This turns off the screen, but not the pump.

NOTE

Turn off the pump screen by pressing the **Screen On/Quick Bolus** button before placing the pump back in its case or any pocket/clothing. Always position the pump screen away from the skin when worn under clothing.

The pump continues to function normally when the screen is not on.

5.6 Turning the Pump Off

To turn the pump off completely, plug the pump into a power source and hold the **Screen On/Quick Bolus** button down for 30 seconds.

5.7 Unlocking the t:slim X2 Pump Screen

The *Lock* screen appears anytime you turn on the screen, and after a bolus or temp rate is requested. To unlock the screen:

1. Press **Screen On/Quick Bolus** button.
2. Tap 1.
3. Tap 2.
4. Tap 3.

- ✓ The pump screen is now unlocked. The last screen that was viewed will be displayed.

You must tap 1–2–3 in sequential order to unlock the pump. If you do not tap

1–2–3 in sequential order, the pump will force you to restart the unlock sequence from the beginning.

If the Security PIN feature is enabled, you will need to enter your PIN after unlocking the screen.

5.8 Edit Time

After powering up your pump for the first time, set the current time and date. Refer back to this section if you need to edit the time for either traveling in a different time zone or adjusting for Daylight Savings Time.

⚠ PRECAUTION

ALWAYS make sure that the correct time and date are set on your pump. Not having the correct time and date setting may affect safe insulin delivery. When editing time, always check that the AM/PM setting is accurate, if applicable. AM is to be used from midnight until 11:59 AM. PM is to be used from noon until 11:59 PM.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.

3. Tap **Device Settings**.
4. Tap **Time and Date**.
5. Tap **Edit Time**.
6. Tap **Time**.
7. Using the on-screen keypad, enter the hour and minutes. Verify and tap .
8. Tap **Time of Day** to set AM or PM, or tap the **24-hour Time** on/off toggle setting to on.
9. Verify the correct time is set and tap .

Any edits to Time or Date will not be saved until you tap .

5.9 Edit Date

1. From the *Time and Date* screen tap **Edit Date**.
2. Tap **Day**.

3. Using the on-screen keypad enter the current day. Verify and tap .
4. Tap **Month**.
5. Find and tap the current month displayed on the right. Use **Up/Down Arrow** to view months not displayed.
6. Tap **Year**.
7. Using the on-screen keypad enter the current year. Verify and tap .
8. Verify the correct date is set and tap .

Tap the **Tandem logo** to return to the *Home* screen.

5.10 Basal Limit

The Basal Limit setting allows you to set a limit to the Basal Rate that is set in the Personal Profiles, as well as the amount of insulin that will be delivered when using a Temp Rate.

CHAPTER 5 • Getting Started

You are unable to set any Basal Rates or temp Basal Rates that exceed the Basal Limit. You can set your Basal Limit from 0.2 to 15 units per hour. Work with your healthcare provider to set the proper Basal Limit.

NOTE

If you are setting your Basal Limit after you have set any of your Personal Profiles, you cannot set your Basal Limit lower than any of your existing Basal Rates.

The default Basal Limit is 3 units per hour. If you are updating your pump from a version that did not previously have the Basal Limit setting, the Basal Limit will be set to a value two times the highest Basal Rate setting in your pump.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap **Pump Settings**.

5. Tap **Basal Limit**.



6. Using the on-screen keypad, enter a Basal Limit amount that is between 0.2 – 15 units.
 7. Tap .
 8. Review the Basal Limit value and tap .
 9. Confirm settings and tap .
- ✓ A *SETTING SAVED* screen is temporarily displayed.

5.11 Display Settings

The display settings for your t:slim X2 pump includes Screen Timeout.

You can set the Screen Timeout to the length of time you want the screen to stay on before it automatically turns off. The default for the Screen Timeout is 30 seconds. The options are 15, 30, 60, and 120 seconds.

You can always turn the screen off before it automatically times out by pressing the **Screen On/Quick Bolus** button.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Device Settings**.
4. Tap **Display Settings**.
5. Tap **Screen Timeout**.
6. Select preferred time and tap .

7. Tap the **Tandem** logo to return to the *Home* screen.

5.12 Sound Volume

The Sound Volume is preset to high. Sound Volume can be personalized for Alarms, Alerts, Reminders, Keypad, Bolus, Quick Bolus, and Fill Tubing. Options for Sound Volume include high, medium, low, and vibrate.

⚠ PRECAUTION

DO NOT use the vibrate feature for alerts and alarms during sleep unless otherwise directed by your healthcare provider. Having the volume for alerts and alarms set to high will help ensure that you don't miss an alert or alarm.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Device Settings**.
4. Tap **Sound Volume**.
5. Tap desired option. Use **Up/Down Arrow** to view additional options.

6. Select preferred volume.
7. Continue to make changes for all Sound Volume options by repeating steps 5 and 6.
8. Tap  when all changes are complete.
9. Tap the **Tandem** logo to return to the *Home* screen.

5.13 Turn Security PIN On or Off

The Security PIN is preset to off. With the Security PIN turned on, you cannot unlock and use the pump without entering the Security PIN. To turn on the Security PIN, follow these steps.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Device Settings**.
4. Tap the **Down Arrow**.
5. Tap **Security PIN**.

6. Tap **Security PIN** to toggle the feature on.
 7. Tap  to create your Security PIN.
 8. Using the keypad, enter a number between four and six digits. A PIN may not begin with the number zero.
 9. Tap .
 10. Tap  to verify your Security PIN.
 11. Use the keypad to repeat and verify the new Security PIN.
 12. Tap .
 - ✓ A *PIN CREATED* screen is displayed.
 13. Tap  to turn the Security PIN on.
 14. Tap .
- It is possible to change your Security PIN or override an old Security PIN if you forget your Security PIN.

CHAPTER 5 • Getting Started

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the Down Arrow.
3. Tap **Device Settings**.
4. Tap the Down Arrow.
5. Tap **Security PIN**.
6. Tap **Change Security PIN**.
7. Tap .
8. Using the keypad, enter the current Security PIN. If you forget your Security PIN, use the override code **314159**.
 - » The override PIN can be used as many times as needed and never resets or changes to another PIN. It can be used to unlock the pump when the Security PIN feature is on. If desired, you may use this as a valid Security PIN.
9. Tap .
10. Tap  to enter a new Security PIN.

11. Use the keypad to enter a new Security PIN.
12. Tap .
13. Tap  to verify your new Security PIN.
14. Use the keypad to repeat and verify the new Security PIN.
15. Tap .
- ✓ A *PIN UPDATED* screen is displayed.
16. Tap .

pair or unpair your smartphone and your pump.

NOTE

Do not turn the mobile connection on if you are not using or do not have access to the t:connect mobile app. Turning the mobile connection on may impact pump battery life.

5.14 Mobile Connection

You can connect one compatible smartphone to the pump to display pump information and perform some pump functions on that smartphone using the t:connect mobile app. See Section 4.3 Connecting to a Smartphone for detailed instructions to

2 t:slim X2 Insulin Pump Features

CHAPTER 6

Insulin Delivery Settings

CHAPTER 6 • Insulin Delivery Settings

6.1 Personal Profiles Overview

⚠ WARNING

DO NOT start to use your pump before consulting with your healthcare provider to determine which features are most appropriate for you. Only your healthcare provider can determine and help you adjust your Basal Rate(s), Carb Ratio(s), Correction Factor(s), Target BG, and duration of insulin action. In addition, only your healthcare provider can determine your CGM settings and how you should use your sensor trend information to help you manage your diabetes. Incorrect settings can result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

A Personal Profile is a group of settings that define basal and bolus delivery within specific time segments throughout a 24-hour period. Each profile can be personalized with a name. Within a Personal Profile the following can be set:

- **Timed Settings:** Basal Rate, Correction Factor, Carb Ratio and Target BG.

- **Bolus Settings:** Insulin Duration and Carbohydrates setting (on/off).

NOTE

In order to turn on Control-IQ™ technology, the Timed Settings must be complete for every time segment, and the Carbohydrates setting must be turned on in the Bolus Settings.

The t:slim X2™ pump uses the settings in your active profile to calculate the delivery of basal insulin, food boluses and correction boluses based on your Target BG. If you only define a Basal Rate in Timed Settings, your pump will only be able to deliver basal insulin and standard and extended boluses. Your pump will not calculate correction boluses.

Up to six different Personal Profiles can be created and up to 16 different time segments can be set in each Personal Profile. Having several Personal Profiles provides more flexibility for your body and lifestyle. For example, you could have “Weekday” and “Weekend” profiles if you have different insulin delivery needs on weekdays and weekends, based on schedule, food intake, activity, etc.

NOTE

Some of the Personal Profile settings are overridden when Control-IQ technology is turned on. See Chapter 30 Introduction to Control-IQ Technology.

6.2 Creating a New Profile

Creating Personal Profiles

You can create up to six Personal Profiles; however, only one can be active at a time. In the *Personal Profiles* screen, the active profile is positioned at the top of the list and is marked as ON. When you create a Personal Profile, you can set any or all of the following Timed Settings:

- Basal Rate (your Basal Rate in units/ hr)
- Correction Factor (amount 1 unit of insulin lowers BG)
- Carb Ratio (grams of carbohydrate covered by 1 unit of insulin)
- Target BG (your ideal BG level, measured in mg/dL)

Although you do not need to define every setting, some pump features require certain settings to be defined and activated. When you are creating a new profile, your pump prompts you to set up any required settings before you can continue.

The ranges you can set for Timed Settings are:

- Basal (range: 0 and 0.1 to 15 units/hr)

NOTE

The Basal Rate may not exceed the Basal Limit set in Pump Settings (Section 5.10 Basal Limit). If you are setting your Basal Limit after you have set any of your Personal Profiles, you cannot set your Basal Limit lower than any of your existing Basal Rates.

NOTE

If Control-IQ technology is on and the pump has not received a CGM reading for 20 minutes, the system will automatically revert to your programmed basal rate. Examples of CGM readings not being received include when the pump and CGM are out of range, during the sensor startup

period, when a sensor session ends, or when there is a transmitter or sensor error.

WARNING

Control-IQ technology reverts to your programmed basal rate when the pump has not received a CGM reading for 20 minutes. For example, when the pump and CGM are out of range, during the sensor startup period, when a sensor session ends, or when there is a transmitter or sensor error.

- Correction Factor (range: 1 unit:1 mg/dL to 1 unit:600 mg/dL)
- Carb Ratio (range: 1 unit:1 gram to 1 unit:300 grams)

Below a Carb Ratio of 1:10, increments can be entered in 0.1 gram. For example a Carb Ratio of 1:8.2 can be programmed.

- Target BG (range: 70 mg/dL to 250 mg/dL)

In addition, you can set any or all of the following Bolus Settings:

- Insulin Duration (how long a bolus lowers your BG)

- Carbs (ON indicates entering grams of Carb; OFF indicates entering units of insulin)

NOTE

Changing the Carbs setting on the pump changes the bolus calculators on both the pump and the t:connect™ mobile app.

The default settings and ranges for Bolus Settings are as follows:

- Insulin Duration (default: 5 hrs; range: 2 to 8 hrs)

NOTE

When using Control-IQ technology, the insulin duration is set to five hours and cannot be changed. This duration is used for all bolus deliveries as well as for basal adjustments made by Control-IQ technology.

- Carbs (default: dependent on pump history)

NOTE

If you received a new pump with Control-IQ technology, the default setting will be on. If you updated your pump, the default setting will be the same as what you set up on your pump previously. Check to ensure that the

CHAPTER 6 • Insulin Delivery Settings

Carbs setting is on in order to use Control-IQ technology.

Insulin Duration and Insulin on Board (IOB)

Your pump remembers how much insulin your pump has delivered from boluses. It does this by relying on the insulin duration. The insulin duration reflects the amount of time that insulin is actively lowering your BG.

While the insulin duration setting reflects how long insulin from previous boluses lowers your BG, the IOB feature reflects how much insulin is remaining in your body from previous boluses. IOB is always displayed on the *Home* screen and is used in bolus delivery calculations when applicable. When a glucose value is entered during bolus programming, your pump will consider any active IOB and adjusts the calculated bolus if necessary.

The insulin duration time is displayed on the *Home* screen when Control-IQ technology is not enabled.

Consult your healthcare provider to accurately set your insulin duration.

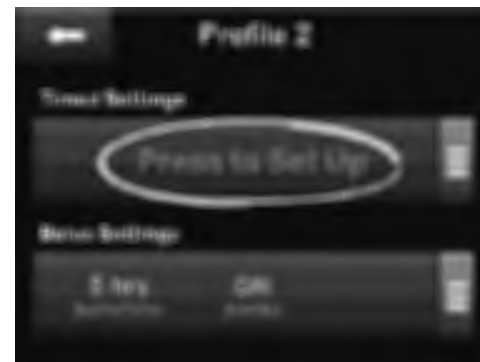
If you have Control-IQ technology enabled, IOB includes all basal delivered above and below the programmed Basal Rate, in addition to all bolus insulin delivered. The insulin duration time is not displayed on the *Home* screen.

Insulin duration is set to 5 hours when Control-IQ technology is enabled and cannot be changed.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap  to create a new profile.
5. Using the on-screen keypad, enter a profile name (up to 16 characters) and tap .

To use the letter keypad, tap once for first letter displayed, two quick taps for middle letter; and three quick taps for the third letter.

6. Tap **Press to Set Up** to begin setting insulin delivery settings.



8.3 Programming a New Personal Profile

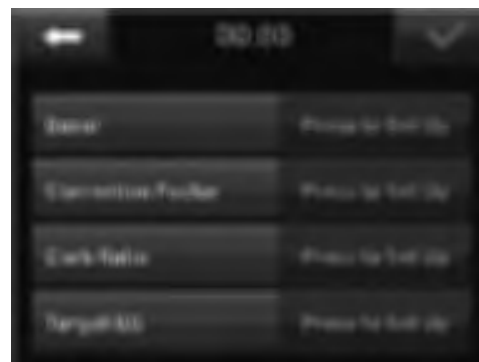
Once the Personal Profile has been created, the settings must be programmed. The first time segment will start at midnight.

- You must program a Basal Rate in order to have a Personal Profile that you can activate.
- You must have Carbs turned on, and you must set a Basal Rate, Correction Factor, Carb Ratio, and Target BG in order to turn Control-IQ technology on.
- Be sure to tap  after entering or changing a value.

PRECAUTION

ALWAYS confirm that the decimal point placement is correct when entering your Personal Profile information. Incorrect decimal point placement can prevent you from getting the proper insulin amount that your healthcare provider has prescribed for you.

Timed Settings



1. Once the new profile has been created, tap **Basal**.
2. Using the on-screen keypad, enter your Basal Rate and tap .

NOTE

If you have previously set a Basal Limit in the Pump Settings, then the Basal Rate entered here must be lower than the Basal Limit entered in the Pump Settings.

3. Tap **Correction Factor**.
4. Using the on-screen keypad, enter your Correction Factor (the mg/dL that 1 unit of insulin will lower BG) and tap .

5. Tap **Carb Ratio**.
6. Using the on-screen keypad, enter your insulin-to-carbohydrate ratio (the grams of carbohydrate to be covered by 1 unit of insulin) and tap .
7. Tap **Target BG**.
8. Using the on-screen keypad, enter your Target BG and tap .

NOTE

Once Control-IQ technology is turned on, the default Target BG is set to 110 mg/dL. For details about target ranges and how Control-IQ technology works, see Chapter 30 Introduction to Control-IQ Technology.

9. Review entered values and tap .
10. Confirm Settings.
 - Tap  if entered data is correct.
 - Tap  to make changes.

CHAPTER 6 • Insulin Delivery Settings

11. Tap  to set the Bolus Settings, or tap  to create additional time segments.



Adding More Time Segments

When adding more time segments, any settings that you entered in the previous time segment are copied and appear in the new segment. This allows you to simply adjust only the specific settings you want, rather than have to enter them all over again.

1. On the *Add Segment* screen, tap **Start Time**.
2. Using the on-screen keypad, enter the time (hour and minutes) that you want the segment to begin, and tap .

3. On the *Add Segment* screen, tap **Time of Day** to select AM or PM, if applicable.

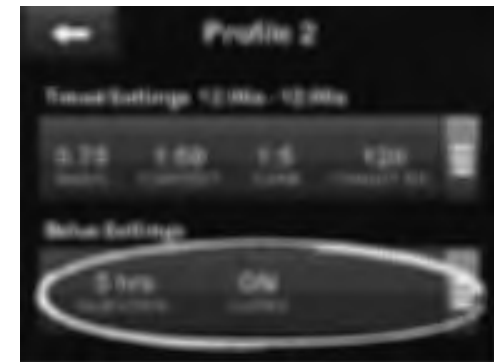
✓ Once a time segment is set beyond 12:00 PM, the default will change to PM.

4. Tap .
5. Repeat steps 1 to 10 from Section 6.2 Creating a New Profile above for each segment you want to create (up to 16).

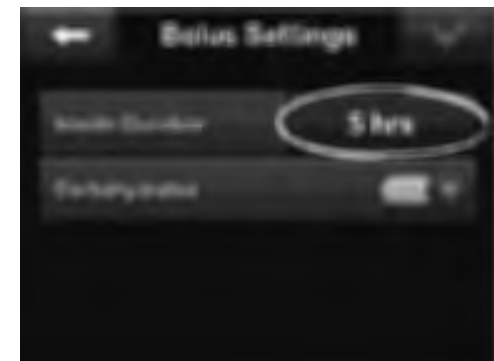
To find time segments in the list that are not displayed on the first screen, tap the **Down Arrow**.

Bolus Settings

1. Tap the **Bolus Settings** panel.



2. Tap **Insulin Duration**.



3. Using the on-screen keypad, enter the desired time for the duration of insulin action (2–8 hrs) and tap .

4. Review entered values and tap .

5. Confirm Settings.

- Tap  if entered data is correct.
- Tap  to make changes.

6. Tap the **Tandem** logo to return to the *Home* screen.

Adding More Personal Profiles

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap .
5. Name the new profile and repeat steps for Timed Settings and Bolus Settings.

NOTE

The Carbohydrates option is turned on by default, but a ratio will still need to be

defined. The Carbohydrates option must be used if Control-IQ technology is enabled.

6.4 Editing or Reviewing an Existing Profile

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to edit or review.
5. Tap **Edit**.

NOTE

To review settings but bypass editing the settings, skip the remaining steps in this section. You can tap  to navigate to the Personal Profiles list or tap the **Tandem** logo to return to the *Home* screen.

6. Tap **Timed Settings** panel.
7. Tap the desired time segment to edit.

8. Tap **Basal**, **Correction Factor**, **Carb Ratio** or **Target BG** to make changes as needed and use the on-screen keypad to enter changes. Tap .

9. View recent changes and tap .

10. Confirm Settings.

- Tap  if entered data is correct.
- Tap  to make changes.

11. Edit other time segments within the Timed Settings by tapping on them and using the same steps described above.

12. Tap  after editing all of the time segments.

13. Tap the **Bolus Settings** panel to change Insulin Duration Carbohydrates as needed. Use the on-screen keypad to enter desired changes. Tap .

14. Confirm Settings.

CHAPTER 6 • Insulin Delivery Settings

- Tap  if entered data is correct.
 - Tap  and make changes.
15. Tap the **Tandem logo** to return to the *Home* screen.

NOTE

To add a time segment, tap  and enter the desired start time.

NOTE

To delete a time segment, tap on the X to the left of the time segment and tap  to confirm.

6.5 Duplicating an Existing Profile

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to duplicate.
5. Tap **Duplicate**.

6. Confirm profile to duplicate by tapping .
 7. Using the on-screen keypad, enter the name (up to 16 characters) for the new profile and tap .
- ✓ *Profile Duplicated* screen is displayed.
 - ✓ A new Personal Profile will be created with the same settings as the profile copied.
8. Tap the **Timed Settings** or **Bolus Settings** panel to make changes to the new profile.

6.6 Activating an Existing Profile

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to be activated.

- The **Activate** and **Delete** options are disabled for the active profile because the profile is already activated. You cannot delete a profile until you have activated another profile.
- If you have only one profile defined, you do not need to activate it (that profile is automatically activated).

5. Tap **Activate**.

- ✓ A screen to confirm the activation request is displayed.

6. Tap .

- ✓ *Profile Activated* screen is displayed.

6.7 Renaming an Existing Profile

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.

4. Tap the name of the Personal Profile to be renamed.
5. Tap **Down Arrow**, and then **Rename**.
6. Using the on-screen keypad, rename the profile name (up to 16 characters) and tap .
7. Tap the **Tandem** logo to return to the *Home* screen.

6.8 Deleting an Existing Profile

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to be deleted.

NOTE

The active Personal Profile cannot be deleted.

5. Tap **Delete**.

6. Tap .

✓ *Profile Deleted* screen is displayed.

7. Tap the **Tandem** logo to return to the *Home* screen.

6.9 Starting a Temporary Basal Rate

A Temp Rate is used to increase or decrease (by percentage) the current Basal Rate for a period of time. This feature can be helpful for situations such as exercise or illness.

When you enter the *Temp Rate* screen, the default values are 100% (current Basal Rate) and a Duration of 0:15 min. The Temp Rate can be set from a minimum of 0% of current Basal Rate to a maximum of 250% of current Basal Rate in increments of 1%.

Duration can be set from a minimum of 15 minutes to a maximum of 72 hours in increments of 1 minute.

If you program a Temp Rate greater than 0% but less than the minimum allowable Basal Rate of 0.1 units/hr,

you will be notified that the selected rate is too low and that it will be set to the minimum allowable rate for delivery.

If you program a Temp Rate more than the maximum allowable Basal Rate of 15 units/hr, or more than your Basal Limit set up in the Pump Settings, you will be notified that the selected rate is too high and that it will be reduced so that it does not exceed the maximum allowable rate for delivery.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap **Temp Rate**.
4. Tap **Temp Rate** again.
5. Using the on-screen keypad enter desired percentage. The current rate is 100%. An increase is greater than 100% and decrease is less than 100%.
6. Tap .

CHAPTER 6 • Insulin Delivery Settings

7. Tap **Duration**. Using the on-screen keypad enter desired length of time for Temp Rate. Tap .

You can always tap **View Units** to see the actual units to be delivered.

8. Verify settings and tap .

- ✓ The *TEMP RATE STARTED* screen is temporarily displayed.

- ✓ The *Lock* screen will be displayed with the icon indicating a Temp Rate is active.

- An T in an orange box means a Temp Rate is active.
- A T in a red box means a Temp Rate of 0 u/hr is active.

NOTE

If a Temp Rate is active when you stop insulin, including when you change a cartridge or infusion set, the Temp Rate timer will remain active. The Temp Rate will be resumed when insulin delivery is resumed as long as there is time remaining on the Temp Rate Timer.

6.10 Stopping a Temp Rate

To stop an active temp rate:

1. From the *Home* screen, tap **OPTIONS**.
 2. Tap **Activity**.
 3. On the *Activity* screen, tap  on the right side of Temp Rate.
 4. On the confirmation screen, tap .
- ✓ The *TEMP RATE STOPPED* screen appears before returning to the *Activity* screen.

2 t:slim X2 Insulin Pump Features

CHAPTER 7

Infusion Site Care and Loading Cartridge

CHAPTER 7 • Infusion Site Care and Loading Cartridge

7.1 Infusion Site Selection and Care**⚠ WARNING**

ALWAYS use only cartridges and insulin infusion sets with matching connectors and follow their instructions for use. Failure to do so may result in over delivery or under delivery of insulin and may cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

ALWAYS carefully follow the instructions for use accompanying your infusion set for proper insertion and infusion site care, as failure to do so could result in over delivery or under delivery of insulin or infection.

⚠ WARNING

DO NOT place your infusion set on any scars, lumps, moles, stretch marks or tattoos. Placing your infusion set in these areas can cause swelling, irritation or infection. This can affect insulin absorption and cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

DO NOT change your infusion set before bedtime or if you will not be able to test your BG

1–2 hours after the new infusion set is placed. It is important to confirm that the infusion set is inserted correctly and delivering insulin. It is also important to respond quickly to any problems with the insertion to ensure continued insulin delivery.

⚠ PRECAUTION

CHECK your infusion site daily for proper placement and leaks. **REPLACE** your infusion set if you notice leaks around the site, or if you suspect your infusion set cannula may have become dislodged. Improperly placed sites or leaks around the infusion site can result in under delivery of insulin.

General Guidelines**Site Selection**

- Your infusion set can be worn anywhere on your body that you would normally inject insulin. Absorption varies from site to site. Discuss options with your healthcare provider.
- The most commonly used sites are the abdomen, upper buttocks, hips, upper arms, and upper legs.

- The abdomen is the most popular site because of access to fatty tissue. If using the abdominal area, **AVOID**:

- Areas that would constrict the site such as the belt line, waistline, or where you would normally bend.
- Areas 2 inches (5 cm) around your belly button.
- **AVOID** sites with any scars, moles, stretch marks, or tattoos.
- **AVOID** site areas within 3 inches (7.6 cm) of your CGM sensor site.

Site Rotation**⚠ PRECAUTION**

CHANGE your infusion set every 48 hours if using Humalog insulin; every 72 hours if using NovoLog insulin. Wash your hands with anti-bacterial soap before handling the infusion set and thoroughly clean the insertion site on your body to avoid infection. Contact your healthcare provider if you have symptoms of infection at your insulin infusion site.

- The infusion set must be replaced and rotated every 48 hours if using

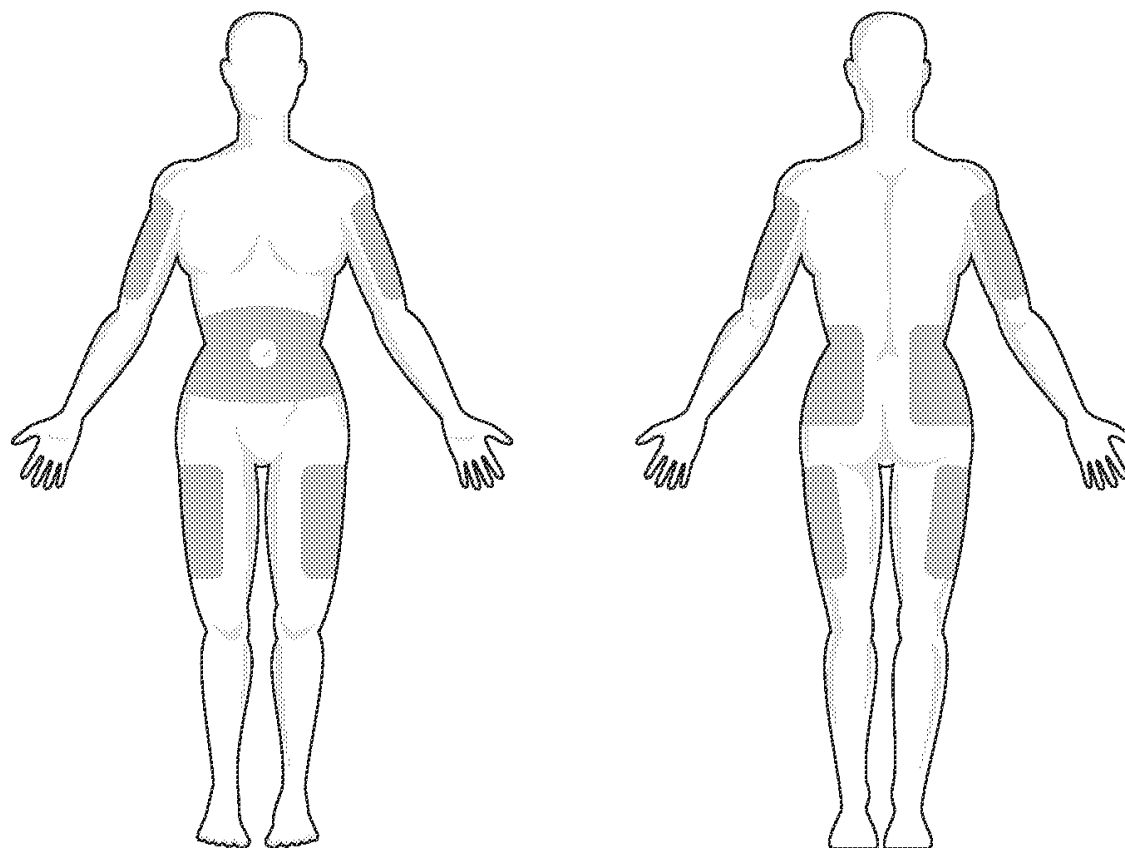
Humalog insulin; every 72 hours if using NovoLog insulin, or more often if needed.

- With experience, you will find areas that not only provide better absorption, but are more comfortable. Keep in mind, using the same areas may cause scarring or lumps which can affect insulin absorption.
- Consult your healthcare provider to establish a rotation schedule that best fits your needs.

Keep it Clean

- When changing your infusion set, use clean techniques to avoid an infection.
- Wash your hands, use antiseptic wipes or infusion site preparation products, and keep the area clean.
- Site preparation products that have both an antiseptic and an adhesive are encouraged.

Areas of Body for Infusion Set Insertion



CHAPTER 7 • Infusion Site Care and Loading Cartridge

7.2 Cartridge Instructions for Use

For complete cartridge labeling, consult the cartridge instructions for use included in the t:slim™ cartridge box.

7.3 Filling and Loading a t:slim X2 Cartridge

This section describes how to fill the cartridge with insulin and load the cartridge into your t:slim X2™ pump. The single-use disposable cartridge can hold up to 300 units (3.0 mL) of insulin.

⚠ WARNING

ONLY use U-100 Humalog or U-100 NovoLog with your pump. Only U-100 Humalog and U-100 NovoLog have been tested and found to be compatible for use in the pump. Use of insulin with greater or lesser concentration can result in an over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

ALWAYS use cartridges manufactured by Tandem Diabetes Care. Use of any other cartridge brand may result in over delivery or under delivery of insulin. This can cause

hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

DO NOT reuse cartridges. Reuse of cartridges may result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

Before you begin, make sure you have the following items:

- 1 unopened cartridge
- 3.0 mL syringe and fill needle
- vial of U-100 Humalog or U-100 NovoLog insulin
- alcohol prep swab
- 1 new infusion set
- infusion set instructions for use

📌 NOTE

The pump will beep or vibrate, depending on your pump settings, while the tubing is filling with insulin. To change the Fill Tubing sound setting, see Section 5.12 Sound Volume.

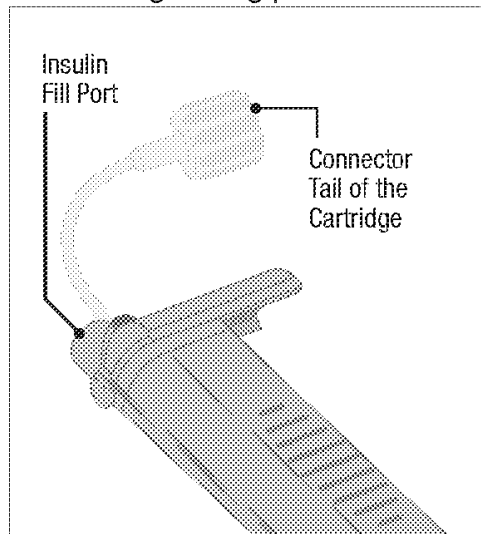
📌 NOTE

DO NOT remove the used cartridge from the pump during the load process until prompted on the pump screen.

📌 NOTE

Control-IQ™ technology will continue to make calculations based on CGM values while the cartridge is being filled. Since there is no insulin delivered during the cartridge fill process, there will be no actual Basal Rate adjustments until the cartridge is filled and loaded back onto the pump. Control-IQ technology will then immediately begin to operate normally.

The illustration identifies the connector and insulin fill port used in the cartridge filling process.



⚠ PRECAUTION

CHANGE your cartridge every 48–72 hours as recommended by your healthcare provider. Wash your hands with anti-bacterial soap before handling the infusion set and thoroughly clean the insertion site on your body to avoid infection. Contact your healthcare provider if you have symptoms of infection at your insulin infusion site.

Instructions for Drawing Insulin from Vial into Syringe

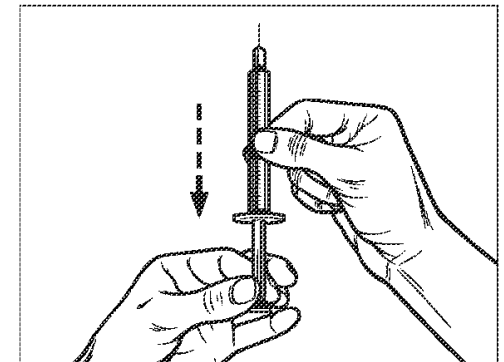
⚠ PRECAUTION

ALWAYS remove all air bubbles from the cartridge before beginning insulin delivery. Ensure there are no air bubbles when drawing insulin into the filling syringe, hold the pump with the white fill port pointed up when filling the tubing, and ensure that there are no air bubbles in the tubing when filling. Air in the system takes space where insulin should be and can affect insulin delivery.

The fill estimate displayed on the pump is the amount of insulin available for delivery. It does not include insulin needed to fill the tubing (up to 30 units) and a small amount of insulin that is not available for delivery. When filling the syringe, add approximately 45 units to the amount of insulin you want available for delivery.

- For example, the pump requires a minimum of 50 units available for delivery after fill tubing has been completed. Fill the syringe with approximately 95 units to have enough to fill your tubing and still have 50 units available for delivery.

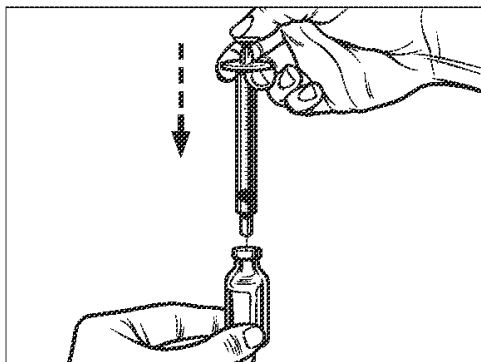
1. Inspect the needle and syringe package for any signs of damage. Discard any damaged product.
2. Wash your hands thoroughly.
3. Wipe the rubber septum of the insulin vial with an alcohol swab.
4. Remove the needle and syringe from their packaging. Securely twist needle onto syringe. Safely remove protective cap from needle by pulling outward.
5. Draw air into syringe up to the amount of insulin desired.



6. With insulin vial upright, insert needle into vial. Inject air from

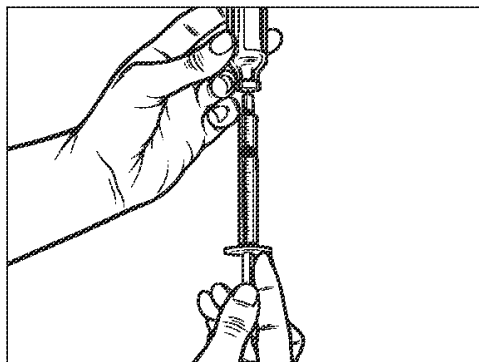
CHAPTER 7 • Insulin Site Care and Loading Cartridge

syringe into vial. Maintain pressure on syringe plunger.

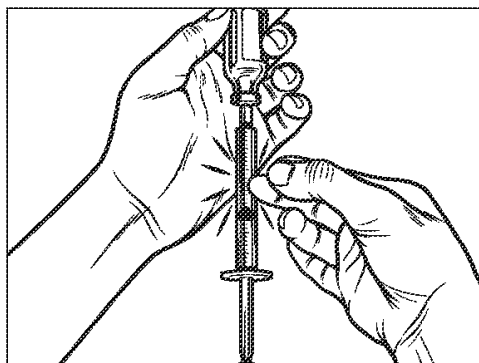


7. With needle still inserted into vial, turn vial and syringe upside down. Release syringe plunger. Insulin will begin to flow from the vial into the syringe.

8. Slowly pull back the plunger to the desired amount of insulin.



9. While the filling needle is still in the vial and upside down, tap the syringe so that any air bubbles rise to the top. Then slowly push the plunger upwards, forcing any air bubbles back into the vial.

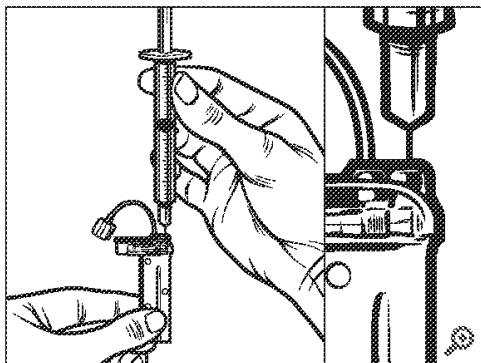


10. Check the syringe for air bubbles and do one of the following:

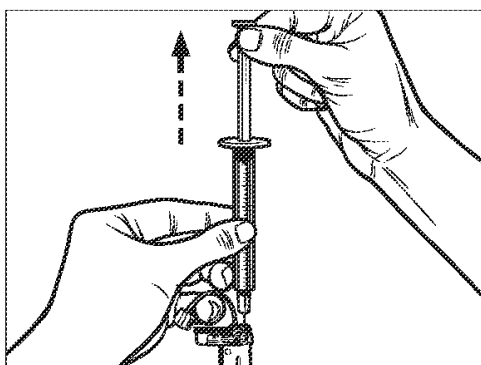
- If there are air bubbles present, repeat step 9.
- If no air bubbles are present, remove the filling needle from the vial.

Instructions for Filling the Cartridge

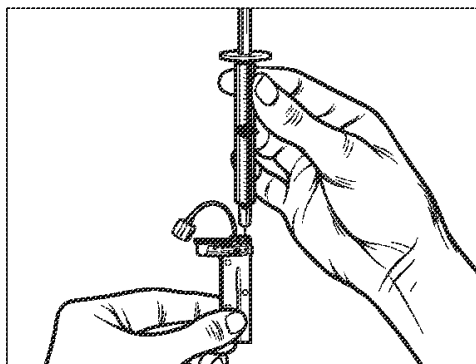
1. Inspect the cartridge package for any signs of damage. Discard any damaged product.
2. Open the package and remove the cartridge.
3. Hold the cartridge upright and gently insert the needle into the white insulin fill port on the cartridge. The needle is not intended to go all the way in, so do not force it.



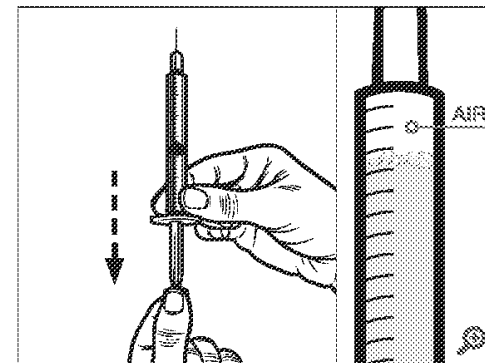
4. Keeping the syringe vertically aligned with the cartridge, and the needle inside the fill port, pull back on the plunger until it is fully retracted. This will remove any residual air from the cartridge. Bubbles will rise toward the plunger.



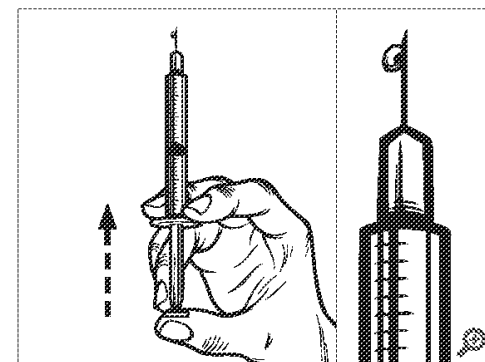
5. Make sure the needle is still in the fill port and release the plunger. Pressure will pull the plunger to its neutral position but it will NOT push any air back inside the cartridge.



6. Withdraw the needle from the fill port.
7. Turn the syringe upright and pull down on the plunger. Flick the barrel to make sure that any air bubbles rise to the top.



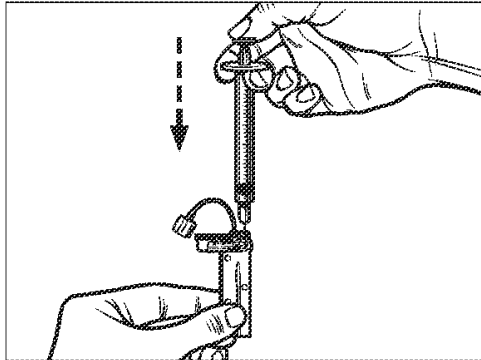
8. Gently press on the plunger to remove air bubbles until insulin fills the needle hub and you see a drop of insulin at the tip of the needle.



9. Re-insert the needle in the fill port and slowly fill the cartridge with insulin. It is normal to feel some

CHAPTER 7 • Infusion Site Care and Loading Cartridge

back pressure as you slowly press on the plunger.



10. Maintain pressure on the plunger while you remove the needle from the cartridge. Check the cartridge for leaks. If you detect insulin leaking, discard the cartridge and repeat entire process with a new cartridge.
11. Always dispose of used needles, syringes, cartridges, and infusion sets following local regulations.

Instructions on How to Install a Cartridge

If this is the very first time you are loading the cartridge, remove the

shipping canister (which is not for human use) from the back of the pump.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Load**.

During the load sequence, the **Tandem** logo is disabled. Tapping it will not return to the *Home* screen.

3. Tap **Change Cartridge**.
4. A screen will display to notify you that all insulin deliveries will be stopped. Tap  to continue.
5. Disconnect the infusion set from your body and tap  to continue.

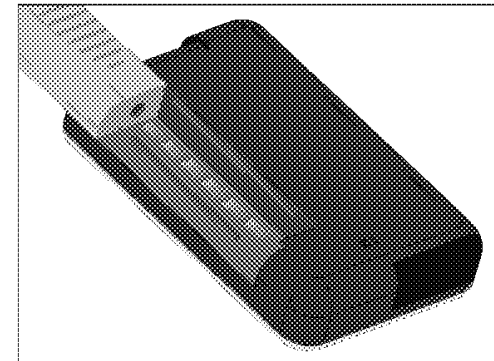
NOTE

This screen will not be displayed if this is the first time loading a new cartridge and you have not started actively pumping.

- ✓ *Preparing for Cartridge* screen is displayed.
6. Remove the used cartridge. If needed, place the cartridge removal

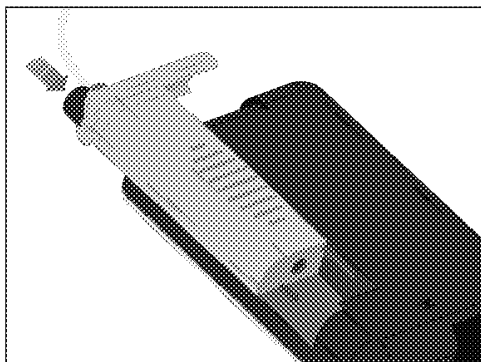
tool or the edge of a coin in the slot at the bottom of the cartridge and twist to aid in the removal of the cartridge.

7. Place the bottom of the cartridge at the end of the pump. Make sure cartridge is lined up to both guide tracks.



8. Push on the circular fill port next to the cartridge tubing to slide the

cartridge onto the pump. Tap the UNLOCK icon when completed.



9. Tap  to continue.

- ✓ *Detecting Cartridge* screen is displayed.
- ✓ After completing the cartridge change, the pump will automatically prompt you to fill the tubing.

10. Tap  to fill the tubing.

⚠ WARNING

DO NOT remove or add insulin from a filled cartridge after loading onto the pump. This will result in an inaccurate display of the insulin level on the *Home* screen and you could run out of insulin before the pump detects an empty

cartridge. This can cause very high BG, or Diabetic Ketoacidosis (DKA).

7.4 Filling Tubing

Filling the Infusion Set Tubing with Insulin

⚠ WARNING

NEVER fill your tubing while your infusion set is connected to your body. Always ensure that the infusion set is disconnected from your body before filling the tubing. Failure to disconnect your infusion set from your body before filling the tubing can result in over delivery of insulin. This can cause hypoglycemia (low BG) events.

This section describes how to fill the infusion set tubing with insulin after you change the cartridge. If you just completed step 10 from the previous section, skip to step 4.

■ NOTE

The pump will beep or vibrate, depending on your pump settings, while the tubing is filling with insulin. To change the Fill Tubing sound setting, see Section 5.12 Sound Volume.

To fill the tubing without changing the cartridge, from the *Home* screen tap **OPTIONS**, tap **Load**, tap **Fill Tubing** and then follow the instructions.

- Tap **NEW** if you installed a new cartridge.
- Tap **FILL** if you did not install a new cartridge and want to continue with filling the tubing.

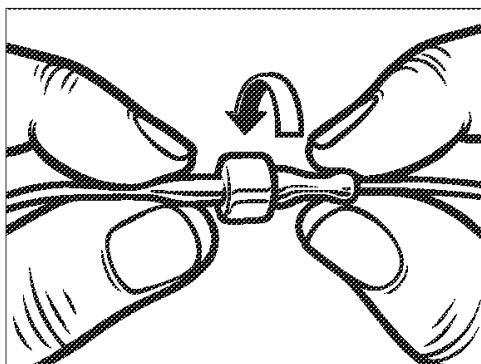
⚠ PRECAUTION

CHECK your infusion set tubing daily for any leaks, air bubbles, or kinks. Air in the tubing, leaks in the tubing, or kinked tubing may restrict or stop insulin delivery and result in under delivery of insulin.

1. Verify that the infusion set is disconnected from your body.
2. Ensure that the new infusion set package is not damaged, and remove the sterile tubing from the package. If the package is damaged or opened, discard properly and use another tubing set. Be careful to keep the tubing connector away from unclean areas.

CHAPTER 7 • Infusion Site Care and Loading Cartridge

3. Attach the infusion set tubing to the tubing connector on the cartridge tubing. Twist clockwise until finger tight and then twist another quarter of a turn to ensure a secure connection.

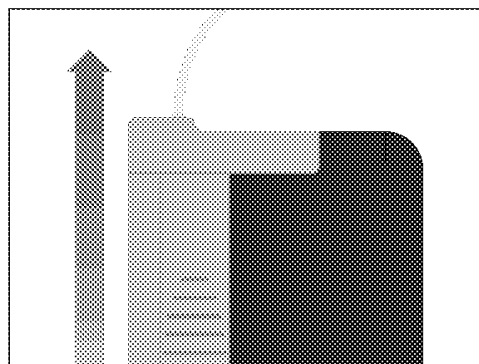


⚠ WARNING

ALWAYS twist the tubing connector between the cartridge tubing and the infusion set tubing an extra quarter of a turn to ensure a secure connection. A loose connection can cause insulin to leak, resulting in under delivery of insulin. This can cause hyperglycemia (high BG) events.

4. Hold the pump vertically to ensure any air in the cartridge will be dispelled first. Tap **START**. The pump will beep and vibrate regularly

while the tubing is being filled, depending on your Sound Volume settings.



- ✓ *Starting Fill* screen is displayed.

The following are approximate amounts of insulin to fill different tubing lengths:

- 10–15 units for 23 inch (60 cm) tubing
- 15–20 units for 32 inch (80 cm) tubing
- 20–25 units for 43 inch (110 cm) tubing

5. Tap **STOP** after 3 drops of insulin are seen at the end of the infusion set tubing.

- ✓ *Stopping Fill* screen is displayed.

- ✓ *Detecting Insulin* screen is displayed.

6. Verify that drops are seen and tap **DONE**.

- If you do not see drops, tap **FILL**. The *Fill Tubing* screen appears, repeat steps 4 and 5 until you see 3 drops of insulin at the end of the tubing.
- The tubing may be filled with a maximum of 30 units of insulin during each fill cycle. If you do not tap **STOP**, a notification screen will appear letting you know that the maximum amount has been filled. Do one of the following:
 - a. If you are finished filling the tubing, tap **DONE**.
 - b. If you want to fill the tubing with more than 30 units, tap **FILL** to

go back to the *Fill Tubing* screen.

- ✓ *Fill Tubing is complete* screen is temporarily displayed.

NOTE

After tubing fill is complete, when the pump returns to the *Home* screen, an estimate of how much insulin is in the cartridge is displayed in the upper right portion of the screen. You will see one of the following on the screen:

- + 40 u More than 40 units detected in the cartridge
- + 60 u More than 60 units detected in the cartridge
- + 120 u More than 120 units detected in the cartridge
- + 180 u More than 180 units detected in the cartridge
- + 240 u More than 240 units detected in the cartridge

After 10 units are delivered, an actual number of units remaining in the cartridge will be displayed on the *Home* screen.

The amount of insulin remaining displayed on the *Home* screen will decrease 5 units at a time (for example, you will see 140, 135, 130, 125). When less than 40 units remain, it will begin decreasing 1 unit at a time (for example, you will see 40, 39, 38, 37) until there is 1 unit remaining.

- ✓ A screen will display to instruct you to insert a new infusion set and connect to the filled tubing.

7.5 Filling Cannula

Filling the Infusion Set Cannula with Insulin

This section describes how to fill the infusion set cannula with insulin after you fill the tubing.

To fill the cannula without filling the tubing, from the *Home* screen, tap **OPTIONS**, tap **Load**, tap **Fill Cannula** and then follow the instructions below.

If you are using a steel needle infusion set, there is no cannula; skip this section.

To Fill the Cannula:

1. Tap **Fill Cannula**.
2. Insert a new infusion set and connect filled tubing to site, then tap .
3. Tap **Edit Fill Amount**.
 - ✓ The cannula fill amount displayed is based on your last cannula fill amount. Filling stops at this amount.
4. Select amount needed for cannula fill.
 - See your infusion set instructions for use for proper cannula fill amount.
 - If the amount needed is not listed, tap **Other amount** and use the on-screen keypad to enter a value between 0.1 to 1.0 unit.
5. Tap **START**.
 - ✓ The *STARTING FILL* screen is displayed.

CHAPTER 7 • Insulin Site Care and Loading Cartridge

- ✓ After fill is complete, *STOPPING FILL* screen is displayed.

NOTE

You can tap **STOP** at any time during the fill process if you want to stop filling the cannula.

- ✓ The screen will return to the *Load* menu if the Site Reminder is turned off.
6. Tap  to resume insulin if finished. Or tap **Site Reminder** to set reminder. If Site Reminder is on, the pump will automatically display the *Site Reminder* screen (see the next section).

7.6 Setting Site Reminder

This section describes how to set the Site Reminder after you fill the cannula.

To set the Site Reminder without filling the cannula, from the *Home* screen, tap **OPTIONS**, tap **Load**, tap **Site Reminder** then follow the instructions below.

1. Tap  if correct. Tap **Edit Reminder** if settings need to be changed.
2. Tap **Remind Me In** and select the number of days (1–3).
- ✓ The default for the Site Reminder is set for 3 days
3. Tap **Remind Me At**. Use the on-screen keypad to enter time and tap .
4. Tap **Time of Day** to change AM or PM, if applicable. Tap .
5. Verify Site Reminder is set correctly and tap .
- ✓ *Setting Saved* screen is displayed.
- ✓ *Load* screen is displayed.
6. Tap .
- ✓ A reminder to test BG in 1 to 2 hours will display.
7. Tap .

NOTE

If this is the first time using your pump and a Personal Profile has not been defined, a screen will notify you that a profile must be activated to resume insulin. Tap **CLOSE**.

- ✓ *RESUMING INSULIN* screen is temporarily displayed.

NOTE

Control-IQ technology will continue to operate while changing a cartridge. If you complete a cartridge change and resume insulin while Control-IQ technology is adjusting insulin, insulin will resume until the next five minute CGM reading. At this time the pump will resume normal operation.

2 t:slim X2 Insulin Pump Features

CHAPTER 8

Manual Bolus

CHAPTER 8

8.1 Manual Bolus Overview**⚠ WARNING**

DO NOT deliver a bolus until you have reviewed the calculated bolus amount. If you deliver an insulin amount that is too high or too low, this could cause hypoglycemia (low BG) or hyperglycemia (high BG) events. You can change the amount of insulin before you deliver your bolus.

⚠ WARNING

Delivering large boluses, or delivering multiple boluses back to back may cause hypoglycemia (low BG) events. Pay attention to IOB and the bolus calculator recommended dose before delivering large or multiple boluses.

⚠ WARNING

If you do not see a reduction in BG after initiating a bolus, it is recommended that you check your infusion set for an occlusion, air bubbles, or for leaks or cannula dislodgement. If the condition persists, call Customer Technical Support or seek medical attention as required.

📌 NOTE

The information in this chapter does NOT apply to boluses delivered automatically by

Control-IQ™ technology. For information about Automatic Bolus Delivery, see Automatic Correction Bolus Delivery in Section 30.2 How Control-IQ Technology Works.

A bolus is a quick dose of insulin that is usually delivered to cover food eaten or to correct high glucose. A bolus can be requested from either the t:slim X2™ insulin pump or the t:connect™ mobile app.

The minimum bolus size is 0.05 units. The maximum bolus size is 25 units. If you attempt to deliver a bolus that is larger than the amount of insulin in the cartridge, a message screen appears indicating that there is not enough insulin to deliver the bolus.

Your t:slim X2 pump offers you the ability to deliver different boluses to cover carbohydrate intake (food bolus) and bring your BG back to target (correction bolus). Food and correction boluses can also be programmed together.

📌 NOTE

If you start a manual bolus request on the pump, you must complete it on the pump. You cannot

request a bolus from the t:connect mobile app while a bolus request is active on the pump.

If Carbs is turned on in your active Personal Profile, you will enter grams of carbohydrate and the bolus will be calculated using your Carb Ratio.

If you are not using Control-IQ technology and Carbs is turned off in your active Personal Profile, you will enter units of insulin to request the bolus.

📌 NOTE

If you deliver a manual bolus, Control-IQ technology will not be able to deliver an automatic correction bolus until 60 minutes after the manual bolus has completed.

Before you use the t:connect™ mobile app to deliver a bolus, ensure your smartphone's security feature (e.g., screen lock, passcode, face recognition) is turned on. Never share your security PIN/password or authorize any other person to access your smartphone via their biometric information to avoid unintentional changes in your delivery of insulin.

NOTE

If your smartphone is not connected to the pump, you can only request a bolus from the pump. For more information on establishing a connection between your smartphone and the pump, see Section 4.3 Connecting to a Smartphone.

PRECAUTION

CHECK your pump's settings regularly to ensure they are correct. Incorrect settings can result in over delivery or under delivery of insulin. Consult your healthcare provider as needed.

8.2 Initiating a Bolus

To request a bolus, tap **BOLUS** on your pump's *Home* screen or tap **Bolus** from the *Navigation* bar in the t:connect mobile app.

WARNING

You have 10 seconds to cancel a bolus after requesting it to completely avoid insulin delivery; both the pump and the t:connect mobile app will say "requesting bolus" during this time. See Section 8.10 Canceling or Stopping a Bolus Using the Pump or Section 8.15 Canceling or Stopping a Bolus Using the t:connect Mobile App for instructions to cancel a bolus.

You can request a bolus using the t:connect mobile app when each of the following conditions are true:

- You have a compatible smartphone (see tandemdiabetes.com/mobilesupport)
- Your smartphone is connected to your pump
- You have a native security feature of your smartphone turned on

See Section 8.11 Bolus Delivery Using the t:connect Mobile App for further instructions to use the t:connect mobile app to request a bolus.

8.3 Correction Bolus Calculation

Once the pump knows your glucose value, it will determine whether to recommend that a correction bolus to be added to any other bolus requested on the *Bolus* screen. The pump can receive your glucose value from manual entry into the pump or the CGM.

When your glucose value is:

- Above Target BG: the insulin for the food bolus and the correction bolus will be added together. If IOB is present, it is subtracted only from the correction portion of the bolus.
- Between 70 mg/dL and Target BG: You will be given an option to reduce the food bolus to account for the lower glucose level. In addition, if IOB is present, it will also be used to reduce the bolus calculation.
- Below 70 mg/dL: The food bolus will be reduced for the low glucose value. In addition, if IOB is present, it will also be used to reduce the bolus calculation.

Always treat hypoglycemia (low BG) with fast-acting carbohydrates according to the instructions of your healthcare provider and then re-test your BG to ensure that the treatment was successful.

CHAPTER 8

Glucose Value Auto-Population with CGM

⚠ PRECAUTION

PAY ATTENTION to the trend information on the *CGM Home* screen, as well as your symptoms, before using CGM values to calculate and deliver a correction bolus. Individual CGM values may not be as accurate as BG meter values.

📌 NOTE

With a CGM that is approved for non-adjunctive use, there is no need to take a fingerstick to make a treatment decision, as long as your symptoms match the CGM readings. The t:slim X2 insulin pump and the t:connect mobile app can automatically use CGM readings in their respective bolus calculators when Control-IQ technology is enabled and there is a valid reading and trend arrow available from the CGM. If your CGM readings don't match your symptoms, it is recommended that you wash your hands thoroughly and use your BG meter to replace the CGM reading in the bolus calculator if the BG meter value matches your symptoms. If you want to align your CGM with your BG meter, you should follow the instructions to calibrate your CGM. Do not take insulin doses too close together, often referred to as stacking insulin. If you have recently given a bolus, you

might wait 60 minutes to see if your readings respond to the bolus.

📌 NOTE

Retrospective analysis of the pivotal study results indicated that there was an increased incidence of CGM values <70 mg/dL five hours after a bolus was delivered when glucose values were auto-populated. See Section 33.10 Additional Analysis of Sensor Glucose Value Auto-Population with CGM for more information.

Your glucose value is automatically entered into the GLUCOSE field on the *Bolus* screen when each of the following conditions are true:

- Control-IQ technology is turned on and available
- A CGM session is active
- A CGM value is present
- A CGM trend arrow is available on the CGM Home screen

📌 NOTE

For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's

product instructions. You can also see Section 25.3 Rate of Change Arrows.

When the CGM reading is automatically populated into the bolus calculator, only the current CGM reading is used to calculate the correction bolus. The trend arrow is not used in the dose calculation. Speak with your healthcare provider for recommendations on how best to utilize the arrows for your correction bolus dosing.

If your healthcare provider has advised you to use the trend arrow to adjust your correction dose, or if you want to change the glucose value used to calculate your correction dose, you can manually override the glucose value auto-populated from your CGM.

To change the glucose value auto-populated from your CGM you can tap on the GLUCOSE value on the

Bolus screen. The following example shows the *Bolus* screen on the pump.



NOTE

If the glucose value auto-populated from your CGM was above or below your Target BG, your pump will present you with the *Above Target* or *Below Target Correction Bolus* confirmation screen.

Correction Bolus Confirmation Screens

To access the *Correction Bolus* confirmation screen on the pump, tap **BOLUS** from the *CGM Home* screen.

- If your CGM value or trend arrow are not available on the *Home* screen, the *Bolus* screen appears.

- If you have a CGM value and trend arrow, the *Correction Bolus* confirmation screen appears (if appropriate).

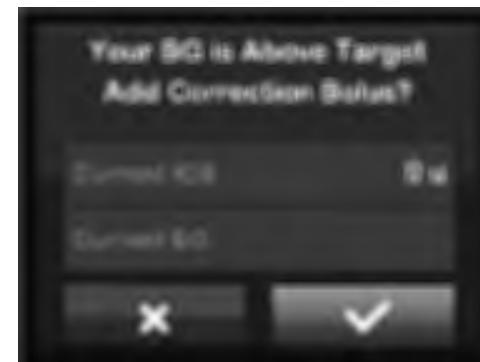
You cannot tap the **Current BG** value on these *Correction Bolus* confirmation screens to change the glucose value auto-populated from your CGM.

Tap either  or  and proceed to the *Bolus* screen to change the glucose value as described above. Once the value is changed, if the manually inputted value is above or below your Target BG, your pump will again present you with the *Above Target* or *Below Target* confirmation screen where you can choose to accept the correction bolus or decline it.

Above Target

If your glucose value is above your Target BG, you can calculate and add a correction bolus to any other bolus you request.

Calculate and add a correction bolus from the pump as follows:



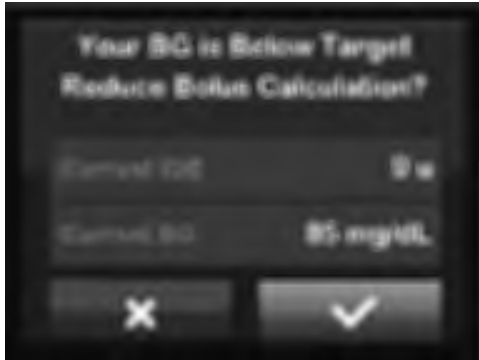
- To accept the correction bolus tap . A correction bolus is calculated and will be added to any food bolus you request on the *Bolus* screen.
- To decline the correction bolus, tap . No correction bolus will be added to any food bolus you request on the *Bolus* screen.

Below Target

If your glucose value is below your Target BG, the pump presents you with the option to calculate and subtract a

CHAPTER 8

correction bolus from any other bolus you request.



Calculate and apply a correction bolus from the pump as follows:

- To accept the correction bolus tap . A correction bolus is calculated and will be subtracted from any food bolus you request on the *Bolus* screen.
- To decline the correction bolus, tap . No correction bolus will be subtracted from any food bolus you request on the *Bolus* screen.

Within Target

If your glucose value is the same value as your Target BG, no *Correction Bolus* screen is displayed.

BG Value Manual Entry

If your glucose value was not auto-populated on the *Bolus* screen based on the conditions needed for that feature, you will need to manually enter your BG value into the pump before confirming bolus delivery. The conditions needed for the auto-populate feature are:

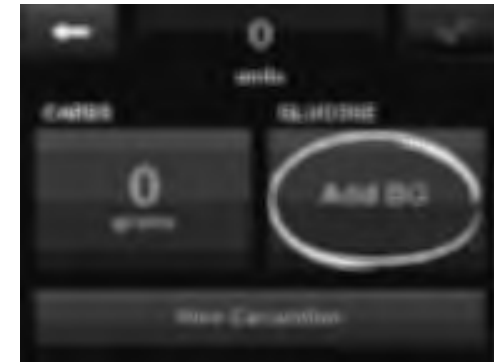
- Control-IQ technology is turned on and available
- A CGM session is active
- A CGM value is present
- A CGM trend arrow is available

NOTE

For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's user guide. You can also see Section 25.3 Rate of Change Arrows.

The *Correction Bolus* confirmation screens are displayed, if appropriate, after you manually enter your BG value on the *Bolus* screen. Manually enter your BG value into the pump as follows:

- From the *Home* screen tap **BOLUS**.
- Tap **Add BG**.



- Using the on-screen keypad, enter your BG value.
- Tap to save the BG value in your pump history.

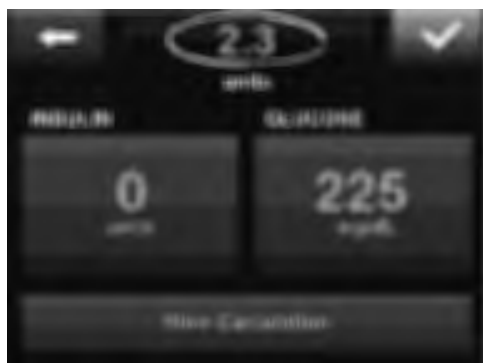
NOTE

This saves the BG value in your pump history whether or not a bolus is delivered.

- Follow the steps in the appropriate Target section above depending on the results of your BG value.

8.4 Bolus Override

You can override the calculated bolus by tapping on the calculated units value and entering the units of insulin you want delivered. The bolus override is always an available option; the following example shows the bolus override on the pump screen.



8.5 Food Bolus Using Units

If you are using Control-IQ technology, skip to Section 8.6 Food Bolus Using Grams. Otherwise, to deliver a food bolus using the pump:

1. From the *Home* screen, tap **BOLUS**.

2. Tap **0 units** on the left side of the screen.
3. Using the on-screen keypad enter units of insulin to be delivered, then tap .

⚠ WARNING

ALWAYS confirm that the decimal point placement is correct when entering bolus information. Incorrect decimal point placement can prevent you from getting the proper amount of insulin that your healthcare provider has prescribed for you.

4. Tap to confirm the units of insulin to be delivered.
 5. Confirm Request.
 - Tap if entered data is correct.
 - Tap to go back to make changes or view calculations.
 6. Tap .
- ✓ The *BOLUS INITIATED* screen is temporarily displayed.

8.6 Food Bolus Using Grams

To deliver a food bolus using the pump:

1. From the *Home* screen, tap **BOLUS**.
2. Tap **0 grams**.
3. Using the on-screen keypad enter grams of carb and tap .
 - To add multiple carb values enter first value, then tap , enter second value, tap . Continue until done.
 - To clear the value entered and start over, tap the back arrow.
4. Check that the grams of carb are entered in the correct location on the screen.
5. Tap to confirm the units of insulin to be delivered.

You can always tap **View Calculation** to display the *Delivery Calculation* screen.

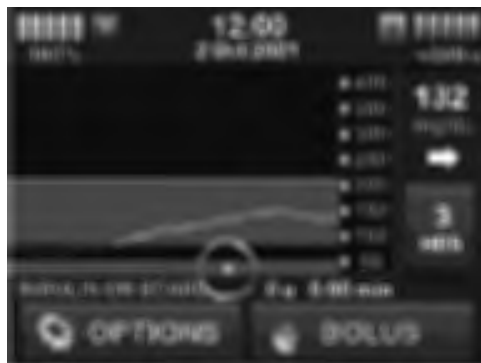
CHAPTER 8

6. Confirm Request.

- Tap  if entered data is correct.
- Tap  to go back to make changes or view calculations.

7. Tap .

- ✓ The *BOLUS INITIATED* screen is temporarily displayed.
- ✓ After the bolus delivery is complete, an icon displays below the CGM graph.

 NOTE

Each bolus icon represents one bolus delivery. Hash marks on the bolus bar denote time increments based on your

graph settings; these hash marks may temporarily obstruct a bolus icon as the graph changes over time.

8.7 Extended Bolus

The Extended Bolus feature allows you to deliver part of the bolus now and part of the bolus slowly over a period of up to 8 hours, or to deliver the whole bolus over an extended period of time. This can be helpful for high fat meals such as pizza or if you have gastroparesis (delayed stomach emptying).

When extending a bolus, any correction bolus amount will always be given in the DELIVER NOW portion. Talk with your healthcare provider to determine if this feature is appropriate for you, as well as for recommendations on the split between now and later and the duration for the later portion.

1. From the *Home* screen, tap **BOLUS**.
2. Tap **0 grams** (or **0 units**).

3. Use the on-screen keypad to enter grams of carb (or units of insulin). Tap .

4. If desired, tap **Add BG**, use the on-screen keypad to enter a glucose value, and tap .

5. Tap  to confirm the units of insulin to be delivered.

You can always tap **View Calculation** to display the *Delivery Calculation* screen.

6. Confirm Request.

- Tap  if entered data is correct.
- Tap  to go back to make changes or view calculations.

7. Tap **EXTENDED** to turn on the extended feature, then tap .

8. Tap **50%** under **DELIVER NOW** to adjust the percentage of the food bolus that is to be delivered immediately.

The percentage value for DELIVER LATER is automatically calculated by the pump. The default is 50% NOW and 50% LATER. The default for DURATION is 2 hours.

9. Use the on-screen keypad to enter the percentage of the bolus to DELIVER NOW and tap .

For the DELIVER NOW portion, the minimum amount is .05 units. If the DELIVER NOW portion is less than .05 units, you will be notified and the DELIVER NOW portion will be set to .05 units.

The DELIVER LATER portion of the extended bolus also has minimum and maximum rates. If you program a DELIVER LATER rate outside of these limits, you are notified and the duration of the DELIVER LATER portion is adjusted.

10. Tap 2 hrs under DURATION.

The default maximum duration for extended bolus delivery is 8 hours.

11. Use the on-screen keypad to adjust the length of time the bolus is to be delivered, then tap .

12. Tap .

You can always tap View Units to display the breakdown of units to be delivered NOW versus LATER.

13. Confirm Request.

- Tap  if entered data is correct.
- Tap  to go back to make changes or view calculations.

14. Tap .

- ✓ The *BOLUS INITIATED* screen is temporarily displayed.

- ✓ After the bolus delivery is complete, an icon displays below the CGM graph.



Only one extended bolus can be active at any given time. However, if the DELIVER LATER portion of an extended bolus is active, you can request another standard bolus.

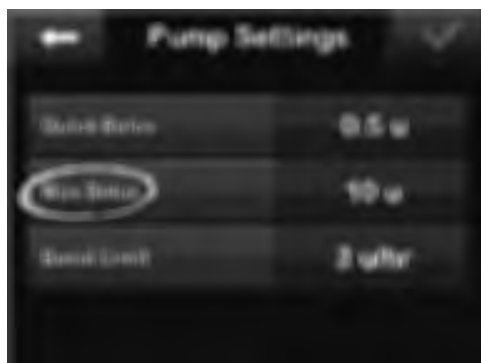
8.8 Max Bolus

The Max Bolus setting allows you to set a limit to the maximum insulin delivery amount for a single bolus.

The default setting for Max Bolus is 10 units, but can be set to any value between 1 to 25 units. To adjust the Max Bolus setting, follow these steps.

CHAPTER 8

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap **Pump Settings**.
5. Tap **Max Bolus**.



6. Using the on-screen keypad, enter the desired amount for maximum bolus (1–25 units) and tap .

NOTE

If you set the max bolus to 25 units and a bolus larger than 25 units is calculated using your Carb Ratio or Correction Factor, after the bolus is delivered a reminder

screen will appear. The option of delivering the remaining amount of the bolus up to an additional 25 units will be given (see Section 13.9 Max Bolus Alerts). You must confirm delivery of this additional amount from your pump.

8.9 Quick Bolus

The Quick Bolus function enables you to deliver a bolus by simply pressing a button, if enabled. It is a way to deliver a bolus by following beep/vibration commands without navigating through or viewing the pump screen.

Quick Bolus can be set to correspond to either units of insulin or grams of carbohydrate. When Control-IQ technology is enabled, it will use the Quick Bolus as a correction bolus if configured as units of insulin, or as a food bolus if configured as grams of carbohydrate. Control-IQ technology uses the information about carbohydrate intake to optimize insulin delivery after eating.

Configure Quick Bolus

The default for the Quick Bolus function is off. Quick Bolus can be set to either units of insulin or grams of carbohydrate. The increment options are 0.5, 1.0, 2.0, and 5.0 units; or 2, 5, 10 and 15 grams.

NOTE

It is recommended to use grams of carbohydrate in a bolus delivery whenever using Control-IQ technology.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap **Pump Settings**.
5. Tap **Quick Bolus**.
6. Tap **Increment Type**.
7. Tap **units of insulin or grams of carbohydrate** to select. Tap .
8. Tap **Increment Amount**.

9. Select the preferred increment amount.

NOTE

The increment amount is added with each press of the **Screen On/Quick Bolus** button when delivering a quick bolus.

10. Review entered values and tap .

11. Confirm Settings.

- Tap  if entered data is correct.
- Tap  to go back to make changes.

12. Tap the **Tandem** logo to return to the *Home* screen.

Deliver a Quick Bolus

If the Quick Bolus function is turned on, you can deliver a bolus by pressing the **Screen On/Quick Bolus** button to deliver your bolus. Quick boluses are delivered as standard boluses (there is no glucose value entry or extended bolus).

PRECAUTION

ALWAYS check the pump screen to confirm correct programming of the bolus amount when you first use the Quick Bolus feature. Checking the screen will ensure that you are correctly using the beep/vibration commands to program the intended bolus amount.

1. Press and hold the **Screen On/Quick Bolus** button. The *Quick Bolus* screen will appear. Listen for two beeps (if sound volume is set to beep) or feel for vibrations (if sound volume is set to vibrate).
2. Press the **Screen On/Quick Bolus** button for each increment until desired amount is reached. The pump will beep/vibrate for each button press.
3. Wait for the pump to beep/vibrate once for each increment pressed to confirm desired amount.
4. After the pump beeps/vibrates, press and hold the **Screen On/Quick Bolus** button for several seconds to deliver the bolus.

NOTE

If you want to cancel the bolus and return to the *Home* screen, tap  on the *Quick Bolus* screen.

If more than 10 seconds have passed with no input, the bolus is canceled and never delivered. In this case, the Incomplete Bolus Alert will be displayed on your pump and (if applicable) on your smartphone via the t:connect mobile app.

You cannot exceed the Max Bolus setting defined in your Pump Settings when using the Quick Bolus feature. Once you reach the Max Bolus amount, a different tone will sound to notify you (if Quick Bolus is set to vibrate, the pump will stop vibrating in response to additional button presses to notify you). Look at the screen to confirm the bolus amount.

You cannot exceed 20 button presses when using the Quick Bolus feature. Once you reach 20 button presses, a different tone will sound to notify you (if Quick Bolus is

CHAPTER 8

set to vibrate, the pump will stop vibrating in response to additional button presses to notify you). Look at the screen to confirm the bolus amount.

If you hear a different tone at any point during programming or the pump stops vibrating in response to button presses, check the screen to confirm the bolus amount. If the *Quick Bolus* screen does not display the correct bolus amount, use the touchscreen to enter bolus information.

- ✓ The *BOLUS INITIATED* screen is temporarily displayed.

NOTE

If Control-IQ technology is on and has adjusted insulin delivery during a Quick Bolus, the remaining Quick Bolus insulin will be delivered.

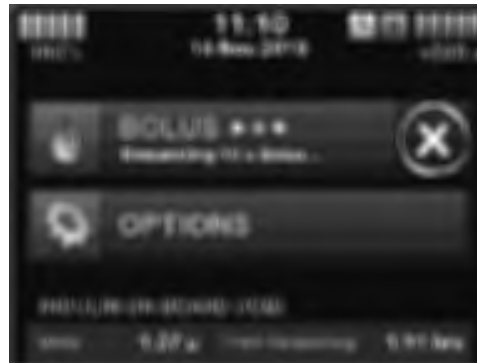
8.10 Canceling or Stopping a Bolus Using the Pump

You have 10 seconds to cancel a bolus after requesting it to completely avoid

insulin delivery; the pump will say “requesting bolus” during this time.

To cancel a bolus request from the pump:

1. Tap 1–2–3 to access the *Home* screen.
2. Tap  to cancel the bolus.



- ✓ **BOLUS** will remain inactive while the bolus is being canceled.

NOTE

Once canceled, **BOLUS** will become active again on the Home screen.

To stop a bolus after delivery has started:

1. Tap 1–2–3 to access the *Home* screen.
2. Tap  to stop delivery.
3. Tap .
- ✓ The *BOLUS STOPPED* screen is displayed and the units delivered are calculated.
- ✓ Units requested and delivered are shown.
4. Tap .

8.11 Bolus Delivery Using the t:connect Mobile App

Before you use the t:connect mobile app to deliver a bolus, enable your smartphone security feature (e.g., screen lock, passcode, face recognition). Never share your security PIN/password or authorize any other person to access your smartphone via

their biometric information to avoid unintentional delivery of insulin.

NOTE

If your smartphone is not compatible with the Bolus Delivery feature set of the t:connect mobile app, you cannot use the t:connect mobile app to request, cancel, or stop a bolus. For an up-to-date list of supported smartphones, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen.

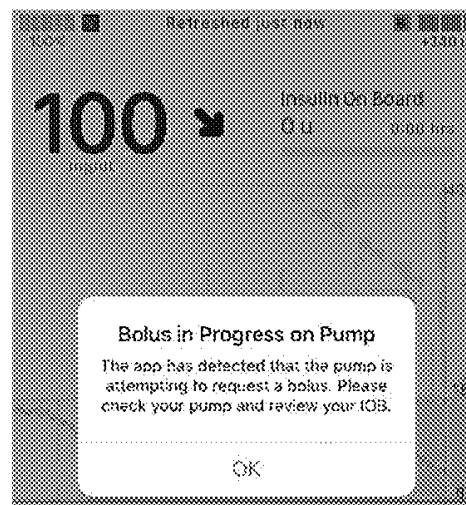
You can use the t:connect mobile app to deliver the following boluses:

- Correction bolus (see Section 8.12 Correction Bolus Using the t:connect Mobile App)
- Override bolus (see Section 8.13 Bolus Override Using the t:connect Mobile App)
- Food bolus using either units of insulin or grams of carbohydrate (see Section 8.14 Food Bolus Using the t:connect Mobile App)

You must use your pump for the following features:

- Extended Bolus (see Section 8.7 Extended Bolus)
- Max Bolus setting (see Section 8.8 Max Bolus)
- Quick Bolus (see Section 8.9 Quick Bolus)

If you request any bolus from the pump, you must complete it on the pump. If you attempt to request a bolus from the t:connect mobile app while a bolus request is active on the pump, the t:connect mobile app will generate the *Bolus in Progress on Pump* notification and prevent you from starting a bolus.



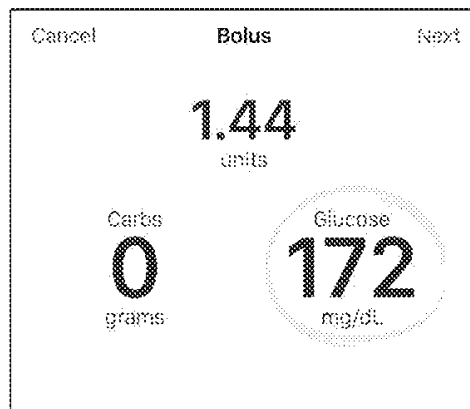
8.12 Correction Bolus Using the t:connect Mobile App

Once the t:connect mobile app knows your glucose value, it will determine whether to recommend that a correction bolus to be added to any other bolus requested on the *Bolus* screen. The t:connect mobile app can receive your glucose value from manual entry into the t:connect mobile app or auto-populate from the CGM. See *Glucose Value Auto-Population with CGM* for more information about automatically populated glucose values.

To change the glucose value auto-populated from your CGM you can tap on the GLUCOSE value on the *Bolus* screen. The following example

CHAPTER 8

shows the *Bolus* screen in the t:connect mobile app.



Correction Bolus Confirmation Screens

To access the Correction Bolus confirmation screen on the t:connect mobile app and enable the Correction Bolus toggle, tap Bolus on the Navigation bar.

- If your CGM value or trend arrow are not available on the Home screen, the Correction Bolus confirmation screen appears after you enter your glucose value into the t:connect mobile app as described above.

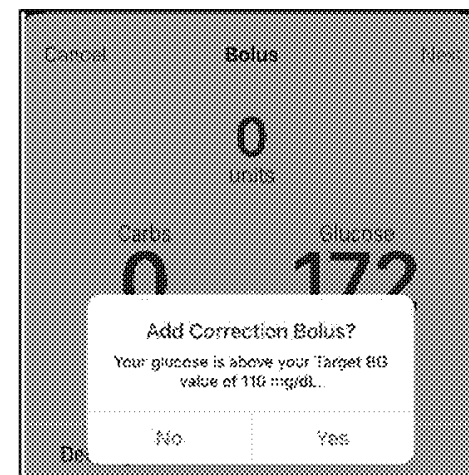
- If you have a CGM value and trend arrow, the Correction Bolus confirmation screen appears when you tap Bolus (if appropriate).

Above Target

If your BG or sensor glucose value is above your Target BG, you can calculate and add a correction bolus to any other bolus you request.

Calculate and add a correction bolus from the t:connect mobile app as follows:

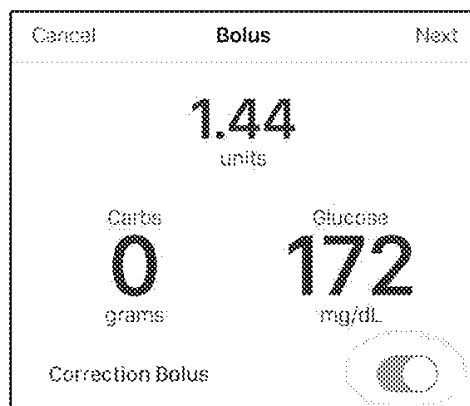
- To accept the correction bolus, tap **Yes** on the *Correction Bolus* confirmation screen.



- To decline the correction bolus, tap **No** on the *Correction Bolus* confirmation screen.

If you tap **Yes**, the Correction Bolus toggle will be turned on. You can later decline the correction bolus by tapping

the Correction Bolus toggle to the OFF position.

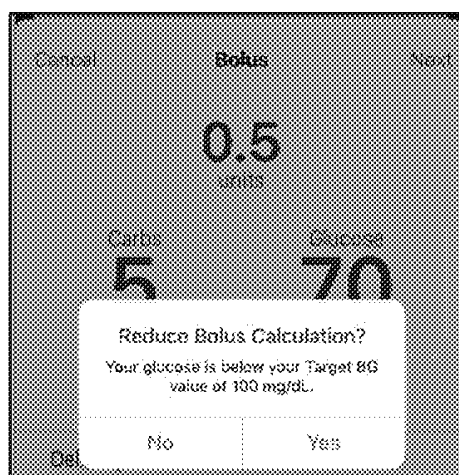


Below Target

If your BG or sensor glucose value is below your Target BG, the t:connect mobile app presents you with the option to subtract a correction bolus from any other bolus you request; any values the t:connect mobile app delivery calculation shows in red are subtracted from the calculated bolus amount.

Calculate and add a correction bolus from the t:connect mobile app as follows:

- To accept the correction bolus, tap **Yes** on the *Correction Bolus* confirmation screen.



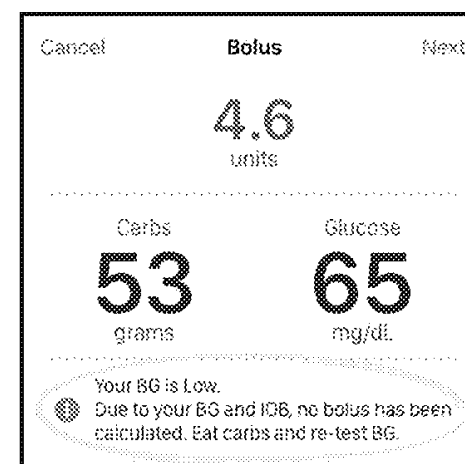
- To decline the correction bolus, tap **No** on the *Correction Bolus* confirmation screen.

If you tap **Yes**, the Correction Bolus toggle will be turned on. You can later decline the correction bolus by tapping the Correction Bolus toggle to the OFF position.

NOTE

If your blood glucose is below 70 mg/dL, the food bolus will be reduced to automatically correct for the low glucose value. In this case,

the Correction toggle will be unavailable, and the t:connect mobile app will display the Low BG Alert in its place.



Within Target

If your BG or sensor glucose value is the same value as your Target BG, no correction bolus will be included in the bolus calculation.

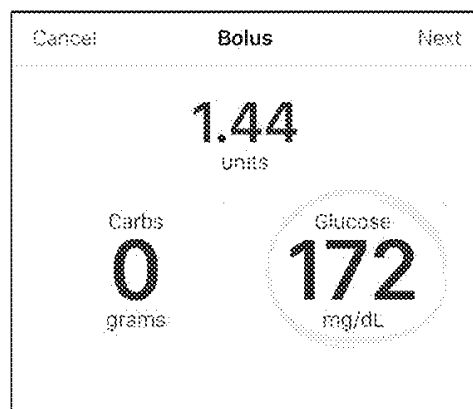
BG Value Manual Entry Using the t:connect Mobile App

Manually enter your BG value into the t:connect mobile app as follows:

- From the navigation bar, tap **Bolus**.

CHAPTER 8

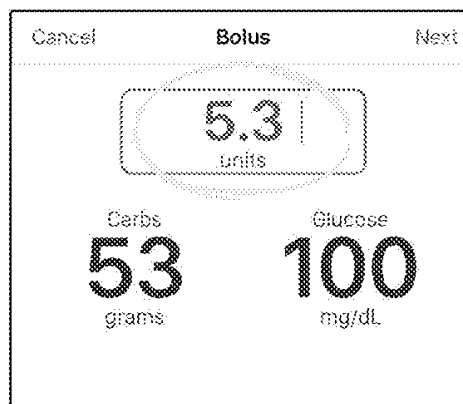
2. Tap Add Glucose.



3. Use the on-screen number keypad to enter your BG value.
4. Tap **Done** (iOS) or **✓** (Android) on the number keypad to save your BG value in your pump history and close the number keypad.
5. Follow the steps in the appropriate Target section above depending on the results of your BG value.

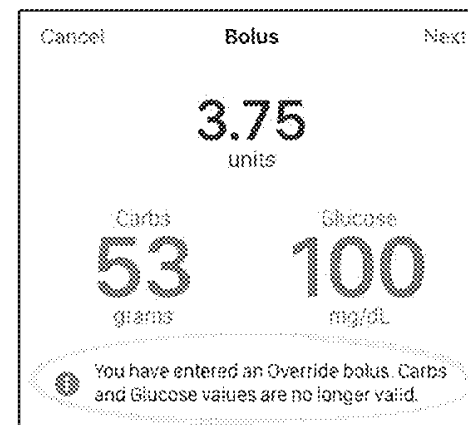
8.13 Bolus Override Using the t:connect Mobile App

You can override the calculated bolus by tapping on the calculated units value and entering the units of insulin you want delivered. The bolus override is always an available option; the following example shows the bolus override in the t:connect mobile app.



If you use the t:connect mobile app to set the override bolus value, the Bolus Override Alert will appear as an

informational message on the *Bolus* screen.



8.14 Food Bolus Using the t:connect Mobile App

To deliver a food bolus using the t:connect mobile app:

1. Tap the **Bolus** icon on the *Navigation* bar.
2. Tap **0 grams** or **0 units** on the left side of the screen, depending on the settings in your active Personal Profile.

3. Use the number keypad to enter units of insulin or grams of carb to be delivered.
4. Tap **Done** (iOS) or  (Android) on the number keypad to close the keypad.
- ✓ The total bolus amount at the top of the screen updates (if applicable).
5. Tap **Next** (iOS) or **→** (Android) to confirm the units of insulin to be delivered.
- ✓ The *Confirm Bolus* screen is temporarily displayed.
6. Confirm request:
 - Tap **Next** (iOS) or  (Android) if entered data is correct.
 - Tap **Back** (iOS) or **X** (Android) to go back to make changes or view calculations.
7. Tap the **Deliver Bolus** icon.
8. The t:connect mobile app will generate a confirmation prompt;

use your smartphone's security feature to confirm the bolus request or tap **Cancel** to return to the *Bolus* screen.

- ✓ The t:connect mobile app returns you to the dashboard.
- 9. A bolus bar appears above the navigation bar until the entire bolus has been delivered, including a cancel/stop button as well as the bolus type and amount requested.

8.15 Canceling or Stopping a Bolus Using the t:connect Mobile App

⚠ WARNING

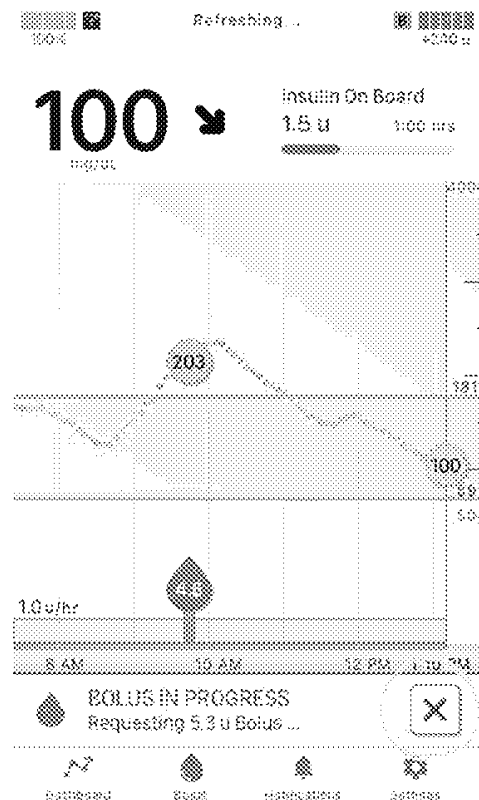
Any time you request a bolus, you have 10 seconds to cancel the bolus after requesting it to completely avoid insulin delivery. Both the pump and the t:connect mobile app will say "requesting bolus" during this time as long as your pump and the t:connect mobile app are connected. You can cancel the bolus from either the pump or the app regardless of how you requested it.

You may cancel or stop any bolus via the t:connect mobile app as long as the t:connect mobile app has a Bluetooth connection to the pump, regardless of whether you initiated the bolus from the pump or the t:connect mobile app.

To cancel a bolus request from the t:connect mobile app:

CHAPTER 8

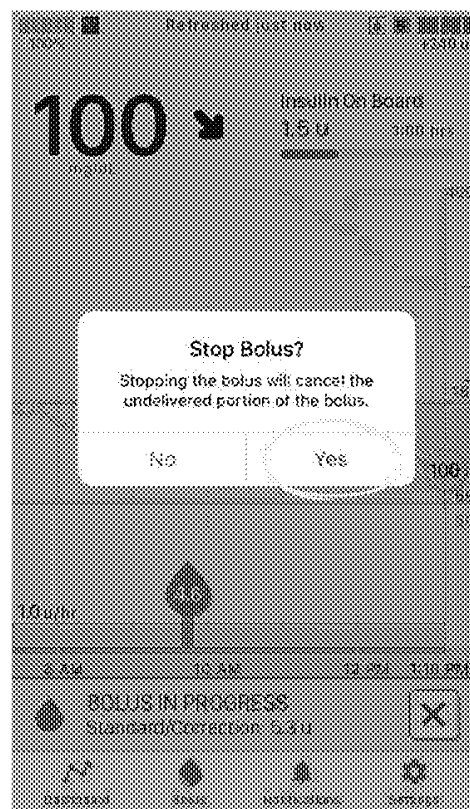
1. Tap  to cancel delivery.



NOTE

The  is always available in the t:connect mobile app as part of the bolus bar during bolus delivery; you don't need to visit the *Bolus* screen to cancel a bolus.

2. Tap **Yes** in the confirmation prompt to cancel the bolus.



- ✓ The Bolus Stopped Alert appears and lists the units delivered as 0.

To stop a bolus after delivery has started:

1. Tap  on the t:connect mobile app bolus bar to stop delivery.
 2. Tap **Yes** on the t:connect mobile app confirmation prompt.
- ✓ The *BOLUS STOPPED* screen is displayed and the units delivered are calculated.
 - ✓ Units requested and delivered are shown.
3. Tap  on the t:connect mobile app informational message.

8.16 Pump Connection Lost

Connection Lost During Bolus Request

If your smartphone becomes disconnected from the pump while you are requesting a bolus before you confirm bolus delivery, the t:connect mobile app generates a Pump Connection Lost Alert. When you

receive this notification, tap **OK** to return to the dashboard.

- No bolus will be delivered. Use the pump to deliver this bolus.
- Check your smartphone's Bluetooth connection and Bluetooth settings.
- You cannot use the t:connect mobile app to request a bolus until you have restored your smartphone's connection to the pump.

Connection Lost During Bolus Delivery

If your smartphone becomes disconnected from the pump while the pump is delivering a bolus, the t:connect mobile app generates a Pump Connection Lost Alert. When you receive this notification, the t:connect mobile app will return you to the dashboard.

- Your pump will still deliver the remainder of the bolus unless you use the pump to stop the bolus.

- You must re-establish the connection between your smartphone and the pump before you use the t:connect mobile app to deliver another bolus. See Section 4.3 Connecting to a Smartphone.

⚠ PRECAUTION

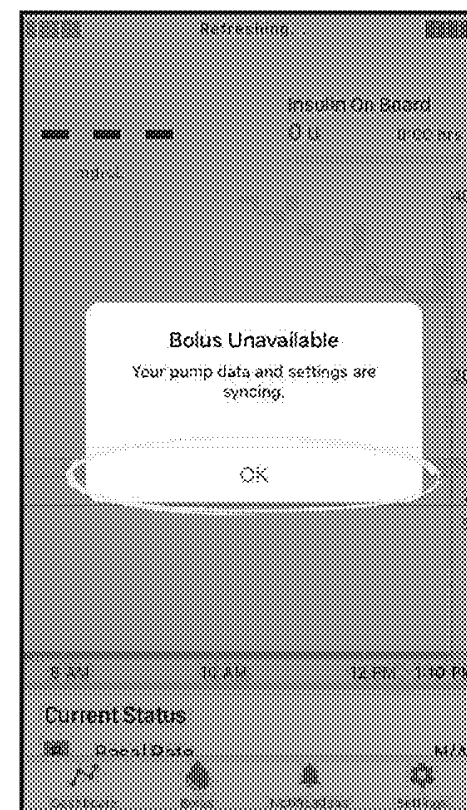
DO NOT ignore symptoms of high and low glucose. If your t:connect mobile app readings do not match your symptoms, check your pump display and confirm that your pump has established a Bluetooth connection with your smartphone.

📌 NOTE

This Mobile Connection setting is not related to your CGM Bluetooth connection. For CGM Bluetooth information, see Section 21.1 About Bluetooth Technology.

Even if the t:connect mobile app has established a connection with the pump, you cannot use the t:connect mobile app to request a bolus until it has received your bolus settings from the pump. If you tap **Bolus** during this time to request a bolus, the t:connect mobile app will generate a Bolus Unavailable Alert as shown in the

following example; tap **OK** to return to the dashboard.



This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 9

Starting, Stopping, or Resuming Insulin

CHAPTER 9 • Starting, Stopping, or Resuming Insulin

9.1 Starting Insulin Delivery

Insulin delivery starts once you have a Personal Profile configured and activated. See Chapter 6 Insulin Delivery Settings for instructions on creating, configuring, and activating a Personal Profile.

9.2 Stopping Insulin Delivery

You can stop all insulin delivery at any time. When you stop all insulin delivery, any active bolus and any active temp rate are immediately stopped. No insulin delivery can take place while your pump is stopped. The pump will present a Resume Pump Alarm to remind you to manually resume insulin after a certain period of time. The default setting for this alarm is 15 minutes.

1. From the *Home* screen, tap **OPTIONS**.
 2. Tap **STOP INSULIN**.
- ✓ A confirmation screen displays.

3. To change the Resume Pump Alarm setting, skip to Step 4. Otherwise, tap  to accept the default setting.
- ✓ The *All Deliveries Stopped* screen appears before returning to the *Home* screen showing the status ALL DELIVERIES STOPPED. A red exclamation mark icon also appears to the right of the time and date.
4. To change the Resume Pump Alarm setting, tap the panel in the middle of the screen.



