

MAR 24 2014

**510(k) SUMMARY
K133593**

Tandem Diabetes Care, Inc. t:slim™ Insulin Delivery System

**Submitter's Name, Address, Telephone Number, Contact Person
and Date Prepared**

Tandem Diabetes Care, Inc.
11045 Roselle Street, Suite 200
San Diego, CA 92121
Phone: 858-255-6331
Facsimile: 858-362-7070

Contact Person: John Sheridan, COO
Contact Email: Jsheridan@tandemdiabetes.com

Date Prepared: November 22, 2013

Common or Usual Name

Insulin infusion pump

Classification Name

Infusion Pump per 21 CFR 880.5725

Predicate Devices

Tandem Diabetes Care, Inc. t:slim™ Insulin Delivery System (K111210)

Purpose of the Special 510(k) notice.

The purpose of this Special 510(k) is to provide an update on the changes made to the cartridge of the t:slim™ Insulin Delivery System. Specifically, the modifications include material/supplier changes to the insulin reservoir, luer, patient line tubing, UV adhesive and the outer pouch of the cartridge.

Intended Use

The t:slim™ Insulin Delivery System is indicated for the subcutaneous delivery of insulin at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater.

Device Description

The t:slim™ Insulin Delivery System is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The scope of this Special 510(k) is limited to changes to the cartridge configuration of the t:slim System.

The t:slim System with the modified cartridge, like the predicate device, consists of the following components and accessories:

1. a software-controlled, programmable insulin infusion pump ("t:slim Pump" or "Pump"),
2. a dedicated, disposable 3mL (300 unit) insulin cartridge ("cartridge");
3. an UnoMedical Comfort™ Infusion Set (K051264), or an equivalently FDA cleared infusion set ("infusion set"); and
4. accessories, including a Becton Dickinson 3mL sterile syringe and 26 gauge sterile needle, or equivalently cleared syringe and needle, as well as an AC power supply with USB for charging the Pump's internal battery, cartridge Instructions for Use, and User's Guide.

The t:slim Pump is a battery operated infusion pump capable of both basal and bolus delivery of insulin. It utilizes a motor-driven mechanism to deliver insulin from within a disposable cartridge, through an infusion set, into a patient's subcutaneous tissue. As with current insulin infusion pumps on the U.S. market, the desired timing and quantity of the insulin delivery is programmed by the user (*i.e.*, the patient). The graphical user interface (GUI) of the t:slim Pump is a capacitive touch screen that displays information used to control the t:slim System. The delivery of insulin is accomplished through a micro-syringe within the head of the cartridge.

The t:slim cartridge is a single-use device, individually packaged and sealed, and provided sterile. The cartridge attaches to the t:slim Pump and is designed to hold up to 3 mL, or 300 units, of insulin. The delivery of insulin is accomplished through a micro-syringe within the head of the cartridge. The Pump has a pressure measurement sensor to estimate the volume of insulin in the insulin reservoir by measuring air pressure in the cartridge. This information is used to provide feedback to the software to determine the insulin volume, detect occlusions and cartridge removal.

Technological Characteristics

The t:slim Insulin Delivery System with modified cartridge has the same technological characteristics as the predicate device. The t:slim System consists of: (1) a software-controlled, programmable insulin infusion pump capable of both basal and bolus delivery of insulin ("t:slim Pump"); (2) a dedicated disposable 3mL (300 unit) insulin cartridge; (3) UnoMedical's Comfort™ Infusion Set (K051264), or an equivalently cleared set; and (4) additional device accessories including a sterile syringe and needle (for cartridge filling) and AC power supply with USB. The material changes were qualified per original device specifications and were shown to meet design requirements.

Performance Data

Verification and qualification testing was performed based on an evaluation of risks for the type of change involved. All the changes made to the cartridge were assessed to make sure all the risks were mitigated (*e.g.*, the infusion flow accuracy, fill volume accuracy, leakage, bond strength and tubing integrity, shelf life, biocompatibility, insulin compatibility *etc.*,) and that no new risks were introduced as a result of these modifications. Material changes were supported by selection of medical grade materials, confirmation of biocompatibility testing per ISO 10993-1, repeated cytotoxicity testing, and leachables/extractables evaluation. Cartridge material changes were also evaluated by specific performance tests to confirm suitability of the material in the production

process through various installation, operational and performance qualification tests (IQ/OQ/PQ), and product inspection and release testing. Completed testing to support substantial equivalence determination include:

- Extractable and Leachables testing
- Chemical composition comparison (FTIR)
- Patient line bond strength testing
- Cartridge Pressure/leak testing
- Package seal integrity testing
- Production IQ/OQ/PQ
- Infusion flow accuracy
- Fill volume accuracy
- Biocompatibility tests
- Insulin Compatibility

Substantial Equivalence

The t:slim System with modified cartridge has the same intended use and indications for use, the same principles of operation, and same technological characteristics as the previously cleared predicate t:slim System. The purpose of this Special 510(k) is to update the materials used in the construction of the disposable cartridge and storage pouch. The verification and process qualification testing confirms that these changes meet the original product specifications. Thus, the proposed t:slim System is substantially equivalent to its predicate.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 24, 2014

John Sheridan
Chief Operating Officer
Tandem Diabetes Care, Inc.
11045 Roselle Street, #200
San Diego, California 92121

Re: K133593

Trade/Device Name: t:slim™ Insulin Delivery System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZG
Dated: February 27, 2014
Received: February 28, 2014

Dear Mr. Sheridan:

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 (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. 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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Mr. Sheridan

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kwame O. Ulmer -S for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number (if known)

K133593

Device Name

t:slim™ Insulin Delivery System

Indications for Use (Describe)

The t:slim™ Insulin Delivery System is indicated for the subcutaneous delivery of insulin at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 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)**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.****FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Digitally signed by Richard C.
Chapman

Date: 2014.03.24 10:38:28 -04'00'

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

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

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K 133593/A001



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FDA CDRH DMC

FEB 24 2014

Received

February 24, 2013

BY HAND DELIVERY

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Attn: Leslie Landree, Ph.D., Branch Chief, Diabetes Branch, Division of Chemistry and Toxicology Devices

Re: Tandem Diabetes Care, Inc.'s t:slim™ Insulin Delivery System (K133593) and t:slim G4™ Insulin Pump with Dexcom G4® Platinum CGM System (Q131013) – Notification of Authorization – Additional Official Correspondent

Dear Dr. Landree:

On behalf of our client Tandem Diabetes Care, Inc., we are writing to advise the Food and Drug Administration ("FDA" or the "agency") of an additional submission correspondent for the regulatory files related to the company's t:slim™ Insulin Delivery System (K133593) and t:slim G4™ Insulin Pump with Dexcom G4® Platinum CGM System (Q131013). For purposes of future interactions with the agency going forward, John Sheridan, chief operating officer for Tandem Diabetes Care, Inc., is authorized as an additional official correspondent to discuss these matters with FDA on the company's behalf. Mr. Sheridan should be the primary FDA contact on all future correspondence; I will remain as an additional correspondent. Mr. Sheridan's contact information is as follows:

John Sheridan
Tandem Diabetes Care, Inc.
11045 Roselle Street, #200
San Diego, CA 92121
Telephone: (858) 255-6345
Facsimile: (858) 362-7070
E-mail: JSheridan@tandemdiabetes.com

An electronic copy ("eCopy") is being provided with this submission, and the eCopy is an exact duplicate of the paper copy.

If you have any questions, please do not hesitate to contact me directly.

78

Sincerely,



Janice Hogan
Partner

janice.hogan@hoganlovells.com
D +1 267 675 4611

cc: John Sheridan, Tandem Diabetes Care, Inc.

Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, PA 19103
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February 24, 2013

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Document Mail Center – W066-G609
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Silver Spring, Maryland 20993-0002

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Re: Tandem Diabetes Care, Inc.'s t:slim™ Insulin Delivery System (K133593) and t:slim G4™ Insulin Pump with Dexcom G4® Platinum CGM System (Q131013) – Notification of Authorization – Additional Official Correspondent

Dear Dr. Landree:

On behalf of our client Tandem Diabetes Care, Inc., we are writing to advise the Food and Drug Administration (“FDA” or the “agency”) of an additional submission correspondent for the regulatory files related to the company’s t:slim™ Insulin Delivery System (K133593) and t:slim G4™ Insulin Pump with Dexcom G4® Platinum CGM System (Q131013). For purposes of future interactions with the agency going forward, John Sheridan, chief operating officer for Tandem Diabetes Care, Inc., is authorized as an additional official correspondent to discuss these matters with FDA on the company's behalf. Mr. Sheridan should be the primary FDA contact on all future correspondence; I will remain as an additional correspondent. Mr. Sheridan's contact information is as follows:

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E-mail: JSheridan@tandemdiabetes.com

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Sincerely,



Janice Hogan
Partner

janice.hogan@hoganlovells.com
D +1 267 675 4611

cc: John Sheridan, Tandem Diabetes Care, Inc.



Phone: (858) 366-6900
Fax: (858) 362-7070
11045 Roselle Street
San Diego, California 92121
www.tandemdiabetes.com

K133593 / 19002

March 24, 2014

By Messenger

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA CDRH DMC

MAR 24 2014

Received

Attn: Leslie Landree, Ph.D., Branch Chief, Diabetes Branch, Division of Chemistry and Toxicology Devices

Re: Tandem Diabetes Care Inc.'s t:slim™ Insulin Delivery System (K133593) and t:slim G4™ Insulin Pump with Dexcom G4® Platinum CGM System (Q131013) – Notification of Authorization – Revised Primary and Secondary Correspondent

Dear Dr. Landree:

Tandem Diabetes Care, Inc. ("Tandem" or the "Company"), is writing to advise the Food and Drug Administration ("FDA" or the "Agency") of an additional submission correspondent for the regulatory files related to the company's t:slim™ Insulin Delivery System (K133593) and t:slim G4™ Insulin Pump with Dexcom G4® Platinum CGM System (Q131013). For purposes of future interactions with the agency going forward, Jenny Fam, who is Tandem's Director of Regulatory Affairs, is authorized as the official correspondent to discuss these matters with FDA on the company's behalf. She should be the primary FDA contact on all future correspondence, and I should be listed as the secondary correspondent. Ms. Fam's contact information is as follows:

Jenny Fam
Tandem Diabetes Care, Inc.
11045 Roselle Street, #200
San Diego, CA 92121
Telephone: (858) 255-6537
Facsimile: (858) 224-1022
E-mail: JFam@tandemdiabetes.com

An electronic copy ("eCopy") is being provided with this submission, and the eCopy is an exact duplicate of the paper copy.

If you have any questions, please do not hesitate to contact me directly.

600

Sincerely,

A handwritten signature in blue ink, appearing to read "John Sheridan".

John Sheridan
Chief Operating Officer
Tandem Diabetes Care, Inc.

cc: Janice Hogan, Hogan Lovells US LLP
Jenny Fam, Tandem Diabetes Care, Inc.



Phone: (858) 366-6900
Fax: (858) 362-7070
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San Diego, California 92121
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John Sheridan
Chief Operating Officer
Tandem Diabetes Care, Inc.

cc: Janice Hogan, Hogan Lovells US LLP
Jenny Fam, Tandem Diabetes Care, Inc.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 24, 2014

John Sheridan
Chief Operating Officer
Tandem Diabetes Care, Inc.
11045 Roselle Street, #200
San Diego, California 92121

Re: K133593

Trade/Device Name: t:slim™ Insulin Delivery System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZG
Dated: February 27, 2014
Received: February 28, 2014

Dear Mr. Sheridan:

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Page 2 – Mr. Sheridan

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Sincerely yours,

Kwame O. Ulmer -S

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 3 – Mr. Sheridan

Concurrence & Template History Page

[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K133593

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Alan Stevens
Branch Chief Sign-Off	Richard Chapman
Division Sign-Off	Kwame O. Ulmer-S 2014.03.24 14:42:42 -04'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1 st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".
4/2/2013	M. McCabe Janicki	Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)..." Replaced broken Compliance link with general link to DSMICA.
4/12/2013	Margaret McCabe	Fixed a typo: Paragraph 1, final sentence, "We remind you,

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement on last page.

510(k) Number (if known)
K133593

Device Name
t:slim™ Insulin Delivery System

Indications for Use (Describe)

The t:slim™ Insulin Delivery System is indicated for the subcutaneous delivery of insulin at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Digitally signed by Richard C.
Chapman

Date: 2014.03.24 10:38:28 -04'00'

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PRASaff@fda.hhs.gov

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(b) (5)



K133593



Hogan Lovells US LLP
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November 22, 2013

By Messenger

510(k) 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

FDA CDRH DMC
NOV 22 2013
Received

Attention: Division of Anesthesiology, General Hospital, Infection Control and Dental Devices

Re: Special 510(k): Device Modification for Tandem Diabetes Care™, Inc.'s
t:slim™ Insulin Delivery System

(b) (4)

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), Tandem Diabetes Care, Inc. ("Tandem" or the "Company"), by its regulatory counsel, is submitting the attached Special 510(k) premarket notification ("Special 510(k)") for its t:slim™ Insulin Delivery System ("t:slim System" or "t:slim") for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater. According to the instructions on the Food and Drug Administration ("FDA" or the "Agency") website, an electronic copy ("eCopy") is provided with this submission and the eCopy is an exact duplicate of the paper copy.

The Tandem t:slim™ Insulin Delivery System is an Insulin Infusion Pump, product code LZG, General Hospital Device Classification Panel, per 21 CFR 880.5725. The t:slim System consists of the following components and accessories: (1) a software-controlled, programmable insulin infusion pump ("t:slim Pump") capable of both basal and bolus delivery of insulin; (2) a dedicated, disposable 3mL (300 unit) insulin cartridge; (3) UnoMedical's Comfort™ Infusion Set (K051264), or an equivalently cleared set; and (4) additional device accessories including a Becton Dickinson 3mL sterile syringe and 26 gauge sterile needle, or equivalently cleared syringe and needle, as well as an AC power supply with USB for charging the Pump's internal battery, cartridge Instructions for Use, and User's Guide.

The scope of this Special 510(k) is limited to the disposable insulin cartridge component of Tandem's t:slim System. Since Tandem follows the principles and guidance described in FDA's January 10, 1997, *Deciding When to Submit a 510(k) for a Change to an Existing Device*, any other

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VDC - 031162/000001 - 5257904 v1

56

changes to the device that the company determines meet the threshold for a 510(k) submission will be reported in future submissions.

The t:slim System with modified cartridge has the same intended use and indications for use, technological characteristics, and principles of operation as the cleared t:slim System. As explained in the attached Special 510(k), the differences between the modified t:slim cartridge and the previously cleared System's cartridge do not raise any new questions of safety or effectiveness. Risk analysis and verification confirm that the modified cartridge is substantially equivalent to the corresponding component of the predicate.

In accordance with the Medical Device User Fee and Modernization Act Amendments of 2012 (MDUFMA III), Tandem has submitted the appropriate application fee. A copy of the User Fee Cover Sheet for this Special 510(k) is provided in **Attachment 7** of this submission.

The information contained herein was provided by Tandem Diabetes Care, Inc. to Hogan Lovells US for submission to the Agency and Tandem is solely responsible for the accuracy and completeness of this submission. We trust that the information provided in the Special 510(k) is sufficient for FDA to find the modified t:slim System substantially equivalent to its predicate device. If you have any additional questions regarding the Special 510(k), please contact me at the phone number below or Ron Warren, Director, Regulatory Affairs, Tandem Diabetes Care at (858) 255-6331. Upon a finding of substantial equivalence, please fax the substantial equivalence letter to me at (267) 675-4601.

Sincerely,



Janice Hogan
Partner
Janice.hogan@hoganlovells.com
D +1 267 675-4600

Attachments

cc: Ron Warren, Director, Regulatory Affairs, Tandem Diabetes Care
Susan Tiedy-Stevenson, Senior Director, Regulatory Sciences, Hogan Lovells US LLP



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November 22, 2013

By Messenger

510(k) 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

Attention: Division of Anesthesiology, General Hospital, Infection Control and Dental Devices

Re: Special 510(k): Device Modification for Tandem Diabetes Care™, Inc.'s
t:slim™ Insulin Delivery System

USER FEE No. (b)(4) Testing

Dear Sir or Madam:

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), Tandem Diabetes Care, Inc. ("Tandem" or the "Company"), by its regulatory counsel, is submitting the attached Special 510(k) premarket notification ("Special 510(k)") for its t:slim™ Insulin Delivery System ("t:slim System" or "t:slim") for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater. According to the instructions on the Food and Drug Administration ("FDA" or the "Agency") website, an electronic copy ("eCopy") is provided with this submission and the eCopy is an exact duplicate of the paper copy.

The Tandem t:slim™ Insulin Delivery System is an Insulin Infusion Pump, product code LZG, General Hospital Device Classification Panel, per 21 CFR 880.5725. The t:slim System consists of the following components and accessories: (1) a software-controlled, programmable insulin infusion pump ("t:slim Pump") capable of both basal and bolus delivery of insulin; (2) a dedicated, disposable 3mL (300 unit) insulin cartridge; (3) UnoMedical's Comfort™ Infusion Set (K051264), or an equivalently cleared set; and (4) additional device accessories including a Becton Dickinson 3mL sterile syringe and 26 gauge sterile needle, or equivalently cleared syringe and needle, as well as an AC power supply with USB for charging the Pump's internal battery, cartridge Instructions for Use, and User's Guide.

The scope of this Special 510(k) is limited to the disposable insulin cartridge component of Tandem's t:slim System. Since Tandem follows the principles and guidance described in FDA's January 10, 1997, *Deciding When to Submit a 510(k) for a Change to an Existing Device*, any other

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VDC - 031162/000001 - 5257904 v1

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

changes to the device that the company determines meet the threshold for a 510(k) submission will be reported in future submissions.

The t:slim System with modified cartridge has the same intended use and indications for use, technological characteristics, and principles of operation as the cleared t:slim System. As explained in the attached Special 510(k), the differences between the modified t:slim cartridge and the previously cleared System's cartridge do not raise any new questions of safety or effectiveness. Risk analysis and verification confirm that the modified cartridge is substantially equivalent to the corresponding component of the predicate.

In accordance with the Medical Device User Fee and Modernization Act Amendments of 2012 (MDUFMA III), Tandem has submitted the appropriate application fee. A copy of the User Fee Cover Sheet for this Special 510(k) is provided in **Attachment 7** of this submission.

The information contained herein was provided by Tandem Diabetes Care, Inc. to Hogan Lovells US for submission to the Agency and Tandem is solely responsible for the accuracy and completeness of this submission. We trust that the information provided in the Special 510(k) is sufficient for FDA to find the modified t:slim System substantially equivalent to its predicate device. If you have any additional questions regarding the Special 510(k), please contact me at the phone number below or Ron Warren, Director, Regulatory Affairs, Tandem Diabetes Care at (858) 255-6331. Upon a finding of substantial equivalence, please fax the substantial equivalence letter to me at (267) 675-4601.

Sincerely,



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Janice.hogan@hoganlovells.com
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Attachments

cc: Ron Warren, Director, Regulatory Affairs, Tandem Diabetes Care
Susan Tiedy-Stevenson, Senior Director, Regulatory Sciences, Hogan Lovells US LLP

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET		Form Approval OMB No. 9010-0120 Expiration Date: December 31, 2013 See OMB Statement on page 5.	
Date of Submission November 22, 2013		User Fee Payment ID Number (b) (4)	
		FDA Submission Document Number (if known) To be assigned	
SECTION A TYPE OF SUBMISSION			
PMA ☐ Original Submission ☐ Premarket Report ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment ☐ Licensing Agreement	PMA & HDE Supplement ☐ Regular (180 day) ☐ Special ☐ Panel Track (PMA Only) ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA & HDE Supplement ☐ Other	PDP ☐ Original PDP ☐ Notice of Completion ☐ Amendment to PDP	510(k) ☒ Original Submission: ☐ Traditional ☒ Special ☐ Abbreviated Complete section I, Page 5) ☐ Additional Information ☐ Third Party
IDE ☐ Original Submission ☐ Amendment ☐ Supplement	Humanitarian Device Exemption (HDE) ☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment	Class II Exemption Petition ☐ Original Submission ☐ Additional Information	Evaluation of Automatic Class III Designation (De Novo) ☐ Original Submission ☐ Additional Information
		Meeting ☐ Pre-510(K) Meeting ☐ Pre-IDE Meeting ☐ Pre-PMA Meeting ☐ Pre-PDP Meeting ☐ Day 100 Meeting ☐ Agreement Meeting ☐ Determination Meeting ☐ Other (specify):	
		Other Submission ☐ 513(g) ☐ Other (describe submission):	
Have you used or cited Standards in your submission? ☐ Yes ☐ No (If Yes, please complete Section I, Page 5)			
SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name Tandem Diabetes Care, Inc.		Establishment Registration Number (if known) 3007981285	
Division Name (if applicable)		Phone Number (including area code) (858) 255-6331	
Street Address 11045 Roselle Street Suite 200		FAX Number (including area code) (858) 362-7070	
City San Diego	State / Province CA	ZIP/Postal Code 92121	Country USA
Contact Name Ron Warren			
Contact Title Director, Regulatory Affairs		Contact E-mail Address RWarren@tandemdiabetes.com	
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name Hogan Lovells US LLP		Phone Number (including area code) (267) 675-4600	
Division Name (if applicable)		FAX Number (including area code) (267) 675-4601	
Street Address 1835 Market Street, 29 th Floor		FAX Number (including area code) (267) 675-4601	
City Philadelphia	State / Province PA	ZIP/Postal Code 19103	Country USA
Contact Name Janice Hogan			
Contact Title Partner		Contact E-mail Address Janice.hogan@hoganlovells.com	

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

☐ New Device ☐ Withdrawal ☐ Additional or Expanded Indications ☐ Request for Extension ☐ Post-approval Study Protocol ☐ Request for Applicant Hold ☐ Request for Removal of Applicant Hold ☐ Request to Remove or Add Manufacturing Site	☐ Change in design, component, or specification: ☐ Software / Hardware ☐ Color Additive ☐ Material ☐ Specifications ☐ Other (<i>specify below</i>)	☐ Location change: ☐ Manufacturer ☐ Sterilizer ☐ Packager
☐ Process change: ☐ Manufacturing ☐ Packaging ☐ Sterilization ☐ Other (<i>specify below</i>)	☐ Labeling change: ☐ Indications ☐ Instructions ☐ Performance Characteristics ☐ Shelf Life ☐ Trade Name ☐ Other (<i>specify below</i>)	☐ Report Submission: ☐ Annual or Periodic ☐ Post-approval Study ☐ Adverse Reaction ☐ Device Defect ☐ Amendment
☐ Response to FDA correspondence:		☐ Change in Ownership ☐ Change in Correspondent ☐ Change of Applicant Address
☐ Other Reason (<i>specify</i>):		

SECTION D2 REASON FOR APPLICATION – IDE

☐ New Device ☐ New Indication ☐ Addition of Institution ☐ Expansion / Extension of Study ☐ IRB Certification ☐ Termination of Study ☐ Withdrawal of Application ☐ Unanticipated Adverse Effect ☐ Notification of Emergency Use ☐ Compassionate Use Request ☐ Treatment IDE ☐ Continued Access	☐ Change in: ☐ Correspondent / Applicant ☐ Design / Device ☐ Informed Consent ☐ Manufacturer ☐ Manufacturing Process ☐ Protocol - Feasibility ☐ Protocol - Other ☐ Sponsor ☐ Report submission: ☐ Current Investigator ☐ Annual Progress Report ☐ Site Waiver Report ☐ Final	☐ Response to FDA Letter Concerning: ☐ Conditional Approval ☐ Deemed Approved ☐ Deficient Final Report ☐ Deficient Progress Report ☐ Deficient Investigator Report ☐ Disapproval ☐ Request Extension of Time to Respond to FDA ☐ Request Meeting ☐ Request Hearing
☐ Other Reason (<i>specify</i>):		

SECTION D3 REASON FOR SUBMISSION - 510(k)

☐ New Device	☐ Additional or Expanded Indications	☐ Change in Technology
☒ Other Reason (<i>specify</i>): Special 510(k) for packaging and materials update, and use of automated processing steps.		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information ☒ 510 (k) summary attached ☐ 510 (k) statement
1	LZG	2		
5		6		

Information on devices to which substantial equivalence is claimed (if known)

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1 K111210	1 t:slim™ Insulin Delivery System	1 Tandem Diabetes Care, Inc.
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Insulin Infusion Pump	
Trade or Proprietary or Model Name for This Device	Model Number
1 t:slim™ Insulin Delivery System	1 N/A
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome)

1 K111210	2 K101727	3 K092394	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing☐ Animal Trials☐ Human Trials**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code LZG	C.F.R. Section (if applicable) 880.5725	Device Class ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification Panel General Hospital		

Indications (from labeling)

The t:slim™ Insulin Delivery System is indicated for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number *(if known)*
To be assigned

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

(b) (4)

☒ Original ☐ Add	Facility Establishment Identifier (FEI) Number 10039506	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name Tandem Diabetes Care, Inc.		Establishment Registration Number 3007981285		
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i> (858) 255-6331		
Street Address 11045 Roselle Street Suite 200		FAX Number <i>(including area code)</i> (858) 362-7070		
City San Diego		State / Province CA	ZIP Code 92121	Country USA
Contact Name Ron Warren		Contact Title Director, Regulatory Affairs		Contact E-mail Address RWarren@tandemdiabetes.com
☐ Original ☐ Add	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i>		
Street Address		FAX Number <i>(including area code)</i>		
City		State / Province	ZIP Code	Country
Contact Name		Contact Title		Contact E-mail Address

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

1	Standards No. 2-156	Standards Organization ISO 10993-1:2009	Standards Title Biological evaluation of medical devices – Part 1: Evaluation and testing	Version	Date 2009
2	2-153	ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity		2009
3	14-297	ISO 11137-1:2006 (R)2010	Sterilization of health care products- Radiation-Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices		2006(R)2010
4	5-40	ISO 14971:2007	Medical Devices – Application of risk management to medical devices		2007
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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.

Refuse to Accept Checklist for Special 510(k)s

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) Number: _____ **Date Received:** _____

Lead Reviewer Name: _____ **Branch:** _____ **Division:** _____ **Office:** _____

Special 510(k) Criteria		
The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.		
	Yes	No
1. 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	✓	
Comments:		
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	✓	
Comments:		
3. Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	✓	
Comments:		
4. The submission includes only summary-level information (i.e., NO test reports with performance data).	✓	
Comments:		

Does the submission meet all 4 criteria above?

- ☒ Yes, submission meets criteria for a Special 510(k). Continue with the remainder of this checklist below.
- ☐ No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist; convert to a Traditional and apply the Traditional checklist.

<u>Organizational Elements</u>			
<i>Failure to include these items alone generally should not result in an RTA designation</i>			
	Yes	No	Comments/ Page
a. Submission contains Table of Contents	✓		Page 019
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	✓		
c. 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>	✓		
Comments:			

<u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u>					
Submission should be designated RTA if not addressed					
Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.					
	- Any “No” answer will result in a “Refuse to Accept” decision. - 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.	Yes	N/A	No	Comments/ Page
A.	Administrative				
1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒		☐	
	Comments:				
2.	510(k) Cover letter that identifies: at a minimum:	☐		☐	
a.	Device trade name or proprietary name	☒		☐	Cover Letter
b.	Device common name	☒		☐	Cover Letter

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	- Any "No" answer will result in a "Refuse to Accept" decision. - 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.	Yes	N/A	No	Comments/ Page
	c. Device class and panel	☒		☐	Cover Letter
	Comments:				
3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also and 801.109) <i>Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.</i>	☒		☐	Attachment 6
	Comments:				
4.	Submission contains 510(k) Summary or 510(k) Statement <i>Either a) or b) must be answered "Yes" to be considered complete.</i> <i>Identify any missing element(s) as Comments.</i>	☒		☐	Attachment 5
a.	Summary contains all elements per 21 CFR 807.92 <i>See also 510(k) Summary Checklist</i>	☒	☐	☐	Attachment 5
b.	Statement contains all elements per 21 CFR 807.93	☐	☒	☐	
	Comments:				
5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) <i>See recommended format</i>	☒		☐	Attachment 8
	Comments:				
6.	Submission contains Class III Summary and Certification <i>See recommended content</i> <i>Form should be signed by a responsible person of the firm, not a consultant. CDRH is not currently able to accept a digital</i>	☐	☒	☐	

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	- Any "No" answer will result in a "Refuse to Accept" decision. - 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.	Yes	N/A	No	Comments/ Page	
	signature. <i>"N/A" only if submission is not a Class III 510(k).</i>					
	Comments:					
7.	If submission relies upon a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed. <i>There should be a completed form for each referenced national or international standard.</i> <i>"N/A" only if submission does not reference any standards.</i>	☒	☐	☐	Attachment 1	
	Comments:					
8.	If this is a bundled submission, the submission has been appropriately bundled [i.e., the correct user fee(s) have been paid for the devices/indications (Section 738 FD&C Act)] See Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission. <i>"N/A" if not a bundled submission</i>	☐	☒	☐		
	Comments:					
9.	The submission identifies related submissions for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions.		☒	☐		
a.	If there are related submissions, within current submission, the sponsor has identified where in the current submission any issues related to substantial		☒	☐		

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)							
Submission should be designated RTA if not addressed							
Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.							
				Yes	N/A	No	Comments/ Page
	•	Any “No” answer will result in a “Refuse to Accept” decision.					
	•	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.					
			equivalence outlined in prior communications are addressed.				
		Comments:					
B.	Device Description						
	10.	If there is a device-specific guidance document or special controls applicable to this submission, documentation has been provided to establish that the submitter has followed the recommendations in the applicable device-specific guidance document or special controls regarding the device description or otherwise met the applicable statutory or regulatory criteria through an alternative approach. <i>Select “No” if the submission does not include a rationale for any omitted information or any alternative approaches. Select “N/A” if there is no device-specific guidance document</i>		☒	☐	☐	
		Comments: <i>Guidance for Industry and FDA Staff – Total Product Life Cycle: Infusion Pump – Premarket Notification [510(k)] Submissions, Draft Guidance (April 23, 2010)</i>					
	11.	All descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:					
		a.	A description of the principle of operation and mechanism of action for achieving the intended therapeutic/diagnostic effect.	☒		☐	Section VI
		b.	A description of all 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.	☒		☐	Section VI

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)							
Submission should be designated RTA if not addressed							
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
				Yes	N/A	No	Comments/ Page
		- Any "No" answer will result in a "Refuse to Accept" decision. - 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.					
		c.	A list and description of each model for which clearance is requested. <i>Select "N/A" if there is only one model.</i>	☒	☐	☐	Section VI
		Comments:					
		12.	A description of all device modification(s) including rationale for each modification.	☒		☐	Sections VI and VII
		Comments:					
		13.	Identification of history of changes made to device since the previous 510(k) clearance	☒		☐	Sections VI and VII
		Comments: The scope of this submission is limited to the t:slim cartridge					
		14.	Where applicable, submission contains engineering drawing(s), schematics, illustrations and/or figures of the device that are clear and legible, and include dimensions	☒	☐	☐	Section VI
		a.	If engineering drawings, schematics, illustrations and/or figures are provided, one is provided for each model to be marketed	☒	☐	☐	Section VI
		Comments:					
		15.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, <i>Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.</i>		☐		
		a.	A description (as detailed in item #12.a. and b. and 14 above) is provided for each component or accessory.	☒		☐	Sections VI and VII

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)								
Submission should be designated RTA if not addressed								
Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.								
- Any “No” answer will result in a “Refuse to Accept” decision. - 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.					Yes	N/A	No	Comments/ Page
		b.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. <i>Select “N/A” if the submission states that the component(s)/ accessory(ies) do not have a prior 510(k) clearance.</i>	☒	☐	☐	Section VII	
		Comments:						
C. Substantial Equivalence Discussion								
		16.	Submitter has identified a predicate(s) device	☒	☐	☐	Section VII	
		a.	Predicate’s 510(k) number, trade name, and model number (if applicable) provided	☒	☐	☐	Section VII and Attachment 5	
		b.	The identified predicate(s) is consistent throughout the submission (i.e., 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)	☒	☐	☐	Section VII and Attachment 5	
		Comments:						
		17.	Submission includes a comparison of the following for the predicate(s) and subject device	☐	☐	☐		
		a.	Indications for use	☒	☐	☐	Section VII and Attachment 5	
		b.	Technology, including features, materials, and principles of operation	☒	☐	☐	Section VII and Attachment 5	
		Comments:						

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	- Any "No" answer will result in a "Refuse to Accept" decision. - 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.	Yes	N/A	No	Comments/ Page
18.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(I)(A) of the FD&C Act) <i>If there is no difference between the subject and predicate(s) with respect to the indications or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences.</i>	☒		☐	Section VII and Attachment 5
	Comments:				
D. Design Control Activities					
19.	Design Control Activities Summary includes all of the following:				
a.	Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis	☒		☐	Section IX and Attachment 9
b.	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.	☒		☐	Attachment 9
c.	Declaration of conformity with design controls, including: <i>All 3 must be present to answer "Yes"</i>	☒		☐	Attachment 4
i.	Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met.				Attachment 4

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)						
Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	- Any "No" answer will result in a "Refuse to Accept" decision. - 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.	Yes	N/A	No	Comments/ Page	
	ii.	Statement that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30			Attachment 4	
	iii.	Statement is signed by the individual responsible for these activities			Attachment 4	
	Comments:					
E.	Proposed Labeling (see also 21 CFR part 801)					
20.	Submission includes proposed labels, labeling (e.g., instructions for use, package insert, operator's manual) and advertisements that describe the device, its intended use, and the directions for use		☒		☐	Section V and Attachments 2 and 3
	a.	All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	☒		☐	Section V and Attachments 2 and 3
	Comments:					
21.	Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).		☒		☐	Cover Letter; Sections V and VII; and Attachment 5
	Comments:					
	Comments:					

Decision: Accept _____ Refuse to Accept _____

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Team Leader Signature: _____ **Date:** _____

Supervisory Signature: _____ **Date:** _____

**Tandem Diabetes Care™, Inc.
t:slim™ Insulin Delivery System
Special 510(k): Device Modification**

November 22, 2013

**Tandem Diabetes Care™, Inc.
11045 Roselle Street, Suite 200
San Diego, CA 92121**

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List of Attachments:

Attachment 1: Standard Data Reports
Attachment 2: Modified t:slim Cartridge Instructions for Use
Attachment 3: Predicate t:slim Cartridge Instructions for Use
Attachment 4: Declaration of Conformity with Design Controls
Attachment 5: 510(k) Summary
Attachment 6: Indications for Use Statement
Attachment 7: Medical Device User Fee Cover Sheet
Attachment 8: Truthful and Accuracy Statement
Attachment 9: Summary of Design Verification and Validation Testing to Support Cartridge Changes

The following information is provided as required by 21 C.F.R. § 807.87 (2003) for Tandem Diabetes Care, Inc. t:slim™ Insulin Delivery System Special 510(k) premarket notification:

I. NAME OF DEVICE

Trade Name: t:slim™ Insulin Delivery System

Common Names: Insulin Infusion Pump

Classification Name: Infusion Pump

II. ESTABLISHMENT REGISTRATION NUMBER

Manufacturer: Tandem Diabetes Care, Inc.
11045 Roselle Street, Suite 200
San Diego, CA 92121

Manufacturer Registration Number: 3007981285

III. DEVICE CLASSIFICATION/FDA REVIEWING BRANCH

The FDA General Hospital Devices Panel has classified the Infusion Pump as a Class II device pursuant to 21 C.F.R. § 880.5725. The Insulin Infusion Pump has been assigned product code LZG.