5. Select the radio button that corresponds with the time you would like the Resume Pump Alarm to display.

- ✓ The pump returns to the confirmation screen.
 - ✓ The pump will save the new alarm time, and will use this setting the next time insulin is manually suspended, unless the pump has been reset, in which case the default setting will be used.
6. Tap .
 - ✓ The *All Deliveries Stopped* screen appears before returning to the *Home* screen showing the status ALL DELIVERIES STOPPED. A red exclamation mark icon also appears to the right of the time and date.

NOTE

If you manually stop insulin delivery, you must manually resume insulin delivery. Control-IQ™ technology does not automatically resume insulin if you stop it manually.

9.3 Resuming Insulin Delivery

If pump screen is not on, press **Screen On/Quick Bolus** button once to turn on your t:slim X2™ pump screen.

1. Tap 1–2–3.
 2. Tap .
- ✓ The *RESUMING INSULIN* screen is temporarily displayed.

– OR –

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **RESUME INSULIN**.
3. Tap .

The *RESUMING INSULIN* screen is temporarily displayed.

9.4 Disconnecting When Using Control-IQ Technology

When you need to disconnect your pump from your body, stop insulin delivery. Stopping insulin delivery tells the system that you are not actively delivering insulin, which also stops Control-IQ technology so that it does not continue to calculate insulin delivery adjustments.

This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 10

t:slim X2 Insulin Pump Information and History

CHAPTER 10 • t:slim X2 Insulin Pump Information and History

10.1 t:slim X2 Pump Info

Your t:slim X2™ pump allows access to information about your pump. In the *Pump Info* screen you have access to items such as your pump Serial Number, Customer Technical Support contact information, website, and software/hardware versions.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Pump Info**.
4. Scroll through the Pump Info using the **Up/Down Arrows**.
5. Tap the **Tandem logo** to return to the *Home* screen.

10.2 t:slim X2 Pump History

Pump History displays a historical log of pump events. At least 90 days of data can be viewed in History. When the maximum number of events is reached,

the oldest events are removed from the history log and replaced with the most recent events. The following can be viewed in Pump History:

Delivery Summary, Total Daily Dose, Bolus, Basal, Load, BG, Alerts and Alarms, Control-IQ, and Complete.

Delivery Summary breaks down total insulin delivery by basal and bolus types into units and percentages. It can be viewed by the selected time period of: Today, 7 Day, 14 Day and 30 Day Average.

Total Daily Dose breaks down basal and bolus delivery into units and percentages for each individual day. You can scroll through each individual day to see your total insulin delivery.

The Bolus, Basal, Load, BG, and Alerts and Alarms are categorized by date. The event details in each report are listed by time.

The Complete section includes all information from each section as well as any changes to settings.

The letter “D” (D: Alert) before an Alert or Alarm indicates the time it was

declared. The letter “C” (C: Alert) indicates the time it was cleared.

Bolus history shows the bolus request, the bolus start time, and the bolus completion time.

- The letters “PB” indicate a bolus requested, canceled, or stopped via the pump.
- The letters “RB” indicate a bolus requested, canceled, or stopped via the t:connect mobile app.

The Control-IQ history shows the historical log of the Control-IQ™ technology status, including when the feature is enabled or disabled, when Basal Rate changes were made, and when Control-IQ technology boluses were delivered. The rate of insulin delivery may change as frequently as every five minutes.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **History**.

4. Tap **Pump History**.
5. Tap desired option.
6. Tap the **Tandem** logo to return to the *Home* screen.

To find the *Help* and *About* screens, from your t:connect mobile app, tap **Settings**.

NOTE

You must access these logs on the pump; the t:connect™ mobile app does not display the pump history logs.

10.3 t:connect Mobile App Info

The t:connect mobile app allows access to information about the t:connect mobile app.

- The *Help* screen gives you access to items such as an in-app guide to t:connect mobile app configuration and use, a list of frequently asked questions, and Customer Technical Support contact information.
- The *About* screen gives you access to items such as the t:connect mobile app instructions for use, legal information, and t:connect mobile app software version.

This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 11

t:slim X2 Insulin Pump Reminders

CHAPTER 11 • Insulin K2 Insulin Pump Reminders

Your pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check your BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

If multiple Reminders, Alerts, and Alarms happen at the same time, Alarms will be displayed first, Alerts will be displayed second, and Reminders will be displayed third. Each must be confirmed separately until all have been acknowledged.

Information in this section will help you learn how to respond to Reminders.

Reminders notify you with a single sequence of three notes or a single vibration depending on the volume/vibrate setting in Sound Volume. They repeat every 10 minutes

until acknowledged. Reminders do not escalate.

11.1 Low BG Reminder

The Low BG Reminder prompts you to re-test your BG after a low glucose value is read. When turning this reminder on, you need to set a low glucose value that triggers the reminder, as well as how much time should pass before the reminder occurs.

The default for this reminder is preset to off. If on, the defaults are Remind Me Below 70 mg/dL, and Remind Me After 15 min, but you can set these values from 70 to 120 mg/dL and 10 to 20 min.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **Low BG**.

6. Low BG is set to on; to turn off, tap **Low BG**.

- a. Tap **Remind Me Below** and using the on-screen keypad, enter a Low BG value (from 70 to 120 mg/dL) that you want to trigger the reminder, then tap .
- b. Tap **Remind Me After** and using the on-screen keypad, enter the time (from 10 to 20 min), then tap .
- c. Tap  when all changes are complete.
- d. Tap the **Tandem logo** to return to the *Home* screen.

To Respond to the Low BG Reminder

To clear the reminder, tap  and then check your glucose.

11.2 High BG Reminder

The High BG Reminder prompts you to re-test your BG after a high glucose

value is read. When you turn this reminder on, you need to set a high glucose value that triggers the reminder, as well as how much time should pass before the reminder occurs.

The default for this reminder is preset to off. If on, the defaults are Remind Me Above 200 mg/dL, and Remind Me After 120 min, but you can set these values from 150 to 300 mg/dL and 1 to 3 hours.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **High BG**.
6. High BG is set to on; to turn off, tap **High BG**.
 - a. Tap **Remind Me Above** and using the on-screen keypad, enter a High BG value (from 150

to 300 mg/dL) that you want to trigger the reminder, then tap



- b. Tap **Remind Me After** and using the on-screen keypad, enter the time (from 1 to 3 hours), then tap
- c. Tap when all changes are complete.

7. Tap the **Tandem** logo to return to the *Home* screen.

To Respond to the High BG Reminder

To clear the reminder tap and then check your glucose.

11.3 After Bolus BG Reminder

The After Bolus BG Reminder prompts you to test your BG at a selected time after bolus delivery. When turning this reminder on, you need to set how much time should pass before the reminder occurs. The default is 1 hour and 30 minutes. It can be set from 1 to 3 hours.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **After Bolus BG**.
6. After Bolus BG is set to on; to turn off, tap **After Bolus BG**.
7. Tap **Remind Me After** and using the on-screen keypad, enter the time (from 1 to 3 hours) that you want to trigger the reminder, then tap .
8. Tap when all changes are complete.
9. Tap the **Tandem** logo to return to the *Home* screen.

To Respond to the After Bolus BG Reminder

To clear the reminder tap and then check BG using your BG meter.

CHAPTER 11 • Using the Tandem Pump Reminders

11.4 Missed Meal Bolus Reminder

The Missed Meal Bolus Reminder lets you know if a bolus was not delivered during a specified time period. Four separate reminders are available. When programming this reminder you need to select the Days, the Start Time, and End Time for each reminder.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **Missed Meal Bolus**.
6. On the Missed Meal Bolus screen, tap which reminder you want to set (Reminder 1 to 4) and do the following:
 - a. Tap **Reminder 1** (or 2, 3, 4).
 - b. Reminder 1 is set to on; to turn off, tap **Reminder 1**.

c. Tap **Selected Days** and tap the day(s) you want the reminder to be on, then tap .

d. Tap **Start Time**, tap **Time** and using the on-screen keypad enter the start time, then tap .

e. Tap **Time of Day** to select AM or PM, if applicable, then tap .

f. Tap **End Time**, tap **Time** and using the on-screen keypad enter the end time, then tap .

g. Tap **Time of Day** to select AM or PM, if applicable, then tap .

h. Tap  when all changes are complete.

7. Tap the **Tandem logo** to return to the *Home* screen.

To Respond to the Missed Meal Bolus Reminder

To clear the reminder tap  and deliver a bolus if necessary.

11.5 Site Reminder

The Site Reminder prompts you to change your infusion set. The default for this reminder is preset to off. If on, the reminder can be set for 1 – 3 days and at a time of day selected by you.

For detailed information on the Site Reminder feature, see Section 7.6 *Setting Site Reminder*.

To Respond to the Site Reminder

To clear the reminder tap  and change your infusion set.

2 t:slim X2 Insulin Pump Features

CHAPTER 12

User Settable Alerts and Alarms

CHAPTER 12 • User-Settable Alerts and Alarms

12.1 Low Insulin Alert

Your t:slim X2™ pump keeps track of how much insulin remains in the cartridge and alerts you when it is low. The default for this alert is preset to 20 units. You can set this alert setting anywhere between 10 and 40 units. When the insulin amount reaches the set value, the Low Insulin Alert beeps/vibrates and appears on the screen. After the alert is cleared, the low insulin indicator (a single red bar on the insulin level display on the *Home* screen appears).

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Alerts**.
5. Tap **Low Insulin**.
6. Using the on-screen keypad, enter the number of units (from 10 to 40 units) that you want the Low Insulin

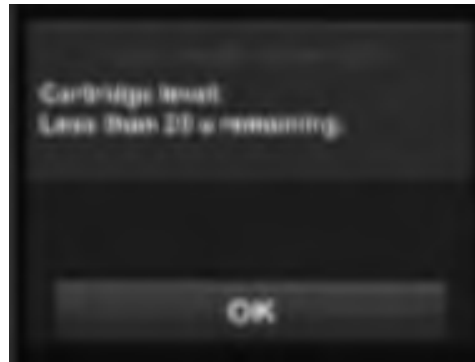
Alert value to be set to, and tap



7. Tap when all changes are complete.

To Respond to the Low Insulin Alert

To clear the alert, tap .

**12.2 Auto-Off Alarm**

Your pump can stop insulin delivery and alert you or whoever is with you if there has been no interaction with the pump within a specified period of time, particularly if you do not wear a CGM or use Control-IQ™ technology.

The default for this alarm is preset to 12 hours. You can set it anywhere between 5 and 24 hours, or off. This alarm notifies you that there has been no interaction with the pump in the specified number of hours and the pump will shut down after 60 seconds.

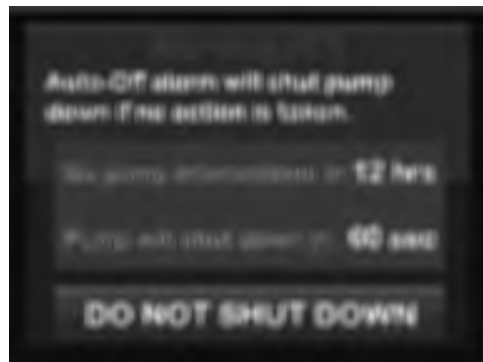
When the number of hours since you have pressed the **Screen On/Quick Bolus** button and tapped any interactive screen option or delivered a Quick Bolus passes the set value, the Auto-Off Alarm beeps and appears on the screen, and insulin delivery stops.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Alerts**.
5. Tap **Auto-Off**.
6. Tap **Auto-Off**. A confirmation screen will appear.
 - Tap to continue.

- Tap  to go back.
- 7. Verify Auto-Off is set to on, then tap **Time**.
- 8. Using the on-screen keypad, enter the number of hours (from 5 – 24 hours) that you want the Auto-Off Alarm to be triggered, and tap .
- 9. Tap , then tap  when all changes are complete.
- 10. Tap the Tandem logo to return to the *Home* screen.

To Respond to Auto-Off Warning

Tap **DO NOT SHUT DOWN**.

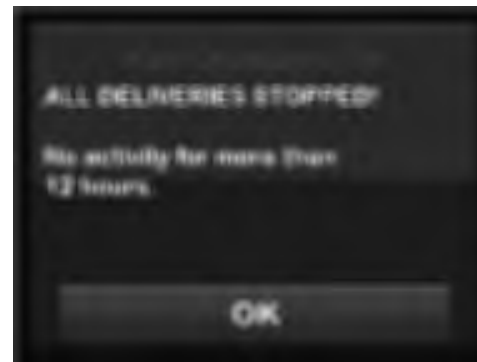


- ✓ The warning clears and the pump returns to normal operation.

If you do not clear the warning within the 60-second countdown period, the Auto-Off Alarm occurs, accompanied by an audible alarm. This alarm notifies you that your pump has stopped delivering insulin.

Auto-Off Alarm Screen

Tap .



- ✓ The *Home* screen appears, indicating a status of All Deliveries Stopped.

You must resume delivery to continue therapy, see Section 9.3 Resuming Insulin Delivery.

12.3 Max Basal Alert

Your pump allows you to set a limit to the Basal Rate that the pump will not allow you to exceed during a Temp Rate.

Once the Basal Limit in the Pump Settings has been set up (see Section 5.10 Basal Limit), you will receive an alert if the following scenarios occur.

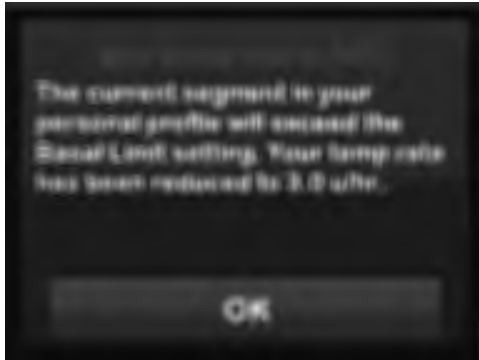
1. A Temp Rate was requested that exceeds the Basal Limit.
2. A Temp Rate is in progress, and a new Personal Profile time segment has begun, causing the Temp Rate to exceed the Basal Limit.

To Respond to Max Basal Alert

Tap  to accept the reduced Temp Rate. The reduced Temp Rate value is

CHAPTER 12 • User Settable Alarms and Alarms

the same Basal Limit value that was set up in Personal Profiles.



2 t:slim X2 Insulin Pump Features

CHAPTER 13

t:slim X2 Insulin Pump Alerts

CHAPTER 13 • t:slim X2 Insulin Pump Alerts

Your pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check you BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

If multiple Reminders, Alerts, and Alarms happen at the same time, Alarms will be displayed first, Alerts will be displayed second, and Reminders will be displayed third. Each must be confirmed separately until all have been confirmed.

Information in this section will help you learn how to respond to Alerts.

Alerts notify you with 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume. They repeat regularly

until acknowledged. Alerts do not escalate.

The t:connect™ mobile app also can provide messages, alerts, and alarms from your t:slim X2™ pump as push notifications on your smartphone. These push notifications will be identical to your pump's display unless otherwise noted in this chapter.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. For more information about connecting your pump and smartphone, see Section 4.3 Connecting to a Smartphone, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

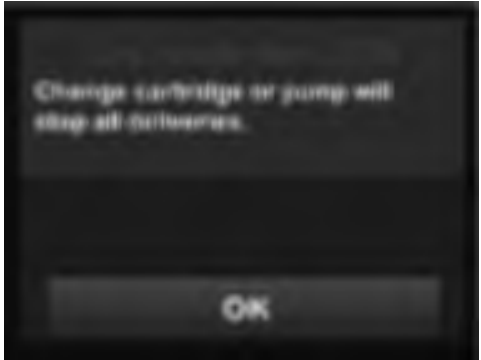
📌 NOTE

There is an additional list of alerts and errors related to CGM use in Chapter 26 CGM Alerts and Errors.

📌 NOTE

There is an additional list of alerts related to Control-IQ™ technology use in Chapter 32 Control-IQ Technology Alerts.

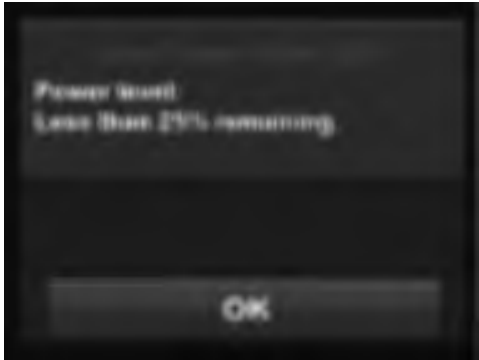
13.1 Low Insulin Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	5 units or less of insulin remain in the cartridge.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Change your cartridge as soon as possible to avoid the EMPTY CARTRIDGE ALARM and running out of insulin.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.2 Low Power Alerts

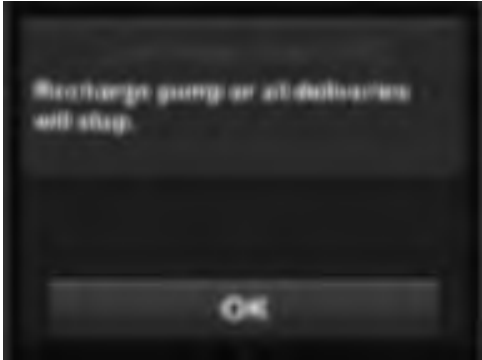
Low Power Alert 1

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Less than 25% of battery power remains.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Charge your pump as soon as possible to avoid the second LOW POWER ALERT.

NOTE

Once the LOW POWER ALERT occurs, the low-power indicator (a single red bar on the battery level display on the *Home* and *Lock* screens) appears.

Low Power Alert 2

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Less than 5% of battery power remains. Insulin delivery will continue for 30 minutes and then the pump will power off and insulin delivery will stop.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Charge your pump immediately to avoid the LOW POWER ALARM and pump power off.

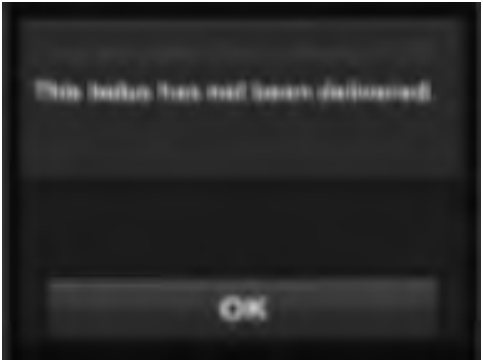
 NOTE

Once the LOW POWER ALERT occurs, the low-power indicator (a single red bar on the battery level display on the *Home* and *Lock* screens) appears.

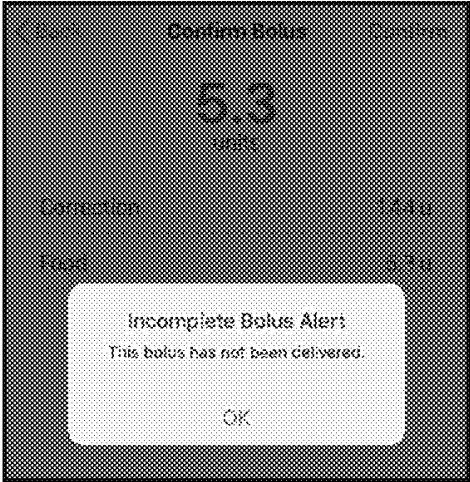
CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.3 Incomplete Bolus Alert

Incomplete Bolus Alert – Pump Screen

Screen	Explanation	
What will I see on the screen? 	What does it mean?	You started a bolus request but did not complete the request within 90 seconds.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap . The <i>Bolus</i> screen will appear. Continue with your bolus request.

Incomplete Bolus Alert – t:connect Mobile App

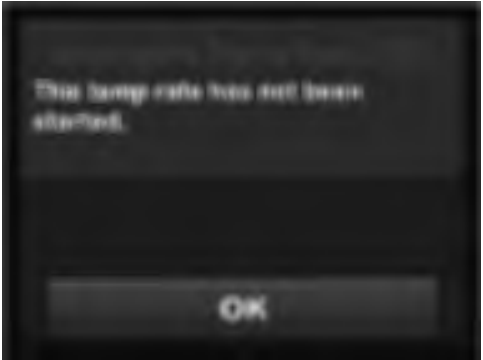
Screen	Explanation	
What will I see in the t:connect mobile app*? 	What does it mean?	You started a bolus request but did not complete the request within 90 seconds.
	How will the t:connect mobile app notify me?	• If the t:connect mobile app is open and on the <i>Bolus</i> screen, an informational message appears. • If you receive the Incomplete Bolus Alert due to interaction with other smartphone features (e.g., answering a call, using another app) or other screens in the t:connect mobile app, you will receive the alert as a notification banner.
	Will the t:connect mobile app re-notify me?	No, the alert remains on the t:connect mobile app screen until you tap OK.
	How should I respond?	Tap OK on the informational message in the t:connect mobile app. The <i>Bolus</i> screen will appear. Continue with your bolus request.

NOTE

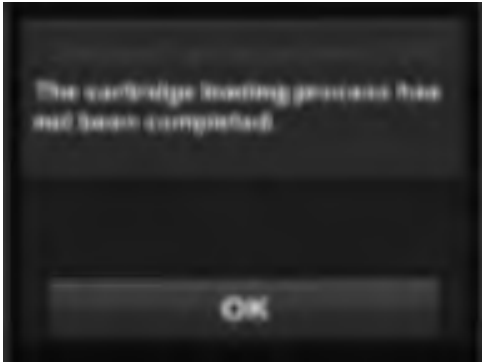
The Incomplete Bolus Alert is the only alert in this chapter that appears differently on the pump. All other pump alerts are identical in the t:connect mobile app.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.4 Incomplete Temp Rate Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	You started to set up a temp rate but did not complete the request within 90 seconds.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	1. Tap . The <i>Temp Rate</i> screen will appear. Continue setting up your temp rate. 2. Tap  if you do not want to continue setting up your temp rate.

13.5 Incomplete Load Sequence Alerts**Incomplete Cartridge Change Alert**

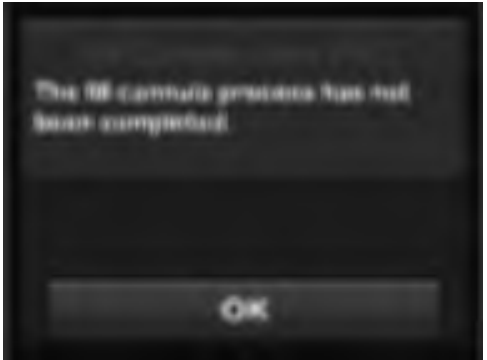
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You selected Change Cartridge from the <i>Load</i> menu but did not complete the process within 3 minutes.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Complete the cartridge change process.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

Incomplete Fill Tubing Alert

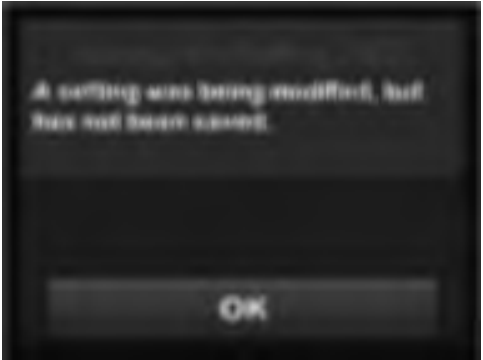
Screen	Explanation	
What will I see on the Screen? 	What does it mean?	You selected Fill Tubing from the <i>Load</i> menu but did not complete the process within 3 minutes.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap . Complete the fill tubing process.

Incomplete Fill Cannula Alert

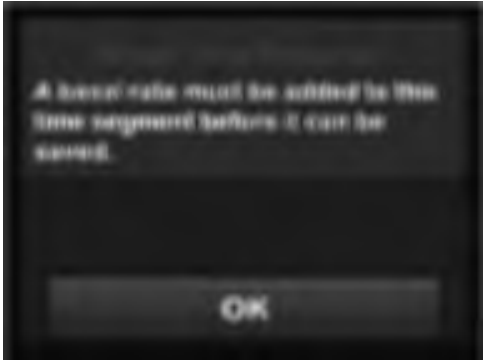
Screen	Explanation	
What will I see on the Screen? 	What does it mean?	You selected Fill Cannula from the <i>Load</i> menu but did not complete the process within 3 minutes.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Complete the cannula fill process.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.6 Incomplete Setting Alert

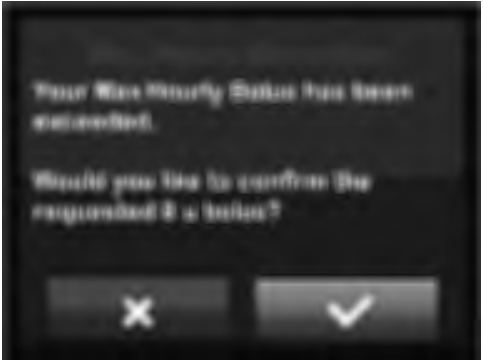
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You started to set up a new Personal Profile or Control-IQ technology setting but did not save or complete the programming within 5 minutes.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap . Complete programming the Personal Profile or Control-IQ technology setting.

13.7 Basal Rate Required Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	You did not enter a Basal Rate in a time segment in Personal Profiles. A Basal Rate must be entered in each time segment (rate can be 0 u/hr).
	How will the System notify me?	Prompt screen only.
	Will the System re-notify me?	No, a Basal Rate must be entered to save the time segment.
	How should I respond?	Tap . Enter a Basal Rate in the time segment.

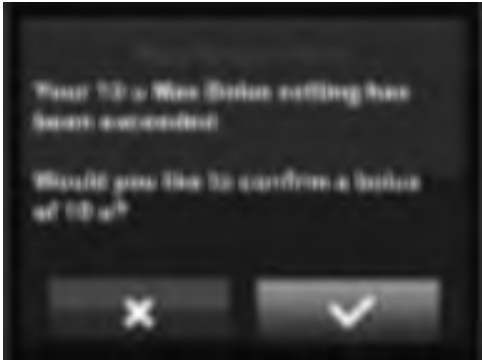
CHAPTER 13 • Insulin X2 Insulin Pump Alerts

13.8 Max Hourly Bolus Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	In the previous 60 minutes, you requested total bolus delivery that is more than 1.5 times your Max Bolus setting.
	How will the System notify me?	Prompt screen only.
	Will the System re-notify me?	No, you must tap  or  to deliver the bolus.
	How should I respond?	• Tap  to return to the <i>Bolus</i> screen and adjust the bolus delivery amount. • Tap  to confirm the bolus.

13.9 Max Bolus Alerts

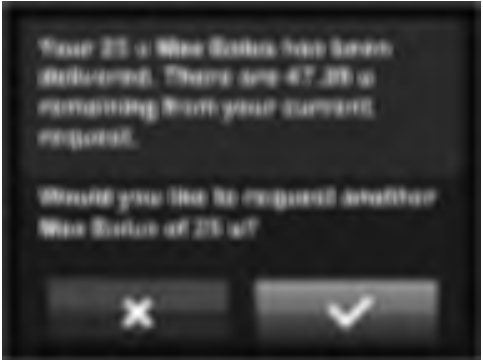
Max Bolus Alert 1

Screen	Explanation	
What will I see on the screen? 	What does it mean?	You requested a bolus larger than the Max Bolus setting in your active Personal Profile.
	How will the System notify me?	Prompt screen only.
	Will the System re-notify me?	No, you must tap  or  to deliver the bolus.
	How should I respond?	• Tap  to return to the <i>Bolus</i> screen and adjust the bolus delivery amount. • Tap  to deliver the amount of your Max Bolus setting.

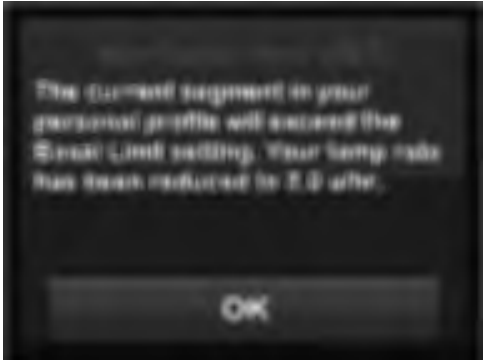
CHAPTER 13 • Insulin X2 Insulin Pump Alerts

Max Bolus Alert 2

The following applies only if you have Carbs turned on in your active Personal Profile and your Max Bolus amount is set to 25 units.

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your Max Bolus is set to 25 units and you requested a bolus larger than 25 units.
	How will the System notify me?	Prompt screen only.
	Will the System re-notify me?	No, you must tap  or  to deliver the remaining amount of the bolus request.
	How should I respond?	Before responding to this Alert, always consider whether your bolus insulin needs have changed since you requested the original bolus. • Tap  to deliver the remaining amount of the bolus request. A confirmation screen will appear. • Tap  if you do not want to deliver the remaining amount of the bolus request.

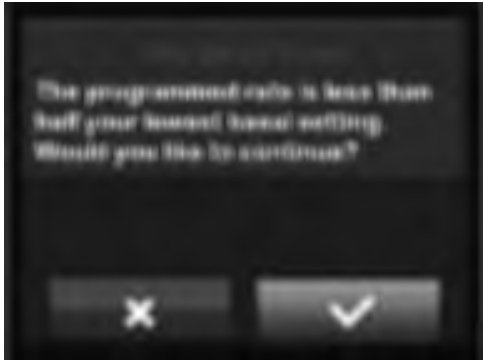
13.10 Max Basal Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	An active Temp Rate exceeds your Basal Limit setting due to a new timed segment activation within Personal Profiles. This alert will only display once your timed segment changes.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibration setting selected in Sound Volume.
	Will the System re-notify me?	No, you must tap  to move forward.
	How should I respond?	Tap  to accept the reduced Temp Rate. The reduced Temp Rate value is the same Basal Limit value that was set up in Personal Profiles.

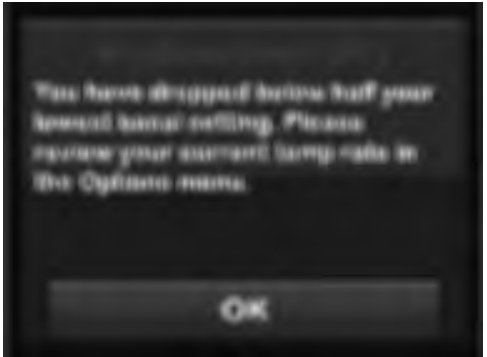
CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.11 Min Basal Alerts

Min Basal Alert 1

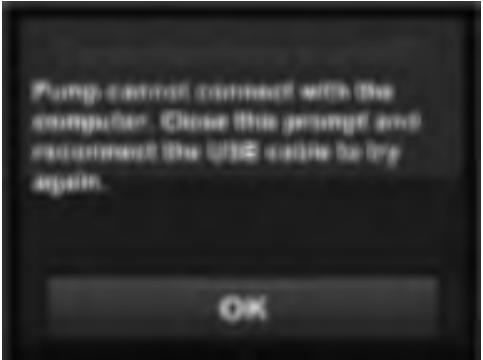
Screen	Explanation	
What will I see on the screen? 	What does it mean?	When entering a Basal Rate or requesting a temp rate, you requested a Basal Rate less than half of the lowest basal rate defined in your Personal Profile.
	How will the System notify me?	Prompt screen only.
	Will the System re-notify me?	No, you must tap  or  to move forward.
	How should I respond?	• Tap  to return to the previous screen to adjust the amount. • Tap  to dismiss the alert and continue with the request.

Min Basal Alert 2

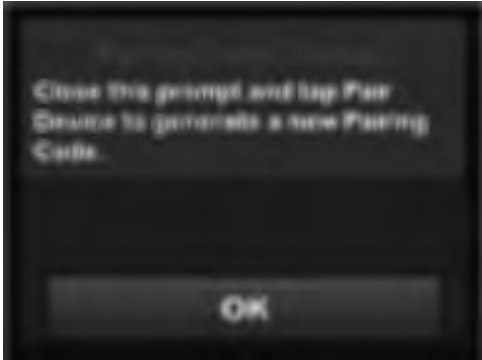
Screen	Explanation	
What will I see on the screen? 	What does it mean?	An active temp rate dropped below half of your lowest basal setting defined in your Personal Profile.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  and review your current temp rate in the <i>Activity</i> menu.

CHAPTER 13 • Insulin X2 Insulin Pump Alerts

13.12 Connection Error Alert

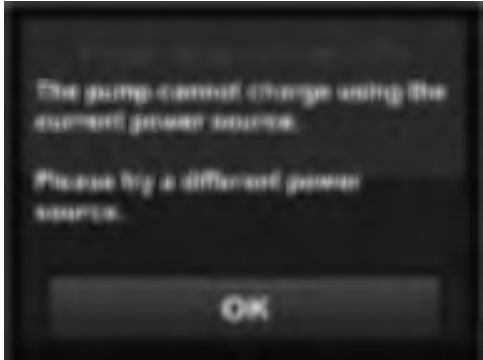
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You connected pump to a computer with the USB cable to charge it or upload data to the t:connect web application and a connection could not be made.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap . Disconnect and reconnect the USB cable to try again.

13.13 Pairing Code Timeout

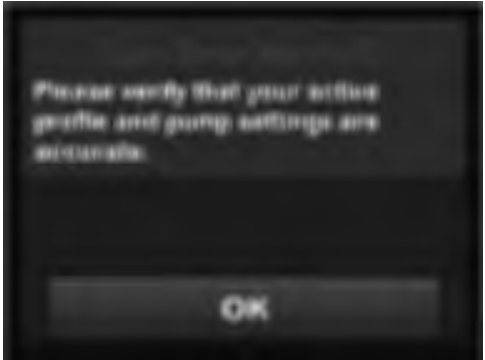
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You attempted to connect a smartphone to the pump, but the pairing process took too long (more than 5 minutes) and was unsuccessful.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	No.
	How should I respond?	Tap  . Try to pair the smartphone again.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.14 Power Source Alert

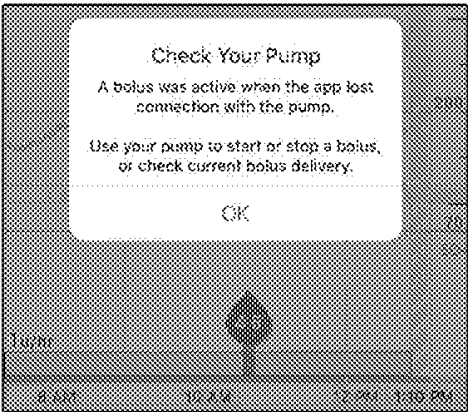
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You connected your pump to a power source that does not have enough power to charge the pump.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Connect the pump to a different power source to charge.

13.15 Data Error Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump encountered a condition that could potentially result in a loss of data.
	How will the System notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap  . Check your Personal Profiles and pump settings to verify that they are accurate. See Section 6.4 Editing or Reviewing an Existing Profile.

CHAPTER 13 • Insulin K2 Insulin Pump Alerts

13.16 Pump Connection Lost Alert - t:connect Mobile App

Screen	Explanation	
What will I see in the t:connect mobile app? 	What does it mean?	You started a bolus request in the t:connect mobile app, but your smartphone became disconnected from your pump before or during bolus delivery.
	How will the t:connect mobile app notify me?	• If the t:connect mobile app is open and on the <i>Bolus</i> screen, an informational message appears. • If bolus delivery is in progress, you will receive the alert as a notification banner.
	Will the t:connect mobile app re-notify me?	No, the alert remains on the t:connect mobile app screen until you tap OK.
	How should I respond?	Tap OK to return to the dashboard. • If bolus delivery is in progress, your pump will still deliver the remainder of the bolus unless you use your pump to stop the bolus. • You cannot use the t:connect mobile app to request another bolus until you have restored your smartphone's connection to the pump.

NOTE

The Pump Connection Lost Alert is the only alert in this chapter that appears in the t:connect mobile app but not on the pump.

2 t:slim X2 Insulin Pump Features

CHAPTER 14

t:slim X2 Insulin Pump Alarms

CHAPTER 14 • t:slim X2 Insulin Pump Alarms

⚠ PRECAUTION

CHECK your pump regularly for potential alarm conditions that may display. It is important to be aware of conditions that may affect insulin delivery and require your attention so you can respond as soon as possible.

Your t:slim X2™ pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check your BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

If multiple Reminders, Alerts, and Alarms happen at the same time, Alarms will be displayed first, Alerts will be displayed second, and Reminders will be displayed third. Each must be confirmed separately until all have been confirmed.

Information in this section will help you learn how to respond to Alarms.

Alarms notify you with 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume. If not acknowledged, alarms escalate to highest volume and vibe. Alarms repeat regularly until the condition that caused the alarm is corrected.

The t:connect™ mobile app also can provide messages, alerts, and alarms from your t:slim X2 pump as push notifications on your smartphone. These push notifications will be identical to your pump's display unless otherwise noted in this chapter.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. For more information about connecting your pump and smartphone, see Section 4.3 Connecting to a Smartphone, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

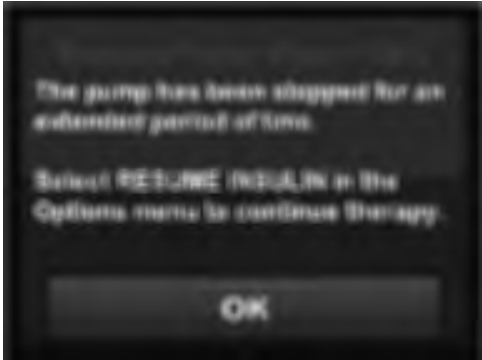
📌 NOTE

There is a list of alerts and errors related to CGM use in Chapter 26 CGM Alerts and Errors.

📌 NOTE

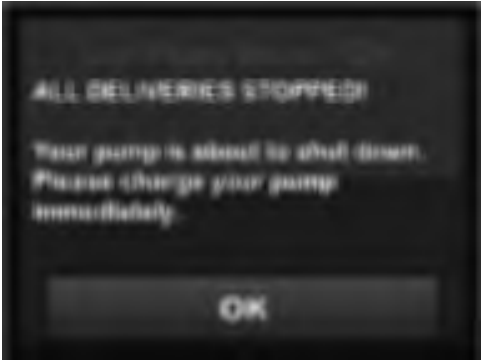
There is a list of alerts related to Control-IQ™ technology use in Chapter 32 Control-IQ Technology Alerts.

14.1 Resume Pump Alarm

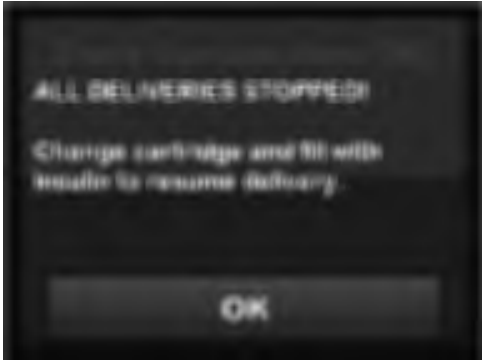
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You selected STOP INSULIN in the <i>Options</i> menu and insulin delivery has been stopped for more than 15 minutes.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes. • If not acknowledged by tapping , the System will re-notify you every 3 minutes at highest volume and vibrate. • If acknowledged by tapping , the System will re-notify you in 15 minutes.
	How should I respond?	To resume insulin, from the <i>Options</i> menu, tap RESUME INSULIN and tap  to confirm.

CHAPTER 14 • Insulin K2 Insulin Pump Alarms

14.2 Low Power Alarm

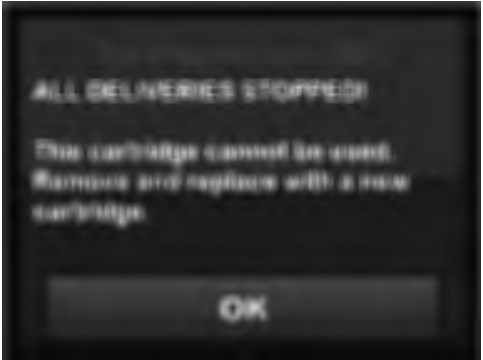
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected a power level of 1% or less remaining and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until no power remains and the pump shuts down.
	How should I respond?	Tap  . Charge your pump immediately to resume insulin delivery.

14.3 Empty Cartridge Alarm

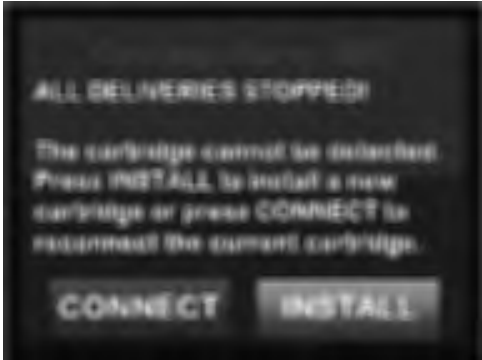
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected that the cartridge is empty and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you change the cartridge.
	How should I respond?	Tap . Change your cartridge immediately by tapping OPTIONS from the <i>Home</i> screen, then Load and follow the instructions in Section 7.3 Filling and Loading a <i>t:slim</i> X2 Cartridge.

CHAPTER 14 • t:slim X2 Insulin Pump Alarms

14.4 Cartridge Error Alarm

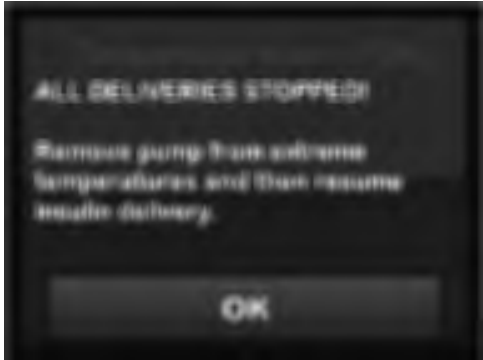
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected that the cartridge could not be used and all deliveries have stopped. This can be caused by cartridge defect, not following the proper procedure to load the cartridge, or over filling the cartridge (with more than 300 units of insulin).
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you change the cartridge.
	How should I respond?	Tap . Change your cartridge immediately by tapping OPTIONS from the <i>Home</i> screen, then Load and follow the instructions in Section 7.3 Filling and Loading a t:slim X2 Cartridge.

14.5 Cartridge Removal Alarm

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected that the cartridge has been removed and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you reconnect the current cartridge or change the cartridge.
	How should I respond?	Tap CONNECT to reattach the current cartridge. Tap INSTALL to load a new cartridge.

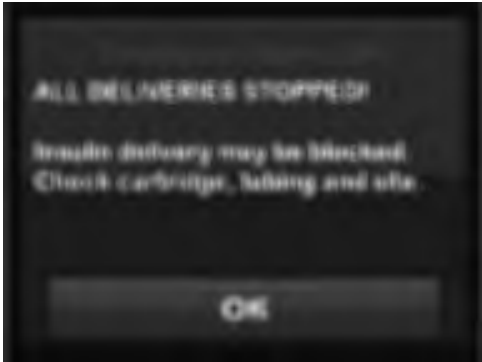
CHAPTER 14 • Insulin K2 Insulin Pump Alarms

14.6 Temperature Alarm

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected an internal temperature below 35°F (2°C) or above 113°F (45°C) or a battery temperature below 35°F (2°C) or above 125°F (52°C) and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until a temperature in the operating range is detected.
	How should I respond?	Tap  . Remove the pump from the extreme temperature and then resume insulin delivery.

14.7 Occlusion Alarms

Occlusion Alarm 1

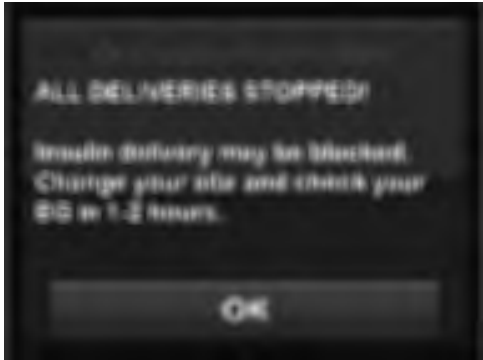
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected that insulin delivery is blocked and all deliveries have stopped. See Section 34.4 t:slim X2 Pump Performance Characteristics for more information on how long it can take the system to detect an occlusion.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you resume insulin delivery.
	How should I respond?	Tap  . Check the cartridge, tubing, and infusion site for any sign of damage or blockage and correct the condition. To resume insulin, from the <i>Options</i> menu, tap RESUME INSULIN and tap  to confirm.

NOTE

If the occlusion alarm occurs during bolus delivery, after tapping , a screen will appear letting you know how much of the requested bolus was delivered before the occlusion alarm. When the occlusion is cleared, some or all of the previously requested insulin volume may be delivered. Test your BG at the time of alarm and follow your healthcare provider's instructions for managing potential or confirmed occlusions.

CHAPTER 14 • Insulin K2 Insulin Pump Alarms

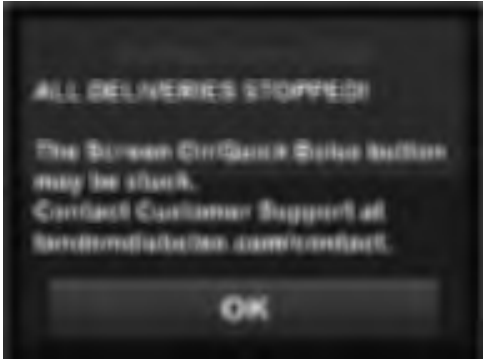
Occlusion Alarm 2

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected a second occlusion alarm shortly after the first occlusion alarm and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you resume insulin delivery.
	How should I respond?	Tap  . Change the cartridge, tubing, and infusion site to ensure proper delivery of insulin. Resume insulin after changing the cartridge, tubing, and infusion site.

■ NOTE

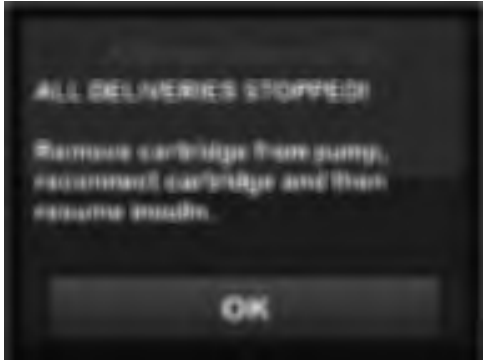
If the second occlusion alarm occurs during bolus delivery, after tapping , a screen will appear letting you know that the amount of bolus delivery could not be determined and was not added to your IOB.

14.8 Screen On/Quick Bolus Button Alarm

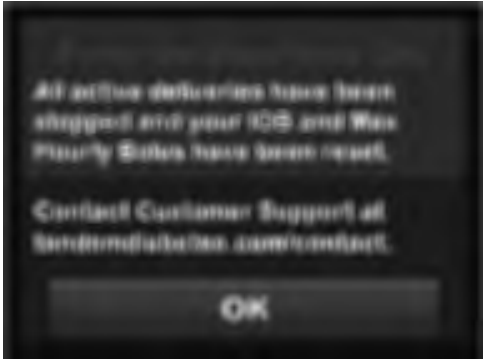
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The Screen On/Quick Bolus button (on the top of your pump) is stuck or not functioning properly and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until the condition is corrected.
	How should I respond?	Tap  . Contact Customer Technical Support.

CHAPTER 14 • Insulin K2 Insulin Pump Alarms

14.9 Altitude Alarm

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected a pressure difference between inside the cartridge and the surrounding air within the validated operating range of -1,300 feet to 10,000 feet (-396 meters to 3,048 meters) and all deliveries have stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until the condition is corrected.
	How should I respond?	Tap  . Remove the cartridge from the pump (this will allow the cartridge to fully vent) and then reconnect the cartridge.

14.10 Reset Alarm

Screen	Explanation	
	What does it mean?	Your pump experienced a reset and all deliveries have been stopped.
	How will the System notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the System re-notify me?	Yes, every 3 minutes until you tap  .
	How should I respond?	Tap  . Contact Customer Technical Support.

This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 15

t:slim X2 Insulin Pump Malfunction

CHAPTER 15 • Insulin X2 Insulin Pump Malfunction

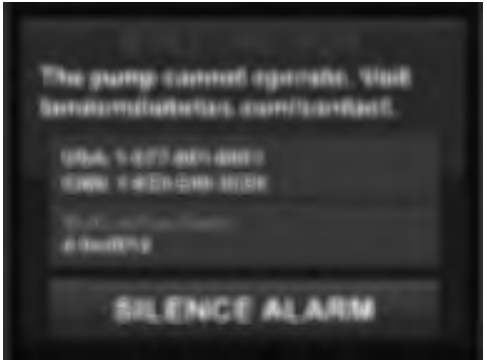
15.1 Malfunction

If your pump detects a system error, the *MALFUNCTION* screen appears and all deliveries are stopped. Contact Customer Technical Support.

Malfunctions notify you with 3 sequences of 3 notes at highest volume and 3 vibrations. They repeat at regular intervals until acknowledged by tapping **SILENCE ALARM**.

⚠ PRECAUTION

ALWAYS check with your healthcare provider for specific guidelines if you want or need to disconnect from the pump for any reason. Depending on the length of time and reason you are disconnecting, you may need to replace missed basal and/or bolus insulin. Check your BG before disconnecting from the pump and again when you reconnect, and treat high and low BG levels as recommended by your healthcare provider.

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected a system error and all deliveries have been stopped.
	How will the System notify me?	3 sequences of 3 notes at highest volume and 3 vibrations.
	Will the System re-notify me?	Yes, every 3 minutes until you acknowledge the malfunction by tapping SILENCE ALARM .
	How should I respond?	• Write down the Malfunction Code number that appears on the screen. • Tap SILENCE ALARM. The <i>MALFUNCTION</i> screen will remain on the pump even though the alarm is silenced. • Contact Customer Technical Support and provide the Malfunction Code number that you wrote down.

This Page is Intentionally Left Blank

2 t:slim X2 Insulin Pump Features

CHAPTER 16

Taking Care of Your Pump

CHAPTER 16 • Taking Care of Your Pump

16.1 Overview

This section provides information on caring for and maintaining your pump.

Cleaning Your Pump

When cleaning your pump, use a damp lint-free cloth. Do not use household or industrial cleaners, solvents, bleach, scouring pads, chemicals, or sharp instruments. Never submerge the pump in water or use any other liquid to clean it. Do not place the pump in the dishwasher or use hot water to clean it. If needed, use only a very mild detergent, such as a bit of liquid soap with warm water. When drying your pump, use a soft towel; never place your pump in a microwave oven or baking oven to dry it.

Maintaining Your Pump

The pump requires no preventative maintenance.

Inspecting Your Pump for Damage**▲ PRECAUTION**

DO NOT use your pump if you think it might be damaged due to dropping it or hitting it against a hard surface. Check that the pump is working properly by plugging a power source into the USB port and confirming that the display turns on, you hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the **Screen On/Quick Bolus** button. If you are unsure about potential damage, discontinue use of the pump and contact Customer Technical Support.

If you drop your pump or it has been hit against something hard, ensure that it is still working properly. Check that the touchscreen is working and clear, and that the cartridge and infusion set are properly in place. Check for leaks around the cartridge and at the tubing connector to the infusion set. Immediately contact Customer Technical Support if you notice any cracks, chips, or other damage.

Storing Your Pump

If you need to stop using your pump for a long period of time, you can place the

pump in storage mode. To place the pump in storage mode, connect the pump to a power source and then press and hold down the **Screen On/Quick Bolus** button for 30 seconds. The pump will beep 3 times before going into storage mode. Disconnect the pump from the power source.

Keep the pump protected when not in use. Store at temperatures between -4°F (-20°C) and 140°F (60°C) and at relative humidity levels between 20% and 90%.

To bring the pump out of storage mode, simply connect the pump to a power source.

Disposing of System Components

Consult Customer Technical Support for instructions for disposal of devices containing electronic waste such as your pump. Follow local regulations for disposal of potentially biohazardous materials such as used cartridges, needles, syringes, infusion sets, and sensors.

2 t:slim X2 Insulin Pump Features

CHAPTER 17

Lifestyle Issues and Travel

CHAPTER 17 • Lifestyle Issues and Travel

17.1 Overview

While the convenience and flexibility of the pump allow most users to participate in a variety of activities, some lifestyle changes may be required. Additionally, your insulin needs may change in response to lifestyle changes.

⚠ PRECAUTION

CONSULT your healthcare provider about lifestyle changes such as weight gain or loss, and starting or stopping exercise. Your insulin needs may change in response to lifestyle changes. Your Basal Rate(s) and other settings may need adjustment.

Physical Activity

The pump can be worn during most forms of exercise, such as running, cycling, hiking, and resistance training. During exercise, the pump can be worn in the provided case, your pocket, or other third-party “sport cases.” When choosing third-party pump cases or stickers, do not cover the six vent holes on the back of the pump.

⚠ PRECAUTION

If you choose to use a pump case or other accessories not provided by Tandem, **DO NOT** cover the six vent holes on the back of the pump. Covering the vent holes could affect insulin delivery.

For activities where contact is a concern, such as baseball, hockey, martial arts, or basketball, you can disconnect from your pump for short periods of time. If planning to disconnect from your pump, discuss a plan with your healthcare provider to compensate for any basal insulin delivery you miss while disconnected, and be sure to continue to check your BG levels. Even if you disconnect your tubing from your infusion site, the pump should continue to receive data from the transmitter as long as it is within the 20-foot (6-meter) range without obstruction.

Aquatic Activities**⚠ PRECAUTION**

AVOID submerging your pump in fluid beyond a depth of 3 feet (0.91 meters) or for more than 30 minutes (IP27 rating). If your pump has been exposed to fluid beyond these limits, check for

any signs of fluid entry. If there are signs of fluid entry, discontinue use of the pump and contact Customer Technical Support.

Your pump is watertight to a depth of 3 feet (0.91 meters) for up to 30 minutes (IP27 rating), but it is not waterproof. Your pump should not be worn while swimming, scuba diving, surfing, or during any other activities that could submerge the pump for an extended period of time. Your pump should not be worn in hot tubs or saunas.

Extreme Altitudes

Some activities, such as hiking, skiing or snowboarding, could expose your pump to extreme altitudes. The pump has been tested at altitudes up to 10,000 feet (3,048 meters) at standard operating temperatures.

Extreme Temperatures

You should avoid activities which could expose your pump to temperatures below 41°F (5°C) or above 98.6°F (37°C), as insulin can freeze at low temperatures or degrade at high temperatures.

Other Activities Which Require Removing Your Pump

⚠ PRECAUTION

If you remove your pump for 30 minutes or longer, it is recommended that you suspend insulin delivery. If insulin is not suspended, Control-IQ™ technology will continue to operate while the pump is removed, and will continue to dose insulin.

There are other activities, such as bathing and intimacy, when it may be more convenient for you to remove your pump. It is safe to do so for short periods of time. If planning to disconnect from your pump, discuss a plan with your healthcare provider for compensating for any basal delivery you miss while disconnected, and be sure to check your BG levels frequently. Missing basal delivery could cause your BG to rise.

Travel

The flexibility afforded by an insulin pump can simplify some aspects of travel, but it still requires planning. Be sure to order your pump supplies before your trip so that you have

enough supplies with you while you're away from home. In addition to pump supplies, you should also always bring the following items:

- The items listed in the Emergency Kit described in Section 1.10 Emergency Kit.
- A prescription for both rapid-acting and long-acting insulin of the type recommended by your healthcare provider in case you need to take insulin by injection.
- A letter from your healthcare provider explaining the medical need for your insulin pump and other supplies.

Traveling by Air

⚠ PRECAUTION

DO NOT expose your pump to X-ray screening used for carry-on and checked luggage. Newer full body scanners used in airport security screening are also a form of X-ray and your pump should not be exposed to them. Notify the security agent that your pump cannot be exposed to X-ray machines and request an alternate means of screening.

Your pump has been designed to withstand common electromagnetic interference including airport metal detectors.

The pump is safe for use on commercial airlines. The pump is a Medical Portable Electronic Device (M-PED). The system complies with radiated emissions requirements defined in RTCA/DO-160G, Section 21, Category M. Any M-PED which meet the requirements of this standard in all modes of operation may be used on board aircraft without the need for further testing by the operator.

Pack your pump supplies in your carry-on luggage. **DO NOT** pack your supplies in checked luggage as it could get delayed or lost.

If traveling, contact Customer Technical Support prior to your trip to obtain a travel loaner pump in case your pump malfunctions outside of Tandem's replacement area.

If you enable Airplane mode on your smartphone, you must maintain an active Bluetooth connection between your smartphone and your pump to use

CHAPTER 17 • Lifestyle Issues and Travel

the t:connect™ mobile app. You can always use your pump to deliver a bolus if you cannot connect your smartphone and pump. Please check with your airline carrier and smartphone manufacturer instructions prior to traveling to determine conditions for using Bluetooth.

⚠ WARNING

ALWAYS use your t:slim X2™ insulin pump for therapy decisions if your Bluetooth connection between your smartphone and pump is disabled.

📌 NOTE

The t:connect mobile app requires an active Bluetooth connection to connect with your pump. If you turn on Airplane mode, make sure you keep Bluetooth enabled to connect to your pump.

3 CGM Features

CHAPTER 18

Important Safety Information When Using the t:slim X2 Insulin Pump with Dexcom G6 CGM

CHAPTER 18 • Important Safety Information When Using the t:slim X2 Insulin Pump with Dexcom G6 CGM

The following includes important safety information related to your CGM and its components. The information presented in this chapter does not represent all warnings and precautions related to the CGM. Visit Dexcom's website for applicable product instructions that also present warnings and precautions.

18.1 Warnings

Using Dexcom G6 with Your t:slim X2™ Insulin Pump

▲ WARNING

DO NOT ignore symptoms of high and low glucose. If your sensor glucose alerts and readings do not match your symptoms, measure your BG with a BG meter even if your sensor is not reading in the high or low range.

▲ WARNING

DO NOT ignore sensor wire fractures. Sensors may fracture on rare occasions. If a sensor wire breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation (redness, swelling, or pain) at the insertion site. If you experience a

broken sensor wire, please report this to Customer Technical Support.

▲ WARNING

DO NOT use Dexcom G6 CGM in pregnant women or persons on dialysis. The System is not approved for use in pregnant women or persons on dialysis and has not been evaluated in these populations. Sensor glucose readings may be inaccurate in these populations and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT use Dexcom G6 CGM in critically ill patients. It is not known how different conditions or medications common to the critically ill population may affect the performance of the System. Sensor glucose readings may be inaccurate in critically ill patients, and solely relying on the sensor glucose alerts and readings for treatment decisions could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT insert the sensor in sites other than the abdomen (belly) or upper buttocks (for ages 2–17 only). Other sites have not been studied and are not approved. Use in other sites might cause

sensor glucose readings to be inaccurate and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT expect CGM alerts until after the 2-hour startup. You will **NOT** get any sensor glucose readings or alerts until after the 2-hour startup ends. During this time you might miss severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

DO NOT use your transmitter if it is damaged/cracked. This could create an electrical safety hazard or malfunction, which might cause electrical shocks.

▲ WARNING

STORE the Dexcom G6 CGM sensor at temperatures between 36°F (2.2°C) to 86°F (30°C) for the length of the sensor's shelf life. You may store the sensor in the refrigerator if it is within this temperature range. The sensor should not be stored in a freezer. Storing the sensor improperly might cause the sensor glucose readings to be inaccurate, and you might miss severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

CHAPTER 18 • Important Safety Information When Using the t:slim X2 Insulin Pump with Dexcom G6 CGM

⚠ WARNING

DO NOT allow young children to hold the sensor, transmitter or transmitter kit box without adult supervision. The sensor and transmitter include small parts that may pose a choking hazard.

⚠ WARNING

If a sensor session is ended, either automatically or manually, you will not receive any CGM alerts. In order to receive CGM alerts, a sensor session must be started and transmitting sensor values to the pump based on a sensor code or sensor calibration.

18.2 Precautions**Using Dexcom G6 CGM with Your t:slim X2 Insulin Pump****⚠ PRECAUTION**

DO NOT open the sensor package until you have washed your hands with soap and water, and let them dry. You may contaminate the insertion site and suffer an infection if you have dirty hands while inserting the sensor.

⚠ PRECAUTION

DO NOT insert the sensor until you have cleaned the skin with a topical antimicrobial solution, such as isopropyl alcohol, and allowed the skin to dry. Inserting into unclean skin might lead to infection. Do not insert the sensor until the cleaned area is dry so the sensor adhesive will stick better.

⚠ PRECAUTION

AVOID using the same spot repeatedly for sensor insertion. Rotate your sensor placement sites, and do not use the same site for two sensor sessions in a row. Using the same site might cause scarring or skin irritation.

⚠ PRECAUTION

AVOID inserting the sensor in areas that are likely to be bumped, pushed or compressed, or areas of skin with scarring, tattoos, or irritation as these are not ideal sites to measure glucose. Insertion in those areas might affect accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

AVOID injecting insulin or placing an infusion set within 3 inches (7.6 cm) of the sensor. The insulin might affect sensor accuracy and could

result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

DO NOT use the sensor if its sterile package has been damaged or opened. Using an unsterile sensor might cause infection.

⚠ PRECAUTION

PAY ATTENTION to the trend information on your *CGM Home* screen, as well as your symptoms, before using CGM values to calculate and deliver a correction bolus. Individual CGM values may not be as accurate as BG meter values.

⚠ PRECAUTION

To calibrate the Dexcom G6 CGM, **ALWAYS** enter the exact BG value that your BG meter displays within 5 minutes of a carefully performed BG measurement. Do not enter sensor glucose readings for calibration. Entering incorrect BG values, BG values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

CHAPTER 18 • Important Safety Information When Using the Insulin X2 Insulin Pump with Dexcom G6 CGM

⚠ PRECAUTION

DO NOT calibrate if your BG is changing at a significant rate, typically more than 2 mg/dL per minute. Do not calibrate when your receiver screen is showing the rising or falling single arrow or double arrow, which indicates that your BG is rapidly rising or falling. Calibrating during significant rise or fall of BG may affect sensor accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

The Dexcom G6 CGM accuracy may be affected when your sensor glucose is changing at a significant rate (i.e., 2 to 3 mg/dL/min or more than 3 mg/dL each minute), such as during exercise or after a meal.

⚠ PRECAUTION

AVOID separating the transmitter and pump by more than 20 feet (6 meters). The transmission range from the transmitter to the pump is up to 20 feet (6 meters) without obstruction. Wireless communication does not work well through water so the range is reduced if you are in a pool, bathtub, or on a water bed, etc. To ensure communication, it is suggested that you face your pump screen out and away from the body, and wear the pump on the same side of the

body that you wear your CGM. Types of obstruction differ and have not been tested. If your transmitter and pump are farther than 20 feet (6 meters) apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

DO NOT use alternative BG site testing (blood from your palm or forearm, etc.) for calibration. Alternative site BG values may be different than those taken from a fingerstick BG value and may not represent the timeliest BG value. Use a BG value taken only from a fingerstick for calibration. Alternative site BG values might affect sensor accuracy and result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

ENSURE that your transmitter ID is programmed into the pump before you use the System if you receive a warranty replacement pump. The pump cannot communicate with the transmitter unless the transmitter ID is entered. If the pump and transmitter are not communicating, you will not receive sensor glucose readings and you

might miss severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

DO NOT discard your transmitter. It is reusable. The same transmitter is used for each session until you have reached the end of the transmitter battery life.

⚠ PRECAUTION

The Dexcom G6 sensor is not compatible with older versions of transmitters or receivers. Do not mix transmitters, receivers, and sensors from different generations.

⚠ PRECAUTION

Taking medications with acetaminophen while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

⚠ PRECAUTION

Hydroxyurea is a medication used in the treatment of diseases including cancer and sickle cell anemia. It is known to interfere with glucose readings from the Dexcom sensor. The use of hydroxyurea will result in sensor glucose readings that are higher than actual glucose

CHAPTER 18 • Important Safety Information When Using the t:slim X2 Insulin Pump with Dexcom G6 CGM

levels. The level of inaccuracy in sensor glucose readings is based on the amount of hydroxyurea in the body. Relying on sensor glucose values while taking hydroxyurea could result in missed hypoglycemia alerts or errors in diabetes management, such as giving a higher dose of insulin than necessary to correct falsely high sensor glucose values. It can also result in errors when reviewing, analyzing and interpreting historical patterns for assessing glucose control. **DO NOT** use the Dexcom CGM readings to make diabetes treatment decisions or assess glucose control when taking hydroxyurea. Use your BG meter and consult with your healthcare provider about alternative glucose monitoring approaches.

18.3 Potential Benefits From Using the t:slim X2 Insulin Pump with CGM

When paired with Dexcom G6 transmitter and sensor, your pump can receive CGM readings every 5 minutes, which are displayed as a trend graph on the *CGM Home* screen. You can also program your pump to alert you when your CGM readings are above or below a given level, or are rising or falling quickly. Unlike the readings from

a standard BG meter, CGM readings allow you to view trends in real time, as well as capture information when you would otherwise be unable to check your blood sugar, such as while you are asleep. This information can be useful for you and your healthcare provider when considering changes to your therapy. In addition, the programmable alerts can help you to spot potential low or high BG sooner than you would using a only a BG meter.

- In some studies, CGM was shown to increase time in the target glucose range. Subjects in these studies had better diabetes control (lowered A1C values, reduced glycemic variability and time spent in low and high BG ranges)^{1, 2, 3} which can help reduce diabetes related complications.^{4, 5} These benefits can be seen especially with using real-time CGM at least six days per week² and were sustained over time.⁶ In some cases, patients perceived an increase in their quality of life and peace of mind when using real-time CGM as well as reporting a high satisfaction with CGM.⁷

¹ Garg S, Zisser H, Schwartz S, et al. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. *Diabetes Care*. 2006; 29(1):44-50.

² JDRF CGM Study Group. Continuous glucose monitoring and intensive treatment of type 1 diabetes. *NEJM*. 2008; 359:1464-76.

³ Battelino T, Phillip M, Bratina N, et al. Effect of continuous glucose monitoring of hypoglycemia in type 1 diabetes. *Diabetes Care* 2011; 34(4):795-800.

⁴ The Diabetes Control and Complications Research Group. The effect of intensive treatment of diabetes on the development and progression of long- term complications of insulin-dependent diabetes mellitus. *NEJM*. 1993; 329:997-1036.

⁵ Ohkubo Y, Kishikawa H, Araki E, et al. Intensive insulin therapy prevents progression of diabetic microvascular complications in Japanese patients with non-insulin dependent diabetes mellitus: a randomized prospective

CHAPTER 18 • Important Safety Information When Using the tslim X2 Insulin Pump with Dexcom G6 CGM

6-year study. *Diabetes Res Clin Pract.* 1995; 28(2):103-117.

⁶ JDRF CGM Study Group. Sustained benefit of continuous glucose monitoring on A1c, glucose profiles, and hypoglycemia in adults with type 1 diabetes. *Diabetes Care* 2009; 32(11):2047-2049.

⁷ JDRF CGM Study Group. Quality-of-Life measures in children and adults with type 1 diabetes. *Diabetes Care* 2010; 33(10):2175-2177.

18.4 Possible Risks From Using the tslim X2 Insulin Pump with CGM

Inserting the sensor and wearing the adhesive patch might cause infection, bleeding, pain and skin irritations (redness, swelling, bruising, itching, scarring, or skin discoloration).

There is a remote chance that a sensor wire fragment could remain under your skin if the sensor wire breaks while you are wearing it. If you think a sensor wire has broken under your skin, contact your healthcare provider and call Customer Technical Support.

Other risks associated with CGM use include the following:

- You will not get sensor glucose alerts when the alert function is turned off, your transmitter and pump are out of range, or when your pump is not showing sensor glucose readings. You might not notice alerts if you are unable to hear them or feel the vibration.
- There are a number of risks as a result of the fact that the Dexcom G6 CGM takes readings from fluid below the skin (interstitial fluid) instead of blood. There are differences in how glucose is measured in the blood compared to how it is measured in interstitial fluid, and glucose is absorbed into the interstitial fluid slower than it is absorbed into the blood, which can cause CGM readings to lag behind readings from a BG meter.

3 CGM Features

CHAPTER 19

Getting to Know Your CGM System

CHAPTER 19 • Getting to Know Your CGM System

19.1 CGM Terminology**Alternate Site BG Testing**

Alternate site BG testing is when you take a BG value on your BG meter using a blood sample from an area on your body other than your fingertip. Do not use alternate site testing to calibrate your sensor.

Applicator

The applicator is a disposable piece that comes attached to the sensor pod and inserts the sensor under the skin. There is a needle inside the applicator that is removed after you insert the sensor.

Calibration

Calibration is when you enter BG values from a BG meter into the System. Calibrations may be needed for your System to show continuous glucose readings and trend information.

CGM

Continuous glucose monitoring.

CGM Reading

A CGM reading is a sensor glucose reading shown on your pump. This

reading is in mg/dL units and is updated every 5 minutes.

HypoRepeat

HypoRepeat is an optional CGM auditory and vibration alert setting that keeps repeating the fixed low alert every 5 seconds until your sensor glucose value rises above 55 mg/dL or you confirm it. This alert can be helpful if you want extra awareness for severe lows.

mg/dL

Milligrams per deciliter. The standard unit of measure for sensor glucose readings.

Receiver

When the Dexcom G6 CGM is used with the pump to display CGM readings, the insulin pump replaces the receiver for the therapeutic CGM. A smartphone with the Dexcom app may be used in addition to the pump to receive sensor readings.

Rise and Fall (Rate of Change) Alerts

Rise and fall alerts occur based on how much and how fast your glucose levels rise or fall.

RF

RF is the abbreviation for radio frequency. RF transmission is used to send glucose information from the transmitter to the pump.

Sensor

The sensor is the part that of the CGM includes an applicator and wire. The applicator inserts the wire under your skin, and the wire measures glucose levels in your tissue fluid.

Sensor Glucose Data Gaps

Glucose data gaps occur when your System is unable to provide a sensor glucose reading.

Sensor Glucose Trends

Glucose trends let you see the pattern of your glucose levels. The trend graph shows where your glucose levels have been during the time shown on the screen and where your glucose levels are now.

Sensor Pod

The sensor pod is the small plastic base of the sensor attached to your skin that holds the transmitter in place.

Startup Period

The startup period is the 2-hour period after you tell the System you inserted a new sensor. Sensor glucose readings are not provided during this time.

Transmitter

The transmitter is the part of the CGM that snaps into the sensor pod and wirelessly sends glucose information to your pump.

Transmitter ID

The transmitter ID is a series of numbers and/or letters that you enter into your pump to let it connect and communicate with the transmitter.

Trend (Rate of Change) Arrows

Trend arrows show how fast your glucose levels are changing. There are seven different arrows that show when your glucose direction and speed change.

CHAPTER 18 • Getting to Know Your CGM System

19.2 Explanation of CGM Pump Icons

The following CGM icons may appear on your pump screen:

CGM Icon Definitions

Symbol	Meaning
	Unknown sensor reading.
	CGM sensor session is active, but the transmitter and pump are out of range.
	The CGM sensor has failed.
	The CGM sensor session has ended.
	Wait 15 minutes calibration error.
	Startup calibration is required (2 BG values).
	Additional startup calibration is required.
	CGM calibration is required.

Symbol	Meaning
	Transmitter error.
	CGM sensor session is active, and the transmitter is communicating with the pump.
	CGM sensor session is active, but the transmitter is not communicating with the pump.
	Sensor startup 0–30 minutes.
	Sensor startup 31–60 minutes.
	Sensor startup 61–90 minutes.
	Sensor startup 91–119 minutes.

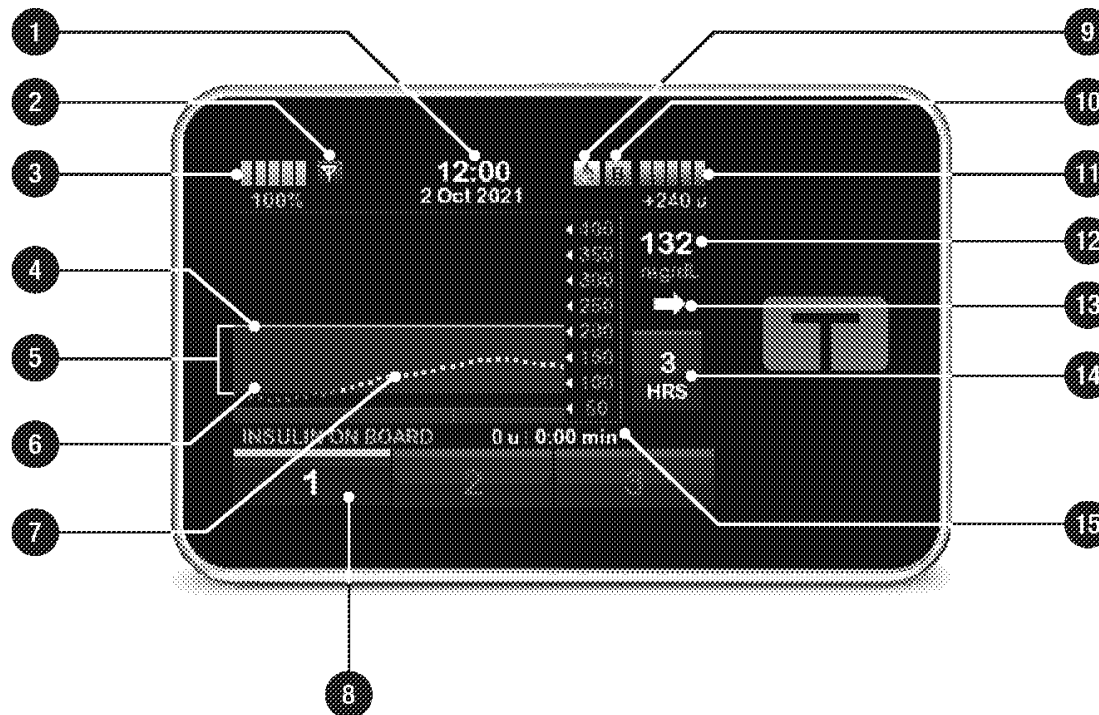
This Page is Intentionally Left Blank

CHAPTER 19 • Getting to Know Your CGM System

19.3 CGM Lock Screen

The *CGM Lock* screen appears anytime you turn on the screen and you are using your pump with a CGM.

1. **Time and Date Display:** Displays the current time and date.
2. **Antenna:** Indicates communication status between pump and transmitter.
3. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
4. **High Glucose Alert Setting.**
5. **Sensor Glucose Target Range.**
6. **Low Glucose Alert Setting.**
7. **Graph of Most Recent Sensor Glucose Readings.**
8. **1–2–3:** Unlocks pump screen.
9. **Active Bolus Icon:** Indicates a bolus is being delivered.
10. **Status:** Displays current system settings and insulin delivery status.
11. **Insulin Level:** Displays the current amount of insulin in the cartridge.
12. **Most Recent 5-Minute Sensor Glucose Reading.**
13. **Trend Arrow:** Indicates direction and rate of change.
14. **Trend Graph Time (HRS):** 1, 3, 6, 12 and 24 hour views available.
15. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.



CHAPTER 19 • Getting to Know Your CGM System

19.4 CGM Home Screen

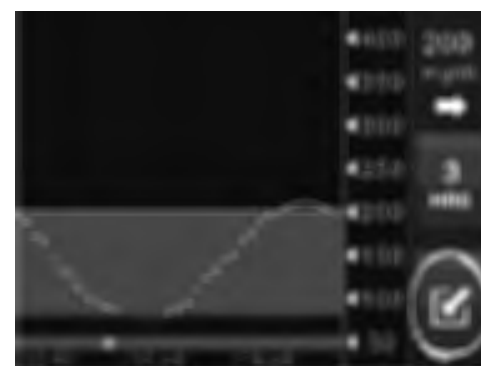
1. **Time and Date Display:** Displays the current time and date.
2. **Antenna:** Indicates communication status between pump and transmitter.
3. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
4. **High Glucose Alert Setting.**
5. **Sensor Glucose Target Range.**
6. **Low Glucose Alert Setting.**
7. **Graph of Most Recent Sensor Glucose Readings.**
8. **Options:** Stop/Resume insulin delivery, manage pump and CGM settings, start/stop activities, load a cartridge, and view history.
9. **Bolus icon:** Denotes a bolus delivery. Each bolus icon represents one bolus delivery even if the icon is temporarily obstructed by the hash marks on the bolus bar as the graph changes over time.
10. **Bolus:** Program and deliver a bolus.
11. **Status:** Displays current system settings and insulin delivery status.
12. **Insulin Level:** Displays the current amount of insulin in the cartridge.
13. **Most Recent 5-Minute Sensor Glucose Reading.**
14. **Trend Arrow:** Indicates direction and rate of change.
15. **Trend Graph Time (HRS):** 1, 3, 6, 12 and 24 hour views available.
16. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.

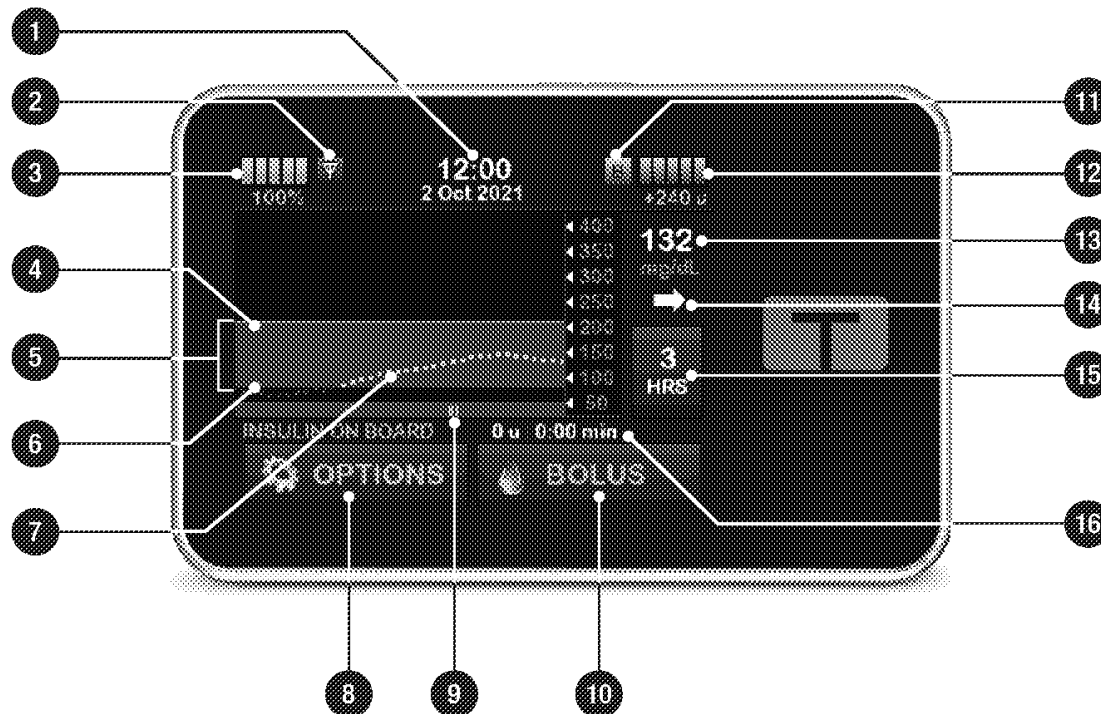
To view CGM information on the full screen:

From the *CGM Home* screen tap anywhere on the CGM trend graph.



Tap the “minimize” icon to return to the *CGM Home* screen.





CHAPTER 19 • Getting to Know Your CGM System

19.5 My CGM Screen

1. **Start Sensor:** Starts a CGM session. If sensor is active, STOP SENSOR will be displayed.
2. **Calibrate CGM:** Enter a calibration BG value. Only active when sensor session is active.
3. **CGM Alerts:** Customize CGM Alerts.
4. **Transmitter ID:** Enter the transmitter ID.
5. **CGM Info:** View the CGM information.



This Page is Intentionally Left Blank

3 CGM Features

CHAPTER 20

CGM Overview

CHAPTER 20 • CGM Overview

20.1 CGM System Overview

This section of the user guide covers instructions for using a CGM with your t:slim X2™ pump. Use of a CGM is optional, but in order to use Control-IQ™ technology, CGM is required. When used, CGM allows readings from your sensor to be displayed on your pump screen. To make treatment decisions during a new sensor startup period, you will also need a commercially available BG meter to use with your System.

As an example, a compatible CGM is the Dexcom G6 CGM System, which consists of a sensor, transmitter, and a receiver.

The Dexcom G6 sensor is a disposable device that is inserted under the skin to continuously monitor glucose levels from interstitial fluid (the fluid under your skin). The Dexcom G6 transmitter connects to the sensor using Bluetooth wireless technology communication and sends readings to the pump display every 5 minutes. The pump display shows sensor glucose readings, a trend graph, and the direction and

rate of change arrows. For information about inserting a Dexcom G6 CGM sensor, placing a Dexcom G6 transmitter, and Dexcom G6 product specifications, visit the manufacturer's website for applicable product instructions and training information.

You can also program your pump to alert you when your CGM readings are above or below a given level, or are rising or falling quickly. If CGM readings become 55 mg/dL or lower, the CGM Fixed Low Alert will sound. This alert is not customizable.

20.2 Device Connection Overview

The Dexcom G6 CGM only allows pairing with one medical device at a time (either the t:slim X2 pump or the Dexcom receiver), but you can still use the Dexcom G6 CGM app and your pump simultaneously using the same transmitter ID. The Dexcom G6 CGM does not connect directly to the t:connect™ mobile app. CGM readings in the t:connect mobile app are provided through the t:slim X2 insulin pump connection.

You can also use both the Dexcom G6 mobile app and t:connect mobile app at the same time. The Dexcom G6 mobile app can be used to start and stop sensor sessions as well as connect with the other Dexcom compatible services. The Dexcom G6 CGM does not connect directly to the t:connect mobile app; CGM readings in the t:connect mobile app are provided via the t:slim X2 pump connection.

Unlike the readings from a standard BG meter, CGM readings allow you to view trends in real time, as well as capture information when you would otherwise be unable to check your BG, such as while you are asleep. This information can be useful for you and your healthcare provider when considering changes to your therapy. In addition, the programmable alerts can help you to spot potential low or high glucose sooner than you would using a only a BG meter.

20.3 Receiver (t:slim X2 Insulin Pump) Overview

To review the icons and controls displayed on the *Home* screen with CGM enabled, see Section 19.4 CGM Home Screen.

20.4 Transmitter Overview

This section provides information about CGM devices that have a separate transmitter. The information contained in this section is specific to the Dexcom G6 CGM and is provided as an example. For information about the Dexcom G6 transmitter, visit the manufacturer's website for applicable product instructions.

Snapping into the transmitter holder, the transmitter wirelessly sends sensor glucose information to your pump. If you have a new transmitter, only open the package when you are ready to use it.

Even if you disconnect your tubing from your infusion site, the pump should continue to receive data from the

transmitter as long as it is within the 20-foot (6 meter) range without obstruction.

If your transmitter is damaged or cracked, do not use it. Immediately contact Customer Technical Support if you notice any cracks or other damage. Do not use the sensor if its sterile package has been damaged or opened.

Transmitter features:

- Reusable
 - Do not discard after sensor session.
 - Only for you, don't share a transmitter.
- Water resistant
- Can transmit data to your pump for up to 20 feet (6 meters). Range is less if you are in or under water.
- Battery lasts approximately 90 days. Pump or smart device prompts you when battery is running low.

- Serial number is on the back
- M-PED designation
 - Emission levels meet IATA standards.
 - May be used on board aircraft without any further testing by the operator.

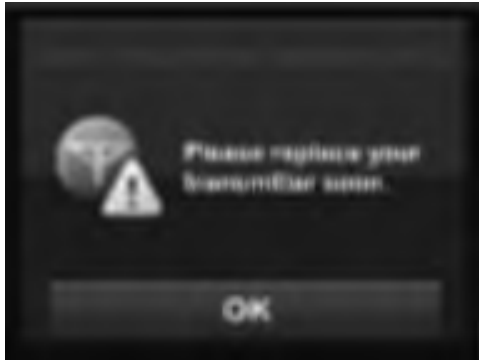
⚠ PRECAUTION

DO keep your transmitter and pump within 20 feet (6 meters) with no obstacles (like walls or metal) between them. Otherwise, they may not be able to communicate. If water is between your transmitter and the pump (for example, if you're showering or swimming) keep them closer to each other. The range is reduced because Bluetooth technology doesn't work as well through water. To ensure communication, it is suggested that you face your pump screen out and away from the body, and wear the pump on the same side of the body that you wear your CGM.

The transmitter battery will last 90 days. Once you see the Low Transmitter Battery Alert, replace the transmitter as soon as possible. Your transmitter

CHAPTER 20 • CGM Overview

battery may drain as quickly as 7 days after this alert occurs.



submerged for up to 8 feet (2.4 meters) and up to 24 hours. Underwater use will affect the ability to communicate with the pump, so the range will be much less than during normal use. Extended contact with water could weaken the adhesive used by your infusion sets and Dexcom CGM sensors and cause them to fall off prematurely.

20.5 Sensor Overview

This section provides information about CGM devices that have a separate sensor. The information contained in this section is specific to the Dexcom G6 CGM and is provided as an example. For information about the Dexcom G6 sensor, visit the manufacturer's website for applicable product instructions.

The Dexcom G6 sensor is water resistant when showering, bathing or swimming if the transmitter is fully snapped in. The sensor has been tested to be water resistant when

3 CGM Features

CHAPTER 21

CGM Settings

CHAPTER 21 • CGM Settings

21.1 About Bluetooth Technology

Bluetooth Low Energy technology is a type of wireless communication used in cell phones and many other devices. Your t:slim X2™ pump uses Bluetooth wireless technology communication to wirelessly pair together with other devices, such as a CGM or smartphone running the t:connect™ mobile app. This allows the pump to wirelessly communicate with paired devices securely and only with each other.

21.2 Disconnecting from the Dexcom Receiver

The Dexcom G6 CGM only allows pairing with one medical device at a time. Ensure your transmitter is not connected to the receiver before pairing with the pump by doing the following:

Before entering your CGM transmitter ID into the pump, turn off the Dexcom G6 receiver and wait 15 minutes. This allows the Dexcom G6 transmitter to forget the connection currently in place with the Dexcom G6 receiver.

NOTE

It is not enough to Stop the Sensor Session on your Dexcom receiver prior to pairing to the pump. The receiver power must be completely off in order to avoid connection problems.

You may still use a smartphone with the Dexcom G6 CGM app and your pump simultaneously with the same transmitter ID.

21.3 Setting CGM Volume

You can set the sound pattern and volume for CGM alerts and prompts to meet your individual needs. Reminders, alerts, and alarms for pump functions are separate from alerts and errors for CGM functions and do not follow the same pattern and volume.

To set your sound volume, see Section 5.12 Sound Volume.

CGM Volume options:**Vibrate**

You can set your CGM to alert you with vibration rather than sound. The only exception to this is the Fixed Low Alert at 55 mg/dL, which alerts you as a

vibration first, followed by beeps 5 minutes later if not confirmed.

Soft

When you want your alert to be less noticeable. This sets all alerts and alarms to lower volume beeps.

Normal

The default profile when you receive your pump. This sets all alerts and alarms to higher volume beeps.

HypoRepeat

Very similar to normal profile, but it continuously repeats the Fixed Low Alert every 5 seconds until your sensor glucose reading rises above 55 mg/dL or the alert is confirmed. This can be helpful if you want extra alerts for severe low sensor glucose readings.

The CGM volume setting that you choose applies to all CGM alerts, errors, and prompts which have their own unique sound pattern, tone and volume. This allows you to identify each alert and error and its meaning.

The Fixed Low Alert at 55 mg/dL cannot be turned off or changed.

The Soft, Normal, and HypoRepeat options have the following sequence:

- The first alert is vibrate only.
- If the alert is not confirmed in 5 minutes, the system vibrates and beeps.
- If the alert is not confirmed in 5 more minutes, the system vibrates and beeps louder. This continues at the same volume every 5 minutes until confirmed.
- If the alert is confirmed and your sensor glucose readings continue to be at or below 55 mg/dL your system repeats the alert sequence in 30 minutes (HypoRepeat option only).

CHAPTER 21 • CGM Settings

Sound Option Descriptions

CGM Volume	Vibrate	Soft	Normal	HypoRepeat
High Alert	2 long vibrates	2 long vibrates + 2 low beeps	2 long vibrates + 2 medium beeps	2 long vibrates + 2 medium beeps
Low Alert	3 short vibrates	3 short vibrates + 3 low beeps	3 short vibrates + 3 medium beeps	3 short vibrates + 3 medium beeps
Rise Alert	2 long vibrates	2 long vibrates + 2 low beeps	2 long vibrates + 2 medium beeps	2 long vibrates + 2 medium beeps
Fall Alert	3 short vibrates	3 short vibrates + 3 low beeps	3 short vibrates + 3 medium beeps	3 short vibrates + 3 medium beeps
Out of Range Alert	1 long vibrate	1 long vibrate + 1 low beep	1 long vibrate + 1 medium beep	1 long vibrate + 1 medium beep
Fixed Low Alert	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps + pause + repeat sequence
All Other Alerts	1 long vibrate	1 long vibrate + 1 low beep	1 long vibrate + 1 medium beep	1 long vibrate + 1 medium beep

To Select Your CGM Volume:

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Device Settings**.
4. Tap **Sound Volume**.
5. Tap the **Down Arrow**.
6. Tap **CGM Alerts**.
7. Tap **Vibrate, Soft, Normal** or **HypoRepeat** to select.
- ✓ Once a value is selected, the pump will return to the previous screen.
8. Tap .

- Hardware Revision
- BLE Hardware ID
- Software Number

You can view this information at any time.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap the **Down Arrow**.
5. Tap **CGM Info**.

21.4 CGM Info

CGM Info contains important information about your device. The following can be found in CGM Info:

- Firmware Revision

This Page is Intentionally Left Blank

3 CGM Features

CHAPTER 22

Setting CGM Alerts

CHAPTER 22 • Setting CGM Alerts

Setting Your CGM Alerts

You can create personal settings for how and when you want the System to tell you what is happening.

 NOTE

The following applies to setting CGM alerts on the pump. If you are using a CGM app, any alerts that have been set up in the app are not automatically transferred to the pump and must be set up separately.

The High and Low Alerts tell you when your sensor glucose readings are outside your target glucose range.

Rise and Fall (rate of change) Alerts let you know when your glucose levels are changing fast.

The System also has a 55 mg/dL Fixed Low Alert that cannot be changed or turned off. This safety feature tells you your sensor glucose level may be dangerously low.

The Out of Range Alert notifies you when the transmitter and pump are not communicating. Keep the transmitter and the pump within 20 feet (6 meters) of each other without obstruction.

When the transmitter and the pump are too far apart, you will not get sensor glucose readings or alerts.

High and Low Glucose Alerts

You can personalize the High and Low Alerts which tell you when your sensor glucose readings are outside of your target sensor glucose range. When you have both your High and Low Alerts turned on, a gray zone on your trend graph shows your target range. The default for the High Alert is on, 200 mg/dL. The default for the Low Alert is on, 80 mg/dL. Consult with your healthcare provider before setting the High and Low Glucose Alert setting.

22.1 Setting Your High Glucose Alert and Repeat Feature

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap **CGM Alerts**.

5. Tap **High and Low**.

6. To Set the High Alert, tap **High Alert**.

7. Tap **Alert Me Above**.

The default setting for the High Alert is 200 mg/dL.

 NOTE

To turn off the High Alert, tap the on/off toggle.

8. Using the on-screen keypad, enter the value above which you want to be notified. It can be set between 120 and 400 mg/dL in 1 mg/dL increments.

9. Tap .

The repeat feature allows you to set a time for the High Alert to sound again and display on your pump as long as your sensor glucose reading remains above the High Alert value. The default value is: Never (the alert will not sound again). You can set the repeat feature to sound again every 15 minutes, 30 minutes, 1

hour, 2 hours, 3 hours, 4 hours, or 5 hours when your sensor glucose reading remains above the High Alert value.

To Set Up the Repeat Feature:

10. Tap **Repeat**.

11. To select the repeat time, tap the time you want the alert to sound again. For instance, if you select 1 hr, the alert will sound every hour as long as your sensor glucose reading remains above the High Alert value.

Use the up and down arrows to view all Repeat options.

✓ Once a value is selected, the pump will return to the previous screen.

12. Tap .

22.2 Setting Your Low Glucose Alert and Repeat Feature

1. From the *Home* screen, tap **OPTIONS**.

2. Tap the **Down Arrow**.

3. Tap **My CGM**.

4. Tap **CGM Alerts**.

5. Tap **High and Low**.

6. To Set the Low Alert, tap **Low Alert**.

7. Tap **Alert Me Below**.

The default setting for the Low Alert is 80 mg/dL.

NOTE

To turn off the Low Alert, tap the on/off toggle.

8. Using the on-screen keypad, enter the value below which you want to be notified. It can be set between 60 and 100 mg/dL in 1 mg/dL increments.

9. Tap .

The repeat feature allows you to set a time for the Low Alert to sound again and display on your pump as long as your sensor glucose reading

remains below the Low Alert value. The default value is: Never (the alert will not sound again). You can set the repeat feature to sound again every 15 minutes, 30 minutes, 1 hour, 2 hours, 3 hours, 4 hours, or 5 hours when your sensor glucose reading remains below the Low Alert value.

To Set Up the Repeat Feature:

10. Tap **Repeat**.

11. To select the repeat time, tap the time you want the alert to sound again. For instance, if you select 1 hr, the alert will sound every hour as long as your sensor glucose reading remains below the Low Alert Value.

Use the up and down arrows to view all repeat options.

✓ Once a value is selected, the pump will return to the previous screen.

12. Tap .

CHAPTER 22 • Setting CGM Alerts

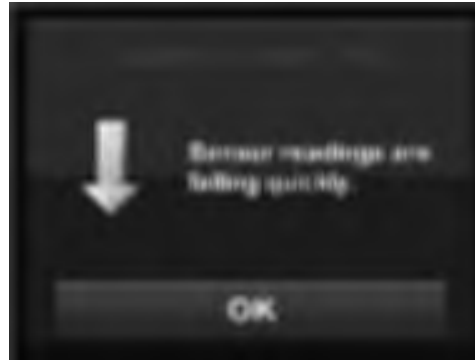
22.3 Rate Alerts

Rate alerts tell you when your glucose levels are rising (Rise Alert) or falling (Fall Alert) and by how much. You can choose to be alerted when your sensor glucose reading is rising or falling 2 mg/dL or more per minute, or 3 mg/dL or more per minute. The default value for both the Fall Alert and the Rise Alert is off. When turned on, the default is 3 mg/dL. Consult with your healthcare provider before setting the Rise and Fall Alerts.