IV. PERFORMANCE STANDARDS

We have reviewed the requirements of Sections 513 and 514 of the Act and are not aware of any requirements of either section applicable to this device. No performance standards or special controls have been developed under Section 514 of the FDC Act for infusion pumps. No special controls apply.

Consistent with FDA's guidance document entitled "Use of Standards in Substantial Equivalence Determinations" (March 12, 2000) and "Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards" (September 17, 2007), Tandem Diabetes Care is including this statement that the modifications of the t:slim™ Insulin Delivery System were implemented based on the following recognized consensus standards instead of providing the test reports demonstrating compliance with these standards:

- ISO 10993-1:2009 – Biological evaluation of medical devices – Part 1: Evaluation and testing
- ISO 10993-5:2009 – Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity
- ISO 11137-1:2006(R)2010 – Sterilization of health care products – Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
- ISO 14971:2007 – Medical devices – Application of risk management to medical devices

A Data Standards Form (FDA Form 3654) is provided in **Attachment 1** for each listed recognized consensus standard.

In addition, Tandem has reviewed the following relevant FDA Guidance Documents, which are applicable to the subject device outlined in this 510(k) notice.

- Guidance for Industry and FDA Staff - Total Product Life Cycle: Infusion Pump - Premarket Notification [510(k)] Submissions (*Draft Guidance*) (April 23, 2010)
- Deciding When to Submit a 510(k) for a Change to an Existing Device, 510(k) Memorandum #K97-1 (January 10, 1997)

V. PROPOSED LABELING

None of the changes described in this Special 510(k) impact the labels or User Guide for the t:slim System. However, since clearance of K111210 for the predicate t:slim System in November 2011, the following modifications have been made to the t:slim Cartridge Instructions for Use to remove potential confusion:

- Information related to minimum fill volume was moved from the “Notes” section of the instructions to be displayed on the pump graphical user interface (GUI). The referenced minimum volume was changed from 0.45 mL to .50 mL to ensure adequate fill volume is confirmed by the pump after tubing has been filled. This is a pump function not controlled by the user so the information related to this instruction is more appropriately shown on the pump display. These modifications do not affect the device’s intended use or indications for use. In accordance with Tandem’s procedures, these minor modifications were verified to confirm conformance with original design specifications. As was verified per the current software requirements specification, the information is displayed on the pump GUI as shown in **Figure 1** below:

If the cartridge is not filled to the minimum fill volume after tubing has been filled, the following screen appears in the load sequence flow.

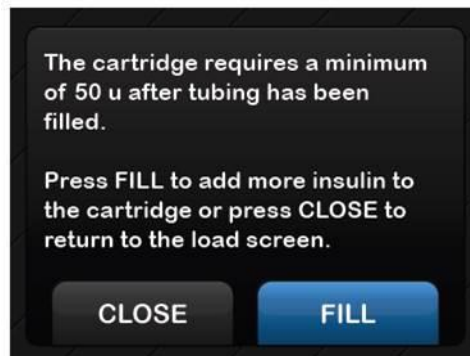


Figure 1

- The Cartridge Instructions for Use were also modified to remove a note regarding the approximate number of units in the pump after cartridge loading and tubing fill. This comment was not precise since actual starting volume is dependent on the amount of insulin used to fill the tubing and patient infusion line tubing length can vary. For instance, a 43” tubing will take more insulin to fill than a 23” tubing and the amount of insulin used to fill the tubing is not included in the starting volume. Cartridge volume is already monitored by the pump software and the estimated cartridge volume is provided on the pump display for the end user.

These modifications do not affect the device’s intended use or indications for use. A copy of the modified t:slim Cartridge Instructions for Use are provided in **Attachment 2**. A copy of the Cartridge Instruction for Use for the predicate device is provided in **Attachment 3**.

VI. DEVICE DESCRIPTION

The t:slim™ Insulin Delivery System is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The scope of this Special 510(k) is limited to changes to the cartridge component of the t:slim System.

The modified t:slim System, like the predicate device, consists of the following components and accessories:

1. a software-controlled, programmable insulin infusion pump (“t:slim Pump” or “Pump”),
2. a dedicated, disposable 3mL (300 unit) insulin cartridge (“cartridge”);
3. an UnoMedical Comfort™ Infusion Set (K051264), or an equivalently FDA cleared infusion set (“infusion set”); and
4. accessories, including a Becton Dickinson 3mL sterile syringe and 26 gauge sterile needle, or equivalently cleared syringe and needle, as well as an AC power supply with USB for charging the Pump’s internal battery, cartridge Instructions for Use, and User’s Guide.

The t:slim Pump with modified cartridge has the same features as the predicate device as shown in **Figure 2**.



FIGURE 2: THE T:SLIM PUMP SHOWN WITH CARTRIDGE

The t:slim cartridge, as shown in **Figure 3**, is labeled as a single-use device and is intended to be replaced at least once every three (3) days, depending on an individual's specific insulin usage or the indications for use of the insulin. It is comprised of the cartridge housing, which protects an inner insulin reservoir, and forms a seal with the housing of the t:slim Pump, a micro-syringe within the cartridge's head, and a patient line with a standard luer connector on the end. Cartridges are individually packaged and sealed, and then gamma sterilized prior to shipping. The housing of the cartridge provides structural integrity and protection for the insulin reservoir, which is a polyethylene bag that is thermally welded to the cartridge head. On the bottom of the cartridge housing is an airtight seal, which is an access point for temperature and pressure sensors.

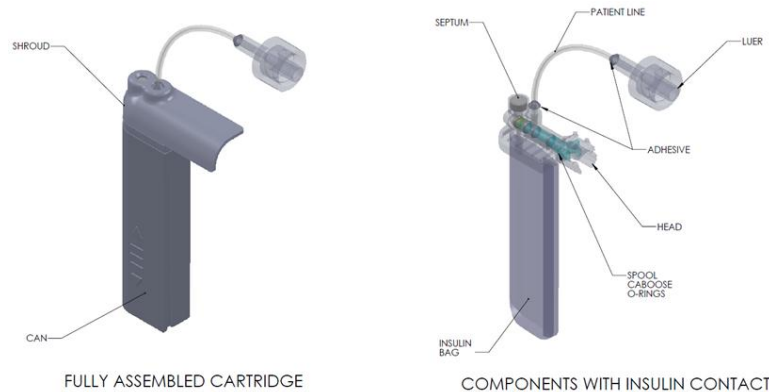
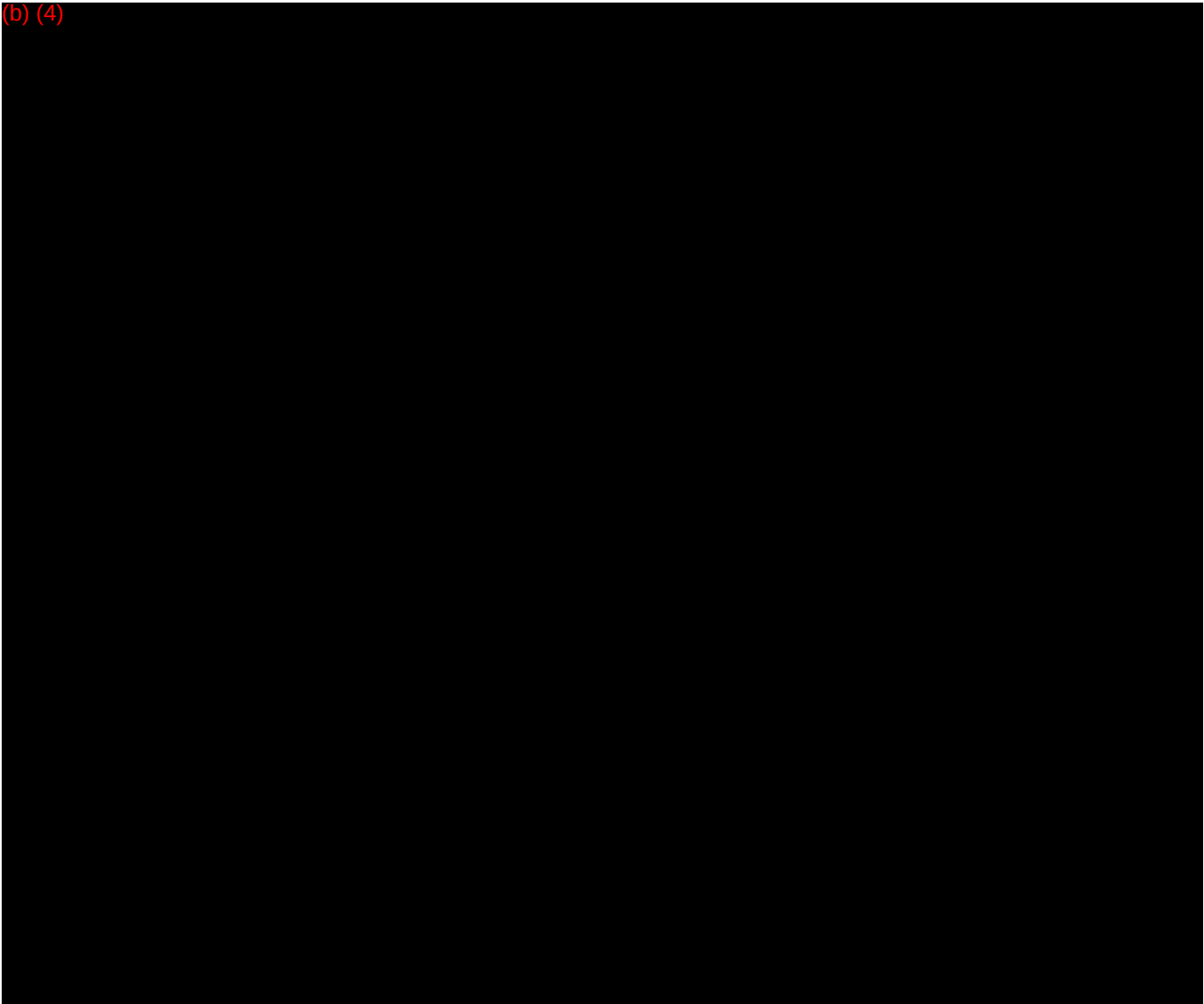


FIGURE 3: CARTRIDGE ON THE T:SLIM PUMP

In the modified cartridge, minor material changes have been made to components that are in contact with the insulin fluid path. As detailed in **Table 1** below, these include a new source for the polyethylene insulin reservoir bag contained within the cartridge housing, a change to the patient line to include an industry-standard UnoMedical polyethylene tubing, and a luer connector change from acrylic to polypropylene commonly used in insulin syringes. In addition, the patient line to luer adhesive was modified to improve bond strength and to facilitate an option to use an automated line/luer bonding process. Lastly, there was a modification to the outer Tyvek layer of the cartridge storage pouch to facilitate automated printing of product information rather than manually applying an adhesive label. Verification testing was performed to qualify all changes and is described in the substantial equivalence summary (**Section VII**) below.

(b) (4)



VII. SUBSTANTIAL EQUIVALENCE

The purpose of this Special 510(k) is to describe modifications to the t:slim System (K111210) cartridge with respect to alternate materials/suppliers used in the construction of the disposable cartridge and storage pouch. These changes do not affect the device intended use or indications for use. The cartridge material modifications are generally related to second sources of component materials that are of the same material type found in the predicate device. The only change in material type was made to the luer connector to utilize a polypropylene resin commonly used in insulin syringes. The changes to material suppliers (second sources) were primarily driven by increased production demands. All material changes were qualified against original device specifications and were shown to meet original design requirements.

Also to facilitate process scale up, there was a modification to the outer Tyvek layer of the cartridge storage pouch. The outer Tyvek layer was changed to include a coated surface to enable the printing of product labeling information directly on the pouch to eliminate use of an adhesive product label. There is no change in the package labeling information nor to the product sterilization process which has been confirmed by a quarterly dose audit.

1. Intended Use and Indications

The t:slim System is intended for the subcutaneous delivery of insulin. The indication for use statement is:

The t:slim Insulin Delivery System is indicated for the subcutaneous delivery of insulin at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater.

Both the intended use and the indication for use remain the same as in the cleared t:slim System (K111210).

2. Technological Characteristics

The modified t:slim cartridge has the same technological characteristics as the predicate device. The t:slim System consists of: (1) a software-controlled, programmable insulin infusion pump capable of both basal and bolus delivery of insulin ("t:slim Pump"); (2) a dedicated disposable 3mL (300 unit) insulin cartridge; (3) UnoMedical's Comfort™ Infusion Set (K051264), or an equivalent cleared infusion set; and (4) additional device accessories including a sterile syringe and needle (for cartridge filling) and AC power supply with USB. The t:slim System and the cartridge component materials are commonly used in electro-mechanical medical equipment.

The changes in this 510(k) notice relate to the disposable insulin cartridge. The cartridge material/supplier changes are primarily related to second sources of material or in the case of the luer connector, an alternate material commonly used in insulin syringes. The modification to the cartridge outer storage pouch was made to facilitate increased production. All material changes were qualified against original device specifications and were shown to meet design requirements. The material changes do not alter the original cartridge requirements specification. Therefore, based on the original design intent of the cartridge, the modifications do not raise new questions of safety or effectiveness. Thus, the modified t:slim System is substantially equivalent to the predicate

device. See **Table 2** for a substantial equivalence chart comparing the similarities and differences between the modified t:slim cartridge and the predicate device.

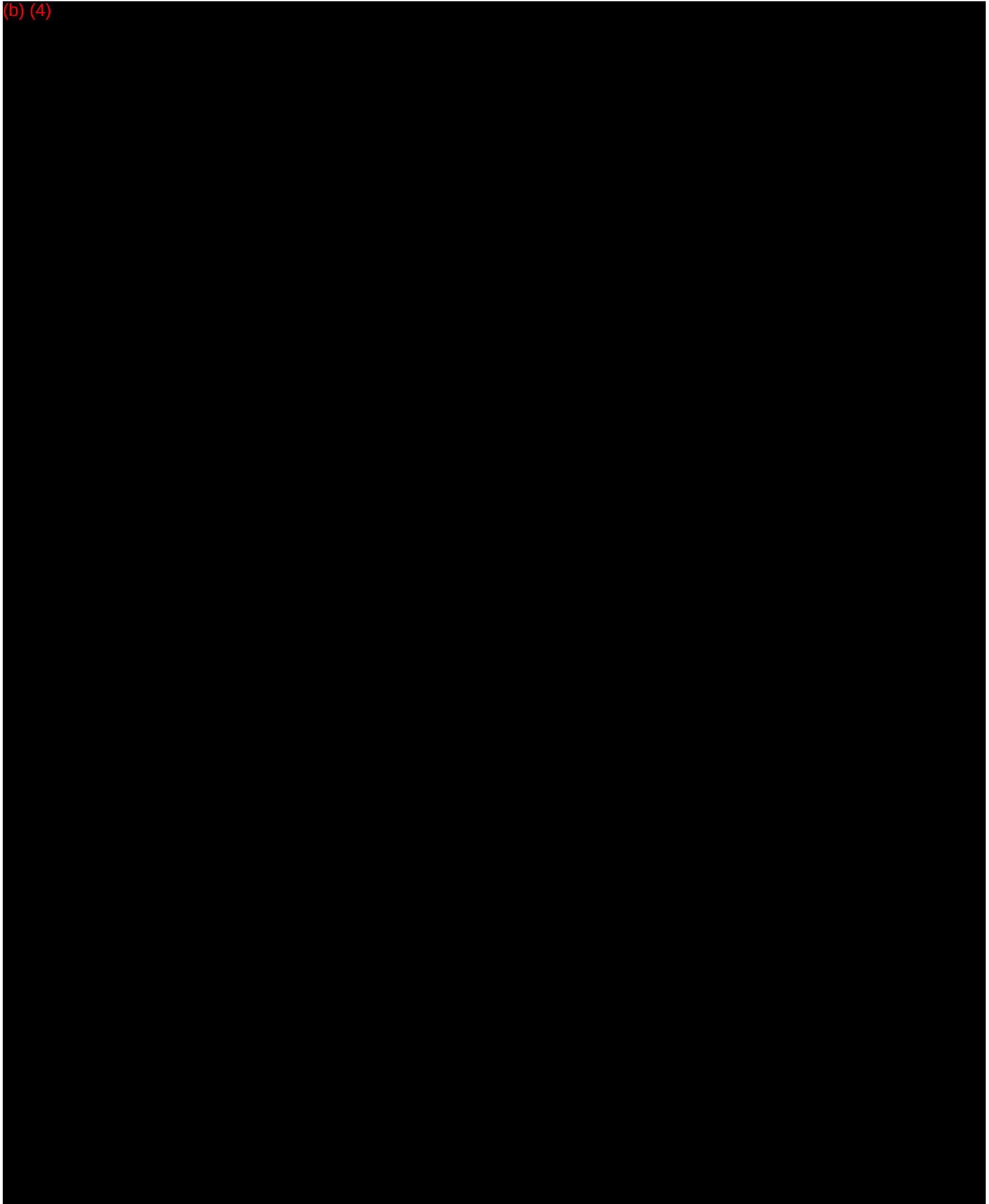
3. Performance Testing

Verification and qualification testing was performed based on the type of change involved. Material changes were supported by selection of medical grade materials, confirmation of biocompatibility testing, repeated toxicity testing, and leachables/extractables evaluation. Cartridge material changes were also evaluated by specific performance tests to confirm suitability of the material in the production process. Changes to the pouch material and the use of new adhesive in the cartridge manufacturing line were evaluated by various installation, operational and performance qualification tests (IQ/OQ/PQ), and confirmed through product inspection and release testing. The test results supporting the cartridge changes are summarized in **Attachment 9**.