Examples

If you set your Fall Alert to 2 mg/dL per minute and your sensor glucose readings fall at this rate or faster, the CGM Fall Alert with one arrow pointing down shows. The pump vibrates or

beeps according to your CGM volume selection.



If you set your Rise Alert to 3 mg/dL per minute and your sensor glucose readings rise at this rate or faster, the CGM Rise Alert with two arrows pointing up shows. The pump vibrates or beeps according to your CGM volume selection.



22.4 Setting Your Rise Alert

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the Down Arrow.
3. Tap **My CGM**.
4. Tap **CGM Alerts**.
5. Tap **Rise and Fall**.
6. Tap **Rise Alert**.
7. To select the default of 3 mg/dL/min, tap

To change your selection, tap **Rate**.

NOTE

To turn off the Rise Alert, tap the on/off toggle.

8. Tap **2 mg/dL/min** to select.
- ✓ Once a value is selected, the pump will return to the previous screen.
9. Tap

22.5 Setting Your Fall Alert

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap **CGM Alerts**.
5. Tap **Rise and Fall**.
6. Tap **Fall Alert**.
7. To select the default of 3 mg/dL/min, tap .

To change your selection, tap **Rate**.

NOTE

To turn off the Fall Alert, tap the on/off toggle.

8. Tap **2 mg/dL/min** to select.
- ✓ Once a value is selected, the pump will return to the previous screen.
9. Tap .

22.6 Setting Your Out of Range Alert

The range from the transmitter to the pump is up to 20 feet (6 meters) without obstruction.

The Out of Range Alert lets you know when your transmitter and pump are not communicating with each other. This alert is on by default.

PRECAUTION

We recommend that you keep the CGM Out of Range Alert turned on to notify you if your CGM is disconnected from your pump whenever you are not actively monitoring your pump status. Your CGM is providing the data that Control-IQ™ technology requires to make predictions to automate insulin dosing.

Keep the transmitter and the pump within 20 feet (6 meters) of each other without obstruction. To ensure communication, it is suggested that you face your pump screen out and away from the body, and wear the pump on the same side of the body that you wear your CGM. When the transmitter and pump are not communicating, you will not get sensor glucose readings or

alerts. The default value is on and will alert after 20 minutes.

The Out Of Range symbol appears on the pump *Home* screen and on the *Out of Range Alert* screen (if turned on) when the transmitter and pump are not communicating. The amount of time out of range also shows on the alert screen. It will continue to re-alert until the transmitter and pump are back in range.

NOTE

Control-IQ technology will continue to operate for the first 15 minutes that the transmitter and pump are out of range. Once the Out of Range condition is present for 20 minutes, Control-IQ technology will stop operation until the two devices are within range.

To Set Your Out of Range Alert:

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap **CGM Alerts**.

CHAPTER 22 • Setting CGM Alerts

5. Tap **Out of Range**.

The default is set to on and the time is set to 20 minutes.

6. To change the time, tap **Alert After**.

7. Using the on-screen keypad, enter the time after which you want to be alerted (between 20 minutes and 3 hours and 20 minutes) then tap



8. Tap .

3 CGM Features

CHAPTER 23

Starting or Stopping a CGM Sensor Session

CHAPTER 23 • Starting or Stopping a CGM Sensor Session

23.1 Enter Your Transmitter ID

To activate the Bluetooth wireless technology communication, you need to enter the unique transmitter ID into your pump. Once the transmitter ID has been entered into your pump, the two devices can be paired, allowing your sensor glucose readings to be displayed on your pump.

If you need to replace your transmitter, you will need to enter the new transmitter ID into your pump. If you need to replace your pump, you will need to re-enter the transmitter ID into your pump.

1. Remove the transmitter from its packaging.

⚠ WARNING

DO NOT use your transmitter if it is damaged/cracked. This could create an electrical safety hazard or malfunction, which might cause electrical shocks.

2. From the *Home* screen, tap **OPTIONS**.

3. Tap the Down Arrow.

4. Tap **My CGM**.

5. Tap **Transmitter ID**.

6. Using the on-screen keypad, enter the unique transmitter ID.

The transmitter ID can be found on the back of your transmitter or on the transmitter box.

The letters I, O, V, and Z are not used in transmitter IDs and should not be entered. If one of these letters is entered, you will be notified that an invalid ID was entered and prompted to enter a valid ID.

7. Tap .

8. To make sure that the correct transmitter ID is entered, you will be prompted to enter it a second time.

9. Repeat step 6 above, then tap .

If the transmitter IDs you entered do not match you will be prompted to start the process again.

- ✓ Once matching values have been entered, you will be returned to the *My CGM* screen and the transmitter ID you entered will be highlighted in orange.

23.2 Start the Sensor

To start a CGM session, follow the steps below.

1. From the *Home* screen, tap **OPTIONS**.

2. Tap the Down Arrow.

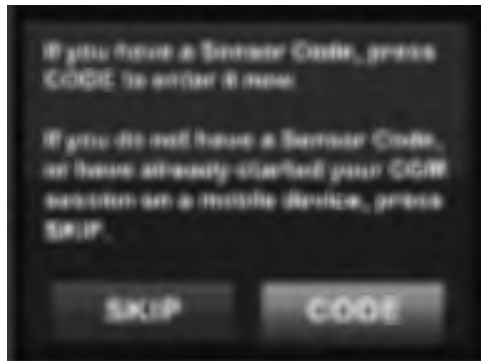
3. Tap **My CGM**.

4. Tap **START SENSOR**.

- ✓ Once you start a sensor session, the **START SENSOR** option is replaced with **STOP SENSOR**.

The following screen displays prompting you to either enter the sensor code, or to skip this step. If you choose to enter the sensor code, you will not be prompted to calibrate for the duration of the sen-

sor session. For information about Dexcom G6 CGM sensor codes, visit the manufacturer's website for applicable user guides.



Tap **CODE** to enter the 4-digit sensor code. If you don't have a code, or if you have already started a sensor session with the Dexcom G6 CGM app, you can tap **SKIP**.

If you don't enter a code into the t:slim X2™ pump, you will need to calibrate your sensor every 24 hours. A prompt to calibrate will be displayed on the pump.

5. Tap  to confirm.

- ✓ The *SENSOR STARTED* screen will appear to let you know your sensor startup has begun.
 - ✓ Your pump will return to the *CGM Home* screen with the 3 hour trend graph and the sensor startup countdown symbol displayed.
6. Check your pump *CGM Home* screen 10 minutes after starting your sensor session to make sure your pump and transmitter are communicating. The antenna symbol should be to the right of the battery indicator and should be white.
 7. If you see the out of range symbol below the insulin level indicator, and the antenna symbol is grayed out, follow these troubleshooting tips:
 - a. Make sure your pump and transmitter are within 20 feet (6 meters) of each other without obstruction. Re-check in 10 minutes to see if the out of range symbol is still active.

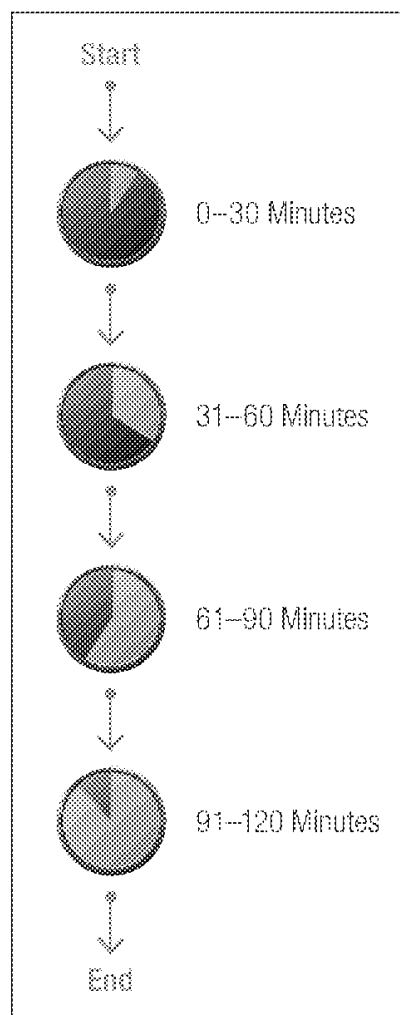
- b. If the pump and transmitter are still not communicating, check the *My CGM* screen to make sure the correct transmitter ID is entered.
- c. If the correct transmitter ID is entered and the pump and transmitter are still not communicating, contact Customer Technical Support.

CHAPTER 23 • Starting or Stopping a CGM Sensor Session

23.3 Sensor Startup Period

As an example, the Dexcom G6 sensor needs a 2-hour startup period to adjust to being under your skin. You will not get sensor glucose readings or alerts until the 2-hour startup period ends. For information about Dexcom G6 CGM sensor startup periods, visit the manufacturer's website for applicable product instructions.

During the startup period, the *CGM Home* screen on your pump shows a 2-hour countdown symbol in the upper right portion of the screen. The countdown symbol fills in over time to show that you are getting closer to the active sensor session..

Sensor Startup Period Timeline**⚠ WARNING**

Continue to use a BG meter and test strips in order to make treatment decisions during the 2-hour startup period.

📌 NOTE

During the sensor startup period, Control-IQ technology will not affect the Basal Rates or deliver automatic correction boluses. The sensor must be actively providing readings for Control-IQ technology to operate.

Examples

For example, if you started your sensor session 20 minutes ago, you would see this countdown symbol on the *CGM Home* screen.



If you started your sensor session 90 minutes ago, you would see this countdown symbol on the *CGM Home* screen.



At the end of the 2-hour startup period, the countdown symbol will be replaced with the current CGM reading.



Follow the instructions in the next chapter to calibrate your sensor. Skip the calibration instructions if you entered a sensor code. You may enter a calibration into the System at any time, even if you have already entered sensor code. Pay attention to your symptoms, and if they do not match the current CGM readings, you may choose to enter a calibration.

Ending Your Sensor Session

When the sensor session ends, you will need to replace the sensor and start a new sensor session. In some cases your sensor session may end early. You may also choose to end the sensor session early. However, if you end a sensor session early, you cannot re-start the session with that same sensor. A new sensor must be used.

NOTE

DO NOT throw away the transmitter at the end of a sensor session. Continue use of the transmitter until the pump notifies you that the transmitter battery is about to expire. Wipe the outside of the transmitter with isopropyl alcohol between sensor sessions.

Sensor glucose alerts and alarms do not work after the sensor session ends. Once the sensor session has ended, CGM readings are not available. If you are using Control-IQ technology, it becomes inactive when a CGM sensor session is ended.

23.4 Automatic Sensor Shut-Off

Your t:slim X2 pump tells you how much time you have left until your sensor session is complete. The *SENSOR EXPIRING SOON* screen shows at 6 hours remaining, 2 hours remaining, and 30 minutes remaining before your session ends. You will continue to receive sensor glucose readings after each reminder.

When you see the *SENSOR EXPIRING SOON* screen:

1. Tap **OK** to return to the previous screen.
- ✓ The *SENSOR EXPIRING SOON* screen will show again when there are 2 hours remaining, and when there are 30 minutes remaining.

CHAPTER 23 • Starting or Stopping a CGM Sensor Session

- ✓ After the final 30 minutes, the *REPLACE SENSOR* screen is displayed.
- 2. Tap .
- ✓ The *CGM Home* screen will appear with the Replace Sensor icon in the place where sensor glucose readings normally show.

New sensor glucose readings do not show on your pump after your sensor session ends. You must remove your sensor and insert a new sensor.

23.5 Ending a Sensor Session Before Automatic Shut-Off

You can end your sensor session at any time before the automatic sensor shutoff. To end your sensor session early:

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.

4. Tap **STOP SENSOR**.

5. Tap  to confirm.

- ✓ The *SENSOR STOPPED* screen is temporarily displayed.
- ✓ The *CGM Home* screen will appear with the Replace Sensor icon in the place where sensor glucose readings normally show.

New sensor glucose readings do not show on your pump after your sensor session ends. You must remove your sensor and insert a new sensor.

23.6 Removing the Sensor and Transmitter

⚠ WARNING

DO NOT ignore broken or detached sensor wires. A sensor wire could remain under your skin. If a sensor wire breaks off under your skin and you can't see it, don't try to remove it. Contact your healthcare provider. Also seek professional medical help if you have symptoms of infection or inflammation (redness, swelling, or pain) at the insertion site. If you experience a

broken sensor, please report this to Customer Technical Support.

For information about removing the Dexcom G6 sensor and Dexcom G6 transmitter, visit the manufacturer's website for applicable product instructions.

3 CGM Features

CHAPTER 24

Calibrating Your CGM System

CHAPTER 24 • Calibrating Your CGM System

24.1 Calibration Overview

If you did not enter a CGM sensor code when starting a sensor session, you will be prompted to calibrate at the following intervals:

- 2-hour startup: 2 calibrations 2 hours after you start your sensor session
- 12-hour update: 12 hours after the 2 hour start up calibration
- 24-hour update: 24 hours after the 2 hour start up calibration
- Every 24 hours: every 24 hours after the 24-hour update
- When notified

On the first day of your sensor session, you must enter four BG values into your pump to calibrate. You must enter one BG value to calibrate every 24 hours after your first startup calibration. The pump will remind you when the System needs these calibrations. In addition, you may be prompted to enter additional BG values to calibrate as needed.

⚠ PRECAUTION

DO NOT calibrate when your trend arrow is up, double-up, down, or double-down because your BG is changing at more than 2 mg/dL per minute.

When calibrating, you must enter your BG values into the pump by hand. You can use any commercially available BG meter. You must calibrate with accurate BG meter values to get accurate sensor glucose readings.

Follow these important instructions when obtaining BG values for calibration:

- BG values used for calibration must be between 40 to 400 mg/dL and must have been taken within the past 5 minutes.
- Your sensor cannot be calibrated if the glucose value from your BG meter is less than 20 mg/dL or greater than 600 mg/dL. For safety reasons, it is recommended that you treat your BG value before calibrating.
- Make sure a sensor glucose reading shows in the upper right

portion of the *CGM Home* screen before calibrating.

- Make sure the antenna symbol is visible to the right of the battery indicator on the *CGM Home* screen and is active (white, not greyed out) before calibrating.
- Always use the same BG meter to calibrate that you routinely use to measure your BG. Do not switch your BG meter in the middle of a sensor session. BG meter and strip accuracy vary between BG meter brands.
- The accuracy of the BG meter used for calibration may affect the accuracy of sensor glucose readings. Follow your BG meter manufacturer's instructions for BG testing.

24.2 Startup Calibration

If you did not enter a sensor code when starting the sensor session, the system will prompt you to calibrate to provide accurate information.

NOTE

The instructions in this section do not apply if you entered the sensor code when you started the sensor session.

Two hours after you start the sensor session, the *CALIBRATE CGM* screen will appear, letting you know that two separate BG values from your BG meter must be entered. You will not see sensor glucose readings until the pump accepts the BG values.

1. From the *CALIBRATE CGM* screen, Tap .
- ✓ The *CGM Home* screen will appear with two blood drops in the upper right portion of the screen. The two blood drops will stay on the screen until you enter two separate BG values to calibrate.
2. Wash and dry your hands, make sure your BG test strips have been stored properly and are not expired, and make sure your BG meter is properly coded (if required).
3. Take a BG measurement using your BG meter. Carefully apply the blood

sample to the test strip following your BG meter manufacturer's instructions.

⚠ PRECAUTION

DO use fingertips to calibrate from your BG meter. Blood from other places may be less accurate and not as timely.

4. Tap **OPTIONS**.
5. Tap the **Down Arrow**.
6. Tap **My CGM**.
7. Tap **Calibrate CGM**.
8. Using the on-screen keypad, enter the BG value from your BG meter.

⚠ PRECAUTION

To calibrate the System, **DO** enter the exact BG value displayed on your BG meter within 5 minutes of a carefully performed BG meter. Do not enter the sensor glucose readings for calibration. Entering incorrect BG values, BG values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe

hypoglycemia (low BG) or hyperglycemia (high BG) events.

9. Tap .
10. Tap  to confirm the calibration.

Tap  if the BG value does not exactly match the reading from your BG meter. The on-screen keypad will reappear. Enter the exact reading from your BG meter.
- ✓ The *CALIBRATION ACCEPTED* screen will appear.
- ✓ The *My CGM* screen will appear.
11. Tap **Calibrate CGM** to enter your second BG value.

✓ The on-screen keypad will appear.
12. Wash and dry your hands, make sure your BG test strips have been stored properly and are not expired, and make sure your BG meter is properly coded (if required).
13. Take a BG measurement using your BG meter. Carefully apply the blood

CHAPTER 24 • Calibrating Your CGM System

sample to the test strip following your BG meter manufacturer's instructions.

14. Follow steps 8–10 to enter your second BG value.

24.3 Calibration BG Value and Correction Bolus

Your t:slim X2™ pump uses the BG value entered for calibration to determine if a correction bolus is needed, or to provide other important information about your insulin on board and BG.

- If you enter a calibration value that is above your Target BG in Personal Profiles, the *Above Target Correction Bolus* confirmation screen will appear. To add a correction bolus, tap . Follow the instructions in Section 8.3 *Correction Bolus Calculation* to deliver a correction bolus.
- If you enter a calibration value that is below your Target BG in Personal Profiles, a message screen will indicate “Your BG is Below Target”,

and other important information will appear on the screen.

- If you enter your Target BG as a calibration value, the pump will return to the *CGM Home* screen.

24.4 Reasons You May Need to Calibrate

You may need to calibrate if your symptoms do not match the glucose values provided by your CGM.

If you see the *CALIBRATION ERROR* screen, you will be prompted to enter a BG value to calibrate in either 15 minutes or 1 hour, depending on the error.

NOTE

Although it is not required, and you will not be prompted to calibrate, you may enter a calibration into the System at any time, even if you have already entered a sensor code. Pay attention to your symptoms, and if they do not match the current CGM readings, you may choose to enter a calibration.

3 CGM Features

CHAPTER 25

Viewing CGM Data on Your t:slim X2 Insulin Pump

CHAPTER 25 • Viewing CGM Data on Your Lilliput X2 Insulin Pump

25.1 Overview

⚠ WARNING

DO NOT ignore how you feel. If your sensor glucose alerts and readings do not match what you're feeling, use your BG meter to make diabetes treatment decisions or, if needed, seek immediate medical attention.

The pump screens in this section illustrate the screen when Control-IQ™ technology is off. For information about CGM screens when Control-IQ technology is on, see Section 31.9 Control-IQ Technology Information on Your Screen.

During an active sensor session, CGM readings are sent to your pump every 5 minutes. This section teaches you how to view your sensor glucose readings and trend information. The trend graph provides additional information that your BG meter does not. It shows your current sensor glucose value, the direction it is changing and how fast it is changing. The trend graph can also show you where your sensor glucose has been over time.

Your BG meter measures glucose in your blood. Your sensor measures glucose from interstitial fluid (the fluid under your skin). Because glucose from different fluids is measured, readings from your BG meter and sensor may not match.

The greatest benefit you get from using continuous glucose monitoring will come from trending information. It is important that you focus on the trends and rate of change on your receiver or pump rather than the exact sensor glucose reading.

Press the **Screen On/Quick Bolus** button to turn the screen on. If a CGM session is active, you will see the *CGM Home* screen with the 3 hour trend graph displayed.



- The current time and date are shown at the top of the screen in the middle.
- Each “dot” on the trend graph is a sensor glucose reading reported every 5 minutes.
- Your High Alert setting shows as an orange line across the trend graph.
- Your Low Alert setting shows as a red line across the trend graph.
- The gray zone highlights your target sensor glucose range, between your High and Low Alert settings.
- Sensor glucose readings are shown in milligrams per deciliter (mg/dL).
- If your sensor glucose reading is between your High and Low Alert settings, it is shown in white.
- If your sensor glucose reading is above your High Alert setting, it is shown in orange.
- If your sensor glucose reading is below your Low Alert setting, it is shown in red.

- If your sensor glucose reading is 55 mg/dL or lower, it is shown in red, regardless of the Low Alert setting.
- The dots on the trend graph display as different colors based on your High and Low Alert settings: white if between High and Low Alert settings, orange if above High Alert setting, red if below Low Alert setting.

25.2 CGM Trend Graphs

You can view your past sensor glucose trend information on your *CGM Home* screen.

1, 3, 6, 12, and 24 hour trend views can be seen. The 3 hour Trend Graph is the default view and will be shown on the *CGM Home* screen even if a different trend graph was shown when the screen turned off.

Your trend graph shows a flat line or dots at 50 or 400 mg/dL when your glucose is outside this range.

To view different Trend Graph times, tap on the Trend Graph Time (HRS) to cycle through the options.

3 Hour Trend Graph (default view) shows you your current sensor glucose reading along with the last 3 hours of sensor glucose readings.



6 Hour Trend Graph shows you your current sensor glucose reading along with the last 6 hours of sensor glucose readings.



12 Hour Trend Graph shows you your current sensor glucose reading along with the last 12 hours of sensor glucose readings.

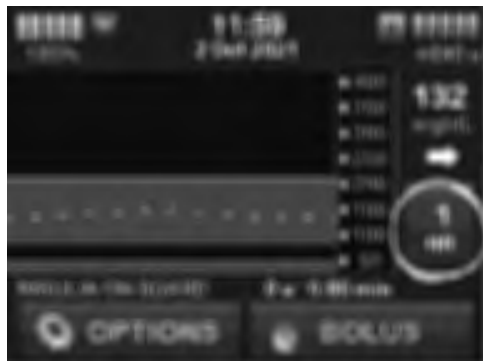


24 Hour Trend Graph shows you your current sensor glucose reading along with the last 24 hours of sensor glucose readings.



CHAPTER 25 • Viewing CGM Data on Your Insulin X2 Insulin Pump

1 Hour Trend Graph shows you your current sensor glucose reading along with the last 1 hour of sensor glucose readings.



LOW shows when your most recent sensor glucose reading is less than 40 mg/dL.



HIGH shows when your most recent sensor glucose reading is greater than 400 mg/dL.



25.3 Rate of Change Arrows

Your rate of change arrows add detail about the direction and speed of sensor glucose change over the last 15–20 minutes.

The trend arrows show below your current sensor glucose reading.



Do not overreact to the rate of change arrows. Consider recent insulin dosing, activity, food intake, your overall trend graph and your BG value before taking action.

If there are missed communications between the sensor and your pump during the last 15–20 minutes due to being out of range or due to an error condition, an arrow may not display. If the trend arrow is missing, and you are concerned that your BG level may be rising or falling, take a BG measurement using your BG meter.

The table below shows the different trend arrows your receiver or pump displays:

Trend Arrow Definitions

	Constant: Your sensor glucose is steady (not increasing/decreasing more than 1 mg/dL each minute). Your sensor glucose could increase or decrease by up to 15 mg/dL in 15 minutes.		Slowly falling: Your sensor glucose is falling 1–2 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease up to 30 mg/dL in 15 minutes.
	Slowly rising: Your sensor glucose is rising 1–2 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase up to 30 mg/dL in 15 minutes.		Falling: Your sensor glucose is falling 2–3 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease up to 45 mg/dL in 15 minutes.
	Rising: Your sensor glucose is rising 2–3 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase up to 45 mg/dL in 15 minutes.		Rapidly falling: Your sensor glucose is falling more than 3 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease more than 45 mg/dL in 15 minutes.
	Rapidly rising: Your sensor glucose is rising more than 3 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase more than 45 mg/dL in 15 minutes.	No Arrow	No rate of change information: The System cannot calculate how fast your sensor glucose is rising or falling at this time.

CHAPTER 25 • Viewing CGM Data on Your Lilliput X2 Insulin Pump

25.4 CGM History

CGM History displays the historical log of CGM events. At least 90 days of data can be viewed in History. When the maximum number of events is reached, the oldest events are removed from the history log and replaced with the most recent events. The following history sections can be viewed:

- Sessions and Calibrations
- Alerts and Errors
- Complete

Each section above is organized by date. If there are no events associated with a date, the day will not be shown in the list.

The Sessions and Calibrations section includes the start time and date for each Sensor Session, the stop time and date for each Sensor Session, and all calibration BG values entered.

The Alerts and Errors section includes the date and time for all Alerts and Errors that occurred. The letter “D” (D: Alert) before an Alert or Alarm indicates

the time it was declared. The letter “C” (C: Alert) indicates the time it was cleared.

The Complete section includes all information from the Sessions and Calibrations and Alerts and Errors sections as well as any changes to settings.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **History**.
4. Tap **CGM History**.
5. Tap section you want to view. Each section is organized by date. Tap the date to view events from that day. Use the **Down Arrow** to scroll to more dates.

25.5 Missed Readings

If your pump misses CGM readings for a period of time, you will see three dashes where the CGM reading typically displays on the *CGM Home*

screen and on the *CGM Lock* screen. The system will automatically attempt to backfill missing data points up to 6 hours in the past when connectivity is restored and readings begin to appear. If the sensor glucose number or trend arrow is missing, and you are concerned that your BG level may be rising or falling, take a BG measurement using your BG meter.

NOTE

Control-IQ technology will continue to operate for the first 15 minutes after CGM readings become unavailable. If connectivity is not restored after 20 minutes, Control-IQ technology will stop operation until CGM readings are available. While Control-IQ technology is not operating, your pump will continue to deliver insulin according to your Personal Profile settings. Once CGM readings are available, Control-IQ technology will automatically resume. For more information, see Chapter 30 *Introduction to Control-IQ Technology*.

3 CGM Features

CHAPTER 26

CGM Alerts and Errors

CHAPTER 26 • CGM Alerts and Errors

Information in this section will help you learn how to respond to CGM alerts and errors. It applies only to the CGM portion of your System. CGM alerts and errors do not follow the same pattern of vibration and beeps as insulin delivery reminders, alerts, and alarms.

The t:connect™ mobile app also can provide messages, alerts, and alarms from your t:slim X2™ pump as push notifications on your smartphone. These push notifications will be identical to your pump's display unless otherwise noted in this chapter.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. For more information about connecting your pump and smartphone, see Section 4.3 *Connecting to a Smartphone*, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

For information on insulin delivery reminders, alerts, and alarms, see

Chapters 13 t:slim X2 Insulin Pump Alerts, 14 t:slim X2 Insulin Pump Alarms, and 15 t:slim X2 Insulin Pump Malfunction.

For information on Control-IQ™ technology alerts, see Chapter 32 *Control-IQ Technology Alerts*.

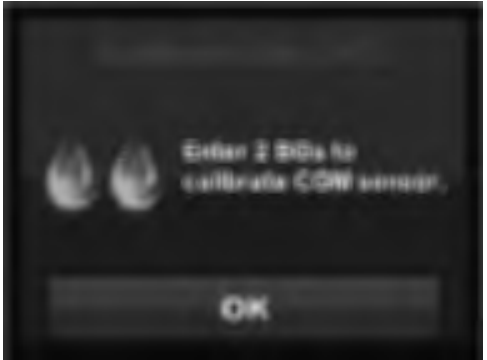
⚠ WARNING

If a sensor session is ended, either automatically or manually, Control-IQ technology is unavailable and will not adjust insulin. In order for Control-IQ technology to be enabled, a sensor session must be started and transmitting sensor values to the pump based on a sensor code or sensor calibration.

⚠ PRECAUTION

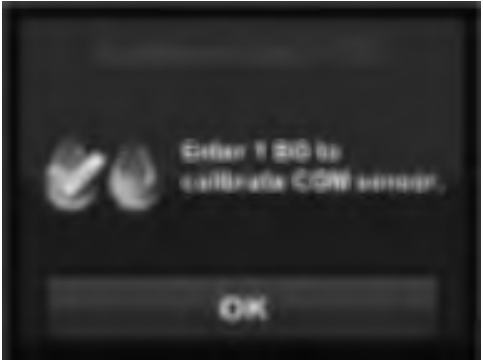
You must customize the CGM alert settings on your t:slim X2 pump and the Dexcom G6 CGM app separately. The alert settings apply to the smartphone and pump separately.

26.1 Startup Calibration Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	2-hour CGM startup period is complete. This will only appear if you did not enter a sensor code.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the System re-notify me?	Yes, every 15 minutes until you calibrate.
	How should I respond?	Tap  and enter 2 separate BG values to calibrate the system and start your CGM session.

CHAPTER 26 • CGM Alerts and Errors

26.2 Second Startup Calibration Alert

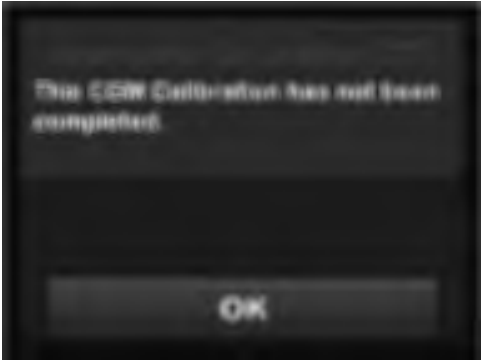
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The System needs an additional BG value to complete startup calibration. This will only appear if you did not enter a sensor code.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the System re-notify me?	Yes, every 15 minutes until second calibration is entered.
	How should I respond?	Tap  and enter a BG value to calibrate the System and start your CGM session.

26.3 12 Hour Calibration Alert

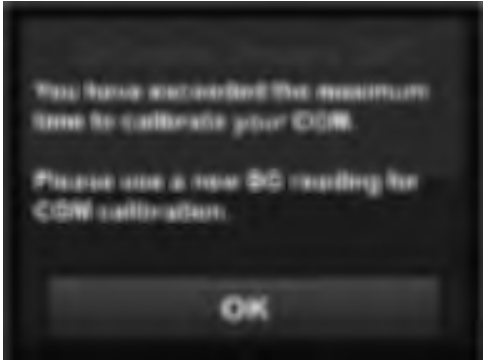
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The System needs a BG value to calibrate. This will only appear if you did not enter a sensor code.
	How will the System notify me?	On screen only with no vibration or beep.
	Will the System re-notify me?	Yes, every 15 minutes.
	How should I respond?	Tap  and enter a BG value to calibrate the system.

CHAPTER 26 • CGM Alerts and Errors

26.4 Incomplete Calibration

Screen	Explanation	
What will I see on the screen? 	What does it mean?	If you start to enter a calibration value using the keypad and do not complete the entry within 90 seconds, this screen appears.
	How will the System notify me?	2 beeps or vibrations depending on Sound Volume selected.
	Will the System re-notify me?	Yes, every 5 minutes until confirmed.
	How should I respond?	Tap  and complete your calibration by entering the value using the on-screen keypad.

26.5 Calibration Timeout

Screen	Explanation	
What will I see on the screen? 	What does it mean?	If you start to enter a calibration value using the keypad and do not complete the entry within 5 minutes, this screen appears.
	How will the System notify me?	2 beeps or vibrations depending on Sound Volume selected.
	Will the System re-notify me?	Yes, every 5 minutes until confirmed.
	How should I respond?	Tap  and obtain a new BG value using your BG meter. Enter the value using the on-screen keypad to calibrate the System.

CHAPTER 26 • CGM Alerts and Errors

26.6 Wait 15 Minute Calibration Error Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The sensor cannot calibrate.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the System re-notify me?	No.
	How should I respond?	Tap  to confirm. Wait 15 minutes then enter 1 more BG value. Wait 15 more minutes. If error screen still appears, enter 1 more BG value. Wait 15 minutes. If no sensor glucose readings appear, the sensor needs to be replaced.

26.7 Calibration Required Alert

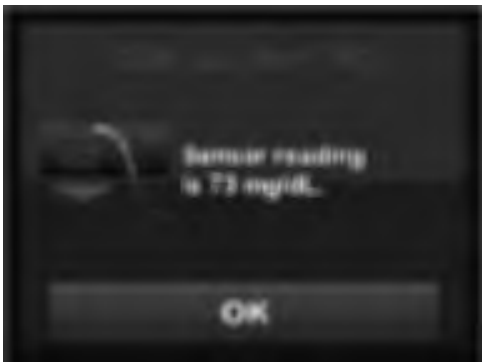
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The System needs a BG value to calibrate. Sensor glucose readings will not be displayed at this time.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the System re-notify me?	Yes, every 15 minutes.
	How should I respond?	Tap  and enter a BG value to calibrate the System.

CHAPTER 26 • CGM Alerts and Errors

26.8 CGM High Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your most recent sensor glucose reading is at or above the High Alert setting.
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes until confirmed or your sensor glucose value drops below the Alert level.
	Will the System re-notify me?	Only if you have turned on the Repeat feature.
	How should I respond?	Tap  to confirm.

26.9 CGM Low Alert

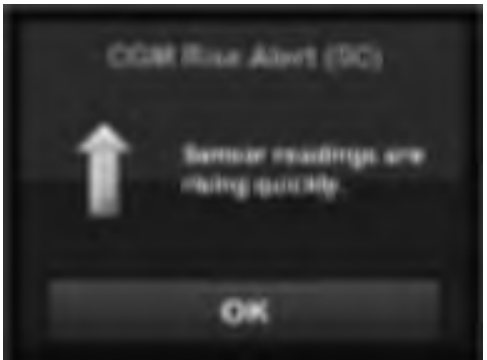
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your most recent sensor glucose reading is at or below the Low Alert setting.
	How will the System notify me?	3 vibrations, then 3 vibrations/beeps every 5 minutes until confirmed or your sensor glucose value goes above the Alert level.
	Will the System re-notify me?	Only if you have turned on the Repeat feature.
	How should I respond?	Tap  to confirm.

CHAPTER 26 • CGM Alerts and Errors

26.10 CGM Fixed Low Alert

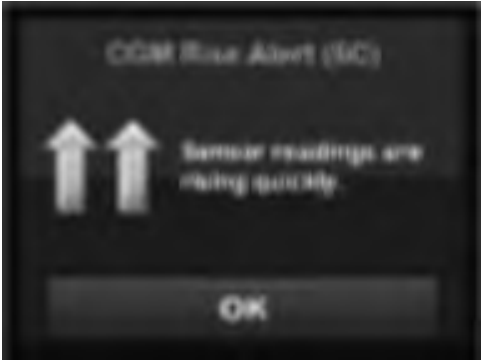
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your most recent sensor glucose reading is at or below 55 mg/dL.
	How will the System notify me?	4 Vibrations, then 4 vibrations/beeps every 5 minutes until confirmed or your sensor glucose value goes above 55 mg/dL.
	Will the System re-notify me?	Yes, 30 minutes after each confirmation until your sensor glucose value goes above 55 mg/dL.
	How should I respond?	Tap  to confirm.

26.11 CGM Rise Alert

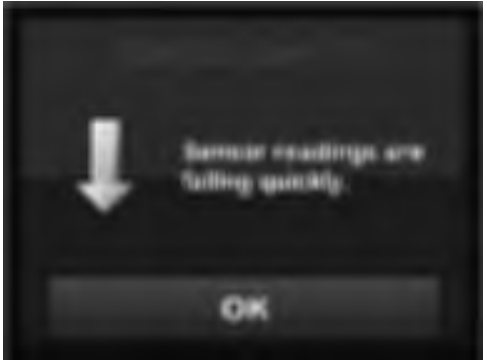
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your sensor glucose levels are rising at 2 mg/dL per minute or faster (at least 30 mg/dL in 15 minutes).
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes or until confirmed.
	Will the System re-notify me?	No.
	How should I respond?	Tap  to confirm.

CHAPTER 26 • CGM Alerts and Errors

26.12 CGM Rapid Rise Alert

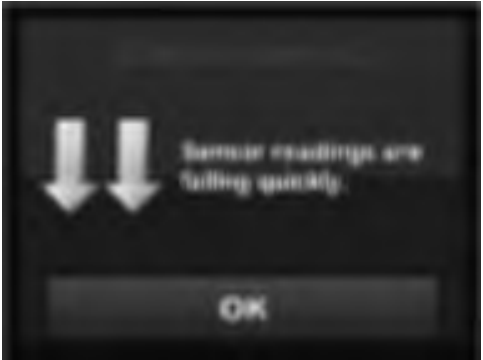
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your sensor glucose levels are rising at 3 mg/dL per minute or faster (at least 45 mg/dL in 15 minutes).
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes or until confirmed.
	Will the System re-notify me?	No.
	How should I respond?	Tap  to confirm.

26.13 CGM Fail Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your sensor glucose levels are falling at 2 mg/dL per minute or faster (at least 30 mg/dL in 15 minutes).
	How will the System notify me?	3 vibrations, then 3 vibrations/beeps every 5 minutes or until confirmed.
	Will the System re-notify me?	No.
	How should I respond?	Tap  to confirm.

CHAPTER 26 • CGM Alerts and Errors

26.14 CGM Rapid Fall Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your sensor glucose levels are falling at 3 mg/dL per minute or faster (at least 45 mg/dL in 15 minutes).
	How will the System notify me?	3 vibrations, then 3 vibrations/beeps every 5 minutes or until confirmed.
	Will the System re-notify me?	No.
	How should I respond?	Tap  to confirm.

26.15 Unknown Sensor Glucose Reading

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The sensor is sending sensor glucose readings that the System does not understand. You will not receive sensor glucose readings.
	How will the System notify me?	On screen only with no vibration or beep.
	Will the System re-notify me?	The 3 dashes will remain on the screen until a new sensor glucose reading is received and displayed in their place. If no sensor glucose readings are received after 20 minutes, the CGM Unavailable Alert will trigger. See Section 26.20 CGM Unavailable.
	How should I respond?	Wait 30 minutes for more information from the system. Do not enter BG values for calibration. The system will not use BG values for calibration when "- - -" appears on the screen.

CHAPTER 26 • CGM Alerts and Errors

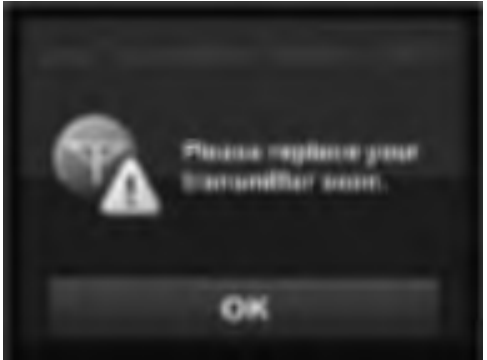
26.16 Out of Range Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The transmitter and pump are not communicating. The pump will not receive sensor glucose readings, and Control-IQ technology is not able to predict sensor glucose levels or adjust insulin delivery.
	How will the System notify me?	1 vibrate, then vibration/beep every 5 minutes until the transmitter and pump are back in range.
	Will the System re-notify me?	Yes, if the transmitter and pump remain out of range.
	How should I respond?	Tap  to confirm and move the transmitter and pump closer together, or remove the obstruction between them.

⚠ WARNING

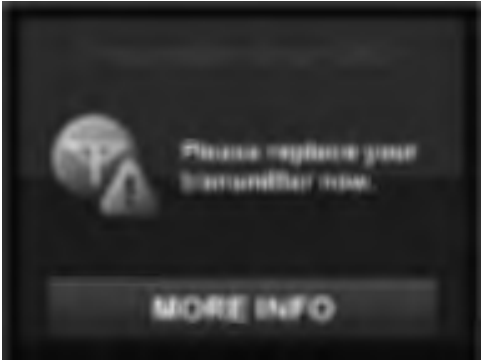
Control-IQ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate settings in your active Personal Profile.

26.17 Low Transmitter Battery Alert

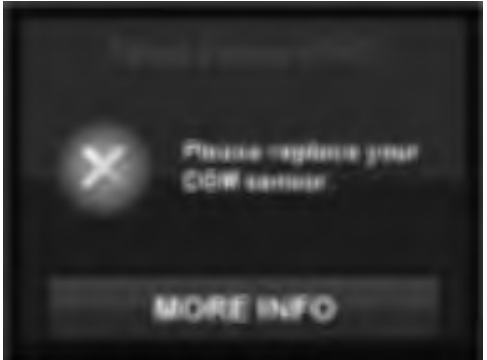
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Transmitter battery is low.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the System re-notify me?	Yes, the alarm will notify you when there are 21, 14, and 7 days of transmitter battery life remaining.
	How should I respond?	Tap  to confirm. Replace the transmitter as soon as possible.

CHAPTER 26 • CGM Alerts and Errors

26.18 Transmitter Error

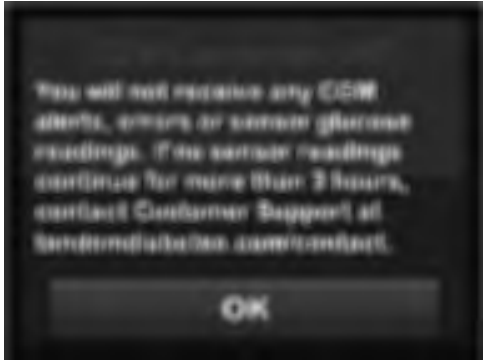
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The transmitter has failed and the CGM session has stopped.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes.
	Will the System re-notify me?	No.
	How should I respond?	Tap MORE INFO. A screen notifying you that your CGM session has stopped but insulin delivery continues will appear. Replace the transmitter immediately.

26.19 Failed Sensor Error

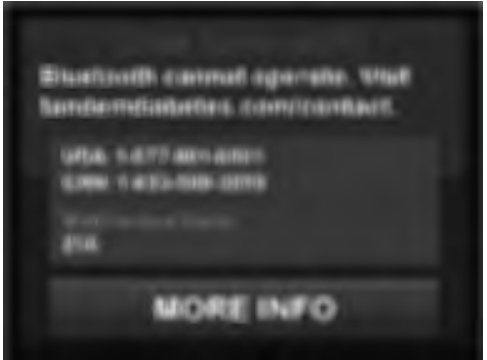
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The sensor is not working properly and the CGM session has stopped.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes.
	Will the System re-notify me?	No.
	How should I respond?	Tap MORE INFO. A screen notifying you that your CGM session has stopped but insulin delivery continues will appear. Replace the sensor and begin a new CGM session.

CHAPTER 26 • CGM Alerts and Errors

26.20 CGM Unavailable

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your CGM session has been stopped for more than 20 minutes and the CGM can no longer be used.
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes or until confirmed.
	Will the System re-notify me?	Yes, every 20 minutes until the CGM session is available. If the condition persists for 3 hours, the Failed Sensor alert will be displayed. See Section 26.19 Failed Sensor Error.
	How should I respond?	Tap  and contact Customer Technical Support.

26.21 CGM System Error

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your CGM System is not working properly; the CGM session has stopped and the CGM can no longer be used.
	How will the System notify me?	1 vibration, then vibration/beep every 5 minutes.
	Will the System re-notify me?	No.
	How should I respond?	Tap MORE INFO . A screen notifying you that your CGM System cannot operate but insulin delivery continues will appear. Call Customer Technical Support.

This Page is Intentionally Left Blank

3 CGM Features

CHAPTER 27

CGM Troubleshooting

CHAPTER 27 • CGM Troubleshooting

This chapter provides helpful tips and instructions to help you fix issues you may have while using the CGM portion of your System.

If the troubleshooting steps in this chapter do not fix your issue, contact Customer Technical Support.

The following tips are specific to troubleshooting the Dexcom G6 CGM connected to your pump. For more information about Dexcom G6 CGM troubleshooting, visit the manufacturer's website for applicable product instructions.

27.1 CGM Pairing Troubleshooting

Possible issue:

Difficulty pairing your Dexcom G6 CGM with your t:slim X2™ insulin pump.

Troubleshooting tip:

The Dexcom G6 CGM only allows pairing with one medical device at a time. Ensure your CGM is not connected to the Dexcom receiver before pairing with the pump. You may still use a smartphone with the Dexcom

G6 CGM app and your t:slim X2 insulin pump simultaneously with the same transmitter ID. See Section 21.2 Disconnecting from the Dexcom Receiver.

27.2 Calibration Troubleshooting

To ensure proper calibration of your CGM, follow these important tips.

Before you take a BG value for calibration, wash your hands, make sure your BG test strips have been stored properly and are not expired, and make sure that your meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions that came with your BG meter or test strips.

Do not calibrate if you see the Out of Range symbol in the place where your sensor glucose readings are normally shown on the screen.

Do not calibrate if you see “- - -” in the place where your sensor glucose readings are normally shown on the screen.

Do not calibrate if your BG value is below 20 mg/dL or above 600 mg/dL.

27.3 Unknown Sensor Reading Troubleshooting

When your CGM cannot provide a sensor glucose reading “- - -” shows in the place where your sensor glucose is normally shown on the screen. This means that the System does not understand the sensor signal temporarily.

Often the System can correct the problem and continue providing sensor glucose readings. If it has been at least 3 hours since your last sensor glucose reading, contact Customer Technical Support.

Do not enter any BG values for calibration when you see “- - -” on your screen. The System will not use a BG value for calibration when this symbol is on your screen.

If you see “- - -” often during a sensor session, follow the troubleshooting tips below before inserting another sensor.

- Make sure your sensor is not expired.
- Make sure your sensor pod is not dislodged or peeling up.
- Make sure your transmitter is snapped in completely.
- Make sure nothing is rubbing the sensor pod (e.g., clothing, seat belts, etc.).
- Make sure to select a good insertion site.
- Make sure your insertion site is clean and dry before sensor insertion.
- Wipe the bottom of the transmitter with a damp cloth or isopropyl alcohol wipe. Place the transmitter on a clean, dry cloth and air dry for 2–3 minutes.

27.4 Out of Range/No Antenna Troubleshooting

⚠ WARNING

Control-IQ™ technology can only adjust insulin delivery when your CGM is in range. If you go

out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate settings in your active Personal Profile

⚠ PRECAUTION

AVOID separating the transmitter and the pump by more than 20 feet (6 meters). The transmission range from the transmitter to the pump is up to 20 feet (6 meters) without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and pump are farther than 20 feet (6 meters) apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

If you see the Out of Range icon on your screen in the place where your sensor glucose reading normally shows, then your t:slim X2 pump is not communicating with your transmitter and sensor glucose readings will not show on your screen. Each time you start a new sensor session, wait 10 minutes for your t:slim X2 pump to start communicating with your transmitter.

When a sensor session is active, you may sometimes experience loss of communication for 10 minutes at a time. This is normal.

If you see the Out of Range icon for more than 10 minutes, move your t:slim X2 pump and CGM transmitter closer together and remove any obstructions. Wait 10 minutes and communication should be restored.

You must enter your transmitter ID correctly into your pump to receive sensor glucose readings (see Section 23.1 Enter Your Transmitter ID). Make sure you have removed your sensor and stopped your sensor session before checking or changing your transmitter ID. You cannot change your transmitter ID during a sensor session.

If you are still having trouble getting sensor glucose readings, contact Customer Technical Support.

27.5 Failed Sensor Troubleshooting

The System may detect issues with your sensor where it cannot determine your glucose reading. The sensor

CHAPTER 27 • CGM Troubleshooting

session ends and the *FAILED SENSOR* screen shows on your t:slim X2 pump. If you see this screen, it means your CGM session has ended.

- Remove your sensor and insert a new sensor.
- To help improve future sensor performance, follow the troubleshooting tips below.
- Make sure your sensor is not expired.
- Make sure your sensor pod is not dislodged or peeling up.
- Make sure your transmitter is snapped in completely.
- Make sure nothing is rubbing the sensor pod (e.g., clothing, seat belts, etc.).
- Make sure you have selected a good insertion site.

27.6 Sensor Inaccuracies

Inaccuracies are usually related to your sensor only and not to your transmitter or pump. Your sensor glucose readings

are meant to be used for trending purposes only. The sensor measures glucose in the fluid under the skin—not in blood, and sensor glucose readings are not identical to readings from your BG meter.

⚠ PRECAUTION

To calibrate the System, **DO** enter the exact BG value that your BG meter displays within 5 minutes of a carefully performed BG measurement. Do not enter sensor glucose values for calibration. Entering incorrect BG values, BG values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

If the difference between your sensor glucose reading and BG value is greater than 20% of the BG value for sensor readings >80 mg/dL or greater than 20 mg/dL for sensor readings <80 mg/dL, wash your hands and take another BG measurement. If the difference between this second BG measurement and the sensor is still greater than 20% for sensor readings >80 mg/dL or greater than 20 mg/dL for sensor readings <80 mg/dL,

recalibrate your sensor using the second BG value. The sensor glucose reading will correct over the next 15 minutes. If you see differences between your sensor glucose readings and BG values outside of this acceptable range, follow the troubleshooting tips below before inserting another sensor:

- Make sure your sensor is not expired.
- Make sure you do not calibrate when “- -” or the Out of Range icon are on the screen.
- Do not use alternative BG site testing (blood from your palm or forearm, etc.) for calibration as alternative site readings may be different than those from a BG value. Use a BG value only from your fingers for calibration.
- Use only BG values between 20–600 mg/dL for calibration. If one or more of your values is outside of this range, the receiver will not calibrate.
- Use the same BG meter you routinely use to measure your BG to

calibrate. Do not switch your BG meter in the middle of a sensor session. BG meter and strip accuracy vary between BG meter brands.

- Before taking a BG measurement for calibration, wash your hands, make sure your BG test strips have been stored properly and are not expired, and make sure that your BG meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions provided with your BG meter or test strips.
- Make sure you are using your BG meter following the manufacturer's instructions to get accurate BG values for calibration.

This Page is Intentionally Left Blank

4 Control-IQ Technology Features

CHAPTER 28

Control-IQ Technology Important Safety Information

CHAPTER 28 • Control-IQ Technology Important Safety Information

The following includes important safety information related to Control-IQ™ technology. The information presented in this chapter does not represent all warnings and precautions related to the System. Pay attention to other warnings and precautions listed throughout this user guide as they relate to special circumstances, features, or users.

28.1 Control-IQ Warnings

▲ WARNING

Control-IQ technology has not been evaluated in pregnant women or persons on dialysis. Sensor glucose readings may be inaccurate in these populations and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

Control-IQ technology has not been evaluated in critically ill patients. It is not known how different conditions or medications common to the critically ill population may affect the performance of the Control-IQ technology. Sensor glucose readings may be inaccurate in critically ill patients, and solely relying on the sensor glucose alerts and readings for treatment

decisions could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

▲ WARNING

Control-IQ technology should not be used by people who use less than 5 units of insulin per day and should not be used by people who weigh less than 20 pounds (9 kilograms), which are the minimum inputs required to initiate Control-IQ technology and for it to operate safely.

▲ WARNING

The t:slim X2™ insulin pump with Control-IQ technology should not be used in children under the age of two years old.

▲ WARNING

Control-IQ technology reverts to your programmed basal rate when the pump has not received a CGM reading for 20 minutes. For example, when the pump and CGM are out of range, during the sensor startup period, when a sensor session ends, or when there is a transmitter or sensor error.

▲ WARNING

If a sensor session is ended, either automatically or manually, Control-IQ technology is

unavailable and will not adjust insulin. In order for Control-IQ technology to be enabled, a sensor session must be started and transmitting sensor values to the pump based on a sensor code or sensor calibration.

▲ WARNING

DO NOT use manual injections or inhaled insulins while using Control-IQ technology. Using insulin not provided by the pump while using closed loop therapy can cause the system to over deliver insulin, which can lead to severe hypoglycemia (low BG) events.

▲ WARNING

DO NOT use Control-IQ technology if you are taking hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anemia. The use of hydroxyurea will result in sensor glucose readings that are higher than actual glucose levels. The level of inaccuracy in sensor glucose readings is based on the amount of hydroxyurea in the body. Control-IQ technology relies on sensor glucose readings to adjust insulin, provide automatic correction boluses, and provide high and low glucose alerts. If Control-IQ technology receives sensor readings that are higher than actual glucose levels, it could result in missed hypoglycemia alerts and errors in diabetes

management, such as delivery of excess basal insulin and correction boluses, including automatic correction boluses. Hydroxyurea can also result in errors when reviewing, analyzing and interpreting historical patterns for assessing glucose control. Use your BG meter and consult with your healthcare provider about alternative glucose monitoring approaches.

28.2 Control-IQ Precautions

⚠ PRECAUTION

If you remove your pump for 30 minutes or longer, it is recommended that you suspend insulin delivery. If insulin is not suspended, Control-IQ technology will continue to operate while the pump is removed, and will continue to dose insulin.

⚠ PRECAUTION

We recommend that you keep the CGM Out of Range Alert turned on to notify you if your CGM is disconnected from your pump whenever you are not actively monitoring your pump status. Your CGM is providing the data that Control-IQ technology requires to make predictions to automate insulin dosing.

This Page is Intentionally Left Blank

4 Control-IQ Technology Features

CHAPTER 29

Getting to Know Control-IQ Technology

CHAPTER 29 • Getting to Know Control-IQ Technology

29.1 Responsible Use of Control-IQ Technology

Systems like the t:slim X2™ insulin pump with Control-IQ™ technology are not substitutes for the active management of diabetes, including manually bolusing for meals. There are common scenarios in which automated systems cannot prevent a hypoglycemic event. Control-IQ technology relies on current CGM sensor readings to function and will not be able to predict sensor glucose values and suspend insulin delivery if a patient's CGM is not functioning properly or their pump is unable to receive the CGM signal. Patients should be instructed to always use the components of the pump system (pump, cartridges, CGM, and infusion sets) according to the applicable instructions for use and check them regularly to make sure they are functioning as expected. Patients should always pay attention to their sensor glucose values, actively monitor and manage BG, and treat accordingly.

29.2 Explanation of Control-IQ Technology Icons

If you have a CGM session active and are using Control-IQ technology, you may see the following additional icons on your pump screen:

Control-IQ Technology Icon Definitions

Symbol	Meaning
	Control-IQ technology is enabled but not actively increasing or decreasing basal insulin delivery.
	Control-IQ technology is increasing basal insulin delivery.
	Control-IQ technology is decreasing basal insulin delivery.
	Control-IQ technology has stopped basal insulin delivery.
	Control-IQ technology is delivering an automatic correction bolus.
	The Sleep Activity is enabled.
	Control-IQ technology delivered an automatic correction bolus.

Symbol	Meaning
	Basal insulin is programmed and being delivered.
	Control-IQ technology is increasing basal insulin delivery.
	Control-IQ technology is decreasing basal insulin delivery.
	Basal insulin delivery is stopped and a Basal Rate of 0 u/hr is active.
	Control-IQ technology is delivering an automatic correction bolus.
	The Exercise Activity is enabled.

CHAPTER 29 • Getting to Know Control-IQ Technology

29.3 Control-IQ Lock Screen

The *Control-IQ Lock* screen appears any time you turn on the screen and you are using your pump with a CGM and Control-IQ technology enabled.

The *Control-IQ Lock* screen is the same as the *CGM Lock* screen, with the following additions. See Section 19.3 CGM Lock Screen.

1. **Control-IQ Technology Status:** Indicates the status of Control-IQ technology.
2. **CGM Graph Shading:** Red shading indicates Control-IQ technology is, or was, delivering 0 units of insulin for the period indicated.



CHAPTER 29 • Getting to Know Control-IQ Technology

29.4 Control-IQ Home Screen

The *Home* screen with Control-IQ technology enabled is identical to the *CGM Home* screen, with the following additions. See Section 19.4 CGM Home Screen.

1. **Control-IQ Technology Status:**
Indicates the status of Control-IQ technology.
2. **Control-IQ Activity Status:**
Indicates an Activity is enabled.
3. **CGM Graph Shading:** Red shading indicates Control-IQ technology is, or was, delivering 0 units of insulin for the period indicated.



CHAPTER 29 • Getting to Know Control-IQ Technology

29.5 Control-IQ Screen

1. **Control-IQ Technology on/off:**
Turns on, or off, Control-IQ technology.
2. **Weight:** Displays your current weight. This value is manually entered in on the numerical keypad.

NOTE

Your weight should be representative of what you weigh when you start Control-IQ technology. Weight can be updated when you visit your healthcare provider. The minimum value for weight is 20 pounds (9 kilograms). The maximum value for weight is 440 pounds (200 kilograms).

3. **Total Daily Insulin:** Displays your current total daily insulin value in units. This value is manually entered in on the numerical keypad.

NOTE

If you don't know your Total Daily Insulin (TDI), speak with your healthcare provider to get this value. The minimum value for TDI is 5 units. The maximum value for TDI is 200 units.



This Page is Intentionally Left Blank

4 Control-IQ Technology Features

CHAPTER 30

Introduction to Control-IQ Technology

CHAPTER 30 • Introduction to Control-IQ Technology

30.1 Control-IQ Technology Overview

Control-IQ™ technology is a feature of the t:slim X2™ pump that automatically adjusts insulin dosing in response to readings from a CGM. The pump can be used with or without Control-IQ technology enabled. The following sections describe how Control-IQ technology works and how it responds to CGM values while you are awake, sleeping, and exercising.

⚠ PRECAUTION

You must continue to take boluses to cover food eaten or to correct a high sensor glucose value. Read all Control-IQ technology instructions before activating Control-IQ technology.

📌 NOTE

The target CGM ranges used by Control-IQ technology are not customizable.

📌 NOTE

The Insulin On Board (IOB) Time Remaining, which indicates how long the total units of insulin from food and correction boluses will be active in the body, is not displayed when Control-IQ technology is enabled due to the

variability of insulin delivery when automatically responding to CGM values. The IOB units will always be displayed on the *Home* and *Lock* screens.

30.2 How Control-IQ Technology Works**⚠ WARNING**

Control-IQ technology is not a substitute for understanding and being ready at any time to take over manual control of your current or future diabetes therapy.

⚠ WARNING

Control-IQ technology is not designed to prevent all hypoglycemia (low BG) or hyperglycemia (high BG).

⚠ WARNING

Control-IQ technology adjusts the delivery of insulin, but does not treat low BG. Always pay attention to your symptoms, manage your BG level, and treat according to the recommendations of your healthcare provider.

⚠ WARNING

Do not use Control-IQ technology unless recommended by your healthcare provider.

⚠ WARNING

Do not use Control-IQ technology until you have received training.

⚠ WARNING

Control-IQ technology relies on current CGM sensor readings and will not be able to accurately predict BG levels and adjust insulin delivery if for any reason your CGM is not functioning properly, or does not transmit three of the last four sensor values to your pump.

⚠ PRECAUTION

We recommend that you enable the High Glucose Alert and the Low Glucose Alert when using Control-IQ technology so that you will be notified if sensor glucose readings are outside of your target range, and you can treat high or low BG according to your healthcare provider's recommendations.

Control-IQ technology responds to the actual CGM readings as well as predicts CGM values 30 minutes in the future. Insulin delivery is automatically adjusted based on the predicted CGM value, your active Personal Profile, and whether or not a Control-IQ technology Activity is enabled.

NOTE

Control-IQ technology activity types are not automatically enabled, and must be set up as a scheduled occurrence or turned on as needed. For more information, see sections 31.5 Schedule Sleep, 31.7 Manually Start or Stop Sleep, and 31.8 Manually Start or Stop Exercise.

Control-IQ technology adjusts insulin delivery in several ways to help keep your actual glucose value within the target range. It will decrease or suspend insulin delivery when predicted sensor glucose values are below a preset treatment value, increase insulin delivery when predicted sensor glucose values are above a preset treatment value, and automatically deliver a correction bolus once per hour, as needed. The automatic correction bolus is based on a predicted sensor glucose value. There are maximum insulin delivery limits based on your Personal Profile settings. These different insulin delivery actions are described below. Each of the insulin delivery adjustments occurs in different ways depending on whether you are using the Sleep Activity, using the Exercise Activity, or neither. For more detail on how insulin adjustments are

made for different activities see Sections Control-IQ Technology With No Activity Enabled, Control-IQ Technology During Sleep, and Control-IQ Technology During Exercise Activity in this chapter.

Personal Profile Basal Rate Delivery

When the predicted CGM value is within the treatment value range (112.5 mg/dL – 160 mg/dL), the pump will deliver insulin at the rate determined by the active Personal Profile settings.

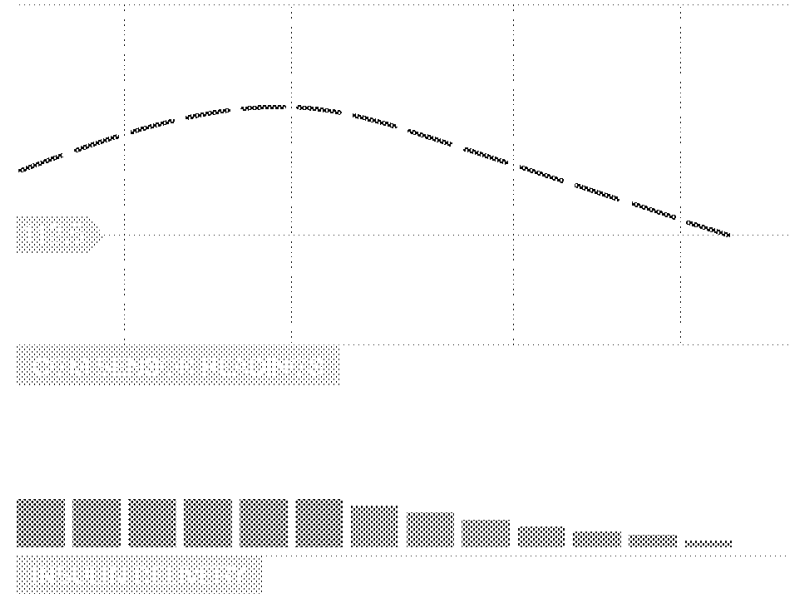
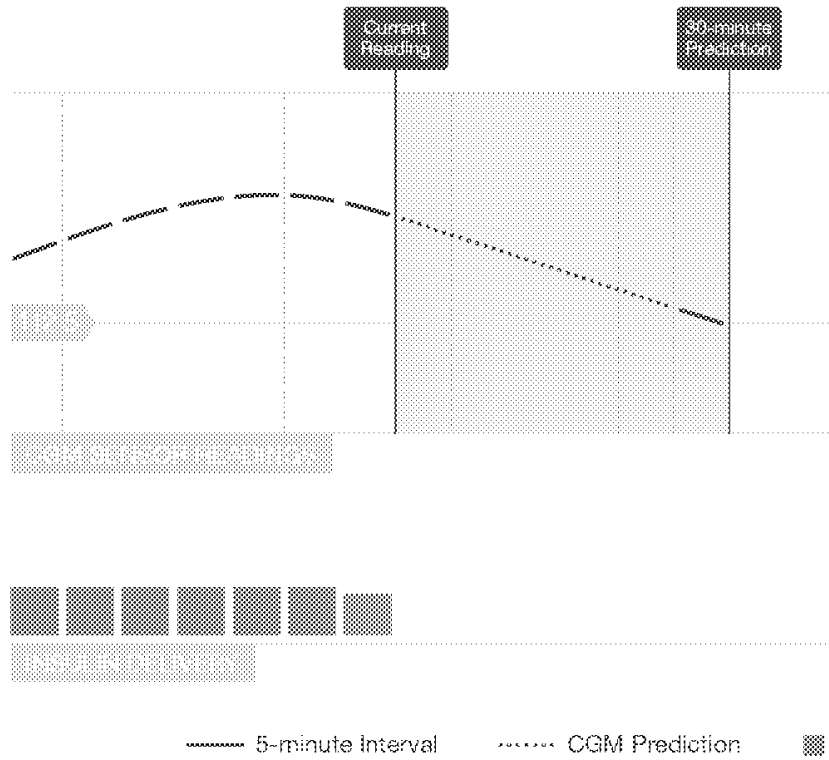
All Personal Profile settings must be completed in order to use Control-IQ technology. See Chapter 6 Insulin Delivery Settings for more information about Personal Profiles.

Decreased Insulin Delivery

When Control-IQ technology predicts that your sensor glucose value will be at or below a preset treatment value (112.5 mg/dL) 30 minutes in the future, the rate of insulin delivery will start decreasing to attempt to keep the actual sensor glucose values within the target range. The following diagrams depict how the system uses 30 minute

predictions to gradually decrease insulin delivery compared to the personal profile Basal Rate. The diagram on the left depicts the prediction, the diagram on the right depicts how the insulin and CGM readings might look if the CGM graph continued on the trend.

CHAPTER 35 • Introduction to Control-IQ Technology



NOTE

Diagrams are for illustrative purposes only and are not intended to reflect actual results.

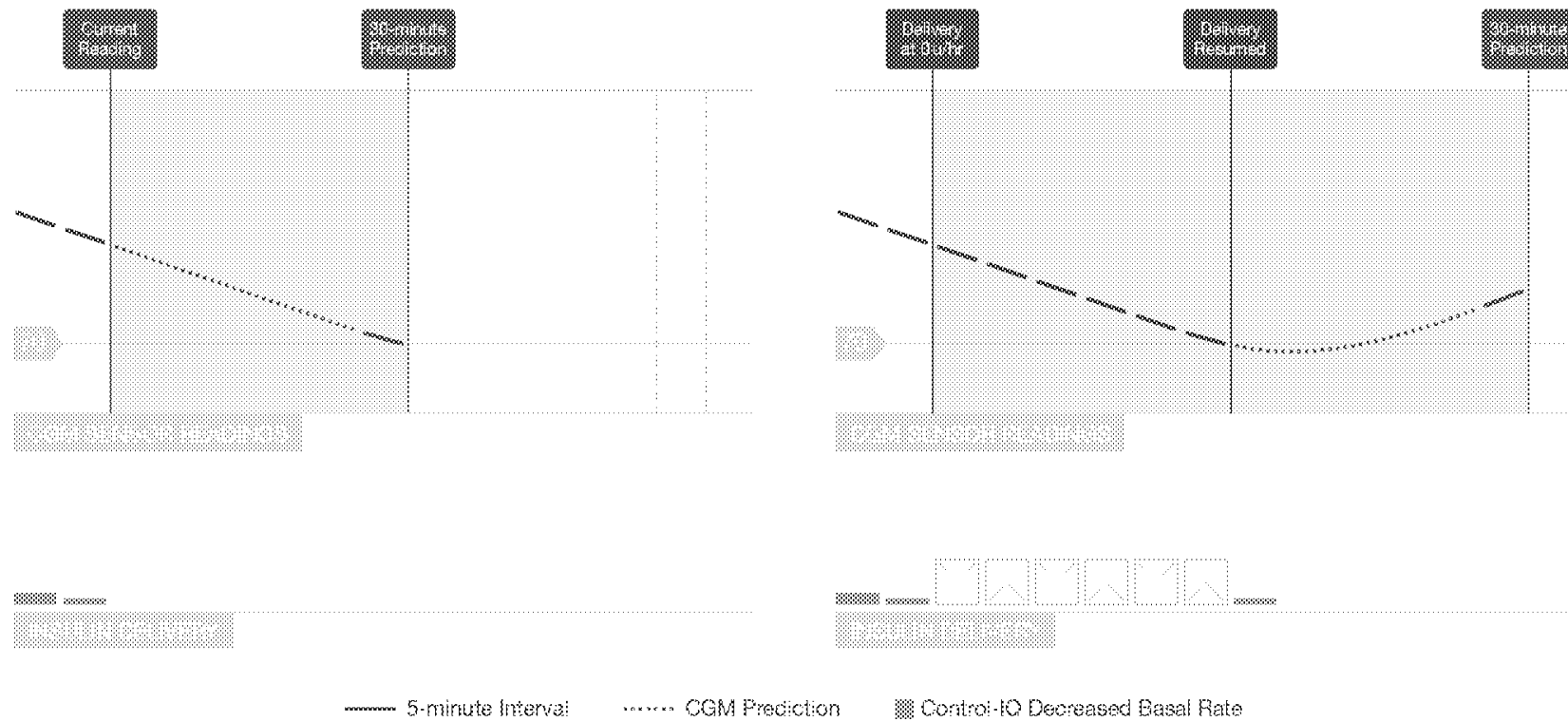
Insulin Decreased or Delivering 0 Units per Hour

Control-IQ technology can reduce the basal delivery to a percent of the Basal Rate in addition to completely suspending. When Control-IQ technology predicts that your sensor glucose value will be lower than a preset treatment value (70 mg/dL) 30 minutes in the future, insulin delivery will decrease and may set the Basal Rate at 0 units per hour if necessary to attempt to keep the actual sensor glucose values within the target range. Manual boluses can still be delivered when Control-IQ technology is decreasing or suspending insulin. The following diagrams depict an illustration of when Control-IQ technology might set the insulin delivery rate to 0 units per hour, and when it will resume at a decreased rate after the 30 minute prediction is above the target sensor glucose value.

■ NOTE

When Control-IQ technology sets the Basal Rate to 0 units per hour, bolus deliveries will continue. This includes starting a new bolus and any remaining bolus from an extended bolus delivery.

CHAPTER 35 • Introduction to Control-IQ Technology



NOTE

Diagrams are for illustrative purposes only and are not intended to reflect actual results.

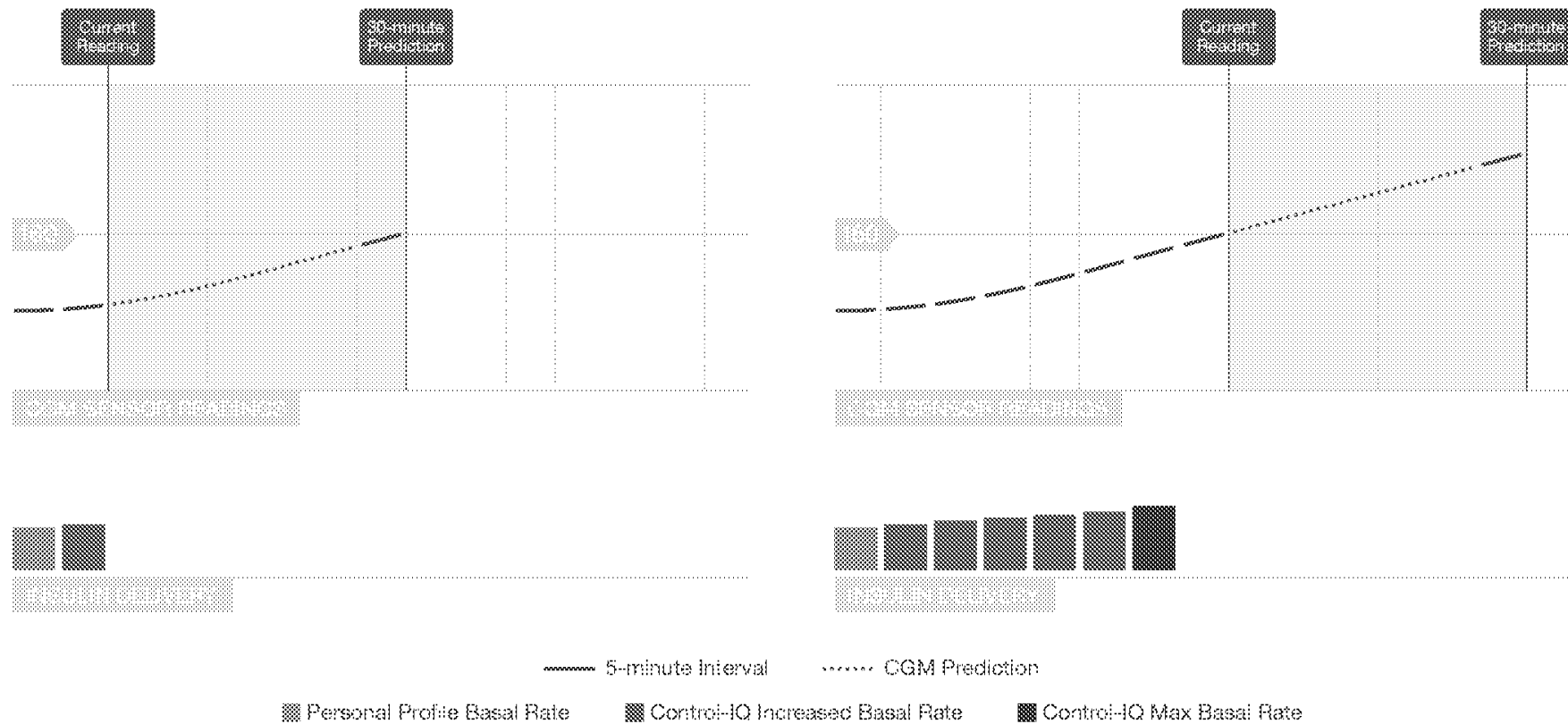
Increasing Insulin Delivery

When Control-IQ technology predicts that your sensor glucose value will be at or above a preset treatment value (160 mg/dL) 30 minutes in the future, the rate of insulin delivery will start increasing to attempt to keep the actual CGM values within the target CGM range. The following diagrams depict when Control-IQ technology might be increasing and delivering at the maximum increased Basal Rate.

Maximum Insulin Delivery

When Control-IQ technology predicts that your sensor glucose value will be above a preset treatment value (160 mg/dL) 30 minutes in the future, but the maximum rate of insulin delivery has been reached, Control-IQ technology stops increasing the insulin delivery rate. The maximum insulin delivery rate is a calculated value that is dependent on an individual's Correction Factor setting (found in the active Personal Profile), the Total Daily Insulin estimated by Control-IQ technology based on actual total daily insulin values, and the current insulin on board (IOB).

CHAPTER 35 • Introduction to Control-IQ Technology



NOTE

Diagrams are for illustrative purposes only and are not intended to reflect actual results.

Automatic Correction Bolus Delivery

When Control-IQ technology predicts that your CGM value will be at or above a preset treatment value (180 mg/dL) 30 minutes in the future, and when Control-IQ technology is either Increasing Insulin Delivery or delivering Maximum Insulin Delivery, the pump will automatically deliver correction boluses to attempt to achieve the target range.

The automatic correction bolus will deliver a total correction bolus calculated based on the Personal Profile Correction Factor and predicted CGM reading. The target sensor glucose for the automatic correction bolus is 110 mg/dL. Automatic correction bolus delivery occurs at most once every 60 minutes, and will not be delivered within 60 minutes of the start, cancellation, or completion of an automatic bolus or manual bolus. For an extended bolus, this 60 minutes does not start until after the DELIVER NOW duration has completed. The percentage and duration between boluses is designed to avoid insulin stacking that may cause unsafe reductions in sensor glucose values.

NOTE

Each automatic correction bolus delivery can be manually canceled or stopped during the delivery in the same way that a Manual Bolus can be stopped. See Section 8.10 Canceling or Stopping a Bolus Using the Pump and Section 8.15 Canceling or Stopping a Bolus Using the t:connect Mobile App.

NOTE

The maximum amount of insulin that an automatic correction bolus will deliver is 6 units. This value cannot be increased, but you may choose to deliver a manual bolus after the automatic correction bolus delivery is complete.

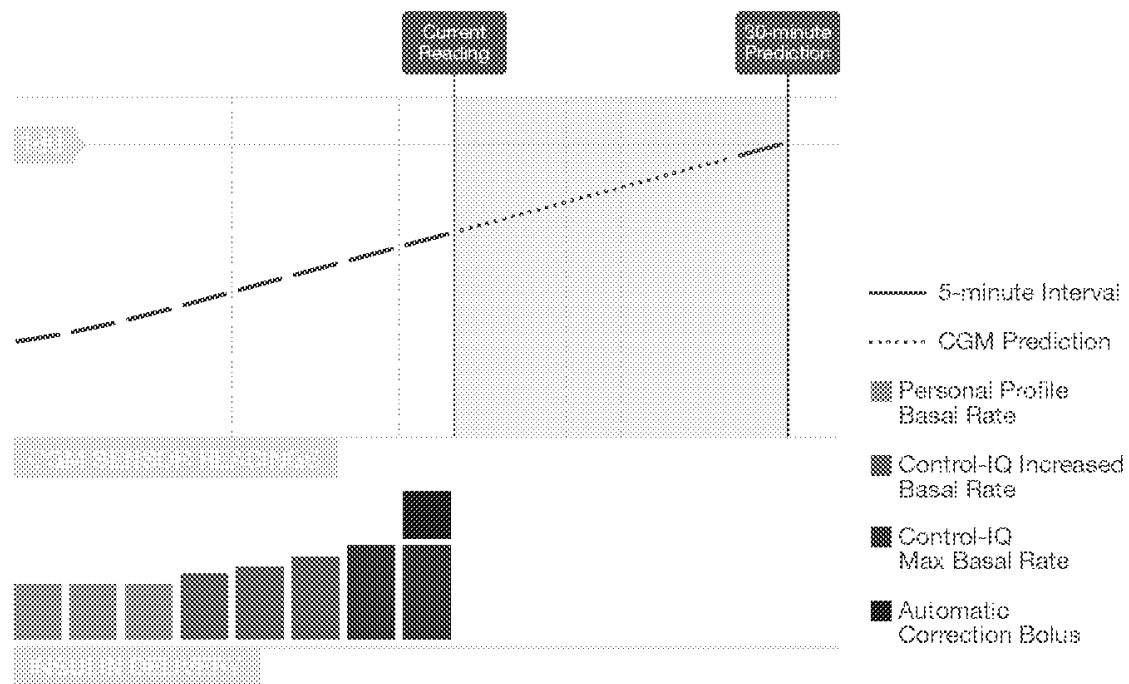
PRECAUTION

The pump does not activate sound or vibration to indicate when an automatic correction bolus delivery has started. The following pump screens indicate that an automatic correction

bolus is being delivered and that an automatic correction bolus was delivered, respectively.



CHAPTER 35 • Introduction to Control-IQ Technology



NOTE

Diagrams are for illustrative purposes only and are not intended to reflect actual results.

30.3 Control-IQ Technology and Activity

When Control-IQ technology is turned on you can choose to activate Sleep or Exercise to help the System adjust the automated insulin dosing settings as described in previous sections.

If you have not started either Sleep or Exercise, the System will use the settings described in the following section.

Control-IQ Technology With No Activity Enabled

The CGM range targeted by Control-IQ technology with no Activity enabled is 112.5–160 mg/dL. This range is wider than the Sleep and Exercise ranges to account for the variability of factors that affect CGM values while people are awake and not exercising.

Decreasing Insulin With No Activity Enabled

Insulin is decreased when Control-IQ technology predicts a CGM reading of ≤ 112.5 mg/dL 30 minutes in the future.

Suspended Insulin With No Activity Enabled

Insulin is set to 0 units/hour when Control-IQ technology predicts a CGM reading ≤ 70 mg/dL 30 minutes in the future.

Increasing Insulin With No Activity Enabled

Insulin is increased when Control-IQ technology predicts a CGM reading of ≥ 160 mg/dL 30 minutes in the future.

Automatic Correction Bolus With No Activity

When no Activity is enabled, Control-IQ technology will deliver automatic correction boluses as described in the Automatic Correction Bolus Delivery section of this chapter.

Control-IQ Technology During Sleep

The Control-IQ technology Sleep Activity range is targeted during scheduled sleep times and when the Sleep Activity is manually started (until it is stopped). See Chapter 31 Configuring and Using Control-IQ Technology and see Section Enable a Sleep Schedule for instructions on setting the hours you plan to sleep and

Section Manually Start Sleep for starting the Sleep Activity manually in that chapter.

The CGM range targeted by Control-IQ technology during the Sleep Activity is 112.5 mg/dL–120 mg/dL. This range is smaller than the target range with no Activity enabled since there are fewer variables that affect CGM values while you are sleeping. During the Sleep Activity, Control-IQ technology will not deliver automatic boluses.

Decreasing Insulin During Sleep Activity

Insulin is decreased when Control-IQ technology predicts a CGM reading of ≤ 112.5 mg/dL 30 minutes in the future.

Suspended Insulin During Sleep Activity

Insulin is set to 0 units/hour when Control-IQ technology predicts a CGM reading ≤ 70 mg/dL 30 minutes in the future.

Increasing Insulin During Sleep Activity

Insulin is increased when Control-IQ technology predicts a CGM reading of ≥ 120 mg/dL 30 minutes in the future.

CHAPTER 30 • Introduction to Control-IQ Technology

Automatic Correction Bolus During Sleep Activity

Automatic correction boluses will not be delivered while Sleep is enabled.

When Control-IQ technology switches back to the settings with no Activity enabled, whether according to scheduled wake time or due to manually stopping Sleep, the transition from the targeted sleep CGM range to targeted settings with no Activity enabled CGM range occurs slowly and can take 30-60 minutes. This helps ensure that actual CGM values transition gradually.

Control-IQ Technology During Exercise Activity

During the Exercise Activity, Control-IQ technology uses the target CGM range 140 mg/dL–160 mg/dL. This target range is smaller and higher than the target range with no Activity enabled to accommodate the likely natural drop in glucose following exercise.

If the Exercise Activity is on when a Sleep Schedule is due to begin, the Sleep Schedule does not start. In this

scenario you must manually start Sleep once you turn Exercise off.

Decreasing Insulin During Exercise Activity

Insulin is decreased when Control-IQ technology predicts a CGM reading of ≤ 140 mg/dL 30 minutes in the future.

Suspended Insulin During Exercise Activity

Insulin is set to 0 units/hour when Control-IQ technology predicts a CGM reading ≤ 80 mg/dL 30 minutes in the future.

Increasing Insulin During Exercise Activity

Insulin is increased when Control-IQ technology predicts a CGM reading of ≥ 160 mg/dL 30 minutes in the future.

Automatic Correction Bolus During Exercise Activity

When the Exercise Activity is enabled, Control-IQ technology will deliver automatic correction boluses as described in the Automatic Correction Bolus Delivery section of this chapter.

See Chapter 31 Configuring and Using Control-IQ Technology for instructions on starting or stopping Exercise.

For a summary of all treatment values and how they are different for each Activity, see the diagram on the next page.

			 Control-IQ	 Sleep Activity	 Exercise Activity
  Delivers	Delivers an automatic correction bolus if sensor glucose is predicted to be above ____ mg/dL.		180	---	180
  Increases	Increases basal insulin delivery if sensor glucose is predicted to be above ____ mg/dL.		160	120	160
  Maintains	Maintains active Personal Profile settings when sensor glucose is between ____ - ____ mg/dL.		112.5 - 160	112.5 - 120	140 - 160
  Decreases	Decreases basal insulin delivery if sensor glucose is predicted to be below ____ mg/dL.		112.5	112.5	140
  Stops	Stops basal insulin delivery if sensor glucose is predicted to be below ____ mg/dL.		70	70	80

This Page is Intentionally Left Blank

4 Control-IQ Technology Features

CHAPTER 31

Configuring and Using Control-IQ Technology

CHAPTER 31 • Configuring and Using Control-IQ Technology

31.1 Required Settings**Required Personal Profile Settings**

In order to use Control-IQ™ technology, the following Personal Profile settings must be configured. See Chapter 6 Insulin Delivery Settings for instructions about setting these values.

- Basal Rate
- Correction Factor
- Carb Ratio
- Target BG
- Carbohydrates turned on in Bolus Settings

Required Control-IQ Technology Pump Settings

In addition to the required Personal Profile settings, there are two values specific to Control-IQ technology that must be set. These are:

- Weight
- Total Daily Insulin

Recommended Control-IQ Technology Pump Settings

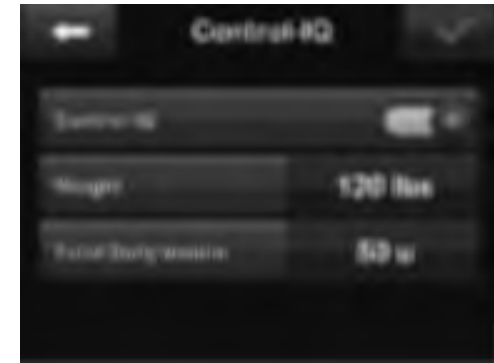
Although Sleep can be started and stopped manually, it is recommended that you schedule sleep. This chapter explains how to do both. The following settings are required to schedule sleep:

- Selected Days
- Start Time
- End Time

31.2 Set Weight

Control-IQ technology cannot be turned on unless Weight is entered. The Weight value may be updated when you visit your healthcare provider.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Control-IQ**.
 - ✓ The *Control-IQ* screen is displayed.



4. Tap **Weight**.
5. Tap **Pounds** or **Kilograms** to set the unit of weight.
6. Tap .
7. Enter the weight value on the numeric keypad. Weight can be set from a minimum of 20 pounds (9 kilograms) to a maximum of 440 pounds (200 kilograms).
8. Tap .
9. If you are done with the Control-IQ settings, tap .
 - ✓ The **SETTING SAVED** screen is temporarily displayed.

31.3 Set Total Daily Insulin

Control-IQ technology cannot be turned on unless Total Daily Insulin is entered. The Total Daily Insulin value is used by Control-IQ technology to calculate the maximum insulin delivery rate and to maintain a safe and effective increase in insulin dose.

The Total Daily Insulin value may be updated when you visit your healthcare provider.

NOTE

Once you have used Control-IQ technology, it will maintain and use the actual total insulin delivered, including the adjustments made to basal and all types of boluses while using the System. It is important to update the Total Daily Insulin setting in the *Control-IQ* screen when you visit your healthcare provider. This value is used for the 2-hour maximum insulin alert.

An estimate of Total Daily Insulin should be entered. Include all types of insulin (basal and bolus) delivered in a 24-hour period. Consult your healthcare provider if you need assistance estimating your insulin requirements.

Enter your Total Daily Insulin Value

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Control-IQ**.
4. Tap **Total Daily Insulin**.
5. Use the numeric keypad to enter the total units of insulin typically required in a 24-hour period. Total Daily Insulin can be set from a minimum of 5 units to a maximum of 200 units.
6. Tap .
7. If you are done with the Control-IQ settings, tap .
- ✓ The **SETTING SAVED** screen is temporarily displayed.
8. When you are done setting up Control-IQ, tap the **Tandem logo** to return to the *CGM Home* screen.

31.4 Turn Control-IQ Technology On or Off

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Control-IQ**.
4. To turn Control-IQ on, tap the toggle next to **Control-IQ**.
5. To turn Control-IQ off, tap the toggle next to **Control-IQ**.
 - Tap  to confirm and turn Control-IQ off.
 - Tap  to leave Control-IQ on.

31.5 Schedule Sleep

Control-IQ technology operates differently during Sleep than with no Activity enabled. Sleep can be scheduled to turn on and off automatically, or it can be turned on and off manually. This section covers how to set Sleep to turn on and off

CHAPTER 31 • Configuring and Using Control-IQ Technology

automatically. For detailed information about how to use Control-IQ technology, see Chapter 30 Introduction to Control-IQ Technology.

You can configure two different Sleep Schedules to account for changes in lifestyle, such as a weekday sleep schedule and a weekend sleep schedule.

NOTE

If you manually start Sleep before a Sleep Schedule begins, it does not impact the scheduled wake time. For example, if your Sleep Schedule is set from 10pm to 6am (22:00 to 6:00), and you start Sleep manually at 9pm (21:00), Sleep will end at 6am (6:00) as scheduled; unless manually stopped.

NOTE

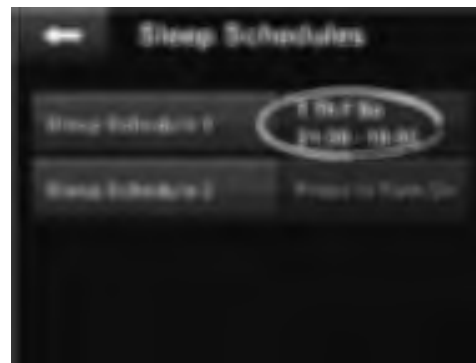
Exercise and Sleep may not be enabled at the same time. If Exercise is active at the time a Sleep Schedule begins, the Sleep Schedule will not enable. However, once Exercise is disabled, the Sleep Schedule will start automatically.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.

3. Tap **Sleep Schedules**.

4. Select which Sleep Schedule to configure.

- If no Sleep Schedules are configured, tap **Sleep Schedule 1**.
- If you are editing an existing schedule, tap the schedule summary that displays to the right of the sleep schedule you want to edit.

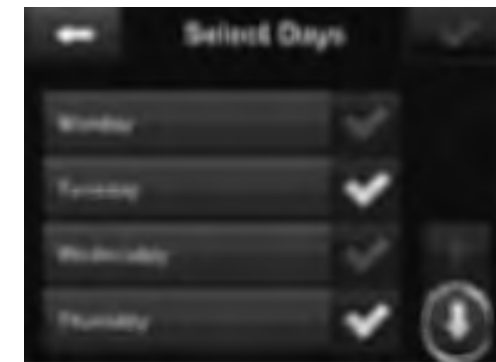


5. On the Sleep Schedule screen, tap **Selected Days**. The default is the current day of the week only, according to the day of the week set on the pump.

6. On the Select Days screen, tap the **checkmark** to the right of each day of the week that you want included in the Sleep Schedule.

When a checkmark is green, the corresponding day of the week is active. To deactivate a day, tap the associated checkmark again so that it turns gray.

Tap the **Down Arrow** to see more days of the week.



7. When you are finished selecting the days, tap .

NOTE

If no days are selected when you tap , the schedule is set to off and the remaining

sleep schedule settings are not displayed. The remaining instructions do not apply to an incomplete schedule.

8. Tap **Start Time**.
9. Tap **Time**. The numbered keypad is displayed.
10. Enter the time you would like the Sleep Schedule to start by entering the number(s) for the hour followed by the minutes. For example, tap 9 3 0 to set the time to 9:30 or 2 1 0 0 to set the time to 21:00.
11. Tap . You are returned to the *Start Time* screen.
12. Tap **AM** or **PM** to set the Time of Day, if applicable.
13. Tap . You are returned to the *Sleep Schedule 1* screen.
14. Tap **End Time**.
15. Tap **Time**. The numbered keypad is displayed.

16. Enter the time you would like the Sleep Schedule to end and tap . You are returned to the *End Time* screen.

17. Tap **AM** or **PM** to set the Time of Day, if applicable.
18. Tap . The *Sleep Schedule 1* screen is displayed.
19. Tap  to save the schedule.
- ✓ The SETTING SAVED screen is temporarily displayed, followed by the *Sleep Schedules* screen.
20. When you are done configuring sleep, tap  to return to the *Activity* screen or tap the **Tandem** logo to return to the *Home* screen.

31.6 Enable or Disable a Sleep Schedule

Once a Sleep Schedule is configured, it is enabled by default when it is saved. If you have multiple Sleep Schedules configured, you can change the

enabled Sleep Schedule or turn them off completely.

Enable a Sleep Schedule

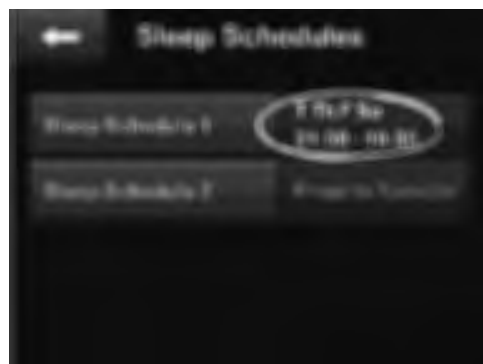
1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap **Sleep Schedules**.
4. Tap the schedule summary next to the name of the Sleep Schedule you want to enable. (If no sleep schedules are configured, see Section 31.5 Schedule Sleep.)
5. Tap the toggle next to the schedule name.
6. Tap .

Disable a Sleep Schedule

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap **Sleep Schedules**.

CHAPTER 31 • Configuring and Using Control-IQ Technology

Tap the schedule summary next to the Sleep Schedule you want to disable.



4. Tap the toggle.

5. Tap .

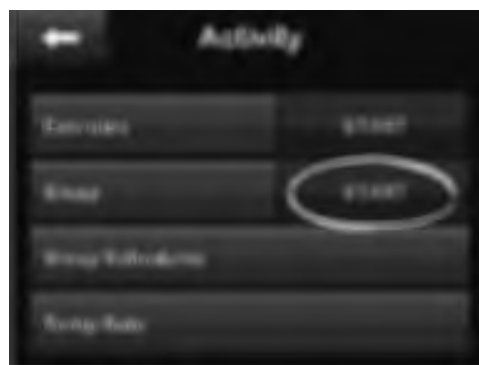
31.7 Manually Start or Stop Sleep

In addition to scheduling sleep, Sleep can be manually started and/or stopped.

Sleep time determines when Control-IQ technology, if enabled, switches to Sleep activity. Control-IQ technology must be on and a CGM session must be active to start Sleep.

Manually Start Sleep

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap the **START** text next to **Sleep**.

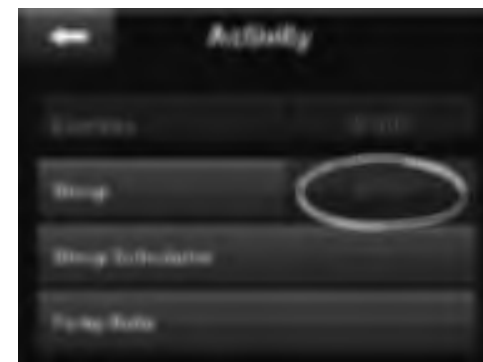


- ✓ A SLEEP STARTED screen is temporarily displayed. The Sleep icon is displayed on the *Home* screen.

Manually Stop Sleep

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.

3. Tap the **STOP** text next to **Sleep**.



- ✓ A SLEEP STOPPED message is temporarily displayed. The Sleep icon is removed from the *Home* screen.

31.8 Manually Start or Stop Exercise

Start Exercise

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap the **START** text next to **Exercise**.

- ✓ An EXERCISE STARTED message is temporarily displayed. The Exercise icon is displayed on the *Home* screen.

Stop Exercise

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap the **STOP** text next to **Exercise**.

- ✓ An EXERCISE STOPPED message is temporarily displayed. The Exercise icon is removed from the *Home* screen.

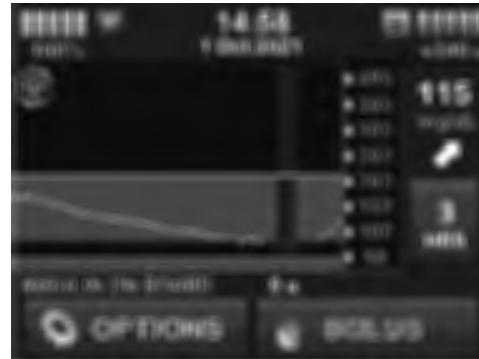
31.9 Control-IQ Technology Information on Your Screen

Control-IQ Technology Status Icon

When Control-IQ technology is on, the CGM Trend Graph displays a diamond icon in the top left corner. This icon uses different colors to communicate information about how Control-IQ technology is operating. Each different

color and its meaning can be found in Section 29.2 Explanation of Control-IQ Technology Icons.

When Control-IQ technology is on but not active (i.e. insulin is being delivered normally), the diamond icon is gray as depicted below. Regardless of the color, the icon always appears in the same place.



Exercise and Sleep Icons

When Exercise or Sleep is turned on, the respective icon displays in the same place on the screen, since they can never be active at the same time. The following image shows the sleep icon

active on the CGM Trend Graph screen.



When Exercise is on, the Exercise icon is displayed in the same location.

Basal Status Icons

There are several basal status icons that display in different colors, each of which communicates information about how Control-IQ technology is operating. Each different color and its meaning can be found in Section 29.2 Explanation of Control-IQ Technology Icons.

CHAPTER 31 • Configuring and Using Control-IQ Technology

The following image highlights where the basal status icons display.



Automatic Correction Bolus Status Icon

When Control-IQ technology is on and delivering an automatic correction bolus, an icon displays to the left of the basal status icon. (The manual bolus icon displays in the same place on the screen; see the Section 3.3 Explanation of t:slim X2 Insulin Pump Icons for the manual bolus icon image.) The following image shows the location of the bolus icon.

NOTE

The text **BOLUS** followed by 3 ellipses displays below the CGM graph. The **Control-IQ** text

appearing below **BOLUS** indicates that there is an automatic correction bolus delivered by Control-IQ technology. The amount of the bolus is also displayed.



CGM Trend Graph Insulin Delivery Suspended

Portions of the CGM Trend Graph that display a red band in the background indicate the times when Control-IQ technology was delivering 0 units/hour.

Each dot on the CGM graph represents a five-minute increment.



4 Control-IQ Technology Features

CHAPTER 32

Control-IQ Technology Alerts

CHAPTER 32 • Control-IQ Technology Alerts

Information in this section will help you learn how to respond to Control-IQ™ technology alerts and errors. It applies only to the Control-IQ technology within your System. The Control-IQ technology alerts follow the same pattern as other pump alerts according to your Sound Volume selection.

The t:connect™ mobile app also can provide messages, alerts, and alarms from your t:slim X2™ pump as push notifications on your smartphone. These push notifications will be identical to your pump's display unless otherwise noted in this chapter.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the t:connect mobile app must be open in the background for pump notifications to be received on your smartphone. For more information about connecting your pump and smartphone, see Section 4.3 Connecting to a Smartphone, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

For information on insulin delivery reminders, alerts, and alarms see Chapters 13 t:slim X2 Insulin Pump Alerts, 14 t:slim X2 Insulin Pump Alarms, and 15 t:slim X2 Insulin Pump Malfunction.

For information on CGM Alerts and Errors, see Chapter 26 CGM Alerts and Errors.

32.1 Out of Range Alert – Control-IQ Technology Disabled

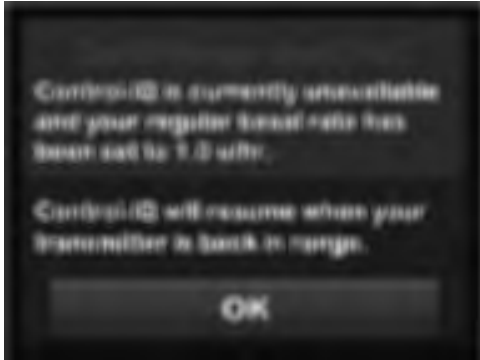
Screen	Explanation	
What will I see on the screen? 	What does it mean?	The transmitter and pump are not communicating. The pump will not receive sensor glucose readings, and Control-IQ technology is not able to predict sensor glucose levels or adjust insulin delivery.
	How will the System notify me?	1 vibrate, then vibration/beep every 5 minutes until the transmitter and pump are back in range.
	Will the System re-notify me?	Yes, if the transmitter and pump remain out of range.
	How should I respond?	Tap  to confirm and move the transmitter and pump closer together, or remove the obstruction between them.

⚠ WARNING

Control-IQ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate settings in your active Personal Profile.

CHAPTER 32 • Control-IQ Technology Alerts

32.2 Out of Range Alert – Control-IQ Technology Enabled

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Control-IQ technology is turned on, but the transmitter and pump are not communicating. The pump will not receive sensor glucose readings. Control-IQ technology will continue to adjust basal rates and deliver automatic correction boluses for the first 20 minutes that the transmitter and pump are out of range. Control-IQ technology will resume automated insulin dosing once the transmitter and pump are back within range.
	How will the System notify me?	1 vibrate, then vibration/beep every 5 minutes until the transmitter and pump are back in range.
	Will the System re-notify me?	Yes, if the transmitter and pump remain out of range.
	How should I respond?	Tap  to confirm and move the transmitter and pump closer together, or remove the obstruction between them.

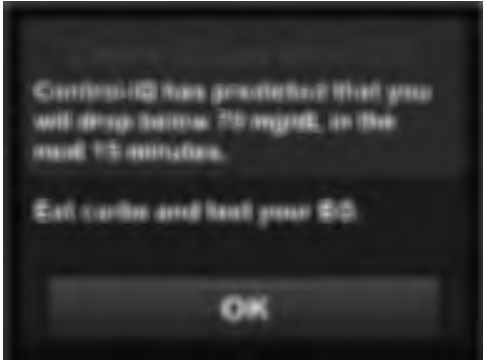
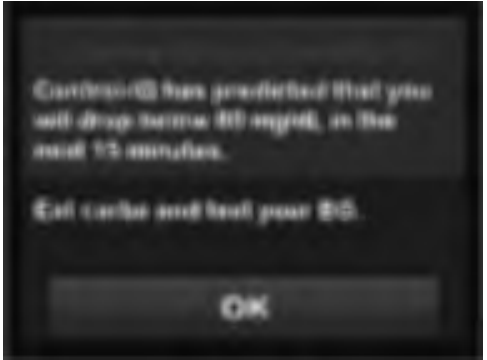
⚠ WARNING

Control-IQ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate settings in your active Personal Profile.

📌 NOTE

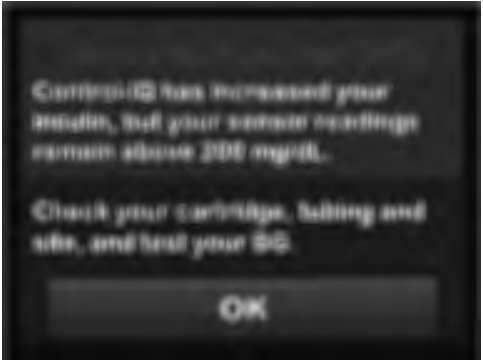
It is recommended that you keep the Out of Range Alert turned on and set to 20 minutes. If your pump and CGM are not connected for 20 minutes, Control-IQ technology will not work. Control-IQ technology will begin working immediately when the transmitter and pump are back within range.

32.3 Control-IQ Technology Low Alert

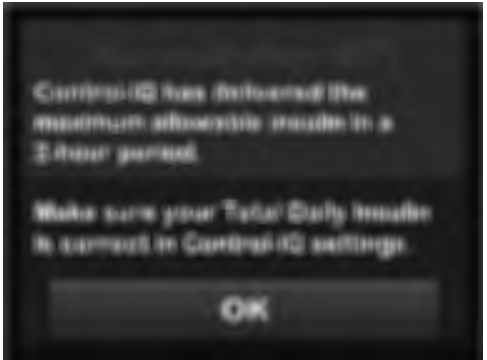
Screen	Explanation	
What will I see on the screen?  	What does it mean?	Control-IQ Low Alert has predicted that your sensor glucose reading will drop below 70 mg/dL, or below 80 mg/dL if Exercise is enabled, in the next 15 minutes.
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes until acknowledged.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Eat carbs and test your BG. Tap  to close the alert screen.

CHAPTER 32 • Control-IQ Technology Alerts

32.4 Control-IQ High Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Control-IQ technology has three hours of CGM data available and has increased insulin delivery, but detects a sensor glucose reading above 200 mg/dL and does not predict that the sensor glucose reading will decrease in the next 30 minutes.
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes until acknowledged.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged, and then every 2 hours if the issue still persists.
	How should I respond?	Check your cartridge, tubing, and site, and test your BG. Treat your high sensor glucose as necessary. Tap  to close the alert screen.

32.5 Max Insulin Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The pump has delivered the maximum allowable 2 hour insulin amount based on your Total Daily Insulin setting. You see this alert when Control-IQ technology has delivered 50% of your Total Daily Insulin (through basal and/or bolus deliveries) over the previous rolling 2 hour window, and detects this condition for 20 minutes in a row. Control-IQ technology will suspend insulin delivery for a minimum of 5 minutes, and then resume insulin delivery once the condition is no longer detected.
	How will the System notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes until acknowledged.
	Will the System re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap .

This Page is Intentionally Left Blank

4 Control-IQ Technology Features

CHAPTER 33

Overview of Control-IQ Technology Clinical Studies

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.1 Introduction

The following data represents the clinical performance of the t:slim X2™ insulin pump with Control-IQ™ technology in multiple studies.

The first pivotal study (DCLP3) included participants ≥ 14 years old. A second pivotal study (DCLP5) included participants 6 years to 13 years old. A third pivotal study (PEDAP) included participants 2 years to < 6 years old. These three studies used the original version of Control-IQ technology (Control-IQ 1.0) and were all randomized control trials (RCTs).

Two more pivotal trials were subsequently performed. The PEDAP trial was extended for a 3-month extension phase where all participants used the study device. High insulin use was evaluated in the Higher-IQ trial, a single arm study. These two studies used an updated version of Control-IQ technology (Control-IQ 1.5).

All participants in all of these studies used the Dexcom G6 CGM.

Control-IQ technology has not been evaluated in children under 2 years of age. The safety and/or effectiveness of Control-IQ technology in children under 2 years of age is unknown.

33.2 Software Version History

Control-IQ 1.5 introduced changes to allow for a wider range of weight and total daily insulin (TDI) input. Other changes were implemented and are outlined in the table below.

Parameter	Control-IQ 1.0	Control-IQ 1.5
Minimum Total Daily Insulin Entry	10 units	5 units
Maximum Total Daily Insulin Entry	100 units	200 units
Minimum Weight Entry	55 pounds	20 pounds
Maximum Weight Entry	308 pounds	440 pounds
Correction Factor Range Accepted by Algorithm	1:10 to 1:200	1:10 to 1:600
Maximum Extended Bolus Duration	2 hours	8 hours
Temporary Basal Rates with Closed-Loop Active	No	Yes
Basal Rate Clipping*	Yes	No
<i>*Limited to 3 units/hour when delivering programmed basal rate</i>		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.3 The DCLP3 Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 6 months under normal conditions in adults and adolescents 14 years of age or older. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to the use of sensor augmented pump (SAP) therapy alone (the control arm), labeled as Control-IQ and SAP in the tables in this section.

168 participants were randomly assigned to use Control-IQ technology or SAP for the study in a 2:1 ratio. The Control-IQ technology arm included 112 participants and the SAP arm included 56 participants. All 168 participants completed the trial.

Baseline characteristics of study participants are provided in this section. The study population consisted of patients with a clinical diagnosis of type 1 diabetes, 14 to 71 years of age, treated with insulin via an insulin pump or injections for at least one year.

Females known to be pregnant were not included.

The summary statistics presented for the DCLP3 describe the primary outcome measure of the sensor glucose time in range between 70-180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study is not designed to determine difference in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm used the original Control-IQ algorithm (Control-IQ 1.0).

The primary outcome sensor time in range 70-180 mg/dL showed a mean adjusted difference 11% improvement with Control-IQ technology use compared to the control arm.

There was one episode of Diabetic Ketoacidosis (DKA), caused by infusion site failure in the Control-IQ arm. There were no severe hypoglycemic events in the DCLP3 with Control-IQ technology use. No other serious adverse events related to the device were reported.

DCLP3: Baseline Characteristics including Demographics at Enrollment (N=168)

Characteristic		Control-IQ (n=112)	SAP (n=56)
Age (years)			
	Mean $\pm$ SD	33 $\pm$ 16	33 $\pm$ 17
	Range	14 to 71	14 to 63
	<18 years	31 (28%)	17 (30%)
	$\geq$ 18 years	81 (72%)	39 (70%)
Sex – Female n (%)		54 (48%)	30 (54%)
Race / Ethnicity*			
	White non-Hispanic	94 (86%)	53 (95%)
	Black / African American	4 (4%)	0 (0%)
	Asian	3 (3%)	2 (4%)
	Native Hawaiian / Other Pacific Islander	1 (<1%)	0 (0%)
	More than one race	7 (6%)	1 (2%)
Income [†]			
	<\$50,000	10 (11%)	2 (4%)
	\$50,000 – <\$100,000	24 (27%)	18 (36%)
	$\geq$ \$100,000	55 (62%)	30 (60%)
Education [‡]			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

DCLP3: Baseline Characteristics including Demographics at Enrollment (N=168) (Continued)

Characteristic		Control-IQ (n=112)	SAP (n=56)
	≤High School Diploma	3 (3%)	6 (11%)
	Associates Degree or Some College	13 (12%)	7 (13%)
	Bachelor's Degree	51 (46%)	21 (38%)
	Master's Degree	32 (28%)	17 (30%)
	Doctoral or Professional Degree	13 (12%)	5 (9%)
Health Insurance [§]			
	Private	102 (94%)	50 (91%)
	CHP or another government / Medicaid	5 (5%)	5 (9%)
	None	2 (2%)	0 (0%)
*Three subjects in the Control-IQ technology arm did not provide race information. †Twenty-three subjects in the Control-IQ technology arm and 6 in SAP arm did not provide income information. ‡Highest level completed by the subject, or the primary caregiver if the participant was <18 years old. One subject in the Control-IQ technology arm did not provide education information. §Three subjects in the Control-IQ technology arm and one in the SAP arm did not provide insurance information.			

Adverse Effects

The following tables provide a full list of adverse events that occurred during the main part of the DCLP3 study:

DCLP3: Types of Adverse Events by Treatment Arm (N=168)

		Number of Events	
		Control-IQ (n=112)	SAP (n=56)
Total Number of Adverse Events		13	3
Adverse Events Related to Study Device			
	Ketosis (Infusion Site Failure)	3	0
	Hyperglycemia (Infusion Site Failure)	4	2
	Hyperglycemia (Defected Cartridge)	1	0
	Diabetic Ketoacidosis (Infusion Set Failure)	1	0
Adverse Effects Not Related to a Study Device			
	Hyperglycemia (User Error)	3	0
	Hyperglycemia (Respiratory Infection)	0	1
	Coronary Bypass Surgery	1	0
	Otitis Externa	1	0
	Concussion	1	0

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Adverse Effects

The following table provides a list of only hyperglycemia or ketosis events during the DCLP3 study:

DCLP3: Hyperglycemia/Ketosis Events by Treatment Arm (N=168)

	Number of Events	
	Control-IQ (n=112)	SAP (n=56)
Ketosis (Infusion Site Failure)	3	0
Hyperglycemia (Infusion Site Failure)	4	2
Hyperglycemia (Defected Cartridge)	1	0
Diabetic Ketoacidosis (Infusion Set Failure)	1	0
Hyperglycemia (User Error)*	3	0
Hyperglycemia (Respiratory Infection)	0	1
<i>*Discontinued pump, forgot to replace</i>		

Intervention Compliance

The following table provides an overview of how often the t:slimX2 insulin pump with Control-IQ technology was used in the Control-IQ arm:

DCLP3: Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over the 6-Month Period (n=112)

	Average Pump Use*	Average Time Control-IQ Available**
Weeks 1–4	100%	91%
Weeks 5–8	99%	91%
Weeks 9–12	100%	91%
Weeks 12–16	99%	91%
Weeks 17–20	99%	91%
Weeks 21–End	99%	82%
Overall	99%	89%
*The denominator is the total possible time within the 6-month study period. **Control-IQ Available is calculated as the percent of time when Control-IQ technology was available and operating normally during the 6-month study period.		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Primary Analysis

The primary outcome of the DCLP3 was to compare the CGM sensor values in range between 70 - 180 mg/dL between the Control-IQ technology and the SAP arms. The data represent the overall system performance 24-hours per day.

DCLP3: Comparison of CGM Values Between Control-IQ and SAP Users (N=168)

Characteristic	Control-IQ	SAP	Difference Between Study Arm and Control Arm
Average Sensor Glucose (std dev)	156 mg/dL (19 mg/dL)	170 mg/dL (25 mg/dL)	-14 mg/dL
Average % 70–180 mg/dL (std dev)	71.4% (11.7%)	59.2% (14.6%)	+11%
Average % >180 mg/dL (std dev)	27% (12%)	38.5% (15.2%)	-10%
Average % <70 mg/dL (std dev)	1.59% (1.15%)	2.25% (1.46%)	-0.88%
Average % <54 mg/dL (std dev)	0.29% (0.29%)	0.35% (0.32%)	-0.10%

The following table describes the average time participants in both the Control-IQ technology arm and the SAP arm spent with sensor glucose levels between 70 - 180 mg/dL by month at baseline and during the study period:

DCLP3: Percentage of Time in Range per Study Arm by Month (N=168)

Month	Control-IQ	SAP
Baseline	61%	59%
Month 1	73%	62%
Month 2	72%	60%
Month 3	71%	60%
Month 4	72%	58%
Month 5	71%	58%
Month 6	70%	58%

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Secondary Analysis

The following table shows secondary analysis comparing the percent of time that participants spent at the indicated sensor glucose levels during the daytime and nighttime for the DCLP3:

DCLP3: Secondary Analysis by Time of Day (N=168)

Characteristic	Unit of Measure	Daytime		Nighttime	
		Control-IQ	SAP	Control-IQ	SAP
Overall Sensor Glucose Control	Average Sensor Glucose (std dev)	158 mg/dL (20 mg/dL)	170 mg/dL (26 mg/dL)	150 mg/dL (18 mg/dL)	170 mg/dL (27 mg/dL)
	Average % Sensor Glucose 70 – 180 mg/dL (std dev)	69.8% (12.4%)	59.4% (14.6%)	76.1% (12.4%)	58.5% (16.2%)

The following table compares the percent of time spent between 70 - 180 mg/dL across the different baseline HbA1c values observed in the DCLP3 study in both treatment arms:

Percentage of Time in Range per Study Arm by Baseline HbA1c (N=168)

Baseline HbA1c	Time in Range	
	Control-IQ	SAP
≤6.5	85%	78%
6.6–7.0	76%	69%
7.1–7.5	71%	49%
7.6–8.0	69%	56%
≥8.1	60%	47%

The following table compares the average HbA1c values for all DCLP3 participants at baseline, after 13 weeks, and after 26 weeks. There was a relative difference of -0.33% between the Control-IQ arm and the SAP arm:

Comparison of HbA1c Values (N=168)

Time Period	Control-IQ	SAP
Baseline	7.40	7.40
After 13 Weeks	7.02	7.36
After 26 Weeks	7.06	7.39

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

The following table compares the change in HbA1c values for participants over the course of the DCLP3:

DCLP3: Change in HbA1c Values from Randomization to 26 Weeks (N=168)

			Number of Subjects (% of Subjects) with Change in HbA1c									
			Decrease >1%		Decrease 0 to 1%		No Change		Increase 0 to 1%		Increase >1%	
			n	%	n	%	n	%	n	%	n	%
Baseline Central Lab HbA1c		n										
5% ≤ HbA1c < 6%	Treatment	8	0	0%	1	13%	0	0%	7	88%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%
6% ≤ HbA1c < 7%	Treatment	30	0	0%	18	60%	3	10%	9	30%	0	0%
	Control	19	0	0%	10	53%	0	0%	9	47%	0	0%
7% ≤ HbA1c < 8%	Treatment	45	4	9%	33	73%	2	4%	5	11%	1	2%
	Control	22	0	0%	11	50%	1	5%	8	36%	2	9%
8% ≤ HbA1c < 9%	Treatment	22	5	23%	15	68%	1	5%	1	5%	0	0%
	Control	13	0	0%	8	62%	0	0%	4	31%	1	8%
9% ≤ HbA1c < 10%	Treatment	4	1	25%	2	50%	0	0%	1	25%	0	0%
	Control	1	0	0%	0	0%	0	0%	1	100%	0	0%
HbA1c ≥ 10%	Treatment	2	2	100%	0	0%	0	0%	0	0%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%

DCLP3: Change in HbA1c Values from Randomization to 26 Weeks (N=168) (Continued)

			Number of Subjects (% of Subjects) with Change in HbA1c									
Overall	Treatment	111	12	11%	69	62%	6	5%	23	21%	1	<1%
	Control	55	0	0%	29	53%	1	2%	22	40%	3	5%

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.4 The DCLP5 Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in children age 6 to 13 years of age. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to the use of SAP therapy alone (the control group).

The study design was very similar to DCLP3. In DCLP5, participants (N=101) were randomly assigned to Control-IQ or SAP in a 3:1 ratio. In this study, the Control-IQ arm included 78 participants. Like the DCLP3, this study population had a clinical diagnosis of type 1 diabetes. Unlike the DCLP3, the DCLP5 had participants 6 to 13 years of age. They were treated with insulin via an insulin pump or injections for at least one year. They weighed ≥ 25 kilograms and ≤ 140 kilograms and took at least 10 units of insulin a day. Females known to be pregnant were not included. Participants were required to be living with at least one parent or guardian knowledgeable about

diabetes and managing diabetes-related emergencies and willing to participate in all training sessions.

No participants were enrolled in the DCLP5 study who had inpatient psychiatric treatment in the past 6 months, the presence of a known adrenal disorder, untreated thyroid disease, cystic fibrosis, severe infectious process not anticipated to resolve prior to study procedures (e.g. meningitis, pneumonia, osteomyelitis), any skin condition in the area of insertion that prevents safe sensor or pump placement (e.g. bad sunburn, pre-existing dermatitis, intertrigo, psoriasis, extensive scarring, cellulitis), abnormal liver function tests (transaminase >3 times the upper limit of normal), or abnormal renal function test results (estimated glomerular filtration rate [GFR] <60 mL/minute/1.7m²). Participants were also excluded for use of any medication, any carcinogenic disease, or other significant medical disorder if that injury, medication, or disease in the judgment of the investigator would affect the completion of the protocol.

The summary statistics presented for the DCLP5 describe the primary outcome measure of the sensor glucose time in range between 70-180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study is not designed to determine difference in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm use the original Control-IQ algorithm (Control-IQ 1.0).

There were no episodes of DKA in the DCLP5. There were no severe hypoglycemic events in the DCLP5 with Control-IQ technology use. No other serious adverse events related to the device were reported.

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
Age (years)			
	6 – 9	21 (27%)	8 (35%)
	10 – 13	57 (73%)	15 (65%)
	Median (IQR)	11 (9, 12)	10 (8, 13)
	Range	6 to 13	6 to 13
Sex – Female n (%)		38 (49%)	12 (52%)
Race / Ethnicity			
	White non-Hispanic	64 (82%)	18 (78%)
	Hispanic or Latino	6 (8%)	2 (9%)
	Black / African American	0 (0%)	0 (0%)
	Asian	1 (1%)	1 (4%)
	More than one race	7 (9%)	2 (9%)
Annual Household Income			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101) (Continued)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
	<\$25,000	0 (0%)	0 (0%)
	\$25,000 – <\$35,000	2 (3%)	0 (0%)
	\$35,000 – <\$50,000	1 (1%)	2 (10%)
	\$50,000 – <\$75,000	5 (7%)	0 (0%)
	\$75,000 – <\$100,000	13 (18%)	4 (19%)
	\$100,000 – <\$200,000	27 (36%)	8 (38%)
	≥\$200,000	26 (35%)	7 (33%)
Parent Education			
	≤High School Diploma	2 (3%)	0 (0%)
	Associates Degree or Some College	5 (6%)	1 (4%)
	Bachelor's Degree	32 (41%)	9 (39%)
	Master's Degree	34 (44%)	11 (48%)
	Doctoral or Professional Degree	5 (6%)	2 (9%)
Health Insurance			

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101) (Continued)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
	Private	70 (90%)	21 (91%)
	CHP or another government / Medicaid	6 (8%)	1 (4%)
	Military	2 (3%)	1 (4%)
	Other	0 (0%)	0 (0%)
	None	0 (0%)	0 (0%)
*Missing data (CLC/SAP): annual household income 4 (5%)/2 (9%), total daily insulin 1 (1%)/0 (0%). All other variables have no missing data.			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Adverse Effects

The following tables provide a full list of adverse events that occurred during the main part of the DCLP5 study:

DCLP5: Types of Adverse Events by Treatment Arm (N=101)

		Number of Events	
		Control-IQ (n=78)	SAP (n=23)
Total Number of Adverse Events		16	3
Adverse Events Related to Study Device			
	Ketosis (Infusion Site Failure)	8	0
	Abscess at Sensor Site (CGM Sensor)	0	2
	Hyperglycemia (Defected Cartridge)	1	0
Adverse Effects Not Related to a Study Device			
	Hypoglycemia (User Error)	1	0
	Ketosis (User Error)	2	1
	Ketosis (Gastroenteritis)	1	0
	Hyperglycemia (User Error)	2	0
	Accidental Over-Delivery of Insulin (User Error)*	1	0
*One subject primed tubing while connected to body. This was a serious adverse event, requiring treatment in the emergency room for hypoglycemia prevention.			

The following table provides a list of only hyperglycemia or ketosis events during the DCLP5 study:

DCLP5: Hyperglycemia/Ketosis Events by Treatment Arm (N=101)

	Number of Events	
	Control-IQ (n=78)	SAP (n=23)
Ketosis (Infusion Site Failure)	8	0
Hyperglycemia (Defected Cartridge)	1	0
Ketosis (User Error)*	2	1
Ketosis (Gastroenteritis)	1	0
Hyperglycemia (User Error) [†]	2	0
<i>*Improper cartridge fill</i> <i>[†]Failed to recharge pump battery</i>		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used in the Control-IQ arm:

DCLP5: Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over the 4-Month Period (n=78)

	Average Time Control-IQ Available*
Weeks 1–4	93.4%
Weeks 5–8	93.8%
Weeks 9–12	94.1%
Weeks 13–End	94.4%
Overall	92.8%
*Control-IQ Available is calculated as the percent of time when Control-IQ technology was available and operating normally during the 4-month study period.	

Primary Analysis

The primary outcome of the DCLP5 was to compare the CGM sensor values in range between 70 - 180 mg/dL between the Control-IQ technology arms and the SAP arms. The data represent the overall system performance 24 hours per day.

DCLP5: Comparison of CGM Values Between Control-IQ and SAP Users (N=101)

Characteristic	Control-IQ	SAP	Difference Between Study Arm and Control Arm
Average Sensor Glucose (std dev)	162 mg/dL (18 mg/dL)	179 mg/dL (26 mg/dL)	-17 mg/dL
Average % 70–180 mg/dL (std dev)	67% (10%)	55% (13%)	+11%
Average % >180 mg/dL (std dev)	31% (10%)	43% (14%)	-10%
Average % <70 mg/dL (std dev)	1.8% (1.38%)	2.1% (1.18%)	-0.40%
Average % <54 mg/dL (std dev)	0.34% (0.35%)	0.38% (0.35%)	-0.07%

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

The following table describes the average time participants in both the Control-IQ technology arm and the SAP arm spent with sensor glucose levels between 70 - 180 mg/dL by month at baseline and during the study period.

DCLP5: Percentage of Time in Range per Study Arm by Month (N=101)

Month	Control-IQ	SAP
Baseline	53%	51%
Month 1	68%	56%
Month 2	68%	54%
Month 3	67%	56%
Month 4	66%	55%

Secondary Analysis

Secondary analysis comparing the percent of time that participants spent at the indicated sensor glucose levels during the daytime and nighttime for the DCLP5 are shown below:

DCLP5: Secondary Analysis by Time of Day (N=101)

Characteristic	Unit of Measure	Daytime		Nighttime	
		Control-IQ	SAP	Control-IQ	SAP
Overall Sensor Glucose Control	Average Sensor Glucose (std dev)	167 mg/dL (21 mg/dL)	179 mg/dL (27 mg/dL)	146 mg/dL (16 mg/dL)	180 mg/dL (27 mg/dL)
	Average % Sensor Glucose 70 – 180 mg/dL (std dev)	63% (11%)	56% (14%)	80% (9%)	54% (16%)

The following table compares the change in HbA1c values for participants over the course of the DCLP5:

DCLP5: Change in HbA1c Values from Randomization to 16 Weeks (N=101)

			Number of Subjects (% of Subjects) with Change in HbA1c									
			Decrease >1%		Decrease 0 to 1%		No Change		Increase 0 to 1%		Increase >1%	
			n	%	n	%	n	%	n	%	n	%
Baseline Central Lab HbA1c		n										
5% ≤ HbA1c < 6%	Treatment	3	0	0%	0	0%	2	67%	1	33%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

DCLP5: Change in HbA1c Values from Randomization to 16 Weeks (N=101) (Continued)

			Number of Subjects (% of Subjects) with Change in HbA1c									
6% ≤ HbA1c < 7%	Treatment	18	0	0%	9	50%	1	6%	8	44%	0	0%
	Control	3	0	0%	1	33%	0	0%	2	67%	0	0%
7% ≤ HbA1c < 8%	Treatment	28	3	11%	20	71%	0	0%	5	18%	0	0%
	Control	8	0	0%	5	63%	0	0%	2	25%	1	13%
8% ≤ HbA1c < 9%	Treatment	20	11	55%	9	45%	0	0%	0	0%	0	0%
	Control	10	0	0%	7	70%	0	0%	3	30%	0	0%
9% ≤ HbA1c < 10%	Treatment	7	5	71%	1	14%	0	0%	1	14%	0	0%
	Control	1	0	0%	1	100%	0	0%	0	0%	0	0%
HbA1c ≥ 10%	Treatment	1	0	0%	1	100%	0	0%	0	0%	0	0%
	Control	1	0	0%	1	100%	0	0%	0	0%	0	0%
Overall	Treatment	77	19	25%	40	52%	3	4%	15	19%	0	0%
	Control	23	0	0%	15	65%	0	0%	7	30%	1	4%

33.5 The PEDAP Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 4 months under normal conditions in preschoolers 2 to <6 years of age. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to Standard Care (SC, the control group), which included SAP therapy and multiple daily injection (MDI) therapy.

The study design was otherwise very similar to DCLP3 and DCLP5. In PEDAP, participants (N=102) were randomly assigned to Control-IQ or SC in a 2:1 ratio.

In this study, the Control-IQ arm included 69 participants, and the SC arm included 34 participants. The study population was similar to the DCLP5 in that the participants had a clinical diagnosis of type 1 diabetes, but they were younger, 2 to 5 years of age. They were treated with insulin via an insulin pump or injections for at least 6 months. They weighed at least 20

pounds (9 kilograms) and took at least 5 unites of insulin per day.

Participants were required to be living with at least one parent or guardian knowledgeable about diabetes and managing diabetes-related emergencies and willing to participate in all training sessions. No participants were enrolled in the PEDAP study who had a history of adrenal insufficiency, untreated thyroid disease, use of oral or injectable steroids within the last 8 weeks, history of chronic renal disease or currently on hemodialysis, hemophilia or any other bleeding disorder, history of >1 severe hypoglycemic event with seizure or loss of consciousness in the last 3 months, history of >1 DKA event in the last 6 months not related to illness, infusion set failure, or initial diagnosis, known ongoing adhesive intolerance, or condition, which in the opinion of the investigator or designee, would put the participant or study at risk. Concurrent use of any non-insulin glucose lowering agent (including GLP-1 agonists, Symlin, DPP-4 inhibitors, and sulfonylureas) was not allowed.

The summary statistics presented for the PEDAP describe the primary outcome measure of the sensor glucose time in range between 70 - 180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study was not designed to determine differences in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow lower weight and total daily insulin dose entry.

The primary outcome sensor time in range 70 - 180 mg/dL showed a mean adjusted difference 12.4% improvement with Control-IQ technology use of the SAP arm, very

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

similar to that seen in the DCLP3 and DCLP5.

There was one episode of DKA, caused by infusion site failure, in the PEDAP Control-IQ arm. There were two cases of severe hypoglycemia in the Control-IQ technology arm and one case in the SC arm. No other serious adverse events related to the device were reported.

Baseline Characteristics

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
Age (years)				
	Mean $\pm$ SD	3.94 $\pm$ 1.24	3.84 (1.23)	4.06 (1.25)
	Range	2.00 to 5.98	2.00 to 5.98	2.02 to 5.90
	2 to <4	47 (46%)	31 (46%)	16 (47%)
	4 to <6	55 (54%)	37 (54%)	18 (53%)
Weight (kg)				
	Mean (SD)	17.7 (4.2)	17.7 (4.7)	17.7 (3.3)
	Range	11.1 to 44.7	11.1 to 44.7	11.8 to 23.9
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase				
	Median (IQR)	0.66 (0.54, 0.79)	0.66 (0.55, 0.77)	0.66 (0.51, 0.80)
	Range	0.26 to 2.12	0.26 to 2.12	0.31 to 1.64
Sex – Female n (%)		52 (51%)	33 (49%)	19 (56%)
Race / Ethnicity				

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102) (Continued)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
	White non-Hispanic	75 (74%)	50 (74%)	25 (74%)
	Black / African American	6 (6%)	4 (6%)	2 (6%)
	Asian	2 (2%)	1 (1%)	1 (3%)
	More than one race	3 (3%)	2 (3%)	1 (3%)
Income*				
	<\$50,000	14 (14%)	8 (12%)	6 (19%)
	\$50,000 – <\$100,000	31 (33%)	19 (30%)	12 (38%)
	≥\$100,000	51 (53%)	37 (57%)	14 (44%)
Parent Education				
	≤High School Diploma	9 (9%)	6 (9%)	3 (9%)
	Technical/Vocational	3 (3%)	2 (3%)	1 (3%)
	Associate Degree	11 (11%)	6 (9%)	5 (15%)
	College Graduate (Bachelor's or higher)	35 (34%)	22 (32%)	13 (38%)
	Advanced Degree (Masters, PhD, MD, etc.)	44 (43%)	32 (47%)	12 (35%)
Health Insurance				

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102) (Continued)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
	Private [‡]	78 (77%)	52 (76%)	26 (79%)
	CHP or another government / Medicaid [†]	22 (24%)	15 (22%)	7 (21%)
	None	1 (<1%)	1 (1%)	0 (0%)
*Missing data (CLC/SC): Health insurance 0/1, annual household income 4/2, BMI percentile 2/0, HbA1c 4/2. All other variables have no missing data. [†]For participants with Private Insurance, 7 participants also had Medicaid, 1 participant also had Medicare, and 1 participant also had other government insurance. [‡]For participants with Medicaid, 1 participant also had other government insurance.				

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Adverse Effects

The following table provides a full list of adverse events that occurred during the main part of the PEDAP study.

PEDAP: Types of Adverse Events by Treatment Arm (N=102)

		Number of Events	
		Control-IQ (n=68)	SC (n=34)
Total Number of Adverse Events		71	14
Severe Hypoglycemic (SH) Events*		2	1
Diabetic Ketoacidosis (DKA) Events [†]		1	0
Other Serious Adverse Events [†] (SAEs)		0	1
Other Adverse Events <i>N Events/N Participants</i>		68/40	12/9
	Hyperglycemia with or without Ketosis Related to Study Device	39/26	0
	Hyperglycemia with or without Ketosis Not Related to Study Device	12/9	8/7
	Hypoglycemia (not severe)	2/2	0/0
	Burn	1/1	0/0

PEDAP: Types of Adverse Events by Treatment Arm (N=102) (Continued)

		Number of Events	
		Control-IQ (n=68)	SC (n=34)
	COVID-19	3/3	0/0
	Fall	1/1	0/0
	Fractured Finger	1/1	0/0
	Gastroenteritis	2/2	2/2
	Hematuria	1/1	0/0
	Medical Device Site Bleeding	1/1	0/0
	Skin Infection	3/2	0/0
	Streptococcal Sore Throat	1/1	0/0
	Upper Respiratory Infection	1/1	0/0
	Vomiting	0/0	2/1
<i>*A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.</i> <i>†DKA events meeting DCCT criteria.</i> <i>‡One participant in the SC group was hospitalized for an asthma flare.</i>			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the PEDAP trial in the intervention arm.

PEDAP Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over 13-week Period (n=68)

	Average Time Control-IQ In Use*
Weeks 1–4	92%
Weeks 5–8	95% (n=67)
Weeks 9–13	95% (n=67)
Overall	94%
*The denominator is the number of days between the beginning of the fourth day after randomization and the end of the day before the 13-week visit, or the end of the day before the last contact date for the participant who dropped out.	

Primary Analysis

The primary outcome of PEDAP was to compare the CGM sensor values in range between 70 - 180 mg/dL between the Control-IQ technology arm and the SC arm. The data represent the overall system performance 24 hours per day.

PEDAP: Percent Time in Range: Primary Endpoint Tested for Superiority (N=101)

Time and Change	Control-IQ (n=67)	SC (n=34)
Baseline	57% (18)	55% (15)
13 Weeks	69% (11) (n=68)	56% (13)
Change from Baseline mean (SD)	12.5% (11.8)	1.0% (6.6)
13 week Adjusted Group Difference (95% CI) [p-value]	12.4% (9.5, 15.3) [<0.001]	

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Secondary Analysis

Change in HbA1c values to baseline subgroups follows:

PEDAP: Change in HbA1c Values to Baseline Subgroups (Treatment n=59, Control n=31)

		N	Baseline mean (SD)	Change from Baseline Mean (SD)
Baseline HbA1c				
<7.0%	Treatment	21	6.4 (0.5)	-0.08 (0.33)
	Control	8	6.5 (0.3)	-0.18 (0.37)
7% ≤ HbA1c < 8%	Treatment	19	7.5 (0.3)	-0.51 (0.34)
	Control	8	7.4 (0.2)	-0.01 (0.36)
HbA1c ≥ 8%	Treatment	19	8.9 (0.9)	-1.22 (0.81)
	Control	15	8.5 (0.4)	-0.31 (0.40)
Overall	Treatment	59	8.9 (0.9)	-1.22 (0.81)
	Control	15	8.5 (0.4)	-0.31 (0.40)

33.6 The PEDAP Extension Phase

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in preschoolers 2 to <6 years of age. The PEDAP extension phase allowed participants in the preceding PEDAP RCT to continue in the trial for an additional 13 weeks during an Extension Phase (N=96), with all participants using Control-IQ use for 3 more months. A subset of participants also performed meal and exercise challenges during the study.

Participants used either Closed-Loop Control (CLC) for the RCT and the extension phase of the study (CLC-CLC), or used Standard Care (SC) for the RCT arm of the study, then switched to CLC during the extension phase (SC-CLC).

Participants in the CLC-CLC arm (N=63, those who continued with Control-IQ) were compared to the SC-CLC group (who were in the standard care arm for the RCT, who

then switched to Control-IQ for the extension, N=33).

The summary statistics presented for the PEDAP Extension Phase describe key CGM outcomes, as well as analysis of secondary endpoints.

All participants in the PEDAP extension phase used the updated Control-IQ algorithm (Control-IQ 1.5).

Key CGM outcomes showed, in the CLC-CLC group, time in range 70 - 180 mg/dL increased from 57% at PEDAP RCT baseline to 70% at the end of the 13-week RCT, and this was sustained during the Extension Phase at 70%, with no significant change comparing the CLC use in the RCT phase to CLC use in the Extension Phase.

In the SC-CLC group, time in range 70 - 180 mg/dL was 55% at the PEDAP RCT baseline, 56% during the RCT, and 68% during the Extension Phase. Comparing standard care from the RCT with use of CLC in the extension, the mean difference in time in range 70 -180 mg/dL was 11.8%.

There were two cases of severe hypoglycemia in the 63 participants in the CLC-CLC group (3%) unrelated to the study device, and no cases among the 33 participants in the SC-CLC group. No cases of DKA were reported. No other serious adverse events related to the device were reported.

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Baseline Characteristics

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
Age at Beginning of Extension Phase (years)				
	Mean (SD)	4.17 (1.23)	4.10 (1.23)	4.32 (1.23)
	Range	2.30 to 6.33	2.33 to 6.33	2.35 to 6.22
	2 to <4	44 (46%)	29 (46%)	15 (45%)
	4 to <6	44 (46%)	31 (49%)	13 (39%)
	6 to <7	8 (8%)	3 (5%)	5 (15%)
Sex – Female n (%)		51 (53%)	32 (51%)	19 (58%)
Weight (kg)				
	Mean (SD)	18.5 (4.4)	18.7 (4.9)	18.2 (3.3)
	Range	12.2 to 47.2	12.7 to 47.2	12.2 to 24.4
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase				
	Median (IQR)	0.69 (0.59, 0.82)	0.69 (0.59, 0.80)	0.69 (0.55, 0.94)
	Range	0.42 to 1.70	0.42 to 1.70	0.44 to 1.38
Race / Ethnicity				

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96) (Continued)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
	White non-Hispanic	81 (84%)	53 (85%)	28 (85%)
	Black / African American	5 (5%)	3 (5%)	2 (6%)
	Asian	2 (2%)	1 (2%)	1 (3%)
	More than one race	8 (8%)	6 (10%)	2 (6%)
Hispanic Ethnicity		14 (15%)	9 (14%)	5 (15%)
Income at RCT Baseline*				
	<\$50,000	13 (14%)	7 (11%)	6 (19%)
	\$50,000 to \$100,000	31 (34%)	19 (33%)	12 (39%)
	>\$100,000	46 (51%)	33 (56%)	13 (42%)
Parent Education at RCT Baseline				
	High School graduate/diploma/GED	7 (7%)	4 (6%)	3 (9%)
	Technical/Vocational	3 (3%)	2 (3%)	1 (3%)
	Associate Degree	11 (11%)	6 (10%)	5 (15%)
	College Graduate (Bachelor's or equivalent)	34 (35%)	22 (35%)	12 (36%)
	Advanced Degree (Masters, PhD, MD, etc.)	41 (43%)	29 (46%)	12 (36%)
Health Insurance at RCT Baseline*				

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96) (Continued)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
	Private [‡]	74 (78%)	49 (78%)	25 (78%)
	Medicare / Medicaid [†]	13 (14%)	9 (14%)	4 (12%)
	Other Government Insurance	8 (8%)	5 (8%)	3 (9%)
<i>*Missing data (CLC-CLC/SC-CLC): Health insurance 0/1, annual household income 4/2. All other variables have no missing data.</i> <i>[†].For participants with Private Insurance, 6 participants also had Medicaid, 1 participant also had Medicare, and 1 participant also had other government insurance.</i> <i>[‡].For participants with Medicaid, 1 participant also had other government insurance.</i>				

Adverse Effects

The following table provides a full list of adverse events that occurred during the PEDAP extension phase. There were no DKA events:

Summary of Adverse Events During PEDAP Extension Phase (N=96)

		Number of Events	
		CLC-CLC (n=63)	SC-CLC (n=33)
Total Number of Adverse Events		46	29
Severe Hypoglycemic (SH) Events* <i>N Events/N Participants</i>		2/2	0/0
Other Serious Adverse Events [†] (SAEs) <i>N Events/N Participants</i>		1/1	0/0
Other Adverse Events <i>N Events/N Participants</i>		43/34	29/16
	Hyperglycemia with or without Ketosis Related to Study Device	20/18	8/8
	Hyperglycemia with or without Ketosis Not Related to Study Device	10/8	12/4
	Hypoglycemia (not severe)	1/1	0/0
	Allergy NOS	1/1	0/0

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Summary of Adverse Events During PEDAP Extension Phase (N=96) (Continued)

		Number of Events	
		CLC-CLC (n=63)	SC-CLC (n=33)
	Cellulitis	0/0	1/1
	COVID-19	3/3	0/0
	Fever	0/0	1/1
	Gastroenteritis	2/2	2/2
	Head Injury	0/0	1/1
	Influenza	1/1	0/0
	Laceration	0/0	1/1
	Pneumonia	1/1	0/0
	Skin Infection	1/1	2/2
	Upper Respiratory Infection	1/1	0/0
	Viral Syndrome	1/1	0/0
	Vomiting	1/1	1/1
*A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions. † One participant in the CLC-CLC group was hospitalized for muscle pain			

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the PEDAP extension phase. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ 1.5).

PEDAP Extension Phase Median Percentage of Time of Closed-Loop System Use

	CLC-CLC	SC-CLC
Weeks 1–13*	94% (n=63)	NA (n=33)
Weeks 14–17	96% (n=63)	96% (n=33)
Weeks 18–21	96% (n=62)	96% (n=32)
Weeks 22–26	96% (n=61)	96% (n=31)
Weeks 14–26**	96% (n=63)	95% (n=33)
<i>*The denominator for Weeks 1–13 is the number of days between the beginning of the fourth day after the randomization and the end of the day before the 13-week visit.</i> <i>**Denominator for Weeks 14–26 is the number of days between the beginning of the fourth day after the Extension Training visit and the end of the day before the 26-week visit, or the end of the day before the last contact date for the participants who dropped out.</i>		

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Key CGM Outcomes

Time in range 70 - 180 mg/dL for all phases of the trial is shown below. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ 1.5).

PEDAP Extension Phase: Percent Time in Range 70 - 180 mg/dL: Primary Endpoint Tested for Superiority (N=96)

Time and Change	CLC-CLC (n=63)	SC-CLC (n=33)
RCT Baseline	57% (18) n=62	55% (15)
Weeks 1-13	70% (11)	56% (13)
Weeks 14-26	70% (11)	68% (9)
26 week Adjusted Group Difference (95% CI) [p-value]*	0.1% (-1.2, 1.4) [0.86]	
*The point estimate and 95% confidence interval for the difference were calculated from a direct likelihood model. This model adjusted for the RCT baseline value of the metric, age, prior CGM and pump use, and site as a random effect. P-values and confidence intervals were adjusted to control the false discovery rate.		

Secondary Analysis

The following table shows secondary analysis of HbA1c outcomes. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ 1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ 1.5):

PEDAP Extension Phase: HbA1c Outcomes*

		N	Baseline mean (SD)
Baseline HbA1c			
RCT Baseline	CLC-CLC	59	7.6 (1.2)
	SC-CLC	32	7.7 (0.9)
Week 13	CLC-CLC	58	7.0 (0.7)
	SC-CLC	32	7.5 (0.9)
Week 26	CLC-CLC	55	7.1 (0.8)
	SC-CLC	28	7.2 (0.7)
*CLC-CLC group used closed-loop control for both the RCT and the extension phase. SC-CLC used standard care for the RCT and closed-loop control for the extension phase.			

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

33.7 The Higher-IQ Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in adults with high insulin needs.

The Higher-IQ study enrolled adults (N=34) with type 1 diabetes using at least one basal rate greater than 3 units/hour, in a single arm, prospective study of Control-IQ technology use for 13 weeks. All participants also performed meal and exercise challenges during the study.

Participants were at least 18 years of age, had type 1 diabetes for at least 1 year, were users of an insulin pump for at least 3 months, had a hemoglobin A1c 10.5% and had a weight ≤ 440 pounds.

Baseline characteristics of study participants are provided below. Participants with more than 1 episode of severe hypoglycemia or DKA in the last 6 months were not included. Females known to be pregnant were not included. Participants with

hemophilia or any other bleeding disorder, history of adrenal insufficiency, untreated thyroid disease, chronic kidney disease which could affect CGM accuracy, history of gastroparesis, or a condition, which in the opinion of the investigator or designee, would put the participant or study at risk were not included.

Treatment with sulfonylureas, meglitinides, or Symlin was not permitted. Participants taking GLP-1 receptor agonists, DPP-4 inhibitors, and/or SGLT-2 inhibitors were allowed to continue these medications if they were on a stable dose for the last 3 months,

The summary statistics presented for Higher-IQ describe key CGM outcomes, as well as analysis of change in HbA1c.

All participants in the Higher-IQ study used the updated Control-IQ algorithm (Control-IQ 1.5).

Key CGM outcomes showed time in range 70 - 180 mg/dL was 64.75% overall, with time in hypoglycemia of 1.04%.

HbA1c decreased from 7.69% at baseline to 6.87% after 13 weeks of Control-IQ use, a decrease of 0.82%.

There were no DKA or severe hypoglycemia events in the study. No other serious adverse events related to the device were reported.

Higher-IQ Baseline Characteristics Including Demographics at Enrollment (N=34)

Characteristic		Single Arm Study (N=34)		
Age (years)				
	Mean (SD)	39.9 (11.9)		
	Range	20 to 66		
Sex – Female n (%)		41.2%		
Weight (kg)				
	Mean (SD)	114.8 (17.4)		
	Range	85.1 to 169.3		
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase				
	Median (IQR)	0.69 (0.59, 0.82)	0.69 (0.59, 0.80)	0.69 (0.55, 0.94)
	Range	0.42 to 1.70	0.42 to 1.70	0.44 to 1.38
Race / Ethnicity				
	White non-Hispanic	34 (100%)		
	Black / African American	2 (5.9%)		
	Native Hawaiian or Other Pacific Islander	1 (2.9%)		
Hispanic Ethnicity		3 (8.8%)		
Highest Level of Education				

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Higher-IQ Baseline Characteristics Including Demographics at Enrollment (N=34)

Characteristic		Single Arm Study (N=34)
	Less than high school	1 (2.9%)
	High School graduate/diploma/GED	4 (11.8%)
	Some college but no degree	8 (23.5%)
	Associate Degree	3 (8.8%)
	College Graduate (Bachelor's or equivalent)	13 (38.2%)
	Advanced Degree (Masters, PhD, MD, etc.)	5 (14.7%)

Adverse Effects

The following table provides a full list of adverse events that occurred during the Higher-IQ study:

Higher-IQ – All Adverse Events (N=34)

		Number of Events
		All Participants Used Control-IQ
Total Number of Adverse Events		38
Severe Hypoglycemic (SH) Events*		0
Diabetic Ketoacidosis (DKA) Events [†]		0
Other Serious Adverse Events [‡] (SAEs)		1
Other Adverse Events <i>N Events/N Participants</i>		37/18
	Hyperglycemia with or without Ketosis Related to Study Device	1/1
	Hyperglycemia with or without Ketosis Not Related to Study Device	0/0
	Bronchitis	1/1
	Chronic Kidney Disease	1/1
	Cough	1/1
	COVID-19	2/2
	Dyslipidemia	1/1
	Hypertension	1/1
	Influenza	3/3

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Higher-IQ – All Adverse Events (N=34) (Continued)

		Number of Events
		All Participants Used Control-IQ
	Ligament Sprain	1/1
	Migraine	1/1
	Myalgia	1/1
	Nausea/Vomiting	2/2
	Oropharyngeal Pain	1/1
	Otitis Externa	1/1
	Otitis Media	2/2
	Pharyngitis Streptococcal	1/1
	Skin Abrasion	1/1
	Sleep Apnea Syndrome	1/1
	Stiff Person Syndrome	1/1
	Tooth Abscess	1/1
	Tooth Fracture	1/1
	Tympanic Membrane Perforation	1/1
	Upper Respiratory Tract Infection	10/7

Higher-IQ – All Adverse Events (N=34) (Continued)

	Number of Events
	All Participants Used Control-IQ
<i>*A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.</i> <i>†DKA events meeting DCCT criteria.</i> <i>‡One participant was hospitalized for new onset atrial fibrillation.</i>	

CHAPTER 33 • Overview of Control-IQ Technology Clinical Studies

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the Higher-IQ trial:

Higher-IQ Intervention Adherence over the 13-week Study Period (N=34)

	Sensor Use (%)	Closed-Loop System Use (%)
Mean (SD)	97.9%	93%

Key CGM Outcomes

Key CGM outcomes are shown below, for overall, daytime, and overnight:

Higher-IQ: Percentage of Time in Glycemic Ranges (N=34)

CGM Time in Range Mean % (SD)	Overall	Daytime	Overnight
BG 70-180mg/dL	64.75% (10.75)	63.47% (10.89)	68.47% (14.81)
BG >180mg/dL	34.21% (11.05)	35.62% (11.25)	30.09% (15.01)
BG ≥250mg/dL	10.45% (6.78)	10.74% (6.29)	9.58% (10.39)
BG 70-140mg/dL	37.87% (10.75)	36.96% (10.81)	40.55% (14.43)
BG <54mg/dL	0.20% (0.22)	0.15% (0.17)	0.35% (0.42)
BG <70 mg/dL	1.04% (0.98)	0.90% (0.90)	1.44% (1.48)

Secondary Analysis

Higher-IQ: Change in Central Lab HbA1c at 13 Weeks (N=34)

	Baseline	13 Weeks	Change from Baseline	P Value
HbA1c (%) Mean (SD)	7.69 (1.08)	6.87 (0.57)	-0.82 (0.73)	p<0.001

This Page is Intentionally Left Blank

5 Technical Specifications and Warranty

CHAPTER 34

Technical Specifications

CHAPTER 34 • Technical Specifications

34.1 Overview

This section provides tables of technical specifications, performance characteristics, options, settings, and electromagnetic compliance information for the t:slim X2™ pump. The specifications in this section meet the international standards set forth in IEC 60601-1 and IEC 60601-2-24.

34.2 t:slim X2 Pump Specifications**t:slim X2 Pump Specifications**

Specification Type	Specification Details
Classification	External PSU: Class II, Infusion Pump. Internally-powered equipment, Type BF applied part. The risk of ignition of flammable anesthetics and explosive gases by the pump is remote. While this risk is remote, it is not recommended to operate the t:slim X2 pump in the presence of flammable anesthetics or explosive gases.
Size	3.13" x 2.0" x 0.6" (L x W x H) - (7.95 cm x 5.08 cm x 1.52 cm)
Weight (with full disposable)	3.95 ounces (112 grams)
Operating Conditions	Temperature: 41°F (5°C) to 98.6°F (37°C) Humidity: 20% to 90% RH non-condensing
Storage Conditions	Temperature: -4°F (-20°C) to 140°F (60°C) Humidity: 20% to 90% RH non-condensing
Atmospheric Pressure	-1,300 feet to 10,000 feet (-396 meters to 3,048 meters)
Moisture Protection	IP27: Watertight to a depth of 3 feet (0.91 meters) for up to 30 minutes
Cartridge Volume	3.0 mL or 300 units
Cannula Fill Amount	0.1 to 1.0 units of insulin

t:slim X2 Pump Specifications (Continued)

Specification Type	Specification Details
Insulin Concentration	U-100
Alarm Type	Visual, audible, and vibratory
Basal Delivery Accuracy at all Flow Rates (tested per IEC 60601-2-24)	$\pm 5\%$ The pump is designed to vent automatically when there is a pressure difference between inside the cartridge and the surrounding air. In certain conditions, such as a gradual elevation change of 1,000 feet (305 meters), the pump may not vent immediately and delivery accuracy can vary up to 15% until 3 units have been delivered or elevation changes by more than 1,000 feet (305 meters).
Bolus Delivery Accuracy at all Volumes (tested per IEC 60601-2-24)	$\pm 5\%$
Patient Protection from Air Infusion	The pump provides subcutaneous delivery into interstitial tissue and does not deliver intravenous injections. Clear tubing aids in detecting air.
Maximum Infusion Pressure Generated and Occlusion Alarm Threshold	30 PSI
Frequency of Basal Delivery	5 minutes for all Basal Rates
Retention Time of Electronic Memory when Internal System Battery is Fully Discharged (including Alarm Settings and Alarm History)	Greater than 30 days
Infusion Set used for Testing	Unomedical Comfort Infusion Set
Typical Operating Time when System is Operating at Intermediate Rate	During normal use, the intermediate rate is 2 units/hr; battery charge can be reasonably expected to last between 4 and 7 days, depending on your use of CGM and the t:connect™ mobile app features from a fully charged state to a totally discharged state

CHAPTER 34 • Technical Specifications

t:slim X2 Pump Specifications (Continued)

Specification Type	Specification Details
Handling of Over-Infusion or Under-Infusion	The method of delivery isolates the insulin chamber from the patient and the software performs frequent monitoring of system status. Multiple software monitors provide redundant protection against unsafe conditions. Over-infusion is mitigated by monitoring glucose, (whether via CGM, BG meter, or both), layering of redundancies and confirmations, and numerous other safeguard alarms. Users are required to review and confirm the details of all bolus deliveries, Basal Rates, and temp rates to ensure certainty before initiating a delivery. In addition, once bolus deliveries are confirmed, the user is given 5 seconds to cancel the delivery before it is started. An optional Auto-Off alarm triggers when the user has not interacted with the pump's user interface for a predefined period of time. Under-infusion is mitigated by occlusion detection and BG monitoring as BG entries are recorded. Users are prompted to treat high BG conditions with a correction bolus.
Bolus Volume at Release of Occlusion (2 units per hour Basal)	Less than 3 units with Unomedical Comfort (110cm) Infusion Set
Residual Insulin Remaining in the Cartridge (unusable)	Approximately 15 units
Minimum Audible Alarm Volume	45 dBA at 1 meter

 NOTE

Accuracies stated in this table are valid for all Tandem Diabetes Care, Inc. branded infusion sets including: AutoSoft™ 90, AutoSoft™ XC, AutoSoft™ 30, VariSoft™, and TruSteel™ branded infusion sets.

USB Charging/Download Cable Specifications

Specification Type	Specification Detail
Tandem P/N	004113
Length	6 feet (2 meters)
Type	USB A to USB Micro B

Power Supply/Charger, AC, Wall Mount, USB Specifications

Specification Type	Specification Detail
Tandem P/N	007866
Input	100 to 240 Volts AC, 50/60 Hz
Output Voltage	5 Volts DC
Max Output Power	5 Watts
Output Connector	USB type A

Computer, USB Connector, Specifications

Specification Type	Specification Detail
Output Voltage	5 Volts DC
Output Connector	USB type A
Safety Standard Compliance	60950-1 or 60601-1 or equivalent

CHAPTER 34 • Technical Specifications

Requirements for Charging from a Computer

The t:slim X2 pump is designed to be connected to a host computer for battery charging and data transfer. The following minimum characteristics are required of the host computer:

- USB 1.1 port (or later)
- Computer compliant with 60950-1 or equivalent safety standard

Connecting the pump to a host computer that is attached to other equipment could result in previously unidentified risks to the patient, operator, or a third party. The user should identify, analyze, evaluate, and control these risks.

Subsequent changes to the host computer could introduce new risks and require additional analysis. These changes can include but are not limited to changing the configuration of the computer, connecting additional items to the computer, disconnecting items from the computer, and updating or upgrading equipment connected to the computer.

▲ WARNING

ALWAYS use the USB cable provided with your t:slim X2 insulin pump to minimize the risk of fires or burns.

34.3 t:slim X2 Pump Options and Settings**t:slim X2 Pump Options and Settings**

Option/Setting Type	Option/Setting Detail
Time	May be set to 12-hour or 24-hour clock (default is 12-hour clock)
Basal Rate Setting Range	0.1 – 15 units/hr
Insulin Delivery Profiles (Basal and Bolus)	6
Basal Rate Segments	16 per delivery profile
Basal Rate Increment	0.001 at programmed rates equal to or greater than 0.1 units/hr
Temp Basal Rate	15 minutes to 72 hours with 1 minute resolution with a range of 0% to 250%
Bolus Setup	Can deliver based on carb input (grams) or insulin input (units). The range for carbs is 1 to 999 grams, the range for insulin is 0.05 to 25 units
Insulin-to-Carb (IC) Ratio	16 time segments per 24-hour period; Ratio: 1 unit of insulin per x grams of carb; 1:1 to 1:300 (can be set by 0.1 below 10)
BG Target Value	16 time segments. 70 to 250 mg/dL in 1 mg/dL increments
Correction Factor	16 time segments; Ratio: 1 unit of insulin reduces BG x mg/dL; 1:1 to 1:600 (1 mg/dL increments)
Duration of Insulin Action	1 time segment; 2 to 8 hours in 1-minute increments (default is 5 hrs)
Bolus Increment	0.01 at volumes greater than 0.05 units
Quick Bolus Increments	When set to units of insulin: 0.5, 1, 2, 5 units (default is 0.5 units); or when set to grams of carb: 2, 5, 10, 15 grams (default is 2 g)

CHAPTER 34 • Technical Specifications

t:slim X2 Pump Options and Settings (Continued)

Option/Setting Type	Option/Setting Detail
Maximum Extended Bolus Time	8 hours
Maximum Bolus Size	25 units
Maximum Automatic Bolus Size	6 units
Low Cartridge Volume Indicator	Status indicator visible on <i>Home</i> screen; Low Insulin Alert is user adjustable from 10 to 40 units (default is 20 units).
Auto-Off Alarm	On or Off (default is on); user-adjustable (5 to 24 hours; default is 12 hours, which you can change when option is set to on).
History Storage	At least 90 days of data
Language	Dependent on region of use. May be set to English, Czech, Danish, Dutch, Finnish, French, German, Italian, Norwegian, Portuguese, Spanish, or Swedish (default is English).
Security PIN	Protects from unintentional access, and blocks access to quick bolus when enabled (default is off).
Screen Lock	Protects from unintentional screen interactions.
Site Reminder	Prompts user to change infusion set. Can be set for 1 to 3 days at a time selected by user (default is off).
Missed Meal Bolus Reminder	Prompts user if a bolus has not occurred during the period of time the reminder is set for. 4 reminders available (default is off).
After Bolus Reminder	Prompts user to test BG at a selected time period after a bolus has been delivered. Can be set between 1 to 3 hours (default is off).
High BG Reminder	Prompts user to retest BG after a High BG has been entered. User selects High BG value and time for reminder. (default is off).

t:slim X2 Pump Options and Settings (Continued)

Option/Setting Type	Option/Setting Detail
Low BG Reminder	Prompts user to retest BG after a Low BG has been entered. User selects Low BG value and time for reminder. (default is off).

CHAPTER 34 • Technical Specifications

34.4 t:slim X2 Pump Performance Characteristics

The t:slim X2 insulin pump delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The following accuracy data was collected on both types of delivery in laboratory studies performed by Tandem.

Basal Delivery

To assess basal delivery accuracy, 32 t:slim X2 pumps were tested by delivering at low, medium, and high Basal Rates (0.1, 2.0, and 15 U/hr). Sixteen of the pumps were new, and 16 had been aged to simulate four years of regular use. For both aged and unaged pumps, eight pumps were tested with a new cartridge, and eight with a cartridge which underwent two years of real time aging. Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid at various time points was used to assess pumping accuracy.

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for low, medium, and high Basal Rate settings for all pumps tested. For the medium and high basal rates, accuracy is reported from the time basal delivery started with no warm-up period. For the minimum Basal Rate, accuracy is reported after a 1-hour warm-up period. For each time period, the tables show the volume of insulin requested in the first row and the volume that was delivered as measured by the scale in the second row.

Low Basal Rate Delivery Performance (0.1 U/hr)

Basal Duration (Number of Units Delivered with 0.1 U/hr Setting)	1 hour (0.1 U)	6 hours (0.6 U)	12 hours (1.2 U)
Amount Delivered [min, max]	0.12 U [0.09, 0.16]	0.67 U [0.56, 0.76]	1.24 U [1.04, 1.48]

Medium Basal Rate Delivery Performance (2.0 U/hr)

Basal Duration (Number of Units Delivered with 2 U/hr Setting)	1 hour (2 U)	6 hours (12 U)	12 hours (24 U)
Amount Delivered [min, max]	2.1 U [2.1, 2.2]	12.4 U [12.0, 12.8]	24.3 U [22.0, 24.9]

High Basal Rate Delivery Performance (15 U/hr)

Basal Duration (Number of Units Delivered with 15 U/hr Setting)	1 hour (15 U)	6 hours (90 U)	12 hours (180 U)
Amount Delivered [min, max]	15.4 U [14.7, 15.7]	90.4 U [86.6, 93.0]	181 U [175.0, 187.0]

Bolus Delivery

To assess bolus delivery accuracy, 32 t:slim X2 pumps were tested by delivering consecutive low, medium, and high bolus volumes (0.05, 2.5, and 25 units). Sixteen of the pumps were new, and 16 had been aged to simulate four years of regular use. For both aged and unaged pumps, eight pumps were tested with a new cartridge, and eight with a cartridge which underwent two years of real time aging. Water was used as a substitute for insulin for this testing. The water was pumped into a container on a scale, and the weight of the liquid at various time points was used to assess pumping accuracy.

Delivered bolus volumes were compared to the requested bolus volume delivery for minimum, intermediate, and maximum bolus volumes. The tables below show average, minimum and maximum bolus sizes observed as well as the number of boluses which were observed to be within the specified range of each target bolus volume.

CHAPTER 34 • Technical Specifications

Summary of Bolus Delivery Performance (n=32 pumps)

Individual Bolus Accuracy Performance	Target Bolus Size [Units]	Mean Bolus Size [Units]	Min Bolus Size [Units]	Max Bolus Size [Units]
Min Bolus Delivery Performance (n=800 boluses)	0.050	0.050	0.000	0.114
Intermediate Bolus Delivery Performance (n=800 boluses)	2.50	2.46	0.00	2.70
Max Bolus Delivery Performance (n=256 boluses)	25.00	25.03	22.43	25.91

Low Bolus Delivery Performance (0.05U) (n=800 boluses)

	Units of Insulin Delivered After a 0.05 U Bolus Request									
	<0.0125 (<25%)	0.0125– 0.0375 (25–75%)	0.0375– 0.045 (75–90%)	0.045– 0.0475 (90–95%)	0.0475– 0.0525 (95–105%)	0.0525– 0.055 (105–110%)	0.055– 0.0625 (110–125%)	0.0625– 0.0875 (125–175%)	0.0875– 0.125 (175–250%)	>0.125 (>250%)
Number and Percent of Boluses Within Range	21/800 (2.6%)	79/800 (9.9%)	63/800 (7.9%)	34/800 (4.3%)	272/800 (34.0%)	180/800 (22.5%)	105/800 (13.1%)	29/800 (3.6%)	17/800 (2.1%)	0/800 (0.0%)

Intermediate Bolus Delivery Performance (2.5U) (n=800 boluses)

	Units of Insulin Delivered After a 2.5 U Bolus Request									
	<0.625 (<25%)	0.625– 1.875 (25–75%)	1.875– 2.25 (75–90%)	2.25– 2.375 (90–95%)	2.375– 2.625 (95–105%)	2.625– 2.75 (105–110%)	2.75– 3.125 (110–125%)	3.125– 4.375 (125–175%)	4.375– 6.25 (175–250%)	>6.25 (>250%)
Number and Percent of Boluses Within Range	9/800 (1.1%)	14/800 (1.8%)	11/800 (1.4%)	8/800 (1.0%)	753/800 (94.1%)	5/800 (0.6%)	0/800 (0.0%)	0/800 (0.0%)	0/800 (0.0%)	0/800 (0.0%)

High Bolus Delivery Performance (25U) (n=256 boluses)

	Units of Insulin Delivered After a 25 U Bolus Request									
	<6.25 (<25%)	6.25– 18.75 (25–75%)	18.75– 22.5 (75–90%)	22.5– 23.75 (90–95%)	23.75– 26.25 (95–105%)	26.25– 27.5 (105–110%)	27.5– 31.25 (110–125%)	31.25– 43.75 (125–175%)	43.75– 62.5 (175–250%)	>62.5 (>250%)
Number and Percent of Boluses Within Range	0/256 (0.0%)	0/256 (0.0%)	1/256 (0.4%)	3/256 (1.2%)	252/256 (98.4%)	0/256 (0.0%)	0/256 (0.0%)	0/256 (0.0%)	0/256 (0.0%)	0/256 (0.0%)

CHAPTER 34 • Technical Specifications

Rate of Delivery

Characteristic	Value
25 Unit Bolus Delivery Speed	2.97 Units/min Typical
2.5 Unit Bolus Delivery Speed	1.43 Units/min Typical
20 Unit Prime	9.88 Units/min Typical

Bolus Duration

Characteristic	Value
25 Unit Bolus Duration	8 minutes 26 seconds Typical
2.5 Unit Bolus Duration	1 minute 45 seconds Typical

Time to Occlusion Alarm*

Operating Rate	Typical	Maximum
Bolus (3 units or Greater)	1 minute 2 seconds	3 Minutes
Basal (2 units/hr)	1 Hour 4 Minutes	2 Hours
Basal (0.1 units/hr)	19 Hours 43 Minutes	36 Hours
*The time to occlusion alarm is based on insulin volume not delivered. During an occlusion event, boluses of less than 3 units may not trigger an occlusion alarm if no basal insulin is being delivered. The bolus amount will reduce the time to occlusion depending on the Basal Rate.		

34.5 Electromagnetic Compatibility

The information contained in this section is specific to the System. This information provides reasonable assurance of normal operation, but does not guarantee such under all conditions. If the System must be used in close proximity with other electrical equipment, the System should be observed in this environment to verify normal operation. Special precautions for electromagnetic compatibility must be taken when using medical electrical equipment. The System must be placed into service with adherence to the EMC information provided here.

▲ WARNING

Use of accessories, cables, adapters, and chargers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

▲ WARNING

ALWAYS use the USB cable provided with your t:slim X2 insulin pump to minimize the risk of fires or burns.

For IEC 60601-1 testing, Essential Performance for the System is defined as follows:

- The System will not over deliver a clinically significant amount of insulin.
- The System will not under deliver a clinically significant amount of insulin without notification to the user.
- The System will not deliver a clinically significant amount of insulin after occlusion release.
- The System will not discontinue reporting CGM data without notification to the user.

This section contains the following tables of information:

- Wireless Co-existence and Data Security
- Electromagnetic Emissions
- Electromagnetic Immunity
- Wireless Technology

34.6 Wireless Co-existence and Data Security

The System is designed to work safely and effectively in the presence of wireless devices typically found at home, work, retail stores, and places of leisure where daily activities occur.

▲ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches to any part of the t:slim X2 pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The System is designed to send and accept Bluetooth wireless technology communication. Communication is not established until you enter the appropriate credentials into your pump.

The System and system components are designed to ensure data security and patient confidentiality using a series of cybersecurity measures, including device authentication, message encryption, and message validation.

CHAPTER 34 • Technical Specifications

34.7 t:connect Mobile App Security

The smartphone's biometric security or other native authentication prevents unauthorized access. Never share your security PIN/password or authorize any other person to access your smartphone via their biometric information to avoid unintentional changes in your delivery of insulin.

⚠ WARNING

DO NOT use a smartphone that has been jailbroken or rooted, or with Android developer mode on. Data may become vulnerable if you install the t:connect mobile app on a smartphone that has been jailbroken or rooted, or uses an unreleased or pre-release operating system. Only download the t:connect mobile app on Google Play™ or from the App Store®. See Section 4.3 Connecting to a Smartphone for t:connect mobile app installation.

If the app becomes corrupted or compromised, uninstall the t:connect mobile app and follow the instructions in Section 4.3 Connecting to a Smartphone to regain a known configuration of the t:connect mobile app.

Once supported, Tandem intends to support a particular smartphone and OS combination for at least one year. When the mobile app is no longer compatible with a particular smartphone or OS, no further security updates will be provided.

■ NOTE

For an up-to-date list of supported mobile devices and operating systems, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the t:connect mobile app *Settings* screen, then tap **App Guide**.

Please report any cybersecurity incident or vulnerability to Tandem Customer Technical Support as soon as you discover it.

34.8 Electromagnetic Emissions

The System is intended for use in the electromagnetic environment specified below. Always make sure that the System is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions, CISPR 11	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions, CISPR 11	Class B	
Harmonic Emissions, IEC 61000-3-2	N/A	
Voltage Fluctuations/Flicker Emissions, IEC 61000-3-3	N/A	The System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

CHAPTER 34 • Technical Specifications

34.9 Electromagnetic Immunity

The System is intended for use in home healthcare electromagnetic environments.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air
Electrical Fast Transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines (100 kHz repetition frequency)	± 2 kV for power supply lines ± 1 kV for input/output lines (100 kHz repetition frequency)
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level
Proximity Field from Wireless Transmitters	385 MHz: 27 V/m @ 18 Hz Pulse modulation 450 MHz: 28 V/m @ FM modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz Pulse modulation 810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz Pulse modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz Pulse Modulation 2450 MHz: 28 V/m @ 217 Hz Pulse modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz Pulse modulation	385 MHz: 27 V/m @ 18 Hz Pulse modulation 450 MHz: 28 V/m @ FM modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz Pulse modulation 810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz Pulse modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz Pulse Modulation 2450 MHz: 28 V/m @ 217 Hz Pulse modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz Pulse modulation
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	70% UR (30% dip in Ur) for 25 cycles 0% Ur (100% dip in Ur) for 1 cycle at 0 degrees 0% Ur (100% dip in Ur) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% Ur (100% dip in Ur) for 250 cycles	70% UR (30% dip in Ur) for 25 cycles 0% Ur (100% dip in Ur) for 1 cycle at 0 degrees 0% Ur (100% dip in Ur) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% Ur (100% dip in Ur) for 250 cycles
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	400 A/m (IEC 60601-2-24)

CHAPTER 34 • Technical Specifications

34.10 Quality of Wireless Service

The manufacturer defines the quality of service of the System as the percent of readings successfully received by the pump, where the CGM transmitter and pump attempt to communicate every 5 minutes. One of the System's essential performance requirements states that the System will not discontinue reporting data and/or information from the CGM to the user without notification.

The System notifies the user of a missed reading, or when the transmitter and pump are out of range of one another in several ways. The first is when a dot is missed on the CGM Trend Graph which will occur within five minutes of the previous reading. The second indication occurs after 10 minutes when the Out of Range Icon is displayed on the *CGM Home* screen. The third is a user settable alert that will notify the user when the transmitter and pump are out of range of one another. Setting this alert is defined in Section 22.6 Setting Your Out of Range Alert.

The System performance requirements state that 90% of readings will be successfully transferred to the pump display while the transmitter and pump are within 20 feet (6 meters) of each other, and no more than 12 consecutive readings (1 hour) will be missed.

For proper use of the t:connect mobile app, the pump and smartphone require successful wireless communication every 5 minutes. The quality of wireless service between the pump and smartphone hosting the t:connect mobile application is assured within 20 feet, unless there is wireless interference caused by other devices in the 2.4 GHz band. This interference may impact the smartphone's ability to maintain this quality of service. To improve the quality of service in the presence of other devices operating in the 2.4 GHz band, decrease the distance between the smartphone and the pump. If connectivity is lost, the t:connect mobile application will provide notification; use your Pump until connectivity improves.

34.11 Wireless Technology

The t:slim X2 insulin pump utilizes wireless technology with the following characteristics:

Wireless Technology Specifications

Specification Type	Specification Detail
Wireless Technology	Bluetooth Low Energy (BLE) version 5.0
Tx/Rx Frequency Range	2.360 to 2.500 GHz
Bandwidth (per channel)	2 MHz
Radiated Output Power (maximum)	+8 dBm
Modulation	Gaussian Frequency-Shift Keying
Data Rate	2 Mbps
Data Communication Range (maximum)	20 feet

CHAPTER 34 • Technical Specifications

34.12 FCC Notice Concerning Interference

The transmitter covered by this user guide has been certified under FCC ID: PH29433.

Although the transmitter has been approved by the United States Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from the transmitter will be free from interference.

Compliance Statement (Part 15.19)

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Warning (Part 15.21)

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC Interference Statement (Part 15.105 (b))

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This portable transmitter with its antenna complies with FCC/IC RF exposure limits for general population/uncontrolled exposure.

34.13 Warranty Information**Warranty****t:slim X2 Insulin Pump**

This warranty is valid only in the United States.

Tandem Diabetes Care, Inc. ("Tandem") warrants the t:slim X2 insulin pump against defects in materials and workmanship, under normal use, for the period of 4 years from the original date of shipment of the pump to the

original end use purchaser (the “Warranty Period”). For any defective t:slim X2 pump covered by the foregoing warranty, Tandem will, at its discretion, repair the pump or replace it with a new or refurbished t:slim X2 pump, subject to the conditions and exclusions stated herein. Repair or replacement of a t:slim X2 pump will not extend the original 4 year warranty, which will continue to apply. If your t:slim X2 pump is replaced, then you must return your original pump to Tandem in accordance with Tandem’s instructions. In the event the defective t:slim X2 pump is not returned, then this warranty shall be void and you will not be entitled to future pump replacement or repairs.

The warranty is valid only if the t:slim X2 pump is used in accordance with Tandem’s instructions for use and this user guide and will not apply if:

- damage results from changes or modifications made to the t:slim X2 insulin pump by the user or third persons after the date of manufacture;

- damage results from service or repairs performed to any part of the t:slim X2 pump by any person or entity other than Tandem;
- the t:slim X2 pump seal is broken;
- a non-Tandem cartridge is used with the t:slim X2 pump;
- damage consists of scratches and wear to surfaces and other externally exposed parts due to wear and tear;
- damage results from an event or accident beyond the control of Tandem; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse.

From time-to-time Tandem may offer software updates for your t:slim X2 pump to help to ensure the up-to-date functionality of your pump or software that are intended to add new features to your t:slim X2 pump. Tandem reserves the right to offer those

updates, if any, in its sole discretion either at no charge or for an additional fee to be determined at a future date. To the extent that an update is offered at no charge, it is considered to be included in the original cost of your pump. Any future software updates will be subject to your acceptance of other terms and conditions that may be applicable at that time, including additional terms that may modify or limit the terms of this Warranty.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the t:slim X2 pump covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate.

This warranty only applies to the t:slim X2 pump and does not apply to other products or accessories. This warranty is valid only in the United States. No employee of Tandem or any other party is authorized to make any warranty in addition to those made in this Warranty.

The remedies provided for in this warranty are the exclusive remedies available for any warranty claims.

CHAPTER 34 • Technical Specifications

Neither Tandem nor its suppliers or distributors shall be liable for losses, liabilities, claims or damages of any kind or nature whatsoever, including, without limitation, any indirect, incidental, consequential, or special damages of any kind caused by or arising out of a defect in the product. All other warranties, express or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

Warranty**t:slim X2 3mL Cartridges**

This warranty is valid only in the United States.

Tandem Diabetes Care, Inc. ("Tandem") warrants its cartridge against defects in materials and workmanship for one use during the period of 3 days after the individual cartridge sterile packaging has been opened, not to exceed 6 months from date of shipment of the cartridge to the end user (the "Warranty Period"). During the Warranty Period, Tandem will replace any defective cartridge, subject to the conditions and exclusions stated herein.

The warranty is valid only if the cartridges are used in accordance with the accompanying instructions for use and user guide and will not apply if:

- the cartridge has been used for more than a single-time use by a single end-user;
- damage results during the improper opening of the sterile package not in conformance with the procedures outlined in the associated instructions for use;
- the sterile package is compromised while in the control of the user by any means other than purposeful opening by the user at the time of intended product use;
- damage results from changes or modifications made to the cartridge by the user or third persons after the date of manufacture;
- damage results from service or repairs performed to any part of the cartridge by any person or entity other than Tandem;

- damage is caused by use of the cartridge with any non-Tandem insulin pump;
- damage results from an event or accident beyond the control of Tandem; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty does not apply to insulin pumps and other accessories. This warranty is valid only in the United States. No employee of Tandem or any other party is authorized to make any warranty in addition to those made in this Warranty.

The remedies provided for in this warranty are the exclusive remedies available for any warranty claims.

Neither Tandem nor its suppliers or distributors shall be liable for losses, liabilities, claims or damages of any kind or nature whatsoever, including, without limitation, any indirect, incidental, consequential, or special damages of any kind caused by or arising out of a defect in the product. All other warranties, express or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

Warranty t:lock™ Infusion Sets

This warranty is valid only in the United States.

Tandem Diabetes Care, Inc. ("Tandem") warrants its infusion sets against defects in materials and workmanship for one use during the period of 3 days after the individual infusion set sterile packaging has been opened, not to exceed 6 months from date of shipment of the infusion set to the end user (the "Warranty Period"). During the Warranty Period, Tandem will replace any defective infusion set, subject to the conditions and exclusions stated herein.

The warranty is valid only if the infusion sets are used in accordance with the accompanying instructions for use and user guide provided with your insulin pump and will not apply if:

- the infusion set has been used for more than a single-time use by a single end-user;
- the sterile package is compromised while in the control of the user by any means other than purposeful opening by the user at the time of intended product use;
- damage results during the improper opening of the sterile package not in conformance with the procedures outlined in the accompanying instructions for use;
- damage results from changes or modifications made to the infusion set by the user or third persons after the date of manufacture;
- damage results from service or repairs performed to any part of the infusion set by any person or entity other than Tandem;

- damage is caused by use of the t:lock infusion set with any non-Tandem insulin pump;
- damage results from an event or accident beyond the control of Tandem; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty does not apply to insulin pumps and other accessories. No employee of Tandem or any other party, including without limitation any authorized distributor, is authorized to make any warranty in addition to those made in this warranty.

The remedies provided for in this warranty are the exclusive remedies available for any warranty claims.

CHAPTER 34 • Technical Specifications

Neither Tandem nor its suppliers or distributors shall be liable for losses, liabilities, claims or damages of any kind or nature whatsoever, including, without limitation, any indirect, incidental, consequential, or special damages of any kind caused by or arising out of a defect in the product. All other warranties, express or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

CGM Warranty

Tandem Diabetes Care does not sell CGM sensors or transmitters and therefore provides no warranty for CGM sensors or transmitters used with the t:slim X2 insulin pump. For more information about CGM warranty information, visit the manufacturer's website.

34.14 Returned Goods Policy

The following represents the returned goods policy applicable only to customers in the United States.

Any insulin pump product ("Pump") that was originally purchased from Tandem

Diabetes Care, Inc. ("Tandem") or one of its authorized distributors within the United States may be returned to Tandem only for the following reasons: (1) during the applicable Warranty Period, if the customer experiences an issue with the Pump that is covered by the Warranty, then Tandem will repair or replace the Pump as provided under the Warranty above, or (2) during the ninety (90) day period after the shipment of the Pump, if the customer discovers that the Pump is not suited for the customer based on a valid, good faith medical reason which has been confirmed by the customer's physician, then Tandem or the authorized distributor will accept the return of the Pump and provide a refund to the customer and/or its insurance company for the amount actually paid for the Pump. Tandem will not accept or be obligated to accept for return any Pump for any other reason. To assure prompt handling when returning a Pump, the customer must first obtain a returned materials authorization (RMA) number from Tandem's or its authorized distributor's Customer Service Department. This RMA number must be clearly written on the outer box. If

Tandem provides a label, the label must be attached or taped to the outer box. If no label is provided, Tandem recommends shipping via insured ground service with a tracking number. Tandem is not responsible for lost or damaged packages.

To obtain an RMA number and shipping address, please contact Tandem Customer Technical Support. Returns pre-authorized by Tandem's authorized distributors should be sent to the distributor authorizing the return, unless other instructions are provided. Returns made without the RMA number will be returned to the customer, freight collect. This policy is subject to applicable law.

34.15 t:slim X2 Insulin Pump Event Data (Black Box)

Your t:slim X2 pump's event data is monitored and logged on the pump. The information stored on the pump may be obtained and used by Customer Technical Support and other internal Tandem personnel in accordance with our Privacy Notice for troubleshooting purposes when a

pump is uploaded to a data management application that supports use of the t:slim X2 pump, or if the pump is returned. Others who may assert a legal right to know, or who obtain your consent to know such information may also have access to read and use this data. Our Privacy Notice is available on our website and through our other applications. The Privacy Notice is available at tandemdiabetes.com/privacy/privacy-policy.

34.16 Product List

For a complete product list, please contact Customer Technical Support.

Insulin Delivery

- t:slim X2 insulin pump with Control-IQ technology
- t:case (pump cover with clip)
- t:slim X2 user guide
- USB cable
- USB charger with power plugs

- cartridge removal tool

Consumables

- cartridge
- t:slim X2 cartridge (t:lock™ connector) with filling syringe and needle
- infusion set (all with t:lock connector)

Infusion sets are available in different cannula sizes, tubing lengths, insertion angles, and may come with or without an insertion device. Some infusion sets have a soft cannula and others have a steel needle.

Contact your local customer support service for available sizes and lengths of the following infusion sets with t:lock connectors:

- AutoSoft 90 infusion set
- AutoSoft 30 infusion set
- VariSoft infusion set
- TruSteel infusion set

Optional Accessories/Replacement Parts

- t:case pump cover (black, blue, pink, purple, turquoise, olive)
- t:holster
- t:slim USB charging cable
- t:slim USB charger
- power plug for t:slim USB charger
- cartridge removal tool
- t:slim screen protector
- USB rubber door

INDEX**A**

AC power adapter	88
Accessories	88
Active Bolus Icon	48, 212
After Bolus BG Reminder	147
Air Bubbles	
Check Tubing	113
Removing Before Delivery	109
Airport Security	199
Alarms	177
Altitude Alarm	188
Auto-Off Alarm	150
Cartridge Error Alarm	182
Cartridge Removal Alarm	183
Empty Cartridge Alarm	181
Low Power Alarm	180
Occlusion Alarms	185, 186
Reset Alarm	189
Resume Pump Alarm	179
Screen On/Quick Bolus Button Alarm	187
Temperature Alarm	184
Alerts	153

Alert Icon, Where to Find	48
Alerts & Reminders	58
Basal Rate Required Alert	165
CGM	229, 251
CGM Rise and Fall	232
CGM, 12 Hour Calibration Alert	255
CGM, Calibrate CGM Alert	259
CGM, Calibration Error Alert	258
CGM, Calibration Timeout Alert	257
CGM, Failed Sensor	271
CGM, Fall Alert	265, 266
CGM, High Alert	260
CGM, Incomplete Calibration Alert	256
CGM, Low Alert	261, 262
CGM, Low Transmitter Battery Alert	269
CGM, Out of Range Alert	268, 319, 320
CGM, Rise Alert	263, 264
CGM, Second Startup Calibration Alert	254
CGM, Startup Calibration Alert	253
CGM, System Error	273
CGM, Transmitter Error	270
CGM, Unavailable	272
Connection Error Alert	172
Control-IQ Technology	317
Control-IQ Technology, High Alert	322
Control-IQ Technology, Low Alert	321

Control-IQ Technology, Max Insulin Alert	323
Data Error Alert	175
High Glucose Alert, Set	230
Incomplete Bolus Alert	158
Incomplete Cartridge Change Alert	161
Incomplete Fill Cannula Alert	163
Incomplete Fill Tubing Alert	162
Incomplete Load Sequence Alerts	161
Incomplete Personal Profile Alert	164
Incomplete Setting Alert	164
Incomplete Temp Rate Alert	160
Low Glucose Alert, Set	231
Low Insulin Alert	150, 155
Low Power Alerts	156, 157
Max Bolus Alerts	167, 168
Max Hourly Bolus Alert	166
Min Basal Alerts	170, 171
Out of Range Alert, Set	233
Power Source Alert	174
Alternate Site BG Testing	208
Altitude	198
Altitude Alarm	188
Aquatic Activities, Pump	198
Arrows	
CGM Trends	249
Up/Down Arrows	56

Auto-Off Alarm	150

B

Basal	40
Basal Rate Required Alert	165
Current Basal Rate	52
Delivery Accuracy	381
Frequency of Delivery	381
in Personal Profiles	99
Set a Temp Rate	103
Stop a Temp Rate	104
Temp Basal Rate	41
Timed Settings	97
Basal Rate Required Alert	165
Battery	88
Battery Level	48, 50
Battery, Charge	89
BG	40
High BG Reminder	146
Low BG Reminder	146
Target BG	40, 96
Target BG in Personal Profiles	99
BG Reminder	147
Bluetooth	224

Bolus	41, 117
Active Bolus Icon	48, 212
After Bolus BG Reminder	147
Bolus Overview	118
Bolus Screen	54
Cancel a Bolus	128, 133
Correction Bolus	41
Delivery Accuracy	381
Extended Bolus	41, 124
Food Bolus Using Grams	123
Food Bolus Using Units	123
in Personal Profiles	100
Quick Bolus	41
Stop a Bolus	128, 133
Timed Settings	97

C

Calculation	54
Calibrate CGM Alert	259
Calibration Alert, 12 Hour	255
Calibration Error Alert	258
Calibration Timeout Alert	257
Cancel a Bolus	128, 133
Cannula	41

Cannula, Fill Cannula	115
Carb Ratio	41
Current Status	52
in Personal Profiles	99
Timed Settings	97
Carbohydrate	41
Carbohydrates	
Carbs, in Personal Profiles	97
Food Bolus Using Grams	123
Food Bolus, on Bolus Screen	54
Carbs	41
Carbs, on Bolus Screen	54
Caring for Your Pump	195
Cartridge	108
Cartridge Tubing	50
Change Cartridge	112
Fill Cartridge	110
Load Cartridge	108, 112
Load the Cartridge	41
Cartridge Error Alarm	182
Cartridge Removal Alarm	183
Cartridge, Warranty	402
CGM	
12 Hour Calibration Alert	255
Alerts and Errors	251

Automatic Sensor Shut-Off	239	History, View	250
Calibrate Blood Glucose Value	244	Incomplete Calibration Alert	256
Calibrate CGM Alert	259	Low BG Alert Default	231
Calibrating Your CGM	241	Low BG Alert Repeat	231
Calibration Error Alert	258	Low Glucose Alert, Set	231
Calibration Overview	242	Low Transmitter Battery Alert	269
Calibration Prompts	210	My CGM Screen	216
Calibration Timeout Alert	257	Out of Range Alert	268, 319, 320
CGM Fall Alert	265, 266	Out of Range Alert, Set	233
CGM High Alert	260	Out of Range/No Antenna, Troubleshooting	277
CGM Info	227	Pair Your CGM	224, 236
CGM Low Alert	261, 262	Rate of Change Arrows	248
CGM Rise Alert	263, 264	Receiver	221
CGM Settings	224	Rise and Fall Alerts	232
CGM System Error	273	Second Startup Calibration Alert	254
CGM Unavailable	272	Sensor Inaccuracies, Troubleshooting	278
Default Volume	224	Sensor Startup Period	238
End a Sensor Session	240	Set Correction Bolus	244
Enter Transmitter ID	224, 236	Set Volume	224
Failed Sensor	271	Start Calibration	242
Failed Sensor, Troubleshooting	277	Start or Stop a CGM Sensor	235
Glucose Trend Arrows	248	Startup Calibration Alert	253
Glucose Trend Graphs	247	Status Symbols	210
High BG Alert Default	230	System Overview	220
High BG Alert Repeat	230	Transmitter Error	270
High Glucose Alert, Set	230	Transmitter ID	236

Troubleshooting	275	Calculate Total Daily Insulin	311
Unknown Sensor Reading	267	During Exercise	306
Unknown Sensor Reading, Troubleshooting	276	During Sleep	305
View Data on Pump, Overview	246	High Alert	322
CGM Fall Alert	265, 266	Home Screen	290
CGM High Alert	260	How it Works	296
CGM ID	236	Increasing Insulin Delivery	301
CGM Low Alert	261, 262	Information on Your Screen	315
CGM Rise Alert	263, 264	Insulin Decreased	297
CGM Safety Information	202	Insulin Suspended	299
CGM System Error	273	Low Alert	321
CGM Unavailable	272	Manually Start or Stop Sleep	314
Charge		Max Insulin Alert	323
AC Power Outlet	88	Maximum Insulin Delivery	301
Car Adapter	89	No Activity Enabled	305
Computer	89	Overview	296
Charge the Pump	88	Personal Profile Basal Rate Delivery	297
Cleaning Your System	196	Required Settings	310
Colors		Responsible Use	286
Explanation of Pump Colors	45	Schedule Sleep	311
Computer Charging Specifications	384	Set Weight	310
Connection Error Alert	172	Start or Stop Exercise	314
Contents, of Pump Package	40	Total Daily Insulin	292
Control-IQ Technology		Turn On or Off	311
Automatic Correction Bolus Delivery	303	Weight	292
		Control-IQ Technology Safety Information	282

Correction Bolus	41
Correction Factor	41, 97
in Personal Profiles	99
Timed Settings	97
Current Status Screen	52

D

Data Error Alert	175
Data, View CGM Overview	246
Date	
Date and Time Display	48
Edit Date	91
Default	
Auto-Off Alarm	150
Basal Temp Rate	103
CGM Default Volume	224
CGM Fall Alert	232
CGM Out of Range Alert	233
CGM Rise Alert	232
Extended Bolus	124
High BG Reminder	147
High Glucose Alert	230
Low BG Reminder	146
Low Glucose Alert	231

Low Insulin Alert	150
Quick Bolus	126
Screen Timeout	92
Site Reminder	148

Delete Personal Profile	103
Delivery Summary	142
Device Settings	60, 92
Disconnect When Filling	113
Display Settings	92
Disposing of System Components	196

E

Edit	
Edit Date	91
Edit Time	91
Site Reminder	116
Electromagnetic Compatibility	393
Electromagnetic Emissions	395
Electromagnetic Immunity	396
Empty Cartridge Alarm	181
End CGM Sensor Session	240
Extended Bolus	41, 124
Default	124

F

Failed Sensor Error	271
Fall Alert, Set	233
Fill	
Fill Cannula	115
Fill Cartridge	110
Fill Port	109, 110
Fill Tubing	113

G

Glucose Rate of Change Arrows	248
Glucose Trend Graphs	247
Grams	
Food Bolus, on Bolus Screen	54
Food Bolus, using	123

H

Healthcare Provider	36
High Alert	
Control-IQ Technology	322
High BG Reminder	146

History

CGM History	250
Control-IQ Technology History	142
Pump History	142
Home Screen	50
Home Screen, CGM	214
Home Screen, Control-IQ Technology	290

I

Icons

Explanation of Icons	43, 210, 287
Incomplete Bolus Alert	158
Incomplete Calibration Alert	256
Incomplete Cartridge Change Alert	161
Incomplete Fill Cannula Alert	163
Incomplete Fill Tubing Alert	162
Incomplete Load Sequence Alerts	161
Incomplete Setting Alert	164
Incomplete Temp Rate Alert	160
Infusion Set Risks	36, 106
Infusion Site Care	106
Infusion Site Care, Pediatric	23
Insulin	

Insulin Duration	97
Insulin Level Display	48, 115
Insulin On Board (IOB)	41, 48
Insulin On Board (IOB) Display	48
Resume Insulin Delivery	138
Stop Insulin Delivery	138, 139
Insulin Duration, in Personal Profiles	97
Insulin on Board (IOB), in Personal Profiles	98
Interference, FCC Notice	400

K

Keypad	62, 64
Letter Keypad	64
Number Keypad	62

L

LED	45
LED, location on Home Screen	50
Lifestyle Issues	197
Load Cartridge	108, 112
Low BG Reminder	146
Low Insulin Alert	150, 155

Low Power Alarm	180
Low Power Alerts	156, 157
Low Transmitter Battery Alert	269

M

Maintaining Your Pump	195
Malfunction	192
Manual Bolus	118
Max Basal Alert	151
Max Bolus	125
Max Bolus Alerts	167, 168
Max Hourly Bolus Alert	166
Max Insulin Alert	
Control-IQ Technology	323
Min Basal Alerts	170, 171
Missed Meal Bolus Reminder	148
My Pump Screen	58

O

Occlusion Alarms	185, 186
Options Screen	56
Out of Range Alert	268, 319, 320

Overview

CGM Overview	220

P

Pediatric

Infusion Site Care	23
Security PIN	23

Personal Profiles

Activate a Profile	102
Add Profiles	101
Copy an Existing	102
Create a New Profile	96
Delete a Profile	103
Edit or View	101
Personal Profiles Overview	96
Program a Personal Profile	99
Rename a Profile	102

Power Adapter, AC	88

Power Source Alert	174

Pump History	142

Pump History, Delivery Summary	142

Pump Info	142

Pump Info, Serial Number	142

Pump Package Contents	40

Pump Performance, Specifications	388

Pump Settings, Specifications	385

Pump Specifications	380

Q

Quick Bolus	41, 126
Pediatric	23

R

Receiver, CGM	221

Reminders	145

After Bolus BG	147

Alerts & Reminders	58

High BG	146

Low BG	146

Missed Meal Bolus	148

Site Reminder	116, 148

Reset Alarm	189

Resume Insulin Delivery	138

Resume Pump Alarm	179

Returned Goods Policy	404

Rise Alert, Set	232

Risks from Using the Pump	36
Risks from Using the System	206

S

Safety Information

CGM	201
Control-IQ Technology	281
Pump	25

Screen On/Quick Bolus Button Alarm	187

Screen Protector	40

Screen Timeout, set	92

Screens

Bolus Screen	54
CGM Home Screen	214
CGM Lock Screen	212
Control-IQ Technology	292
Control-IQ Technology Home Screen	290
Control-IQ Technology Lock Screen	288
Current Status Screen	52
Device Settings	60
Home Screen	50
Letter Keypad Screen	64
Lock Screen	48
My CGM Screen	216

My Pump Screen	58
Number Keypad Screen	62
Options Screen	56
Unlock	90
Second Startup Calibration Alert, CGM	254
Security PIN	93
Pediatric	23
Sensor	
Applicator	208
Automatic Shut-Off	239
Failed Sensor, Troubleshooting	277
Out of Range Alert	268, 319, 320
Out of Range/No Antenna, Troubleshooting	277
Troubleshooting	275
Troubleshooting Sensor Reading	276
Unknown Reading	267
Sensor Startup Period	238
Sensor, Start a Session	236
Sensor, Start Calibration	242
Serial Number	18, 142
Set CGM Volume	224
Settings, Pump Setting Specifications	385
Site Reminder	
Set Site Reminder	148
Site Reminder, Set	116

Sound 93**Specifications**

Computer Charging	384
Electromagnetic Compatibility	393
Electromagnetic Emissions	395
Electromagnetic Immunity	396
Pump	380
Pump Performance	388
Water Resistance	380
Startup Calibration Alert	253
Stop a Bolus	128, 133
Stop a Temp Rate	104
Stop CGM Sensor Session	240
Stop Insulin Delivery	138, 139
Storing Your System	196
Supply Reordering	40

T

Tandem Logo	50, 90
Target BG	40
in Personal Profiles	96, 99
Timed Settings	97
Technical Specifications	379
Temp Rate	

Stop a Temp Rate	104
Temp Rate, Set a Temp Basal Rate	103
Temperature Alarm	184
Temperature, Extreme	198
Time	
Date and Time Display	48
Edit Time	91
Time Segments	96
Time Segments, in Personal Profiles	99
Time Segments	
add to Personal Profile	100
Timed Settings	97
in Personal Profiles	99
Transmitter	
Safety Lock	208
Transmitter Error	270
Transmitter ID	236
Travel	199
Traveling, by Air	199
Trend Graphs, Glucose Trends, Arrows	247
Troubleshooting CGM	275
Tubing	
Cartridge Tubing	50
Fill Tubing	113
Tubing Connector	50, 109, 114

U

Units	42
Food Bolus, on Bolus Screen	54
Food Bolus, Using Units	123
Units, on Bolus Screen	54
Unknown Sensor Reading	267
Unlock the Screen	90
USB	
USB Adapter	89
USB Cable	40, 89
USB Port	50, 89

V

View Calculation	54
Volume	93

W

Warranty	
Cartridges	402
Pump Warranty	400
Water Resistance, Pump	198

Watertight, Pump	198

PATENTS AND TRADEMARKS

Covered by one or more patents. For a list of patents, see tandemdiabetes.com/legal/intellectual-property.