3. Conclusion

In summary, the t:slim System with modified cartridge has the same intended use and indications for use as the previously cleared t:slim System (K111210). In addition, the modified t:slim System has the same principles of operation and essentially the same technological characteristics as the predicate device. Although there are minor differences between the modified t:slim System and its predicate device, namely minor component material changes, those differences do not raise new questions of safety or efficacy. Thus, the modified t:slim System is substantially equivalent to the cleared t:slim System.

(b) (4)



VIII. SOFTWARE INFORMATION

This section is not applicable to the scope of this Special 510(k). While the t:slim System utilizes validated software for the control and operation of the pump, this Special 510(k) relates to changes specific to the t:slim cartridge components and manufacturing process.

IX. DESIGN CONTROL INFORMATION

The design and development of the t:slim™ cartridge modifications involved the use of a risk management process. The changes described in this Special 510(k) notification related to the cartridge component of the t:slim System did not introduce any risks not previously identified in the original risk management report. The risk analysis method used to assess the impact of the modifications was based on ISO 14971:2007 Medical devices -- Application of risk management to medical devices. The design verification tests that were performed as a result of this risk analysis assessment are provided in **Attachment 9**.

In addition, Tandem Diabetes Care, Inc. is providing a Declaration of Conformity with design control requirements, (see **Attachment 4**) which includes:

1. A statement that, as required by the risk analysis, all verification and validation activities completed for the cartridge modifications were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met; and
2. A statement that the manufacturing facility is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

These statements are signed by the designated individual responsible for those particular activities.

X. BIOCOMPATIBILITY INFORMATION

As noted in **Table 1** above, the materials of the modified t:slim cartridge have been evaluated as compared to the materials of the predicate device. The modifications are primarily second sources of the same type of material or, in the case of the luer connector material change, the material used is USP VI medical grade commonly used in insulin syringes. The materials have evidence of biocompatibility per ISO 10993-1 requirements and have a safe history of use in other medical device applications. Because second source components were generally of the same material type, their comparability to the original components was confirmed through repeat testing. This testing included cytotoxicity, extractables and leachables evaluation, and chemical composition analysis (FTIR). The results of this testing demonstrated safety of the material and a nearly identical chemical composition profile. Based on these results, the materials were found to meet the product design requirements for biocompatibility.

XI. STERILIZATION / CLEANING / DISINFECTION / SHELF LIFE

As noted in **Table 1** above, the modification to the cartridge outer storage pouch was made so that the package label can be pre-printed on the pouch in lieu of manually applying an adhesive label to the pouch to facilitate increased production volume. There is no change to the way cartridges are individually packaged and sealed, and the gamma sterilization process remains as validated for the predicate device (ISO 11137-2 VDM²⁵ method, sterility assurance level (SAL) = 10^{-6}). A recent quarterly dose audit (inclusive of the outer pouch change) was completed to confirm the continued acceptability of the sterilization cycle. Seal integrity testing was performed to demonstrate that the packaging material meets its original specifications to maintain a sterile barrier.

XII. FINANCIAL DISCLOSURES

Tandem Diabetes Care is not submitting clinical data in support of this Special 510(k) notice. For this reason, FDA's regulation regarding clinical investigators' financial interests and arrangements, i.e., 21 C.F.R. § 54.4, do not apply. Thus, the Company is not providing a disclosure or certification to the absence of any disclosable financial interests or arrangements.

XIII. 510(K) SUMMARY

Attachment 5 of this submission contains the Company's 510(k) Summary.

XIV. CONFIDENTIALITY

Tandem Diabetes Care, Inc. considers its intent to market the modified t:slim™ Insulin Delivery System as confidential commercial information. The Company has not disclosed its intent to submit a premarket notification for this device modification to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore, requests FDA not to disclose the existence of this application until such time as final action on the submission is taken.

In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 C.F.R. § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that

you consult with the Company as provided in 21 C.F.R. § 20.45 before making any part of this submission publicly available.

XV. SUBMITTER'S NAME AND ADDRESS

Tandem Diabetes Care, Inc.
11045 Roselle Street, Suite 200
San Diego, CA 92121

Phone: 858-255-6363

Facsimile: 858-362-7070

XVI. CONTACT PERSON AND TELEPHONE/FACSIMILE NUMBERS

Janice Hogan
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1835 Market Street, 29th Floor

OR

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Facsimile: 858-362-7070

Philadelphia, PA 19103

Phone: (267) 675-4600

Facsimile: (267) 675-4601

As Regulatory Counsel to: Tandem Diabetes Care, Inc.

XVII. MEDICAL DEVICE USER FEE

The Company has remitted the Medical Device User Fee of \$2,480.00 (for a small business) concurrent with this submission to the Food and Drug Administration, A copy of the Medical Device User Fee Cover Page is provided in **Attachment 7**.

XVIII. INDICATIONS FOR USE STATEMENT

The company's Indications for Use Statement for t:slim™ Insulin Delivery System is provided in **Attachment 6**.

XIX. TRUTHFUL AND ACCURACY STATEMENT

The company's signed Truthful and Accuracy statement is included in **Attachment 8**.

Attachment 1

Standards Data Report Forms for Premarket Notifications

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE¹

ISO 10993-1: 2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing

Please answer the following questions

Yes No

Is this standard recognized by FDA²? ☒ ☐

FDA Recognition number³ # 2-156

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☐ ☒
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵? ☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard? ☐ ☒
If yes, was the guidance document followed in preparation of this 510k? ☐ ☐

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 10993-1: 2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. ♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		
Paperwork Reduction Act Statement Public reporting burden for this collection of information is estimated to average 1 hour 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: Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850 <i>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.</i>		

Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE¹

ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in-vitro cytotoxicity

Please answer the following questions

Yes

No

Is this standard recognized by FDA²? ☒ ☐FDA Recognition number³ # 2-153Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).Does this standard include more than one option or selection of tests? ☐ ☒
If yes, report options selected in the summary report table.Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵? ☐ ☐Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.Is there an FDA guidance⁶ that is associated with this standard? ☐ ☒
If yes, was the guidance document followed in preparation of this 510k? ☐ ☐

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier]
[title of standard] [date of publication]² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in-vitro cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
----------------	---------------	--

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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.

Department of Health and Human Services
 Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE ¹

ISO 11137-1:2006/(R)2010-Sterilization of health care products-Radiation-Part 1: Requirements for development, validation

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number ³ # 14-297

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☒ ☐
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☐ ☒
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? ☐ ☒
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? ☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard? ☐ ☒
 If yes, was the guidance document followed in preparation of this 510(k)? ☐ ☐

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 11137-1:2006/(R)2010-Sterilization of health care products-Radiation-Part 1: Requirements for development, validation

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE ¹

ISO 14971:2007-Medical Devices-Application of risk management to medical devices

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number ³ # 5-40

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☐ ☒
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? ☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard? ☒ ☐
If yes, was the guidance document followed in preparation of this 510(k)? ☒ ☐

Title of guidance: Total Product Life Cycle:Infusion Pump-Premarket Notification [510(k)] Submissions Draft Guidance

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISO 14971:2007-Medical Devices-Application of risk management to medical devices		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. ♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		
Paperwork Reduction Act Statement		
Public reporting burden for this collection of information is estimated to average 1 hour 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: Center for Devices and Radiological Health 1350 Piccard Drive Rockville, MD 20850 <i>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.</i>		

Attachment 2

Modified t:slim Cartridge Instructions for Use



TANDEM™
DIABETES CARE

t:slim™ 3mL Cartridge (300 units)
Instructions for Use
REF: 003380 (10 pack) / REF: 003379

INDICATIONS FOR USE

The t:slim™ Insulin Delivery System is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater.

CONTRAINDICATIONS

The t:slim cartridge is contraindicated for use with products other than U-100 Humalog® and U-100 NovoLog®.

WARNINGS

- The t:slim cartridge is sterile, non-pyrogenic, and for single use only.
- Do not use if package has been opened or damaged.
- Dispose of filling syringe and needle safely in a sharps container.
- Failure to remove air from filling syringe and tubing may result in inaccurate delivery of medication.
- Always disconnect infusion set from body when filling cartridge with insulin or while priming tubing.
- Refer to insulin's package insert for proper handling.

PRECAUTIONS

- Insulin should be at room temperature before filling cartridge.
- Do not store filled cartridges.
- Check for leaks regularly after changing cartridge and infusion set.

- The first set-up should be done in the presence of your healthcare professional.
- Attach only insulin compatible infusion sets with luer connectors to the cartridge.
- Minimize contact with insulin. Wash hands thoroughly after handling any device that contains insulin.

CAUTION

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

CARTRIDGE FILLING SUPPLIES

You will need the following:

- » One t:slim cartridge
- » One 3mL filling syringe (supplied)
- » One 26 gauge filling needle (supplied)
- » One vial of NovoLog or Humalog insulin
- » One alcohol prep swab

Note: The cartridge can be filled to a maximum volume of 3mL (300 units).

CARTRIDGE FILLING INSTRUCTIONS

NEW CARTRIDGE SHOULD BE INSERTED INTO T:SLIM PUMP PRIOR TO FILLING WITH INSULIN.

Refer to t:slim pump and infusion set user guides for detailed installation and priming instructions.

Use proper aseptic techniques while performing the following:

1. Inspect cartridge package for any indication of damage. Discard any damaged product.
2. Wash your hands thoroughly.
3. Open package and remove cartridge. Insert empty cartridge onto t:slim pump as prompted.
4. Clean rubber septum on insulin vial with alcohol prep swab.
5. Remove needle and syringe from their packaging. Securely twist needle onto syringe.
6. Safely remove protective cap from needle by pulling outward.
7. Draw air into syringe up to the desired amount of insulin (3mL maximum).
8. With insulin vial upright, insert needle into vial. Inject air from syringe into vial. Maintain pressure on syringe plunger.
9. With needle still inserted into vial, turn vial and syringe upside down. Release syringe plunger. Pressure will push plunger and let the insulin flow from vial into syringe.
10. If needed, pull plunger to withdraw additional insulin. Do not fill syringe with more than 3mL.
11. Remove any air bubbles from syringe into vial by flicking barrel of syringe and gently pushing on plunger.
12. Remove needle from insulin vial.
13. Gently insert needle straight down into white insulin fill port of a new cartridge pre-loaded onto t:slim pump. With pump upright, depress syringe plunger to fill cartridge as prompted by the pump.
14. While maintaining pressure on syringe plunger, remove needle from insulin fill port.
15. Check for leaks.
16. Dispose of used needles and other components in accordance with local laws.
17. Complete load instructions as prompted by t:slim pump.

	Use By Date (MM/DD/YYYY)
	Do Not Re-Use
	See Instructions for Use
	Method of Sterilization: Gamma
	Model Number
	No Latex
	No Pyrogenic
	Temperature Limits -4°F (-20°C) to 140°F (+60°C)



11045 Roselle Street
San Diego, CA 92121 USA

Phone: 1-877-801-6901
www.tandemdiabetes.com

Patents Pending
© 2012 Tandem Diabetes Care, Inc.

R_x Only P/N 002146 Rev. D 20120216

t:slim™ is a trademark of Tandem Diabetes Care, Inc.
Humalog® is a registered trademark of Eli Lilly and Company.
NovoLog® is a registered trademark of Novo Nordisk A/S.

Attachment 3

Predicate t:slim Cartridge Instructions for Use



TANDEM™
DIABETES CARE

t:slim™ 3mL Cartridge (300 units)
Instructions for Use
REF: 003380 (10 pack) / REF: 003379

INDICATIONS FOR USE

The t:slim™ Cartridge is indicated as a reservoir for the delivery of rapid-acting insulin by a t:slim ambulatory infusion pump. NovoLog® and Humalog® have been tested by Tandem Diabetes Care and found to be safe for use in the t:slim pump. NovoLog was tested for up to 72 hours and Humalog was tested for up to 48 hours, as labeled.

- The first set-up should be done in the presence of your healthcare professional.
- Attach only insulin compatible infusion sets with luer connectors to the cartridge.
- Minimize contact with insulin. Wash hands thoroughly after handling any device that contains insulin.

CONTRAINDICATIONS

The t:slim cartridge is contraindicated for use with products other than Humalog and NovoLog.

CAUTION

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

WARNINGS

- The t:slim cartridge is sterile, non-pyrogenic, and for single use only.
- Do not use if package has been opened or damaged.
- Dispose of filling syringe and needle safely in a sharps container.
- Failure to remove air from filling syringe and tubing may result in inaccurate delivery of medication.
- Always disconnect infusion set from body when filling cartridge with insulin or while priming tubing.
- Refer to insulin's package insert for proper handling.

CARTRIDGE FILLING SUPPLIES

You will need the following unopened sterile supplies:

- » One t:slim cartridge
- » One 3mL filling syringe (supplied)
- » One 26 gauge filling needle (supplied)
- » One vial of NovoLog or Humalog insulin
- » One alcohol prep swab

Note: The cartridge should be filled with a minimum of 0.45mL (45 units).

Note: The cartridge can be filled to a maximum volume of 3mL (300 units). After cartridge has completed load function in the pump, approximately 280 units of insulin is available for delivery.

PRECAUTIONS

- Insulin should be at room temperature before filling cartridge.
- Do not store filled cartridges.
- Check for leaks regularly after changing cartridge and infusion set.

CARTRIDGE FILLING INSTRUCTIONS

NEW CARTRIDGE SHOULD BE INSERTED INTO t:SLIM PUMP PRIOR TO FILLING WITH INSULIN.

Refer to t:slim pump and infusion set user guides for detailed installation and priming instructions.

1. Inspect cartridge package for any indication of damage. Discard any damaged product.
2. Open package and remove cartridge. Insert empty cartridge onto t:slim pump as prompted.
3. Wash your hands thoroughly
4. Clean rubber septum on insulin vial with alcohol prep swab.
5. Remove needle and syringe from their packaging. Securely twist needle onto syringe.
6. Safely remove protective cap from needle by pulling outward.
7. Draw air into syringe up to the desired amount of insulin (3mL maximum).
8. With insulin vial upright, insert needle into vial. Inject air from syringe into vial. Maintain pressure on syringe plunger.
9. With needle still inserted into vial, turn vial and syringe upside down. Release syringe plunger. Pressure will push plunger and let the insulin flow from vial into syringe.
10. If needed, pull plunger to withdraw additional insulin. Do not fill syringe with more than 3mL.
11. Remove any air bubbles from syringe into vial by flicking barrel of syringe and gently pushing on plunger.
12. Remove needle from insulin vial.
13. Gently insert needle straight down into white insulin fill port of a new cartridge pre-loaded onto t:slim pump. With pump upright, depress syringe plunger to fill cartridge as prompted by the pump.
14. While maintaining pressure on syringe plunger, remove needle from insulin fill port.
15. Dispose of used needles and other components in accordance with local laws.
16. Complete load instructions as prompted by t:slim pump.

	Use By Date (MM/DD/YYYY)
	Do Not Re-Use
	See Instructions for Use
	Method of Sterilization: Gamma
	Model Number
	No Latex
	No Pyrogenic
	Temperature Limits -4°F (-20°C) to 140°F (+60°C)



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Phone: 1-877-801-6901
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Patents Pending
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Rx Only P/N 002146 Rev. B (04/2011)

t:slim™ is a trademark of Tandem Diabetes Care, Inc.
Humalog® is a registered trademark of Eli Lilly and Company.
NovoLog® is a registered trademark of Novo Nordisk A/S.

Attachment 4

Declaration of Conformity with Design Controls



Phone: (858) 366-6900
Fax: (858) 362-7070
11045 Roselle Street
San Diego, California 92121
www.tandemdiabetes.com

Declaration of Conformity to Design Controls

To the best of my knowledge, the verification activities for Tandem Diabetes Care, Inc.'s t:slim Insulin Delivery System, as required by the risk analysis, for the modification described in this premarket notification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

The manufacturing facility (Establishment Registration No. 3007981285) is in conformance with the design control requirements as specified in 21 C.F.R. § 820.30 and the records are available for review.

A handwritten signature in blue ink, appearing to read 'John Sheridan', written over a horizontal line.

John Sheridan
Chief Operating Officer

11-21-13

Date

Attachment 5

510(k) Summary

510(k) SUMMARY

Tandem Diabetes Care, Inc. t:slim™ Insulin Delivery System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Tandem Diabetes Care, Inc.
11045 Roselle Street, Suite 200
San Diego, CA 92121
Phone: 858-255-6331
Facsimile: 858-362-7070

Contact Person: Ron Warren, Director, Regulatory Affairs
Contact Email: rwarren@tandemdiabetes.com

Date Prepared: November 22, 2013

Common or Usual Name

Insulin infusion pump

Classification Name

Infusion Pump per 21 CFR 880.5725

Predicate Devices

Tandem Diabetes Care, Inc. t:slim™ Insulin Delivery System (K111210)

Purpose of the Special 510(k) notice.

The t:slim™ Insulin Delivery System is a modification to the previously cleared t:slim™ Insulin Delivery System.

Intended Use

The t:slim™ Insulin Delivery System is indicated for the subcutaneous delivery of insulin at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater.

Device Description

The t:slim™ Insulin Delivery System is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The scope of this Special 510(k) is limited to changes to the cartridge configuration of the t:slim System.

The t:slim System with the modified cartridge, like the predicate device, consists of the following components and accessories:

1. a software-controlled, programmable insulin infusion pump (“t:slim Pump” or “Pump”),
2. a dedicated, disposable 3mL (300 unit) insulin cartridge (“cartridge”);
3. an UnoMedical Comfort™ Infusion Set (K051264), or an equivalently FDA cleared infusion set (“infusion set”); and
4. accessories, including a Becton Dickinson 3mL sterile syringe and 26 gauge sterile needle, or equivalently cleared syringe and needle, as well as an AC power supply with USB for charging the Pump’s internal battery, cartridge Instructions for Use, and User’s Guide.