Tandem Diabetes Care, the Tandem Diabetes Care logo, t:connect, t:slim X2, and Control-IQ are either registered trademarks or trademarks of Tandem Diabetes Care, Inc., in the U.S. and/or other countries. t:lock, t:slim X2, AutoSoft, TruSteel, and VariSoft are trademarks of Tandem Diabetes Care, Inc. Dexcom and Dexcom G6 are either registered trademarks or trademarks of Dexcom, Inc. in the United States and/or other countries. The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Tandem Diabetes Care, Inc. is under license. All other third party marks are the property of their respective owners.

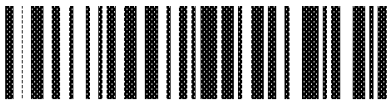




UNITED STATES:
(877) 801-6901
tandemdiabetes.com

CANADA:
(833) 509-3598
tandemdiabetes.ca

OTHER COUNTRIES:
tandemdiabetes.com/contact



1012260_B
AW-1012259_B
2023-OCT-26

© 2023 Tandem Diabetes Care, Inc. All rights reserved.



TANDEM
Diabetes Care

510(K) SUMMARY

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)



TANDEM
Diabetes Care

510(K) SUMMARY

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Thanks Christin. Thanks for the heads up on the delay.

Given the time zone difference, it would be appreciated if you can send it by 3 PM Eastern time on Oct 30, 2023. Would that be reasonable?

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image007.png@01DA08CC.809C52D0]<<http://www.fda.gov/>>

[cid:image008.jpg@01DA08CC.809C52D0]<<https://www.facebook.com/FDA>>

[cid:image009.jpg@01DA08CC.809C52D0] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQlslo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJpOnlrp90Xo0UwJUyBibVEkc2HcBqPoCs9g9N_NFMoHDAxr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image010.jpg@01DA08CC.809C52D0]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image011.jpg@01DA08CC.809C52D0]
<https://secure-web.cisco.com/1c6NVqVSfV2kjjznn-UlA0J4oUTRapVCu10_n_AyTYEq2nEyp_lnxIiz0fkdh-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLomGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCYll4AJqcO7Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image012.jpg@01DA08CC.809C52D0]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-P64NYh2n8dNKlev2arzrrrUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdhrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Friday, October 27, 2023 11:52 AM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Would it be possible for us to send you the labeling documents and 510(k) summaries by COB Monday, October 30th?

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Thursday, October 26, 2023 12:33 PM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>

Subject: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Can you please send your finalized and complete Labeling documents and 510k summaries for the pump (k232380) and Control IQ (k232382)?

It would be great if you can send it by COB Oct 27, 2023.

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, W062 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>

?: 301.796.9573

[cid:image013.png@01DA08CC.809C52D0]<<http://www.fda.gov/>>

[cid:image014.jpg@01DA08CC.809C52D0]<<https://www.facebook.com/FDA>>

[cid:image015.jpg@01DA08CC.809C52D0] <https://twitter.com/US_FDA>

[cid:image016.jpg@01DA08CC.809C52D0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image017.jpg@01DA08CC.809C52D0] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image018.jpg@01DA08CC.809C52D0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Hi Suvajyoti,

My apologies, please see IFU and 510(k) summaries as 3 separate files attached.

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Monday, October 30, 2023 5:14 PM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

My apologies. Usually, in our final stages of finalization, we need these documents as separate attachments. Can you resend the following as separate documents?

1. Finalized label - user guide (one since it's the same one for both submissions k232380 and k232382)
2. 510k summary for k232380
3. 510k summary for k232382

I can generate the IFU form on my end, so that won't be necessary.

I tried to print them separately as three PDFs but could not, probably because its protected on your end? Below is the error I keep getting. If you can send the above request first thing tomorrow morning (10/31) that would be much appreciated.

[cid:image013.png@01DA0B59.0C71A420]

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image014.png@01DA0B59.0C71A420] <<http://www.fda.gov/>>

[cid:image015.jpg@01DA0B59.0C71A420] <<https://www.facebook.com/FDA>>

[cid:image016.jpg@01DA0B59.0C71A420] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCUCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJW>

vO9_SYvb8-IGlf0t1w_ADO-
yDsJpTOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image017.jpg@01DA0B59.0C71A420]
<http://www.youtube.com/user/USFoodandDrugAdmin> [cid:image018.jpg@01DA0B59.0C71A420]
<http://secure-web.cisco.com/1c6NVqVSfv2kjznn-
U1A0J4oUTRapVCu10_n_AyTYEq2nEyp_lnxIiz0fkdh-
QoytaqVxWfZhoJkuVQM_G5MsBRPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-
gePHDDPgIMKJwJdLomGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCYll4AJqc07Gx7nhZg/http
%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image019.jpg@01DA0B59.0C71A420]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrrUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdhrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Sent: Monday, October 30, 2023 2:50 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington
<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see final IFU and 510(k) summaries for K232380 and K232382 attached.

Thank you,

Christin

From: Christin Dunn

Sent: Friday, October 27, 2023 10:05 AM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington
<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Thank you, Suvajyoti!

Yes, that time is reasonable.

Have a great weekend,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Friday, October 27, 2023 8:56 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington
<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ -
Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when
responding, opening attachments, or clicking links.

Thanks Christin. Thanks for the heads up on the delay.

Given the time zone difference, it would be appreciated if you can send it by 3 PM
Eastern time on Oct 30, 2023. Would that be reasonable?

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image014.png@01DA0B59.0C71A420]<<http://www.fda.gov/>>

[cid:image015.jpg@01DA0B59.0C71A420]<<https://www.facebook.com/FDA>>

[cid:image016.jpg@01DA0B59.0C71A420] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_Syvb8-IGlf0t1w_ADo-yDsJPtOn1rp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image017.jpg@01DA0B59.0C71A420]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image018.jpg@01DA0B59.0C71A420]
<http://secure-web.cisco.com/1c6NVqVSfv2kjjznn-UlA0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdh-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgiMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCYll4AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image019.jpg@01DA0B59.0C71A420]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback
regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRrxnEXGvvXlGb7eTpskXQlVK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Sent: Friday, October 27, 2023 11:52 AM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington
<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling
and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or
open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Would it be possible for us to send you the labeling documents and 510(k) summaries by
COB Monday, October 30th?

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Thursday, October 26, 2023 12:33 PM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>

Subject: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k
summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when
responding, opening attachments, or clicking links.

Hi Christin,

Can you please send your finalized and complete Labeling documents and 510k summaries
for the pump (k232380) and Control IQ (k232382)?

It would be great if you can send it by COB Oct 27, 2023.

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics
(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories
(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health
(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, W062 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>

?: 301.796.9573

[cid:image020.png@01DA0B59.0C71A420]<<http://www.fda.gov/>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

[cid:image021.jpg@01DA0B59.0C71A420] <<https://www.facebook.com/FDA>>
[cid:image022.jpg@01DA0B59.0C71A420] <https://twitter.com/US_FDA>
[cid:image023.jpg@01DA0B59.0C71A420] <<http://www.youtube.com/user/USFoodandDrugAdmin>>
[cid:image024.jpg@01DA0B59.0C71A420] <<http://www.flickr.com/photos/fdaphotos/>>
[cid:image025.jpg@01DA0B59.0C71A420]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Hi Christin,

Thanks for reaching out.

In case there are any additional questions or concerns, I am hoping to communicate them over in the next week or so.

Have a great weekend.

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image002.png@01D9FDEB.340BF100]<<http://www.fda.gov/>>

[cid:image003.jpg@01D9FDEB.340BF100]<<https://www.facebook.com/FDA>>

[cid:image004.jpg@01D9FDEB.340BF100] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_Syvb8-IGlf0tlw_ADo-yDsJtOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAxR6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image005.jpg@01D9FDEB.340BF100]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image006.jpg@01D9FDEB.340BF100]
<http://secure-web.cisco.com/1c6NVqVSfv2kjjzn-UlA0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdh-QoytaqVxWfZhoJkuVQM_G5MsbRPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLomGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCyll14AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image007.jpg@01D9FDEB.340BF100]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZwF9-0wUmd-P64NYh2n8dNKlev2arzrrrUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Friday, October 13, 2023 3:34 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232380@docs.fda.gov; k232382@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: [EXTERNAL] Status of K232380 and K232382

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

We have received FDA's decision to proceed forward with interactive review for K232380 and K232382.

Can you please let us know when we can expect to receive additional questions?

Thank You and Best Regards,

[signature_225592142]

Christin Dunn

Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different

12400 High Bluff Drive, San Diego CA 92130

tandemdiabetes.com<<https://tandemdiabetes.com/>>

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

(b)(4)

Suvajyoti Guha

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Tuesday, October 31, 2023 1:22 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: [EXTERNAL] RE: k232380 - Tandem - ACE Pump - Edits for 510k summary

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Request received.

(b)(4)

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Tuesday, October 31, 2023 10:18 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington <LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>

Subject: k232380 - Tandem - ACE Pump - Edits for 510k summary

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Attached are some edits for the 510k summary for the pump.

(b)(4)

(b)(4)

Can you please provide updated version before COB today?

Thanks and please let me know if you have any questions.

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucml15989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, W062 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image002.png@01DA0BFD.7012C280]<<http://www.fda.gov/>>

[cid:image003.jpg@01DA0BFD.7012C280]<<https://www.facebook.com/FDA>>

[cid:image004.jpg@01DA0BFD.7012C280] <https://twitter.com/US_FDA>

[cid:image005.jpg@01DA0BFD.7012C280] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image006.jpg@01DA0BFD.7012C280] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image007.jpg@01DA0BFD.7012C280]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here

<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Thank you! You have a great weekend as well. ऀँँ

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Friday, October 13, 2023 12:38 PM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; k232382@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: RE: Status of K232380 and K232382

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Thanks for reaching out.

In case there are any additional questions or concerns, I am hoping to communicate them over in the next week or so.

Have a great weekend.

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01D9FDD2.5B5F1DE0]<<http://www.fda.gov/>>

[cid:image002.jpg@01D9FDD2.5B5F1DE0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01D9FDD2.5B5F1DE0] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJPtOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image004.jpg@01D9FDD2.5B5F1DE0]

<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image005.jpg@01D9FDD2.5B5F1DE0]

<https://secure-web.cisco.com/1c6NVqVSfV2kjznn-UlA0J4oUTRapVCu10_n_AyTYEq2nEyp_lnxIiz0fkdH-QoytaqVxWfZhoJkuVQM_G5MsbRPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBoRwewttCYH7Gm0I2nqxYQoCyl14AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image006.jpg@01D9FDD2.5B5F1DE0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkeqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXqLVK2YA15GWctEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkeqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXqLVK2YA15GWctEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkeqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXqLVK2YA15GWctEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkeqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXqLVK2YA15GWctEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkeqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXqLVK2YA15GWctEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkeqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXqLVK2YA15GWctEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkeqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXqLVK2YA15GWctEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkeqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXqLVK2YA15GWctEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkeqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXqLVK2YA15GWctEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkeqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXqLVK2YA15GWctEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkeqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXqLVK2YA15GWctEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Sent: Friday, October 13, 2023 3:34 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>;
k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>; Lan Herrington
<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: [EXTERNAL] Status of K232380 and K232382

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

We have received FDA's decision to proceed forward with interactive review for K232380 and K232382.

Can you please let us know when we can expect to receive additional questions?

Thank You and Best Regards,

[signature_225592142]

Christin Dunn

Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different

12400 High Bluff Drive, San Diego CA 92130

tandemdiabetes.com<<https://tandemdiabetes.com/>>

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

Please see 510(k) summary for K232380 with the requested edits attached.

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Tuesday, October 31, 2023 10:24 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: RE: [EXTERNAL] RE: k232380 - Tandem - ACE Pump - Edits for 510k summary

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

(b)(4)

Suvajyoti Guha

From: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Sent: Tuesday, October 31, 2023 1:22 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington <LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: [EXTERNAL] RE: k232380 - Tandem - ACE Pump - Edits for 510k summary

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Request received.

(b)(4)

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Tuesday, October 31, 2023 10:18 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington <LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>

Subject: k232380 - Tandem - ACE Pump - Edits for 510k summary

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Attached are some edits for the 510k summary for the pump.

(b)(4)

(b)(4)

Can you please provide updated version before COB today?

Thanks and please let me know if you have any questions.

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, W062 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image002.png@01DA0BEB.51309750]<<http://www.fda.gov/>>

[cid:image003.jpg@01DA0BEB.51309750]<<https://www.facebook.com/FDA>>

[cid:image004.jpg@01DA0BEB.51309750] <https://twitter.com/US_FDA>

[cid:image005.jpg@01DA0BEB.51309750] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image006.jpg@01DA0BEB.51309750] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image007.jpg@01DA0BEB.51309750]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



U.S. FOOD & DRUG
ADMINISTRATION

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Hi,

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

November 3, 2023</br></br><p>We have completed our review. Please refer to the attached letter for details.</p>

<p>If you have any questions, please contact the lead reviewer assigned to your submission, Suvajyoti Guha.</p>

<p>*** This is a system-generated email notification ***</p>

Thank you! You have a great weekend as well. 😊

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Friday, October 13, 2023 12:38 PM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232380@docs.fda.gov; k232382@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: RE: Status of K232380 and K232382

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

Thanks for reaching out.

In case there are any additional questions or concerns, I am hoping to communicate them over in the next week or so.

Have a great weekend.

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>
Sent: Friday, October 13, 2023 3:34 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232380@docs.fda.gov; k232382@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: [EXTERNAL] Status of K232380 and K232382

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

We have received FDA's decision to proceed forward with interactive review for K232380 and K232382.

Can you please let us know when we can expect to receive additional questions?

Thank You and Best Regards,



Christin Dunn
Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different
12400 High Bluff Drive, San Diego CA 92130
tandemdiabetes.com

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.



Hi Suvajyoti,

Would it be possible for us to send you the labeling documents and 510(k) summaries by COB Monday, October 30th?

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Thursday, October 26, 2023 12:33 PM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov
Subject: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

 Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

Can you please send your finalized and complete Labeling documents and 510k summaries for the pump (k232380) and Control IQ (k232382)?

It would be great if you can send it by COB **Oct 27, 2023**.

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer
Division of Applied Mechanics (DAM)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993
✉: Suvajyoti.Guha@fda.hhs.gov
☎: 301.796.9573



« » * * *

Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>





Food and Drug Administration
Office Location
Business Address
Phone Number

Premarket Notification 510(k) Review

Post-Review Reminders

☐ For SE Decisions: Upload SE Letter, and PDFs of IFU form and 510(k) Summary (if included) in DocMan.

To add reminders, type the reminder in the text field to the left then press the Tab key.

Date: November 1, 2023

Reviewer: Suvajyoti Guha

510(k)# K232380 **Subject:** Traditional

Applicant: Tandem Diabetes Care, Inc.

Contact Name: Christin Dunn

Correspondent Firm: Tandem Diabetes Care, Inc.

Received Date: August 8, 2023

Pro Code(s): QFG **Class:** II **Reg #:** 880.5730

Device Trade Name: t:slim X2 Insulin Pump with Interoperable Technology (with t:connect Mobile App)

Contact Title: Senior Regulatory Affairs Specialist

Phone: (858) 401-1641 **Email:** cdunn@tandemdiabetes.com

Due Date: November 6, 2023

Reg Name: Alternate Controller Enabled Infusion Pump

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K203234	QFG	t:slim X2 Insulin Pump with Interoperable Technology (with t:connect mobile app)	Tandem Diabetes Care, Inc.

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Digital Signature Concurrence Table (Doc ID: 04500.16.00)

This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.

For each of the specific issues identified in the recommended requests to the applicant above, I and/or if applicable contributing consulting reviewer(s) (and or supervisors), have provided a statement of basis for the request(s); and either cited as part of it an available, applicable, and relevant final rule, statute, final guidance, or FDA-recognized consensus standard, or confirmed to the best of my ability for requests: add all relevant numbers here, else delete that there is no final rule, statute, final guidance, or FDA-recognized consensus standard available, applicable, and relevant to the request(s).

I also confirm, if applicable, that contributing consulting reviewers (and or supervisors) have provided the above attestation.

Reviewer Sign-Off

Suvajyoti Guha -S

Digitally signed by Suvajyoti

Guha -S

Date: 2023.11.01 13:39:49 -04'00'

You too!

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Friday, August 11, 2023 2:59 PM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232380@docs.fda.gov; k232382@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>
Subject: RE: [EXTERNAL] RE: K232380 and K232382 - Lead Reviewer and RTA items

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.
hanks Christin.

We have received the information.

Thanks again and have a nice weekend.

Suvajyoti Guha

From: Christin Dunn <CDunn@tandemdiabetes.com>
Sent: Friday, August 11, 2023 4:19 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232380@docs.fda.gov; k232382@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>
Subject: [EXTERNAL] RE: K232380 and K232382 - Lead Reviewer and RTA items

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello Suvajyoti,

Pleasure to meet you and I look forward to working with you.

Please see my responses below:

(b)(4)

Thank you,



Christin Dunn
Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different
12400 High Bluff Drive, San Diego CA 92130
tandemdiabetes.com

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Friday, August 11, 2023 12:41 PM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232380@docs.fda.gov; k232382@docs.fda.gov
Subject: K232380 and K232382 - Lead Reviewer and RTA items

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.
i Christin,

I am the lead reviewer for K232380 and K232382. Can you please provide your responses to the following questions by **3 PM Eastern Time Monday August 14** —

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

K232380

(b)(4)

K232382

(b)(4)

Thanks, and looking forward to working with you on both submissions.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).



Thanks Christin.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01D9E583.3EFFAC80]<<http://www.fda.gov/>>

[cid:image002.jpg@01D9E583.3EFFAC80]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01D9E583.3EFFAC80] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJtOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAxR6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image004.jpg@01D9E583.3EFFAC80]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image005.jpg@01D9E583.3EFFAC80]
<http://secure-web.cisco.com/1c6NVqVSfv2kjjnn-U1A0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdh-QoytaqVxWfZhoJkuVQM_G5MsBRPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCyll14AJqcO7Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image006.jpg@01D9E583.3EFFAC80]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RmiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZWf9-0wUmd-P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdhrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Tuesday, September 12, 2023 2:02 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: RE: [EXTERNAL] RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our response below:

(b)(4)

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Tuesday, September 12, 2023 7:42 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington
<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: RE: [EXTERNAL] RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 -
interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when
responding, opening attachments, or clicking links.

Hi Christin,

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01D9E583.3EFFAC80]<<http://www.fda.gov/>>

[cid:image002.jpg@01D9E583.3EFFAC80]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01D9E583.3EFFAC80] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJpTOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image004.jpg@01D9E583.3EFFAC80]

<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image005.jpg@01D9E583.3EFFAC80]
<https://secure-web.cisco.com/1c6NVqVSfv2kjjzn-UlA0J4oUTRapVCu10_n_AyTYEq2nEyp_lnxIiz0fkdH-QoytaqVxWfZhoJkuVQM_G5MsbRPgvSCB5PGeVwtpbhJUixavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLomGyRK9DisBh6HqQxExQyi07VdBORWewttCYH7Gm0I2nqxYQoCYll4AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image006.jpg@01D9E583.3EFFAC80]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback
regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRrxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZWf9-0wUmd-P64NYh2n8dNKlev2arzrrrUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

From: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Sent: Monday, September 11, 2023 2:32 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington
<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: [EXTERNAL] RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 -
interactive questions

CAUTION: This email originated from outside of the organization. Do not click links or
open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our response to the additional questions sent on September 6th.

Thank you,

Christin

From: Christin Dunn

Sent: Wednesday, September 6, 2023 12:59 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>

Subject: RE: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive
questions

Hi Suvajyoti,

I'm confirming receipt of the additional questions.

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Wednesday, September 6, 2023 6:34 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>

Subject: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when
responding, opening attachments, or clicking links.

Hi Christin,

Can you please respond to the following interactive questions by COB Sep 11, 2023 -

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image007.png@01D9E583.3EFFAC80]<<http://www.fda.gov/>>

[cid:image008.jpg@01D9E583.3EFFAC80]<<https://www.facebook.com/FDA>>

[cid:image009.jpg@01D9E583.3EFFAC80] <https://twitter.com/US_FDA>

[cid:image010.jpg@01D9E583.3EFFAC80] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image011.jpg@01D9E583.3EFFAC80] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image012.jpg@01D9E583.3EFFAC80]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here

<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Hi Suvajyoti,

I'm confirming receipt of your questions.

We will reach out to you if we have any questions.

Thank you,

[signature_225592142]

Christin Dunn

Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different

12400 High Bluff Drive, San Diego CA 92130

tandemdiabetes.com<<https://tandemdiabetes.com/>>

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Friday, August 18, 2023 6:59 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Maiorana, Anthony <Anthony.Maiorana@fda.hhs.gov>; Balsam, Joshua <Joshua.Balsam@fda.hhs.gov>

Subject: K232380 and K232382 - miscellaneous interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Can you please respond to the following interactive questions? For 1-4 below I request that you provide your responses by COB August 25, 2023.

For response 5 below, I request that you provide your response by COB August 22, 2023 and cc our Human Factors SME Dr. Anthony Maiorana.

(b)(4)

(b)(4)

(b)(4)

If you have any follow up questions for me related to the above, please direct them to me by 4 PM today eastern time as I will be on leave for part of next week.

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image002.png@01D9D1AD.2721BC50]<<http://www.fda.gov/>>

[cid:image003.jpg@01D9D1AD.2721BC50]<<https://www.facebook.com/FDA>>

[cid:image004.jpg@01D9D1AD.2721BC50] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf81gYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDs_jPtOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image005.jpg@01D9D1AD.2721BC50]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image006.jpg@01D9D1AD.2721BC50]
<http://secure-web.cisco.com/1c6NVqVSfV2kjznn-UlA0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdH-QoytaqVxWfZhoJkuVQM_G5MsbRPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBorWewttCYH7Gm0I2nqxYQoCyll4AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image007.jpg@01D9D1AD.2721BC50]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YA15GWcTEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdhrhcustomerservice%3FID%3D1914%26S%3DE>).

Thanks Lan. We have received your response.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Lan Herrington <LHerrington@tandemdiabetes.com>

Sent: Monday, October 23, 2023 3:26 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232380@docs.fda.gov; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; k232382@docs.fda.gov; Christin Dunn <CDunn@tandemdiabetes.com>

Subject: [EXTERNAL] RE: k232380 and k232382 - Tandem - Control IQ 1.5 - (b)(4)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello Suvajyoti,

(b)(4)

Thanks.

Lan

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Monday, October 23, 2023 11:23 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; k232382@docs.fda.gov

Subject: RE: k232380 and k232382 - Tandem - Control IQ 1.5 - (b)(4)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin and Lan,

Thanks for providing the responses.

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573





Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Friday, October 20, 2023 4:43 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; k232382@docs.fda.gov

Subject: [EXTERNAL] RE: k232380 and k232382 - Tandem - Control IQ 1.5 - (b)(4)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our responses to your questions attached.

(b)(4)

I will be out of office next Monday and Tuesday (October 23rd & 24th), please send any inquiries to Lan Herrington (cc'ed).

Thank you and have a great weekend,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Monday, October 16, 2023 9:55 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; k232382@docs.fda.gov

Subject: k232380 and k232382 - Tandem - Control IQ 1.5 - (b)(4)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

Please see the following interactive items. Can you please provide your response and updated (b)(4) documents by COB Oct 20, 2023?

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics (DAM)

Office of Science and Engineering Laboratories (OSEL)

Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

✉: Suvajyoti.Guha@fda.hhs.gov

☎: 301.796.9573



• • • • •

Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



Hi Christin,

Can you please respond to the following interactive questions by COB Sep 11, 2023 -

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image001.png@01D9E09F.4D1BF500]<<http://www.fda.gov/>>

[cid:image002.jpg@01D9E09F.4D1BF500]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01D9E09F.4D1BF500] <https://twitter.com/US_FDA>

[cid:image004.jpg@01D9E09F.4D1BF500] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01D9E09F.4D1BF500] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01D9E09F.4D1BF500]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

You too!

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Friday, August 11, 2023 2:59 PM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; k232382@docs.fda.gov; Lan Herrington
<LHerrington@tandemdiabetes.com>

Subject: RE: [EXTERNAL] RE: K232380 and K232382 - Lead Reviewer and RTA items

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Thanks Christin.

We have received the information.

Thanks again and have a nice weekend.

Suvajyoti Guha

From: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Sent: Friday, August 11, 2023 4:19 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>;
k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>; Lan Herrington
<LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>

Subject: [EXTERNAL] RE: K232380 and K232382 - Lead Reviewer and RTA items

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello Suvajyoti,

Pleasure to meet you and I look forward to working with you.

Please see my responses below:

K232380

(b)(4)

K232382

(b)(4)

Thank you,

[signature_225592142]

Christin Dunn

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different
12400 High Bluff Drive, San Diego CA 92130
tandemdiabetes.com<<https://tandemdiabetes.com/>>

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>>
Sent: Friday, August 11, 2023 12:41 PM
To: Christin Dunn <CDunn@tandemdiabetes.com<<mailto:CDunn@tandemdiabetes.com>>>
Cc: k232380@docs.fda.gov<<mailto:k232380@docs.fda.gov>>;
k232382@docs.fda.gov<<mailto:k232382@docs.fda.gov>>
Subject: K232380 and K232382 - Lead Reviewer and RTA items

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

I am the lead reviewer for K232380 and K232382. Can you please provide your responses to the following questions by 3 PM Eastern Time Monday August 14 -

(b)(4)

Thanks, and looking forward to working with you on both submissions.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image002.png@01D9CC64.91498250]<<http://www.fda.gov/>>

[cid:image003.jpg@01D9CC64.91498250]<<https://www.facebook.com/FDA>>

[cid:image004.jpg@01D9CC64.91498250] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8T07yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJpTOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image005.jpg@01D9CC64.91498250]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image006.jpg@01D9CC64.91498250]
<http://secure-web.cisco.com/1c6NVqVSfV2kjznn-UlA0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdH-QoytaqVxWfZhoJkuVQM_G5MsbRPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCy114AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image007.jpg@01D9CC64.91498250]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).



U.S. FOOD & DRUG
ADMINISTRATION

November 3, 2023

Tandem Diabetes Care, Inc.
Christin Dunn
Senior Regulatory Affairs Specialist
12400 High Bluff Drive
San Diego, California 92130

Re: K232380

Trade/Device Name: t:slim X2 Insulin Pump with Interoperable Technology
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate Controller Enabled Infusion Pump
Regulatory Class: Class II
Product Code: QFG
Dated: August 4, 2023
Received: August 8, 2023

Dear Christin Dunn:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Joshua Balsam -S

Joshua M. Balsam, Ph.D.

Branch Chief

Division of Chemistry

and Toxicology Devices

OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Hello Suvaiyoti, we received your questions and will provide response by 9/28. Thank you. Lan

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Thursday, September 21, 2023 9:06:18 AM

To: Lan Herrington <LHerrington@tandemdiabetes.com>; Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232382@docs.fda.gov <k232382@docs.fda.gov>; k232380@docs.fda.gov <k232380@docs.fda.gov>

Subject: K232382 - Tandem - Control IQ 1.5 (b)(4)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Thanks for responding to the (b)(4) questions. We have additional questions related to the (b)(4). Can you please provide your response by COB 9/28?

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).



Thanks Christin.

We have received the information.

Thanks again and have a nice weekend.

Suvajyoti Guha

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Friday, August 11, 2023 4:19 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232380@docs.fda.gov; k232382@docs.fda.gov; Lan Herrington
<LHerrington@tandemdiabetes.com>

Subject: [EXTERNAL] RE: K232380 and K232382 - Lead Reviewer and RTA items

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello Suvajyoti,

Pleasure to meet you and I look forward to working with you.

Please see my responses below:

K232380

(b)(4)

K232382

(b)(4)

Thank you,

[signature_225592142]

Christin Dunn

Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different

12400 High Bluff Drive, San Diego CA 92130

tandemdiabetes.com<<https://tandemdiabetes.com/>>

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>
Sent: Friday, August 11, 2023 12:41 PM
To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>
Cc: k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>;
k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>
Subject: K232380 and K232382 - Lead Reviewer and RTA items

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

I am the lead reviewer for K232380 and K232382. Can you please provide your responses to the following questions by 3 PM Eastern Time Monday August 14 -

(b)(4)

Thanks, and looking forward to working with you on both submissions.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image008.png@01D9CC7D.7F003A80]<<http://www.fda.gov/>>

[cid:image009.jpg@01D9CC7D.7F003A80]<<https://www.facebook.com/FDA>>

[cid:image010.jpg@01D9CC7D.7F003A80] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJPtOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAxR6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image011.jpg@01D9CC7D.7F003A80]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image012.jpg@01D9CC7D.7F003A80]
<https://secure-web.cisco.com/1c6NVqVSfV2kjznn-UlA0J4oUTRapVCu10_n_AyTYEq2nEyp_lnxIiz0fkdh-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-

gePHDDPgIMKJwJdLOmGyRK9DisBh6HgQxEQyi07VdBorWewttCYH7Gm0I2nqxYQoCy114AJqcO7Gx7nhZg/http
%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image013.jpg@01D9CC7D.7F003A80]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback
regarding the customer service you have received (click here<https://secure-
web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-
cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-
P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06jlP_IeF_3WlUE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A
%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

Hi Suvajyoti,

My apologies, please see IFU and 510(k) summaries as 3 separate files attached.

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Monday, October 30, 2023 5:14 PM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

 Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

My apologies. Usually, in our final stages of finalization, we need these documents as separate attachments. Can you resend the following as separate documents?

1. Finalized label – user guide (one since it's the same one for both submissions k232380 and k232382)
2. 510k summary for k232380
3. 510k summary for k232382

I can generate the IFU form on my end, so that won't be necessary.

I tried to print them separately as three PDFs but could not, probably because its protected on your end? Below is the error I keep getting. If you can send the above request first thing tomorrow morning (10/31) that would be much appreciated.



Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10003 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>
Sent: Monday, October 30, 2023 2:50 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see final IFU and 510(k) summaries for K232380 and K232382 attached.

Thank you,

Christin

From: Christin Dunn

Sent: Friday, October 27, 2023 10:05 AM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Thank you, Suvajyoti!

Yes, that time is reasonable.

Have a great weekend,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Friday, October 27, 2023 8:56 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Thanks Christin. Thanks for the heads up on the delay.

Given the time zone difference, it would be appreciated if you can send it by 3 PM Eastern time on Oct 30, 2023. Would that be reasonable?

Thanks,
Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-8673



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Friday, October 27, 2023 11:52 AM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Would it be possible for us to send you the labeling documents and 510(k) summaries by COB Monday, October 30th?

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Thursday, October 26, 2023 12:33 PM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov

Subject: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Christin,

Can you please send your finalized and complete Labeling documents and 510k summaries for the pump (k232380) and Control IQ (k232382)?

It would be great if you can send it by COB **Oct 27, 2023**.

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics (DAM)

Office of Science and Engineering Laboratories (OSEL)

Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

✉: Suvajyoti.Guha@fda.hhs.gov

☎: 301.796.9573



x p n x v

Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



Hi Christin,

Can you please send your finalized and complete Labeling documents and 510k summaries for the pump (k232380) and Control IQ (k232382)?

It would be great if you can send it by COB **Oct 27, 2023**.

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics (**DAM**)

Office of Science and Engineering Laboratories (**OSEL**)

Center for Devices and Radiological Health (**CDRH**)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

✉: Suvajyoti.Guha@fda.hhs.gov

☎: 301.796.9573



x p x x v

Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



SECTION 4. 510(K) COVER LETTER

FDA/CDRH/DCC

August 4, 2023

AUG 08 2023

Document Mail Center (WO66-G609)

RECEIVED

Office of Device Evaluation

K232380

Center for Devices and Radiological Health

Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

To Whom it May Concern,

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act (as amended) and as required in 21 CFR 807, Tandem Diabetes Care, Inc. ("Tandem" or the "Company") is submitting the Traditional 510(k) Notification for a change to our Alternate Controller Enabled (ACE) pump, t:slim X2 insulin pump, for which it intends to market. The t:slim X2 insulin pump has been previously cleared under K201214, and K203234.

The Application Contact is:

Christin Dunn

Senior Regulatory Affairs Specialist

(858) 401-1641

CDunn@tandemdiabetes.com

The secondary contact is:

Lan Herrington

Director, Regulatory Affairs

(858) 255-6378

LHerrington@tandemdiabetes.com



Tandem Diabetes Care, Inc. regards the information provided in this premarket notification and all related correspondence as confidential and proprietary, and requests that such information be afforded the maximum protection provided by 18 U.S.C. § 1905, 21 U.S.C. § 331(j), 5 U.S.C. § 552, and other applicable laws. Further, this notification contains information that is trade secret or confidential commercial information under 21 CFR §20.61 and therefore, exempt from disclosure under the Freedom of Information Act (FOIA). We request that FDA consults with Tandem as provided in 21 CFR §20.47 prior to public disclosure of information contained herein.

According to the instructions on the Food and Drug Administration ("FDA" or the "Agency") website, an electronic copy ("eCopy") is provided. Tandem will utilize the Customer Collaboration Portal (CCP) available via CGRD to submit this Notification.

If you have any additional questions regarding the Traditional 510(k), please contact me by phone or by email provided above.

Sincerely,

(b)(6)

Christin Dunn

Senior Regulatory Affairs Specialist

(858) 401-1641

cdunn@tandemdiabetes.com

CC.:

Sowmya Arunkumar, Vice President, Regulatory Affairs, Arunkumar@Tandemdiabetes.com

David Berger, Executive Vice President & Chief Operating Officer, Dberger@Tandemdiabetes.com

Hi Suvajyoti,

Thank you for the time and effort in reviewing these submissions and thank you for the feedback.

(b)(4)

Best Regards,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Friday, November 3, 2023 8:44 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>; Lan Herrington <LHerrington@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; k232382@docs.fda.gov; Balsam, Joshua <Joshua.Balsam@fda.hhs.gov>; Maiorana, Anthony <Anthony.Maiorana@fda.hhs.gov>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: Follow up items on your ACE Pump (K232380) and iAGC (K232382)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Christina and Lan,

Congratulations on the clearance of the t-slim pump and the Control IQ 1.5

(b)(4)

(b)(4)

Thanks, and please let us know if you have any follow up questions on these two feedbacks.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 82, Rm. 2229 | 10963 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).





510(k) Premarket Notification

(Traditional)

t:slim X2 Insulin Pump with Interoperable Technology

(with t:Connect Mobile App)

Tandem Diabetes Care, Inc.

August 8, 2023



CONTENTS

SECTION 1.	510(K) SCREENING CHECKLIST.....	6
SECTION 2.	MEDICAL DEVICE USER FEE COVER SHEET	46
SECTION 3.	CDRH PREMARKET REVIEW SUBMISSION COVER SHEET	49
SECTION 4.	510(K) COVER LETTER.....	57
SECTION 5.	INDICATIONS FOR USE STATEMENT	59
SECTION 6.	510(K) SUMMARY	61
SECTION 7.	TRUTHFUL AND ACCURATE STATEMENT	67
SECTION 8.	CLASS III SUMMARY AND CERTIFICATION	69
SECTION 9.	FINANCIAL DISCLOSURES.....	70
SECTION 10.	DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS.....	77
10.1	PERFORMANCE STANDARDS – SPECIAL CONTROLS	77
10.2	SPECIAL CONTROLS (880.5730).....	77
10.3	VOLUNTARY STANDARDS	87
10.4	GUIDANCE DOCUMENTS	87
SECTION 11.	DEVICE DESCRIPTION	88
11.1	INTENDED USE	88
11.2	TECHNOLOGICAL CHARACTERISTICS	88
11.2.1	t:slim X2 with Interoperable Technology	88
11.2.2	Accessories	91
11.2.3	Principles of Operation.....	92
11.3	INSULIN PUMP PACKAGED CONTENTS.....	94
SECTION 12.	EXECUTIVE SUMMARY/PREDICATE COMPARISON	100
12.1	EXECUTIVE SUMMARY	100
12.2	CHANGES IMPLEMENTED SINCE THE MOST RECENT 510(K) (PREDICATE DEVICES –K203234).....	101
SECTION 13.	SUBSTANTIAL EQUIVALENCE DISCUSSION.....	104
13.1	INTENDED USE/ INDICATIONS FOR USE	104
13.2	TECHNOLOGICAL CHARACTERISTICS	104
13.3	CONCLUSIONS.....	107
SECTION 14.	PROPOSED LABELING	108
SECTION 15.	STERILIZATION AND SHELF LIFE.....	109
SECTION 16.	BIOCOMPATIBILITY	110
SECTION 17.	SOFTWARE.....	111
SECTION 18.	ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY	120
SECTION 19.	PERFORMANCE TESTING – BENCH	121
SECTION 20.	PERFORMANCE TESTING – ANIMAL	122
SECTION 21.	PERFORMANCE TESTING – CLINICAL	123



LIST OF ATTACHMENTS

Attachment 1 Draft User Guide for the t:slim X2 Insulin Pump with Interoperable Technology and includes the user guide; 128

Attachment 2 Redline of the User Guide. 537

Attachment 3 Pediatric Artificial Pancreas (PEDAP) trial: A Randomized Controlled Comparison of the Control- IQ technology Versus Standard of Care in Young Children in Type 1 Diabetes study protocol and report 948



LIST OF TABLES

Table 1 Acceptance Checklist for Traditional 510(k)s	6
Table 2 Alternate Controller Enabled Insulin Infusion Pump Special Controls	77
Table 3 New Pump	94
Table 4 New Replacement Pump	94
Table 5 Medicare Pump	95
Table 6 Refurbished Pump	96
Table 7 Accessory Kit	97
Table 8 Insulin cartridge 10-Pack	98
Table 9 Insulin cartridge 2-Pack	98
Table 10 Changes Made Since Previous 510(k) K203234.....	102
Table 11 Substantial Equivalence Table	105
Table 12 Software Version History	111
Table 13 Differences Between PEDAP Clinical Trial Software	123



LIST OF FIGURES

Figure 1 The t:slim Insulin Delivery System 89

Figure 2 Cartridge loaded on Pump 90

Figure 3 Dexcom G6 Transmitter and Sensor 91



SECTION 1. 510(K) SCREENING CHECKLIST

Table 1 Acceptance Checklist for Traditional 510(k)



Appendix A. Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review. FDA recommends that the submitter include this completed checklist as part of the application.

510(k)#:

Date Received by DCC:

510(k) Lead Reviewer:

Center:

Office:

Division:

Decision: ☐ Accept ☐ Refuse to Accept

If Accept, notify the submitter.

If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ☐ Yes ☐ No

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

Preliminary Questions			
Answers in the shaded blocks indicate consultation with an identified Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. <i>Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i>	☒	☐	☐



If the product does not appear to be a device or such a combination product, mark "No."			
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. <i>Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i> If submission should not be reviewed by your Center mark "No."	☒	☐	☐
Comments:			
3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: (a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? (b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. <i>Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i> If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☒
Comments:			
4. Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in section 503(g)(5)(C)(ii)-(v) of the FD&C Act? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. <i>Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.</i>	☐	☐	☒
Comments:			



5. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., class III type and PMA required, or class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark “No.”	☒	☐	☐
Comments:			
6. Is there a pending PMA for the same device with the same indications for use? If “Yes,” consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☒	☐
Comments:			
7. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If “Yes,” consult with the CDRH Office of Product Evaluation and Quality/Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark “N/A.” Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☒	☐
Comments:			

- If the answer to 1 or 2 appears to be “No,” then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 3a or 3b appears to be “No,” then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 4 is “Yes,” then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is “No”, the lead reviewer should consult division management and other Center resources to determine the appropriate action. Note that, for a device which is clearly ineligible for a 510(k) submission (such as a device type which is class III requiring PMA or



class I/II and 510(k) exempt), this may be considered a basis for a refusal to accept the submission. A 510(k) submitted for a class I/II, 510(k)-exempt device that trips the limitations of the exemption would not be refused on this basis.

- If the answer to 6 is “Yes,” then stop review of the 510(k), contact CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.
- If the answer to 7 is “Yes,” then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

Organizational Elements				
Failure to include these items should not result in an RTA designation.				
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	*Page #
1.	Submission contains a Table of Contents.	☒	☐	
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	☒	☐	
3.	All pages of the submission are numbered. <i>All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).</i>	☒	☐	
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) <i>If type of 510(k) is not designated, review as a Traditional 510(k).</i>	☒	☐	
Comments:				

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed.
• Any “No” answer will result in a “Refuse to Accept” decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.		Yes	No	N/A	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
A.	Administrative				
1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).	☒	☐		
	Comments:				
2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):				50
a.	Device trade/proprietary name	☒	☐		50
b.	Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐		50
	Comments:				
3.	Submission contains an Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). <i>See recommended format</i> (https://www.fda.gov/media/86323/download).	☒	☐		59
	Comments:				
4.	Submission contains a 510(k) Summary or 510(k) Statement. <i>Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.</i>	☒	☐		61
	Comments:				



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.		Yes	No	N/A	*Page #
5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l). <i>See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).</i>	☒	☐		67
	Comments:				
6.	Submission is a class III 510(k) Device. <i>Select "N/A" only if submission is not a class III 510(k).</i>	☐		☒	N/A
a.	Contains class III Summary and Certification per 21 CFR 807.87(k). <i>See recommended content (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary). Select "N/A" only if submission is not a class III 510(k).</i>	☐	☐	☒	N/A
	Comments:				
7.	Submission contains clinical data. <i>Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a, b, and c below are omitted from the checklist.</i>	☒		☐	948
a.	Submission includes completed Financial Certification (FDA Form 3454, available at https://www.fda.gov/media/70465/download) or Disclosure (FDA Form 3455, available at https://www.fda.gov/media/69872/download) information for each covered clinical study included in the submission. <i>Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the guidance entitled "Financial Disclosures by Clinical Investigators," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/financial-disclosure-clinical-investigators.</i>	☒	☐	☐	70



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (see FDA Form 3674 which can be obtained at https://www.fda.gov/about-fda/reports-manuals-forms/forms) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. <i>Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j).</i>	☒	☐	☐	73
		c.	Statements of Compliance for Clinical Investigations <i>Select "N/A" if the submission does not contain any clinical data from investigations (as defined in 21 CFR 812.3(h)) to demonstrate substantial equivalence.</i> <i>For multicenter clinical investigations involving both United States (US) and outside United States (OUS) sites, part (i) should be addressed for the US sites and part (ii) should be addressed for the OUS sites. 21 CFR 812.28 applies to all OUS clinical investigations that enroll the first subject on or after February 21, 2019.</i> <i>Please refer to the guidance document entitled "Acceptance of Clinical Data to Support Medical Device Applications and Submissions - Frequently Asked Questions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-clinical-data-support-medical-device-applications-and-submissions-frequently-asked for more information.</i>	☒		☐	73



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.								
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					Yes	No	N/A	*Page #
			i.	For each clinical investigation conducted in the US, the submission includes a statement that the investigation was conducted in compliance with 21 CFR parts 50, 56, and 812 (or, with respect to part 56, that it was not subject to the regulations under 21 CFR 56.104 or 56.105). <u>OR</u> The submission includes a brief statement of the reason for noncompliance with 21 CFR parts 50, 56, and/or 812. <i>Select "N/A" if the clinical investigations were conducted solely OUS.</i>	☒	☐	☐	73
			ii.	For each clinical investigation conducted OUS, the submission includes a statement that the clinical investigations were conducted in accordance with good clinical practice (GCP) as described in 21 CFR 812.28(a)(1). <u>OR</u> The submission includes a waiver request in accordance with 21 CFR 812.28(c). <u>OR</u> The submission includes a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected. <i>Select "N/A" if the clinical investigations were conducted solely inside the US.</i>	☐	☐	☒	
			Comments:					



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
8.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). OR States that there were no prior submissions for the subject device. <i>Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download). This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).</i>	☒	☐		50
a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. <i>To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.</i> <i>Select "N/A" if the submitter states there were no prior submissions.</i>	☐	☐	☒	N/A
	Comments:				
9.	The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). <i>This includes both FDA-recognized and non-recognized consensus standards. Select "N/A" if the submission does not utilize voluntary consensus standards.</i>	☒		☐	87
a.	The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐	87



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		i.	The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "<u>Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</u>," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. OR If citing general use of a standard as noted in FDA's guidance "<u>Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</u>," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☐	☒		
		b.	The submission cites non-FDA-recognized voluntary consensus standard(s).	☐		☒	N/A
		i.	The basis of use is included along with the underlying information or data that supports how the standard was used.	☐	☐		
	Comments:						
	Combination Product Provisions – Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.					☒	N/A
	10.	Submission identifies the product as a combination product.		☐	☐		



	11.	The combination product contains as a constituent part an approved drug as defined in section 503(g)(5)(B) of the FD&C Act. Select “N/A” if the combination product does not contain as a constituent part an approved drug. Please also select “N/A” if a right of reference or use for the drug constituent part(s) is included with the submission. If “N/A” is selected, part a below is omitted from the checklist.	☐		☒	N/A



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		a.	The submission includes appropriate patent statement or certification and a statement that the submitter will give notice, as applicable. See section 503(g)(5)(A)&(C) of the FD&C Act.	☐	☐	☒	N/A
			Comments:				
B.	Device Description						
	12.	The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>		☒		☐	77
		a.	The submission addresses device description recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i>	☒	☐	☐	77



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		b.	The submission includes device description information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.</i>	☒	☐	☐	77
		Comments:					
	13.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).		☒	☐		
		Comments:					
	14.	The submission includes descriptive information for the device, including the following:					
		a.	A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐		92
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐		88
		c.	A list and description of each device for which clearance is requested. <i>Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.</i>	☒	☐	☐	94



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. OR Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). <i>In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.</i>	☒	☐		89
			Comments:				
	15.		Device is intended to be marketed with accessories and/or as part of a system. <i>Select "N/A" if the device is not intended to be marketed with accessories and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist.</i>	☒		☐	91
		a.	Submission includes a list of all accessories to be marketed with the subject device.	☒	☐		91
		b.	Submission includes a description (as detailed in item 14a., 14b., and 14d. above) of each accessory. <i>Select "N/A" if the accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.</i>	☐	☐	☒	N/A
		c.	A 510(k) number is provided for each accessory that received a prior 510(k) clearance. AND A statement is provided that identifies accessories that have not received prior 510(k) clearance.	☐	☐	☒	N/A
			Comments:				



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
C.	Substantial Equivalence Discussion					
	16.	Submitter has identified a predicate device(s), including the following information:				
	a.	Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).</i>	☒	☐		104
	b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☒	☐		104
		Comments:				
	17.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)]. <i>See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.</i>				104



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
	a.	Indications for use <i>If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.</i>	☒	☐			104
	b.	Technology, including technical specifications, features, materials, and principles of operation <i>Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.</i> <i>FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.</i>	☒	☐			104
		Comments:					
D.	Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)						
	18.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐			108
	a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐			108
	b.	Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes adequate directions for use (see 21 CFR 801.5) OR - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐			150



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.		Yes	No	N/A	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
	Comments:				
19.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		131
	Comments:				
20.	Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's final rule, " <u>Use of Symbols in Labeling</u> " (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). <i>Select "N/A" if not indicated for prescription use.</i>	☒	☐	☐	151 152
	Comments:				
21.	The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>	☒		☐	77
	a. The submission addresses labeling recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i>	☒	☐	☐	77



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		b.	The submission includes labeling information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.</i>	☒	☐	☐	77
			Comments:				
	22.		If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. <i>Select "N/A" if not an in vitro diagnostic device.</i>	☐	☐	☒	N/A
			Comment:				
E.	Sterilization <i>If an in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.</i>					☒	N/A



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
Submission states that the device and/or accessories, if applicable, are: <i>(one of the below must be checked)</i> ☐ Provided sterile, intended to be single-use ☐ Requires processing during its use-life ☐ Non-sterile when used (and no processing required) ☐ Information regarding the sterility status of the device is not provided (if this box is checked, please also check one of the two boxes below) ☐ Sterility status not needed for this device (e.g., software-only device) ☐ Sterility status needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist.</i> <i>If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No."</i> <i>The "Requires processing during its use-life" option refers to devices falling into one of the four categories below:</i> • <i>Supplied sterile and requires reprocessing prior to subsequent patient use</i> • <i>Supplied non-sterile and requires user to process the device for initial use, as well as to reprocess the device after each use</i> • <i>Reusable medical device (single-user) reprocessed between each use</i> • <i>Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use</i> <i>Please refer to the FDA guidance document "<u>Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling</u>," available at https://www.fda.gov/regulatory-information/search-fda-</i>		☐	☐	☒	N/A



	<u>guidance- documents/reprocessing-medical-devices-health-care-settings-validation- methods-and-labeling, for additional information.</u>				
	Comments:				
23.	Assessment of the need for cleaning and subsequent disinfection or sterilization information.	☐	☐	☒	N/A



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		a.	Identification of device and/or accessories, if applicable, that are provided sterile. <i>Select "N/A" if no part of the device or accessories are provided sterile.</i>	☐	☐	☒	N/A
		b.	Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected. <i>Select "N/A" if no part of the device are accessories are end user sterilized or disinfected.</i>	☐	☐	☒	N/A
		c.	Identification of device and/or accessories, if applicable, that are reusable. <i>Select "N/A" if no part of the device or accessories, are reusable.</i>	☐	☐	☒	N/A
			Comments:				
	24.		If the device and/or accessories, if applicable, are provided sterile: <i>Select "N/A" if no part of the device or accessories are provided sterile, otherwise complete a-f below.</i>			☒	N/A
		a.	Sterilization method is stated for each device (including dose for radiation sterilization)	☐	☐		
		b.	A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date). <i>Note: the sterilization validation report is not required.</i>	☐	☐		
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. <i>Select "N/A" if not sterilized using chemical sterilants.</i>	☐	☐	☐	
		d.	Sterility Assurance Level (SAL) stated	☐	☐		
		e.	Submission includes description of packaging	☐	☐		



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]). <i>Select "N/A" if not labeled "non-pyrogenic."</i>	☐	☐	☒	N/A
			Comments:				
	25.		If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected: <i>Select "N/A" if no part of the device or accessories are reusable or end user sterilized or disinfected, otherwise complete a-d below.</i>			☒	N/A
		a.	Cleaning method is provided in labeling for each device and/or accessory, if applicable. <i>Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization.</i>	☐	☐	☐	
		b.	Disinfection method is provided in labeling for each device and/or accessory, if applicable. <i>Select "N/A" if not disinfected (i.e., undergoes terminal sterilization) prior to use.</i>	☐	☐	☐	
		c.	Sterilization method is provided in labeling for each device and/or accessory, if applicable. <i>Select "N/A" if not sterilized (i.e., undergoes disinfection) prior to use.</i>	☐	☐	☐	



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		d.	Device types in this submission are listed in the Federal Register (FR) Notice entitled "<u>Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications</u>" (Reprocessing FR Notice, available at https://www.federalregister.gov/documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable). <i>Device types identified in the Reprocessing FR Notice represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection. Select "N/A" if the device type in the submission is not included in the Reprocessing FR Notice.</i>	☐		☒	N/A
		i.	If device types in this submission are included in the Reprocessing FR Notice, the submission includes protocols and test reports for validating the reprocessing instructions. <i>Select "N/A" if the device type in the submission is not included in the Reprocessing FR Notice.</i>	☐	☐	☒	N/A
		Comments:					
	26.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding sterility and/or reprocessing that is applicable to the subject device. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>		☐		☒	N/A



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		a.	The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. <u>OR</u> The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i>	☐	☐	☐	
		b.	The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. <u>OR</u> The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.</i>	☐	☐	☐	
			Comments:				
F.	Shelf-Life						
	27.		Proposed shelf life/ expiration date stated <u>OR</u> Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation.	☐	☒		N/A



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
	Comments:				
28.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life. <i>Select "N/A" if the device is not provided sterile.</i>	☐	☐	☒	N/A
	Comments:				
29.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). <u>OR</u> Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☐	☐	☒	N/A
	Comments:				
G.	Biocompatibility <i>If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.</i>			☒	N/A



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
	Submission states that there: <i>(one of the below must be checked)</i> ☐ Are direct or indirect tissue-contacting components ☐ Are no direct or indirect tissue-contacting components ☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below) Tissue contact information not needed for this device (e.g., software- only device) Tissue contact information is needed or need unclear	☐	☐		N/A
Comments: See page 110					
30.	Submission includes a list identifying each tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☐	☐		
	Comments:				
31.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter).	☐	☐		
	Comments:				



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
32.	For a biocompatibility assessment of tissue-contacting components, submission includes: - Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "<u>Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'</u>" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. - For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "<u>Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'</u>" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "<u>Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'</u>" provided for each completed test. <u>OR</u> A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☐	☐		
	Comments:				
H.	Software				



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
	Submission states that the device: <i>(one of the below must be checked)</i> ☒ Does contain software/firmware ☐ Does not contain software/firmware ☐ Information on whether device contains software/firmware is not provided (if this box checked, please also check one of the two boxes below) ☐ Software/firmware information not needed for this device (e.g., surgical suture, condom) ☐ Software/firmware information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "does not contain" or "not provided and not needed" is selected, the software-related criteria below are omitted from the checklist. If information on software is not provided, and this information is needed or the need is unclear, select "No."</i>	☒	☐		111
	Comments:				
33.	Submission includes a statement of software level of concern and rationale for the software level of concern	☐	☒		
	Comments: There have been no major design changes to software that would exceed the threshold of a new 510(k).				



	34.	All applicable software documentation provided based on level of concern identified by the submitter, as described in “<u>Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices</u>,” available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale). <i>Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device.</i>	☐	☒		



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
	Comments:				
I.	Cybersecurity				
	Submission states that the device: <i>(one of the below must be checked)</i> ☒ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.) ☐ Does not contain external interfaces as described above ☐ Information on whether device has external interfaces is not provided (if this box is checked, please also check one of the two boxes below) ☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom) ☐ Cybersecurity information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "does not contain" or "not provided and not needed" is selected, the cybersecurity criteria below are omitted from the checklist. If information on cybersecurity is not provided, and this information is needed or the need is unclear, select "No."</i>	☒	☐		111
35.	All applicable documentation identified by the submitter, as described in "<u>Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices</u>," available at <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0</u>. OR Submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☒	☐		111
	Comments: There have been no changes to Cybersecurity since the previous 510(k) submission.				



J.	Electrical Safety and EMC				



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
	Electrical Safety: Submission states that the device: <i>(one of the below must be checked)</i> ☐ Does require electrical safety evaluation ☐ Does not require electrical safety evaluation ☐ Information on whether device requires electrical safety evaluation is not provided (if this box checked, please also check one of the two boxes below) ☐ Electrical safety information not needed for this device (e.g., surgical suture, condom) ☐ Electrical safety information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "does not require" or "not provided and not needed" is selected, the electrical safety criteria below are omitted from the checklist. If information on electrical safety is not provided, and it is needed or the need for this information is unclear, select "No."</i>	☐	☐	☒	120
36.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard). <u>OR</u> Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐	☐		
	Comments: No changes have been made to Electrical Safety since the last 510(k) submission.				



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
EMC: Submission states that the device: <i>(one of the below must be checked)</i> ☐ Does require EMC evaluation ☐ Does not require EMC evaluation ☐ Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ EMC information not needed for this device (e.g., surgical suture, condom) ☐ EMC information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "does not require" or "not provided and not needed" is selected, the EMC criteria below are omitted from the checklist. If information on EMC is not provided, and it is needed or the need for this information is unclear, select "No."</i>		☐	☐	☒	120
Comments: No changes have been made to EMC since the last 510(k) submission.					
37.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, a device-specific standard). OR Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐	☐	☒	
Comments: No changes have been made to EMC since the last 510(k) submission.					



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
K.	Performance Data General <i>If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section L.</i>			☒	N/A
Comments:					
38.	Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. Select "N/A" if the submission appropriately does not include performance data or there are no completed tests without a Declaration of Conformity.	☐	☐	☒	N/A
	a. Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.). Select "N/A" if the submission does not include performance data.	☐	☐	☒	N/A
Comments:					



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
39.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding performance data that is applicable to the subject device. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>		☐		☒	N/A
	a.	The submission addresses performance data recommendations outlined in the device-specific guidance. <u>OR</u> The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i>	☐	☐	☒	N/A
	b.	The submission includes performance data that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. <u>OR</u> The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there are no applicable special controls or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.</i>	☐	☐	☒	N/A
	Comments:					



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
40.	If literature is referenced in the submission, submission includes: <i>Select "N/A" if the submission does not reference literature. If "N/A" is selected, parts a and b below are omitted from the checklist.</i> <i>Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.</i>				☒	N/A
	a.	Legible reprints or a summary of each article.	☐	☐		
	b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☐	☐		
	Comments:					
41.	For each completed animal study, the submission provides the following: <i>Select "N/A" if no animal study was conducted. If "N/A" is selected, parts a-c below are omitted from the checklist. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist.</i>				☒	N/A
	a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☐	☐		
	b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☐	☐		
	c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), OR, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐	☐		
	Comments:					



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.		Yes	No	N/A	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
L.	Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))				
	Submission indicates that device: <i>(one of the below must be checked)</i> ☐ Is an in vitro diagnostic device ☒ Is not an in vitro diagnostic device <i>If "is not" is selected, the performance data-related criteria below are omitted from the checklist.</i>				
42.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:				
a.	Precision/reproducibility	☐	☐	☐	
b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff).	☐	☐	☐	
c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐	
d.	Analytical specificity	☐	☐	☐	
	Comments:				
43.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding performance data that is applicable to the subject device. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>	☐	☐	☐	



Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. <u>OR</u> The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i>	☐	☐	☐	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. <u>OR</u> The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.</i>	☐	☐	☐	
			Comments:				



Digital Signature Concurrence Table	
Reviewer Sign-Off	
Management Sign-Off (digital signature optional)*	

*Management review of checklist and concurrence with decision required.



SECTION 2. MEDICAL DEVICE USER FEE COVER SHEET

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) TANDEM DIABETES CARE INC 12400 High Bluff Drive San Diego CA 92130 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****7508	2. CONTACT NAME Lan Herrington 2.1 E-MAIL ADDRESS Lherrington@tandemdiabetes.com 2.2 TELEPHONE NUMBER (include Area code) 760-7079619 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm) <u>Select an application type:</u> ☒ Premarket notification(510(k)); except for third party ☐ 513(g) Request for Information ☐ Biologics License Application (BLA) ☐ Premarket Approval Application (PMA) ☐ Modular PMA ☐ Product Development Protocol (PDP) ☐ Premarket Report (PMR) ☐ 30-Day Notice ☐ De Novo Request 3.1 Select a center ☒ CDRH ☐ CBER 3.2 Select one of the types below ☒ Original Application <u>Supplement Types:</u> ☐ Efficacy (BLA) ☐ Panel Track (PMA, PMR, PDP) ☐ Real-Time (PMA, PMR, PDP) ☐ 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) ☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA ☒ NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:	
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? ☒ YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.) ☐ NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)	
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. ☐ This application is the first PMA submitted by a qualified small business, including any affiliates ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only ☐ The sole purpose of the application is to support conditions of use for a pediatric population ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) ☐ YES ☒ NO	
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI-STATUS@fda.hhs.gov or 301-796-8118	

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

12-Jul-2023

Form FDA 3601 (07/22)

["Close Window"](#) [Print Cover sheet](#)



SECTION 3. CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 08/08/2023	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)

SECTION A TYPE OF SUBMISSION

PMA & PDP ☐ Original ☐ Modular Submission ☐ Amendment ☐ Report (annual or PAS) ☐ Report Amendment ☐ Other: ☐ Premarket Report (reprocessed SUD) ☐ Licensing Agreement	PMA/PDP Supplement ☐ 180 day - PAS protocol or labeling change, location change, trade name change ☐ 180 day - Design or labeling change ☐ Special CBE ☐ Panel Track ☐ 30-day Notice ☐ Real-time Review ☐ Amendment to PMA/PDP Supplement	510(k) ☒ Original Submission: ☒ Traditional ☐ Special ☐ Abbreviated ☐ 3rd Party Traditional ☐ 3rd Party Special ☐ 3rd Party Abbreviated ☐ Dual Track (Dual 510(k) and CLIA Waiver by Application) ☐ Amendment ☐ Supplement	CLIA CLIA Categorization Record (CR) ☐ Original ☐ Amendment CLIA Waiver by Application (CW) ☐ Original ☐ Amendment ☐ Supplement	Q-Submission ☐ Pre-Submission ☐ Informational Meeting ☐ Submission Issue Meeting ☐ Day 100 Meeting ☐ Agreement Meeting ☐ Determination Meeting ☐ Study Risk Determination ☐ Other (Specify below)
IDE ☐ Original IDE: ☐ Amendment to Original IDE ☐ Supplement: ☐ Amendment to Supplement ☐ Report: ☐ Amendment to Report	HDE ☐ Original Submission ☐ Amendment to Original ☐ Report ☐ Report Amendment ☐ HDE Supplement: ☐ 75-day Supplement ☐ 30-day Notice ☐ Special CBE ☐ Amendment to Supplement	Class II Exemption Petition ☐ Original Submission ☐ Additional Information Emergency Use Authorization ☐ Original ☐ Supplement ☐ Amendment ☐ Report	De Novo ☐ Original: ☐ Direct ☐ Post-NSE ☐ Amendment ☐ Supplement Pre-Emergency Use Authorization ☐ Original ☐ Supplement ☐ Amendment	Other Submission ☐ 513(g) ☐ Appeal ☐ Other (Briefly describe submission below)

Expanded Access to Devices

- ☐ Compassionate Use Request NOT associated with an IDE
☐ Follow-up Report for Compassionate Use NOT associated with an IDE
☐ Emergency Use Follow-up Report NOT associated with an IDE

SECTION B APPLICANT / SPONSOR

Company/Institution Name Tandem Diabetes Care, Inc.		Establishment Registration Number/FEI (if known)	
Street Address 12400 High Bluff Drive		City San Diego	
State/Province CA	ZIP/Postal Code 92130	Country USA	
Contact Name Christin Dunn		Contact Title Senior Regulatory Affairs Specialist	
Division Name (if applicable)		Phone Number (including area code) (858) 401-1641	
Fax Number (including area code)		Contact Email Address cdunn@tandemdiabetes.com	

SECTION C OFFICIAL CORRESPONDENT (e.g., may be a consultant and/or 510(k) Third Party) (if different from Section B)

Company/Institution Name		Establishment Registration Number/FEI (if known)	
Street Address		City	
State/Province	ZIP/Postal Code	Country	
Contact 1 Name		Contact 1 Title	
Contact 1 Division Name (if applicable)		Contact 1 Phone Number (including area code)	
Contact 1 Fax Number (including area code)	Contact 1 Email Address		
Contact 2 Name		Contact 2 Title	
Contact 2 Division Name (if applicable)		Contact 2 Phone Number (including area code)	
Contact 2 Fax Number (including area code)	Contact 2 Email Address		
Contact 3 Name		Contact 3 Title	
Contact 3 Division Name (if applicable)		Contact 3 Phone Number (including area code)	
Contact 3 Fax Number (including area code)	Contact 3 Email Address		

To add another set of Section C items, please click on the button to the right. May be repeated as needed.

Add Section C

SECTION D INTENDED USE POPULATION

Check all that apply.

☐ Adults Only (greater than 21 years of age)	☐ Neonate/Newborn (birth through 28 days)	☐ Other (Specify below)
☒ Adults and Pediatrics	☐ Infant (from 29 days to 2 years of age)	
	☒ Child (from 2 years to 12 years of age)	
	☒ Adolescent (from 12 years to 18 years of age)	
	☒ Transitional Adolescent A (18 through 21 years of age)	
	☐ Transitional Adolescent B (18 through 21 years of age)	

SECTION E PRODUCT INFORMATION – APPLICABLE TO ALL SUBMISSIONS

	Trade Name
1	t:slim X2 Insulin Pump With Interoperable Technology (with t:connect Mobile App)
2	
3	
4	
5	
Common/Generic Name (Include if no Trade Name)	

SECTION F PRIOR RELATED SUBMISSIONS FOR THIS DEVICE OR STUDYFDA document numbers of all prior related submissions (*regardless of outcome*) or state no prior submission in box 1.

1 (b)(4)	2 DEN180058	3 K201214
4 K203234	5	6
7	8	9
10	11	12

SECTION G PRODUCT CLASSIFICATION – APPLICABLE TO ALL SUBMISSIONSProduct Code(s) (*when applicable*) (*If more than one, please separate with commas.*)

QFG

C.F.R. Section (*If applicable*)

880.5730

Classification Panel/Medical Specialty

Clinical Chemistry

Device Class

☐ Class I ☒ Class II ☐ Class III ☐ Unclassified**SECTION H1 REASON FOR APPLICATION – PMA, PDP, OR HDE**

- ☐
- New Device
-
- ☐
- STED

☐ Post-approval Study Protocol☐ HDE Request for Annual Distribution Number (ADN)☐ Change in Design, Component, or Specification:

- ☐
- Software/Hardware
-
- ☐
- Color Additive
-
- ☐
- Material
-
- ☐
- Specifications
-
- ☐
- Other (
- Specify below*
-)

☐ Location Change:

- ☐
- Manufacturer
-
- ☐
- Sterilizer
-
- ☐
- Packager

☐ Report Submission:

- ☐
- Annual or Periodic
-
- ☐
- Post-approval Study

☐ Process Change:

- ☐
- Manufacturing
-
- ☐
- Packaging
-
- ☐
- Sterilization
-
- ☐
- Vendor/Supplier Change
-
- ☐
- Other (
- Specify below*
-)

☐ Labeling Change:

- ☐
- Indications
-
- ☐
- Instructions
-
- ☐
- PAS update
-
- ☐
- Performance Characteristics
-
- ☐
- Shelf Life
-
- ☐
- Trade Name
-
- ☐
- Other (
- Specify below*
-)

☐ Amendment:

- ☐
- Withdrawal
-
- ☐
- Change in Ownership
-
- ☐
- Change in Correspondent
-
- ☐
- Change of Address
-
- ☐
- Request for Extension
-
- ☐
- Response to FDA Correspondence
-
- ☐
- Other (
- Specify below*
-)

☐ Bundle Submission – *If this is selected, list in the spaces below any PMAs in the Bundle.*

1	2	3
4	5	6
7	8	9

SECTION H2**REASON FOR APPLICATION – IDE**☐ Original IDE☐ Supplement:

- ☐ New Study/New Protocol
- ☐ Change in Correspondent
- ☐ Change in Manufacturer
- ☐ Change in Sponsor
- ☐ Change in Design
- ☐ Change in Informed Consent
- ☐ Change in Manufacturing
- ☐ Change in Protocol
- ☐ 5-Day Notice – Device or Manufacturing
- ☐ 5-Day Notice – Protocol
- ☐ Compassionate Use Request (under an IDE)
- ☐ Live Case Request
- ☐ Request Deviation from Protocol
- ☐ Expansion of Study (Study/Sites)
- ☐ Extension of Time to Submit Annual Report or Respond to FDA Letter

Supplement (Continued)

- ☐ Request for Waiver
- ☐ IRB Certification
- ☐ Request for CMS Recategorization
- ☐ Study Resumed
- ☐ Study Suspension
- ☐ Other (Specify below)

☐ Report:

- ☐ Adverse Effect
- ☐ Final, Study Completed
- ☐ Annual Progress
- ☐ Interim Progress
- ☐ Semiannual Investigator List
- ☐ Failure to Obtain Informed Consent
- ☐ Compassionate Use Follow-up
- ☐ Emergency Use
- ☐ Live Case Follow-up
- ☐ Completion of Patient Enrollment
- ☐ Completion of Patient Follow-up
- ☐ Other (Specify below)

☐ Amendment to Original IDE:

- ☐ Amendment Before Final Decision
- ☐ Response to Refuse to Accept
- ☐ Response to Disapproval
- ☐ Response to Approval with Conditions
- ☐ Withdrawal
- ☐ Other (Specify below)

☐ Amendment to Supplement:

- ☐ Response to Disapproval
- ☐ Response to Approval with Conditions
- ☐ Withdrawal
- ☐ Amendment Before Final Decision (additional information)
- ☐ Other (Specify below)

☐ Amendment to Report:

- ☐ Response to Deficiency Letter
- ☐ Withdrawal
- ☐ Amendment Before Final Decision (additional information)
- ☐ Other (Specify below)

SECTION H3**REASON FOR SUBMISSION – Q-SUBMISSION**☐ Pre-Submission:

- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Request Email Response
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-con

☐ Submission Issue Meeting:

- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Request Email Response
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-con

☐ Additional Information☐ Change in Legal Entity:

- ☐ Change in Correspondent
- ☐ Change in Sponsors
- ☐ Change in Manufacturer
- ☐ Other (Specify below)

☐ Agreement Meeting:

- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference

☐ Determination Meeting:

- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference

☐ Informational Meeting:

- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-Con

☐ Other (Specify):

SECTION H4**REASON FOR SUBMISSION – 510(k)**

- ☒ Original
☐ Withdrawal of Original

- ☐ Amendment Before Final Decision:
☐ Change in Ownership
☐ Change in Correspondent
☐ Withdrawal

- ☐ Supplement:
☐ Response to Refuse to Accept (RTA)
☐ Response to Additional Information Request
☐ Withdrawal

- ☐ Amendment After Final Decision

- ☐ Reprocessed SUD

- ☐ Corrective Action

- ☐ STED

- ☐ Third Party (Complete Section C)

- ☐ Other Reason (Specify):

Information on devices to which substantial equivalence is claimed (If known)

	510(k) Number	Trade Name	Submitter	Product Code
Primary Predicate (A)	K203234	t:slim X2 Insulin Pump with Interoperable Technology (with t:connect mobile app)	Tandem Diabetes Care, Inc.	QFG
Predicate or Reference Device (B)				

To add another Predicate or Reference Device (B) entry row, please click on the button to the right. May be repeated as needed.

Add Device Information

SECTION H5**DE NOVO SUBMISSIONS**

- ☐ Post NSE De Novo: Number of the 510(k) that was NSE'd in the past 30 days:
☐ Withdrawal

SECTION H6**REASON FOR APPLICATION – CLIA**

Includes CLIA Parent Document number, CR number, or CW number.

- ☐ CLIA Categorization Record (CR):
- ☐ CLIA Categorization of marketed device (include marketing submission number)
 - ☐ CLIA Categorization of device exempt from premarket review
 - ☐ Additional information regarding an open CR (include CR number)
- ☐ CLIA Waiver by Application (CW):
- ☐ Request for CLIA Waiver by Application for marketed device (include marketing submission number)
 - ☐ Request for Dual 510(k) Clearance and CLIA Waiver by Application (include Pre-submission number)
 - ☐ Response to FDA correspondence
 - ☐ Additional information regarding an open CW (include CW number)

- ☐ Other Reason (Specify)

SECTION I MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

Applicable only to IDEs

Note: Submission of this information does not affect Registration and Listing.

FDA Document Number (if known)

☐ Original ☐ Add ☐ Delete		Facility Establishment Identifier (FEI) Number		☐ Manufacturer ☐ Contract Manufacturer		☐ Contract Sterilizer ☐ Repackager/Relabeler	
Company/Institution Name				Establishment Registration Number/FEI (if known)			
Street Address				City			
State/Province		ZIP/Postal Code		Country			
Contact 1 Name				Contact 1 Title			
Contact 1 Division Name (if applicable)				Contact 1 Phone Number (including area code)			
Contact 1 Fax Number (including area code)			Contact 1 Email Address				
Contact 2 Name				Contact 2 Title			
Contact 2 Division Name (if applicable)				Contact 2 Phone Number (including area code)			
Contact 2 Fax Number (including area code)			Contact 2 Email Address				
Contact 3 Name				Contact 3 Title			
Contact 3 Division Name (if applicable)				Contact 3 Phone Number (including area code)			
Contact 3 Fax Number (including area code)			Contact 3 Email Address				

To add another set of Section I items, please click on the button to the right. May be repeated as needed.

Add Section I

SECTION J UTILIZATION OF STANDARDS

Note: Please see guidance document titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" for details on the Declaration of Conformity.

How to fill out this section:

Recognition Number: State the FDA recognition number. If the standard is not recognized, write **NR**.

Declaration of Conformity or General Use: Select 'Declaration of Conformity' if including a "Declaration of Conformity to a Recognized Standard" statement. For all other uses, select 'General Use' and indicate if you have made deviations from the Recognized/Non-recognized standard.

Standard: State the Standards Development Organization (SDO), the Designation Number (including year), and the Title.

Location: State the section and/or the page number(s) in the submission where the standard is applied.

Examples

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 ☒	8-185	Declaration of Conformity	If General Use, Deviation?	ASTM F451-08, standard specification for acrylic bone cement.	Section 3, p. 15
2 ☒	3-44	General Use	If General Use, Deviation? Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4, p. 32

Entries for Utilization of Standards

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1	☒	Declaration of Conformity	If General Use, Deviation?		

To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Standard

SECTION K

UTILIZATION OF CDRH GUIDANCE DOCUMENTS

How to fill out this section:

Title: Enter the title of the guidance documents used in the preparation of your premarket submission. CDRH guidance documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>.

Entries for Utilization of CDRH Guidance Documents

	Title of Guidance Document
1	Infusion Pumps Total Product Life Cycle - Guidance for Industry and FDA Staff
☒	
2	Deciding When to Submit a 510(k) for a Change to an Existing Device
☒	

To add another row for Section K, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Document

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average .5 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



SECTION 4. 510(K) COVER LETTER

August 4, 2023

Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

To Whom it May Concern,

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act (as amended) and as required in 21 CFR 807, Tandem Diabetes Care, Inc. ("Tandem" or the "Company") is submitting the Traditional 510(k) Notification for a change to our Alternate Controller Enabled (ACE) pump, t:slim X2 insulin pump, for which it intends to market. The t:slim X2 insulin pump has been previously cleared under K201214, and K203234.

The Application Contact is:

Christin Dunn
Senior Regulatory Affairs Specialist
(858) 401-1641
CDunn@tandemdiabetes.com

The secondary contact is:

Lan Herrington
Director, Regulatory Affairs
(858) 255-6378
LHerrington@tandemdiabetes.com



Tandem Diabetes Care, Inc. regards the information provided in this premarket notification and all related correspondence as confidential and proprietary, and requests that such information be afforded the maximum protection provided by 18 U.S.C. § 1905, 21 U.S.C. § 331(j), 5 U.S.C. § 552, and other applicable laws. Further, this notification contains information that is trade secret or confidential commercial information under 21 CFR §20.61 and therefore, exempt from disclosure under the Freedom of Information Act (FOIA). We request that FDA consults with Tandem as provided in 21 CFR §20.47 prior to public disclosure of information contained herein.

According to the instructions on the Food and Drug Administration ("FDA" or the "Agency") website, an electronic copy ("eCopy") is provided. Tandem will utilize the Customer Collaboration Portal (CCP) available via CGRD to submit this Notification.

If you have any additional questions regarding the Traditional 510(k), please contact me by phone or by email provided above.

Sincerely,

(b)(6)

Christin Dunn

Senior Regulatory Affairs Specialist

(858) 401-1641

cdunn@tandemdiabetes.com

CC.:

Sowmya Arunkumar, Vice President, Regulatory Affairs, Sarunkumar@Tandemdiabetes.com

David Berger, Executive Vice President & Chief Operating Officer, Dberger@Tandemdiabetes.com



SECTION 5. INDICATIONS FOR USE STATEMENT

The Indications for Use Statement for Tandem's t:slim X2 Insulin Pump with Interoperable Technology is provided on the next page

The intended use of the current device is the same as that for the predicate device with the addition of lowering the age indication to 2 years of age and greater and the removal of compatible insulins, recommended during the review of 510(k) K223213.

Indications for Use

510(k) Number (if known)

Device Name

t:slim X2 Insulin Pump with Interoperable Technology

Indications for Use (Describe)

The t:slim X2 insulin pump with interoperable technology (the Pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use in individuals 2 years of age and greater.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



SECTION 6. 510(K) SUMMARY

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)



SECTION 7. TRUTHFUL AND ACCURATE STATEMENT



t:slim X2 Insulin Pump with Interoperable Technology

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 C.F.R. R. § 807.87(l))**

I certify that, in my capacity as Executive Vice President & Chief Operating Officer of Corporate of Tandem Diabetes Care, Inc. responsible for Regulatory Affairs, Quality Assurance and Clinical Affairs, I believe that to the best of my knowledge, that all data and information submitted in this premarket notification and truthful and accurate and that no material fact has been omitted.

(b)(6)

Signature

David Berger

Name

Aug 4, 2023

Date

Kxxxxxx



SECTION 8. CLASS III SUMMARY AND CERTIFICATION

The Tandem t:slim X2 Insulin Pump with Interoperable Technology is a Class II device and therefore, a Class III Summary and Certification is not required for this 510(k) notification.



SECTION 9. FINANCIAL DISCLOSURES

Clinical testing was performed to demonstrate the safety and effectiveness of the device for 2- to 5-year old patient populations. Pursuant to 21 CFR § 54.4(a)(3) and in accordance with the FDA Guidance for Clinical Investigators, Industry, and FDA Staff, Financial Disclosure by Clinical Investigators February 2013 are provided for each covered clinical study included in the submission on the next page.

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable check box.

- ☐ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		

- ☒ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).
- ☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME Christin Dunn	TITLE Senior Regulatory Affairs Specialist
FIRM/ORGANIZATION Tandem Diabetes Care, Inc.	
SIGNATURE Christin Dunn Digitally signed by Christin Dunn Date: 2023.08.03 12:56:27 -07'00'	DATE (mm/dd/yyyy) 08/03/2023

This section applies only to the requirements of the Paperwork Reduction Act of 1995.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Do NOT send your completed form to the PRA Staff email address below.

Department of Health and Human Services
Food and Drug Administration
Office of Operations
PRAStaff@fda.hhs.gov



Below is the list of investigators involved in the clinical trial associated with this application:

(b)(6)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter Tandem Diabetes Care, Inc.		2. Date of the Application/Submission 08/08/2023	
3. Address Address 1 (Street address, P.O. box, company name c/o) 12400 High Bluff Drive Address 2 (Apartment, suite, unit, building, floor, etc.) City San Diego State/Province/Region CA Country US ZIP or Postal Code 92130		4. Telephone and Fax Numbers (Include country code if applicable and area code) (Tel): (858) 366-6900 (Fax):	

PRODUCT INFORMATION

5. For Drugs/Biologics: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Control-IQ Technology

t:slim X2 Insulin Pump

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number
(If number previously assigned)

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes (See instructions for additional information and explanation)
- ☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.
- ☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.
- ☒ C. I certify that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that the requirements of 42 U.S.C. 282(j), including any applicable provisions of 42 CFR part 11, have been met.

Certification Statement / Information section continued on page 2

CERTIFICATION STATEMENT / INFORMATION (Continued)

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," for which you (the sponsor/applicant/submitter) are the "responsible party" under 42 U.S.C. § 282(j)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act referenced in the application/ submission which this Certification accompanies. (Add continuation page as necessary.)

NCT Number(s): NCT04796779

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Christin Dunn	Senior Regulatory Affairs Specialist

12. Address

Address 1 (Street address, P.O. box, company name c/o)

12400 High Bluff Drive

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

San Diego

State/Province/Region

CA

Country

US

ZIP or Postal Code

92130

13. Telephone and Fax Numbers

(Include country code if applicable and area code)

(Tel): (858) 401-1641

(Fax):

14. Date of Certification

08/04/2023

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative (Sign)

Sign

Christin Dunn

Digitally signed by Christin Dunn
Date: 2023.08.04 14:41:48 -07'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

INSTRUCTIONS FOR COMPLETION OF FORM FDA 3674 – CERTIFICATION OF COMPLIANCE

Under 42 U.S.C. § 282(j)(5)(B), with Requirements for ClinicalTrials.gov Data Bank

Form FDA 3674 must accompany an application/submission, including certain amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. Name of Sponsor/Applicant/Submitter – This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.

2. Date – This is the date of the application/submission which the certification accompanies or should have accompanied, if submitted at a subsequent date.

3. & 4. Provide complete address, telephone number, and fax number of the sponsor/applicant/submitter.

5. Product Information – ***For Drugs/Biologics:*** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/ gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. ***For Devices:*** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

Use a continuation page only if you have filled in all available spaces.

6. Type of Application/Submission – Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified (i.e. a new IND clinical protocol), check the box labeled “Other.”

7. IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number – If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

8. Serial Number – In some instances a sequential serial number is assigned to the submission/application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.

9. Certification – This section contains three different check-off boxes.

Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply because no data from clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply at the time of submission of the certification to any clinical trials for which data are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials for which data are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies and for which the sponsor/applicant/submitter is the “responsible party” of the applicable clinical trial included in the application/ submission. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, and any provisions of 42 CFR part 11 that apply to one or more of the applicable clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies have been met by the sponsor/applicant/ submitter as the “responsible party.”

10. National Clinical Trial (NCT) Numbers – If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from *www.ClinicalTrials.gov* for each applicable clinical trial for which the sponsor/applicant/submitter is the “responsible party” and for which data is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term “NCT” will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of “applicable clinical trials” for which data is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies and for which the sponsor/applicant/submitter is the “responsible party.” Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT number(s) for the “applicable clinical trial(s)” for which data is included, relied upon, or otherwise referred to in the application/ submission. Use a continuation page only if you have filled in all available spaces.

11. Name and Title of Person Who Signed in number 11 – Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.

12 & 13. Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 15.

14. Provide the date the certification is signed. This date may be different from the date provided in number 2.

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative – The person signing the certification must sign in this field.



**SECTION 10. DECLARATIONS OF CONFORMITY AND SUMMARY
REPORTS**

10.1 PERFORMANCE STANDARDS – SPECIAL CONTROLS

None

10.2 SPECIAL CONTROLS (880.5730)

The special controls written into the regulation (880.5730) for the Tandem Diabetes Care t:slim X2 Insulin Pump with Interoperable Technology DEN180058 are provided below along with identification of any impact to compliance as a result of this 510(k) application.

Table 2 Alternate Controller Enabled Insulin Infusion Pump Special Controls

SPECIAL CONTROL	SUBJECT DEVICE
(1) Design verification and validation must include the following: (i) Evidence demonstrating that device infusion delivery accuracy conforms to defined user needs and intended uses and is validated to support safe use under actual use conditions. (A) Design input requirements must include delivery accuracy specifications under reasonably foreseeable use conditions, including ambient temperature changes, pressure changes (e.g., head-height, backpressure, atmospheric), and, as appropriate, different drug fluidic properties.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter verified and validated infusion delivery accuracy.



SPECIAL CONTROL	SUBJECT DEVICE
(B) Test results must demonstrate that the device meets the design input requirements for delivery accuracy under use conditions for the programmable range of delivery rates and volumes. Testing shall be conducted with a statistically valid number of devices to account for variation between devices.	
(ii) Validation testing results demonstrating the ability of the pump to detect relevant hazards associated with drug delivery and the route of administration (e.g., occlusions, air in line, etc.) within a clinically relevant timeframe across the range of programmable drug delivery rates and volumes. Hazard detection must be appropriate for the intended use of the device and testing must validate appropriate performance under the conditions of use for the device.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter the ability of the pump to detect relevant hazards associated with drug delivery and the route of administration (e.g., occlusions, air in line, etc.) within a clinically relevant timeframe across the range of programmable drug delivery rates and volumes.
(iii) Validation testing results demonstrating compatibility with drugs that may be used with the pump based on its labeling. Testing must include assessment of drug stability under reasonably foreseeable use conditions that may affect drug stability (e.g., temperature, light exposure, or other factors as needed).	There are no changes to the t:slim X2 insulin pump in this 510(k) that alters the compatibility with drugs.



SPECIAL CONTROL	SUBJECT DEVICE
(iv) The device parts that directly or indirectly contact the patient must be demonstrated to be biocompatible. This shall include chemical and particulate characterization on the final, finished, fluid contacting device components demonstrating that risk of harm from device-related residues is reasonably low.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter device parts that directly or indirectly contact the patient or biocompatibility.
(v) Evidence verifying and validating that the device is reliable over the ACE pump use life, as specified in the design file, in terms of all device functions and in terms of pump performance.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter the devices ability to be reliable over the ACE pump use life, as specified in the design file, in terms of all device functions and in terms of pump performance.
(vi) The device must be designed and tested for electrical safety, electromagnetic compatibility, and radio frequency wireless safety and availability consistent with patient safety requirements in the intended use environment.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter electrical safety, electromagnetic compatibility, and radio frequency wireless safety and availability consistent with patient safety requirements in the intended use environment.
(vii) For any device that is capable of delivering more than one drug, the risk of cross-channeling drugs must be adequately mitigated.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter validated drug delivery.



SPECIAL CONTROL	SUBJECT DEVICE
(viii) For any devices intended for multiple patient use, testing must demonstrate validation of reprocessing procedures and include verification that the device meets all functional and performance requirements after reprocessing.	Device is not intended for multiple patient use.
(2) Design verification and validation activities must include appropriate design inputs and design outputs that are essential for the proper functioning of the device that have been documented and include the following: (i) Risk control measures shall be implemented to address device system hazards and the design decisions related to how the risk control measures impact essential performance shall be documented.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter the risk control measures implemented to address device system hazards and documentation of how the risk control measures impact essential performance
(ii) A traceability analysis demonstrating that all hazards are adequately controlled and that all controls have been validated in the final device design.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter the traceability analysis demonstrating that all hazards are adequately controlled and that all controls have been validated in the final device design.
(3) The device shall include validated interface specifications for digitally connected	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter



SPECIAL CONTROL	SUBJECT DEVICE
devices. These interface specifications shall, at a minimum, provide for the following: (i) Secure authentication (pairing) to external devices.	secure authentication (pairing) to external devices.
(ii) Secure, accurate, and reliable means of data transmission between the pump and connected devices.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter the secure, accurate, and reliable means of data transmission between the pump and connected devices.
(iii) Sharing of necessary state information between the pump and any digitally connected alternate controllers (e.g., battery level, reservoir level, pump status, error conditions).	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter sharing of necessary state information between the pump and any digitally connected alternate controllers.
(iv) Ensuring that the pump continues to operate safely when data is received in a manner outside the bounds of the parameters specified.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter the pumps ability to continue to operate safely when data is received in a manner outside the bounds of the parameters specified.
(v) A detailed process and procedure for sharing the pump interface specification with digitally connected devices and for validating the correct implementation of that protocol.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter processes and procedures for sharing the pump interface specification with digitally connected devices and for validating the correct implementation of that protocol.



SPECIAL CONTROL	SUBJECT DEVICE
(4) The device must include appropriate measures to ensure that safe therapy is maintained when communications with digitally connected alternate controller devices is interrupted, lost, or re-established after an interruption (e.g., reverting to a pre-programmed, safe drug delivery rate). Validation testing results must demonstrate that critical events that occur during a loss of communications (e.g., commands, device malfunctions, occlusions, etc.) are handled appropriately during and after the interruption.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter the measures taken to ensure that safe therapy is maintained when digitally connected alternate controller devices is interrupted, lost, or reestablished.
(5) The device design must ensure that a record of critical events is stored and accessible for an adequate period to allow for auditing of communications between digitally connected devices and to facilitate the sharing of pertinent information with the responsible parties for those connected devices. Critical events to be stored by the system must, at a minimum, include: (i) A record of all drug delivery	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter records of drug delivery.
(ii) Commands issued to the pump and pump confirmations	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter



SPECIAL CONTROL	SUBJECT DEVICE
	commands issued to the pump and pump confirmations.
(iii) Device malfunctions	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter storage of device malfunctions.
(iv) Alarms and alerts and associated acknowledgements	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter alarms and alerts and associated acknowledgements.
(v) Connectivity events (e.g., establishment or loss of communications)	There are no changes to the t:slim X2 insulin pump in this 510(k) application that alter connectivity events storage.
(6) Design verification and validation must include results obtained through a human factors study that demonstrates that an intended user can safely use the device for its intended use.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter the results of the Human Factors Validation testing performed.
(7) Device labeling must include the following: (i) A prominent statement identifying the drugs that are compatible with the device, including the identity and concentration of those drugs as appropriate.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alters the current drug labeling.



SPECIAL CONTROL	SUBJECT DEVICE
(ii) A description of the minimum and maximum basal rates, minimum and maximum bolus volumes, and the increment size for basal and bolus delivery, or other similarly applicable information about drug delivery parameters.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter the description of the minimum and maximum basal rates, minimum and maximum bolus volumes, and the increment size for basal and bolus delivery, or other similarly applicable information about drug delivery parameters.
(iii) A description of the pump accuracy at minimum, intermediate, and maximum bolus delivery volumes and the method(s) used to establish bolus delivery accuracy. For each bolus volume, pump accuracy shall be described in terms of the number of bolus doses measured to be within a given range as compared to the commanded volume. An acceptable accuracy description (depending on the drug delivered and bolus volume) may be provided as follows for each bolus volume tested, as applicable: Number of bolus doses with volume that is <25 percent, 25 percent to <75 percent, 75 percent to <95 percent, 95 percent to <105 percent, 105 percent to <125 percent, 125 percent to <175 percent, 175 to	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter descriptions of the pump accuracy at minimum, intermediate, and maximum bolus delivery volumes and the method(s) used to establish bolus delivery accuracy.