The t:slim Pump is a battery operated infusion pump capable of both basal and bolus delivery of insulin. It utilizes a motor-driven mechanism to deliver insulin from within a disposable cartridge, through an infusion set, into a patient’s subcutaneous tissue. As with current insulin infusion pumps on the U.S. market, the desired timing and quantity of the insulin delivery is programmed by the user (*i.e.*, the patient). The graphical user interface (GUI) of the t:slim Pump is a capacitive touch screen that displays information used to control the t:slim System. The delivery of insulin is accomplished through a micro-syringe within the head of the cartridge.

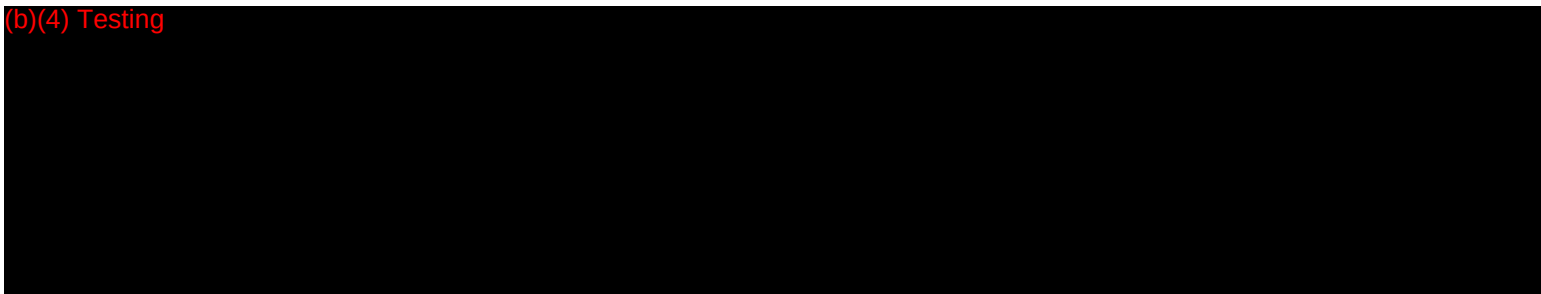
The t:slim cartridge is a single-use device, individually packaged and sealed, and provided sterile. The cartridge attaches to the t:slim Pump and is designed to hold up to 3 mL, or 300 units, of insulin. The delivery of insulin is accomplished through a micro-syringe within the head of the cartridge. The Pump has a pressure measurement sensor to estimate the volume of insulin in the insulin reservoir by measuring air pressure in the cartridge. This information is used to provide feedback to the software to determine the insulin volume, detect occlusions and cartridge removal.

Technological Characteristics

The t:slim Insulin Delivery System with modified cartridge has the same technological characteristics as the predicate device. The t:slim System consists of: (1) a software-controlled, programmable insulin infusion pump capable of both basal and bolus delivery of insulin (“t:slim Pump”); (2) a dedicated disposable 3mL (300 unit) insulin cartridge; (3) UnoMedical’s Comfort™ Infusion Set (K051264), or an equivalently cleared set; and (4) additional device accessories including a sterile syringe and needle (for cartridge filling) and AC power supply with USB. The material changes were qualified per original device specifications and were shown to meet design requirements.

Performance Data

(b)(4) Testing



(b) (4)



Substantial Equivalence

The t:slim System with modified cartridge has the same intended use and indications for use, the same principles of operation, and same technological characteristics as the previously cleared predicate t:slim System. The purpose of this Special 510(k) is to update the materials used in the construction of the disposable cartridge and storage pouch. The verification and process qualification testing confirms that these changes meet the original product specifications. Thus, the proposed t:slim System is substantially equivalent to its predicate.

Attachment 6

Indications for Use Statement

Indications for Use Statement

510(k) Number (if known): _____

Device Name: t:slim™ Insulin Delivery System

Indications for Use:

The t:slim™ Insulin Delivery System is indicated for the subcutaneous delivery of insulin at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater.

Prescription Use X
(Per 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Attachment 7

Medical Device User Fee Cover Sheet

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER (b) (6) Write the Payment Identification number
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: http://www.fda.gov/oc/mdufma/cover-sheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) TANDEM DIABETES CARE, INC 11045 ROSELLE ST., SUITE 200 SAN DIEGO CA 92121 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****7508	2. CONTACT NAME Ronald Warren 2.1 E-MAIL ADDRESS rwarren@tandemdiabetes.com 2.2 TELEPHONE NUMBER (include Area code) 858-2556331 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 858-3627070	
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		
3.1 Select a center ☒ CDRH ☐ CBER <u>3.2 Select one of the types below</u> ☒ 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: SBD149001		
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 our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) ☐ NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; 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 ☐ The sole purpose of the application is to support conditions of use for a pediatric population ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only ☐ 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. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]		
(b) (6)		NOT SUBMITTED FOR THIS PREMARKET APPLICATION 21-Nov-2013

["Close Window"](#) [Print Cover sheet](#)

Attachment 8

Truthful and Accuracy Statement



Phone: (858) 366-6900
Fax: (858) 362-7070
11045 Roselle Street
San Diego, California 92121
www.tandemdiabetes.com

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURACY STATEMENT
(As required by 21 C.F.R. § 807.87(j))**

I certify that, in my capacity as Chief Operating Officer of Tandem Diabetes Care, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification for the t:slim Insulin Delivery System are truthful and accurate and that no material fact has been omitted.

A handwritten signature in blue ink, appearing to read 'John Sheridan', written over a horizontal line.

John Sheridan
Chief Operating Officer

A handwritten date '11-21-13' in blue ink, written over a horizontal line.

Date

Attachment 9

(b)(4) Testing



**COVER SHEET MEMORANDUM**Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

From: Reviewer Name Alan Stevens
Subject: 510(k) Number K133593
To: The Record

Please list CTS decision code: SE - Substantially Equivalent

- ☐ Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)
- ☐ Hold (Additional Information or Telephone Hold)
- ☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page (<i>Attach IFU</i>)	×	
510(k) Summary or 510(k) Statement (<i>Attach Summary or Statement</i>)	×	
Truthful and Accurate Statement (<i>Must be present for a Final Decision</i>)	×	
Is the device Class III?		×
Does firm reference standards? (If yes, please attach <u>Form 3654</u> .)	×	
Is this a combination product?		×
Is this a reprocessed single use device? (See <u>Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices</u> .)		×
Is this device intended for pediatric use only?		×
Is this a prescription device? (If both prescription & OTC, check both boxes.)	×	
Is clinical data necessary to support the review of this 510(k)?		×
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		×
Does this device include an Animal Tissue Source?		×
All Pediatric Patients age <= 21		×
Neonate/Newborn (Birth to 28 days)		×
Infant (29 days to < 2 years)		×
Child (2 years to <12 years)		×
Adolescent (12 years to <18 years)	×	
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)	×	
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)	×	

Nanotechnology

X

Is this device subject to the Tracking Regulation? ([Medical Device Tracking Guidance](#))

X

Regulation Number: 21 CFR 880.5725**Class:** II**Product Code:** LZG**Additional Product Codes:****Digital Signature Concurrency Table**

(Not all signatures may be required)

Branch Chief Sign-Off

Digitally signed by
Richard C. Chapman
Date: 2014.03.24
10:43:00 -04'00'

Division Sign-Off

Kwame O. Ulmer
2014.03.24 14:39:54 -04'00'



December 23, 2013

Phone: (858) 366-6900
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11045 Roselle Street
San Diego, California 92121
www.tandemdiabetes.com

By Messenger

510(k) 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

FDA CDRH DMC

DEC 23 2013

Received

Attention: Alan Stevens, General Hospital Devices Branch (WO66-2561)

Re: Response to FDA's December 6, 2013, Refuse to Accept Notification for Tandem Diabetes Care™, Inc.'s t:slim™ Insulin Delivery System (K133593)

Dear Mr. Stevens:

Tandem Diabetes Care, Inc. ("Tandem" or the "Company"), is responding to the Food and Drug Administration's ("FDA" or the "Agency") Refuse to Accept ("RTA") notification issued on December 6, 2013, regarding the company's t:slim™ Insulin Delivery System ("t:slim") Special 510(k) premarket notification (K133593). Per FDA's request, two copies of the response are included herein, including 1 paper copy and 1 electronic copy ("eCopy"). According to the instructions on the FDA website, the eCopy provided with this submission is an exact duplicate of the paper copy. For FDA's convenience of review, each of the issues raised in the RTA email correspondence is listed in the attachment, followed by the company's response.

Tandem believes that the information provided with this response adequately address each of the Agency's comments in the RTA checklist. Therefore, the t:slim Special 510(k) notification meets the criteria established for administrative completeness, allowing FDA to accept the Special 510(k) notification for filing and continue with the substantive review of the submission. If you have any additional questions regarding the 510(k) notice, please contact me at the number below. Upon clearance of the device, please fax the substantial equivalence letter to me at (858) 362-7070.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Ron Warren'.

Ron Warren
Director, Regulatory Affairs
Tandem Diabetes Care

+1 8582556331

Attachments

cc: Janice Hogan, Partner, Hogan Lovells US LLP
Susan Tiedy-Stevenson, Senior Director, Regulatory Sciences, Hogan Lovells US LLP



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Fax: (858) 362-7070
11045 Roselle Street
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December 23, 2013

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Ron Warren
Director, Regulatory Affairs
Tandem Diabetes Care

+1 8582556331

Attachments

cc: Janice Hogan, Partner, Hogan Lovells US LLP
Susan Tiedy-Stevenson, Senior Director, Regulatory Sciences, Hogan Lovells US LLP

Attachment 1: Current User Guide (Document No. 004898, Rev. C)



TANDEM[®]
DIABETES CARE

DOCUMENT NUMBER:	4898
DOCUMENT TITLE:	User Guide
DOCUMENT NOTES	

DOCUMENT INFORMATION:

REVISION: C	VAULT: Part - rel
DOC TYPE: Part	STATUS: Release

DATE INFORMATION:

EFFECTIVE DATE: 11 Oct 2012	RELEASE DATE: 11 Oct 2012
------------------------------------	----------------------------------

CONTROL INFORMATION:

AUTHOR: DGRIMES	OWNER: DGRIMES
PREVIOUS NUMBER:	CHANGE NUMBER: ECO-002136

t:slim®
Insulin Pump



User Guide

touch simplicity™



TANDEM®
DIABETES CARE

t:s m[®] nsu n De ve y System Use Guide
t:s m[®] and Tandem Diabetes Care[®] a e eg ste ed t adema ks of Tandem Diabetes Care, nc.
touch s mp c ty[™] s a t adema k of Tandem Diabetes Care, nc.

Humaog[®] s a eg ste ed t adema k of E L y and Company.
NovoLog[®] s a eg ste ed t adema k of Novo No d sk A/S.
Comfo t[™] s a t adema k of Unomed ca A/S.
B uetooth[™] s a eg ste ed t adema k of B uetooth S G, nc.

Tandem Diabetes Care, nc.
San Dego, CA
(858) 366-6900
www.tandemdabetes.com
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t:slim Pump User Guide

At Tandem Diabetes Care, nc. we sten c ose y to the diabetes community n o de to unde stand you needs. We ecognze and espect the mpo tance of you dec s on to beg n nsu n pump the apy as a membe of ou fam y. We a so ecognze that you pump pu chase s on y the beg n ng of you eat onsh p w th Tandem. Ou comm tment goes much deepe than s mp y supply ng p oducts to he p you n you diabetes management. We p edge to be he e to suppo t you w th t a n ng and educat on th ough ou netwo k of C n ca Diabetes Spec a sts. We a so p edge to be he e to suppo t you w th ou ded cated Custome Techn ca Suppo t.

This t:s m Use Guide s des gned to ass st you w th the featu es and funct ons of the t:s m Pump and ca t dge. t p oves mpo tant wa n ngs and caut ons on p ope ope at on to ensu e you safety, as we as techn ca nfo mat on. t a so p oves step-by-step ust at ve nst uct ons on how to p ope y p og am, manage and ca e fo you t:s m Pump.

Need he p? We a e he e fo you 24 hou s a day, 7 days a week at 1-877-801-6901.

CAUTION

We know you can't wa t to use your t:s m Pump f your tra n ng has not been schedu ed, ca us at 1-877-801-6901. Do not de ver nsu n w th your t:s m Pump unt you have comp eted your tra n ng.

Changes n equipment, softwa e, o p ocedu es occu pe od ca y; nfo mat on desc b ng these changes w be ncuded n futu e ed t ons of th s Use Guide. Please contact Tandem Diabetes Care Custome Techn ca Suppo t at 1-877-801-6901 to obta n a ep acement copy of the Use Guide that s the co ect ve s on fo you pump.

No pa t of th s pub cat on may be ep oduced, sto ed n a et eva system, no t ansm tted n any fo m o by any means, e ect on c o mechan ca, w thout the p o w tten pe m ss on of Tandem Diabetes Care, nc., San Dego, Ca fo n a, USA. This document s p oted by copy ght aw.

Tandem Diabetes Care, nc.
11045 Rose e St eet
San Dego, CA 92121
USA

Custome Techn ca Suppo t: **1-877-801-6901**

Tandem Diabetes Care, Inc. Patient Bill of Rights

1. Patients have the right to good quality service and high professional standards that are continually maintained and reviewed.
2. A patient has the right to have all records pertaining to his or her medical care treated as confidential, except as otherwise provided by law or third party contractual arrangements.
3. A patient has the right to respectful service provided by competent personnel.
4. A patient, or when appropriate, a patient's representative has the right to be informed of his or her rights at the earliest possible time.
5. A patient has the right to have their personal preferences heard.
6. A patient has the right to be free from all forms of abuse or harassment.
7. A patient has the right to receive services in a safe setting. A safe setting includes environmental safety, infection control, security, protection of emotional health and safety, including respect, dignity, and comfort, as well as physical safety.
8. A patient has the right to medical services including training without discrimination based upon race, color, religion, gender, sexual preference, national origin or source of payment.
9. A patient shall not be denied the right to designate a legally authorized individual or agency, who is authorized, to act on his or her behalf.
10. Tandem Diabetes Care shall provide a patient, or patient designee, upon written request, access to all information contained in the patient information record.
11. Except for medical emergencies, Tandem Diabetes Care must obtain the necessary informed consent prior to the start of collection or sharing of personal medical information as it relates to the purchase of Tandem products and/or services.
12. Tandem Diabetes Care is committed to ensuring the safety of its customers. Tandem has implemented policies covering situations when a Tandem employee believes that a customer is suffering from a medical emergency, including contacting the appropriate emergency medical care.
13. A patient has a right to full information and counseling on the availability of known financial resources for his or her health care received by Tandem Diabetes Care for the purpose of beneficiary coverage of Tandem Product and Services.
14. A patient has the right to examine and receive a detailed explanation of his or her financial bill.
15. A patient has the right to be advised when they are being considered for a medical care research program. In this occurrence, Tandem Diabetes Care will send an informed consent agreement to a patient, requesting their participation in a clinical investigation.
16. A patient has the right to decide whether their personal health information could be used for any fundraising efforts.
17. A patient, and when appropriate, a patient's representative has the right to have any concerns, complaints and grievances addressed. Sharing concerns, complaints and grievances will not compromise a patient's care, treatment or services.
18. If a patient has a concern, complaint, or grievance, he or she may contact Tandem Diabetes Care Customer Support by:
 - » Calling Customer Support 1-877-801-6901
 - » Writing a letter to Tandem Diabetes Care
ATTN: Customer Support and sending it to
11045 Rose Street San Diego, CA 92121

Patient Responsibilities

1. Patients and their families when appropriate are responsible for providing correct and complete information when requesting assistance with insurance verification and other services provided by Tandem Diabetes Care.
2. Patients and their families are responsible for reporting unexpected changes with their medical, financial, or insurance condition.
3. Patients and their families are responsible for asking questions when they do not understand the service being provided or the reason for the information being requested.
4. Patients and their families are responsible for following the product training, instructions for use and service that have been developed by Tandem Diabetes Care and agreed to by a patient.
5. Patients and their families are responsible for the outcomes if they do not follow the product instructions for use, service and payment plans.
6. Patients and their families are responsible for being considerate of Tandem Diabetes Care's staff and property, as well as other patients and their property.
7. Patients and their families are responsible to promptly meet any financial obligation agreed to with Tandem Diabetes Care.
8. Patient and their family agree to hold harmless Tandem Diabetes Care from any expenses they may incur as a result of Tandem contacting the appropriate emergency medical care on their behalf.

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

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Section 1

Welcome

Chapter 1

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1.1 Purpose of this Guide

The User Guide describes the use of the t:s m nsu n De ve y System (t:s m System). The intended use of the t:s m System is for the Continuous Subcutaneous nsu n nfus on (CS), at set and va abe ates, for the management of diabetes me tus n pe sons equ ng nsu n, fo nd v dua s 12 yea s of age and g eate .

WARNING

United States (U.S.) Federal law restricts this device to sale by or on the order of a physician.

If you are unable to use the t:s m System according to the instructions in this User Guide, you may be putting your health and safety at risk. Be sure to speak with your healthcare provider if you have questions or concerns about using your pump properly.

CAUTION

Before using your t:s m Pump, ensure that you have been appropriately trained on its use by a certified t:s m Pump trainer.

Read all of the instructions provided in this User Guide before using your t:s m Pump, and monitor your blood glucose (BG) with the guidance of your healthcare provider. According to the American Association of Diabetes Educators' white paper *Insulin Pump Therapy: Guidelines for Successful Outcomes*, patients should routinely check the BG levels at least 4 times daily (optimal 6–8 times daily) in order to detect hyperglycemia and hypoglycemia early. Undetected hyperglycemia or hypoglycemia can result without proper monitoring.

1.2 Working with your Healthcare Provider

Any caution 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 your individual infusion therapy. Your healthcare provider can help you establish diabetes management guidelines that best fit your lifestyle and needs.

Your needs will influence how your healthcare provider helps you enter your initial pump settings. If you have any questions about diabetes management after you start using your t:s m Pump, do not hesitate to contact your healthcare provider.

1.3 Important Safety Information

This section covers important safety information, including indications for use and contraindications, what to keep in an emergency kit, and warnings and precautions. In case of an emergency, call 911 (U.S. only).

CAUTION

Before using your t:s m Pump, ensure that you have been appropriately trained on its use by a certified t:s m Pump trainer. Incorrect use of your t:s m Pump or failure to follow the appropriate instructions in this User Guide can lead to serious injury or even death. If you have questions or need further clarification on your t:s m Pump use, ask your healthcare provider or call our around-the-clock Customer Technical Support Department at 1-877-801-6901.

Your t:slim Pump is designed only for the Continuous Subcutaneous Insulin Infusion (CSII) of U-100 insulin; it is not intended for use with any other delivery substance. Consult your healthcare provider before using your t:slim Pump to determine which programming features are most appropriate for you. Only your healthcare provider can determine your basal rate, insulin-to-carbohydrate ratios, correction factors, BG target, and duration of insulin action. Additionally:

- Ensure that any small components on your t:slim Pump and its accessories are kept away from small children who could potentially ingest them.
- Avoid changing your infusion set before bedtime or if you will not be able to test your BG at least 1–2 hours after a new set is placed.
- Always check that your cartridge has insulin to last through the night.
- Unless otherwise recommended by your healthcare provider, do not use the vibrate feature during sleep; rather, set the volume to high for all alarms and alerts.
- Since air bubbles can compromise delivery accuracy, always remove all bubbles when drawing insulin into syringe; always hold the pump with the white insulin fill port pointed up when filling cartridge; and always ensure that there are no air bubbles in the tubing when filling.
- Ensure that the t:slim Pump you use for therapy has all your personal settings programmed with your specific treatment plan.
- If you damage or drop your t:slim Pump, ensure that it is still working properly. If you are unsure as to potential damage, call Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

1.4 Emergency Kit

Make sure that you always have an insulin syringe and a vial of insulin with you as a backup for emergency situations. You should also always have an appropriate emergency kit with you. Talk with your healthcare provider regarding what items this kit should include.

Supplies to Carry Everyday:

- Blood glucose testing supplies: meter, strips, lancets, meter batteries
- Fast-acting carbohydrate for low blood glucose
- Extra snack for longer coverage than fast-acting carbohydrate
- Glucagon emergency kit (for recurrent, severe hypoglycemia)
- Rapid-acting insulin and syringes
- Infusion sets (a minimum of two)
- Insulin pump cartridges (a minimum of two)
- Infusion site preparation products (antiseptic wipes, skin adhesive)
- Ketone-testing strips
- t:slim Wallet Card (for troubleshooting tips and pump settings)
- Diabetes identification card or jewelry

CAUTION

- » Your t:s m Pump is designed to deliver insulin reliably, but because it uses on-demand rapid-acting insulin, you will not have long-acting insulin in your body. In order to prevent Diabetic Ketoacidosis (DKA) or a very high BG, you must be prepared to inject insulin if delivery is interrupted for any reason. Only use U-100 insulin, as any lesser or greater concentration can result in serious health consequences.
- » Never fill your tubing while your infusion set is connected to your body. Doing so can result in unintended delivery of insulin, which can result in serious injury or death.
- » If you have any questions regarding these cautions, call your healthcare provider or Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.
- » 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 compensate for missed basal and/or bolus insulin. Check your blood glucose before disconnecting from the pump and again when you reconnect.

1.5 Indications for Use and Contraindications

Indications for Use

The t:s m insulin Delivery System is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater.

Contraindications

The t:slim Pump is not intended for anyone unable or unwilling to:

- Test BG levels as recommended by your healthcare provider
- Demonstrate adequate carbohydrate-counting skills (preferred, but not required)
- Maintain sufficient diabetes self-care skills
- See your healthcare provider(s) regularly

You must also have adequate vision and/or hearing in order to recognize your t:s m Pump alerts.

1.6 Verification of Proper Functionality

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

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

In addition, before using your t:slim Pump, ensure the following:

- Press the Screen On/Quick Bolus Button to illuminate the screen so that you can easily read the display
- When the screen is illuminated, the touch screen responds to your finger tap

CAUTION

If any of these conditions fail to occur, do NOT use the t:slim Pump, as this may be an indication that the pump's alarms, alerts, and other built-in safety features may not be working properly. If the pump is connected to your body, disconnect the infusion set from your body and contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

1.7 Warnings and Precautions

When using your t:slim Pump, always take precautions regarding the following:

- Radiology and Medical Procedures
- Extreme Temperatures
- Amusement Park Rides
- Aircraft Without Cabin Pressurization
- Small Parts Potentially Ingestible by Children
- Do Not Use in the Presence of Flammable Anesthetics or Explosive Gases
- Air Travel
- Submersion in Fluid
- Other Precautions

Radiology and Medical Procedures

If you are going to have an X-ray, computed tomography (CAT) scan, magnetic resonance imaging (MRI), or other exposure to radiation, take off your t:slim Pump and remove it from the procedure room. If you have questions, contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901. Your t:slim Pump, however, has been designed to withstand common electromagnetic interference, including airport and department store security systems. Refer to Electromagnetic Compatibility in section 19.5 for more detailed information.

In addition to radiology procedures, there are a number of other medical procedures which will require you to remove your t:slim Pump, most notably:

- **Pacemaker/Implantable Cardioverter Defibrillator (AICD)** – Disconnect your t:slim Pump and leave it outside the procedure room during the insertion of the pacemaker device and reprogramming (the infusion set can remain in place).
- **Cardiac Catheterization** – Disconnect your t:slim Pump and leave it outside the procedure room.
- **Nuclear Stress Test** – Disconnect your t:slim Pump and leave it outside the procedure room during the scan (it can remain connected during the injection of radioisotopes).

There are also other procedures where you should proceed with caution, most notably:

- **Laser Surgery** – Your t:slim Pump and infusion set can usually be worn during the procedure. However, some lasers can create interference and cause your t:slim Pump to set off an alarm.
- **General Anesthesia** – Depending on the equipment being used, you may or may not need to remove your t:slim Pump. Be sure to ask your healthcare provider.

There is no need to disconnect from electrocardiograms (EKGs) or colonoscopies.

Extreme Temperatures

Avoid exposure of your t:s m Pump to temperatures below 40°F (5°C) or above 99°F (37°C), as insulin solutions can freeze at low temperatures or degrade at high temperatures. Do not steam, sterilize, or autoclave your t:s m Pump at any time.

Amusement Park Rides

Very powerful electromagnets are sometimes used on “free-fall” rides. Remove your t:s m Pump and do not take it on these types of rides. Also, on high-speed/high-gravity roller coasters, you should disconnect (NOT stop or suspend) your pump as well.

Aircraft Without Cabin Pressurization

Disconnect (NOT stop or suspend) your t:s m Pump before flying in an aircraft without cabin pressurization on planes used for operations or combat missions (pressurized or not).

Small Parts Potentially Ingestible by Children

Insulin pumps, including the t:s m Pump, include small parts (such as pieces of the infusion set, tubing, USB port cover, and cartridge components) that could be ingested by children. Therefore, keep your t:s m Pump and accessories out of the reach of children.

Do Not Use in the Presence of Flammable Anesthetics or Explosive Gases

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:s m Pump in the presence of flammable anesthetics or explosive gases.

Submersion in Fluid

The t:s m Pump is watertight to a depth of 3 feet for up to 30 minutes (PX7 rating). If your t:s m Pump has been submerged, check your pump for any signs of fluid entry. If there are signs of fluid entry, disconnect the set from your body, and contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

Air Travel

Follow TSA and airline guidelines whenever traveling with medical equipment. For further information, contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

Other Precautions

Be sure to heed these other important precautions regarding your t:slim Pump:

- If your t:slim Pump is damaged, disconnect the set from your body, and contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.
- Always follow proper aseptic (clean) technique when handling your pump and cartridge:
 - » Wash your hands with anti-bacterial soap before handling.
 - » Use only sterile, unopened products, such as needles, cartridges, and infusion sets.
 - » Thoroughly clean the insertion site on your body.
- Your t:slim Pump is a sealed device that should be opened and repaired only by the manufacturer. If your t:slim Pump seal is broken the warranty is voided and your t:slim Pump is no longer watertight.

- Conduct regular checks of your t:slim Pump and infusion set, particularly:
 - » Check that you luer-lock connection between the cartridge tubing and the infusion set tubing is tight and secure.
 - » Check your infusion site for proper placement and leaks. Improperly placed sites or leaks around the infusion site can result in under-infusion.
 - » Check your infusion set tubing for any damage, leaks, or kinks while using your t:slim Pump. Damaged, leaking, or kinked tubing may result in stop insulin delivery and result in under-infusion.
 - » Check your t:slim Pump's pepsina settings to ensure that they are correct.
 - » Check your t:slim Pump's audible tones and vibratory alerts to ensure they are easily detectable.
- Use only single-use, disposable t:slim cartridges. The efficacy of your t:slim Pump cannot be guaranteed if cartridges other than those manufactured by Tandem Diabetes Care, Inc. are used or if cartridges are filled more than once. Use of cartridges not manufactured by Tandem Diabetes Care, Inc. or reuse of cartridges may result in over-infusion or under-infusion and may cause serious injury or death.
- Use only FDA cleared infusion sets with a standard luer-lock connection and consult its instructions for use. Failure to do so may result in over-infusion or under-infusion and may cause serious injury or death. Change your infusion set every 48–72 hours. Consult your healthcare provider for more information.
- Do not disconnect the luer-lock connection between the cartridge tubing and the infusion set tubing. If the connection comes loose, disconnect the infusion set from the site (from your body) before tightening to avoid unintentional insulin delivery.
- Always dispose of used cartridges and infusion sets following your community's regulations. Insulin can be absorbed through the skin, so wash your hands thoroughly after handling any insulin-holding device.
- Regularly check your t:slim Pump screen for potential failure conditions that may display.
- Everyone who connects additional equipment to the pump configures a medical system, and is therefore responsible to ensure that the system complies with the requirements of standard IEC60601-1-1.

1.8 Conventions of this Guide

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

Convention	Explanation
Bold text	Text that is bolded and in a different font than the rest of the sentence or step indicates an onscreen or physical button name.
Touch Screen	The front glass screen of your pump which displays a programming operation and a arm/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 Boots Button is the on your physical/hardware button on your t:slim Pump).
Hold	Keep pressing a button or touching an icon or menu until its functions complete.
Menu	A set of options on your touch screen that allow you to perform specific tasks.
Icon	An image on your touch screen that indicates an option or item of information or a symbol on the back of your t:slim Pump or its packaging.

Chapter 2

Introduction

2.1	Welcome	17
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2.3	Explanation of Symbols	18
2.4	Explanation of t:slim® Colors	18
2.5	Warranty Information	19

2.1 Welcome

Congratulations on the purchase of your new t:slim System. You decide to use insulin pump therapy as a sign of your commitment to your diabetes care. The t:slim Pump is designed using the latest technology. The following pages provide step-by-step illustrated instructions on how to properly program, manage, and care for your pump.

2.2 What your t:slim Insulin Delivery System Package Includes

Your t:slim System should contain the following items:

1. t:slim Insulin Pump
2. t:slim Screen Protector (pre-applied)
3. Protective Case with Rotatable Clip
4. USB Cable (6 ft.)
5. Wall Power USB Adapter
6. Car Power USB Adapter
7. t:slim Reference Guide
8. Emergency Wallet Card
9. USB Memory Card (with User Guide)

If any of these items are missing, contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

NOTE

Your t:slim Pump is shipped from Tandem Diabetes Care, Inc. with a clear screen protector. Do not remove the screen protector. Additional screen protectors can be ordered by contacting Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

NOTE

Your t:slim Pump is shipped from Tandem Diabetes Care, Inc. 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 therapy.

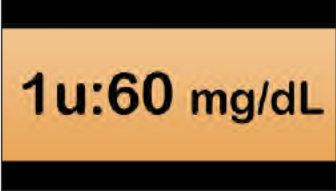
2.3 Explanation of Symbols

The following are symbols (and their descriptions), which you may find on your t:slim Pump and/or its packaging:

	Caut ion; Consu t Manua for mportant Safety Documentat on		ype BF App ed Part (pat ent so at on, not def br ator protected)
	Consu t nstruct ons for Use		Manufacturer
	Ser a Number of Dev ce		For sa e by or on the order of a phys c an on y (U.S.)
	Part Number		D rect Current (DC) vo tage
	Water-t ght Equ pment (protected aga nst the effects of temporary mmers on n water)		

2.4 Explanation of t:slim Colors

Touch Screen Colors

Blue 	The use of blue text may relate to bolus delivery activity.
Orange 	The orange text relates to t:slim's setup or delivery settings.
Orange Highlight 	The orange highlighted area indicates a recent change made to a setting.

LED 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 90 seconds indicates the pump is functioning normally. 3 green blinks every 90 seconds indicate the pump is charging.

2.5 Warranty Information

Warranty

t:slim Insulin Pump

Tandem Diabetes Care, Inc. ("Tandem") warrants the t:slim insulin pump against defects in materials and workmanship for the period of 4 years from the original date of shipment of the pump to the original end user/purchaser (the "Warranty Period"). During the Warranty Period, Tandem will replace any defective t:slim Pump, subject to the conditions and exclusions stated herein.

The warranty is valid only if the t:slim Pump is used in accordance with Tandem's instructions and will not apply:

- If damage results from changes or modifications made to the t:slim Pump by the user or third persons after the date of manufacture;
- If damage results from service or repairs performed to any part of the t:slim Pump by any person or entity other than Tandem;
- If the t:slim Pump seal is broken;
- If a non-Tandem cartridge is used with the t:slim Pump;
- If damage results from a force majeure or other event beyond the control of Tandem; or
- If damage results from negligence or improper use, including but not limited to improper storage or physical abuse.

This warranty shall be personal to the original end user/purchaser. Any sale, rental or other transfer or use of the Tandem Pump covered by this warranty to or by a user other than the original end user/purchaser shall cause this warranty to immediately terminate. This warranty only applies to the Tandem Pump and does not apply to other products or accessories.

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 ANY INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGE OF ANY NATURE OR KIND CAUSED BY OR ARISING OUT OF A DEFECT IN THE PRODUCT. ALL OTHER WARRANTY ES, EXPRESS OR IMPLIED, ARE EXCLUDED, INCLUDING THE WARRANTY ES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Warranty

Infusion Sets and Cartridges

Tandem Diabetes Care, Inc. ("Tandem") warrants its infusion sets and cartridges against defects in materials and workmanship for the period 3 days after the individual cartridge/infusion set sterile packaging has been opened, not to exceed 6 months from date of shipment of the infusion set or cartridge to the end user (the "Warranty Period"). During the Warranty Period, Tandem will replace any defective cartridge or infusion set, subject to the conditions and exclusions stated herein.

The warranty is valid only if the infusion sets and cartridges are used in accordance with Tandem's instructions and will not apply:

- If the infusion set or cartridge has been used for more than a single-time use by a single end-user;
- If damage results during the improper opening of the sterile package not in conformance with the procedures outlined in the associated Instructions for Use;
- If 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;
- If damage results from changes or modifications made to the infusion set or cartridge by the user or third persons after the date of manufacture;
- If damage results from service or repairs performed to any part of the infusions set or cartridge by any person or entity other than Tandem;
- If damage is caused by use of the cartridge or infusion set with any non-Tandem insulin pump;
- If damage results from a force majeure or other event beyond the control of Tandem; or
- If 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 user/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 user/purchaser shall cause this warranty to immediately terminate. This warranty does not apply to insulin pumps and other accessories.

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 ANY INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGE OF ANY NATURE OR KIND CAUSED BY OR ARISING OUT OF A DEFECT IN THE PRODUCT. ALL OTHER WARRANTY ES, EXPRESS OR IMPLIED, ARE EXCLUDED, INCLUDING THE WARRANTY ES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Chapter 3

t:slim® Pump Overview

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3.1 t:slim Pump Overview

You t:slim Pump uses touch screen technology. To activate and interact with your t:slim Pump, use the pad of your finger to quickly and lightly tap on the screen. Do not use your finger or another object to interact with the screen. It will not activate the screen or its functions.

Your t:slim 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.

NOTE

t:slim has several safety features to prevent unintentional interaction with the touch screen. The screen must be unlocked by tapping 1–2–3 in sequence. On all screens, three non-active areas of the touch screen are tapped before an active area is tapped, the screen will turn off to prevent accidental button presses.

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.

3.2 t:slim System Terminology

Basal

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

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 blood glucose goal, an exact number, not a range. When a BG is entered in the t:slim 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 an elevated BG. With t:slim Pump it can be delivered as a Standard, a Correction, an Extended, or a Quick Bolus.

Cannula

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

Carb

Carbs or Carbohydrates are 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 one unit of insulin will cover. Also known as insulin-to-carbohydrate ratio.

Correction Bolus

A correction bolus is given to correct elevated BG.

Correction Factor

A correction factor is the amount of BG that is owed by one unit of insulin. Also known as the insulin Sensitivity Factor (SF).

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 t:slim Pump, enter the DELIVER NOW position to dose a percentage of insulin immediately and the remaining percentage over a period of time.

Grams

Grams are a unit of measurement for carbohydrates.

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 is also related 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 owe the BG) in the body after a bolus has been delivered.

Load

Load refers to the process of removing, replacing and fitting a new catheter 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 Quick Bolus Button) is a way to deliver a bolus by following beep/vibration commands without navigating through or viewing the t:slim 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.

Units

Units are the measurement for insulin.