SPECIAL CONTROL	SUBJECT DEVICE
250 percent, and >250 percent of the commanded amount.	
(iv) A description of the pump accuracy at minimum, intermediate, and maximum basal delivery rates and the method(s) used to establish basal delivery accuracy. For each basal rate, pump accuracy shall be described in terms of the amount of drug delivered after the basal delivery was first commanded, without a warmup period, up to various time points. The information provided must include typical pump performance, as well as worst-case pump performance observed during testing in terms of both over-delivery and under-delivery. An acceptable accuracy description (depending on the drug delivered) may be provided as follows, as applicable: The total volume delivered 1 hour, 6 hours, and 12 hours after starting delivery for a typical pump tested, as well as for the pump that delivered the least and the pump that delivered the most at each time point.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter descriptions of the pump accuracy at minimum, intermediate, and maximum basal delivery rates and the method(s) used to establish basal delivery accuracy.
(v) A description of delivery hazard alarm performance, as applicable. For occlusion alarms, performance shall be reported at minimum, intermediate, and maximum	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter descriptions of delivery hazard alarm performance.



SPECIAL CONTROL	SUBJECT DEVICE
delivery rates and volumes. This description must include the specification for the longest time period that may elapse before an occlusion alarm is triggered under each delivery condition, as well as the typical results observed during performance testing of the pumps.	
(vi) For wireless connection enabled devices, a description of the wireless quality of service required for proper use of the device.	There are no changes to the t:slim X2 insulin pump in this 510(k) that alter descriptions of the wireless quality of service required for proper use of the device.
(vii) For any infusion pumps intended for multiple patient reuse, instructions for safely reprocessing the device between uses.	Not applicable, the t:slim X2 insulin pump is for single patient use.



10.3 VOLUNTARY STANDARDS

- ANSI/AAMI/EN ISO 14971:2019 + A11:2021 Medical Devices - Application of Risk Management to Medical Devices
- ANSI AAMI IEC 62304:2006/A1:2016 Medical Device Software - Software Life Cycle Processes

10.4 GUIDANCE DOCUMENTS

- Infusion Pumps Total Product Life Cycle - Guidance for Industry and FDA Staff - (December 2, 2014)
- Deciding When to Submit a 510(k) for a Change to an Existing Device (October 25, 2017).



SECTION 11. DEVICE DESCRIPTION

11.1 INTENDED USE

The t:slim X2 Insulin Pump with Interoperable Technology (the Pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

The Pump is intended for single patient, home use and requires a prescription.

The Pump is indicated for use in individuals two years of age and greater.

11.2 TECHNOLOGICAL CHARACTERISTICS

11.2.1 T:SLIM X2 WITH INTEROPERABLE TECHNOLOGY

The CGM Enabled Insulin Pump (as shown in Figure 1) is an ambulatory, battery operated, rate programmable infusion pump designed for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. A custom accessory disposable cartridge is motor-driven to deliver patient programmed basal rates and boluses through an FDA-cleared infusion set into subcutaneous tissue.

The Insulin Pump consists of:

- a user-operated interface display
- an electronic microprocessor software control system, including the Bluetooth radio module and signal processing algorithms allowing the pump to receive CGM data from an iCGM
- motor and encoder
- rack drive mechanism and



- an audible speaker and a vibrator to provide alarms, alerts and reminders to the user.

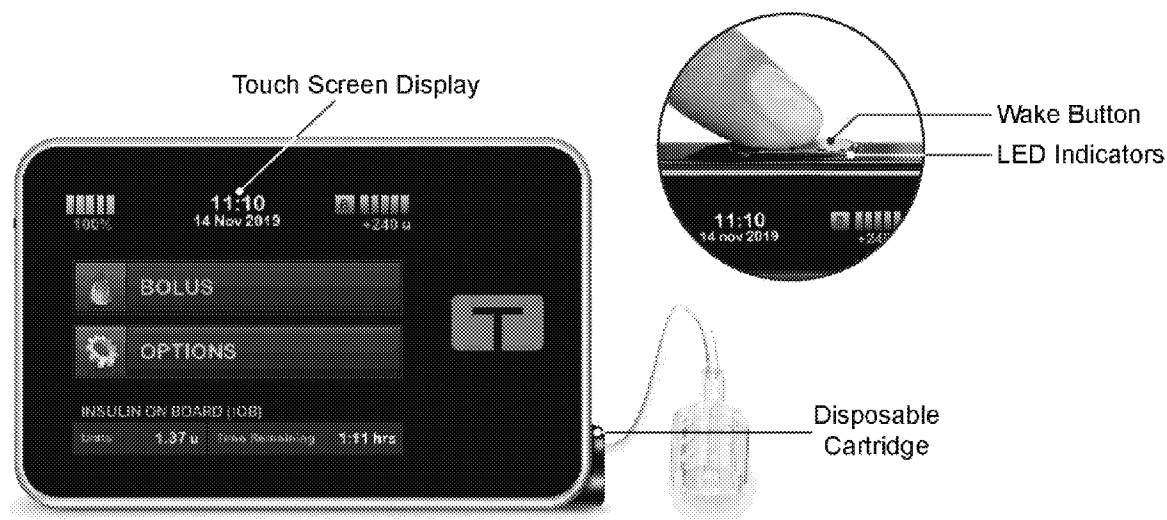


Figure 1: The t:slim Insulin Delivery System

The front of the CGM Enabled Insulin Pump includes a color touch screen display that has a capacitive touch panel that detects a finger touch. The Screen On Button on the side of the Insulin Pump is surrounded by an LED indicator light. This button is used to turn on the touch screen display so that the user can operate their System. The Screen On Button also provides users with a quick bolus option, which is a feature that allows a user to program and deliver a bolus of insulin through a sequence of presses, without use of the touch screen. The System provides audio and vibratory feedback to the user to confirm the delivery. In the case of an incomplete sequence, the bolus is canceled.

An electrically-isolated USB port is located on one end of the pump, which is covered by a protective rubber door. The USB port is accessible to patients and when connected with a power supply, is used to charge the internal lithium polymer battery or can be used to download data to and from a computer. The pump provides the user with an indication of the remaining battery power on the display and alerts when the battery power is low.



The insulin cartridge, as shown loaded on the Insulin Pump in Figure 2, is designed to hold up to 3 mL, or 300 units, of U-100 insulin. It is labeled as a single-use device and is intended to be replaced at least once every three days, depending on an individual's specific insulin usage or the indications for use of the insulin. A micro-syringe within the head of the cartridge is a valve piston system. The micro-syringe, coupled with the Pump's motor-control system, manages the delivery of insulin from the insulin reservoir into the patient line. The insulin fill port is a septum on the cartridge head, through which the patient fills the insulin reservoir. The patient line is an access point for insulin delivery.



Figure 2: Cartridge loaded on Pump

The iCGM wirelessly sends glucose readings to the Pump which may be used instead of the iCGM receiver. The pump receives the data sent by the iCGM Transmitter. In addition, it is responsible for monitoring the reported glucose levels and based on thresholds set by users in consultation with healthcare providers, identify high or low glucose levels, as well as rapidly rising or falling glucose conditions. Finally, the pump is responsible for monitoring the functionality of the iCGM Sensor and Transmitter. An example of an iCGM that is compatible with the System is the Dexcom G6 Continuous Glucose Monitoring System. This is an Integrated Continuous Glucose Monitoring System approved by FDA in 2022 under K223931 (Class II, QBJ). The Dexcom G6 Transmitter and Sensor is shown in Figure



3.

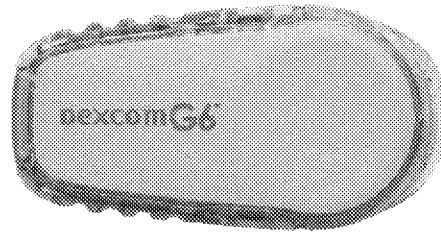


Figure 3: Dexcom G6 Transmitter and Sensor

11.2.2 ACCESSORIES

In addition to the above described primary components of the device, the System includes several accessories listed below.

- Bolus Calculator (independent);
- Dosing Algorithm (independent);
- iCGM supplied separately;
- Compatible FDA cleared infusion sets supplied separately;
- Exelint 3mL sterile syringe and 26 gauge sterile needle, or equivalent FDA- cleared syringe and needle;
- Wall charger, power supplies with USB for charging the pump's internal battery;
- USB Cable;
- Case or Belt clip.



11.2.3 PRINCIPLES OF OPERATION

To operate the System, a patient or parent/guardian must first be trained on its setup and use, based on the instructions within the User's Guide. The desired timing and quantity of insulin delivery (bolus or basal) is programmed by the patient. The patient uses the Screen On/Quick Bolus button and touch screen to control and monitor insulin delivery and view CGM data.



When used with an iCGM, the t:slim X2 System is designed to replace fingerstick blood glucose testing for diabetes treatment decisions. The t:slim X2 System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the t:slim X2 System results should be based on the trends and patterns seen with several sequential readings over time.

The t:slim X2 System is compatible with Interoperable Automated Glycemic Controllers, such as Basal-IQ Technology (K193483) and Control IQ Technology (DEN190034 and K200467) to aid in diabetes management.

The software included in the Insulin Pump also controls the following features:

- Basal Therapy – directing delivery of a continuous flow rate of insulin as programmed by the user;
- Bolus Therapy – directing delivery of bolus of insulin;
- Safety Monitoring – occlusion detection and notification of low supply (battery or insulin);
- CGM alert conditions- receives alert setting from user interface and applies them to estimated glucose values;
- Self Test; and
- Manufacturing and Calibration Support.

The system graphical user interface (“GUI”) allows the user to enter calibration data for the CGM, enter parameters for CGM alerts, display estimated glucose readings transmitted from the CGM Mobile Sensor and enter commands for the pump functions. The System GUI displays CGM Sensor glucose readings, trend graphs, direction and rate of change arrow.



11.3 INSULIN PUMP PACKAGED CONTENTS

Below is a list of components included in the shipped device. There are four configurations available for shipping from Tandem; New Pump, New Replacement Pump, Medicare, and a Refurbished Replacement Pump. The packaged sterile insulin cartridge is also available in a box of 10 or 2 cartridges.

Table 3 New Pump

TITLE	DESCRIPTION
Pump, Unpackaged, t:slim X2, Global	The unpackaged pump as described above
Cartridge Insert, t:slim	A dummy cartridge to fill the space on the pump where the cartridge will go when the user adds it.
Label, Clear (b)(4), 2"	A small 2 inch in diameter sticky polypropylene circle to seal box lid shut
Box, Pump, t:slim X2 Global	See Labeling section for full detail
Tray, Insert, Pump, t:slim X2 Global	Protective packaging
Label, UDI, Pump, t:slim X2	See Labeling section for full detail

Table 4 New Replacement Pump

TITLE	DESCRIPTION
Pump, Unpackaged, t:slim X2, Global	The unpackaged pump as described above
Insert, Foam, Pump Return, 3 Piece	Protective packing



TITLE	DESCRIPTION
Postcard, t:slim X2, Replacement Pump	Protective packing
Box, Pump, Replacement	See Labeling section for full detail
Sleeve, t:slim X2, Replacement	See Labeling section for full detail
Label, UDI, pump, t:slim X2	See Labeling section for full detail
Labels, Clear (b)(4) 2"	Two small 2 inch in diameter sticky (b)(4) circle to adhere the sleeve to the box.

Table 5 Medicare Pump

TITLE	DESCRIPTION
Pump, Unpackaged, t:slim X2, Global	The unpackaged pump as described above that was refurbished.
Cartridge Insert, t:slim	A dummy cartridge to fill the space on the pump where the cartridge will go when the user adds it.
Labels, Clear Acetate, 2"	A small 2 inch in diameter sticky (b)(4) circle to seal box lid shut
Box, Pump, t:slim X2, Global	See Labeling section for full detail
Tray, Insert, Pump, t:slim X2 Global	See Labeling section for full detail
Label, UDI, Pump, t:slim X2	See Labeling section for full detail



TITLE	DESCRIPTION
Label, Medicare Only, Pump	A small 2 inch in diameter label designating the pump for Medicare only

Table 6 Refurbished Pump

TITLE	DESCRIPTION
Refurbished Pump, Unpackaged Ambulatory Insulin, t:slim X2	The unpackaged pump as described above that was refurbished.
Labels, Clear Polypropylene, 2" in diameter	Two small 2 inch in diameter sticky (b)(4) circle to adhere the sleeve to the box.
Insert, Foam, Pump Return, 3 Piece	Protective packing
Box, Pump, Replacement	See Labeling section for full detail
Sleeve, t:slim X2, Replacement	See Labeling section for full detail
Postcard, t:slim X2, Replacement Pump	See Labeling section for full detail
Label, UDI, Pump, t:slim X2	See Labeling section for full detail

**Table 7 Accessory Kit**

TITLE	DESCRIPTION
Charger, AC, Wall Mount, USB Out,	An AC to DC transformer that plugs into a standards U.S. wall outlet and has a female USB connection.
Cable, 2m, USB, Ferrite, A to Micro B, Shielded	The cable to connect the pump to the charger described above.
Getting Started Guide, t:connect	See Labeling section for full detail
Tool, Cartridge Removal	A small plastic tool used to assist the user in removing the cartridge from the pump when necessary
T:case, Black, t:slim, Global	A plastic case for the pump
Accessories Box, t:slim X2, Global	See Labeling section for full detail
User Guide, Mobile Bolus, t:slim X2	See Labeling section for full detail
Small Tray Insert, Accessories Box, t:slim X2, Global	Protective packaging
Label, Clear, (b)(4) 2" in diameter	A small 2 inch sticky (b)(4) circle to seal box lid shut
Label, UDI, Kit, Accessories, t:slim X2	See Labeling section for full detail

**Table 8 Insulin cartridge 10-Pack**

TITLE	DESCRIPTION
Cartridge, Sterilized, t:slim t:lock, Global	The unpackaged cartridge as described above
Syringe/Needle, 3ML, 26G, 3/8"	Standard needle and syringe for filing cartridge with insulin
Pouch, Cartridge, (b)(4) t:slim, t:lock, Global	Sterile barrier Tyvek pouch
Cartridge Box, 10 Pack, t:slim X2, Global	See Labeling section for full detail
Instructions for Use, 3mL Cartridge, t:slim X2 Global	See Labeling section for full detail
Labels, Clear (b)(4) 2"	A small 2 inch in diameter sticky acetate circle to seal box lid shut
Label, UDI, t:slim, t:lock, Cartridge, 10 Pack	See Labeling section for full detail

**Table 9 Insulin cartridge 2-Pack**

TITLE	DESCRIPTION
Cartridge, Sterilized, t:slim, t:lock Global	The unpackaged cartridge as described above
Syringe/Needle, 3ML, 26G, 3/8"	Standard needle and syringe for filing cartridge with insulin
Pouch, Cartridge, (b)(4) t:slim, t:lock Global	Sterile barrier Tyvek pouch
Cartridge Box, 2 Pack, t:slim X2, Global	See Labeling section for full detail
Instructions for Use, 3mL Cartridge, t:slim X2	See Labeling section for full detail (b)(4)
Labels, Clear, (b)(4) 2" in diameter	A small 2 inch in diameter sticky (b)(4) circle to seal box lid shut
Label, UDI, t:slim, t:lock, Cartridge, 2Pack, Global	See Labeling section for full detail



SECTION 12. EXECUTIVE SUMMARY/PREDICATE COMPARISON

12.1 EXECUTIVE SUMMARY

This Traditional 510(k) describes a change to the indications for use for the t:slim X2 Insulin Pump with Interoperable Technology. The indications for use will be expanded to include persons of age 2 years and greater. The device was classified as Class II in DEN180058 and the software was updated in a subsequent 510(k) (K201214) to implement a User Settable Maximum Insulin Basal Rate feature. The addition of the t:connect mobile app was added in K203234.

The t:slim X2 Insulin Pump with Interoperable Technology (the Pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use in individuals 2 years of age and greater.

The t:slim X2 insulin pump with Control-IQ technology is designed for use with rapid acting insulin analogs that have been tested and found to be safe for use in the pump:

- NovoLog/NovoRapid U-100 insulin
- Humalog U-100 insulin

The t:slim X2 Insulin Pump is compatible with Interoperable Automated Glycemic Controllers, such as

(b)(4)

to aid in diabetes

management. In addition, the t:slim X2 Insulin Pump is compatible with iCGM systems cleared under 21 CFR 862.1355 and marketed separately from the ACE Pump and Interoperable Automated Glycemic Controllers.

The Tandem Device Updater (TDU) is also used to update t:slim X2 Insulin Pumps to the current software versions available from Tandem Diabetes Care, Inc. including Control-IQ technology. t:connect software may also be used with the system to upload data from the pump.



The t:slim X2 Insulin Pump described in this submission has the same intended use, indications for use as the Tandem predicate device K203234 except for the change in indications for use to lower the age to 2 years of age and greater and the removal of compatible insulins. This change in indications is supported by clinical data.

Tandem has demonstrated that the t:slim X2 Insulin Pumps with Interoperable Technology is safe and effective as intended. There are no changes contemplated to the user interfaces as a result of this 510(k) application. Tandem previously completed validation of the user interface through a series of formative and summative human factors studies that were presented in the DeNovo application. The age group 6 years and older participated in the human factors studies that were also provided.

Through this series of tests and system risk analysis, Tandem demonstrated that the System satisfies all functional performance and safety requirements, meets its intended use, and is reasonably safe for the intended user population.

The t:slim X2 Insulin Pump with Interoperable Technology has the same intended use and technological characteristics as the t:slim X2 Insulin Pump with Interoperable Technology predicate device. The indications for use are modified to lower the age indication to 2 years from 6 years. Clinical data provided demonstrates evidence of safety and effectiveness. A substantial equivalence table comparing the devices and the Tandem predicate device is provided in Section XII.

12.2 CHANGES IMPLEMENTED SINCE THE MOST RECENT 510(K) (PREDICATE DEVICES –K203234)

Tandem has included a list of hardware and software changes implemented since the Predicate Device was cleared that did not trigger the requirements for a submission of a new 510(k). Changes were evaluated per Guidance for Industry and Food and Drug Administration Staff: *Deciding When to Submit A 510(K) For a Change to an Existing Device* published October 2017, see Table 10.

Changes were implemented according to Tandem Quality Management System which includes but is not limited to, risk assessments, verification and validation and approvals prior to implementation.



Table 10 Changes Made Since Previous 510(k) K203234

Identifier	Change Type	Detail Of Change in Relation to Device	Rationale for Modification(S)
(b)(4)	Software Change (ACE pump version (b)(4))	(b)(4)	(b)(4)
	Software Change (Mobile app version (b)(4))		
	Software Change (Mobile app version (b)(4))		



(b)(4)	Software Change (Mobile app version (b)(4)	(b)(4)
	Software Change (Mobile app version (b)(4)	
	Software Change (Mobile app version (b)(4)	



SECTION 13. SUBSTANTIAL EQUIVALENCE DISCUSSION

As explained in detail below, the purpose of this Traditional 510(k) is to lower the indications for use to 2 years of age and greater. The PEDAP clinical study was performed and is provided in this 510(k) application to support this change.

13.1 INTENDED USE/ INDICATIONS FOR USE

The intended use and indications for use of the t:slim X2 Insulin Pump with Interoperable Technology have not changed with the exception of lowering the age indication from 6 years of age and greater to 2 years of age and greater and to remove the compatible insulins.

The modified t:slim X2 Insulin Pump with Interoperable Technology is substantially equivalent to the predicate device with respect to intended use and indications for use. Therefore, the t:slim X2 Insulin Pump with Interoperable Technology device satisfies the first criterion for a finding of substantial equivalence.

13.2 TECHNOLOGICAL CHARACTERISTICS

There are no changes to the technological characteristics of the t:slim X2 Insulin Pump with Interoperable Technology as part of this change. This 510(k) is limited to lowering the age indication to 2 years of age and greater. The table below illustrates that the Subject Device, when compared to the Predicate Device, is identical in all factors that could affect the safety and/or effectiveness.

A summary of the changes made to the t:slim X2 Insulin Pump with Interoperable Technology are summarized in Table 11 below.



Table 11 Substantial Equivalence Table

(b)(4)



(b)(4)



13.3 CONCLUSIONS

As discussed above, the changes that have been made to the indications for use do not negatively affect the safety and performance of the device. The modified indications for use do not introduce any new risks and do not raise different questions of safety and effectiveness. Therefore, the device satisfies the criteria for a finding of substantial equivalence.

The previously approved indications for use and clinical data support the substantial equivalence of lowering the age indication to persons of 2 years of age and greater. The design of the t:slim X2 Insulin Pump with Interoperable Technology is unchanged. Thus, the modified Tandem t:slim X2 Insulin Pump with Interoperable Technology is substantially equivalent to the predicate device.

As discussed above, the changes that have been made to the indications for use do not negatively affect the safety and performance of the device. The Tandem subject device is substantially equivalent to the predicate device, result in a product that is substantially equivalent to the predicate t:slim X2 Insulin Pump with Interoperable Technology device(K203234). The previously approved indications for use and clinical data support the substantial equivalence of lowering the age indication to persons of 2 years of age and greater. The design of the t:slim X2 Insulin Pump with Interoperable Technology is unchanged. Thus, the modified Tandem t:slim X2 Insulin Pump with Interoperable Technology may be considered substantially equivalent to the predicate device.



SECTION 14. PROPOSED LABELING

This section provides the draft labeling in the following attachments:

Attachment 1 Draft User Guide for the t:slim X2 Insulin Pump with Interoperable Technology and includes the user guide;

Attachment 2 Redline of the User Guide.

The labeling is being updated to change the age indication to 2 years of age and greater. Additionally, the compatible insulins have been removed from the indications for use and moved to a new section called "Compatible Insulins".



SECTION 15. STERILIZATION AND SHELF LIFE

There are no changes to the sterilization method, SAL, or shelf life compared to the predicate device, t:slim X2 Insulin Pump with Interoperable Technology (K203234).



SECTION 16. BIOCOMPATIBILITY

There have been no changes to the patient-contacting or insulin fluid path contacting components of the t:slim X2 Insulin Pump submission compared to the information provided in the predicate device, t:slim X2 Insulin Pump with Interoperable Technology (K203234).



SECTION 17. SOFTWARE

This submission does not include any software changes compared to the predicate device, t:slim X2 Insulin Pump with Interoperable Technology (K203234).

Table 12 Software Version History

VERSION	DATE	CHANGES
(b)(4)		



VERSION	DATE	CHANGES
(b)(4)		



VERSION	DATE	CHANGES
(b)(4)		



VERSION	DATE	CHANGES
(b)(4)		



VERSION	DATE	CHANGES
(b)(4)		



VERSION	DATE	CHANGES
(b)(4)		



VERSION	DATE	CHANGES
(b)(4)		



VERSION	DATE	CHANGES
(b)(4)		



VERSION	DATE	CHANGES
(b)(4)		

Therefore, the software version 7.6.0.1 has no impact on the functionality of Control-IQ 1.5, as described in the concurrent Control-IQ submission.



SECTION 18. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

There is no new information regarding electromagnetic compatibility and electrical safety of the insulin pump compared to the predicate device, t:slim X2 Insulin Pump with Interoperable Technology (K203234).



SECTION 19. PERFORMANCE TESTING – BENCH

The performance and specification of the t:slim X2 Insulin Pump remain the same. Additional Bench testing was not required in association with this application as the change is limited to the addition of the 2- to 5-year-old age population. No hardware changes were made in this application.

(b)(4)



SECTION 20. PERFORMANCE TESTING – ANIMAL

There was no animal testing performed in association with this application.



SECTION 21. PERFORMANCE TESTING – CLINICAL

A prospective clinical study, (b)(4) “The Pediatric Artificial Pancreas (PEDAP) trial: A Randomized Controlled Comparison of the Control- IQ technology Versus Standard of Care in Young Children in Type 1 Diabetes”, was performed to support the revised indication for use, changing the age from 6 years and greater, to 2 years and greater.

The prospective study consisted of two phases, the Randomized Control Trial (RCT) phase and the extension phase. Both phases of the study were designed to use the t;slim X2 insulin pumps.

The software version used in the initial phase of the study is Control-IQ (b)(4)

The software version used in the extension phase of the study is Control-IQ (b)(4)

Table 12 Software Version History includes a summary of changes.

(b)(4)



(b)(4)



(b)(4)



The study showed that for those participants who continued closed-loop use after the RCT (the CLC-CLC group), Time in range (TIR) which increased from 57% at RCT baseline to 70% at the end of the 13-week RCT, and was sustained during the Extension Phase at 70%, with no significant change comparing the CLC use in the RCT phase to CLC use in the Extension Phase (difference = 0.1%, 95% CI -1.2 to 1.4%, $p=0.86$). Similar sustained beneficial effects were seen in the other CGM metrics. Mean HbA1c was 7.6% at RCT baseline, 7.0% at the end of the RCT, and 7.1% at the end of the Extension Phase. The beneficial effects were sustained during the Extended Use period.

In those who switched from standard care (SC) to closed-loop control for the extension phase of the study (the SC-CLC group), TIR was 55% at RCT baseline, 56% during the RCT, and 68% during the Extension Phase. Comparing standard care with use of CLC, the mean difference was 11.8% (95% CI 9.6 to 14.1%, $P<0.001$). Similar sustained beneficial effects were seen in the other CGM metrics. Mean HbA1c was 7.7% at RCT baseline, 7.5% at the end of the RCT, and 7.2% at the end of the Extension Phase. A significant reduction in time <70 mg/dL and time <54 mg/dL was observed comparing the Extension Phase with the RCT phase. The beneficial effects were sustained during the Extended Use period. There were only 2 severe hypoglycemia events unrelated to the modified Control-IQ and no DKA events.

(b)(4)

In both the CLC-CLC group and SC-CLC group, there were few serious adverse events. Two severe hypoglycemia events occurred, unrelated to the study device. There were no DKA events.



In summary, in this 13-week Extension Phase plus Extended Use period following completion of the PEDAP RCT involving children 2 to <6 years of age with T1D, use of a hybrid closed-loop system with Control-IQ technology was safe and effective over a sustained period of time, comprising a total system use combining the RCT, Extension Phase, and Extended Use period of (b)(4)

(b)(4)

The clinical report supporting this submission is provided in:

Attachment 3 Pediatric Artificial Pancreas (PEDAP) trial: A Randomized Controlled Comparison of the Control- IQ technology Versus Standard of Care in Young Children in Type 1 Diabetes study protocol and report

The extension phase clinical study report can be found in the 510(k) for Control-IQ 1.5 that has been submitted concurrently with this 510(k).



Attachment 1

t:slim X2

Insulin Pump

WITH Control-IQ TECHNOLOGY

User Guide



MG/DL

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)



Attachment 2

t:slim X2

Insulin Pump

WITH Control-IQ TECHNOLOGY



User Guide



MG/DL

Page 538 of 1672
CONFIDENTIAL

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)



Attachment 3

SPONSOR, COORDINATING CENTER DIRECTOR, AND SENIOR STATISTICIAN**SIGNATURES**

STUDY TITLE: The Pediatric Artificial Pancreas (PEDAP) trial: A Randomized Controlled Comparison of the Control-IQ technology Versus Standard of Care in Young Children in Type 1 Diabetes

Note: This report includes only the RCT component of the clinical trial. A separate report will encompass the Extension Phase and Ancillary Study components.

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

SPONSOR:

NAME	Marc D. Breton, PhD
AFFILIATION	University of Virginia
SIGNATURE	(b)(6)
DATE	11/11/2022

COORDINATING CENTER DIRECTOR

NAME	John Lum, MS
AFFILIATION	JAEB Center for Health Research
SIGNATURE	John Lum I am digitally signing this document
DATE	2022-11-12 16:23-05:00

SENIOR STATISTICIAN

NAME	Craig Kollman, PhD
AFFILIATION	JAEB Center for Health Research
SIGNATURE	Craig Kollman I am digitally signing this document
DATE	2022-11-14 15:22-05:00

Study Title	The Pediatric Artificial Pancreas (PEDAP) trial: A Randomized Controlled Comparison of the Control-IQ technology Versus Standard of Care in Young Children in Type 1 Diabetes
ClinicalTrials.gov Identifier	NCT04796779
Test Product	t:slim X2 with Control-IQ and Dexcom G6 system
Study Design/Indication Studied	Randomized trial in children 2 to <6 years old with type 1 diabetes
Sponsor:	Marc D. Breton, PhD; University of Virginia
Protocol Identifying Number	NA
Development Phase of Study	Phase 3
Study Initiation Date (first enrollment)	21 Apr 2021
Study Completion Date:	12 Apr 2022
Study Clinical Director	R. Paul Wadwa, MD
Sponsor's Responsible Signatory	Marc D. Breton, PhD
Sponsor's Contact	Marc D. Breton, PhD
Good Clinical Practice	Study performed in compliance with Good Clinical Practices, including the archiving of essential documents
Prior reports for same study	None
Date of Final Report	09 Nov 2022

SYNOPSIS

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Section 11: Appendix

TABLE OF CONTENTS

(b)(4)

(b)(4)

(b)(4)

11.1

APPENDIX 11.1

General

1 **The Pediatric Artificial Pancreas (PEDAP) trial: A**
2 **Randomized Controlled Comparison of the Control-**
3 **IQ technology Versus Standard of Care in Young**
4 **Children in Type 1 Diabetes**

5 **Study Sponsor**

6 Marc D. Breton, Ph.D.
7 University of Virginia
8 Center for Diabetes Technology

9 **Protocol Chair**

10 R. Paul Wadwa, MD
11 Barbara Davis Center
12 University of Colorado

13 **Participating Institutions**

14 University of Virginia, Charlottesville, Virginia
15 Barbara Davis Center, University of Colorado, Colorado
16 Stanford University, California

17 **Coordinating Center**

18 Jaeb Center for Health Research
19

20
21
22
23 **Version Number: v11.0**

24 **DECEMBER 3, 2021**

25

KEY ROLES

Sponsor Chair / IDE Chair	
Name, degree	Marc D. Breton, Ph.D.
Institution Name	University of Virginia, Center for Diabetes Technology
Protocol Chair/Director	
Name, degree	R. Paul Wadwa, MD
Institution Name	Barbara Davis Center, University of Colorado
JCHR Coordinating Center Director	
Name, degree	John Lum, MS
Institution Name	Jaeb Center for Health Research
Medical Monitor	
Name, degree	Roy Beck, M.D., Ph.D.
Institution Name	Jaeb Center for Health Research

26

27

28

PROTOCOL VERSION HISTORY

Version Number	Author(s)	Approver	Effective Date	Revision Description
1.0	R. Paul Wadwa John Lum Roy Beck	R. Paul Wadwa	23 Nov 2020	Original protocol
2.0	John Lum	R. Paul Wadwa	21 Dec 2020	Pre-clinical revisions to accommodate requests for changes by IRB and FDA reviewers
3.0	John Lum	R. Paul Wadwa	13 Jan 2021	Pre-clinical revisions to accommodate request by IRB reviewers for changes to framing of extension phase participation
4.0	John Lum	R. Paul Wadwa	29 Jan 2021	Pre-clinical revisions to visit window details in Chapters 5 and 6 to ensure that window definitions are consistent between RCT and Extension period and that associated body text agrees with visit window table text. Initial version used for study.
5.0	Shannon Hiser, John Lum	R. Paul Wadwa	7 May 2021	Addition of inclusion criterion requiring U.S. residency; typo correction in 9.2.4
6.0	John Lum	R. Paul Wadwa	16 Jun 2021	Addition of SUS Questionnaire, addition of the use of the new version of Control-IQ for the extension phase of the study, updated statistical analyses for the extension phase of the study.
7.0	John Lum	R. Paul Wadwa	15 Jul 2021	Per FDA request, inclusion of all study participants in the 13 week + 3 day call, 14-week call, and 15-week visit
8.0	John Lum	R. Paul Wadwa	10 Sep 2021	Addition of ancillary study during Extension Phase to obtain system performance data during meal/exercise challenges; associated revisions to Stats chapter, plus minor unrelated Stats edits.
9.0	John Lum	R. Paul Wadwa	04 Oct 2021	Revisions to exercise and meal bolus challenges to address FDA requests during IDE review
10.0	John Lum	R. Paul Wadwa	26 Oct 2021	Revisions to exercise and meal bolus challenges to address IRB requests during IRB review
11.0	John Lum	R. Paul Wadwa	03 Dec 2021	Introduction of Extended Use period

29

30

TABLE OF CONTENTS

31 CHAPTER 1: BACKGROUND INFORMATION 22

32 1.1 Introduction..... 22

33 1.2 Rationale 22

34 1.3 Potential Risks and Benefits of the Investigational Device 23

35 1.3.1 Known Potential Risks..... 23

36 1.3.1.1 Potential Risks and Benefits of the CLC System 23

37 1.3.1.2 Risk of Hypoglycemia 23

38 1.3.1.3 Risk of Hyperglycemia 23

39 1.3.1.4 Fingerstick Risks..... 23

40 1.3.1.5 Subcutaneous Catheter Risks (CGM) 23

41 1.3.1.6 Risk of Device Reuse..... 24

42 1.3.1.7 Questionnaires and Focus Groups 24

43 1.3.1.8 Other Risks 24

44 1.3.2 Known Potential Benefits 25

45 1.3.3 Risk Assessment 25

46 1.4 General Considerations..... 25

47 CHAPTER 2: STUDY ENROLLMENT AND SCREENING 27

48 2.1 Participant Recruitment and Enrollment..... 27

49 2.1.1 Informed Consent and Authorization Procedures..... 27

50 2.2 Participant Inclusion Criteria 27

51 2.3 Participant Exclusion Criteria..... 28

52 2.4 Eligibility Assessment and Baseline Data Collection..... 29

53 2.5 Historical Information..... 29

54 2.6 Screening Testing and Procedures 29

55 2.7 Screen Failures..... 30

56 CHAPTER 3: CGM RUN-IN PHASE..... 31

57 3.1 CGM Run-in Phase Overview 31

58 3.2 Initiation of CGM 31

59 3.2.1 CGM Training..... 31

60 3.3 Blood Glucose and Ketone Testing 32

61 3.4 Assessment of Successful Completion of the Run-in Phase..... 32

62	3.5 Optimization of Insulin Therapy.....	33
63	CHAPTER 4: RANDOMIZATION VISIT	34
64	4.1 Visit Timing.....	34
65	4.1.1 Randomization	34
66	4.1.2 Baseline HbA1c Determination	34
67	CHAPTER 5: MAIN STUDY PROCEDURES	35
68	5.1 Visit and Contact Schedule.....	35
69	5.2 CGM Initiation and Training.....	35
70	5.3 Procedures for the CLC Group.....	35
71	5.3.1 Study Pump Training	35
72	5.3.2 Initiation of Pump by MDI Participants.....	36
73	5.3.3 System Use Guidelines	37
74	5.3.4 Home Use of the Study System.....	37
75	5.3.5 Study Device Download	38
76	5.3.6 3-Day Phone Contact	38
77	5.3.7 1-Week Phone Contact	38
78	5.3.8 2-Week Visit	38
79	5.4 Procedures for the SC Group.....	39
80	5.4.1 Study Device Data Download.....	39
81	5.4.2 1-Week Phone Contact	39
82	5.4.3 2-Week Visit	39
83	5.5 Follow-up Visits and Phone Contacts for Both Groups	40
84	5.5.1 Visits	40
85	5.5.2 Phone Contacts.....	40
86	5.5.3 Optimization of Insulin Therapy.....	40
87	5.5.4 13-Week Visit	41
88	5.6 Early Termination Visit (If Applicable)	41
89	5.7 Unscheduled Visits	41
90	CHAPTER 6: EXTENSION PHASE PROCEDURES	42
91	6.1 Visit and Contact Schedule.....	42
92	6.2 Study Pump Initiation	42
93	6.3 Visits, Videoconferences, and Phone Calls for All Participants.....	43
94	6.3.1 13-Week + 3-Day Phone Contact	43

95	6.3.2 14-Week Phone Contact	43
96	6.3.3 15-Week Visit	43
97	6.3.4 19-Week Visit	43
98	6.3.5 23-Week Phone Call	43
99	6.3.6 26-Week Visit	43
100	6.3.7 Optimization of Insulin Therapy.....	43
101	6.4 Unscheduled Visits	43
102	6.5 Participant Access to Study Device at Study Closure	44
103	CHAPTER 7: EXTENDED USE PERIOD PROCEDURES	45
104	7.1 Visit and Contact Schedule.....	45
105	7.2 Visits, Videoconferences, and Phone Calls for Participants Re-Initiating Study Pump Use	
106	After a Gap in Use	45
107	7.2.1 Study Pump Retraining Visit	45
108	7.2.2 3-Day Phone Contact	46
109	7.2.3 1-Week Phone Contact	46
110	7.3 Visits, Videoconferences, and Phone Calls for All Participants.....	46
111	7.3.1 13-Week Visit and Subsequent Visits Every 13 Weeks	46
112	7.3.2 Final Visit.....	46
113	7.3.3 Optimization of Insulin Therapy.....	46
114	7.4 Unscheduled Visits	47
115	7.5 Participant Access to Study Device at Study Closure	47
116	CHAPTER 8: STUDY DEVICES.....	48
117	8.1 Description of the Investigational Device	48
118	8.1.1 Insulin Pump	48
119	8.1.2 Continuous Glucose Monitoring.....	48
120	8.1.3 Blood Glucose Meter and Strips	48
121	8.1.4 Ketone Meter and Strips	48
122	8.1.5 Study Device Accountability Procedures	48
123	8.1.6 Blood Ketone Testing	48
124	8.2 Safety Measures.....	48
125	8.2.1 CGM Calibration	48
126	8.2.2 System Failure	49
127	8.2.3 Hypoglycemia Threshold Alert and Safety Protocol	49

128	8.2.4 Hyperglycemia Threshold Alert and Safety Protocol	49
129	CHAPTER 9: TESTING PROCEDURES, QUESTIONNAIRES, AND FOCUS GROUPS	51
130	9.1 Laboratory Testing	51
131	9.1.1 HbA1c:	51
132	9.2 Questionnaires	51
133	9.2.1 PedsQL Diabetes Module – Parent	51
134	9.2.2 Pediatric Inventory for Parents	51
135	9.2.3 INSPIRE Survey – Parent	51
136	9.2.4 Pittsburgh Sleep Quality Index (PSQI) – Parent	52
137	9.2.5 Hypoglycemia Fear Survey-Parent (HFS-P)	52
138	9.2.6 Hypoglycemia Confidence Scale	52
139	9.2.7 System Usability Scale (SUS)	52
140	9.3 Focus Groups	53
141	CHAPTER 10: UNANTICIPATED PROBLEM, ADVERSE EVENT, AND DEVICE ISSUES REPORTING	54
142	10.1 Unanticipated Problems	54
143	10.2 Adverse Events	54
144	10.2.1 Definitions	54
145	10.2.2 Reportable Adverse Events	55
146	10.2.3 Hypoglycemic Events	56
147	10.2.4 Hyperglycemic/Ketotic Events	56
148	10.2.5 Relationship of Adverse Event to Study Device	57
149	10.2.6 Severity (Intensity) of Adverse Events	57
150	10.2.7 Expectedness	58
151	10.2.8 Coding of Adverse Events	58
152	10.2.9 Outcome of Adverse Events	58
153	10.3 Reportable Device Issues	59
154	10.4 Timing of Event Reporting	59
155	10.5 Safety Oversight	60
156	10.6 Stopping Criteria	60
157	10.6.1 Participant Discontinuation of Study Device	60
158	10.6.2 Criteria for Suspending or Stopping Overall Study	61
159	CHAPTER 11: MISCELLANEOUS CONSIDERATIONS	62
160	11.1 Drugs Used as Part of the Protocol	62

161	11.2 Collection of Medical Conditions and Medications	62
162	11.3 Prohibited Medications, Devices, Treatments, and Procedures.....	62
163	11.4 Precautionary Medications, Treatments, and Procedures	62
164	11.5 Prophylactic Medications, Treatments, and Procedures	62
165	11.6 Rescue Medications, Treatments, and Procedures.....	63
166	11.7 Participant Compensation	63
167	11.8 Participant Withdrawal	63
168	11.9 Confidentiality	63
169	CHAPTER 12: STATISTICAL CONSIDERATION	64
170	12.1 Statistical and Analytical Plans.....	64
171	12.2 Statistical Hypotheses	64
172	12.3 Sample Size.....	64
173	12.4 Efficacy Outcome Measures	65
174	12.4.1 Primary Efficacy Endpoint	65
175	12.4.2 Secondary Efficacy Endpoints	65
176	12.4.2.1 Secondary Efficacy Endpoints Included in Hierarchical Analysis	65
177	12.4.2.2 Other Secondary Efficacy Endpoints	65
178	12.4.3 CGM Metrics Calculations	66
179	12.5 Analysis Datasets and Sensitivity Analyses	67
180	12.5.1 Per Protocol Analyses	67
181	12.5.2 Other Sensitivity Analyses.....	67
182	12.6 Analysis of the Primary Efficacy Endpoint	68
183	12.7 Analysis of the Secondary Endpoints	68
184	12.7.1 Hierarchical Analyses	68
185	12.7.2 Other Endpoint Analyses	69
186	12.8 Safety Analyses.....	70
187	12.9 Intervention Adherence.....	71
188	12.10 Protocol Adherence and Retention	71
189	12.11 Baseline Descriptive Statistics	71
190	12.12 Device Issues	72
191	12.13 Planned Interim Analyses	72
192	12.14 Subgroup Analyses	72
193	12.15 Multiple Comparison/Multiplicity	73

194	12.16 Exploratory Analyses.....	73
195	12.17 Extension Phase	74
196	12.17.1 Exclusion of Ancillary Study Data	75
197	12.18 Extended Use Period.....	75
198	CHAPTER 13: DATA COLLECTION AND MONITORING	76
199	13.1 Case Report Forms and Device Data	76
200	13.2 Study Records Retention	76
201	13.3 Quality Assurance and Monitoring.....	76
202	13.4 Protocol Deviations.....	77
203	CHAPTER 14: ETHICS/PROTECTION OF HUMAN PARTICIPANTS.....	78
204	14.1 Ethical Standard	78
205	14.2 Institutional Review Boards.....	78
206	14.3 Informed Consent Process	78
207	14.3.1 Consent Procedures and Documentation	78
208	14.3.2 Participant and Data Confidentiality.....	78
209	CHAPTER 15: ANCILLARY STUDY TO TEST CONTROL-IQ SYSTEM WITH MEAL BOLUS AND EXERCISE	
210	CHALLENGES	80
211	15.1 Objective.....	80
212	15.2 Sample Size.....	80
213	15.3 Eligibility Criteria.....	80
214	15.4 Study Procedures	80
215	15.5 Outcomes and Analysis Plan	82
216	Safety Monitoring.....	83
217	CHAPTER 16: REFERENCES.....	84
218		

219

LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
AP	Artificial Pancreas
BG	Blood Glucose
BT/BTLE	Bluetooth, Bluetooth low energy
CRF	Case Report Form
CGM	Continuous Glucose Monitoring System
CLC	Closed-Loop Control
CSII	Continuous Subcutaneous Insulin Injection
CTR	Control-to-Range
DiAs	Diabetes Assistant
DKA	Diabetic Ketoacidosis
EC	European Commission
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HbA1c	Hemoglobin A1c
ID	Identification
iDCL	International Diabetes Closed Loop
IDE	Investigational Device Exemption
IOB	Insulin-on-Board
IQR	Interquartile Range
JDRF	Juvenile Diabetes Research Foundation
LGS	Low Glucose Suspend
PLGS	Predictive Low Glucose Suspend
POC	Point-of-Care
QA	Quality Assurance
QC	Quality Control
RBM	Risk-Based Monitoring
RCT	Randomized Control Trial
SC	Standard of Care group
SD	Standard Deviation
TDD	Total Daily Dose
UI	User Interface

220

221

222

Signature Page

223 Translation of the UVA Advanced Automated Insulin Delivery
224 Systems to Clinical Care in Young Children: Glycemic Control,
225 Regulatory Acceptance, and Optimization of Day to Day Use

226

Protocol Identifying Number: PEDAP

227

IND/IDE Sponsor: University of Virginia

228

Version Number: 11.0

229

03 DEC 2021

Protocol Chair	
Name, Institution	R. Paul Wadwa, M.D. / University of Colorado – Barbara Davis Center
Signature/Date	
Sponsor (IDE Holder)	
Name/Institution	Marc D. Breton, Ph.D. / University of Virginia
Signature/Date	
Coordinating Center Director	
Name, Institution	John Lum, MS / Jaeb Center for Health Research
Signature/Date	
Medical Monitor	
Name, Institution	Roy Beck, MD, Ph.D. / Jaeb Center for Health Research
Signature/Date	

CLINICAL CENTER PRINCIPAL INVESTIGATOR STATEMENT OF COMPLIANCE

Protocol Title: **The Pediatric Artificial Pancreas (PEDAP) trial: A Randomized Controlled Comparison of the Control-IQ technology Versus Standard of Care in Young Children in Type 1 Diabetes**

Protocol Version/Date: 11.0 / 03 DEC 2021

I have read the protocol specified above. In my formal capacity as a Clinical Center Principal Investigator, my duties include ensuring the safety of the study participants enrolled under my supervision and providing the Jaeb Center for Health Research, with complete and timely information, as outlined in the protocol. It is understood that all information pertaining to the study will be held strictly confidential and that this confidentiality requirement applies to all study staff at this clinical center.

This trial will be carried out in accordance with ICH E6 Good Clinical Practice (GCP) and as required by the following: United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

As the Principal Investigator, I will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), or other approved Ethics Committee, except where necessary to eliminate an immediate hazard(s) to the trial participants.

All key personnel (all individuals responsible for the design and conduct of this trial) have completed Human Participants Protection Training and Good Clinical Practice Training. Further, I agree to ensure that all staff members involved in the conduct of this study are informed about their obligations in meeting the above commitments.

Investigator's Signature _____ Date: ____ / ____ / ____
dd mm yyyy

Investigator's Name: _____

Clinical Center Name/Number: _____

PROTOCOL SUMMARY

PARTICIPANT AREA	DESCRIPTION
Title	The Pediatric Artificial Pancreas (PEDAP) trial: A Randomized Controlled Comparison of the Control-IQ technology Versus Standard Care in Young Children in Type 1 Diabetes
Précis	A randomized controlled trial of at-home closed loop system vs. standard care (defined as either multiple daily injections of insulin [MDI] or use of an insulin pump without hybrid closed-loop control capabilities [low-glucose suspend or predictive low-glucose suspend functionality is permitted]) in youth age 2 to <6 years old.
Investigational Device	t:slim X2 with Control-IQ and Dexcom G6 system
Objectives	The objective of the study is to assess efficacy, quality of life, and safety of a closed loop control (CLC) system (t:slim X2 with Control-IQ Technology) in a randomized controlled trial with partial crossover.
Study Design	First phase: a 13-week parallel group randomized clinical trial with 2:1 randomization to intervention with the closed loop system vs. standard care (SC); Second Phase: following the RCT, a 13-week period where the Standard Care (SC) group will transition to use CLC and the experimental arm will extend the use of CLC for the same period. After 26 weeks, participants may continue using CLC for an additional Extended Use period. A subset of participants will be invited to join an optional exercise/meal challenge ancillary study.
Number of Clinical Centers	~3 US clinical centers
Endpoints	<u>Efficacy</u> The primary outcome for the RCT is time in target range 70-180 mg/dL (TIR) measured by CGM in CLC group vs. SC group over 13 weeks The primary outcome for the extension phase assessed separately for each treatment group is change in TIR comparing extension phase with RCT phase. <u>Quality of Life</u> Patient-reported outcome questionnaires will be completed. <u>Safety</u> The key safety outcomes are severe hypoglycemia and ketoacidosis.
Population	Inclusion Criteria 1. Clinical diagnosis, based on investigator assessment, of type 1 diabetes for at least 6 months and using insulin for at least 6 months 2. Familiarity and use of a carbohydrate ratio for meal boluses. 3. Age ≥ 2 and <6 years old 4. Living with one or more parent/legal guardian knowledgeable about emergency procedures for severe hypoglycemia and able to contact emergency services and study staff. 5. Investigator has confidence that the parent can successfully operate all study devices and is capable of adhering to the protocol 6. Willingness to switch to lispro (Humalog) or aspart (Novolog) if not using already, and to use no other insulin besides lispro (Humalog) or aspart (Novolog) during the study for participants using a study-provided Tandem pump during the study. 7. Total daily insulin dose (TDD) at least 5 U/day 8. Body weight at least 20 lbs

PARTICIPANT AREA	DESCRIPTION
	9. Willingness not to start any new non-insulin glucose-lowering agent during the course of the trial 10. Participant and parent(s)/guardian(s) willingness to participate in all training sessions as directed by study staff. 11. Parent/guardian proficient in reading and writing English 12. Live in the United States, with no plans to move outside the United States during the study period Exclusion Criteria 1. Concurrent use of any non-insulin glucose-lowering agent (including GLP-1 agonists, Symlin, DPP-4 inhibitors, SGLT-2 inhibitors, sulfonylureas). 2. Hemophilia or any other bleeding disorder 3. History of >1 severe hypoglycemic event with seizure or loss of consciousness in the last 3 months 4. History of >1 DKA event in the last 6 months not related to illness, infusion set failure, or initial diagnosis 5. History of chronic renal disease or currently on hemodialysis 6. History of adrenal insufficiency 7. Hypothyroidism that is not adequately treated 8. Use of oral or injectable steroids within the last 8 weeks 9. Known, ongoing adhesive intolerance 10. Plans to receive blood transfusions or erythropoietin injections during the course of the study 11. A condition, which in the opinion of the investigator or designee, would put the participant or study at risk 12. Currently using any closed-loop system, or using an insulin pump that is incompatible with use of the study CGM 13. Participation in another pharmaceutical or device trial at the time of enrollment or during the study 14. Employed by, or having immediate family members employed by Tandem Diabetes Care, Inc., or having a direct supervisor at place of employment who is also directly involved in conducting the clinical trial (as a study investigator, coordinator, etc.); or having a first-degree relative who is directly involved in conducting the clinical trial
Sample Size	Up to 150 screened participants with the goal of randomizing 102 participants.
Treatment Groups	• Intervention Group: t:slim X2 with Control-IQ Technology and Study CGM. • Control Group: Standard care (SC) - defined as either multiple daily injections of insulin (MDI) or use of an insulin pump without hybrid closed-loop control capabilities (low-glucose suspend or predictive low-glucose suspend functionality is permitted) in conjunction with study CGM All participants will be offered to extend the study for an additional 13 weeks, with the SC group switching to the t:slim X2 with Control-IQ System after the 13-week RCT period. After 26 weeks, participants may continue using CLC for an additional Extended Use period.
Participant Duration	~26-32 weeks for RCT and Extension Phase, depending on duration of run-in phase; up to an additional ~7 months in Extended Use period
Protocol Overview/Synopsis	After consent is signed, eligibility will be assessed. Eligible participants not currently using an insulin pump and Dexcom G5 or Dexcom G6 CGM with minimum data requirements will initiate a run-in phase of 2 to 6 weeks that will be customized based on whether the participant is already

PARTICIPANT AREA	DESCRIPTION
	a CGM user. Participants who skip or successfully complete the run-in will be randomly assigned 2:1 to an intervention using Tandem t:slim X2 with Control-IQ Technology or the standard care control group using existing insulin therapy in conjunction with study CGM. All participants will continue their participation by using the t:slim X2 with Control-IQ system in an Extension Phase. [Figure 1] After 26 weeks, participants may continue using CLC for an additional Extended Use period through no later than July 31, 2022. A subset of participants will complete an optional exercise/meal challenge ancillary study.

259

260

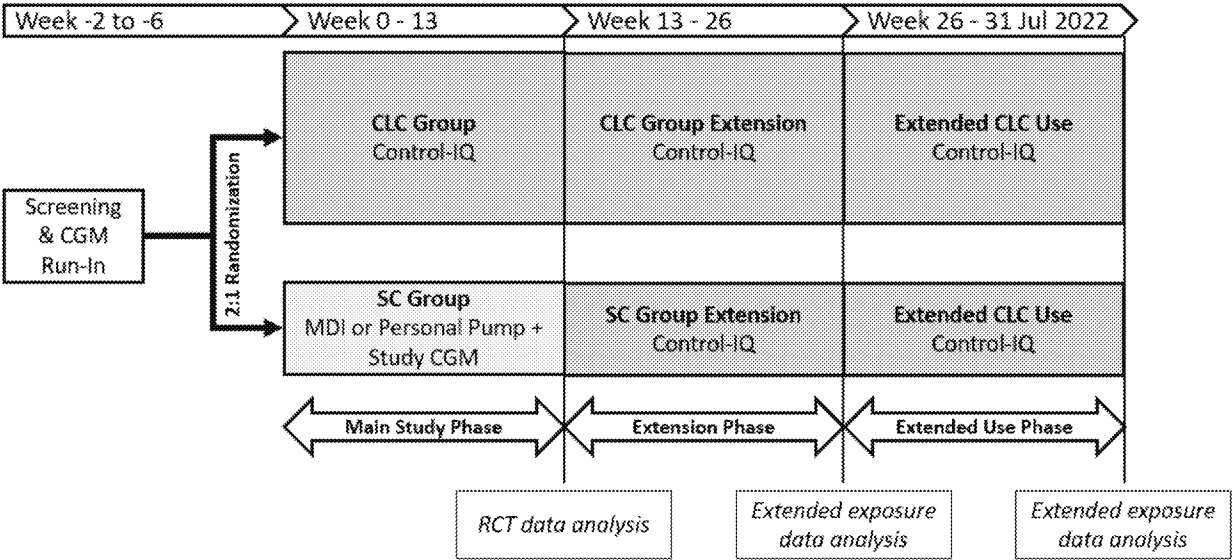
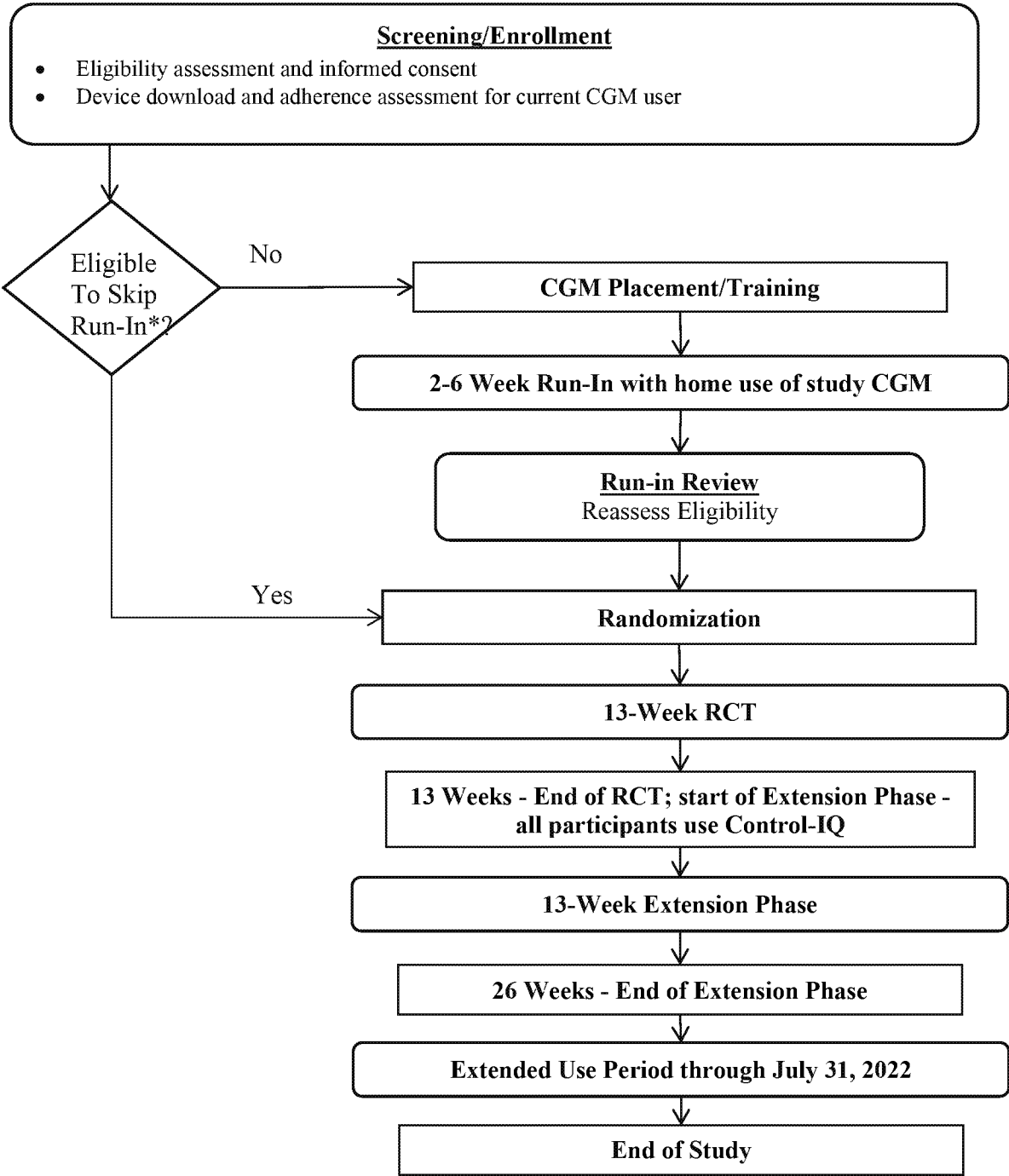


Figure 1: Study Design: Participants Randomized 2:1 Control-IQ Control (CLC) vs. Standard Care (SC) Groups. Extension phase with partial crossover of SC Group switching to use Control-IQ. Subsequent Extended Use period through no later than July 31, 2022.

266

SCHEMATIC OF STUDY DESIGN



*Current use of Dexcom G5 or G6 CGM with readings captured on at least 11 out of the previous 14 days

267

268

Figure 2: Overview of Study Design

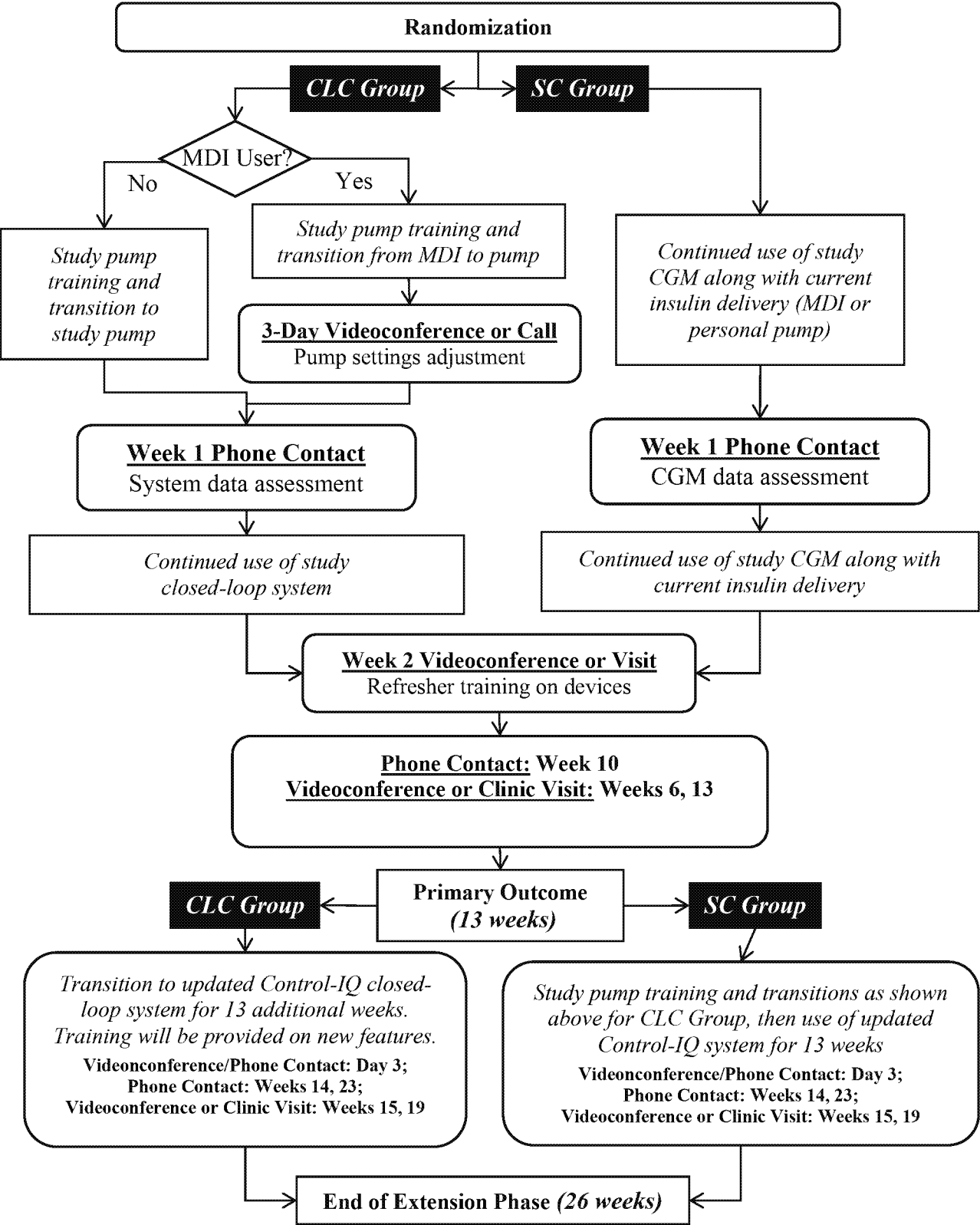
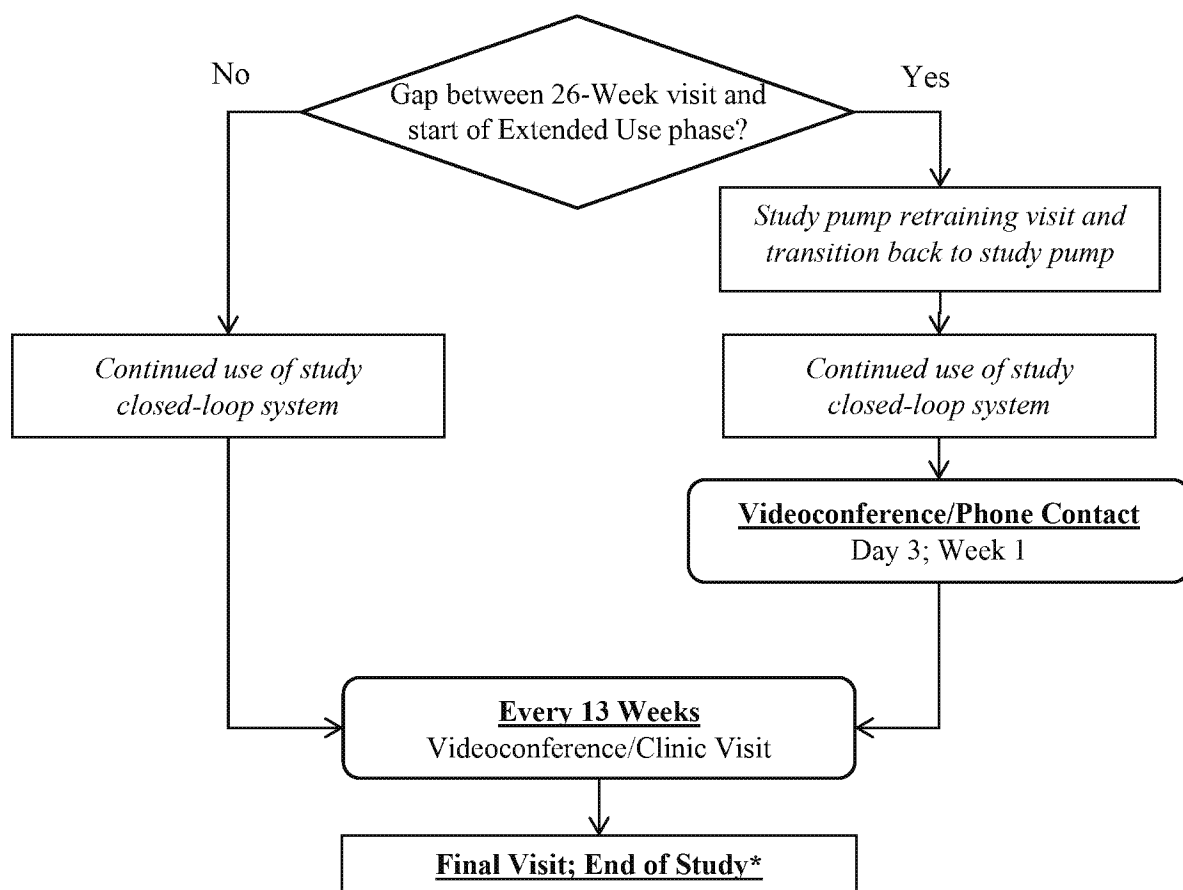


Figure 3: Schematic of Study Design (Post-Randomization through 26 Weeks)



* Final Visit to occur no later than July 31, 2022

Figure 4: Schematic of Study Design (Extended Use Period)

273

	Pre	Pre	0	3d ¹	1w	2w	6w	10w	13w	13w + 3d	14w	15w	19w	23w	26w
Visit (V), Videoconference (VC), or Phone (P)	VC/V	VC/V	VC/V	VC/ P	P	VC/V	VC/ V	P	VC/ V	VC/ P	P	VC/ V	VC/ V	P	VC/ V
Comment	Screen/ Enroll	Run-in	Rand												
Eligibility Assessment	X	X	X												
HbA1c (Central lab)			X						X						X
Device Data download(s)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Review diabetes management and AEs		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Questionnaires as defined in section 9.2	X								X						X

274 ¹ Only for participants on MDI at enrollment assigned to the CLC group

275

276 **Table 1. Schedule of Study Visits and Procedures (through 26-Week Visit)**

277

Days/Weeks after 26-Week Visit =>	0 ²	3d ²	1w ²	13w	26w, 39w, etc.	Final Visit
Visit (V), Videoconference (VC), or Phone (P)	VC/V	VC/ P	VC/ P	VC/V	VC/V	VC/V
Eligibility Assessment ^{1,2}	X					
Study Pump Retraining ²	X					
HbA1c (Central lab)				X	X	
Device Data download(s)		X	X	X	X	X
Review diabetes management and AEs		X	X	X	X	X

286

287 ¹ Participants are eligible to initiate Extended Use period if they completed the 26-Week Visit within the prior 4 months

288 ² Only for participants who had a gap between the 26-Week Visit and the initiation of the Extended Use period during
 289 which they stopped use of the study pump and reverted to MDI or personal pump insulin therapy

290

291 **Table 2. Schedule of Study Visits and Procedures (Extended Use Period)**

292

293

Chapter 1: Background Information

1.1 Introduction

The Tandem X2 insulin pump with Control-IQ Technology is a third-generation closed-loop control (CLC) system retaining the same control algorithm that was initially tested by UVA's DiAs system and then implemented in the inControl system (TypeZero Technologies, Inc.).

The system has received FDA approval for use in individuals ≥ 6 years old following a pair of pivotal trials that demonstrated the system's safety and efficacy, first in participants ≥ 14 years old (1) and then subsequently in participants ≥ 6 years old (2).

Closed-Loop Control System

The Closed-Loop Control System contained in t-slim X2 with Control-IQ Technology is described in Master File MAF-2032/A008. Control-IQ Technology is derived from inControl previously described in IDE# G160097, G160181, G150240 and G140169/S010. The CLC is an "artificial pancreas" (AP) application that uses advanced closed loop control algorithms to automatically manage blood glucose levels for people with Type 1 Diabetes. The system modulates insulin to keep blood glucose in a targeted range. The system components include the t:slim X2 with Control-IQ Technology and the Dexcom CGM G6.



Figure 5. t:slim X2 with Control-IQ and Dexcom G6 system

1.2 Rationale

The objective of this randomized clinical trial is to assess the efficacy and safety of the Control-IQ closed loop system over a 13-week period compared with standard care. In addition, the data from this trial may be used for subsequent regulatory submissions for this system in the age group studied.

The extension phase will allow for additional exposure time to the Tandem t:slim X2 with Control-IQ Technology and evaluation of the SC arm after crossing over to use Control-IQ for a 13-week period.

320 **1.3 Potential Risks and Benefits of the Investigational Device**

321 Risks and Benefits are detailed below. Loss of confidentiality is a potential risk; however, data are
322 handled to minimize this risk. Hypoglycemia, hyperglycemia and ketone formation are always a
323 risk in participants with type 1 diabetes and participants will be monitored for these events.

324 **1.3.1 Known Potential Risks**

325 **1.3.1.1 Potential Risks and Benefits of the CLC System**

326 Even though the study system has been tested prior to this study, there is still a risk that parts of
327 the system may not function properly. The following are possible reasons the system may deliver
328 too much insulin or incorrectly stop insulin delivery:

- 329 • CGM sensor reads higher or lower than the actual glucose level which increases risk for
330 hypoglycemia and hyperglycemia with automated insulin delivery system;
- 331 • Device malfunctions that could produce a suspension of insulin delivery or over delivery
332 of insulin.

333 **1.3.1.2 Risk of Hypoglycemia**

334 As with any person having type 1 diabetes and using insulin, there is always a risk of having a low
335 blood sugar (hypoglycemia). The frequency of hypoglycemia should be no more and possibly less
336 than it would be as part of daily living. Symptoms of hypoglycemia can include sweating,
337 jitteriness, and not feeling well. Just as at home, there is the possibility of fainting or seizures
338 (convulsions) and that for a few days the participant may not be as aware of symptoms of
339 hypoglycemia. A CGM functioning poorly and significantly over-reading glucose values could
340 lead to inappropriate insulin delivery.

341 **1.3.1.3 Risk of Hyperglycemia**

342 Hyperglycemia and ketonemia could occur if insulin delivery is attenuated or suspended for an
343 extended period or if the pump or infusion set is not working properly. A CGM functioning poorly
344 and significantly under-reading glucose values could lead to inappropriate suspension of insulin
345 delivery.

346 **1.3.1.4 Fingerstick Risks**

347 At various times several drops of blood will be removed by fingerstick. This is a standard method
348 used to obtain blood for routine hospital laboratory tests. Pain is common at the time of lancing.
349 In about 1 in 10 cases, a small amount of bleeding under the skin will produce a bruise. A small
350 scar may persist for several weeks. The risk of local infection is less than 1 in 1000. This should
351 not be a significant contributor to risks in this study as fingersticks are part of the usual care for
352 people with diabetes.

353 **1.3.1.5 Subcutaneous Catheter Risks (CGM)**

354 Participants using the CGM will be at low risk for developing a local skin infection at the site of
355 the sensor needle placement. If a catheter is left under the skin for more than 24 hours, it is possible

356 to get an infection where it goes into the skin, with swelling, redness and pain. There may be
357 bleeding where the catheter is put in and bleeding under the skin causes a bruise (1 in 10 risk).

358 Study staff should verbally alert the participant that on rare occasions, the CGM may break and
359 leave a small portion of the sensor under the skin that may cause redness, swelling or pain at the
360 insertion site. The participant should be further instructed to notify the study coordinator
361 immediately if this occurs.

362 **1.3.1.6 Risk of Device Reuse**

363 The study CGM system is labeled for single use only. The sensor (the component of the system
364 that enters the skin) will be single use only. The receiver, if used, is a hand-held device. The
365 transmitter and receiver may be reused during the study after cleaning the device using a hospital-
366 approved cleaning procedure. The transmitter is attached to the sensor but does not enter the skin.
367 Participants will be informed that FDA or relevant national authorities have approved these devices
368 for single use and that by using them among multiple patients, bloodborne pathogens (i.e. Hepatitis
369 B) may be spread through the use of multiple users.

370 The study insulin pump is labeled for single-patient use. During the study, this device may be
371 reused after cleaning adhering to a hospital-approved cleaning procedure. All infusion set
372 equipment will be single patient use only (infusion set insertion kits, tubing, cartridges etc.)
373 Participants will be informed that FDA or relevant national authorities typically approve the insulin
374 pump device for single use and that by using them among multiple patients, bloodborne pathogens
375 (i.e. Hepatitis B) may be spread through the use of multiple users.

376 The study blood glucose meter and blood ketone meter are labeled for single-patient use.
377 During the study, only one person can use each device as there are rare risks that bloodborne
378 pathogens (i.e. Hepatitis B) may be spread through the use of multiple users.

379 **1.3.1.7 Questionnaires and Focus Groups**

380 As part of the study, parents of participants will complete questionnaires which include questions
381 about their private attitudes, feelings and behavior related to the investigational equipment as well
382 as managing diabetes. Parents may also participate in a focus group session to explore their
383 feelings about using the closed-loop system. It is possible that some people may find these
384 questionnaires or focus groups to be mildly upsetting. Similar questionnaires and focus groups
385 have been used in previous research and these types of reactions have been uncommon.

386 **1.3.1.8 Other Risks**

387 Some participants may develop skin irritation or allergic reactions to the adhesives used to secure
388 the CGM, or to secure the insulin infusion sets for the continuous subcutaneous insulin infusion.
389 If these reactions occur, different adhesives or “under-taping” (such as with IV 3000, Tegaderm,
390 etc.) will be tried, sites will be rotated frequently, and a mild topical steroid cream or other
391 medication may be required.

392 Whenever the skin is broken there is the possibility of an infection. The CGM and pump infusion
393 sites are inserted under the skin. It is possible that any part that is inserted under the skin may

394 cause an infection. These occur very infrequently, but, if an infection was to occur, oral and/or
395 topical antibiotics can be used. The risk of skin problems could be greater if you use a sensor for
396 longer than it is supposed to be used. Therefore, participants (and parents) will be carefully
397 instructed about proper use of the sensor.

398 Data downloaded from the CGM, pump, and the home glucose and ketone meter will be collected
399 for the study as measures of diabetes self-management behaviors. Some people
400 may be uncomfortable with the researchers' having such detailed information about their daily
401 diabetes habits.

402 **1.3.2 Known Potential Benefits**

403 One purpose of this research is to reduce the frequency of hypoglycemia and severe hypoglycemic
404 events. Hypoglycemia is the number one fear of many individuals and families with someone who
405 has type 1 diabetes and this fear often prevents optimal glycemic control.

406 It is expected that this protocol will yield increased knowledge about using an automated
407 closed-loop system to control the glucose level and is intended to develop data to support future
408 device approval in the age group studied. The individual participant may not benefit from study
409 participation.

410 **1.3.3 Risk Assessment**

411 Based on the facts that (1) children with diabetes experience mild hypoglycemia and
412 hyperglycemia frequently as a consequence of the disease and its management, (2) the study
413 intervention involves periodic automated insulin dosing that may reduce the likelihood of
414 hypoglycemia, and periodic automated attenuation of insulin delivery that may reduce the
415 likelihood of hyperglycemia, (3) if any, hypo and/or hyperglycemia occur, mitigations are in place,
416 and have been tested in prior studies using the investigational device system in the home setting,
417 that limit the likelihood of excessive insulin dosing or prolonged withdrawal of insulin, and (4)
418 rapid reversal of hypoglycemia and hyperglycemia can be achieved, it is the assessment of the
419 investigators that this protocol falls under DHHS 45 CFR 46.405 and 21 CFR 50.52 as a clinical
420 investigation involving greater than minimal risk but presenting the prospect of direct benefit to
421 individual subjects. In addition, it is the belief of the investigators that this study also presents
422 prospect of general benefit to others with diabetes.

423 **1.4 General Considerations**

424 The study is being conducted in compliance with the policies described in the study policies
425 document, with the ethical principles that have their origin in the Declaration of Helsinki, with the
426 protocol described herein, and with the standards of Good Clinical Practice (GCP).

427 There is no restriction on the number of participants to be enrolled by each clinical center toward
428 the overall recruitment goal.

429 The protocol is considered a significant risk device study, due to the fact that the closed loop
430 system is experimental in the population under study. Therefore, an investigational device

431 exemption (IDE) from the U.S. Food and Drug Administration (FDA) is required to conduct the
432 study.

Chapter 2: Study Enrollment and Screening

2.1 Participant Recruitment and Enrollment

Enrollment will proceed with the goal of having 102 participants randomized. A maximum of 150 individuals may be enrolled into screening for the study in order to achieve this goal.

Study participants will be recruited at ~3 clinical centers in the United States without regard to gender, race, or ethnicity. There is no restriction on the number of participants to be enrolled by each clinical center toward the overall recruitment goal.

The study team will make every effort to have the following minimum numbers of participants complete the trial in the specified subgroups at the time of enrollment:

- Approximately two-thirds of the participants with most recent available HbA1c $\geq 7.5\%$
- Approximately 30 participants in the age range ≥ 24 months to < 48 months
- At least 20% of participants who are on multiple daily injections (MDI) rather than pump

2.1.1 Informed Consent and Authorization Procedures

Potential eligibility may be assessed as part of a routine-care examination. Before completing any procedures or collecting any data that are not part of usual care, electronic informed consent will be obtained.

A parent/legal guardian (referred to subsequently as “parent”) will be provided with the Informed Consent Form to read and will be given the opportunity to ask questions either via phone/videoconference or by mail or email. If the parent and child are interested in the study, the investigator will schedule a virtual or in-person visit to discuss study, and if the parent and child agree to participate, the Informed Consent Form will be electronically signed through the JCHR website. A copy of the electronically signed consent form can be printed by the parent and another copy will be printed by the site to add to the participant’s study record.

As part of the informed consent process, the parent will be asked to sign an authorization for release of personal information. This may be done electronically with the consent, or on paper if the site requires their own process. The investigator, or his or her designee, will review the study-specific information that will be collected and to whom that information will be disclosed. After speaking with the parent, questions will be answered about the details regarding authorization.

A participant is considered enrolled when the informed consent form has been electronically signed and HIPAA authorization has been provided.

2.2 Participant Inclusion Criteria

Individuals must meet all of the following inclusion criteria in order to be eligible to participate in the study.

- 466 1. Clinical diagnosis, based on investigator assessment, of type 1 diabetes for at least 6 months
467 and using insulin for at least 6 months
- 468 2. Familiarity and use of a carbohydrate ratio for meal boluses.
- 469 3. Age ≥ 2 and < 6 years old
- 470 4. Living with one or more parent/legal guardian knowledgeable about emergency procedures for
471 severe hypoglycemia and able to contact emergency services and study staff.
- 472 5. Investigator has confidence that the parent can successfully operate all study devices and is
473 capable of adhering to the protocol
- 474 6. Willingness to switch to lispro (Humalog) or aspart (Novolog) if not using already, and to use
475 no other insulin besides lispro (Humalog) or aspart (Novolog) during the study for participants
476 using a study-provided Tandem pump during the study.
 - 477 • *Study will not be providing insulin; therefore, participants will need to have access to*
478 *either lispro or aspart*
- 479 7. Total daily insulin dose (TDD) at least 5 U/day
- 480 8. Body weight at least 20 lbs
- 481 9. Willingness not to start any new non-insulin glucose-lowering agent during the course of the
482 trial (see section 2.3)
- 483 10. Participant and parent(s)/guardian(s) willingness to participate in all training sessions as
484 directed by study staff.
- 485 11. Parent/guardian proficient in reading and writing English
- 486 12. Live in the United States, with no plans to move outside the United States during the study
487 period

488 **2.3 Participant Exclusion Criteria**

489 Individuals meeting any of the following exclusion criteria at baseline will be excluded from study
490 participation.

- 491 1. Concurrent use of any non-insulin glucose-lowering agent (including GLP-1 agonists, Symlin,
492 DPP-4 inhibitors, SGLT-2 inhibitors, sulfonyleureas).
- 493 2. Hemophilia or any other bleeding disorder
- 494 3. History of > 1 severe hypoglycemic event with seizure or loss of consciousness in the last 3
495 months
- 496 4. History of > 1 DKA event in the last 6 months not related to illness, infusion set failure, or
497 initial diagnosis
- 498 5. History of chronic renal disease or currently on hemodialysis
- 499 6. History of adrenal insufficiency
- 500 7. Hypothyroidism that is not adequately treated

- 501 8. Use of oral or injectable steroids within the last 8 weeks
- 502 9. Known, ongoing adhesive intolerance
- 503 10. Plans to receive blood transfusions or erythropoietin injections during the course of the study
- 504 11. A condition, which in the opinion of the investigator or designee, would put the participant or
- 505 study at risk (specified in the study procedure manual); the investigator will take into account
- 506 the participant's HbA1c level, compliance with current diabetes management, and prior acute
- 507 diabetic complications
- 508 12. Currently using any closed-loop system, or using an insulin pump that is incompatible with
- 509 use of the study CGM
- 510 13. Participation in another pharmaceutical or device trial at the time of enrollment or during the
- 511 study
- 512 14. Employed by, or having immediate family members employed by Tandem Diabetes Care, Inc.,
- 513 or having a direct supervisor at place of employment who is also directly involved in
- 514 conducting the clinical trial (as a study investigator, coordinator, etc.); or having a first-degree
- 515 relative who is directly involved in conducting the clinical trial

516 **2.4 Eligibility Assessment and Baseline Data Collection**

517 Potential participants will be evaluated for study eligibility through the elicitation of a medical

518 history and local laboratory testing as needed in the judgment of the investigator (as part of usual

519 care).

520 The screening visit and subsequent scheduled study visits may be conducted virtually via

521 videoconference at the discretion of the study investigator, for example due to institutional

522 restrictions or the participant or investigator's preference for a remote visit. Study staff will

523 discuss the feasibility of conducting virtual visits with each participant and provide support as

524 needed to ensure adequate access. The screening visit must be completed within 28 days of

525 participant enrollment.

526 **2.5 Historical Information**

527 A history will be elicited from the parent and extracted from available medical records with

528 respect to the participant's diabetes history, current diabetes management, other past and current

529 medical problems, past and current medications, and drug allergies.

530 **2.6 Screening Testing and Procedures**

531 At the Screening Visit the following procedures will be performed:

- 532 • Informed consent process
- 533 • Assessment of eligibility
- 534 • Contact information (retained at the clinical center and not entered into study database)
- 535 • Demographics (date of birth, sex, race and ethnicity)

- 536 • Measurement of height/weight
- 537 ○ If the visit is conducted virtually, a verbal report of the participant's weight and
- 538 verbal report of height will be acceptable. A scale will be provided for
- 539 participants who do not already have a scale at home.
- 540 • Determination of most recent HbA1c level from medical records or verbal report
- 541 • Participants' parents will complete a set of baseline questionnaires, described in
- 542 section 9.2.

543 **2.7 Screen Failures**

544 Individuals who do not initially meet study eligibility requirements may be rescreened at a later
545 date per investigator discretion.

Chapter 3: CGM Run-In Phase

3.1 CGM Run-in Phase Overview

This phase must begin (supplies shipped) within 3 days of completion of the Screening visit. The purpose of this CGM run-in phase is to 1) assess compliance with study procedures and 2) to introduce the study CGM to study participants without current use of a Dexcom CGM.

Participants who currently use a Dexcom G5 or G6 with CGM data captured on at least 11 out of the previous 14 days prior to the time of enrollment can skip the run-in phase. Participants who do not currently use a Dexcom G5 or G6 CGM, or who do use that CGM but have readings captured on fewer than 11 out of the previous 14 days prior to time of enrollment, will be required to participate in the CGM run-in phase.

Participants and their parent(s) will receive training on the study CGM as detailed below. This will be an unblinded use of the study CGM.

3.2 Initiation of CGM

Study CGM supplies will be provided to the participant either in-person at the clinic, or via delivery by other means (personal delivery, overnight shipment, etc.).

Once the supplies have been received, the participant and parent will be instructed to use the study CGM on a daily basis. Participants using a personal CGM prior to the study will discontinue the personal CGM beginning in this period.

3.2.1 CGM Training

CGM training (in-person or via videoconference) will be provided by a qualified trainer to participants not currently using a personal CGM identical to the study CGM as to how to use it in real-time to make management decisions and how to review the data after an upload for retrospective review. The participating child will participate in training sessions to the degree judged appropriate by the parent and trainer. CGM training will include:

- Instruction on how to insert the sensor and transmitter, including observation/supervision of placement of a sensor
- Instruction on how to calibrate the CGM unit, if needed
- Guidance on accessing the CGM trace, either through a manufacturer-provided software app or via a study-provided CGM receiver unit, or via a personal insulin pump if participants use a pump that integrates with the study CGM
- Parents will be asked to perform fingerstick blood glucose measurements in accordance with the labeling of the study CGM device

A copy of the study CGM user's guide will be provided to the participant's parents.

579 3.3 Blood Glucose and Ketone Testing

580 Participants will receive supplies for blood glucose and ketone testing.

- 581 • Blood glucose testing

- 582 ○ Participants will be provided with a study blood glucose meter, test strips, and standard
583 control solution to perform quality control (QC) testing at home per manufacturer
584 guidelines.

- 585 ○ All study blood glucose meters will be QC tested with control solution if available prior to
586 dispensation and during all office visits. A tested meter will not be used in a study if it
587 does not read within the target range at each concentration per manufacturer labeling.

- 588 ○ Participants will be reminded to use the study blood glucose meter for all fingerstick BGs
589 during the study.

- 590 ○ Participants will be given guidelines for treatment of low or high blood glucose.

- 591 • Blood ketone testing

- 592 ○ Participants will be provided with a study blood ketone meter, test strips, standard control
593 solution to perform QC testing at home per manufacturer guidelines, and
594 software/hardware needed to download meter datafiles.

- 595 ○ All study blood ketone meters will be QC tested with control solution if available prior to
596 dispensation and during all office visits. A tested meter will not be used in a study if it
597 does not read within the target range at each concentration per manufacturer labeling.

- 598 ○ Participants will be instructed to perform blood ketone testing as described in section 7.1.6.

- 599 ○ Participants will be given guidelines for treatment of elevated blood ketones

- 600 • Participants will be required to have glucagon at home. Participants who currently do not have
601 one will be given a prescription for glucagon (either emergency kit or nasal glucagon per
602 investigator discretion for participants over 4 years of age).

603 3.4 Assessment of Successful Completion of the Run-in Phase

604 Enrolled participants will have a follow-up visit or videoconference approximately 14 days after
605 initiation of the run-in phase to assess progress or successful completion of the phase. If needed,
606 one or more interim visits or videoconference/phone contacts may occur to assist the participant
607 with any CGM use issues. Procedures will include downloading of the study CGM data and the
608 following:

609 Assessment of compliance with the use of CGM for at least 11 out of the prior 14 days

610 Assessment of skin reaction in areas where a CGM sensor was worn or other safety issues
611 associated with CGM use

612 Assessment of eligibility to continue to the randomized control trial (RCT) phase of the study

613

614 Participants Using a Personal CGM at Enrollment

615 Participants who had currently been using a personal CGM at the time of enrollment (but did not
616 meet requirements to skip run-in) and satisfy the CGM use criteria above without any major safety
617 issues and otherwise meet study eligibility requirements can be randomized.

618 Participants who fail to meet the minimum CGM use requirement, or who the investigator believes
619 may benefit from an extension of the CGM run-in period, may at the investigator's discretion be
620 allowed to continue CGM run-in for a maximum of two additional 2-week periods. These
621 participants will have a follow-up visit or videoconference approximately 14 days after each prior
622 assessment for a reassessment using the same procedures as described above.

623 Participants who do not meet CGM use requirements after three 2-week periods of CGM run-in or
624 otherwise fail to meet study eligibility requirements will be withdrawn from the study.

625 Participants Not Using a Personal CGM at Enrollment

626 Participants who had not currently been using a personal CGM at the time of enrollment will be
627 assessed as described above. If there are no major safety issues and the investigator believes that
628 the participant will remain adherent to use of the study CGM, the participant will be asked to
629 continue the run-in phase for an additional 2-week period to establish baseline glycemic control
630 while using the study CGM. These participants will have a follow-up visit or videoconference
631 approximately 14 days for a second follow-up visit with the same visit procedures as described
632 above.

633 Participants who fail to meet the minimum CGM use requirement at the second follow-up, or who
634 the investigator believes may benefit from a further extension of the CGM run-in period, may at
635 the investigator's discretion be allowed to continue CGM run-in for one additional 2-week period.
636 These participants will have a follow-up visit or videoconference approximately 14 days after the
637 second follow-up visit for a reassessment using the same procedures as described above.

638 Participants who do not meet CGM use requirements after three 2-week periods of CGM run-in or
639 otherwise fail to meet study eligibility requirements will be withdrawn from the study.

640 **3.5 Optimization of Insulin Therapy**

641 Data will be obtained from CGM and/or pump downloads prior to CGM run-in review contacts.
642 Adjustments to pump settings (basal rates, correction factor, insulin-to-carbohydrate ratio, etc.) or
643 injection strategies will be made in response to major trends observed in the CGM data, with
644 flexibility for clinicians to adhere to guidelines and practices established at each individual practice
645 rather than a fixed set of heuristics for all clinical centers.

Chapter 4: Randomization Visit

4.1 Visit Timing

The visit, which may be in-clinic or virtual, may occur on the same day as the Screening or Run-in Review Visit, or on a subsequent day. If deferred, the randomization visit should occur no more than 14 days after successful completion of the run-in phase or within 14 days of screening if run-in is skipped.

4.1.1 Randomization

Eligible participants will be randomly assigned to one of two treatment groups in a 2:1 ratio:

1. Control-IQ Closed-Loop Control (CLC) Group
2. Standard Care (SC) Group

The participant's randomization group assignment is determined by completing a Randomization Visit case report form on the study website. The randomization list will use a permuted block design, stratified by clinical center.

The participant will be included in the data analysis regardless of whether or not the protocol for the assigned randomization group is followed. Thus, the investigator must not randomize a participant until he/she is convinced that the participant/parent will accept assignment to either of the two groups.

It was decided that it was more important to stratify randomization by clinical center than by factors such as baseline time in range, HbA1c, or device use since these factors will be easier to adjust for in analysis than will clinical center.

4.1.2 Baseline HbA1c Determination

A capillary blood sample will be obtained for baseline HbA1c determination. Capillary collection supplies will be provided to the participant within 3 days of randomization. This may occur either in-person at the clinic, or via delivery by other means (personal delivery, overnight shipment, etc.).

Chapter 5: Main Study Procedures

5.1 Visit and Contact Schedule

During the RCT period, visits and contacts will be scheduled as outlined in Table 3 below:

Table 3: RCT Visit and Phone Contact Schedule

Target Day/Week	Contact Type ¹	Target/Allowable Window (around Target Day/Week)
3 days ²	VC/P	± 2 days
1 week	P	± 2 days
2 weeks	VC/V	± 4 days
6 weeks	VC/V	± 7 days
10 weeks	P	± 7 days
13 weeks	VC/V	± 7 days

¹ Contact Types are defined as Clinic Visit (V), Videoconference (VC), or Phone call (P); Phone calls may be replaced by Videoconferences or Clinic Visits and Videoconferences may be replaced by Clinic Visits at investigator discretion

² Only for participants on MDI at enrollment assigned to the CLC group; timing will be with respect to the start of home use of the study system, rather than with respect to the start of the RCT

Additional contacts or visits may occur as needed.

5.2 CGM Initiation and Training

Participants who skipped CGM run-in will be provided with study CGM supplies and training as described in section 3.2 and instructed to use the study CGM on a daily basis. Participants currently using a personal CGM identical to the study CGM may skip the training.

Provision of CGM supplies and training should be completed within 3 days of randomization.

5.3 Procedures for the CLC Group

The study pump, associated supplies, and training will be provided to participants assigned to the CLC group within 3 days of randomization. Dispensation of supplies may occur either in-person at the clinic, or via delivery by other means (personal delivery, overnight shipment, etc.).

5.3.1 Study Pump Training

Parents of participants will receive study pump training by a qualified trainer. The participating child will participate in training sessions to the degree judged appropriate by the parent and trainer. Pump training (in-person or via videoconference) will be provided by a qualified trainer to all CLC Group participants.

Parents will be fully instructed on the study insulin pump. The trainer will discuss differences from the participant's personal pump, if applicable, in important aspects such as calculation of insulin on board and correction boluses and optional additional topics such as: infusion site initiation,

696 cartridge/priming procedures, setting up the pump, charging the pump, navigation through menus,
697 bolus procedures including stopping a bolus, etc.

698 Parents will be instructed to change the study insulin pump infusion set at least once every 3 days
699 or per manufacturer guidelines, whichever is shorter.

700 Parents will be trained to use the bolus calculator following the standard t:slim X2 training if they
701 are not already using the t:slim X2 bolus calculator. Parent/guardians with prior
702 education/experience with using this bolus calculator will be offered refresher training.

703 • The study team will assist the parent in study pump infusion site initiation and will start
704 the participant on the study pump. The study pump will be programmed with the
705 participant's usual basal rates and pump parameters, if applicable. The participant's
706 personal pump, if any, will be removed.

707 • The parent will be supervised with the study pump during at least one meal or snack bolus
708 to ensure participant understanding of the pump features.

709 • The parent will be encouraged to review the literature provided with the pump and infusion
710 sets after the training is completed.

711 • The parent will be trained on severe hypoglycemia emergency procedures including
712 removal of the study pump and administration of glucagon.

713 Pump training specific to the Control-IQ Technology functions will include:

714 • How to turn on and off Control-IQ technology.

715 • How to understand when Control-IQ is increasing or decreasing basal rates.

716 • How to administer a meal or correction boluses

717 • What to do when exercising while using the system

718 • How to enable the sleep function and set the sleep schedule

719 • The parent will be assessed for understanding of the system interface and how to react to
720 safety/alert messages.

721 The parent will be given a User Guide as a reference.

722 **5.3.2 Initiation of Pump by MDI Participants**

723 For MDI participants being started on the study pump, an initial basal insulin profile will be
724 customized on a per-participant basis. Total daily insulin dose will be reduced by approximately
725 20% as a general rule, with a recommended method outlined in a separate procedures' manual.
726 Further adjustments to total daily dose (TDD) and intraday basal rate profile may be made during
727 the initial 2-week use period.

728 Participants and parent(s) will complete training on the study pump as described above, with
729 additional emphasis on topics relevant to new pump users, such as infusion site initiation,
730 cartridge/priming procedures, setting up the pump, charging the pump, navigation
731 through menus, bolus procedures including stopping a bolus, etc.

732 The study team will assist the participant/parent in study pump infusion site initiation and will start
733 the participant on the study pump. The study pump will be programmed with the participant's
734 insulin requirements.

735 **5.3.3 System Use Guidelines**

736 The participant/parent will be instructed to use the system in closed-loop mode except if insulin is
737 delivered by any means other than the study pump (e.g. injection of subcutaneous insulin via
738 syringe in the event of infusion site failure). If insulin is delivered by any means other than the
739 study pump, the parent will be instructed to turn off Control-IQ for approximately four hours.

740 The parent will also be instructed to contact study staff if the participating child has illness with
741 an elevated temperature >101.5 degrees Fahrenheit (38.6 degrees Celsius), other periods of
742 significant illness, or during periods of use of medications such as epinephrine for the emergency
743 treatment of a severe allergic reaction or asthma attack in addition to use of oral or injectable
744 glucocorticoids to determine if closed-loop use should be temporarily discontinued.

745 Parents will be provided with sufficient supplies to last until the subsequent visit.

746 Parents will be provided with contact information and will be asked to call the study clinical staff
747 for any health-related issues and for technical issues with the system. Participants may use the
748 study pump without Control-IQ activated and study CGM during periods of component
749 disconnections or technical difficulties. Parents will also receive study staff contact information
750 to ask any questions they may have during the study.

751 Study staff will discuss with the parent that routine contact is required and will make arrangements
752 with the parent for the contacts. If the parent cannot be reached, the participant's other contact
753 methods will be utilized, including the emergency contact. Parents who are not compliant with
754 the arranged contacts on two separate occasions may be discontinued at the discretion of the
755 investigator.

756 Upon completion of the CGM or study pump training components, as applicable, study staff will
757 document, using a checklist, that the parent is familiar with the functions/features/tasks addressed
758 during the training.

759 Parents will be provided Hypoglycemia, Hyperglycemia and Ketone Guidelines (section 8.2) for
760 when their glucose levels are >300 mg/dL for more than 90 minutes or >400 mg/dL at any time or
761 <70 mg/dL or ketones ≥ 1.0 mmol/L.

762 **5.3.4 Home Use of the Study System**

763 After training on the study system has been completed, participants will proceed with home use
764 (meaning free-living use at school, home, etc.) of the study pump.

765 Parents may use available manufacturer-provided software and features of the study CGM related
766 to mobile data access or remote monitoring, but will be instructed not to use any third-party
767 components for this purpose.

768 5.3.5 Study Device Download

769 Parents will be instructed to download the study CGM and pump and ketone meter prior to each
770 phone or videoconference contact or on at least an every 4-week basis throughout the remainder
771 of the study.

772 5.3.6 3-Day Phone Contact

773 For participants who were on MDI at the time of enrollment, study staff will perform a phone call
774 or videoconference with the parent within 3 (± 2) days following initiation of study pump use.

775 The following will occur:

- 776 • Assessment of compliance with study device use by review of any available device data
- 777 • Assessment of adverse events, adverse device effects, and device issues
- 778 • Study staff will answer any questions related to device use and follow the procedure for
779 insulin pump optimization described above using the study CGM available data from the
780 previous two weeks.

781 5.3.7 1-Week Phone Contact

782 Study staff will perform a phone call/videoconference with the parent within 7 (± 2) days following
783 randomization.

784 The following will occur:

- 785 • Assessment of compliance with study device use by review of any available device data
- 786 • Assessment of adverse events, adverse device effects, and device issues
- 787 • Study staff will answer any questions related to device use and follow the procedure for
788 insulin pump optimization described above using the study CGM available data from the
789 previous two weeks.

790 5.3.8 2-Week Visit

791 Participants will have a follow-up visit 14 (± 4) days from the date of randomization.

792 The parent will be offered review training to address any questions on the use of the study device
793 including meal bolus strategies and strategies related to pump use and exercise.

794 The following will occur:

- 795 • Assessment of compliance with study device use by review of any available device data
- 796 • Assessment of adverse events, adverse device effects, and device issues
- 797 • Study staff will answer any questions related to device use and follow the procedure for
798 insulin pump optimization described above using the study CGM available data from the
799 previous two weeks.

- At in-clinic visits, the blood glucose meter and study ketone meter will be downloaded and QC tested with control solution.

5.4 Procedures for the SC Group

Participants in the SC group will continue to use their existing insulin therapy (personal pump or MDI) for the treatment of their diabetes, in conjunction with use of the study CGM, study blood glucose meter, and study ketone meter.

If a participant is using a pump with an LGS/PLGS feature, he/she will be allowed to continue using this feature during the trial.

Parents may use available manufacturer-provided software and features of the study CGM related to mobile data access or remote monitoring, but will be instructed not to use any third-party components for this purpose.

5.4.1 Study Device Data Download

Parents will be instructed to upload/email data from the study CGM and study ketone meter using commercially available software prior to each phone or videoconference contact below for clinician review. Parents will be provided with any software and hardware needed to perform these data uploads.

5.4.2 1-Week Phone Contact

Study staff will perform a phone call/videoconference with the participant 7($\pm$ 2) days following randomization.

The following will occur:

- Assessment of compliance with study device use by review of any available device data
- Assessment of adverse events, adverse device effects, and device issues
- Study staff will answer any questions related to device use

5.4.3 2-Week Visit

Participants will have a follow-up visit 14 ($\pm$ 4) days from the date of randomization.

The parent will be offered review training on the use of SC during the remainder of the study, including meal bolus strategies and strategies related to exercise.

The following will occur:

- Assessment of compliance with study device use by review of any available device data
- Assessment of adverse events, adverse device effects, and device issues
- Study staff will review uploaded CGM data, answer any questions related to device use, and provide any recommendations for insulin therapy adjustment.

- If visit is in-clinic, the study blood glucose meter and study ketone meter will be downloaded and QC tested.

The parent will be instructed to upload data from the study CGM and ketone meter at least once every 4 weeks for the remainder of the study.

5.5 Follow-up Visits and Phone Contacts for Both Groups

After the first 2 weeks, the schedule for remaining follow-up contacts is the same for both treatment groups. Study staff will discuss with the parent that periodic contact is required and will make arrangements with the parent for the contacts. If the parent cannot be reached, the participant's other contact methods will be utilized, including the emergency contact.

5.5.1 Visits

A follow-up in-clinic visit will occur at 6 weeks (± 7 days). The following procedures are performed in both groups, unless otherwise specified below:

Assessment of compliance with study device use by review of any available device data

Assessment of adverse events, adverse device effects, and device issues

Download of device data (study system or personal pump and study CGM, study BG meter, study ketone meter); in the case of videoconferences, participants will upload or email available data prior to the visit, including CGM, pump, and ketone meter, so that clinic staff can review and download the data

5.5.2 Phone Contacts

A follow-up phone call or videoconference will occur at 10 weeks (± 7 days). At the discretion of the investigator, this scheduled phone contact may be replaced by an in-clinic visit.

The following procedures are performed in both treatment groups:

- Review of available CGM, ketone meter, and/or system data to identify any safety issues associated with current insulin therapy and diabetes management approach

- Assessment of adverse events, adverse device effects, and device issues

Additional phone contacts may be performed as needed.

5.5.3 Optimization of Insulin Therapy

If needed for safety reasons at the criteria of the physician at each clinical center, optimization may be done via phone contacts, videoconferences, or in-clinic visits.

Data will be obtained from CGM and/or pump downloads during the contact. Adjustments to pump settings (basal rates, correction factor, insulin-to-carbohydrate ratio, etc.) or injection strategies will be made in response to major trends observed in the CGM data, with flexibility for clinicians to adhere to guidelines and practices established at each individual practice rather than a fixed set of heuristics for all clinical centers.

866 **5.5.4 13-Week Visit**

867 All participants will have a 13-Week (± 7 days) visit during which the following will occur:

- 868 • Collection of a blood sample to send to the central laboratory for HbA1c determination.
- 869 • Completion of questionnaires
- 870 • Weight and height measurements will be repeated
- 871 • Assessment of adverse events, adverse device effects, and device issues
- 872 • Download of device data (study system or personal pump and study CGM, study BG meter,
- 873 study ketone meter) as available

874 **5.6 Early Termination Visit (If Applicable)**

875 Participants will be asked to come for an end of study visit in the event of withdrawal or early
876 termination.

877 **5.7 Unscheduled Visits**

878 Participants may have unscheduled visits during the study period if required for additional device
879 training or other unanticipated needs per the study investigator discretion.

880

Chapter 6: Extension Phase Procedures

At the conclusion of the 13-week RCT, all participants will use the Control-IQ closed-loop system during a 13-week Extension Phase.

An updated version of the Control-IQ system with enhanced usability will be used during the Extension Phase. Participants assigned to the SC group during the RCT period will receive training based on the updated pump as described below. Participants assigned to the CLC group will receive a brief training session to review any new or changed features of the pump.

Initiation of the updated Control-IQ pump may be deferred by up to 2 weeks if needed, with the participant continuing on the treatment used during the RCT period during this time and the overall duration of the Extension Phase increasing by up to 2 weeks.

6.1 Visit and Contact Schedule

During the Extension period, visits and contacts will be scheduled as outlined in Table 4 below:

Table 4: Extension Phase Visit and Phone Contact Schedule

Target Day/Week ¹	Contact Type ²	Target/Allowable Window (around Target Day/Week)
13 weeks + 3 days	VC/P	± 2 days
14 weeks	P	± 2 days
15 weeks	VC/V	± 4 days
19 weeks	VC/V	± 7 days
23 weeks	P	± 7 days
26 weeks	VC/V	± 7 days

¹ The “13 weeks” and subsequent visit targets reflect a participant who had no delay between the 13-week visit of the RCT and initiation of use of the updated Control-IQ pump. Targets and associated windows may be shifted by up to 2 weeks for participants whose initiation is delayed.

² Contact Types are defined as Clinic Visit (V), Videoconference (VC), or Phone call (P); Phone calls may be replaced by Videoconferences or Clinic Visits and Videoconferences may be replaced by Clinic Visits at investigator discretion

6.2 Study Pump Initiation

Participants assigned to the SC group during the initial 13-Week RCT period will initiate use of the updated study pump either the same day as the 13-Week visit or within 2 weeks of this visit. The procedures described in section 5.3 above will be followed to initiate these participants on the study pump.

Participants assigned to the CLC group during the RCT period will switch to the updated version of the Control-IQ system and will receive training on its new features. This will occur either the same day as the 13-Week visit or within 2 weeks of this visit.

908 **6.3 Visits, Videoconferences, and Phone Calls for All Participants**

909 **6.3.1 13-Week + 3-Day Phone Contact**

910 Study staff will perform a phone call or videoconference with the parent within 3 (± 2) days
911 following initiation of Extension Phase study pump use. Procedures will mirror those described in
912 section 5.3.6 above.

913 **6.3.2 14-Week Phone Contact**

914 Participants will have a phone call or videoconference at 14 Weeks (± 2 days). Procedures will
915 mirror those described in section 5.3.7 above.

916 **6.3.3 15-Week Visit**

917 Participants will have a follow-up visit at 15 Weeks (± 4 days). Procedures will mirror those
918 described in section 5.3.8 above.

919 **6.3.4 19-Week Visit**

920 A follow-up in-clinic visit will occur at 19 weeks (± 7 days). Procedures will mirror those
921 described in section 5.5.1 above.

922 **6.3.5 23-Week Phone Call**

923 A follow-up phone call will occur at 23 weeks (± 7 days). Procedures will mirror those described
924 in section 5.5.2 above.

925 **6.3.6 26-Week Visit**

926 A follow-up in-clinic visit will occur at 26 weeks (± 7 days). Procedures will mirror those
927 described in section 5.5.4 above.

928 Participants will have the opportunity to participate in Focus Group sessions as described in
929 section 9.3 below.

930 Participants will be given the option to continue use of the Control-IQ closed-loop system during
931 an additional Extended Use period as described in the next chapter. Participants who do not wish
932 to continue to the Extended Use period will be switched back to the insulin pump or MDI
933 therapy that was in use prior to the study.

934 **6.3.7 Optimization of Insulin Therapy**

935 If needed for safety reasons at the criteria of the physician at each clinical center, optimization
936 may be done via phone contacts, videoconferences, or in-clinic visits as described in section
937 5.5.3 above.

938 **6.4 Unscheduled Visits**

939 Participants may have unscheduled visits during the study period if required for additional device
940 training or other unanticipated needs per the study investigator discretion.

941 **6.5 Participant Access to Study Device at Study Closure**

942 Participants not continuing to the Extended Use period will return all investigational study devices
943 and supplies (insulin pump, CGM and related supplies). Participants may keep the study ketone
944 meter and study glucometer if these devices are not marked for investigational use only.

945

Chapter 7: Extended Use Period Procedures

At the 26-Week Visit of the Extension Phase, participants will be given the option to continue use of the Control-IQ closed-loop system during an additional Extended Use period. Participants who completed the 26-Week Visit before the addition of this Extended Use period to the study protocol will be eligible to rejoin the study and participate as long as they completed their 26-Week Visit within the prior 4 months.

The same version of the Control-IQ system in use during the 13-Week Extension Phase will be used during the Extended Use period.

Informed Consent will be obtained from eligible participants who are interested in participating in the Extended Use period. The informed consent process will mirror the process described above in section 2.1.1.

7.1 Visit and Contact Schedule

During the Extended Use period, visits and contacts will be scheduled as outlined in Table 5 below:

Table 5: Extended Use Period Visit and Phone Contact Schedule

Target Day/Week with respect to initiation of Extended Use period	Contact Type ¹	Target/Allowable Window (around Target Day/Week)
0 days (Retraining) ²	VC/V	N/A
3 days ²	VC/P	± 2 days
1 week ²	VC/P	± 2 days
13 weeks	VC/V	± 7 days
26 weeks	VC/V	± 7 days
Final Visit	VC/V	N/A

¹ Contact Types are defined as Clinic Visit (V), Videoconference (VC), or Phone call (P); Phone calls may be replaced by Videoconferences or Clinic Visits and Videoconferences may be replaced by Clinic Visits at investigator discretion

² Only for participants who had a gap between the 26-Week Visit and the initiation of the Extended Use period during which they stopped use of the study pump and reverted to MDI or personal pump insulin therapy

7.2 Visits, Videoconferences, and Phone Calls for Participants Re-Initiating Study Pump Use After a Gap in Use

7.2.1 Study Pump Retraining Visit

Participants who had a gap between the 26-Week Visit and the initiation of the Extended Use period during which they reverted to MDI or personal pump insulin therapy will have a visit to receive retraining on the study pump prior to re-initiation of study pump use.

971 The procedures described in section 5.3 above will be followed to re-initiate these participants on
972 the study pump.

973 **7.2.2 3-Day Phone Contact**

974 Study staff will perform a phone call or videoconference with the parent within 3 (± 2) days
975 following re-initiation of study pump use. Procedures will mirror those described in section 5.3.6
976 above.

977 **7.2.3 1-Week Phone Contact**

978 Participants will have a phone call or videoconference within 7 days (± 2 days) following re-
979 initiation of study pump use. Procedures will mirror those described in section 5.3.7 above.

980 **7.3 Visits, Videoconferences, and Phone Calls for All Participants**

981 **7.3.1 13-Week Visit and Subsequent Visits Every 13 Weeks**

982 A follow-up in-clinic visit will occur 13 weeks (± 7 days) after the start of the Extended Use period.
983 The following procedures will be performed in both groups:

- 984 • Collection of a blood sample to send to the central laboratory for HbA1c determination
- 985 • Assessment of compliance with study device use by review of any available device data
- 986 • Assessment of adverse events, adverse device effects, and device issues
- 987 • Download of device data (study system or personal pump and study CGM, study BG meter,
988 study ketone meter); in the case of videoconferences, participants will upload or email
989 available data prior to the visit, including CGM, pump, and ketone meter, so that clinic
990 staff can review and download the data

991 Every 13 weeks (± 7 days) thereafter, another follow-up clinic visit will occur involving the same
992 procedures described above.

993 **7.3.2 Final Visit**

994 A final follow-up in-clinic or videoconference visit will occur no later than July 31, 2022.
995 Procedures will mirror those described in section 7.3.1 above, except that no blood sample will
996 be collected.

997 Participants will be switched back to the insulin pump or MDI therapy that was in use prior to
998 the study.

999 **7.3.3 Optimization of Insulin Therapy**

1000 If needed for safety reasons at the criteria of the physician at each clinical center, optimization
1001 may be done via phone contacts, videoconferences, or in-clinic visits as described in section
1002 5.5.3 above.

1003 7.4 Unscheduled Visits

1004 Participants may have unscheduled visits during the study period if required for additional device
1005 training or other unanticipated needs per the study investigator discretion.

1006 7.5 Participant Access to Study Device at Study Closure

1007 Participant will return all investigational study devices and supplies (insulin pump, CGM and
1008 related supplies) at study closure. Participant may keep the study ketone meter and study
1009 glucometer if these devices are not marked for investigational use only.

1010 Chapter 8: Study Devices

1011 8.1 Description of the Investigational Device

1012 8.1.1 Insulin Pump

1013 The study system will include the Tandem t:slim X2 with Control-IQ technology.

1014 8.1.2 Continuous Glucose Monitoring

1015 The study CGM will include Dexcom G6 transmitter and sensors. The CGM sensor will be
1016 replaced at least once every 10 days.

1017 8.1.3 Blood Glucose Meter and Strips

1018 Blood glucose levels will be measured using the study's blood glucose meter (glucometer) and the
1019 CGM device will be calibrated if needed using the study glucometer and strips in accordance with
1020 the manufacturer's labeling.

1021 8.1.4 Ketone Meter and Strips

1022 Blood ketone levels will be measured using the Abbott Precision Xtra meter and strips in
1023 accordance with the manufacturer's labeling. The blood glucose meter component of the Precision
1024 Xtra device will not be used.

1025 8.1.5 Study Device Accountability Procedures

1026 Device accountability procedures will be detailed in the clinical center procedures manual.

1027 8.1.6 Blood Ketone Testing

1028 Participants to perform QC testing at home per manufacturer guidelines.

1029 All study blood ketone meters will be QC tested with control solution if available during all office
1030 visits. A tested meter will not be used in a study if it does not read within the target range at each
1031 concentration per manufacturer labeling. The participant will be instructed to contact study staff
1032 for a replacement of the meter, test strips, and control solution if a meter fails QC testing at home.

1033 Participants will be instructed on how to perform blood ketone testing.

1034 Participants will be given guidelines for treatment of elevated blood ketones.

1035 8.2 Safety Measures

1036 8.2.1 CGM Calibration

1037 Throughout the study, participants will be instructed to calibrate the study CGM in accordance
1038 with manufacturer labelling.

1039 8.2.2 System Failure

1040 If the CGM signal becomes unavailable for more than 20 minutes consecutively, Control-IQ or
1041 closed loop will not operate to automatically adjust insulin. If the CGM is not connected, the
1042 system will revert to usual function of the pump and deliver insulin with the insulin dosing
1043 parameters programmed in the system for that individual. Resumption of Closed-Loop will
1044 occur automatically once CGM signal is available again.

1045 If the study system is unable to activate Control-IQ for any reason, the pump will automatically
1046 revert to preprogrammed basal insulin delivery without any need for instruction from the user.

1047 If the pump detects a system error that does not allow it to operate, the Malfunction Alarm will
1048 display and the participant will be instructed to contact Tandem Technical Support via the study
1049 team.

1050 8.2.3 Hypoglycemia Threshold Alert and Safety Protocol

1051 During the course of the study, participants will be permitted to change the CGM low glucose
1052 threshold alert setting on their device or mobile app, but will be instructed to choose a value no
1053 less than 70 mg/dL.

1054 The t:slim X2 with Control-IQ system will issue a predictive hypoglycemia alert (Control-IQ Low
1055 Alert) when the system predicts BG <70 mg/dL within the next 15 minutes (<80 mg/dL when
1056 exercise mode is activated).

1057 If the participant receives a Control-IQ Low Alert, a message appears on the user interface (UI)
1058 that is accompanied by vibration followed by vibrations and/or sound if not acknowledged by the
1059 user in 5 minutes. This alert remains on the screen until acknowledged by the user. The user is
1060 prompted to test blood sugar and treat with carbs.

1061 8.2.4 Hyperglycemia Threshold Alert and Safety Protocol

1062 During the course of the study, participants will be permitted to change the CGM high glucose
1063 threshold alert setting on their device or mobile app, but will be instructed to choose a value no
1064 greater than 300 mg/dL.

1065 The t:slim X2 with Control-IQ system will issue a predictive hyperglycemia alert (Control-IQ
1066 High Alert) when the system has increased insulin delivery, but detects a CGM value above 200
1067 mg/dL and does not predict the value will decrease in the next 30 minutes.

1068 If the participant receives a Control-IQ High Alert, a message appears on the UI that is
1069 accompanied by vibration followed by vibrations and/or sound if not acknowledged by the user in
1070 5 minutes. This alert remains on the screen until acknowledged by the user. The user is prompted
1071 to check the site for occlusion and test blood glucose.

1072 If a participant's CGM reading is >300 mg/dL for over 90 minutes or $\geq$ 400 mg/dL at any point, or
1073 if CGM reading is >250 mg/dL more than 3 hours after a meal, the participant took correction

1074 insulin, and CGM didn't decrease by at least 50 mg/dL, the participant will be instructed to take
1075 the following steps:

1076 Inspect infusion site for problems

1077 Perform a blood glucose meter check.

1078 If the blood glucose is >300 mg/dL, check for blood ketones with the study ketone meter.

1079 If the ketone level is ≥ 1.0 mmol/L, take correction insulin, change insulin (pump) infusion site and
1080 contact study staff.

1081 If a participant administers correction insulin via insulin syringe, participants will be instructed to
1082 turn Control-IQ off for approximately four hours.

1083 **Chapter 9: Testing Procedures, Questionnaires, and Focus Groups**

1084 **9.1 Laboratory Testing**

1085 **9.1.1 HbA1c:**

1086 Performed at the Randomization visit, 13-Week visit, and 26-Week visit

1087 Blood samples will be sent to the central laboratory for sample analysis using an NGSP approved
1088 method.

1089 **9.2 Questionnaires**

1090 The questionnaires listed below are completed by participants' parents at Screening, 13 weeks,
1091 and 26 weeks for all participants except as noted. The questionnaires will be family and age
1092 appropriate and are described briefly below. The procedures for administration are described in
1093 the clinical center procedures manual.

1094 Pediatric Quality of Life – Parent

1095 Pediatric Inventory for Parents

1096 INSPIRE Survey – Parent

1097 Pittsburgh Sleep Quality Index (PSQI) – Parent

1098 Fear of Hypoglycemia Survey-Parents (HFS-P)

1099 Hypoglycemia Confidence Scale (HCS)

1100 System Usability Scale (SUS) (Closed-Loop participants only at 13 and 26 weeks)

1101 Administration time is approximately 35 minutes.

1102 **9.2.1 PedsQL Diabetes Module – Parent**

1103 This is a 32-item scale developed and validated for the measurement of diabetes-specific quality
1104 of life. Participants record the extent to which their child experienced each of 32 problems
1105 related to diabetes in the prior month.

1106 Administration time is approximately 5 minutes.

1107 **9.2.2 Pediatric Inventory for Parents**

1108 This is a widely-used, 42-item measure of parenting stress designed for parents of youth with
1109 type 1 diabetes.

1110 Administration time is approximately 6 minutes.

1111 **9.2.3 INSPIRE Survey – Parent**

1112 The INSPIRE (Insulin Delivery Systems: Perceptions, Ideas, Reflections and Expectations) survey
1113 was developed to assess various aspects of a user's experience regarding automated insulin

1114 delivery for both patients and family members. The surveys include various topics important to
1115 patients with type 1 diabetes and their family members based upon >200 hours of qualitative
1116 interviews and focus groups. The parent pre-assessment survey and parent post-assessment survey
1117 both contain 19 items. Response options for all surveys include a 5-point Likert scale from strongly
1118 agree to strongly disagree, along with an N/A option.

1119 Administration time is approximately 5 minutes.

1120 **9.2.4 Pittsburgh Sleep Quality Index (PSQI) – Parent**

1121 An abbreviated 9-question version of the Pittsburgh Sleep Quality Index (PSQI), a validated tool
1122 for assessing self-reported sleep quantity and quality, will be completed by parents. Seven
1123 component scores are derived, each scored 0 (no difficulty) to 3 (severe difficulty). The
1124 component scores are summed to produce a global score (range 0 to 21). Higher scores indicate
1125 worse sleep quality.

1126 Administration time is approximately 3 minutes.

1127 **9.2.5 Hypoglycemia Fear Survey-Parent (HFS-P)**

1128 The Hypoglycemia Fear Survey-Parent is a validated tool of 25 items to assess parents' anxiety
1129 and behavior concerning possible hypoglycemia. Items are rated on a 5-point Likert scale
1130 (0=never, 4=always), with higher scores indicating higher fear of hypoglycemia.

1131 Administration time is approximately 4 minutes.

1132 **9.2.6 Hypoglycemia Confidence Scale**

1133 The scale comprises 8 items and measures confidence hypoglycemia can be treated or prevented
1134 in various situations.

1135 Administration time is approximately 3 minutes.

1136 **9.2.7 System Usability Scale (SUS)**

1137 The System Usability Scale (SUS) is a 10-item questionnaire that measures the overall usability
1138 of a system. It is a valid and reliable measure of the perceived usability of a system and is
1139 technology-agnostic. The questionnaire presents statements with five response options (anchoring
1140 the options from strongly disagree to strongly agree) and asks users to rate their agreement to the
1141 statements. User scores are transformed into a composite score, from 0 to 100, and this score is
1142 taken as an overall measure of the system's usability; higher scores indicate better perceived
1143 usability.

1144 Administration time is approximately 5 minutes.

1145

1146 9.3 Focus Groups

1147 Focus groups will be completed following the 26-Week Visit. The focus groups will be conducted
1148 virtually using HIPAA-approved software.

1149 Focus groups will include 3-5 individuals and a script of open-ended questions to gather feedback
1150 and reactions to the closed loop system, the clinical trial, and QoL changes. There will also be time
1151 for discussion of content raised by parents. If parents are able to have the child participant attend
1152 briefly to answer a few questions, this will be attempted.

1153 Sessions will be audio- and video-taped and transcribed by a professional transcription service.
1154 Otherwise, these recordings will not be shared for any non-study purposes. Transcriptions will use
1155 a code for participants, such as "Participant 1", and will not contain names or other identifiers of
1156 participants.

Chapter 10: Unanticipated Problem, Adverse Event, and Device Issues

Reporting

10.1 Unanticipated Problems

Site investigators will promptly report to the Coordinating Center on an eCRF all unanticipated problems meeting the criteria below. Problems meeting IRB reporting requirements will be reported to the IRB within 7 calendar days of the site becoming aware of the problem. For this protocol, an unanticipated problem is an incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied
- Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research)
- Suggests that the research places participants or others at a greater risk of harm than was previously known or recognized (including physical, psychological, economic, or social harm)

The Coordinating Center also will report to the IRB all unanticipated problems not directly involving a specific site such as unanticipated problems that occur at the Coordinating Center or at another participating entity such as a pharmacy or laboratory. These instances must be reported to the JCHR IRB within seven calendar days of recognition. The Director of the Human Research Protection Program will report to the appropriate regulatory authorities if the IRB determines that the event indeed meets the criteria of an Unanticipated Problem requiring additional reporting.

10.2 Adverse Events

10.2.1 Definitions

Adverse Event (AE): Any untoward medical occurrence in a study participant, irrespective of the relationship between the adverse event and the device(s) under investigation.

Serious Adverse Event (SAE): Any untoward medical occurrence that:

Results in death.

Is life-threatening; (a non-life-threatening event which, had it been more severe, might have become life-threatening, is not necessarily considered a serious adverse event).

Requires inpatient hospitalization or prolongation of existing hospitalization.

1191 Results in persistent or significant disability/incapacity or substantial disruption of the ability to
1192 conduct normal life functions (sight threatening).

1193 Is a congenital anomaly or birth defect.

1194 Is considered a significant medical event by the investigator based on medical judgment (e.g., may
1195 jeopardize the participant or may require medical/surgical intervention to prevent one of the
1196 outcomes listed above).

1197 Unanticipated Adverse Device Effect (UADE): Any serious adverse effect on health or safety or
1198 any life-threatening problem or death caused by, or associated with, a device, if that effect,
1199 problem, or death was not previously identified in nature, severity, or degree of incidence in the
1200 investigational plan or application (including a supplementary plan or application), or any other
1201 unanticipated serious problem associated with a device that relates to the rights, safety, or welfare
1202 of participants (21 CFR 812.3(s)).

1203 Adverse Device Effect (ADE): Any untoward medical occurrence in a study participant which the
1204 device may have caused or to which the device may have contributed (Note that an Adverse Event
1205 Form is to be completed in addition to a Device Deficiency or Issue Form, unless excluded from
1206 reporting as defined in section 10.3). *An event that occurs solely due to participant (i.e., user)*
1207 *error in which the device functions properly generally will not be considered an ADE unless it is*
1208 *determined that the instructions on the screen of the device or user manual (or similar training*
1209 *materials) may have contributed to the event (note: the event may still meet criteria for reporting*
1210 *as an adverse event).*

1211 Device Complaints and Malfunctions: A device complication or complaint is something that
1212 happens to a device or related to device performance, whereas an adverse event happens to a
1213 participant. A device complaint may occur independently from an AE, or along with an AE.
1214 An AE may occur without a device complaint or there may be an AE related to a device complaint.
1215 A device malfunction is any failure of a device to meet its performance specifications or otherwise
1216 perform as intended. Performance specifications include all claims made in the labeling for the
1217 device. The intended performance of a device refers to the intended use for which the device is
1218 labeled or marketed. (21 CFR 803.3). Note: for reporting purposes, sites will not be asked to
1219 distinguish between device complaints and malfunctions.

1220 **10.2.2 Reportable Adverse Events**

1221 For this protocol, a reportable adverse event includes any untoward medical occurrence that meets
1222 one of the following criteria:

- 1223 1. An SAE or an AE associated with a visit to a hospital emergency department
- 1224 2. An ADE as defined in section 10.2.1, unless excluded from reporting in section 10.3
- 1225 3. An AE as defined in section 10.2.1 occurring in association with a study procedure
- 1226 4. An AE as defined in section 10.2.1 not related to a device issue which leads to temporary or
1227 permanent discontinuation of a study device
- 1228 5. An AE as defined in section 10.2.1 that affects the participant's ability to complete any study
1229 procedures

- 1230 6. Hypoglycemia meeting the definition of severe hypoglycemia as defined below
- 1231 7. Diabetic ketoacidosis (DKA) as defined below or in the absence of DKA, a hyperglycemic or
- 1232 ketosis event meeting the criteria defined below
- 1233 Hypoglycemia and hyperglycemia not meeting the criteria below will not be recorded as adverse
- 1234 events unless associated with an Adverse Device Effect. Skin reactions from sensor placement are
- 1235 only reportable if severe and/or required treatment.
- 1236 All reportable AEs—whether volunteered by the participant, discovered by study personnel during
- 1237 questioning, or detected through physical examination, laboratory test, or other means—will be
- 1238 reported on an AE form online. Each AE form is reviewed by the Medical Monitor to assess safety
- 1239 and to verify the coding and the reporting that is required.
- 1240 **10.2.3 Hypoglycemic Events**
- 1241 Hypoglycemia not associated with an Adverse Device Effect is only reportable as an adverse event
- 1242 when the following definition for severe hypoglycemia is met: the event required assistance of
- 1243 another person due to altered consciousness, and required another person to actively administer
- 1244 carbohydrate, glucagon, or other resuscitative actions. This means that the participant was
- 1245 impaired cognitively to the point that he/she was unable to treat himself/herself, was unable to
- 1246 verbalize his/ her needs, was incoherent, disoriented, and/or combative, or experienced seizure or
- 1247 loss of consciousness. These episodes may be associated with sufficient neuroglycopenia to
- 1248 induce seizure or loss of consciousness. If plasma glucose measurements are not available during
- 1249 such an event, neurological recovery attributable to the restoration of plasma glucose to normal is
- 1250 considered sufficient evidence that the event was induced by a low plasma glucose concentration.
- 1251 When a hypoglycemic event meets the above reporting requirements, a Hypoglycemia Form
- 1252 should be completed in addition to the Adverse Event Form. Severe hypoglycemia events should
- 1253 be considered to be serious adverse events with respect to reporting requirements.
- 1254 **10.2.4 Hyperglycemic/Ketotic Events**
- 1255 Hyperglycemia not associated with an Adverse Device Effect is only reportable as an adverse
- 1256 event when one of the following criteria is met:
- 1257 the event involved DKA, as defined by the Diabetes Control and Complications Trial (DCCT) and
- 1258 described below
- 1259 evaluation or treatment was obtained at a health care provider facility for an acute event involving
- 1260 hyperglycemia or ketosis, or the participant contacted the site and received guidance on how to
- 1261 manage the hyperglycemia/ketosis
- 1262 blood ketone level ≥ 1.0 mmol/L, even if there was no communication with a health care provider
- 1263 at the time of the event
- 1264 Hyperglycemic events are classified as DKA if the following are present:
- 1265 Symptoms such as polyuria, polydipsia, nausea, or vomiting;

1266 Serum ketones ≥ 1.5 mmol/L or large/moderate urine ketones;
1267 Either arterial blood pH < 7.30 or venous pH < 7.24 or serum bicarbonate (or CO_2) < 15 ; and
1268 Treatment provided in a health care facility
1269 When a hyperglycemia/ketotic qualifies as an SAE as defined in section 10.2.1, a
1270 Hyperglycemia/DKA Form should be completed in addition to the Adverse Event Form. Events
1271 meeting DKA criteria should be considered to be serious adverse events with respect to reporting
1272 requirements. Hyperglycemia events not meeting criteria for DKA generally will not be considered
1273 as serious adverse events unless one of the SAE criteria in section 10.2.1 is met.

1274 **10.2.5 Relationship of Adverse Event to Study Device**

1275 The study investigator will assess the relationship of any adverse event to be related or unrelated
1276 by determining if there is a reasonable possibility that the adverse event may have been caused by
1277 the study device.

1278 To ensure consistency of adverse event causality assessments, investigators should apply the
1279 following general guideline when determining whether an adverse event is related:

1280 Yes

1281 There is a plausible temporal relationship between the onset of the adverse event and the study
1282 intervention, and the adverse event cannot be readily explained by the participant's clinical state,
1283 intercurrent illness, or concomitant therapies; and/or the adverse event follows a known pattern of
1284 response to the study intervention; and/or the adverse event abates or resolves upon discontinuation
1285 of the study intervention or dose reduction and, if applicable, reappears upon re-challenge.

1286 No

1287 Evidence exists that the adverse event has an etiology other than the study intervention (e.g.,
1288 preexisting medical condition, underlying disease, intercurrent illness, or concomitant
1289 medication); and/or the adverse event has no plausible temporal relationship to study intervention.

1290 **10.2.6 Severity (Intensity) of Adverse Events**

1291 The severity (intensity) of an adverse event will be rated on a three point scale: (1) mild, (2)
1292 moderate, or (3) severe. A severity assessment is a clinical determination of the intensity of an
1293 event. Thus, a severe adverse event is not necessarily serious. For example, itching for several
1294 days may be rated as severe, but may not be clinically serious.

- 1295 • MILD: Usually transient, requires no special treatment, and does not interfere with the
1296 participant's daily activities.
- 1297 • MODERATE: Usually causes a low level of inconvenience, discomfort or concern to the
1298 participant and may interfere with daily activities, but is usually ameliorated by simple
1299 therapeutic measures and participant is able to continue in study.

- 1300 • SEVERE: Interrupts a participant's usual daily activities, causes severe discomfort, may
- 1301 cause discontinuation of study device, and generally requires systemic drug therapy or
- 1302 other treatment.

1303 **10.2.7 Expectedness**

1304 For a serious adverse event that is considered possibly related to study device, the Medical
1305 Monitor will classify the event as unexpected if the nature, severity, or frequency of the event is
1306 not consistent with known risk information.

1307 **10.2.8 Coding of Adverse Events**

1308 Adverse events will be coded using the MedDRA dictionary. To facilitate coding, the site will
1309 enter a preliminary MedDRA code which the Medical Monitor may accept or change (the Medical
1310 Monitor's MedDRA coding will be used for all reporting). The Medical Monitor will review the
1311 investigator's assessment of causality and may agree or disagree. Both the investigator's and
1312 Medical Monitor's assessments will be recorded. The Medical Monitor will have the final say in
1313 determining the causality as well as whether an event is classified as a serious adverse event and/or
1314 an unanticipated adverse device effect.

1315 **10.2.9 Outcome of Adverse Events**

1316 The outcome of each reportable adverse event will be classified by the investigator as follows:

1317 RECOVERED/RESOLVED – The participant recovered from the AE/SAE without sequelae.
1318 Record the AE/SAE stop date.

1319 RECOVERED/RESOLVED WITH SEQUELAE – The event persisted and had stabilized without
1320 change in the event anticipated. Record the AE/SAE stop date.

1321 FATAL – A fatal outcome is defined as the SAE that resulted in death. Only the event that was
1322 the cause of death should be reported as fatal. AEs/SAEs that were ongoing at the time of death;
1323 however, were not the cause of death, will be recorded as “resolved” at the time of death.

1324 NOT RECOVERED/NOT RESOLVED (ONGOING) – An ongoing AE/SAE is defined as the
1325 event was ongoing with an undetermined outcome.

- 1326 ○ An ongoing outcome will require follow-up by the site in order to determine the final
- 1327 outcome of the AE/SAE.

- 1328 ○ The outcome of an ongoing event at the time of death that was not the cause of death,
- 1329 will be updated and recorded as “resolved” with the date of death recorded as the stop
- 1330 date.

1331 UNKNOWN – An unknown outcome is defined as an inability to access the participant or the
1332 participant's records to determine the outcome (for example, a participant that was lost to follow-
1333 up).

1334 If any reported adverse events are ongoing when a participant completes the study (or withdraws),
1335 adverse events classified as UADEs will be followed until they are either resolved, or have no
1336 prospect of improvement or change, even after the participant has completed all applicable study
1337 visits/contacts. For all other adverse events, data collection will end at the time the participant

1338 completes the study. Note: participants should continue to receive appropriate medical care for an
1339 adverse event after their participation in the study ends.

1340 **10.3 Reportable Device Issues**

1341 All UADEs and ADEs as defined in section 10.2.1 will be reported on both a device issue form
1342 and AE form, except for skin reactions from CGM sensor placement or pump infusion set
1343 placement that do not require pharmacologic treatment. As noted in section 10.2.1, events that
1344 occur due to participant (user) error generally will not require completion of a device issue form.
1345 Such 'errors' could include improper use of an insulin pump or using a pump infusion set or
1346 CGM sensor for a period of time longer than its labeling.

1347 Device complaints and device malfunctions will be reported except in the following
1348 circumstances. These occurrences are expected and will not be reported on a Device Issue Form
1349 assuming criteria for a UADE or ADE have not been met:

1350 CGM sensor lasting fewer days than expected per manufacturer

1351 CGM tape adherence issues

1352 Battery lifespan deficiency due to inadequate charging or extensive wireless communication

1353 Intermittent device component disconnections/communication failures not requiring system
1354 replacement or workaround/resolution not specified in user guide/manual.

1355 Device issues clearly addressed in the user guide manual that do not require additional
1356 troubleshooting

1357 **10.4 Timing of Event Reporting**

1358 SAEs possibly related to a study device or study participation and UADEs must be reported to
1359 the Coordinating Center within 24 hours of the site becoming aware of the event. This can occur
1360 via phone or email, or by completion of the online serious adverse event form and device issue
1361 form if applicable. If the form is not initially completed, it should be completed as soon as
1362 possible after there is sufficient information to evaluate the event. All other reportable ADEs and
1363 other reportable AEs should be submitted by completion on the online form within 7 days of the
1364 site becoming aware of the event.

1365 The Coordinating Center will notify all participating investigators of any adverse event that is
1366 serious, related, and unexpected. Notification will be made within 10 working days after the
1367 Coordinating Center becomes aware of the event.

1368 Each principal investigator is responsible for reporting serious study-related adverse events and
1369 abiding by any other reporting requirements specific to his/her Institutional Review Board or
1370 Ethics Committee. Sites must report all serious, related adverse events within seven calendar
1371 days.

1372 Upon receipt of a qualifying event, the Sponsor will investigate the event to determine if a
1373 UADE is confirmed, and if indicated, report the results of the investigation to all overseeing
1374 IRBs, and the FDA within 10 working days of the Sponsor becoming aware of the UADE per

1375 21CFR 812.46(b) (2). The Medical Monitor must determine if the UADE presents an
1376 unreasonable risk to participants. If so, the Medical Monitor must ensure that all investigations,
1377 or parts of investigations presenting that risk, are terminated as soon as possible but no later than
1378 5 working days after the Medical Monitor makes this determination and no later than 15 working
1379 days after first receipt notice of the UADE.

1380 Device malfunctions will be handled by the Sponsor or designee as described below. In the case
1381 of a CGM transmitter or sensor device malfunction, information will be forwarded to Dexcom by
1382 the site personnel, to be handled by their complaint management system.

1383 **10.5 Safety Oversight**

1384 The study Medical Monitor will review all adverse events and adverse device events that are
1385 reported during the study. SAEs typically will be reviewed within 24 hours of reporting. Other
1386 AEs typically will be reviewed on a weekly basis. Additionally, the Medical Monitor will review
1387 compiled safety data at periodic intervals (generally timed to the review of compiled safety data
1388 by the DSMB).

1389 The Protocol Chair will be informed of all cases of severe hypoglycemia and DKA and the
1390 Medical Monitor's assessment of relationship to the study device; and informed of all reported
1391 device issues.

1392 A Data and Safety Monitoring Board (DSMB) will be informed of all cases of severe
1393 hypoglycemia and diabetic ketoacidosis irrespective of device relationship, all device-related
1394 SAEs, and all UADEs at the time that they occur during the study and will review compiled
1395 safety data at periodic intervals. The DSMB also will be informed of any ADEs not meeting
1396 criteria for a UADE if the Medical Monitor requests the DSMB review. The DSMB can request
1397 modifications to the study protocol or suspension or outright stoppage of the study if deemed
1398 necessary based on the totality of safety data available. Details regarding DSMB review will be
1399 documented in a separate DSMB document.

1400 **10.6 Stopping Criteria**

1401 **10.6.1 Participant Discontinuation of Study Device**

1402 In the case of an unanticipated system malfunction resulting in a severe hypoglycemia or DKA
1403 event (or a malfunction that could have led to severe hypoglycemia or DKA), use of the study
1404 pump will be suspended while the problem is diagnosed. The UADE will be reported to the IRB,
1405 DSMB, and FDA. After assessment of the problem and any correction, use of the closed-loop
1406 functionality will not be restarted until approval is received from the IRB, DSMB, and FDA.

1407 In the absence of a device malfunction, use of the study pump by a participant will be
1408 discontinued if any of the following occur:

1409 The investigator believes it is unsafe for the participant to continue on the intervention. This could
1410 be due to the development of a new medical condition or worsening of an existing condition; or
1411 participant behavior contrary to the indications for use of the device that imposes on the
1412 participant's safety

1413 The participant's parent requests that the treatment be stopped

1414 Two distinct episodes of DKA as defined in section 10.2.4

1415 Two distinct severe hypoglycemia events as defined in section 10.2.3

1416 One episode of DKA as defined in section 10.2.4 and one severe hypoglycemia event as defined
1417 in section 10.2.3

1418 Each DKA or severe hypoglycemia event will be reviewed by the Medical Monitor and by the
1419 DSMB with respect to determination of cause and whether the occurrence of the event can be
1420 attributed to use of the Control-IQ closed-loop feature.

1421 An additional requirement for continued study pump use following a single DKA or severe
1422 hypoglycemia event will be that (1) the site investigator believes that the event is explainable,
1423 unlikely to recur, and that it is safe for the participant to continue to use the system and (2) the
1424 Medical Monitor and DSMB concur. If either the Medical Monitor or DSMB determines that the
1425 occurrence of the event indicates that it is not safe for the participant to continue to use the study
1426 pump, use will be discontinued.

1427 Even if the study device system is discontinued, the participant will be encouraged to remain in
1428 the study through the final study visit

1429 **10.6.2 Criteria for Suspending or Stopping Overall Study**

1430 In the case of an unanticipated system malfunction resulting in a severe hypoglycemia or severe
1431 hyperglycemia event (as defined in section 10.2.4), use of the study pump will be suspended while
1432 the problem is diagnosed.

1433 In addition, study activities could be similarly suspended if the manufacturer of any constituent
1434 study device requires stoppage of device use for safety reasons (e.g. product recall). The affected
1435 study activities may resume if the underlying problem can be corrected by a protocol or system
1436 modification that will not invalidate the results obtained prior to suspension.

1437 The study Medical Monitor and DSMB will review all adverse events and adverse device events
1438 that are reported during the study. SH and DKA event review will occur for each such event on an
1439 expedited basis, and compiled safety data, including SH and DKA event rates, will be reviewed at
1440 approximately 6-month intervals. The DSMB will be provided with age-specific DKA and SH
1441 rates from the T1D Exchange registry for means of comparison. The Medical Monitor or DSMB
1442 may request suspension of study activities or stoppage of the study if deemed necessary based on
1443 the totality of safety data available.

1444 Chapter 11: Miscellaneous Considerations

1445 11.1 Drugs Used as Part of the Protocol

1446 Participants will use lispro, aspart, or glusiline rapid-acting insulin prescribed by their personal
1447 physician.

1448 11.2 Collection of Medical Conditions and Medications

1449 Pre-Existing Condition: Any medical condition that is either present at screening, a chronic
1450 disease, or a prior condition that could impact the participant's health during the course of the
1451 study (e.g., prior myocardial infarction or stroke).

1452 *Medical Conditions during the study:* In addition to conditions meeting the reporting
1453 requirements for an adverse event or device issue as described above, the following medical
1454 conditions should also be reported: (1) new diagnosis of a chronic disease (i.e., not present at the
1455 time of enrollment), and (2) any medical condition that could affect the participant's ability to
1456 carry out any aspect of the protocol or could affect an outcome assessment.

1457 *Medications:* All medication for the treatment of chronic pre-existing conditions, medical
1458 conditions (including medical conditions that do not require recording), and/or adverse events
1459 that the participant is currently taking at screening and during the course of the study should be
1460 recorded. Nutraceuticals and preventative treatment also should be recorded. Medications only
1461 taken as needed either can be recorded when prescribed or only recorded if used during the
1462 study. Glucagon for treatment of severe hypoglycemia will only be recorded if used during the
1463 study.

1464 11.3 Prohibited Medications, Devices, Treatments, and Procedures

1465 Participants using glulisine at the time of enrollment will be asked to contact their personal
1466 physician to change their prescribed personal insulin to lispro or aspart for the duration of the trial
1467 in the case they are randomized to experimental arm.

1468 Treatment with any non-insulin glucose-lowering agent (including GLP-1 agonists, Symlin, DPP-
1469 4 inhibitors, SGLT-2 inhibitors, biguanides, sulfonylureas and naturaceuticals) will not be
1470 permitted.

1471 The investigational study devices (t:slim X2 insulin pump, study CGM systems) must be removed
1472 before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) or diathermy treatment.
1473 Participants may continue in the trial after temporarily discontinuing use if requiring one of the
1474 treatments above.

1475 11.4 Precautionary Medications, Treatments, and Procedures

1476 Not applicable.

1477 11.5 Prophylactic Medications, Treatments, and Procedures

1478 Not applicable.

1479 **11.6 Rescue Medications, Treatments, and Procedures**

1480 All participants will be required to have a commercially available glucagon (or glucagon analog)
1481 preparation for treatment as needed of severe hypoglycemia.

1482 **11.7 Participant Compensation**

1483 Participant compensation will be specified in the informed consent form.

1484 **11.8 Participant Withdrawal**

1485 Participation in the study is voluntary, and a participant may withdraw at any time. For participants
1486 who withdraw, their data will be used up until the time of withdrawal.

1487 **11.9 Confidentiality**

1488 For security and confidentiality purposes, participants will be assigned an identifier that will be
1489 used instead of their name. Protected health information gathered for this study will be shared
1490 with the coordinating center, the Jaeb Center for Health Research in Tampa, FL. De-identified
1491 participant information may also be provided to research sites involved in the study.

1492 **Chapter 12: Statistical Consideration**

1493 **12.1 Statistical and Analytical Plans**

1494 The approach to sample size and statistical analyses are summarized below. A detailed statistical
1495 analysis plan will be written and finalized prior to the completion of the study.

1496 **12.2 Statistical Hypotheses**

1497 The primary outcome for this study is CGM-measured % in range 70-180 mg/dL over a 13-week
1498 period. The intervention will be considered effective if the Closed-Loop Control [CLC] is
1499 superior to Standard Care [SC] using a statistical significance of $\alpha=0.05$ and the model specified
1500 below in Section 6 (i.e., $p < 0.05$).

1501 The null/alternative hypotheses are:

- 1502 a. *Null Hypothesis*: There is no difference in mean CGM-measured % in range 70-180
1503 mg/dL over 13 weeks between SC and CLC
1504 b. *Alternative Hypothesis*: The mean CGM-measured % in range 70-180 mg/dL over 13
1505 weeks is different for SC and CLC.

1506 **12.3 Sample Size**

1507 Based on data from the DCLP5 study mentioned above, we conservatively estimate the standard
1508 deviation (SD) for the primary outcome, time in range (TIR), to be 10%. A sample size of N=90
1509 subjects (60 in the CLC arm and 30 in the SC arm) therefore will give 90% power to detect a 7.5%
1510 improvement in TIR with a two-sided test and type 1 error of 5%. Accounting for potential attrition
1511 rate of up to 10%, the total sample size for the PEDAP Study is estimated at N=102.

1512
1513 The following table shows the minimum detectable difference with a total sample size N=90 for
1514 key secondary outcomes. The observed standard deviations are taken from the DCLP5 study.

Outcome	Standard Deviation			Correlation with Baseline	Effective SD ^a	Detectable Difference with N=90 ^b
	CLC (n=78)	SC (N=22)	Pooled (N=100)			
% >250 mg/dL ^c	5.5%	9.9%	6.5%	0.69	4.7%	3.4%
Mean Glucose ^d	18	26	20	0.68	14	10
HbA1c	0.8%	0.9%	0.8%	0.70	0.6%	0.4%
% <70 mg/dL ^c	1.07%	1.13%	1.08%	0.61	0.86%	0.63%
% <54 mg/dL ^c	0.23%	0.23%	0.23%	0.54	0.19%	0.14%

1515 a – After accounting for the baseline value as a covariate in the regression model.
1516 b – With 90% power and two-sided type 1 error rate = 5%.
1517 c – Outcomes with a skewed distribution winsorized at the 10th and 90th percentiles.
1518 d – Units for mean glucose are mg/dL.

1519 12.4 Efficacy Outcome Measures**1520 12.4.1 Primary Efficacy Endpoint**

- 1521 • CGM-measured % in range 70-180 mg/dL

1522 12.4.2 Secondary Efficacy Endpoints**1523 12.4.2.1 Secondary Efficacy Endpoints Included in Hierarchical Analysis**

1524 The following secondary endpoints will be tested in a hierarchical fashion as described in
1525 section 12.7.1.

- 1526 • CGM-measured % above 250 mg/dL
- 1527 • CGM-measured mean glucose
- 1528 • HbA1c at 13 weeks
- 1529 • CGM-measured % below 70 mg/dL
- 1530 • CGM-measured % below 54 mg/dL

1531 12.4.2.2 Other Secondary Efficacy Endpoints

1532 The following endpoints are considered exploratory. Type 1 error for these endpoints will be
1533 controlled using the false discovery rate (FDR) instead of the familywise error rate (FWER).

1534 CGM-Measured:

- 1535 • % above 180 mg/dL
- 1536 • % in range 70-140 mg/dL
- 1537 • glucose variability measured with the coefficient of variation (CV)
- 1538 • glucose variability measured with the standard deviation (SD)
- 1539 • % <60 mg/dL
- 1540 • low blood glucose index (LBGI)*
- 1541 • hypoglycemic events (defined as at least 15 consecutive minutes <54 mg/dL)
- 1542 • hyperglycemic events (defined as at least 90 consecutive minutes >300 mg/dL)
- 1543 • % >300 mg/dL
- 1544 • high blood glucose index (HBGI)*
- 1545 • % in range 70-180 mg/dL improvement from baseline to 13 weeks $\geq 5\%$
- 1546 • % in range 70-180 mg/dL improvement from baseline to 13 weeks $\geq 10\%$
- 1547 • % time in range 70-180 mg/dL >70% and % time <70 mg/dL <4%

1548 HbA1c:

- 1549 • HbA1c <7.0% at 13 weeks
- 1550 • HbA1c <7.5% at 13 weeks
- 1551 • HbA1c improvement from baseline to 13 weeks >0.5%
- 1552 • HbA1c improvement from baseline to 13 weeks >1.0%
- 1553 • HbA1c relative improvement from baseline to 13 weeks >10%

- 1554 • HbA1c absolute improvement from baseline to 13 weeks >1.0% or HbA1c <7.0% at 13
1555 weeks

1556 Questionnaires

- 1557 • PedsQL Diabetes Module – total score and 5 subscales:
1558 ○ Diabetes
1559 ○ Treatment I
1560 ○ Treatment II
1561 ○ Worry
1562 ○ Communication
- 1563 • Pediatric Inventory for Parents (PIP) 2 domains each with a total score and 4 subscales for
1564 (5x2=10 difference scores)
1565 ○ Frequency
1566 ▪ Total Score
1567 ▪ Communication
1568 ▪ Medical Care
1569 ▪ Role Function
1570 ▪ Emotional Functioning
1571 ○ Difficulty
1572 ▪ Same total + 4 subscales as above for Frequency
- 1573 • INSPIRE (CLC arm only)
1574 • Pittsburgh Sleep Quality Index (PSQI) global score
1575 • Fear of Hypoglycemia Survey for Parents (HFS-P) – total score, 2 subscales and 4 factor
1576 scores:
1577 ○ Behavior
1578 ▪ Avoidance
1579 ▪ Maintain high BG
1580 ○ Worry
1581 ▪ Helplessness
1582 ▪ Social consequences

1583
1584 *Note that LBGI and HBGI will be calculated using all available CGM readings as described
1585 below. Therefore, they may not be comparable to the same metrics calculated with SMBG data.

1586 Other:

- 1587 • Insulin
1588 ◆ Total daily insulin (units/kg)
1589 ◆ Percentage of total insulin delivered via basal
1590 • Weight and Body Mass Index (BMI)

1591 **12.4.3 CGM Metrics Calculations**

1592 Randomization is preceded by 2-6 weeks of CGM run-in, which will be used in the calculation
1593 of baseline CGM metrics. For participants who are eligible to skip the run-in, comparable

1594 amount of CGM data from their own sensors will be taken before randomization visit to
1595 calculate baseline CGM metrics.

1596 CGM data starting from randomization visit through the 13-week visit will be included in the
1597 calculation of each CGM metric. Percentages in range 70-180 mg/dL (and all other CGM-based
1598 metrics) will be calculated giving equal weight to each CGM point for each participant.

1599 **12.5 Analysis Datasets and Sensitivity Analyses**

1600 All analyses comparing the CLC arm with SC arm will follow intention-to-treatment approach,
1601 which means participants will be analyzed in the treatment arm assigned by randomization
1602 regardless of actual system use. All randomized participants will be included in the primary
1603 analysis and secondary hierarchical analyses of CGM metrics. For other secondary outcomes,
1604 only participants with non-missing outcome data will be included.

1605 Safety outcomes will be reported for all enrolled participants, irrespective of whether the
1606 participant was randomized or the study was completed.

1607 **12.5.1 Per Protocol Analyses**

1608 Per-protocol analyses will be performed for primary outcome and secondary hierarchical
1609 outcomes only if >5% of participants will be excluded:

- 1610 • CLC arm: Closed loop mode active for at least 80% of the time
- 1611 • SC arm: CGM use for at least 80% of the time

1612 **12.5.2 Other Sensitivity Analyses**

1613 Confounding

1614 A sensitivity analysis will also be conducted if potential confounding factors collected at
1615 baseline are detected.

1616 The imbalance will be assessed based on clinical judgement reviewing the distributions in the
1617 two treatment arms, not on a p-value. The person making this judgement will be unaware of
1618 whether there is an association between baseline variables and study outcome. All variables
1619 obtained on a continuous scale will be entered into the models as continuous variables, unless it
1620 is determined that a variable does not have a linear relationship with the outcome. In such a case,
1621 categorization and/or transformation will be explored.

1622 Exclude First 2 Weeks of CGM Data

1623 The primary analysis will be repeated by excluding the first 2 weeks of post-randomization CGM
1624 data.

1625 Missing Data

1626 Missing data will be handled using direct likelihood method for the primary analysis. It is worth
1627 noting that all statistical methods for handling missing data rely on untestable assumptions and

1628 there is no one correct way to handle missing data. Our goal is to minimize the amount of
1629 missing data so that the results will not be sensitive to which statistical method is used.

1630 To that end, sensitivity analyses will be performed to explore whether results are similar for
1631 primary analysis when using different methods. The following methods will be applied:

- 1632 • Rubin's multiple imputation with treatment group in the imputation model
- 1633 • Available cases only
- 1634 • Multiple imputation with pattern mixture model assuming the dropout trajectory of the
1635 CLC group was that of the SC group (Mallinckrodt and Clark, 2003) (3)

1636 **12.6 Analysis of the Primary Efficacy Endpoint**

1637 Summary statistics (mean $\pm$ SD or median (quartiles)) will be reported by treatment group for the
1638 CGM-measured % in range 70-180 mg/dL at baseline, 13 weeks intervention and change from
1639 baseline to 13 weeks.

1640 CGM-measured % in range 70-180 mg/dL between two treatment arms will be compared using a
1641 linear mixed effects regression model while adjusting for baseline CGM-measured % in range
1642 70-180 mg/dL, age, prior CGM and pump use, and clinical center (random effect). A point
1643 estimate, 95% confidence interval and two-sided p-value will be reported for the treatment effect
1644 based on the linear regression model and a 5% level will be used to declare statistical
1645 significance. Residual values will be examined for an approximate normal distribution. If values
1646 are highly skewed then robust regression using M-estimation will be used instead. However,
1647 previous experience suggests that the residual values for % time glucose in target range will
1648 follow an approximately normal distribution. Imbalances between groups in important covariates
1649 are not expected to be of sufficient magnitude to produce confounding. However, the presence of
1650 confounding will be evaluated in the sensitivity analyses by including factors potentially
1651 associated with the outcome for which there is an imbalance between groups (12.5.2).

1652 In the primary analysis, any missing data at baseline or follow-up will be handled using direct
1653 likelihood. A longitudinal linear regression model will be fit with the percent of time in range at
1654 baseline and follow-up as the dependent variable. This model will adjust for age, prior CGM use
1655 and pump use as fixed effects and clinical center as a random effect. This model adjusts for
1656 baseline time in range by forcing the treatment groups to have the same mean value at baseline.

1657 **12.7 Analysis of the Secondary Endpoints**

1658 Point estimates and confidence intervals for the treatment arm differences will be presented for
1659 all secondary metrics. The models will adjust for the corresponding baseline metric, age, prior
1660 CGM and pump use, and clinical center (random effect).

1661 **12.7.1 Hierarchical Analyses**

1662 To preserve the overall type 1 error for selected key secondary endpoints, a hierarchical testing
1663 procedure will be used. If the primary analysis for time in range described above results in a
1664 statistically significant result ($p < 0.05$), then testing (similar to the model described above
1665 for the primary outcome) will proceed to the next outcome metric in the following order:

- 1666 • CGM-measured % in range 70-180 mg/dL (primary outcome)
- 1667 • CGM-measured % above 250 mg/dL
- 1668 • CGM-measured mean glucose
- 1669 • HbA1c at 13 weeks
- 1670 • CGM-measured % below 70 mg/dL
- 1671 • CGM-measured % below 54 mg/dL
- 1672

1673 This process continues iteratively moving to the next variable down on the list until a non-
1674 significant result ($p \geq 0.05$) is observed, or all six variables have been tested. If a non-significant
1675 result is encountered, then formal statistical hypothesis testing is terminated and any variables
1676 below on the list are not formally tested.

1677 Regardless of the results of the hierarchical testing, summary statistics appropriate to the
1678 distribution will be tabulated by treatment arm for each hierarchical outcome. A 95% confidence
1679 interval for the treatment arm difference will also be calculated for all five secondary hierarchical
1680 outcomes listed above. However, a confidence interval that excludes zero will not be considered
1681 a statistically significant result if an outcome variable higher on the hierarchical list failed to
1682 reach statistical significance.

1683 Analysis for each of the CGM metrics listed above for the hierarchical analysis will parallel the
1684 analysis described for the primary outcome in Section 12.6.

1685 HbA1c at 13 weeks will be compared between the two treatment arms using a linear model while
1686 adjusting for baseline HbA1c, age, prior CGM and pump use, and clinical center (random
1687 factor). Missing data will be handled using direct likelihood in a regression model including all
1688 available central laboratory HbA1c measurements at baseline and 13-week visits.

1689 For all above analyses, regression diagnostics will be employed analogous to as described in
1690 Section 12.6 for the primary outcome.

1691 **12.7.2 Other Endpoint Analyses**

1692 For all other secondary endpoints, only participants with non-missing data will be included in
1693 analyses (available cases method). Summary statistics (mean $\pm$ SD, median (IQR) or n (%))
1694 appropriate to the distribution will be tabulated for them at baseline, 13 weeks and for the
1695 changes from baseline to 13 weeks. For continuous outcomes, linear regression models will be
1696 used to compare the treatment effects while adjusting for corresponding baseline values (e.g.,
1697 baseline % in range 70-140 mg/dL for comparing change in % in range 70-140 mg/dL from pre-
1698 randomization CGM wear to 13 weeks post-randomization period), age, prior CGM and pump
1699 use, and clinical center as a random effect. Comparisons of body weight and BMI will also be
1700 adjusted for gender.

1701 For CGM-measured hypoglycemia/hyperglycemia events, event rates per week will be compared
1702 using similar linear mixed effects regression models as described above for the primary outcome.

1703

1704 Binary HbA1c and CGM Outcomes

1705 For the binary HbA1c outcomes, risk-adjusted percentages by treatment group will be computed
1706 at 13 weeks from a logistic regression model. The logistic regression will adjust for baseline
1707 HbA1c (as a continuous factor), age, prior CGM and pump use as fixed effects, and clinical site
1708 as a random effect. Similar analyses will be done for the binary CGM outcomes.

1709 Questionnaires

1710 For each questionnaire, mean $\pm$ SD or percentiles appropriate to the distribution will be given by
1711 treatment group at baseline and 13 weeks. Group comparisons will be conducted for the total
1712 score (mean score) and subscales from participant version and parent version separately using
1713 similar linear models as described above. The INSPIRE and SUS post-treatment surveys will
1714 only be administered to the CLC group at the 13-week visit, and thus the scores will only be
1715 tabulated.

1716 Focus Groups

1717 Qualitative data from focus groups will be analyzed using NVIVO (release 11.2; QSR
1718 International) to organize and manage the entire corpus of focus group data. Analysis begins
1719 with an initial coding procedure to capture and describe the range of responses to the
1720 intervention. A second, more focused and detailed level of coding will be applied to major
1721 categories of findings in the initial review to determine themes in response to the clinical trial,
1722 use of the closed loop system, and quality of life changes. The video data from the co-regulation
1723 interaction will be submitted to the validated coding system and frequencies of positive and
1724 negative interactions, treatment discussions, and CLC comments will be calculated with simple
1725 descriptive statistics. Change from pre to post treatment will be analyzed in the similar GLM
1726 framework to evaluate whether there is improvement in co-regulation across the study.

1727 Boxplots

1728 Boxplots stratified by treatment group will be given for the primary outcome and each of the key
1729 secondary endpoints in specified time periods over the 13-week course of follow-up.

1730 **12.8 Safety Analyses**

1731 All randomized participants will be included in these analyses and all their post-randomization
1732 safety events will be reported. Any pre-randomization adverse events will be tabulated separately
1733 and will include any participants who were never randomized.

1734 Safety analyses of the main study (randomized trial phase) will include events occurring on or
1735 after randomization until and including the 13-week visit or Day 105 from randomization,
1736 whichever occurs first. Safety analyses of the extension phase will include subsequent events
1737 until the last visit date or the last event date (whichever is later).

1738 For the following outcomes, the number of events will be tabulated by treatment group. Formal
1739 statistical comparisons (main study phase only) will be performed if there are enough events (at
1740 least 5 events combined between the two treatment groups):

- 1741 • Number of SH events and SH event rate per 100 person-years

- 1742 • Number of DKA events and DKA event rate per 100 person-years
- 1743 • Other serious adverse events
- 1744 • Any adverse event rate
- 1745 • Number of calendar days with any ketone level ≥ 1.0 mmol/L (if ≥ 5 total calendar days
- 1746 combined)
- 1747 • Worsening of HbA1c from baseline to 13 weeks by $>0.5\%$
- 1748 • Investigational device related (intervention group only):
- 1749 ○ Adverse device effects (ADE)
- 1750 ○ Serious adverse device events (SADE)
- 1751 ○ Unanticipated adverse device effects (UADE)

1752

1753 For DKA and SH events, if enough events, the rates will be compared between the two treatment

1754 arms during the main study phase using a robust Poisson regression. The regression will adjust

1755 for the participant-reported number of SH events 12 months prior to the start of the study and

1756 clinical center as random effect. The amount of follow up will be included as an offset covariate

1757 to compare the rates. A similar analysis will be done for DKA, if at least 5 total DKA events

1758 among both treatment groups.

1759

1760 **12.9 Intervention Adherence**

1761 The following tabulations and analyses will be performed by treatment group to assess

1762 intervention adherence for the study:

- 1763 • Sensor use –percent time of use, overall for 13-week visit

1764 For CLC arm only, the following will be tabulated to assess adherence:

- 1765 • Closed loop system use –percent time of use, overall for 13-week visit
- 1766 • % time in different operational modes - overall and by specified time periods

1767 **12.10 Protocol Adherence and Retention**

1768 The following tabulations and analyses will be performed by treatment group to assess protocol

1769 adherence for the study:

- 1770 • Number of protocol and procedural deviations
- 1771 • Flow chart accounting for all enrolled participants up to randomization
- 1772 • Flow chart of all randomized participants at all scheduled visits and phone contacts post
- 1773 treatment initiation
- 1774 • Number of and reasons for unscheduled visits and phone calls
- 1775 • Number of participants who stopped treatment and reasons

1776 **12.11 Baseline Descriptive Statistics**

1777 Baseline demographic and clinical characteristics of the cohort of all randomized participants

1778 will be summarized in a table using summary statistics appropriate to the distribution of each

1779 variable. Descriptive statistics will be displayed by treatment group for the following:

- 1780 • Age
- 1781 • Sex
- 1782 • Race/Ethnicity
- 1783 • Parent's income, education, and/or insurance status
- 1784 • Diabetes duration
- 1785 • Insulin method before enrollment (pump vs. MDI)
- 1786 • CGM use before enrollment
- 1787 • HbA1c
- 1788 • BMI %
- 1789 • Participant-reported number of SH and DKA 12 months prior to the start of the study
- 1790 • Baseline CGM metrics including:
 - 1791 • % in range 70-180 mg/dL
 - 1792 • % time > 180 mg/dL
 - 1793 • Mean glucose
 - 1794 • % time < 70 mg/dL
 - 1795 • % time < 54 mg/dL

1796 **12.12 Device Issues**

1797 The following tabulations and analyses will be performed by treatment group to assess device
1798 issues:

- 1799 • Device malfunctions requiring study team contact and other reported device issues
- 1800 • Rate of different failure events and alarms per 24 hours recorded by the Control-IQ system –
1801 overall and by month

1802 **12.13 Planned Interim Analyses**

1803 No formal interim efficacy analyses are planned. The analysis of the RCT will be performed on
1804 completion of the RCT prior to the completion of the extension phase.

1805 In addition, the DSMB will review safety data at intervals, with no formal stopping rules.

1806 **12.14 Subgroup Analyses**

1807 In exploratory analyses, the primary outcome (time 70-180 mg/dL), % time <70 mg/dL and HbA1c
1808 at 13 weeks will be assessed separately in various subgroups. Subgroups will be defined according
1809 to the baseline value of the factors, which will be noted in the SAP. Tests for interaction
1810 with treatment group will be performed.

1811 Interpretation of subgroup analyses will be viewed with caution, particularly in the absence of an
1812 overall significant difference. For continuous variables, results will be displayed in subgroups
1813 based on cutpoints although the analysis will utilize the variable as continuous. If there is
1814 insufficient sample size in a given subgroup, the cutpoints for continuous measures may be
1815 adjusted per the observed distribution of values. Cutpoint selection for display purposes will be
1816 made masked to the outcome data.

12.15 Multiple Comparison/MultiplicityPrimary Analysis

Since there will be a single comparison for the primary outcome (CGM-measured % 70-180 mg/dL), no adjustment is needed.

Secondary Hierarchical Analyses

The hierarchical testing procedure described above in section 12.7.1 will be used to control the overall type 1 error for the primary outcome plus five key secondary outcomes identified above.

All Other Secondary Analyses

For comparison of all other efficacy endpoints, the false discovery rate will be controlled using the adaptive Benjamini-Hochberg procedure (4).

P-values from safety analyses, sensitivity analyses, and per-protocol analyses will not be adjusted for multiple comparisons.

12.16 Exploratory AnalysesCGM Metrics

In addition to the analysis for the CGM-measured endpoints described earlier, separate analyses will be conducted for daytime and nighttime of the following metrics:

- % time in range 70-180 mg/dL
- Mean glucose
- % above 180 mg/dL
- % below 70 mg/dL
- coefficient of variation

Above selected CGM metrics also will be reported by restricting the CGM data in the CLC arm based on following criteria. No p-values will be calculated for following analyses.

- using only the CGM data when the closed-loop is active

Additional Insulin Metrics

The following insulin metrics will be tabulated by treatment groups at baseline, 13 weeks and for the changes from baseline to 13 weeks. No p-values will be calculated for these metrics.

- Total daily basal insulin (units/kg)
- Total daily bolus insulin (units/kg)
- Total daily manual bolus (units/kg)
- Total daily automated bolus (units/kg)
- Total daily short-acting injections for injection users

1852 The following will be calculated for the CLC group in the 1-week prior to randomization and by
1853 1-week follow-up periods from pump data only:

- 1854 • Total daily insulin (units/kg)
- 1855 • Total daily basal insulin (units/kg)
- 1856 • Total daily bolus insulin (units/kg)
 - 1857 ○ Total daily manual bolus (units/kg)
 - 1858 ○ Total daily automated bolus (units/kg)
- 1859 • Number of manual insulin doses per day
- 1860 • Number of manual insulin doses with carb announcement per day

1861

1862 **12.17 Extension Phase**

1863 Analyses for the extension phase will be primarily exploratory.

1864

1865 For both treatment arms, summary statistics will be given for all outcomes listed above in
1866 Section 12.4 at RCT baseline (pre-randomization), 13 weeks, and 26 weeks. In addition, boxplots
1867 will be constructed for each of the outcome metrics listed above showing both treatment arms
1868 over the course of the combined RCT and extension (where both arms using CLC) phases.

1869 Formal statistical comparisons between the two study phases (i.e., primary RCT and extension
1870 phases) will be performed for key outcome measures including:

- 1871 • CGM-measured % in range 70-180 mg/dL
- 1872 • CGM-measured % above 250 mg/dL
- 1873 • CGM-measured mean glucose
- 1874 • HbA1c at 13 weeks
- 1875 • CGM-measured % below 70 mg/dL
- 1876 • CGM-measured % below 54 mg/dL
- 1877 • PedsQL Diabetes Module – total score
- 1878 • Pediatric Inventory for Parents (PIP)
 - 1879 ➤ Frequency domain total score
 - 1880 ➤ Difficulty domain total score
- 1881 • INSPIRE Survey
- 1882 • Pittsburgh Sleep Quality Index (PSQI) global score
- 1883 • Fear of Hypoglycemia Survey for Parents (HFS-P) – total score
- 1884 • Hypoglycemia Confidence Scale (HCS)
- 1885 • System Usability Scale (SUS)

1886 For each of these outcomes a longitudinal regression model will be fit combining data from the
1887 RCT and extension phases accounting for the correlated data from repeated measures. Treatment
1888 group will be a time dependent factor in this model. A point estimate and 95% confidence
1889 interval will be given for the estimated effects of each CLC version used during the study, both
1890 with respect to SC and with respect to one another. Safety analyses of the Extension Phase will
1891 include events occurring on or after the Extension training visit until the end of the 26-Week visit

1892 or the end of Day 105 from the Extension training visit — whichever occurs first. Safety
1893 outcomes will include those specified in section 12.8 with the exception of worsening of HbA1c.

1894 Summary statistics appropriate to the distribution will be tabulated without any formal
1895 comparisons by treatment group for the safety outcomes noted in section 12.8.

1896 **12.17.1 Exclusion of Ancillary Study Data**

1897 According to Chapter 14, during the extension phase, 30 – 40 participants will be sought to
1898 enroll in an ancillary study to test the Control-IQ system with meal bolus and exercise
1899 challenges. The analyses for this ancillary study are specified in Section 14.5. Data collected
1900 from the start of each of these challenges until 5:59 AM the following morning will be excluded
1901 from the analysis of the extension phase.

1902

1903 **12.18 Extended Use Period**

1904 Analyses for the extended use phase will be exploratory.

1905

1906 Summary statistics will be given for all outcomes listed above in Section 12.4 for each of the 13-
1907 week periods following initiation of the Extended Use period. In addition, boxplots will be
1908 constructed for each of the outcome metrics listed above for these periods.

1909

1910 Safety analyses of the Extended Use period will include events until the last visit date or the last
1911 event date (whichever is later). Safety outcomes will include those specified in section 12.8 with
1912 the exception of worsening of HbA1c.

1913

1914

Chapter 13: Data Collection and Monitoring

1915 13.1 Case Report Forms and Device Data

1916 The main study data are collected on electronic case report forms (CRFs). When data are directly
1917 collected in electronic case report forms, this will be considered the source data. For any data
1918 points for which the eCRF is not considered source (e.g. lab results that are transcribed from a
1919 printed report into the eCRF), the original source documentation must be maintained in the
1920 participant's study chart or medical record. This source must be readily verifiable against the
1921 values entered into eCRF. Even where all study data are directly entered into the eCRFs at office
1922 visits, evidence of interaction with a live subject must be recorded (e.g., office note, visit record,
1923 etc.).

1924 Electronic device data files are obtained from the study software and individual hardware
1925 components. These electronic device files are considered the primary source documentation.

1926 13.2 Study Records Retention

1927 Each participating site will maintain appropriate medical and research records for this trial, in
1928 compliance with ICH E6 and regulatory and institutional requirements for the protection of
1929 confidentiality of participants.

1930 Study documents should be retained for a minimum of 2 years after the last approval of a marketing
1931 application in an ICH region and until there are no pending or contemplated marketing applications
1932 in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical
1933 development of the investigational product. These documents should be retained for a longer
1934 period, however, if required by local regulations. No records will be destroyed without the written
1935 consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the
1936 investigator when these documents no longer need to be retained.

1937 13.3 Quality Assurance and Monitoring

1938 Designated personnel from the Coordinating Center will be responsible for maintaining quality
1939 assurance (QA) and quality control (QC) systems to ensure that the clinical portion of the trial is
1940 conducted and data are generated, documented and reported in compliance with the protocol,
1941 Good Clinical Practice (GCP) and the applicable regulatory requirements, as well as to ensure
1942 that the rights and wellbeing of trial participants are protected and that the reported trial data are
1943 accurate, complete, and verifiable. Adverse events will be prioritized for monitoring.

1944 A risk-based monitoring (RBM) plan will be developed and revised as needed during the course
1945 of the study, consistent with the FDA "Guidance for Industry Oversight of Clinical
1946 Investigations — A Risk-Based Approach to Monitoring" (August 2013). Study conduct and
1947 monitoring will conform with 21 Code of Federal Regulations (CFR) 812. This plan describes in
1948 detail who will conduct the monitoring, at what frequency monitoring will be done, at what level
1949 of detail monitoring will be performed, and the distribution of monitoring reports.

1950 The data of most importance for monitoring at the site are participant eligibility and adverse
1951 events. Therefore, the RBM plan will focus on these areas. As much as possible, remote
1952 monitoring will be performed in real-time with on-site monitoring performed to evaluate the
1953 verity and completeness of the key site data. Elements of the RBM may include:

- 1954 • Qualification assessment, training, and certification for sites and site personnel
- 1955 • Oversight of Institutional Review Board (IRB) coverage and informed consent procedures
- 1956 • Central (remote) data monitoring: validation of data entry, data edits/audit trail, protocol
1957 review of entered data and edits, statistical monitoring, study closeout
- 1958 • On-site monitoring (site visits): source data verification, site visit report
- 1959 • Agent/Device accountability
- 1960 • Communications with site staff
- 1961 • Patient retention and visit completion
- 1962 • Quality control reports
- 1963 • Management of noncompliance
- 1964 • Documenting monitoring activities
- 1965 • Adverse event reporting and monitoring

1966 Coordinating Center representatives or their designees may visit the study facilities at any time in
1967 order to maintain current and personal knowledge of the study through review of the records,
1968 comparison with source documents, observation and discussion of the conduct and progress of the
1969 study. The investigational site will provide direct access to all trial related sites, source
1970 data/documents, and reports for the purpose of monitoring and auditing by the sponsor, and
1971 inspection by local and regulatory authorities.

1972 **13.4 Protocol Deviations**

1973 A protocol deviation is any noncompliance with the clinical trial protocol, GCP, or procedure
1974 requirements. The noncompliance may be either on the part of the participant, the investigator,
1975 or the study site staff. As a result of deviations, corrective actions are to be developed by the site
1976 and implemented promptly.

1977 The site PI/study staff is responsible for knowing and adhering to their IRB requirements. Further
1978 details about the handling of protocol deviations will be included in the monitoring plan.

1979 **Chapter 14: Ethics/Protection of Human Participants**

1980 **14.1 Ethical Standard**

1981 The investigator will ensure that this study is conducted in full conformity with Regulations for
1982 the Protection of Human Participants of Research codified in 45 CFR Part 46, 21 CFR Part 50, 21
1983 CFR Part 56, and/or the ICH E6.

1984 **14.2 Institutional Review Boards**

1985 The protocol, informed consent form(s), recruitment materials, and all participant materials will
1986 be submitted to the IRB for review and approval. Approval of both the protocol and the consent
1987 form must be obtained before any participant is enrolled. Any amendment to the protocol will
1988 require review and approval by the IRB before the changes are implemented to the study. All
1989 changes to the consent form will be IRB approved; a determination will be made regarding whether
1990 previously consented participants need to be re-consented.

1991 **14.3 Informed Consent Process**

1992 **14.3.1 Consent Procedures and Documentation**

1993 Informed consent is a process that is initiated prior to the individual's agreeing to participate in
1994 the study and continues throughout the individual's study participation. Extensive discussion of
1995 risks and possible benefits of participation will be provided to the participants and their families.
1996 Consent forms will be IRB-approved and the participant will be asked to read and review the
1997 document. The investigator will explain the research study to the participant and answer any
1998 questions that may arise. All participants will receive a verbal explanation in terms suited to
1999 their comprehension of the purposes, procedures, and potential risks of the study and of their
2000 rights as research participants. Participants will have the opportunity to carefully review the
2001 written consent form and ask questions prior to signing.

2002 The participants should have the opportunity to discuss the study with their surrogates or think
2003 about it prior to agreeing to participate. The participant will sign the informed consent document
2004 prior to any procedures being done specifically for the study. The participants may withdraw
2005 consent at any time throughout the course of the trial. A copy of the informed consent document
2006 will be given to the participants for their records. The rights and welfare of the participants will
2007 be protected by emphasizing to them that the quality of their medical care will not be adversely
2008 affected if they decline to participate in this study.

2009 **14.3.2 Participant and Data Confidentiality**

2010 Participant confidentiality is strictly held in trust by the participating investigators, their staff,
2011 and the sponsor(s) and their agents. This confidentiality is extended to cover testing of
2012 biological samples and genetic tests in addition to the clinical information relating to
2013 participants. Therefore, the study protocol, documentation, data, and all other information
2014 generated will be held in strict confidence. No information concerning the study or the data will
2015 be released to any unauthorized third party without prior written approval of the sponsor.

2016 The study monitor, other authorized representatives of the sponsor, representatives of the IRB,
2017 regulatory agencies or company supplying study product may inspect all documents and records
2018 required to be maintained by the investigator, including but not limited to, medical records
2019 (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical
2020 study site will permit access to such records.

2021 The study participant's contact information will be securely stored at each clinical site for
2022 internal use during the study. At the end of the study, all records will continue to be kept in a
2023 secure location for as long a period as dictated by the reviewing IRB, institutional policies, or
2024 sponsor requirements.

2025 Study participant research data, which is for purposes of statistical analysis and scientific reporting,
2026 will be transmitted to and stored at the Jaeb Center for Health Research (JCHR). This will not
2027 include the participant's contact or identifying information, unless otherwise specified in the
2028 informed consent form. Rather, individual participants and their research data will be identified
2029 by a unique study identification number. The study data entry and study management systems
2030 used by clinical sites and by JCHR research staff will be secured and password protected. At the
2031 end of the study, all study databases will be de-identified and archived at the JCHR and the
2032 University of Virginia Center for Diabetes Technology.

2033

2034 **Chapter 15: Ancillary Study to Test Control-IQ System with Meal**

2035 **Bolus and Exercise Challenges**

2036 **15.1 Objective**

2037 This Ancillary Study will assess the safety of using the study system during exercise and meal
2038 bolus-related challenges. Outcome data are expected to be used to support regulatory filings for
2039 the device system.

2040 **15.2 Sample Size**

2041 Participation in the Ancillary Study will be offered to participants who are currently in the
2042 Extension Phase of the main study. The goal for sample size is to have 30-40 individuals
2043 participate in the Ancillary Study.

2044 **15.3 Eligibility Criteria**

2045 Participants must be currently in the Extension Phase of the main study, with at least 2 weeks
2046 and no more than 11 weeks completed to ensure sufficient comfort with the study pump and
2047 sufficient time to complete the protocol below.

2048 Inclusion in the Ancillary Study requires investigator judgment that it is safe for the individual to
2049 participate.

2050 **15.4 Study Procedures**

2051 On the day of enrollment into the Ancillary Study, informed consent will be obtained from
2052 interested participants, and eligibility will be verified.

2053 A paper logbook will be provided to participants that includes a page to record details about each
2054 challenge and procedural instructions about how participants will conduct these challenges. This
2055 material will be reviewed with each participant.

2056 During home use, each participant will perform 3 exercise and meal bolus-related challenges
2057 (details below) appropriate for the age of the participant. Each challenge will be separated from
2058 the other challenges by at least 48 hours. Before starting each challenge, caregivers of the child
2059 must assure the child has a working CGM and Control-IQ is active. If activity is paused during
2060 an exercise-related challenge, the challenge may be continued to allow for continuation of the
2061 activity if the participant is able and willing to continue.

2062 Participants will receive a guidance document for performing the challenges that includes the
2063 following safety mitigations:

- 2064 • The participant's parent or guardian must remain with the child at all times and
2065 monitor CGM readings frequently during and for at least two hours after completion
2066 of each challenge.

- 2067 • The hyperglycemia safety protocol described in section 8.2.4 will be followed during
2068 each challenge.
- 2069 • The parent/guardian must have an on-call phone number for the study team prior to
2070 initiation of each challenge.
- 2071 • CGM glucose must be ≥ 120 mg/dL prior to initiation of each exercise-related
2072 challenge.
- 2073 • Exercise may not be initiated during an exercise-related challenge if the CGM trend
2074 arrows on the study insulin pump indicate Falling glucose (down arrow) or Rapidly
2075 Falling glucose (double down arrow).
- 2076 • Snacks and glucagon must be available for use during and after each exercise-related
2077 challenge.
- 2078 • Control-IQ exercise activity mode must be activated at least 30 minutes prior to the
2079 start of exercise during each exercise-related challenge and kept active for at least 30
2080 minutes after completion of the exercise period.
- 2081 • Additional carbohydrate may be given as needed at the start of, during, or after each
2082 exercise-related challenge.
- 2083 • The temporary basal rate feature of the study pump may be used if desired to reduce
2084 insulin delivery during the exercise period of each exercise-related challenge.
- 2085 • Fingersticks will be performed for any low CGM value < 70 mg/dL, and any exercise
2086 should be stopped if BG is confirmed < 70 mg/dL. Exercise may be stopped for
2087 concerns for CGM decreasing at any time, even if CGM is > 70 mg/dL.
- 2088 • A parent/guardian will sleep in the same home as the child overnight and closely
2089 monitor CGM readings following days when one of the challenges was performed.
- 2090 Contact with the study investigator may be initiated at any time.

2091 Challenge Details:

2092 **Missed Meal Bolus Challenge:** Participants will skip their meal bolus for an afternoon meal of
2093 at least 20 grams carbohydrate. The meal timing and carb amount and any additional snacks
2094 given will be recorded on a study exercise log. Additional insulin boluses may be given for
2095 hyperglycemia as needed. The hyperglycemia safety protocol described in section 8.2.4 will be
2096 followed.

2097 **Full Meal Bolus Plus Exercise Challenge:** Participants will receive a full meal bolus for an
2098 afternoon meal of at least 20 grams carbohydrate. The pump's Exercise Activity setting will be
2099 turned on upon completion of the meal. Beginning 30 minutes after completion of the meal, a
2100 parent/guardian will try to keep the child physically active (walking, running, playing) for at
2101 least 30 minutes if possible, or longer if desired. This can be mixed with mild activity. The meal
2102 timing and carb amount, the actual stop and start time of exercise, any associated hypoglycemia
2103 treatments, and any additional snacks given will be recorded on a study exercise log.

2104 **Exercise Challenge:** At least 2 hours after the child finishes an afternoon meal, a
2105 parent/guardian will try to keep the child physically active (walking, running, playing) for at
2106 least 30 minutes if possible, or longer if desired. This can be mixed with mild activity. The
2107 pump's Exercise Activity setting will be turned on 90 minutes after completion of the meal. The
2108 meal timing and carb amount of the last meal prior to exercise, the actual start and stop time of
2109 exercise, any associated hypoglycemia treatments, and any additional snacks given will be
2110 recorded on a study exercise log.

2111 A challenge may be stopped for any reason, including participant non-cooperation, or concern
2112 for hypoglycemia, or repeated hypoglycemia.

2113 **15.5 Outcomes and Analysis Plan**

2114 A separate statistical analysis plan will be written for the Ancillary Study.

2115 Outcomes will include the following:

2116 **Key Safety Outcomes:**

- 2117 • Severe hypoglycemia
- 2118 • Other adverse events

2119 All adverse events will be listed. Listings will include Participant ID, the event, whether the
2120 event was serious, whether the event was related to the study device, the event outcome, and a
2121 description of the event.

2122

2123 **Other Outcomes**

- 2124 • CGM-measured % <54 mg/dL overnight (all challenge types)
- 2125 • CGM-measured % <70 mg/dL overnight (all challenge types)
- 2126 • CGM-measured % >180 mg/dL overnight (all challenge types)
- 2127 • CGM-measured % <54 mg/dL during the two hours immediately following the start of
- 2128 exercise for each exercise-related challenge
- 2129 • CGM-measured % <70 mg/dL during the two hours immediately following the start of
- 2130 exercise for each exercise-related challenge
- 2131 • CGM-measured % >180 mg/dL during the four hours following the announced meal, or
- 2132 until the next meal bolus is given, for the missed meal bolus challenge
- 2133 • CGM-measured % >300 mg/dL during the four hours following the announced meal, or
- 2134 until the next meal bolus is given, for the missed meal bolus challenge

2135 The percentage of time spent below 54 mg/dL from 10 PM – 5:59 AM the night of an exercise
2136 challenge will be compared with percentage of time spent below 54 mg/dL the previous night
2137 using a linear mixed effects regression model. A point estimate, 95% confidence interval and
2138 two-sided p-value will be reported for the challenge effect based on the linear regression model
2139 and a 5% level will be used to declare statistical significance. Residual values will be examined
2140 for an approximate normal distribution. If values are highly skewed, then robust regression using
2141 M-estimation will be used instead. Analysis of the percentage of time spent below 70 mg/dL 10

2142 PM – 5:59 AM the night of an exercise challenge will be performed in the same manner.

2143

2144 The percentage of time spent above 180 mg/dL from 10 PM – 5:59 AM the night of a missed
2145 meal bolus challenge will be compared with percentage of time spent above 180 mg/dL the
2146 previous night using a linear mixed effects regression model. A point estimate, 95% confidence
2147 interval and two-sided p-value will be reported for the challenge effect based on the linear
2148 regression model and a 5% level will be used to declare statistical significance. Residual values
2149 will be examined for an approximate normal distribution. If values are highly skewed, then
2150 robust regression using M-estimation will be used instead. Analysis of the percentage of time
2151 spent above 300 mg/dL 10 PM – 5:59 AM the night of a missed meal bolus challenge will be
2152 performed in the same manner.

2153

2154 CGM-measured % <54 mg/dL during the two hours immediately following the start of exercise
2155 for each exercise challenge will be compared between the two exercise challenge groups using a
2156 paired *t*-test. CGM-measured % <70 mg/dL during this same period will be analyzed in the same
2157 manner.

2158

2159 For each challenge type, the mean, standard deviation, and range will be given for the outcomes
2160 listed above relevant to the challenge type. Summary statistics for the overnight periods
2161 preceding the challenges will be presented with summary statistics for each challenge type.

2162 **Safety Monitoring**

2163 Safety oversight will be the same as for the main study, as described in Chapter 10:.

2164

Chapter 16: References

- 2165 1. Brown S, Kovatchev B, Raghinaru D, Lum JW, Buckingham BA, Kudva YC, Laffel LM,
2166 Levy CJ, Pinsker JE, Wadwa RP, Dassau E, Doyle FJ, Anderson SM, Church MM, Dadlani
2167 V, Ekhlaspour L, Forlenza GP, Isganaitis E, Lam DW, Kollman C, and Beck RW, for the
2168 iDCL Trial Research Group: Six-Month Randomized, Multicenter Trial of Closed-Loop
2169 Control in Type 1 Diabetes. N Engl J Med. 2019 Oct 31;381(18):1707-1717. doi:
2170 10.1056/NEJMoa1907863.
- 2171 2. Breton MD, Kanapka LG, Beck RW, Ekhlaspour L, Forlenza GP, Cengiz E, Schoelwer M,
2172 Ruedy KJ, Jost E, Carria L, Emory E, Hsu LJ, Oliveri M, Kollman CK, Dokken BB, Weinzimer
2173 SA, DeBoer MD, Buckingham BA, Cherñavvsky D, and Wadwa RP, for the iDCL Trial
2174 Research Group: A Randomized Trial of Closed-Loop Control in Children with Type 1
2175 Diabetes. N Engl J Med. 2020 Aug 27;383(9):836-845. doi: 10.1056/NEJMoa2004736.
- 2176 3. Mallinckrodt CH, Clark WS, et al: Assessing responses profiles from incomplete longitudinal
2177 clinical trial data under regulatory considerations, J. Biopharm. Stat., 2003; 13(2): 179-190.
- 2178 4. Benjamini, Y. and Hochberg, Y. (1995) Controlling the false discovery rate: a practical and
2179 powerful approach to multiple testing. J. R. Statist. Soc. B, 57, 289–300.

Pediatric Artificial Pancreas Study (PEDAP) Trial

Primary Study Phase (RCT)

Statistical Analysis Plan

Version 3.1

Corresponds to Version 11.0 of the Protocol

27 **Version History**

SAP Version	Author	Approver	Effective Date	Revision Description	Study Stage	Protocol Version
1.0	Colleen Bauza	Craig Kollman	March 11, 2021	Original Version	Enrollment has not started yet	4.0
2.0	Zack Reed	Craig Kollman	August 4, 2021	Removed winsorization analysis. Added more sensitivity analyses. Added analysis plan for extension phase.	RCT phase recruitment and follow-up in progress. No data analyses performed yet.	8.0
3.0	Zack Reed	Craig Kollman	February 10, 2022	Moved Extension phase section to a separate SAP. Added analysis window for Baseline. Corrected RCT safety analysis endpoint so that it agrees with the Protocol. Added omitted questionnaires (Hypoglycemia Confidence Scale and System Usability Scale) to Section 5.2.2. Corrected typos and inconsistencies. Clarified DCLP5 reference.	RCT and Extension phase recruitment and follow-up in progress.	11.0
3.1	Zack Reed	Craig Kollman	May 11, 2022	Removed analysis window for questionnaires, insulin metrics, and weight/BMI at Baseline. Reverts to analysis plan for SAP v2.0 and earlier because these variables are not measured at randomization. Clarified that Baseline insulin metrics must come from the Diabetes Screening CRF. End date for CGM metrics by 1-day periods will be Day 18 rather than the 2-week visit date. Removed exploratory insulin analyses that require pre-randomization pump data. Corrected grammar and typos.	All randomized participants have completed the RCT phase. Extension and Extended Use phases in progress.	11.0

28

29

30 **Author:** _____

31

32

33 **Senior Statistician:** _____

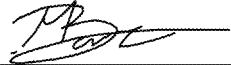
34

35

36 **JCHR Project Director:** _____

37

38

39 **Sponsor:**  _____

40

41

1. Study Overview

The following table provides an overview of the PEDAP Trial.