USB Cable

USB is the abbreviation for Universal Serial Bus. The USB cable connects into the t:slim Pump's micro USB port.

3.3 Screen Lock



1. Time and Date Display: Displays the current time and date.

2. Alert Icon: Indicates an alert, 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 connection (lightning bolt) will display.

4. INSULIN ON BOARD (IOB): Amount and time remaining of any active insulin on board.

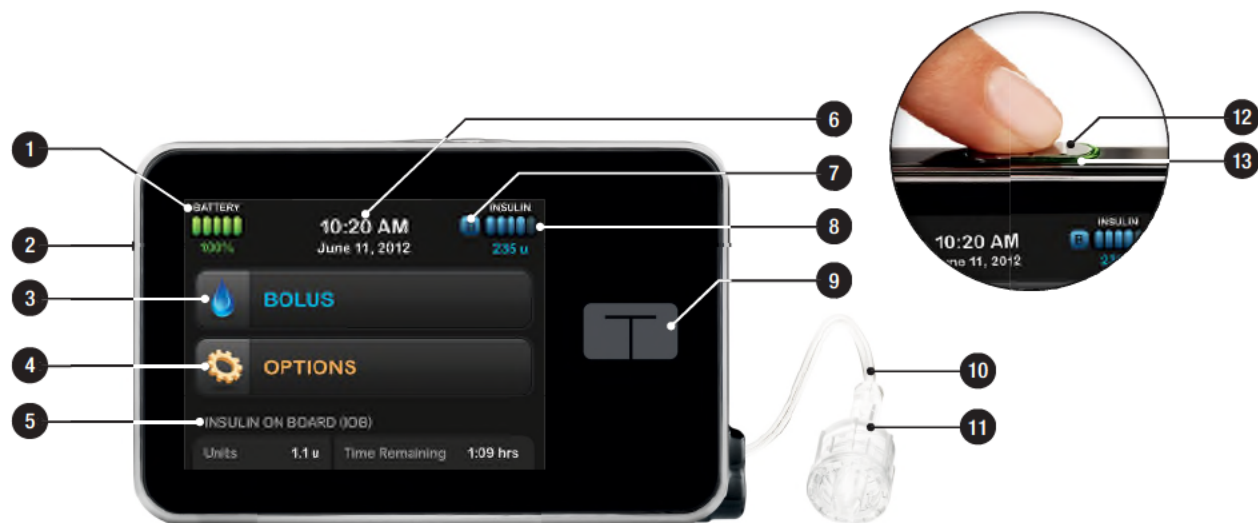
5. Active Bolus Icon: Indicates a bolus is active.

6. Status: Displays current pump settings and insulin delivery status.

7. INSULIN Level: Displays the current amount of insulin in the catheter.

8. Tandem Logo: Returns to the Home Screen.

3.4 Home Screen



1. BATTERY Level: Displays the level of battery power remaining. When connected for charging, the charging connection button will display.

2. USB Port: Port to charge your t:slim Pump battery. Close the cover when not in use.

3. BOLUS: Program and deliver a bolus.

4. OPTIONS: Stop/Resume insulin delivery, manage Pump Settings, Load cartridge, program a Temp Rate, 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 pump 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.

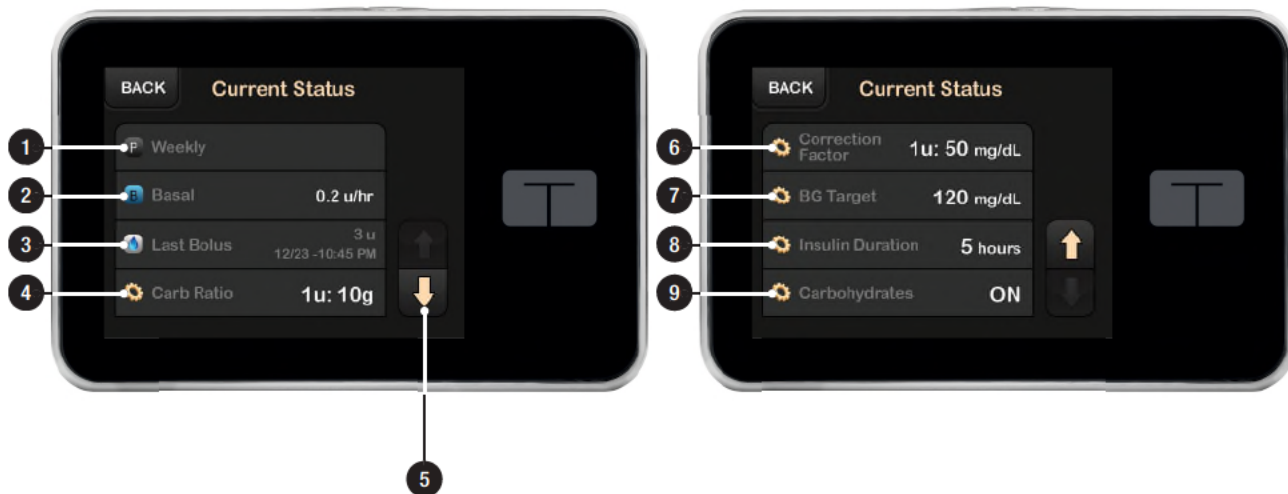
10. Cartridge Tubing: Tubing that is attached to the cartridge.

11. Luer-Lock Connection: Connects the cartridge tubing to the infusion set tubing.

12. Screen On/Quick Bolus Button: Turns the t:slim Pump screen on/off or programs a Quick Bolus (activated).

13. LED Indicator: Illuminates when connected to a power supply and indicates proper functionality.

3.5 Status Screen



1. Profile: Displays current active Profile of e.

2. Basal: Displays current basal rate being delivered. (Temp Rate: reflects displayed in units/h.)

3. Last Bolus: Displays the amount, date and time of last bolus.

4. Carb Ratio: Displays current carb ratio used to calculate bolus.

5. Up/Down Arrow: Indicates the edit mode information.

6. Correction Factor: Displays current correction factor used to calculate bolus.

7. BG Target: Displays current BG target used to calculate bolus.

8. Insulin Duration: Displays current insulin duration used to calculate insulin on board.

9. Carbohydrates: Indicates whether feature is On or Off.

NOTE

NA represents Not Applicable (does not apply).

NOTE

The status screen is for display only, no changes can be made from this screen.

3.6 Bolus Screen

Using Grams



1. **BACK:** Returns to the Home Screen.

2. **CARBS:** Entering grams of carbs to be consumed.

3. **Units:** Displays total units calculated.

4. **View Calculation:** Displays how the insulin dose was calculated using the current settings.

5. **BG:** Entering blood glucose level.

6. **NEXT:** Moves to next step.

Using Units



1. **BACK:** Returns to the Home Screen.

2. **INSULIN:** Entering units of insulin.

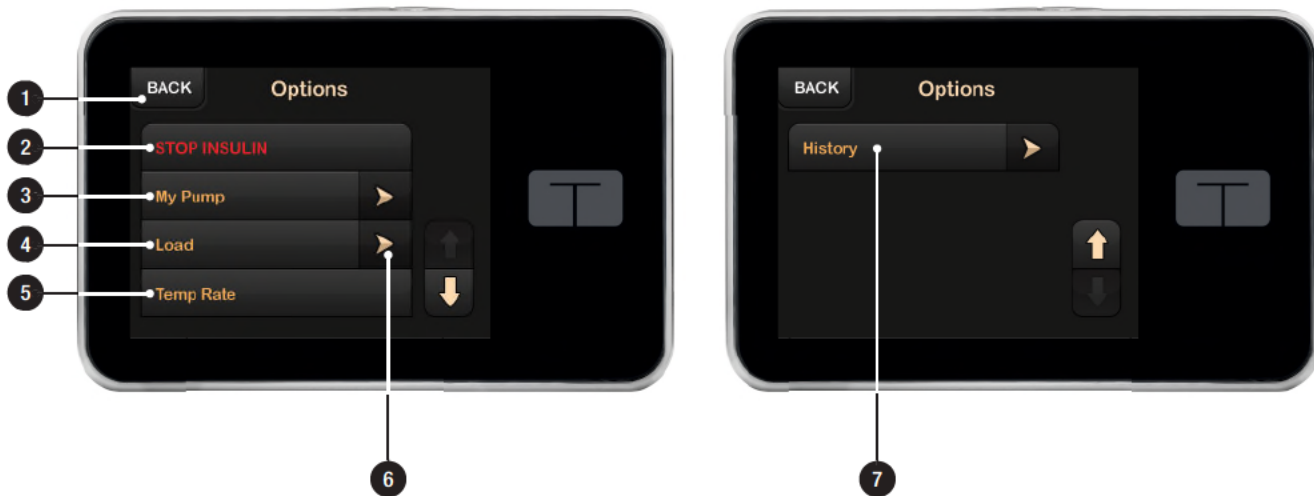
3. **Units:** Displays total units calculated.

4. **View Calculation:** Displays how the insulin dose was calculated using the current settings.

5. **BG:** Entering blood glucose level.

6. **NEXT:** Moves to next step.

3.7 Options Screen



1. **BACK:** Returns to the Home Screen.

2. **STOP INSULIN:** Stops insulin delivery. If insulin delivery is stopped, **RESUME INSULIN** will be displayed.

3. **My Pump:** Personal Profiles, Alert Settings, Pump Settings, and Pump Info.

4. **Load:** Change Catheter, Filter Tubing, Filter Cannula, and Site Reminders.

5. **Temp Rate:** Programs a temporary basal rate.

6. **Menu Arrows:** Indicates additional menu options are available.

7. **History:** Displays historical log of pump events.

3.8 My Pump Screen



1. Personal Profiles: A group of settings that defines basal and bolus delivery.

2. Alert Settings: Customize Reminders and Alerts.

3. Pump Settings: Customize Quick Bolus, Pump Volume, Screen Options, and Time and Date.

4. Pump Info: Displays t:slim Pump serial number, Customer Technical Support phone number and website.

3.9 Number Keypad Screen



1. Value Entered.

2. BACK: Returns to previous screen.

3. Keypad Numbers.

4. +/-: Allows numbers to be added on gram screen. If units, this displays as a decimal point.

5. DONE: Completes task and saves information entered.

6. Units/Grams: Value of what is entered.

7. ←: Deletes last number entered.

NOTE

If changing an existing number, begin by tapping the numbers on the keypad to override the current value.

3.10 Letter Keypad Screen



1. Name of Profile.

2. **BACK:** Returns to previous screen.

3. **Space:** Enters a space.

4. **123:** Changes keypad mode from letters (ABC) to numbers (123).

5. **SAVE:** Saves entered information.

6. **Letters:** Tap once for first letter displayed, two quick taps for middle letter, and three quick taps for third letter.

7. **←:** Deletes last letter or number entered.

NOTE

For changing an existing name, begin by tapping the letters on the keypad to enter new text. The maximum number of characters is 16.

Section 2

Key Pump Features

Chapter 4

Getting Started

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WARNING

Before you can safely and effectively use your t:s m Pump, it is very important that you carefully follow the procedures in these sections.

The t:s m Pump continues to operate normally while charging and full pump functionality is available, therefore, insulin therapy does not need to be interrupted.

If you choose to disconnect 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 compensate for missed basal and/or bolus insulin. Check your blood glucose before disconnecting from the pump and again when you reconnect.

4.1 Charging t:slim Pump

Your t:s m Pump is shipped in a factory set state for minimum battery usage. The pump can only be switched from the off state to an operational state by charging the pump.

The t:s m Pump is powered by an internal lithium polymer rechargeable battery. Included with the pump are accessories for charging from wall, automobile outlets, and a PC USB port. Upon receipt of the pump, you should charge it using the AC charger for at least 2.5 hours to ensure a full charge.

WARNING

In order to maintain compliance with the EC 60601-1 safety standard, the pump must be charged with a power supply that conforms to either EC 60601-1 or EC 60950-1, or an equivalent safety standard, when connected to an alternating current (AC) mains power source.

To Charge the Pump

1. Plug the 2-prong end of the AC charger into a grounded AC electrical outlet.
2. Plug the USB cable into the AC charger and the other end into the micro USB port of your t:slim Pump. The screen illuminates.

You may also charge the t:s m Pump by connecting the supplied charge adapter to an auxiliary power outlet and the USB cable to the pump, or connect the pump to a USB port on a PC that complies with EC 60950 (or equivalent) safety standard.

WARNING

When using the DC vehicle adapter charger, 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 a alternating current (AC) mains is prohibited.

CAUTION

When you are connected to the pump and to a charging source, take caution when moving further than the length of the USB cable. Failure to do so may result in the cannula becoming dislodged at the infusion site. For this reason it is recommended not to charge the pump while sleeping.

When you charge the t:slim Pump, the following should occur:

- The screen illuminates
- An audible alert
- The LED (edge around the Screen On/Quick Bolus Button) illuminates green
- A vibrating alert
- A charge symbol (lightning bolt) on the battery level indicator appears

CAUTION

If any of these conditions fail to occur, do NOT use the t:slim Pump, as this may be an indication that the pump's alarms, alerts, and other built-in safety features may not be working properly. If the t:slim Pump is connected to your body, disconnect the set from your body and contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

NOTE

Before using a Mac or PC to charge the t:slim Pump, it is recommended that a driver be installed on the computer. This can be done by downloading the app/cable from the USB Memory Card that is included in the t:slim System. Depending on your computer, charging time will vary. The pump will display a CONNECT ON ERROR ALERT message if it is not charging properly (refer to section 15.10).

Charging Tips

Tandem Diabetes Care, Inc. recommends periodically checking the battery level and status, charging the pump for a short period of time every day (10–15 minutes), and avoiding frequent full discharges.

NOTE

If the battery is fully discharged, the Home Screen will not power on immediately when connected to a charging source. The LED around the Screen On/Quick Bolus Button will blink green every 2 seconds until there is enough charge to power on the touch screen.

4.2 Turning On t:slim Pump Screen

1. To turn on your t:slim Pump screen, press the **Screen On/Quick Bolus** Button, located on the top of the pump, once.

▷ The Screen Lock screen will be displayed.

NOTE

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

NOTE

Upon completion of programming a feature, tap the Tandem Logo to return to the Home Screen or tap BACK to return to the previous screen.



4.3 Unlocking t:slim Pump 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.



NOTE

You must tap 1–2–3 in sequential order to unlock the pump. If you do not press 1–2–3 in sequential order, the pump will force you to restart the unlock sequence from the beginning.

NOTE

The pump will return to the Screen Lock position after a bolus and temporary basal are requested.

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/cloth to prevent unintentional interactions with the touchscreen. Always position the pump screen away from the skin when worn under clothing.

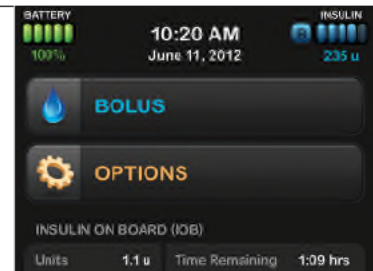
4.4 Edit Time

After powering up your t:s m Pump for the first time, set the current time and date. Refer back to this section if you need to edit the time for the time zone or adjusting for Daylight Savings Time.

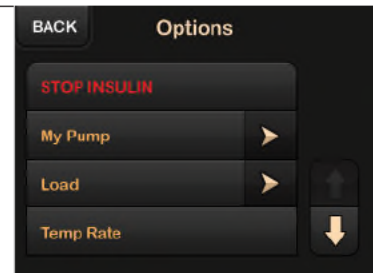
CAUTION

It is very important to set the current time and date accurately to ensure precise settings, and thus, facilitate safe insulin delivery. When editing time, always ensure that the AM/PM settings are accurate. AM is to be used from midnight until 11:59 AM. PM is to be used from noon until 11:59 PM.

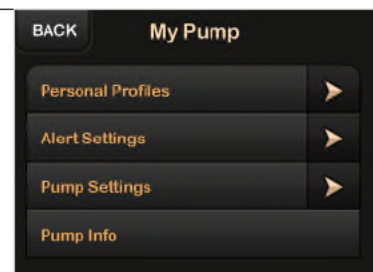
1. From the Home Screen, tap **OPTIONS**.



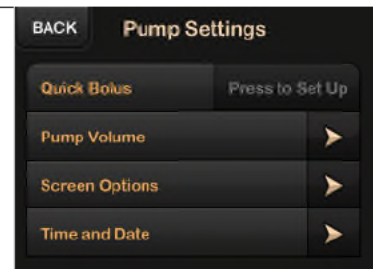
2. Tap **My Pump**.



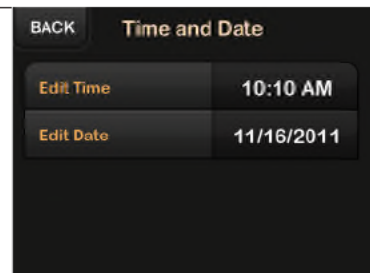
3. Tap **Pump Settings**.



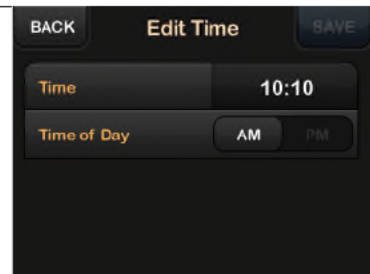
4. Tap **Time and Date**.



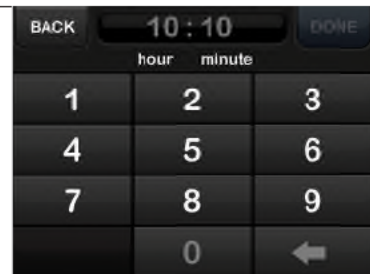
5. Tap **Edit Time**.



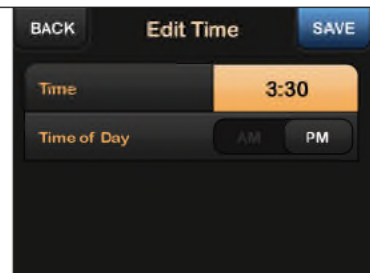
6. Tap **Time**.