Table 1. Study Overview

PARTICIPANT AREA	DESCRIPTION
Title	The Pediatric Artificial Pancreas (PEDAP) trial: A Randomized Controlled Comparison of the Control-IQ technology Versus Standard Care in Young Children in Type 1 Diabetes
Précis	A randomized controlled trial of at-home closed loop system vs. standard care (defined as either multiple daily injections of insulin [MDI] or use of an insulin pump without hybrid closed-loop control capabilities [low-glucose suspend or predictive low-glucose suspend functionality is permitted]) in youth age 2 to <6 years old.
Investigational Device	t:slim X2 with Control-IQ and Dexcom G6 system
Objectives	The objective of the study is to assess efficacy, quality of life, and safety of a closed loop control (CLC) system (t:slim X2 with Control-IQ Technology) in a randomized controlled trial with partial crossover.
Study Design¹	First phase: a 13-week parallel group randomized clinical trial with 2:1 randomization to intervention with the closed loop system vs. standard care (SC); Second Phase: following the RCT, a 13-week period where the Standard Care (SC) group will transition to use CLC and the experimental arm will extend the use of CLC for the same period. After 26 weeks, participants may continue using CLC for an additional Extended Use period. A subset of participants will be invited to join an optional exercise/meal challenge ancillary study.
Number of Clinical Centers	~3 US clinical centers
Endpoints	<u>Efficacy</u> The primary outcome for the RCT is time in target range 70-180 mg/dL (TIR) measured by CGM in CLC group vs. SC group over 13 weeks The primary outcome for the extension phase assessed separately for each treatment group is change in TIR comparing extension phase with RCT phase. <u>Quality of Life</u> Patient-reported outcome questionnaires will be completed. <u>Safety</u> The key safety outcomes are severe hypoglycemia and ketoacidosis.
Population	Inclusion Criteria 1. Clinical diagnosis, based on investigator assessment, of type 1 diabetes for at least 6 months and using insulin for at least 6 months 2. Familiarity and use of a carbohydrate ratio for meal boluses. 3. Age ≥ 2 and <6 years old 4. Living with one or more parent/legal guardian knowledgeable about emergency procedures for severe hypoglycemia and able to contact emergency services and study staff. 5. Investigator has confidence that the parent can successfully operate all study devices and is capable of adhering to the protocol 6. Willingness to switch to lispro (Humalog) or aspart (Novolog) if not using already, and to use no other insulin besides lispro (Humalog)

PARTICIPANT AREA	DESCRIPTION
	or aspart (Novolog) during the study for participants using a study-provided Tandem pump during the study. 7. Total daily insulin dose (TDD) at least 5 U/day 8. Body weight at least 20 lbs 9. Willingness not to start any new non-insulin glucose-lowering agent during the course of the trial 10. Participant and parent(s)/guardian(s) willingness to participate in all training sessions as directed by study staff. 11. Parent/guardian proficient in reading and writing English 12. Live in the United States, with no plans to move outside the United States during the study period Exclusion Criteria 1. Concurrent use of any non-insulin glucose-lowering agent (including GLP-1 agonists, Symmlin, DPP-4 inhibitors, SGLT-2 inhibitors, sulfonylureas). 2. Hemophilia or any other bleeding disorder 3. History of >1 severe hypoglycemic event with seizure or loss of consciousness in the last 3 months 4. History of >1 DKA event in the last 6 months not related to illness, infusion set failure, or initial diagnosis 5. History of chronic renal disease or currently on hemodialysis 6. History of adrenal insufficiency 7. Hypothyroidism that is not adequately treated 8. Use of oral or injectable steroids within the last 8 weeks 9. Known, ongoing adhesive intolerance 10. Plans to receive blood transfusions or erythropoietin injections during the course of the study 11. A condition, which in the opinion of the investigator or designee, would put the participant or study at risk 12. Currently using any closed-loop system, or using an insulin pump that is incompatible with use of the study CGM 13. Participation in another pharmaceutical or device trial at the time of enrollment or during the study 14. Employed by, or having immediate family members employed by Tandem Diabetes Care, Inc., or having a direct supervisor at place of employment who is also directly involved in conducting the clinical trial (as a study investigator, coordinator, etc.); or having a first-degree relative who is directly involved in conducting the clinical trial
Sample Size	Up to 150 screened participants with the goal of randomizing 102 participants.
Treatment Groups	• Intervention Group: t:slim X2 with Control-IQ Technology and Study CGM. • Control Group: Standard care (SC) - defined as either multiple daily injections of insulin (MDI) or use of an insulin pump without hybrid closed-loop control capabilities (low-glucose suspend or predictive low-glucose suspend functionality is permitted) in conjunction with study CGM All participants will be offered to extend the study for an additional 13 weeks, with the SC group switching to the t:slim X2 with Control-IQ System after the 13-week RCT period. After 26 weeks, participants may continue using CLC for an additional Extended Use period.

PARTICIPANT AREA	DESCRIPTION
Participant Duration	~26-32 weeks for RCT and Extension Phase, depending on duration of run-in phase; up to an additional ~7 months in Extended Use period
Protocol Overview/Synopsis	After consent is signed, eligibility will be assessed. Eligible participants not currently using an insulin pump and Dexcom G5 or Dexcom G6 CGM with minimum data requirements will initiate a run-in phase of 2 to 6 weeks that will be customized based on whether the participant is already a CGM user. Participants who skip or successfully complete the run-in will be randomly assigned 2:1 to an intervention using Tandem t:slim X2 with Control-IQ Technology or the standard care control group using existing insulin therapy in conjunction with study CGM. All participants will continue their participation by using the t:slim X2 with Control-IQ system in an Extension Phase. After 26 weeks, participants may continue using CLC for an additional Extended Use period through no later than July 31, 2022. A subset of participants will complete an optional exercise/meal challenge ancillary study.

¹ This SAP is restricted to the RCT Phase. Analyses of the Extension Phase, Extended Use Period, and Ancillary Study are specified in a separate SAP.

48 The following table provides an overview of the schedule of study visits, phone contacts, and key procedures.

49

50 **Table 2. Schedule of Study Visits and Procedures During the RCT and Extension Phases¹**

	Pre	Pre	0	3d ²	1w	2w	6w	10w	13w	13w + 3d	14w	15w	19w	23w	26w
Visit (V), Videoconference (VC), or Phone (P)	VC/V	VC/V	VC/V	VC/ P	P	VC/ V	VC/ V	P	VC/ V	VC/ P	P	VC/ V	VC/ V	P	VC/ V
Comment	Screen/ Enroll	Run-in	Rand												
Eligibility Assessment	X	X	X												
HbA1c (Central lab)			X						X						X
Device Data download(s)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Review diabetes management and AEs		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Questionnaires as defined in section 9.2 of the Protocol	X								X						X

51 ¹ This SAP is restricted to the RCT phase. Analyses of the Extension phase are specified in a separate SAP.

52 ² Only for participants on MDI at enrollment assigned to the CLC group

53

54

2. Comparison with the Protocol

This SAP is consistent with version 11.0 of the protocol except for the following:

- The Hypoglycemia Confidence Scale and System Usability Scale have been added to the list of questionnaires in Section 5.2.2.
- Changed sensitivity analysis in Section 6.3 to include all hierarchical outcomes instead of just % in range 70-180 mg/dL.
- A sensitivity analysis including CGM data after the 13-week visit has been added (Section 6.3).
- Exploratory analyses that require pre-randomization pump data have been removed.

3. Primary Statistical Hypotheses

The primary outcome for this study is CGM-measured % in range 70-180 mg/dL over a 13-week period. The intervention will be considered effective if the Closed-Loop Control [CLC] is superior to Standard Care [SC] using a statistical significance of $\alpha=0.05$ and the model specified below in Section 7 (i.e., $p < 0.05$).

The null/alternative hypotheses are:

- Null Hypothesis:* There is no difference in mean CGM-measured % in range 70-180 mg/dL over 13 weeks between SC and CLC
- Alternative Hypothesis:* The mean CGM-measured % in range 70-180 mg/dL over 13 weeks is different for SC and CLC.

4. Sample size

Based on data from the DCLP5 study (Breton et al.), we conservatively estimate the standard deviation (SD) for the primary outcome, time in range (TIR), to be 10%. A sample size of N=90 subjects (60 in the CLC arm and 30 in the SC arm) therefore will give 90% power to detect a 7.5% improvement in TIR with a two-sided test and type 1 error of 5%. Accounting for potential attrition rate of up to 10%, the total sample size for the PEDAP Study is estimated at N=102.

The following table shows the minimum detectable difference with a total sample size N=90 for key secondary outcomes. The observed standard deviations are taken from the DCLP5 study.

Outcome	Standard Deviation			Correlation		Detectable Difference with N=90 ^b
	CLC (n=78)	SC (N=22)	Pooled (N=100)	with Baseline	Effective SD ^a	

% >250 mg/dL ^c	5.5%	9.9%	6.5%	0.69	4.7%	3.4%
Mean Glucose ^d	18	26	20	0.68	14	10
HbA1c	0.8%	0.9%	0.8%	0.70	0.6%	0.4%
% <70 mg/dL ^c	1.07%	1.13%	1.08%	0.61	0.86%	0.63%
% <54 mg/dL ^c	0.23%	0.23%	0.23%	0.54	0.19%	0.14%

a – After accounting for the baseline value as a covariate in the regression model.

b – With 90% power and two-sided type 1 error rate = 5%.

c – Outcomes with a skewed distribution winsorized at the 10th and 90th percentiles.

d – Units for mean glucose are mg/dL

5. Outcome Measures

5.1. Primary Efficacy Outcome

- The primary outcome is CGM-measured % in range 70-180 mg/dL

5.2. Secondary Efficacy Outcomes

5.2.1. Hierarchical Outcomes

The following secondary outcomes will be tested in a hierarchical fashion between the intervention arms as described in Section 7.2.1.

- CGM-measured % above 250 mg/dL
- CGM-measured mean glucose
- HbA1c at 13 weeks
- CGM-measured % below 70 mg/dL
- CGM-measured % below 54 mg/dL

5.2.2. Other Secondary Efficacy Outcomes

The following outcomes are considered exploratory.

- CGM-Measured:
 - % above 180 mg/dL
 - % in range 70-140 mg/dL
 - glucose variability measured with the coefficient of variation (CV)
 - glucose variability measured with the standard deviation (SD)
 - % <60 mg/dL
 - low blood glucose index (LBGI)*
 - hypoglycemic events (defined as at least 15 consecutive minutes <54 mg/dL)
 - hyperglycemic events (defined as at least 90 consecutive minutes >300 mg/dL)
 - % >300 mg/dL
 - high blood glucose index (HBGI)*
 - % in range 70-180 mg/dL improvement from baseline to 13 weeks $\geq 5\%$
 - % in range 70-180 mg/dL improvement from baseline to 13 weeks $\geq 10\%$

- % time in range 70-180 mg/dL >70% and % time <70 mg/dL <4%
 - HbA1c:
 - HbA1c <7.0% at 13 weeks
 - HbA1c <7.5% at 13 weeks
 - HbA1c improvement from baseline to 13 weeks >0.5%
 - HbA1c improvement from baseline to 13 weeks >1.0%
 - HbA1c relative improvement from baseline to 13 weeks >10%
 - HbA1c absolute improvement from baseline to 13 weeks >1.0% or HbA1c <7.0% at 13 weeks
 - Questionnaires:
 - PedsQL Diabetes Module – total score and 5 subscales:
 - Diabetes
 - Treatment I
 - Treatment II
 - Worry
 - Communication
 - Pediatric Inventory for Parents (PIP) 2 domains each with a total score and 4 subscales for (5x2=10 difference scores)
 - Frequency
 - Total Score
 - Communication
 - Medical Care
 - Role Function
 - Emotional Functioning
 - Difficulty
 - Same total + 4 subscales as above for Frequency
 - INSPIRE (CLC arm only)
 - Pittsburgh Sleep Quality Index (PSQI) global score
 - Fear of Hypoglycemia Survey for Parents (HFS-P) – total score, 2 subscales and 4 factor scores:
 - Behavior
 - Avoidance
 - Maintain high BG
 - Worry
 - Helplessness
 - Social consequences
 - Hypoglycemia Confidence Scale (HCS)
 - System Usability Scale (SUS; CLC arm only)
- *Note that LBGI and HBGI will be calculated using all available CGM readings as described below.
- Other:
 - Insulin
 - Total daily insulin (units/kg)
 - Percentage of total insulin delivered via basal

- Weight and Body Mass Index (BMI)

5.3. Calculation of CGM Metrics

- Baseline: CGM data to calculate baseline metrics will either come from the run-in period, or from the participant's personal CGM device if the run-in is not necessary:
 - If an enrolled participant is currently using a Dexcom G5 or G6 with CGM data captured on at least 11 out of the 14 days prior to enrollment, then he/she can proceed directly to randomization.
 - Otherwise, the participant will need to go through 2-6 weeks of run-in that includes CGM use, prior to randomization.
 - In either case, the last 2 weeks of CGM data prior to randomization will be used in the calculation of baseline CGM metrics. If <168 hours of CGM data are available for any reason (e.g., lost data or device failure), then the baseline metrics will not be calculated and will be set to missing.
- Follow-up:
 - CGM metrics will be calculated by pooling all CGM readings in the 13-week period starting from the fourth day after the randomization visit up through the 13-week visit. If a participant drops out before completing the 13-week visit, all available data through the last visit date will be included for calculating CGM metrics. Minimum 168 hours of CGM data will be required to calculate CGM metrics.
 - A separate set of CGM metrics will be calculated by excluding the first two weeks of CGM data following the randomization visit for a sensitivity analysis with ≥ 168 hours of CGM data required.
- All CGM metrics at baseline and follow-up will be calculated giving equal weight to each sensor reading for each participant.
- HIGH and LOW values from the sensor will be imputed as 401 and 39, respectively.

5.4. Calculation of Insulin Metrics

Insulin metrics describe the seven days prior to the visit.

- Baseline insulin metrics will use data reported from the Diabetes Screening CRF.
- Insulin metrics will be calculated at 13 weeks using Tandem pump data where available, otherwise using data reported on the CRF.
 - If pump data are available, insulin metrics will be calculated from the pump data using data in the 7 days prior to the visit. Insulin data on 5 of 7 days will be required to calculate insulin metrics.

5.5. Questionnaires

All questionnaires will be scored according to the instructions given in the reference manual/documentation for the questionnaire. In case no manual exists for a given questionnaire or the manual does not provide guidance on how to handle missing data, then the following criteria will be applied:

- At least 75% of the questions must be completed to be included in the analysis.

- This 75% rule will be applied separately for the total score and each subscale (where applicable) so it is possible the sample size will be different for some subscales.
- The score used for analysis will be based on the average among the questions that were answered and then scaled accordingly.

5.6. Analysis Windows

Analysis windows apply to HbA1c measured at randomization and the following outcomes measured at the 13-week visit:

- HbA1c
- Insulin metrics
- Weight/BMI
- Questionnaires

This does not apply to the CGM metrics using data from the Tandem pump which are calculated as described above.

Data from visits occurring in the following windows will be included in the analysis:

Visit (Target Date)	From Day ^a	Thru Day ^a
Randomization ^b (0 days)	-3	21
13 weeks (91 days)	76	112

a – Days from randomization, inclusive.

b – Window for randomization applies to HbA1c only.

6. Analysis Datasets and Sensitivity Analyses

6.1. Analysis Datasets

All analyses comparing the CLC arm with SC arm will follow intention-to-treatment approach, which means participants will be analyzed in the treatment arm assigned by randomization regardless of compliance. All randomized participants will be included in the primary analysis and secondary hierarchical analyses of CGM metrics. For other secondary outcomes, only participants with non-missing outcome data will be included.

Safety outcomes will be reported for all enrolled participants, irrespective of whether the participants were randomized or the study was completed.

6.2. Per-Protocol Analyses

The following per-protocol analyses will be performed for the primary outcome and secondary hierarchical outcomes only if >5% of participants will be excluded:

- CLC group: Closed loop mode active for at least 80% of the time
- SC group: CGM use for at least 80% of the time

6.3. Other Sensitivity Analyses

The following sensitivity analyses will be conducted for the primary outcome and all outcomes listed in the hierarchy in Section 5.2.1.

Confounding:

A sensitivity analysis will be conducted if potential confounding factors collected at baseline are detected. The baseline factors listed in Section 11 will be assessed for imbalance between treatment groups.

The imbalance will be assessed based on clinical judgement reviewing the distributions in the two treatment arms, not on a p-value. The person making this judgement will be unaware of whether there is an association between baseline variables and study outcome. All variables obtained on a continuous scale will be entered into the models as continuous variables, unless it is determined that a variable does not have a linear relationship with the outcome. In such a case, categorization and/or transformation will be explored.

Exclude First 2 Weeks of CGM Data

The analysis will be repeated by excluding the first 2 weeks of post-randomization CGM data.

Include CGM Data after the 13-week visit

It is anticipated that some subjects will spend up to two additional weeks under the RCT treatment while they await the equipment necessary to begin the extension phase. CGM data collected during this period will not be included in the calculations for the preceding analyses. To determine what impact these data may have had on the models, the data will be pooled together with the data from the RCT phase, and the models will be refit, with any major discrepancies noted.

Missing Data:

Missing data will be handled using direct likelihood method for the hierarchical analyses. It is worth noting that all statistical methods for handling missing data rely on untestable assumptions and there is no one correct way to handle missing data. Our goal is to minimize the amount of missing data so that the results will not be sensitive to which statistical method is used.

To that end, sensitivity analyses will be performed to explore whether results are similar for primary analysis when using different methods. The following methods will be applied:

- Rubin's multiple imputation with treatment group in the imputation model
- Available cases only
- Multiple imputation with pattern mixture model assuming the dropout trajectory of the CLC group was that of the SC group (Mallinckrodt and Clark, 2003)

7. Efficacy Analysis

7.1. Primary Analysis

This study's primary outcome is CGM measured % time in range 70-180 mg/dL over 13 weeks.

Summary statistics (mean $\pm$ SD or median (quartiles)) will be reported by treatment group for the CGM-measured % in range 70-180 mg/dL at baseline, 13 weeks intervention and change from baseline to follow-up.

CGM-measured % in range 70-180 mg/dL between two treatment arms will be compared using a linear mixed effects regression model while adjusting for age, prior CGM and pump use, and clinical center (random effect). Baseline CGM-measured % in range 70-180 mg/dL will be accounted for in the direct likelihood model as described below in the Missing Data paragraph. A point estimate, 95% confidence interval and two-sided p-value will be reported for the treatment effect based on the linear regression model and a 5% level will be used to declare statistical significance. Residual values will be examined for an approximate normal distribution. If values are highly skewed, then robust regression using M-estimation will be used instead. However, previous experience suggests that the residual values for % time glucose in target range will follow an approximately normal distribution.

Imbalances between groups in important covariates are not expected to be of sufficient magnitude to produce confounding. However, the presence of confounding will be evaluated in the sensitivity analyses by including factors potentially associated with the outcome for which there is an imbalance between groups (Section 6.3).

Missing Data

In the primary analysis, any missing data at baseline or follow-up will be handled using direct likelihood. A longitudinal linear regression model will be fit with the percent of time in range at baseline and follow-up as the dependent variable. This model will adjust for age, prior CGM use and pump use as fixed effects and clinical center as a random effect. This model adjusts for baseline time in range by forcing the treatment groups to have the same mean value at baseline.

7.2. Analysis of Secondary Endpoints

Point estimates and confidence intervals for the treatment arm differences will be presented for all secondary metrics. Analyses will parallel those described above for the primary outcome.

7.2.1. Hierarchical Analyses

To preserve the overall type 1 error for selected key secondary endpoints, a hierarchical testing procedure will be used. If the primary analysis for time in range described above results in a statistically significant result ($p < 0.05$), then testing (similar to the model described above for the primary outcome) will proceed to the next outcome metric in the following order:

- CGM-measured % in range 70-180 mg/dL (primary outcome)
- CGM-measured % above 250 mg/dL
- CGM-measured mean glucose
- HbA1c at 13 weeks
- CGM-measured % below 70 mg/dL
- CGM-measured % below 54 mg/dL

This process continues iteratively moving to the next variable down on the list until a non-significant result ($p \geq 0.05$) is observed, or all six variables have been tested. If a non-significant

result is encountered, then formal statistical hypothesis testing is terminated and any variables below on the list are not formally tested.

Regardless of the results of the hierarchical testing, summary statistics appropriate to the distribution will be tabulated by treatment arm for each hierarchical outcome. A 95% confidence interval for the treatment arm difference will also be calculated for all hierarchical secondary outcomes listed above. However, a confidence interval that excludes zero will not be considered a statistically significant result if an outcome variable higher on the hierarchical list failed to reach statistical significance.

Analysis for each of the CGM metrics listed above for the hierarchical analysis will parallel the analysis described for the primary outcome in Section 7.1.

Analyses for HbA1c at 13 weeks will parallel those of the primary outcome. Missing data will be handled using direct likelihood in a regression model including all available central laboratory HbA1c measurements at baseline and 13-week visits.

For all above analyses, regression diagnostics will be employed analogous to as described in Section 7.1 for the primary outcome.

7.3. Other Secondary Analyses

For all other secondary endpoints, only participants with non-missing data will be included in analyses (available cases method). Summary statistics (mean $\pm$ SD, median (IQR) or n (%)) appropriate to the distribution will be tabulated for them at baseline, 13 weeks and for the changes from baseline to 13 weeks. For continuous outcomes noted in Section 5.2., analyses will parallel those described for the primary outcome. Comparisons of body weight and BMI will also be adjusted for gender.

For CGM-measured hypoglycemia/hyperglycemia events, event rates per week will be compared using similar linear mixed effects regression models as described above for the primary outcome.

Binary CGM and HbA1c Outcomes

For the binary HbA1c outcomes, risk-adjusted percentages by treatment group will be computed at 13 weeks from a logistic regression model (Kleinman and Norton, 2009). The logistic regression will adjust for baseline HbA1c (as a continuous factor), age, prior CGM and pump use as fixed effects, and clinical site as a random effect. Similar analyses will be done for the binary CGM outcomes.

Questionnaires

For each questionnaire, mean $\pm$ SD or percentiles appropriate to the distribution will be given by treatment group at baseline and 13 weeks. Group comparisons will be conducted for the total score (mean score) and subscales from the parent version using similar linear models as described above. The INSPIRE and SUS post-treatment surveys will only be administered to the CLC group at the 13-week visit, and thus the scores will only be tabulated.

Boxplots

Boxplots stratified by treatment group will be given for the primary outcome and each of the key secondary endpoints listed in Section 7.2.1 (i.e., hierarchical CGM metrics) in 4 week and 1-

week periods over the 13 week course of follow-up. Additionally, boxplots will be given for the primary outcome and each of the key secondary CGM-measured endpoints in 1-day periods over the first 2 weeks of follow-up.

As noted above, the following periods will be given for hierarchical CGM metrics:

- CGM metrics by 4-week periods: Starting from the fourth day after the randomization visit, CGM metrics will be calculated within each 4-week period (Week 1-4, Week 5-8, and Week 9-13). The 13 week visit date will be used as end date of the Week 9-13 period. A minimum of 168 hours of CGM data in each 4-week period will be required for the calculation.
- CGM metrics by 1-week periods: Starting from the fourth day after the randomization visit, CGM metrics will be calculated within each 1-week period. The 13 week visit date will be used as end date of the Week 12-13 period. Minimum 72 hours of CGM data in each 1-week period will be required for the calculation.
- CGM metrics by 1-day periods: Starting from the fourth day after the randomization visit, CGM metrics will be calculated within each day. Day 18 of follow-up will be used as end date of the analysis period. Minimum 17 hours of CGM data in each 1-day period will be required for the calculation.

7.4. Formal Statistical Comparisons of Treatment Groups

With the exceptions of the INSPIRE and System Usability questionnaires, all secondary outcomes noted in Section 5.2 will have formal statistical comparisons of treatment groups.

8. Safety Analysis

All randomized participants will be included in these analyses and all their post-randomization safety events will be tabulated. Any pre-randomization adverse events will be tabulated separately and will include any participants who were never randomized. Safety analyses of the main study (randomized trial phase) will include events occurring on or after randomization until and including the 13-week visit date or randomization date + 105 days whichever is earlier.

For the following outcomes, the number of events will be tabulated by treatment group. Formal statistical comparisons (main study phase only) will be performed if there are enough events (at least 5 events combined between the two treatment groups):

- Number of SH events and SH event rate per 100 person-years
- Number of DKA events and DKA event rate per 100 person-years
- Other serious adverse events
- Any adverse event rate
- Number of calendar days with any ketone level ≥ 1.0 mmol/L (if ≥ 5 total calendar days combined)
- Worsening of HbA1c from baseline to 13 weeks by $>0.5\%$
- Investigational device related (intervention group only):

- Adverse device effects (ADE)
- Serious adverse device events (SADE)
- Unanticipated adverse device effects (UADE)

For DKA and SH events, if enough events (i.e., at least 5 events combined over both treatment groups) for each outcome, the rates will be compared between the two treatment arms during the main study phase using a robust Poisson regression. The regression will adjust for the participant-reported number of SH events 12 months prior to the start of the study and clinical center as random effect. If one of the treatment groups has zero events then a Poisson model will not converge and Barnard's exact test will be used instead. The amount of follow-up will be included as an offset covariate to compare the rates. A similar analysis will be done for DKA, if at least 5 total DKA events among both treatment groups.

9. Intervention Adherence

Closed Loop System

The amount of closed loop system use for the CLC group will be calculated from downloaded data over the period from the fourth day after randomization until the day before the 13-week visit. Any dropouts will be included prior to the time of dropout and their percentage will be prorated accordingly.

- Time in closed loop overall.
- Time in closed loop by 4-week periods: Starting from the fourth day after the randomization visit, percent time in closed loop will be calculated within each 4-week period (Week 1-4, Week 5-8, and Week 9-13). The 13-week visit date will be used as end date of the Week 9-13 period.
- Percent time in different operational modes overall and by 4-week periods (the last interval will contain Weeks 9-13) will be tabulated and boxplots will be created by these 4-week periods.

Sensor Use

The amount of CGM sensor use for both treatment groups will be calculated from downloaded data in the same way as closed-loop system use described above.

Percent time sensor use overall will be tabulated by treatment group and boxplots will be created.

10. Protocol Adherence and Retention

The following tabulations and analyses will be performed by treatment group to assess protocol adherence for the study:

- Number of protocol and procedural deviations
- Flow chart accounting for all enrolled participants up to randomization
- Flow chart of all randomized participants at all scheduled visits and phone contacts post treatment initiation

- Number of and reasons for unscheduled visits and contacts
- Number of participants who stopped treatment and reasons

11. Baseline Descriptive Statistics

Baseline demographic and clinical characteristics of the cohort of all randomized participants will be summarized in a table using summary statistics appropriate to the distribution of each variable. Descriptive statistics will be displayed by treatment group for the following:

- Age
- Gender
- Race/ethnicity
- Parent's income, education, and/or insurance status
- Diabetes duration
- Insulin method before enrollment (pump vs. MDI)
- CGM use before enrollment
- HbA1c
- BMI %
- Participant-reported number of SH and DKA 12 months prior to the start of the study
- Baseline CGM metrics including:
 - % in range 70-180 mg/dL
 - % time >250 mg/dL
 - Mean glucose
 - % time <70 mg/dL
 - % time <54 mg/dL

12. Device Issues

The following tabulations and analyses will be performed by treatment group to assess device issues:

- Device malfunctions requiring study team contact and other reported device issues
- Rate of different failure events and alarms per 24 hours recorded by the Control-IQ system – overall and by month

13. Planned Interim Analyses

No formal interim efficacy analyses are planned. The analysis of the RCT will be performed on completion of the RCT prior to the completion of the extension phase.

The DSMB will review safety data at intervals, with no formal stopping rules.

14. Subgroup Analyses

In exploratory analyses, the primary outcome (% time 70-180 mg/dL), % time <70 mg/dL and HbA1c at 13 weeks will be assessed separately in various subgroups. Subgroups will be defined

according to the baseline value of the factors listed below. Statistical analysis will involve tests for interaction with treatment group.

Interpretation of subgroup analyses will be viewed with caution, particularly in the absence of an overall significant difference. For continuous variables, results will be displayed in subgroups based on cutpoints although the analysis will utilize the variable as continuous, except for age which will be analyzed both as a continuous variable and in two age groups. If there is insufficient sample size in a given subgroup, the cutpoints for continuous measures may be adjusted per the observed distribution of values. Cutpoint selection for display purposes will be made masked to the outcome data.

- Age (<4 vs. ≥4)
- Gender
- Race/Ethnicity
- Parent's income, education, and/or insurance status
- Diabetes duration
- Insulin method before enrollment (pump vs MDI)
- CGM use before enrollment
- Baseline HbA1c
- Body mass index (%)
- Participant-reported number of SH and DKA 12 months prior to the start of the study
- Clinical center (test for random effects interaction with treatment group)
- Baseline CGM metrics including:
 - % time in range 70-180 mg/dL
 - % time >250 mg/dL
 - Mean glucose
 - % time <70 mg/dL
 - % time <54 mg/dL
- The p-value for any categorical variable will only be calculated if there are a minimum of 10 participants per treatment group.

15. Multiple Comparisons

Hierarchical Analyses

The hierarchical testing procedure described above will be used to control the overall type 1 error for the primary outcome plus five key secondary outcomes identified above.

All Other Secondary Analyses

For comparison of all other efficacy endpoints, the false discovery rate (FDR) will be controlled using the adaptive Benjamini-Hochberg method adapted using the two-stage test. FDR adjusted p-values will be calculated separately for the following categories:

- All other CGM metrics
- HbA1c analyses
- Insulin, weight, and BMI
- Questionnaires

- Subgroup analyses for % time 70-180 mg/dL and HbA1c at 13 weeks
- Subgroup analyses for % time < 70 mg/dL

P-values from safety analyses, sensitivity analyses and per-protocol analyses will not be adjusted for multiple comparisons.

16. Exploratory Analyses

CGM Metrics

In addition to the analysis for the hierarchical CGM-measured endpoints described earlier, separate analyses will be conducted with the appropriate statistics for daytime (6:00am – 9:59pm) and nighttime (10:00 PM – 5:59 AM) separately. No p-values will be calculated for following analyses.

- % time in range 70-180 mg/dL
- Mean glucose
- % above 250 mg/dL
- % below 70 mg/dL
- Coefficient of variation

Above selected CGM metrics will also be reported by restricting the CGM data in the CLC arm based on following criterion. No p-values will be calculated for following analyses.

- using only the CGM data when the closed-loop is active

Hierarchical CGM metrics noted above will also be calculated for daytime period (06:00AM to 9:59PM) and overnight period (10:00PM to 05:59AM) separately. Minimum 126 hours of CGM data will be required to calculate daytime metrics and minimum 42 hours of CGM data will be required to calculate overnight metrics. If <168 hours of CGM data available for combined day and night, then CGM metrics will not be calculated separately for daytime and overnight periods.

Additional Insulin Metrics

The following insulin metrics will be tabulated by treatment group at baseline, 13 weeks and for the changes from baseline to 13 weeks. No p-values will be calculated for these metrics.

- Total Daily Insulin for Pump Users (units/kg)
 - Total daily basal insulin (units/kg)
 - Total daily bolus insulin (units/kg)
- Total Daily Insulin for Injection Users (units/kg)
 - Total daily basal insulin (units/kg)
 - Total daily bolus insulin (units/kg)
 - Total daily short-acting injections

17. Additional Analyses after SAP Version 1.0

17.1. FDA Review

Following FDA review of this SAP, the following analyses were added.

- The plausibility of the missing at random assumption will be evaluated by comparing the baseline characteristics listed in Section 11 for completers versus dropouts.
- A two-way tipping point sensitivity analysis will be done to assess how strong a deviation from the missing at random assumption would need to be to affect study conclusions:
 - Start with Rubin's imputation as listed above initially assuming missing at random.
 - Shift imputed values by a fixed amount in each treatment arm to represent a bias from selective dropout.
 - Calculate estimated treatment delta and p-value on the resulting dataset using the model described in Section 7.
 - Repeat this process using various pairs of shift values for the treatment and control arms.
 - Characterize which pairs of shift values result in a statistically significant difference in the treatment arm comparison.

17.2. Extension Phase, Extended Use Period, Ancillary Study

Details for the analyses of the Extension Phase, the Extended Use Period, and the Ancillary Study are specified in a separate SAP.

18. References

Breton MD, Kanapka LG, Beck RW, Ekhlaspour L, Forlenza GP, Cengiz E, Schoelwer M, Ruedy KJ, Jost E, Carria L, Emory E, Hsu LJ, Oliveri M, Kollman CK, Dokken BB, Weinzimer SA, DeBoer MD, Buckingham BA, Chernavsky D, and Wadwa RP, for the iDCL Trial Research Group: A Randomized Trial of Closed-Loop Control in Children with Type 1 Diabetes. *N Engl J Med.* 2020 Aug 27;383(9):836-845. doi: 10.1056/NEJMoa2004736.

Kleinman LC, Norton EC. What's the risk? A simple approach for estimating adjusted risk measures from nonlinear models with logistic regression. *Health Services Research* 2009; 44(1): 2009 Feb.

Mallinckrodt CH, Clark WS, et al: Assessing responses profiles from incomplete longitudinal clinical trial data under regulatory considerations, *J. Biopharm. Stat.*, 2003; 13(2): 179-190.

PEDAP CRF Listing by Visit

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

CONSENT TO TAKE PART IN A RESEARCH STUDY

STUDY TITLE: The Pediatric Artificial Pancreas (PEDAP) trial: A Randomized Controlled Comparison of the Control-IQ technology Versus Standard of Care in Young Children in Type 1 Diabetes

STUDY DOCTOR'S INFORMATION

Name:

Contact Number:

Site Name:

Site Address:

Emergency (24-hour) Number:

Study Coordinator Name/Contact:

SUMMARY

In this form, when it says “you” it is referring to your child as the participant, or to the person under your care that would be in the study if you are a legally authorized representative (LAR). Please see the next section called “Legally Authorized Representatives (LAR)” for more information about who can be a LAR. This would be like a parent reviewing the information for their child to be in the study. In this case, “you” would mean “your child.”

This consent form will give you important information about this study. It will help you decide if you would like to take part in the study. You do not have to be in this study. You can stop the study at any time. You should read and discuss all the information in this consent form with the study doctor.

- The study is being done to look at how well an investigational automated insulin delivery system (“study system”) works in young children with type 1 diabetes. The study will find out how safe the system is compared to a regular insulin pump or daily injections of insulin along with an added glucose monitor.
- The study system is investigational for purposes of this study and is not approved by the Food and Drug Administration (FDA). For this reason, it is called experimental in this study.
- You will be asked to be in the study for about 6-7 months. The study includes several phases, described below. These phases will include fingersticks to draw blood. You and your child will also insert small sensors or catheters under your child’s skin when using study devices.
 - If needed, you and your child will train on the study glucose monitor and practice using it for several weeks.
 - Then your child will start the main phase which is about 3 months. In this phase, your child will be randomly assigned (like flipping of a coin) into one of two groups. Your child’s group will either use the study system or will keep using their current insulin pump or daily insulin injections. Both groups will use the study glucose monitor.

- The last phase is also about 3 months. For this phase, your child will switch to the study system if they were in the group that did not use the study system during the first phase.
- The study is designed so you can participate from home without visiting the clinic.
- You may have the option to be part of a focus group so we can learn more.
- The most likely risks to your child are pain, bruising, redness, and temporary discomfort from the fingerstick when blood is drawn or discomfort when a sensor or catheter is being inserted into the skin.
- The possible benefits are a better understanding of your child's diabetes or a positive impact on you and your child's ability to manage their diabetes. Your child also may not benefit from this study, but that is what the study is trying to find out. The information gained from the study may help other children with type 1 diabetes in the future.
- If you do not want your child to participate, you may seek other options for your child which include standard treatment like continuing with your child's current diabetes management regimen or participation in other research studies.

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

A "minor" is a person under the age of 18. A LAR for a minor is a natural or adoptive parent, a legal custodian, or a legal guardian.

WHAT IS INFORMED CONSENT?

You are being asked to take part in this research study because your child has type 1 diabetes and uses insulin. The goal of this study is to learn things that may help children with diabetes.

Your child's study doctor will be talking with you about this study and this form. You can take as much time as you need to think about whether or not you want your child to be in this study. You can also take a copy of this form with you to discuss with friends, family, or other doctors to help you decide. Please read this document carefully. Do not agree to be in this study unless all of your questions have been answered.

You do not have to allow your child to be in this study. If you decide not to be in this study, you and your child will not be treated differently as people just because you didn't want to be in this study. Also, your child's regular care will not be impacted.

WHO IS DOING THE STUDY?

This study is being done by your study team. It is being paid for by The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Tandem Diabetes Care is providing insulin pumps and related supplies. Dexcom is providing glucose monitoring supplies. Other companies may also provide study supplies.

The Jaeb Center for Health Research will use study funding to organize the study. Your study doctor and clinic staff will use the funding to carry out this study. The name of the study doctor and the doctor's

contact information is listed on the first page of this form. If one of the study doctors gets money or benefits from a company that makes the devices in this study, then they have to tell the Jacob Center.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn whether an investigational automated insulin delivery system (“study system”) for young children with type 1 diabetes can safely improve blood glucose (sometimes called blood sugar) control. The system uses continuous glucose monitoring (CGM), an insulin pump, and a software algorithm to automatically give insulin and control blood glucose. It is also sometimes called a “closed-loop” system.

The CGM sensor has a thin needle that is inserted just under the skin. It measures the glucose in the fluid under the skin and shows this information on the insulin pump every 5 minutes. The sensor needs to be changed about every 10 days. The insulin pump has a catheter that is inserted under the skin. It needs to be changed about every 3 days.

The study system is made by a company called Tandem Diabetes Care and is called t:slim X2 with Control-IQ. A similar version of the system has been tested in previous studies with adults and older children. These studies did not find increased risk for high or low blood glucose or other problems. The study system is experimental and can only be used for research. The U.S. Food and Drug Administration (FDA) has approved its use in this research study. Tandem Diabetes Care plans to use the results of this study to apply for FDA approval for the system to be used in younger children.

We expect up to 150 people will take part in this study for about 6-7 months at about 3 different clinical centers in the United States.

WHO CAN PARTICIPATE IN THIS STUDY?

In general, to take part in this study, your child must:

- Have type 1 diabetes and have used insulin for at least 6 months
- Have a parent/LAR familiar with the use of a carbohydrate ratio for meal boluses
- Be at least 2 and less than 6 years old
- Be willing to switch to a different insulin type during the study if your study doctor says your type will not work with the study insulin pump
- Have a total daily insulin dose (TDD) of at least 5 U/day
- Weigh at least 20 pounds
- Be willing not to start any new glucose-lowering drugs during the study
- Live in the United States, with no plans to move outside the United States during the study period

Also, your child must not:

- Take any medicine but insulin to lower blood glucose
- Have certain medical conditions your study doctor will ask about, such as bleeding disorders, kidney disease, and glandular disease

- Have had more than 1 severe hypoglycemic event in the last 3 months involving a seizure or loss of consciousness
- Have had more than 1 diabetic ketoacidosis (DKA) event in the last 6 months, not counting any event when diabetes was first diagnosed
- Have used any oral or injectable steroid drugs within the last 8 weeks
- Have any skin allergy or intolerance to adhesives used with CGM or infusion set parts
- Have any plans to receive blood transfusions during the study
- Currently use any closed-loop system, or use an insulin pump that can't be used with the study CGM
- Participate in another drug or device study at the same time as this study
- Have any immediate family members who work for Tandem Diabetes Care or who are directly involved in running this study

Your study doctor and staff will review more health-related requirements with you. Your study doctor will also check to make sure you can read and write English well enough to use the system safely.

WHAT WILL HAPPEN IN THIS STUDY?

This study will take about 6-7 months for your child to complete. The study is designed so you can do your study visits from home via videoconference (e.g. Zoom) without visiting the clinic if you and your study doctor prefer. So, the word “visit” below means either an in-clinic visit or a videoconference. The next sections list what will happen during the study.

Screening Visit

If you and your child agree to participate, you will provide your electronic signature to confirm your willingness to participate. Then we will ask you and your child some questions to make sure he/she qualifies and it is safe for him/her to be in this study.

- Collection of information about you and your child: This may include contact information, diabetes history, past and current medical conditions, surgical procedures, allergies, medications and supplements, family history, and whether or not your child has various symptoms. You will be asked for details about your child's insulin therapy and most recent HbA1c measurement.
- Measurement of your child's height and weight. We will provide a scale to measure weight if you do not already have one at home.
- Your child's current personal doctor or provider may be someone who is not part of your study doctor's office. If so, the study doctor will contact your child's personal doctor's office to talk about your child's participation in the study and get some health information. To allow this, you will be asked to sign a release of information form that tells the personal doctor's office that it is okay to communicate health information with the study doctor's office. **The study doctor's office must be able to verify key health information from the personal doctor's office for your child's safety. If this cannot be done, then your child cannot be in the study.**

We will give you a study blood glucose meter and blood ketone meter to use during the study. Your child will need to perform blood glucose tests to calibrate the CGM (if it ever requires calibration) and respond to system alarms. Your child will need to perform a ketone test if your glucose level is higher

than 300 mg/dL for more than 90 minutes, or greater than 400 mg/dL at any time. You will receive a cable, software, and computer, if necessary, so you can download data from the study ketone meter. We will give you and your child instructions on how to use and maintain your meters.

You and your child will be asked to keep a glucagon emergency kit on hand at home. If you and your child need a prescription for the glucagon emergency kit, you can ask your study doctor.

You will be asked to complete a set of questionnaires about your experience as a parent of a young child with type 1 diabetes.

The screening visit will last 1 to 2 hours.

CGM Run-In

If your child currently uses a CGM that is the same brand as the study CGM for at least 11 out of the last 14 days, your child will skip to the Main Phase of the study described below. Otherwise, your child will have a run-in period with the study CGM devices as described in this section.

Your child will wear the study CGM for 2 weeks

- Your study team will provide you with CGM supplies in person or have the supplies delivered to you.
- You and your child will be taught how to use the CGM including putting in a new sensor after 10 days. You will have to replace the sensor sooner if it comes out.
- Your child will use the CGM at home for 2 weeks. You should follow your normal routine during this time for meals, fingersticks, and insulin boluses.
- You and your child will have a follow-up visit after 2 weeks.
- Study staff will download the study CGM data to determine if your child wore it often enough to continue in the study—at least 11 out of 14 days. They will also check for any skin reaction in areas where your child wore the CGM.
- Study staff may suggest changes to help you and your child improve your child's blood glucose control.

If your child's study doctor thinks it is necessary, your child may repeat this 2-week run-in once or twice. If your child was not using any CGM when you began the study, you must wear the CGM for a minimum of 4 weeks.

Main Phase

If your child skipped the CGM use phase above, the procedures described below could occur as part of the Screening visit. Otherwise, a separate visit will occur at least 2 weeks after the Screening visit.

If your child qualifies to start the main phase of the study, you and your child will again be asked if you have any questions about the study. We want to make sure that if you and your child continue, you understand the study and feel that you and your child can follow the procedures needed in either study group.

You and your child will use a kit to get a fingerstick blood sample to measure your child's HbA1c level. Study staff will give you the kit and help you use it. The kit can be used in the clinic or at home and is then sent to a central lab for analysis. If you use the kit at home, you must drop it in a mailbox (regular U.S. mail) within 24 hours of using it.

At this visit, a computer program will be used to select whether or not your child will be given the Control-IQ closed-loop study system or use the study CGM with your child's current insulin pump or daily insulin injections. This is like flipping a coin to decide which group your child is assigned. The computer will assign the groups so that 2 out of every 3 participants are in the Control-IQ group, with the other 1 participant being in the Standard Care (SC) group. This is done completely randomly. Neither the study doctors nor you will not get to choose which group your child is in. Your child will continue the care in the assigned group for approximately 3 months.

You may use available software apps from the CGM manufacturer for mobile data access or remote monitoring during the study. You may not use any software not from the manufacturer.

SC Group

If assigned to this group, your child will continue to use his or her personal insulin pump or multiple daily injections of insulin along with the study CGM at home. If you are currently using a low blood glucose suspend (i.e. PLGS; LGS) feature on your child's insulin pump that works with the study CGM, you may continue to use that during the study. We will call you and your child after the first week to see how your child is doing with the study CGM. You and your child will have a visit after the second week so we can answer any questions you and your child may have and review your child's glucose data. Study staff may suggest changes to help you improve your child's blood glucose control. You will then continue to use the study CGM at home for a total of 13 weeks. You and your child will have a series of phone contacts and visits during this period as shown in the table below.

You and your child will be asked to upload data from the study CGM and ketone meter during the study. You and your child will do this before each scheduled clinic visit or phone call, and otherwise at least once every 4 weeks. You will be given all necessary equipment to do this.

Closed-Loop Group

If assigned to this group, you and your child will be trained to use the study system including the Tandem t:slim X2 with Control-IQ technology and Dexcom G6 CGM. Using the study system in closed-loop mode will automatically adjust your child's insulin delivery based on the CGM glucose readings. You and your child can always stop closed-loop mode at any time and take over control of your child's insulin pump. If your child was on multiple daily injections of insulin at the beginning of the study, your study doctor will decide what insulin pump settings your child will start with. These settings may be adjusted during the study.

Training may happen during one or more sessions. By the end of training, you and your child will be expected to perform certain tasks without help from study staff members. You and your child will be given a User Guide as a reference. You will be provided with study staff contact information that can help you should you need help.

Your child will use the study system at home, day and night. If your child switched from insulin injections to the study system, you will have a phone call or videoconference after using the system for about 3 days. All participants will have a phone call with study staff after about 1 week to review your experience. Your child will continue to use the system for another week followed by a visit to review training and answer any questions you and your child have. Study staff may suggest changes to help you improve your blood glucose control. Then you will use the study system at home for about 11 more weeks. You will have a series of phone contacts and visits during this period as shown in the table below.

You should use the study system in closed-loop mode whenever possible. In the following situations, you should contact study staff to determine whether temporarily to stop closed-loop use:

- Your child has a fever above 101.5 degrees Fahrenheit
- Your child has a major illness
- Your child needs to use certain medications including epinephrine (e.g. for the emergency treatment of a severe allergic reaction or asthma attack) or oral or injectable steroids

You and your child will be asked to upload data from the study CGM, pump, and ketone meter during the study. You and your child should do this before each scheduled visit or phone call, and otherwise at least once every 4 weeks. You will be given all necessary equipment to do this.

You and your child will be able to contact study staff at any time with a question, problem, or concern.

Scheduled Visits After First Two Weeks (In-Clinic or Videoconference)

The schedule for additional visits is the same for everyone in the study. The main reason for these visits is to troubleshoot any problems and ask you and your child about any changes in your child's health.

Follow-up visits will occur at 6 weeks and 13 weeks.

The following procedures will be performed in both groups at each visit, unless otherwise listed below:

- Assessment of study device use
- Review of any problems or events that have occurred
- Download of study device data
- Fingerstick blood sample for HbA1c (13 weeks)
- Completion of Questionnaires (13 weeks)
- Height and Weight measurement will be repeated (13 weeks)

Scheduled Phone Calls

In addition to the 1-week phone call described above, study staff will call you and your child after about 10 weeks. The schedule for this call is the same for everyone in the study.

Phone Call Procedures

- Discussion of your child's use of the study devices
- Discussion of any changes in your child's health
- Review of available study device data to identify any safety issues

The Main Phase of the study will end at the 13-week visit.

Extension Study Phase

After the Main Phase of the study has ended, data will be collected for an additional 13 weeks. If you have been using the Control-IQ system, you will switch to an updated version of that system for the additional 13 weeks. If you have not been using the Control-IQ system, you will switch to using that same updated system for 13 weeks.

The updated system has some new features to improve its usability. You and your child will receive training on use of the system. As above, you and your child will be asked to upload data from your child's study CGM, study pump, and ketone meter at least once every 4 weeks.

Scheduled Visits and Phone Calls During Extension Phase

You will have a phone call or videoconference after about 3 days to check how the updated system is working for you. You will have additional phone calls at 14 and 23 weeks and additional visits at 15 and 19 weeks.

Phone calls and visits will include:

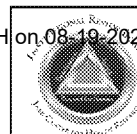
- Assessment of study device use
- Review of any problems or events that have occurred
- Download of study device data

Final Visit (26-week Visit)

The final study visit will be about 26 weeks after the Screening visit. Procedures will be similar to those described for the Screening and follow-up visits. You and your child will be asked to return some study devices as instructed by study staff at this visit. If needed, your child will be switched back to the insulin pump he or she was using before entering the study. You and your child will complete another set of questionnaires with similar topics as before. There will be a final fingerstick for HbA1c tests. Height and weight measurements will also be repeated.

Focus Groups

Your child may be asked to take part in an online group with other participants during the study. The purpose of the group will be to hear about people's experiences with the device systems and how they affect the people who use them. Although we would like as many people as possible to be in a focus group, this will be optional. Your child can still be in the study even if you or your child does not want to be in a focus group.



The table below shows what will happen at each phone call and visit:

	CGM Run- in	0	3d ¹	1w	2w	6w	10w	13w	13w + 3d	14w	15w	19w	23w	26w
		MAIN STUDY PHASE							EXTENSION PHASE					
Visit (V), Videoconference (VC), or Phone (P)	VC/V	VC/ V	VC/ P	P	VC/ V	VC/ V	P	VC/ V	VC/ P	P	VC/ V	VC/ V	P	VC/ V
Review if you can continue in the study	X	X												
Fingerstick for HbA1c		X						X						X
Device Data download(s)	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Review diabetes management and any new medical problems	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Questionnaires	X							X						X

¹ Only for participants on daily insulin injections at enrollment assigned to the CLC group

WHAT ARE THE RISKS OF THIS STUDY?

If you choose to take part in this study, you need to know that there are some side effects or risks of being in this study.

These deserve careful thought. This study may include risks that are unknown at this time.

Risks related to your child's normal medical care are not listed in this form. We encourage you and your child to discuss these with your child's study doctor, your child's primary care provider, or another health care professional.

Study System Risks

There is a risk that parts of the closed-loop study system may not work properly. As a result, your child could receive less or more insulin than needed and be at risk for high or low blood glucose. The following are common ways the study system might not work correctly:

- CGM sensor reads higher or lower than your child's actual glucose level
- CGM sensor stops working or cannot communicate with the system. If this occurs, the insulin pump will start delivering its preset basal rates within approximately 20 minutes.

Risk of Low Blood Glucose

As with any person who uses insulin, there is always a risk of having a low blood glucose (hypoglycemia). Low blood glucose should not happen more often during the study than before the study. Symptoms of low blood glucose can include:

- Sweating
- Shaking
- Not feeling well
- Fainting
- Seizures (convulsions)

In very rare cases, low blood glucose can lead to brain damage or death. Even if low blood glucose does occur, it almost always goes away quickly with treatment to raise the blood glucose.

Risk of High Blood Glucose

High blood glucose also should not happen more often during the study than before the study. High blood glucose usually does not cause many obvious symptoms, but your child may become thirsty, or have a higher level of glucose in his or her urine. In severe cases of hyperglycemia, diabetic ketoacidosis (DKA) or coma may occur. DKA can lead to kidney failure, irregular heartbeat, heart attack, muscle breakdown, and even death.

Fingerstick Risks

About 2 drops (0.1 teaspoon) of blood will be removed by fingerstick to test blood glucose levels. It hurts when the lancet goes into your child's finger but not for long. In about 1 in 10 times a small amount of bleeding under the skin will produce a bruise. A small scar may persist for several weeks. The risk of an infection is less than 1 in 1000. This should not be a significant contributor to risks in this study as fingersticks are part of the usual care for people with diabetes.

Continuous Glucose Monitoring Sensor Risks

Potential risks from using a CGM include:

- Discomfort when the sensor is inserted into the skin (common)
- Itchiness, redness, bleeding and bruising at the insertion site (unlikely to rare)
- Tape allergies (rare)
- Infection at the site of sensor insertion (rare)

Insulin infusion Risks

Potential risks from using an insulin pump to deliver insulin under your skin include:

- Discomfort when the infusion set catheter is inserted into the skin (common)
- Itchiness, redness, bleeding and bruising at the insertion site (unlikely to rare)
- Tape allergies (rare)
- Infection at the site of sensor insertion (rare)

Risk of Sharing the Continuous Glucose Monitor

The FDA approves a continuous glucose monitor as a 'single use device'. This means that they recommend that only one person use this device as there is a rare risk that a blood borne pathogen, such

as Hepatitis B, may be spread if used with multiple patients. In the study, we will not reuse CGM receiver, transmitter, or sensor parts in more than one patient.

Risk of Sharing the Insulin Pump

The FDA approves an insulin pump for ‘single-patient use’. They suggest that only one person use this device as there is a rare risk that a blood borne pathogen, such as Hepatitis B, may be spread if used with multiple patients. In the study, we will not reuse an insulin pump in more than one patient.

Risk of Re-using the Blood Glucose Meter or Ketone Meter

The FDA approved these meters for ‘single-patient use’. This means that they recommend that only one person use this device as there is a rare risk that a blood borne pathogen, such as Hepatitis B, may be spread if used with multiple patients. In the study, we do not plan to reuse these meters.

Questionnaire Risks

The questions asked on the questionnaires will include questions about you and your child’s personal attitudes, and behaviors related to diabetes. It is possible you may find these questions to be upsetting. Similar questionnaires have been used in other studies, and this reaction is uncommon. You can refuse to answer any questions that make you feel uncomfortable. You can decide not to answer questions, take a break, or stop taking part in the study at any time. There are no physical risks present. Many precautions will be made to keep your child’s information confidential, but this is not a guarantee.

Other Risks

Some people may develop skin irritation or allergic reactions to the adhesives used to secure the CGM or insulin infusion sets. If these reactions occur, your study doctor will try different adhesives or taping approaches. A mild topical steroid cream or other medication may be required.

Unknown Risks

It is always possible that anyone using a device for the first time may have an allergic reaction. Also, there may be additional risks from the device or the study procedures that are not known. If we find out that there are any new risks, you will be told about them. You will be able to decide if you want your child to continue in the study based on this new information.

Risks to Confidentiality

This study will be capturing some information about your child that includes identifiable, personal information, like your child’s date of birth. The study has procedures in place to protect that information. It is also possible that someone could recognize you from the focus group. There is a chance that a loss of that protection could occur. This would be a loss of confidentiality. Please see the “How will my information be protected and kept confidential” section below for more information.

The study doctor and staff will use your contact information to call, text or email you during the study. They may do this to send you things like appointment reminders. Study staff may also arrange videoconferences with you (e.g. Zoom) during the study. The videoconferences will not be recorded. Study staff are not allowed to send you identifiable health information by text or regular email because it is unsecure. This means that there is a risk that a message may be seen by someone that is not supposed to see it, like when an email gets hacked. Your email, phone number and your name/your child’s name

will likely be in the text or email. If you think that the study doctor's office has texted or emailed information that they should not have please contact JCHR at 813-975-8690 and ask to speak to the IRB Administrator. If you text or send a regular email to the study doctor's office, this is unsecure and what you put in the text or email is not protected. You may receive calls, text messages, or emails once per week or more often.

Please discuss the risks with your study doctor or any other health care provider.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?

The possible benefits are a better understanding of your child's diabetes or a positive impact on you and your child's ability to manage their diabetes. Your child also may not benefit from this study, but that is what the study is trying to find out. Children who take part in this research study will add to new knowledge that may help other children with type 1 diabetes.

ARE THERE OTHER OPTIONS THAN BEING IN THIS STUDY?

If your child does not take part in this study, your options include standard treatment like continuing with your child's current diabetes management regimen, other research studies, or you may choose not to do anything. Your child's study doctor will discuss these choices with you.

CAN I STOP BEING IN THE STUDY?

You and your child can stop being in the study at any time. If you decide to stop being in this study, you and your child will not be treated differently as people. Also, your child's regular care will not be impacted. Please talk to your study doctor or staff so they know why you are stopping the study and can help you do so safely.

If we find out that there is any important new information about the study, you will be told about it. You will be able to decide if you want your child to continue in the study based on this new information.

The study may stop or the study doctor may decide to take your child out of the study at any time. You do not have to give permission for the study to stop or for the study doctor to remove your child from the study. You will be told if this happens.

Some reasons why you may be removed from the study include:

- The doctors feel that it is in your child's best interest
- The doctors think that being in the study may cause your child harm
- If your child experiences an injury related to the study
- If your child needs additional or different medication
- If you or your child do not follow the study instructions

If your child withdraws, is removed from the study, or the study is stopped, your child may continue to receive care like your child normally would if your child were not in this study, but your child will no longer be able to use the device.

ARE THERE COSTS RELATED TO TAKING PART IN THE STUDY?

The costs of routine treatment, office visits, and tests that are part of your child's regular care will be billed to you or your child's insurance company like they normally would if your child were not in a study. The study will pay for testing that is specifically for this study. The following study devices will be provided to you at no cost:

- CGM system and CGM sensors
- Study Insulin pump, infusion sets, and reservoirs/cartridges while using the closed-loop system
- Blood glucose meter, test strips, lancets, and control solution
- Blood ketone meter, test strips, lancets, and control solution
- If necessary, a computer and scale

At the end of the study, or if you decide to withdraw your child from the study, you must return the investigational devices and computer, if one was borrowed for the study, to the study team listed on the front page. You may be permitted to keep the scale, blood ketone meter and blood glucose meter. Any additional tests and procedures will be billed to you or your child's insurance company like they normally would.

IS THERE PAYMENT FOR TAKING PART IN THIS STUDY?

If your child takes part in the study, you will receive up to \$300 for participation. These payments will be paid as follows:

- Screening Visit: \$50
- Randomization Visit: \$50
- 2-week Visit: \$50
- 6-week Visit: \$50
- 13-week Visit: \$50
- Extension Phase Completion: \$50

If you withdraw your child from the study, you will still be paid for the visits that your child has completed. You will not receive extra payments for visits that are required as part of your child's normal care or for visits that are for treating an illness or injury.

The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form. The samples collected will only be used for HbA1c and will not be used for whole genome sequencing or other genetic research.

Because payments made to you for participating in this study may be reported to the IRS as income, you may need to provide your social security number or a Form W-9 to your study doctor's office. These will not be shared outside of your doctor's office, other than as required by the IRS.

WHAT HAPPENS IF I HAVE AN ILLNESS OR INJURY FROM BEING IN THE STUDY?

If your child has an illness or injury that is related to your child's participation in the study, then you can get care for your child like you normally would. If you have an emergency, please seek emergency care as soon as possible. Please tell the emergency doctor that your child is in a research study. Please also tell your study doctor about the emergency as soon as you can. The study does not plan to provide costs for care or other expenses relating to illnesses or injuries. Your study doctor, the study doctor's office, the Jaeb Center, and Tandem Diabetes Care are not planning to cover payment for lost wages, direct losses, or indirect losses.

CONTACT INFORMATION FOR QUESTIONS OR PROBLEMS

If you have questions about this study; a research illness or injury; or have concerns, suggestions or questions about the study, then contact your study doctor using the contact information on the first page of this form.

Contact the Jaeb Center for Health Research Institutional Review Board (IRB) Office at 813-975-8690 or irb@jaeb.org if you:

- Have questions about your rights as a research participant
- Wish to talk about your concerns or suggestions about the research
- Want additional information about the research, or
- Want to provide comments about the research.

HOW WILL MY INFORMATION BE PROTECTED AND KEPT CONFIDENTIAL?

As required by law, study-related records with identifying information will be kept confidential. Safety measures for the access, security, and privacy of your information have been put in place by law. Your child's date of birth and initials may be used in the study to help the researchers keep the right information together. This information will be protected as described below. Unless the law requires it, your child's name, address, social security number, telephone number, or any other directly identifying information will not be used to identify you.

Certificate of Confidentiality

NIDDK has given us a Certificate of Confidentiality for this study. This adds special protection for study information that identifies your child and allows us, in some cases, to refuse to give out information that could identify your child without your consent. This could be done when the information is requested by a federal, state, local court or public agency. If your child needs medical help, we may still share your child's identifiable information. As described in this form or in other cases, we may share identifiable information. For example, if the government inspects us, they may see your child's identifiable information. Your child's study doctor and research team will follow local laws and will tell the local or state authorities:

- if certain diseases are present;
- if they suspect neglect, abandonment, or abuse of your child; and

- if your study doctor or research team learn that your child plans to harm him/herself or someone else

Purpose of Authorization

We have rules to protect information about your child. Federal and state laws also protect your child's information. By giving your electronic signature, you are giving your permission, called your "authorization," for the use and disclosure of information protected by the law.

You must electronically sign, including the Protected Health Information Authorization statement if you want your child to be in the study. When you provide your electronic signature, you give permission for the use and sharing of your child's Protected Health Information (PHI) for the study. PHI is health information that identifies your child. Your authorization is beneficial and important for the study. Without your authorization, your child will not be able to be in this study.

Using and Sharing Your PHI

Your study doctor will collect information about your child. This information includes things learned from study procedures as well as your child's name, address, date of birth, and information from your child's medical records. These are examples of identifiable information and may be used to confirm you and your child's identity when you consent to participate in the study. After the consent process is complete, a code number without and identifiable information will replace your child's name, address, telephone number, or social security number in the results given to the Jaeb Center for Health Research in Tampa, Florida.

The following people or companies involved in this study may see your child's study results with things like your date of birth, initials, and date of procedures:

- Your study doctor's office
- Your child's personal doctor's office, if different than your study doctor's office
- Jaeb Center for Health Research
- University of Virginia Center for Diabetes Technology
- Tandem Diabetes Care
- Dexcom, Inc.
- Advanced Research and Diagnostics Laboratory, University of Minnesota
- Researchers who are part of the study

The study doctor's office **will not** share study results that can identify your child except as explained in this form or when required by law. The Jaeb Center and your study doctor's office will guard the privacy of your child's study PHI.

Who Can Receive and Use Your Study Information?

It is possible that people outside of this doctor's office and the Jaeb Center may need to see or receive your child's information from this study. Some examples include government agencies (such as the Food and Drug Administration), committees that monitor safety, other sites in the study, and companies that are providing either funding or supplies for the study, laboratories, and centers that may receive

images. In most cases the information will have a code number with it instead of your child's name, address, telephone number, or social security number.

There are some situations where the information will not have a code number but may include your child's name, address, telephone number, or social security number (PHI). Once PHI is disclosed by your study doctor and the clinic staff, it may no longer be covered by the privacy laws. Everyone who needs to see your child's information will be told it is confidential, but we cannot guarantee full confidentiality once it leaves the doctor's office.

Can You Cancel Your Authorization?

You may cancel your permission for the collection of your child's study PHI at any time. You will need to contact your study doctors and give them a written notice of cancellation, or you may contact the JCHR IRB Office at 813-975-8690 or irb@jaeb.org. When you cancel your permission or when you withdraw from the study directly, you are no longer part of the study. No new information about your child will be gathered for the study, except when there is a safety concern related to the study. If there is a safety concern, your entire medical record may need to be reviewed.

The Jaeb Center will receive all the information that was collected for the study up to the time that you cancel or withdraw from the study. The Jaeb Center will receive any new information about any safety concerns that may be related to the study.

When Will the Use and Sharing of Your PHI Stop?

Some of your child's study PHI does not have a code number with it. Your permission for the use and sharing of your child's PHI lasts 50 years from the date that you provide your electronic signature or until the end of the study, whichever comes first.

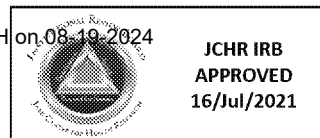
The rest of your child's study information that is not PHI does have a code number with it. When it is collected, it becomes part of a research report. Your permission for the use and sharing of this coded information will never end. This coded data does not have your child's name, address, telephone number, or social security number.

Other Considerations

The information collected in the study may be used in future studies without additional permission from you. This may include research done by other researchers. The information that may be shared will not contain any information that could identify your child. There may still be a chance that someone could identify your child, but this is not likely. A copy of the information collected as part of the study will be made public in a dataset. This will be done after the study ends. This dataset will not contain any PHI. The study results will also be made public. These results will not have any information that could identify your child.

Study results without the identifiable information may be shared in medical journals and at scientific meetings. Your records will be confidential. No one will share your identity in a medical journal or at a scientific meeting.

Results from the study will not be sent to you.



You will have communication with the study doctor's office by phone, text, or by video (like Zoom, FaceTime, or Skype). There is a chance that someone could see or hear the conversation like they could if you were speaking or texting with anyone.

Clinical Trial Reporting

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by law. This Web site will not include information that can identify your child. At most, the Web site will include a summary of the results. You can search this Web site at any time. A copy of one of the study consent form templates will also have to be posted on a federal Web site.



ELECTRONIC ATTESTATION PAGES

(b)(4)

(b)(4)

(b)(4)

APPENDIX 11.2

Participant Data Listings: Pre-Randomization

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

APPENDIX 11.3

Participant Data Listings: Baseline

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

11.3.02d

4

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

11.3.07

1

Baseline Main CGM Metrics

(b)(4)

(b)(4)

(b)(4)

(b)(4)

11.3.08

1

Baseline Secondary CGM Metrics

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

APPENDIX 11.4

Participant Data Listings: RCT

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

11.4.05c

1

Individual Efficacy - Insulin Pump Therapy Settings Reported on CRF

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

APPENDIX 11.5

Participant Data Listings: Patient Reported Outcomes

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

APPENDIX 11.6

Adverse Event Listings

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

11.7

APPENDIX 11.7

Device Issue Listings

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

APPENDIX 11.8

Protocol Deviation Listings

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

APPENDIX 11.9

SAE Case Report Forms and Narratives

(b)(4)

PEDAP : Pediatric Artificial Pancreas (PEDAP)

Adverse Event Form

(b)(4)

(b)(4)

(b)(4)

(b)(4)

PEDAP : Pediatric Artificial Pancreas (PEDAP)

Adverse Event Form

(b)(4)

(b)(4)

(b)(4)

PEDAP : Pediatric Artificial Pancreas (PEDAP)**Adverse Event Form**

(b)(4)

(b)(4)

(b)(4)

(b)(4)

PEDAP : Pediatric Artificial Pancreas (PEDAP)**Adverse Event Form**

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

PEDAP : Pediatric Artificial Pancreas (PEDAP)**Adverse Event Form**

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

11.10

APPENDIX 11.10

Miscellaneous

(b)(4)

Hi Suvajyoti,

Please see our responses to your questions attached.

(b)(4)

I will be out of office next Monday and Tuesday (October 23rd & 24th), please send any inquiries to Ian Herrington (cc'ed).

Thank you and have a great weekend,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Monday, October 16, 2023 9:55 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; k232382@docs.fda.gov

Subject: k232380 and k232382 - Tandem - Control IQ 1.5 - **(b)(4)**

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Please see the following interactive items. Can you please provide your response and updated **(b)(4)** documents by COB Oct 20, 2023?

(b)(4)

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image001.png@01DA0351.2F6B81E0]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA0351.2F6B81E0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA0351.2F6B81E0] <https://twitter.com/US_FDA>

[cid:image004.jpg@01DA0351.2F6B81E0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01DA0351.2F6B81E0] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01DA0351.2F6B81E0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



Subject Matter Expert (SME) Review

Date: August 30, 2023

SME Reviewer: I-Lin Wu

Expertise: Software

Submission # K232382, K232380

Applicable Review Guide (if used): Software/Firmware

Is this review for a Pre-Submission, Submission Issue Request, or Expedited Program (Breakthrough/STeP) Interaction? No

Applicant: Tandem Diabetes Care, Inc.

Device Trade Name: Control-IQ
Technology

Optional Classification Information:

Pro Code(s): QJI **Class:** II **Reg #:** 862.1356

Reg Name: Interoperable
Automated Glycemic Controller

Pro Code(s): QFG **Class:** II **Reg #:** 880.5730

Reg Name: Alternate controller
enabled infusion pump

Rx/OTC: Rx

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

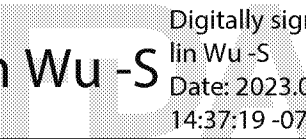
(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Digital Signature Concurrence Table (Doc ID: 04504.04.02)	
For each of the specific issues identified in the recommended requests to the applicant above, I have provided a statement of basis for the request(s); and either cited as part of it an available, applicable, and relevant final rule, statute, final guidance, or FDA-recognized consensus standard, or confirmed to the best of my ability that there is no final rule, statute, final guidance, or FDA-recognized consensus standard available, applicable, and relevant to the request(s).	
Reviewer Sign-Off	Digitally signed by I-lin Wu -S Date: 2023.09.27 14:37:19 -07'00'

Hi Suvajyoti,

I'm confirming receipt of your questions.

We will reach out to you if we have any questions.

Thank you,



Christin Dunn
Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different
12400 High Bluff Drive, San Diego CA 92130
tandemdiabetes.com

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Friday, August 18, 2023 6:59 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Maiorana, Anthony <Anthony.Maiorana@fda.hhs.gov>; Balsam, Joshua <Joshua.Balsam@fda.hhs.gov>

Subject: K232380 and K232382 - miscellaneous interactive questions

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

I Christin,

Can you please respond to the following interactive questions? For 1-4 below I request that you provide your responses by COB **August 25, 2023**.

For response 5 below, I request that you provide your response by **COB August 22, 2023** and cc our Human Factors SME Dr. Anthony Maiorana.

(b)(4)

(b)(4)

If you have any follow up questions for me related to the above, please direct them to me by 4 PM today eastern time as I will be on leave for part of next week.

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).



Hello Suvajyoti,

Pleasure to meet you and I look forward to working with you.

Please see my responses below:

K232380

(b)(4)

K232382

(b)(4)

Thank you,



Christin Dunn
Senior Regulatory Affairs Specialist

P + 1 (858) 401-1641

Tandem Diabetes Care | positively different
12400 High Bluff Drive, San Diego CA 92130
tandemdiabetes.com

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution, or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Friday, August 11, 2023 12:41 PM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; k232382@docs.fda.gov

Subject: K232380 and K232382 - Lead Reviewer and RTA items

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

I am the lead reviewer for K232380 and K232382. Can you please provide your responses to the following questions by **3 PM Eastern Time Monday August 14** –

K232380

(b)(4)

K232382

(b)(4)

Thanks, and looking forward to working with you on both submissions.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10963 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).



Hi Suvajyoti,

(b)(4)

Best Regards,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Thursday, September 21, 2023 9:06 AM
To: Lan Herrington <LHerrington@tandemdiabetes.com>; Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov
Subject: K232382 - Tandem - Control IQ 1.5 - (b)(4)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

(b)(4)

by COB 9/28?

Can you please provide your response

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).



Hello Suvajyoti,

(b)(4)

(b)(4)

Please feel free to

contact me if you have any questions.

Thanks.

Lan

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Monday, October 23, 2023 11:23 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; k232382@docs.fda.gov

Subject: RE: k232380 and k232382 - Tandem - Control IQ 1.5 -

(b)(4)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin and Lan,

Thanks for providing the responses.

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01DA05AB.F5392380]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA05AB.F5392380]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA05AB.F5392380] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJpTOn1rp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image004.jpg@01DA05AB.F5392380]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image005.jpg@01DA05AB.F5392380]
<http://secure-web.cisco.com/1c6NVqVSfV2kjznn-UlA0J4oUTRapVCu10_n_AyTYEq2nEyp_lnxIiz0fkdH-QoytaqVxWfZhoJkuVQM_G5MsbRPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCy114AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image006.jpg@01DA05AB.F5392380]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3WlUE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdhrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com<<mailto:CDunn@tandemdiabetes.com>>>

Sent: Friday, October 20, 2023 4:43 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>>

Cc: k232380@docs.fda.gov<<mailto:k232380@docs.fda.gov>>; Lan Herrington <LHerrington@tandemdiabetes.com<<mailto:LHerrington@tandemdiabetes.com>>>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com<<mailto:SArunkumar@tandemdiabetes.com>>>; k232382@docs.fda.gov<<mailto:k232382@docs.fda.gov>>

Subject: [EXTERNAL] RE: k232380 and k232382 - Tandem - Control IQ 1.5 - (b)(4)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see our responses to your questions attached.

(b)(4)

I will be out of office next Monday and Tuesday (October 23rd & 24th), please send any inquiries to Lan Herrington (cc'ed).

Thank you and have a great weekend,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>>

Sent: Monday, October 16, 2023 9:55 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>;
k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>

Subject: k232380 and k232382 - Tandem - Control IQ 1.5 - (b)(4)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Please ~~see the following~~ interactive items. Can you please provide your response and updated (b)(4) documents by COB Oct 20, 2023?

(b)(4)

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, W062 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image007.png@01DA05AB.F5392380]<<http://www.fda.gov/>>

[cid:image008.jpg@01DA05AB.F5392380]<<https://www.facebook.com/FDA>>

[cid:image009.jpg@01DA05AB.F5392380] <https://twitter.com/US_FDA>

[cid:image010.jpg@01DA05AB.F5392380] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image011.jpg@01DA05AB.F5392380] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image012.jpg@01DA05AB.F5392380]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here

<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Hi Christin,

Attached are some edits for the 510k summary for the pump.

(b)(4)

(b)(4)

Can you please provide updated version before COB today?

Thanks and please let me know if you have any questions.

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

? : 301.796.9573

[cid:image001.png@01DA0BFB.FD848BF0]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA0BFB.FD848BF0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA0BFB.FD848BF0] <https://twitter.com/US_FDA>

[cid:image004.jpg@01DA0BFB.FD848BF0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01DA0BFB.FD848BF0] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01DA0BFB.FD848BF0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Hi Suvajyoti,

Request received.

(b)(4)

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Tuesday, October 31, 2023 10:18 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>

Subject: k232380 - Tandem - ACE Pump - Edits for 510k summary

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Attached are some edits for the 510k summary for the pump.

(b)(4)

(b)(4)

Can you please provide updated version before COB today?

Thanks and please let me know if you have any questions.

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>

?: 301.796.9573

[cid:image008.png@01DA0BE4.0F303EC0]<<http://www.fda.gov/>>

[cid:image009.jpg@01DA0BE4.0F303EC0]<<https://www.facebook.com/FDA>>

[cid:image010.jpg@01DA0BE4.0F303EC0] <https://twitter.com/US_FDA>

[cid:image011.jpg@01DA0BE4.0F303EC0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image012.jpg@01DA0BE4.0F303EC0] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image013.jpg@01DA0BE4.0F303EC0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

Please see 510(k) summary for K232380 with the requested edits attached.

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Tuesday, October 31, 2023 10:24 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: RE: [EXTERNAL] RE: k232380 - Tandem - ACE Pump - Edits for 510k summary

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Thanks Christin for catching that. That would be great.

Suvajyoti Guha

From: Christin Dunn <CDunn@tandemdiabetes.com>
Sent: Tuesday, October 31, 2023 1:22 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: [EXTERNAL] RE: k232380 - Tandem - ACE Pump - Edits for 510k summary

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Request received.

(b)(4)

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Tuesday, October 31, 2023 10:18 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>
Subject: k232380 - Tandem - ACE Pump - Edits for 510k summary

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Attached are some edits for the 510k summary for the pump (b)(4)

(b)(4)

Can you please provide updated version before COB today?

Thanks and please let me know if you have any questions.

Suvajyoti Guha, PhD

Mechanical Engineer
Division of Applied Mechanics (DAM)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993
✉: Suvajyoti.Guha@fda.hhs.gov
☎: 301.796.9573





Hi Suvajyoti,

I'm confirming receipt of the additional questions.

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Wednesday, September 6, 2023 6:34 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov
Subject: k232380 and k232382 - Tandem - Pump and Control IQ 1.5 - interactive questions

 Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.
i Christin,

Can you please respond to the following interactive questions by COB Sep 11, 2023 –

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer
Division of Applied Mechanics (DAM)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993
✉: Suvajyoti.Guha@fda.hhs.gov
☎: 301.796.9573



• < x v x

Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>



Hi Christin,

I am the lead reviewer for K232380 and K232382. Can you please provide your responses to the following questions by **3 PM Eastern Time Monday August 14** —

K232380

(b)(4)

K232382

(b)(4)

Thanks, and looking forward to working with you on both submissions.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10963 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

Hello Suvaiyoti, we received your questions and will provide response by 9/28. Thank you. Lan

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Thursday, September 21, 2023 9:06:18 AM

To: Lan Herrington <LHerrington@tandemdiabetes.com>; Christin Dunn <CDunn@tandemdiabetes.com>

Cc: k232382@docs.fda.gov <k232382@docs.fda.gov>; k232380@docs.fda.gov <k232380@docs.fda.gov>

Subject: K232382 - Tandem - Control IQ 1.5 - (b)(4)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi,

(b)(4)

(b)(4)

Can you please provide your response by COB 9/28?

(b)(4)

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image007.png@01D9EC84.05C1DE90]<<http://www.fda.gov/>>

[cid:image008.jpg@01D9EC84.05C1DE90]<<https://www.facebook.com/FDA>>

[cid:image009.jpg@01D9EC84.05C1DE90] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJPtOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image010.jpg@01D9EC84.05C1DE90]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image011.jpg@01D9EC84.05C1DE90]
<http://secure-web.cisco.com/1c6NVqVSfv2kjznn-U1A0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdh-QoytaqVxWfZhoJkuVQM_G5MsbRPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOwewttCYH7Gm0I2nqxYQoCYll4AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image012.jpg@01D9EC84.05C1DE90]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvX1Gb7eTpSkXQ1VK2YAi5GWcTEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

Received. Thanks Christin.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-0573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>
Sent: Monday, October 30, 2023 8:48 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>; David Berger <DBerger@tandemdiabetes.com>
Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

My apologies, please see IFU and 510(k) summaries as 3 separate files attached.

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Monday, October 30, 2023 5:14 PM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

My apologies. Usually, in our final stages of finalization, we need these documents as separate attachments. Can you resend the following as separate documents?

1. Finalized label –user guide (one since it's the same one for both submissions k232380 and k232382)
2. 510k summary for k232380
3. 510k summary for k232382

I can generate the IFU form on my end, so that won't be necessary.

I tried to print them separately as three PDFs but could not, probably because its protected on your end? Below is the error I keep getting. If you can send the above request first thing tomorrow morning (10/31) that would be much appreciated.



Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>
Sent: Monday, October 30, 2023 2:50 PM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see final IFU and 510(k) summaries for K232380 and K232382 attached.

Thank you,
Christin

From: Christin Dunn
Sent: Friday, October 27, 2023 10:05 AM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Thank you, Suvajyoti!

Yes, that time is reasonable.

Have a great weekend,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Friday, October 27, 2023 8:56 AM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Thanks Christin. Thanks for the heads up on the delay.

Given the time zone difference, it would be appreciated if you can send it by 3 PM Eastern time on Oct 30, 2023. Would that be reasonable?

Thanks,
Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-9573



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received ([click here](#)).

From: Christin Dunn <CDunn@tandemdiabetes.com>
Sent: Friday, October 27, 2023 11:52 AM
To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>
Subject: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Would it be possible for us to send you the labeling documents and 510(k) summaries by COB Monday, October 30th?

Thank you,
Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>
Sent: Thursday, October 26, 2023 12:33 PM
To: Christin Dunn <CDunn@tandemdiabetes.com>
Cc: k232382@docs.fda.gov; k232380@docs.fda.gov
Subject: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

i Christin,

Can you please send your finalized and complete Labeling documents and 510k summaries for the pump (k232380) and Control IQ (k232382)?

It would be great if you can send it by COB **Oct 27, 2023**.

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer
Division of Applied Mechanics (DAM)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993
✉: Suvajyoti.Guha@fda.hhs.gov
☎: 301.796.9573



Excellent customer service is important to us. Please provide your feedback here <https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>





November 3, 2023

Tandem Diabetes Care, Inc.
Christin Dunn
Senior Regulatory Affairs Specialist
12400 High Bluff Drive
San Diego, California 92130

Re: K232380

Trade/Device Name: t:slim X2 Insulin Pump with Interoperable Technology
Regulation Number: 21 CFR 880.5730
Regulation Name: Alternate Controller Enabled Infusion Pump
Regulatory Class: Class II
Product Code: QFG
Dated: August 4, 2023
Received: August 8, 2023

Dear Christin Dunn:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.

Branch Chief

Division of Chemistry

and Toxicology Devices

OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
k232380

Device Name
t:slim X2 Insulin Pump with Interoperable Technology

Indications for Use (Describe)

The t:slim X2 Insulin Pump with Interoperable Technology (the pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use in individuals 2 years of age and greater.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



510(K) SUMMARY FOR K232380

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92), the 510(k) Summary for the t:slim X2 Insulin Pump with Interoperable Technology is provided below:

Submitter Information

Name	Tandem Diabetes Care, Inc. 12400 High Bluff Drive San Diego, CA 92130 Phone: 858-366-6900
Applicant Contact	Christin Dunn Senior Regulatory Affairs Specialist Phone: 858-401-1641 cdunn@tandemdiabetes.com Tandem Diabetes Care, Inc. 12400 High Bluff Drive San Diego, CA 92130
Secondary Contact	Lan Herrington Director, Regulatory Affairs (858) 255-6378 LHerrington@tandemdiabetes.com Tandem Diabetes Care, Inc. 12400 High Bluff Drive San Diego, CA 92130
Date Prepared:	October 26, 2023



Device Identification

Trade name	t:slim X2 Insulin Pump with Interoperable Technology
Common name	alternate controller enabled insulin infusion pump
Regulation Name	alternate controller enabled insulin infusion pump
Classification number	21 CFR 880.5730
Product code	QFG
Regulatory class	II
Predicate devices	t:slim X2 Insulin Pump with Interoperable Technology (with t:connect mobile app (K203234)

Intended Use

The t:slim X2 Insulin Pump with Interoperable Technology (the Pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

The Pump is intended for single patient, home use and requires a prescription.

The Pump is indicated for use in individuals 2 years of age and greater.

Description

The t:slim X2 Insulin Pump with Interoperable Technology is an ambulatory, battery operated, rate-programmable infusion pump designed for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

The t:slim X2 insulin pump includes a disposable cartridge with a 300 unit reservoir which is filled with insulin by the user with the use of the syringe and needle. The cartridge needs to be changed every 48-72 hours depending on the type of insulin used.

The pump is motor driven to deliver patient programmed basal rates and boluses through an



infusion set into subcutaneous tissue. The desired timing and quantity of insulin delivery (bolus or basal) is programmed by the patient based on their healthcare provider's recommendations.

The pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices.

The t:connect mobile app enables a user to connect a smartphone to the pump using Bluetooth® wireless technology to display pump information and perform some pump functions on the smartphone as well as display pump notifications. The t:connect mobile app can transmit pump and therapy data from the pump to the cloud as long as the user's smartphone is connected to the internet.

The pump is designed to be able to receive and display alerts and alarms to users based on information received from other interoperable devices.

The pump is compatible with Interoperable Automated Glycemic Controllers, such as Basal-IQ Technology (K193483) and Control IQ Technology (K200467) to aid in diabetes management. The latter is being submitted concurrently.

In addition, the Subject Device is compatible with iCGM systems cleared under K223931 21 CFR 862.1355.



Technological Characteristics Compared to Predicate Device

	Predicate Device T: Slim X2 Insulin Pump with Interoperable Technology (K203234)	Subject Device (K232380)
Intended Use/Indication for Use	The t:slim X2 insulin pump with interoperable technology (the Pump) is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The Pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The Pump is intended for single patient, home use and requires a prescription. The Pump is indicated for use with NovoLog or Humalog U-100 insulin. The Pump is indicated for use in individuals 6 years of age and greater.	Different: Removal of the compatible insulins NovoLog and Humalog from indications. Moved to compatible insulins section of the user guide. The Pump is indicated for use in individuals 2 years of age and greater.



	Predicate Device T: Slim X2 Insulin Pump with Interoperable Technology (K203234)	Subject Device (K232380)
Technological Characteristics	The t:slim X2 insulin pump with interoperable technology is an ambulatory, battery operated, rate-programmable infusion pump designed for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The device includes a disposable cartridge which is motor driven to deliver patient programmed basal rates and boluses through an infusion set into subcutaneous tissue.	Same
Classification	II	Same
Product Code	QFG	Same
Specific Drug/Biological Use	U-100 Insulin	Same
Pump Type	ACE pump, t:slim X2 system	Same
Components	Infusion Pump, Sterile disposable insulin cartridge	Same



	Predicate Device T: Slim X2 Insulin Pump with Interoperable Technology (K203234)	Subject Device (K232380)
Accessories	Compatible FDA cleared infusion sets 3 mL sterile syringe and 26 gauge needle (for filling cartridge). AC power supply and DC car adaptor power supply with USB. Tandem Device Updater. Alternate USB Cable.	Similar DC car adaptor power supply is not provided with the subject device.

The t:slim X2 insulin pump with interoperable technology is an ambulatory, battery operated, rate-programmable infusion pump designed for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The subject device is the same as the predicate device with the following changes:

- Lowered the age indication to individuals of 2 years of age and greater.

Performance Data

Clinical testing was performed to support the expanded age indication. The clinical data demonstrates that the device shows continued assurance of safety and effectiveness.

Evaluation and adherence of the Special Controls listed in 21 CFR 880.5730 demonstrate the continued assurance of the safety and effectiveness of the device.

Substantial Equivalence

The subject device serves the same function as the predicate device with the addition of the 2–5 year-old population. The clinical testing provided in this 510(k) demonstrate that the t:slim X2 Insulin Pump with Interoperable Technology is the same as the predicate device in safety and effectiveness. Therefore, the subject device has been evaluated to be substantially equivalent to the predicate device and does not raise new or different questions of safety or effectiveness.

Hi Suvajyoti,

Thank you for the time and effort in reviewing these submissions and thank you for the feedback.

(b)(4)

Best Regards,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Sent: Friday, November 3, 2023 8:44 AM

To: Christin Dunn <CDunn@tandemdiabetes.com>; Lan Herrington
<LHerrington@tandemdiabetes.com>

Cc: k232380@docs.fda.gov; k232382@docs.fda.gov; Balsam, Joshua
<Joshua.Balsam@fda.hhs.gov>; Maiorana, Anthony <Anthony.Maiorana@fda.hhs.gov>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: Follow up items on your ACE Pump (K232380) and iAGC (K232382)

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christina and Lan,

Congratulations on the clearance of the t-slim pump and the Control IQ 1.5!

(b)(4)

(b)(4)

(b)(4)

Thanks, and please let us know if you have any follow up questions on these two feedbacks.

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01DA0E3A.50571FB0]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA0E3A.50571FB0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA0E3A.50571FB0] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDs_jPtOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA>

[cid:image004.jpg@01DA0E3A.50571FB0]

<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image005.jpg@01DA0E3A.50571FB0]

<http://secure-web.cisco.com/1c6NVqVSfV2kjznn-U1A0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdH-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCyll14AJqcO7Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F>

[cid:image006.jpg@01DA0E3A.50571FB0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvX1Gb7eTpSkXQ1VK2YAi5GWcTEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

>).

>).

>).

>).

>).

Hi Christin,

My apologies. Usually, in our final stages of finalization, we need these documents as separate attachments. Can you resend the following as separate documents?

1. Finalized label - user guide (one since it's the same one for both submissions k232380 and k232382)
2. 510k summary for k232380
3. 510k summary for k232382

I can generate the IFU form on my end, so that won't be necessary.

I tried to print them separately as three PDFs but could not, probably because its protected on your end? Below is the error I keep getting. If you can send the above request first thing tomorrow morning (10/31) that would be much appreciated.

[cid:image013.png@01DA0B6D.957BA4A0]

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01DA0B4F.D3F34B70]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA0B4F.D3F34B70]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA0B4F.D3F34B70] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_Syvb8-IGlf0t1w_ADo-yDs_jPtOnlrp90Xo0UwJUyBlbVEkc2HcBqPoCs9g9N_NFMoHDAXr6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image004.jpg@01DA0B4F.D3F34B70]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image005.jpg@01DA0B4F.D3F34B70]
<http://secure-web.cisco.com/1c6NVqVSfV2kjznn-U1A0J4oUTRapVCu10_n_AyTYEq2nEyp_lnxIiz0fkdh-QoytaqVxWfZhoJkuVQM_G5MsbrPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBOrWewttCYH7Gm0I2nqxYQoCyll4AJqcO7Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image006.jpg@01DA0B4F.D3F34B70]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YAi5GWcTEweL2ygi-yMZwF9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPDQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com>

Sent: Monday, October 30, 2023 2:50 PM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov>

Cc: k232382@docs.fda.gov; k232380@docs.fda.gov; Lan Herrington <LHerrington@tandemdiabetes.com>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Please see final IFU and 510(k) summaries for K232380 and K232382 attached.

Thank you,

Christin

From: Christin Dunn

Sent: Friday, October 27, 2023 10:05 AM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>; k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington <LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Thank you, Suvajyoti!

Yes, that time is reasonable.

Have a great weekend,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>>

Sent: Friday, October 27, 2023 8:56 AM

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>; k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>; Lan Herrington <LHerrington@tandemdiabetes.com<mailto:LHerrington@tandemdiabetes.com>>; Sowmya Arunkumar <SArunkumar@tandemdiabetes.com<mailto:SArunkumar@tandemdiabetes.com>>

Subject: RE: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Thanks Christin. Thanks for the heads up on the delay.

Given the time zone difference, it would be appreciated if you can send it by 3 PM Eastern time on Oct 30, 2023. Would that be reasonable?

Thanks,

Suvajyoti Guha, PhD

Lead Reviewer (On Detail)

Division of Chemistry and Toxicology Devices | OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 62, Rm. 2229 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-9573

[cid:image001.png@01DA0B4F.D3F34B70]<<http://www.fda.gov/>>

[cid:image002.jpg@01DA0B4F.D3F34B70]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01DA0B4F.D3F34B70] <https://secure-web.cisco.com/1WRRqguz08h8HWOWMxJVQ1slo6cm-MDf8lgYCuQKKbSMSnIEKr4TsEKgXCixlo6vrH_lx9axUNnIccQknwG9c_4JUaRHZ2FU5ubpx4c9CgVB8TO7yzJWvO9_SYvb8-IGlf0t1w_ADo-yDsJPtOn1rp90Xo0UwJUyB1bVEkc2HcBqPoCs9g9N_NFMoHDAxR6MG8GVkz8GRoSSrcWYDlyBYzg/https%3A%2F%2Ftwitter.com%2FUS_FDA> [cid:image004.jpg@01DA0B4F.D3F34B70]
<<http://www.youtube.com/user/USFoodandDrugAdmin>> [cid:image005.jpg@01DA0B4F.D3F34B70]
<http://secure-web.cisco.com/1c6NVqVSfV2kjznn-U1A0J4oUTRapVCu1O_n_AyTYEq2nEyp_lnxIiz0fkdH-QoytaqVxWfZhoJkuVQM_G5MsBRPgvSCB5PGeVwtpbhJUiXavwE97sYwVt8Mo6d8v_N86E9R-gePHDDPgIMKJwJdLOmGyRK9DisBh6HqQxEQyi07VdBoRwewttCYH7Gm0I2nqxYQoCyl14AJqc07Gx7nhZg/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image006.jpg@01DA0B4F.D3F34B70]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (click here<https://secure-web.cisco.com/1dVgYZgcWQ3PDIn4ZPeX06uTAkEqiW6wcFDahwMwBML-UZHWKC3RMiAwVZr-cElu4gzEtucxrYj-MwioKnRxnEXGvvXlGb7eTpSkXQlVK2YA15GWcTEweL2ygi-yMZWf9-0wUmD-P64NYh2n8dNKlev2arzrrhUMGgDJPdQ06j1P_IeF_3W1UE6x2_mnyAo3FtawVhTrNd3sczIcTone9g/https%3A%2F%2Fwww.research.net%2Fs%2Fcdrhcustomerservice%3FID%3D1914%26S%3DE>).

From: Christin Dunn <CDunn@tandemdiabetes.com<<mailto:CDunn@tandemdiabetes.com>>>

Sent: Friday, October 27, 2023 11:52 AM

To: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>>

Cc: k232382@docs.fda.gov<<mailto:k232382@docs.fda.gov>>;
k232380@docs.fda.gov<<mailto:k232380@docs.fda.gov>>; Lan Herrington
<LHerrington@tandemdiabetes.com<<mailto:LHerrington@tandemdiabetes.com>>>; Sowmya
Arunkumar <SArunkumar@tandemdiabetes.com<<mailto:SArunkumar@tandemdiabetes.com>>>

Subject: [EXTERNAL] RE: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Suvajyoti,

Would it be possible for us to send you the labeling documents and 510(k) summaries by COB Monday, October 30th?

Thank you,

Christin

From: Guha, Suvajyoti <Suvajyoti.Guha@fda.hhs.gov<<mailto:Suvajyoti.Guha@fda.hhs.gov>>>

Sent: Thursday, October 26, 2023 12:33 PM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

To: Christin Dunn <CDunn@tandemdiabetes.com<mailto:CDunn@tandemdiabetes.com>>

Cc: k232382@docs.fda.gov<mailto:k232382@docs.fda.gov>;
k232380@docs.fda.gov<mailto:k232380@docs.fda.gov>

Subject: k232382 and k232380 - Tandem - ACE Pump + Control IQ - Labeling and 510k summaries

Warning: This email came from outside of Tandem Diabetes Care. Be careful when responding, opening attachments, or clicking links.

Hi Christin,

Can you please send your finalized and complete Labeling documents and 510k summaries for the pump (k232380) and Control IQ (k232382)?

It would be great if you can send it by COB Oct 27, 2023.

Thanks,

Suvajyoti Guha, PhD

Mechanical Engineer

Division of Applied Mechanics

(DAM<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm299952.htm>>)

Office of Science and Engineering Laboratories

(OSEL<<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm>>)

Center for Devices and Radiological Health

(CDRH<<https://www.fda.gov/MedicalDevices/default.htm>>)

10903 New Hampshire Ave, WO62 Rm 2233, Silver Spring, MD 20993

*: Suvajyoti.Guha@fda.hhs.gov<mailto:Suvajyoti.Guha@fda.hhs.gov>

?: 301.796.9573

[cid:image007.png@01DA0B4F.D3F34B70]<<http://www.fda.gov/>>

[cid:image008.jpg@01DA0B4F.D3F34B70]<<https://www.facebook.com/FDA>>

[cid:image009.jpg@01DA0B4F.D3F34B70] <https://twitter.com/US_FDA>

[cid:image010.jpg@01DA0B4F.D3F34B70] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image011.jpg@01DA0B4F.D3F34B70] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image012.jpg@01DA0B4F.D3F34B70]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please provide your feedback here
<https://www.research.net/s/cdrhcustomerservice?ID=6020&S=E>

August 16, 2023</br></br>

Acceptance Review Notification - Accepted

<p>An administrative acceptance review was conducted on your submission K232380, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review.</p>

<p>The lead reviewer assigned to your submission is me, Suvajyoti Guha. The file is being reviewed in Office of Health Technology 7, Division of Chemistry and Toxicology Devices. The first line supervisor is the Assistant Director, Diabetes. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.</p>

<p>We will contact you should we require any additional information during the course of the substantive review. FDA aims to apply the least burdensome principles when requesting additional information. </p>

<p>If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.</p>

<p>*** This is a system-generated email notification ***</p>