7. Using the onscreen keypad, enter the hour and minutes. Verify and tap **DONE**.



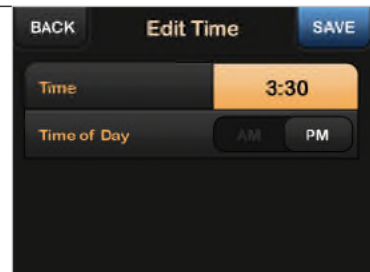
8. Tap **Time of Day** to set AM or PM.



9. Verify the correct time is set and tap **SAVE**.

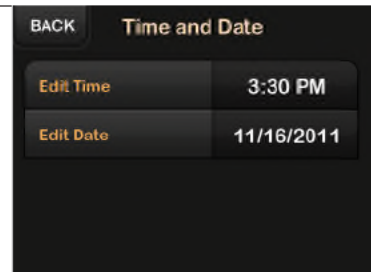
NOTE

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

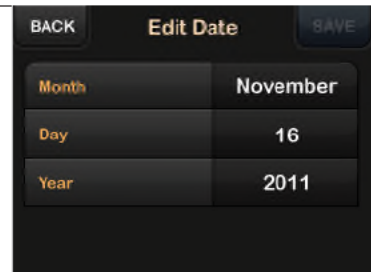


4.5 Edit Date

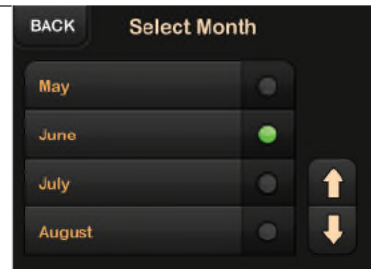
1. From the Time and Date screen tap **Edit Date**.



2. Tap **Month**.

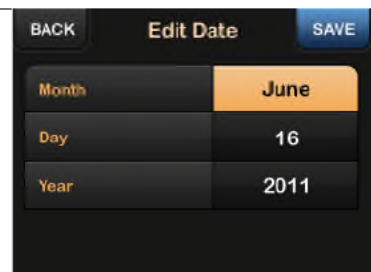


3. Find and tap current month displayed on the right. Use Up/Down Arrow to view months not displayed.

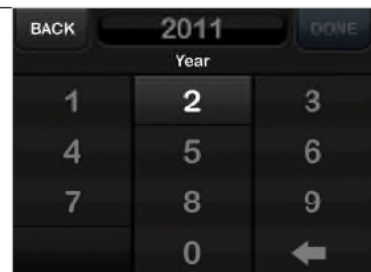


4. Tap **Day**. Using the onscreen keypad enter the current day. Verify and tap **DONE**.

5. Tap **Year**.



6. Using the onscreen keypad enter the current year. Verify and tap **DONE**.



7. Verify the correct date is set and tap **SAVE**.
8. Tap **Tandem Logo** to return to the Home Screen.

The screenshot shows a mobile application interface for editing a date. At the top, there are three buttons: 'BACK' on the left, 'Edit Date' in the center, and 'SAVE' on the right. Below these buttons is a date selection interface. It consists of three rows, each with a label on the left and a value on the right. The first row is labeled 'Month' and shows 'June'. The second row is labeled 'Day' and shows '21'. The third row is labeled 'Year' and shows '2012'. The 'Year' row is highlighted with an orange background.

Chapter 5

Infusion Site Care and Loading Cartridge

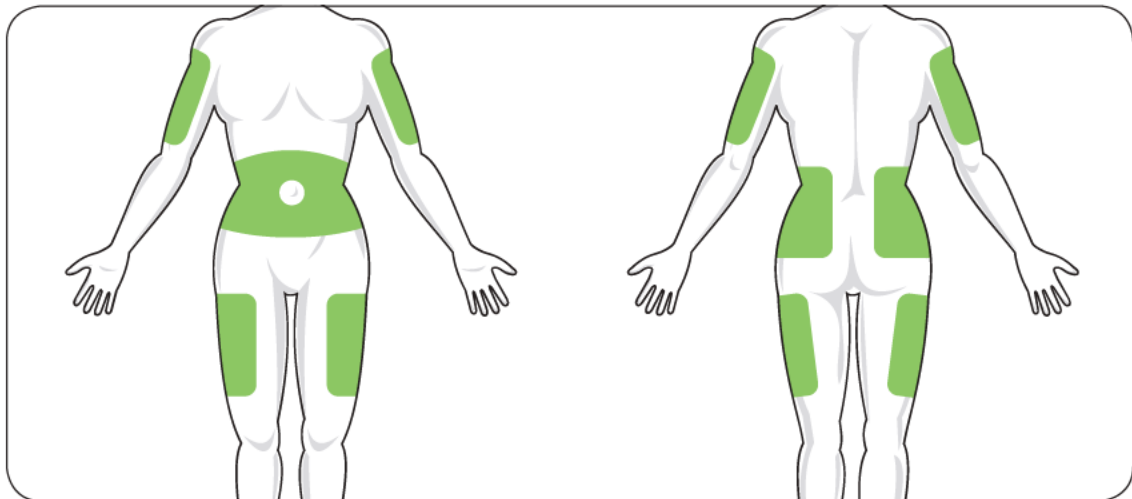
5.1	Infusion Site Selection and Care.....	42
5.2	Cartridge Instructions for Use.....	43
5.3	Loading and Filling a t:slim Cartridge	44
5.4	Filling Tubing	49
5.5	Filling Cannula	51
5.6	Setting Site Reminder	52

5.1 Infusion Site Selection and Care

WARNING

- » Use only FDA cleared insulin infusion sets with a standard Luer-lock connection and consult the instructions for use. Failure to do so may result in over-infusion or under-infusion and may cause serious injury or death. Change your infusion set every 48–72 hours. Consult your healthcare provider for more information.
- » Use only single-use disposable cartridges. Failure to do so may result in over-infusion or under-infusion and may cause serious injury or death.
- » Use only Humalog® or NovoLog® U-100 insulin. Failure to do so may result in serious health consequences.

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 obstruct the site such as the belt line, waist line, or where you would normally bend.
 - » Areas 2 inches around your belly button.
 - » Any scars, moles, stretch marks, or tattoos.

Site Rotation

- The infusion set must be replaced and rotated every two to three days, 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 area clean to avoid contamination.
- Site preparation products that have both an antiseptic and an adhesive are encouraged.

5.2 Cartridge Instructions for Use

Symbols

	Use By Date (MM/DD/YYYY)
	Do Not Re-Use
	See instructions for Use
	Method of Sterilization: Gamma

	Mode Number
	No Latex
	Non Pyrogenic
	Temperature Limits -4°F (-20°C) to 140°F (+60°C)

t:s m 3mL cartridge (300 units)

REF: 003380 (10 pack) / REF: 003379

Indications for Use

The cartridge is indicated as a device for the delivery of rapid-acting insulin with the t:s m Pump. Humalog® and NovoLog® have been tested by Tandem Diabetes Care, Inc. and found to be safe for use in the t:s m Pump. Humalog® was tested for up to 48 hours as above, NovoLog® was tested for up to 72 hours.

WARNING

United States (U.S.) Federal law restricts this device to sale by or on the order of a physician.

Contraindications

The cartridge is contraindicated for use with products other than Humalog® and NovoLog®.

WARNING

- » The cartridge is sterile, non-pyrogenic, and for single-use only.
- » Do not use if package has been opened or damaged.
- » Dispose of filling syringe and needle safely in a sharps container.
- » Failure to remove air from filling syringe and tubing may result in inaccurate delivery of medication.
- » Always disconnect infusion set from body when filling cartridge with insulin or when priming tubing.
- » Refer to the insulin manufacturer's package insert for proper handling.

CAUTION

- » Insulin should be at room temperature before filling cartridge.
- » Do not store filled cartridges.
- » Check for leaks regularly after changing cartridge and infusion set.
- » The first set-up should be done in the presence of your healthcare provider.
- » Attach only FDA cleared insulin infusion sets compatible with your connectors to the cartridge.
- » Minimize contact with insulin. Wash hands thoroughly after handling any device that contains insulin.

5.3 Loading and Filling a t:slim Cartridge

This section describes how to load the cartridge into your t:slim Pump and fill the cartridge with insulin. The single-use, disposable cartridge can hold up to 300 units (3.0 mL) of insulin.

CAUTION

Inspect the cartridge to ensure that there is no damage. Never use a cartridge that is damaged (cracks, dislodged tip connectors, etc). If there is damage, call Tandem Diabetes Care Customer Technical Support at 1-877-801-6901 to request a replacement cartridge.

CAUTION

Before you begin, verify that the infusion set is NOT connected to your body.

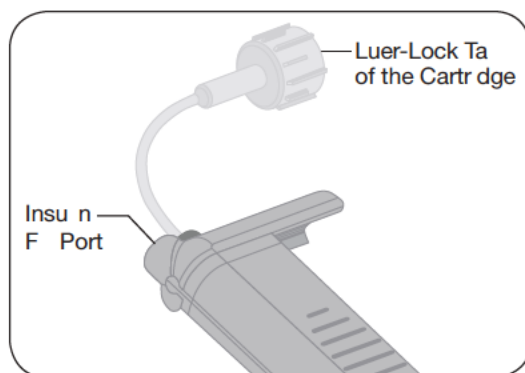
Before you begin, make sure you have the following items:

- 1 unopened, disposable, sterile, single-use cartridge
- Vial of Humalog® or NovoLog® insulin
- 3.0 mL syringe and fill needle
- Alcohol prep swab
- 1 new infusion set

NOTE

Do NOT remove the cartridge during the Load process until prompted on the t:slim Pump screen.

The illustration below identifies the luer-lock and insulin fill port used in the cartridge filling process

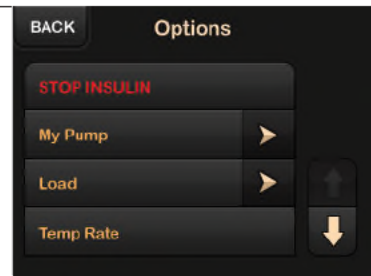


1. From the Home Screen, tap **OPTIONS**.

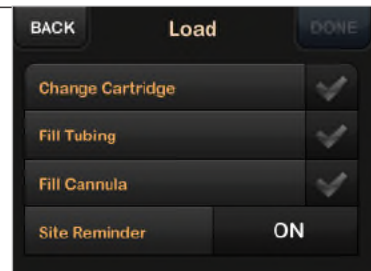
2. Tap **Load**.

NOTE

During the load sequence, the Tandem Logo is disabled. Tapping it will not return to the Home Screen.



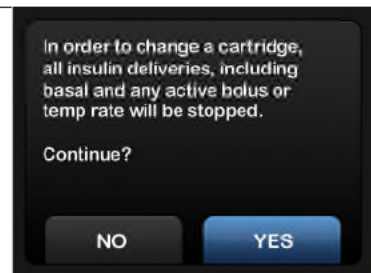
3. Tap **Change Cartridge**.



4. Screen will display that all insulin deliveries will be stopped. Tap **YES**.

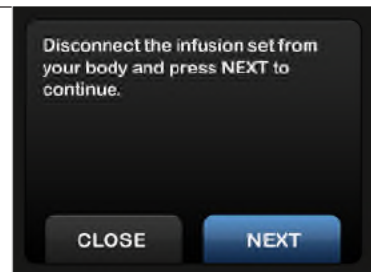
NOTE

This screen will not be displayed if this is the first time loading a new cartridge and you have not started active pump.



5. Disconnect the infusion set from your body and tap **NEXT** to continue.

➤ Preparing for Cartridge screen is displayed.



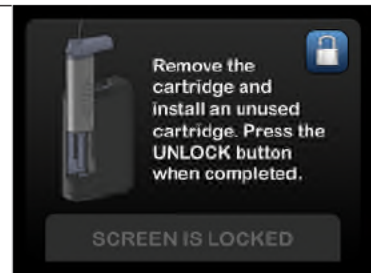
6. Remove the cartridge and install an unused cartridge. Tap **UNLOCK** when completed.

CAUTION

- » If this is the very first time you are loading the cartridge, remove the shipping canister (which is not for human use, as indicated on its label) from the back of the pump.
- » Do not fill the cartridge until prompted by instructions on the pump screen.

NOTE

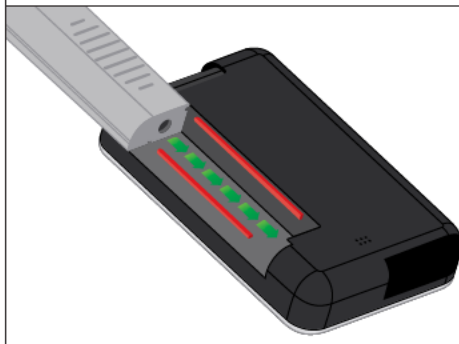
If needed, place the edge of a coin in the slot at the bottom of the cartridge and twist to aid in the removal of the cartridge.



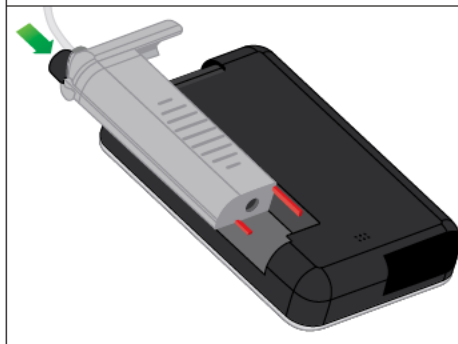
Instructions on How to Install a Cartridge

1. Inspect cartridge package for any indication of damage. Discard any damaged product.
2. Open package and remove cartridge.

3. Place bottom of the cartridge at the end of the pump. Make sure cartridge is lined up to both guide tracks.



4. Push on the circular fill port next to the cartridge tubing to slide the cartridge onto the pump.



7. Tap **NEXT**.

- ▷ Detecting Cartridge and Removing Air from Cartridge screens are displayed.



Instructions for Drawing Insulin from Vial into Syringe

CAUTION

Use only the syringe and needle provided by Tandem Diabetes Care, Inc. to fill the cartridge. After filling the cartridge and before connecting and filling the tubing, reduce the possibility of trapped air in the cartridge by holding your T:s m Pump vertically with the cartridge insulin port on top.

1. Wash your hands and remove the needle and syringe from their package. Securely twist needle onto syringe.
2. Safely remove protective cap from needle by pulling outward.
3. Draw air into syringe up to the amount of insulin desired. The cartridge requires a minimum fill of 50 units after tubing has been filled. The amount of insulin required to fill tubing should be added to the total amount drawn from the insulin vial. For approximate tubing fill amounts, see section 5.4. The maximum fill is 300 units.
4. Wipe the rubber septum of the insulin vial with an alcohol swab.
5. With insulin vial upright, insert needle into vial. Inject air from syringe into vial. Maintain pressure on syringe plunger.
6. With needle still inserted into vial, turn vial and syringe upside down. Release syringe plunger. Pressure will push plunger and let the insulin flow from vial into syringe.
7. Release the pressure on the plunger and slowly withdraw the desired amount of insulin (equal to the amount of air you filled previously) from the vial into the syringe.
8. While the filling needle is still in the vial and upside down, tap the syringe and slowly push its plunger upwards, forcing any air bubbles back into the vial.
9. Check the syringe for air bubbles and do one of the following:
 - » If there are air bubbles present, repeat step 8.
 - » If no air bubbles are present, remove the filling needle from the vial.

Instructions on How to Fill a Cartridge

1. When prompted on the pump screen, fill the cartridge by gently inserting the syringe needle into the white insulin fill port on the t:slim Cartridge. The screen will automatically lock during this sequence.
2. Hold the pump upright (as shown to the right). Slowly depress the syringe plunger to inject insulin into the cartridge (you may feel some back pressure as you fill the cartridge).
3. While maintaining pressure on the plunger, remove the syringe needle from the cartridge. Check the area around the white insulin fill port for leaks. If you detect insulin is leaking from the white insulin fill port, discard the cartridge and repeat entire process with a new cartridge. If you need a replacement cartridge, call Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.
4. Dispose of used needles in a labeled sharps container in accordance with local requirements.



CAUTION

The maximum cartridge fill amount is 300 units. Do not overfill or 'top off' when filling the cartridge as the additional amount cannot be delivered. This can lead to a cartridge error, which will require a new cartridge.

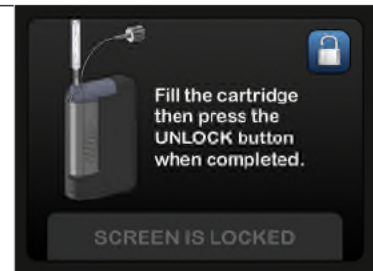
NOTE

If a cartridge is filled with between 240 and 300 units, the insulin level will display +240 on the Home Screen. The insulin level decreases in increments of 5 units between 240 and 40 and in one (1) unit increments below 40.

WARNING

Do not remove or add insulin from a filled cartridge. This will result in an inaccurate display of the insulin level on the Home Screen.

8. Fill the cartridge and tap **Unlock**.



9. Tap **NEXT**.

▷ Cartridge Changed screen is displayed.

NOTE

After completing the cartridge change, the pump will automatically prompt you to fill tubing.



5.4 Filling Tubing

Filling the Infusion Set Tubing with Insulin

This section describes how to fill the infusion set tubing with insulin.

WARNING

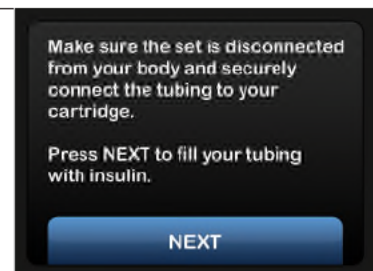
Never fill the infusion set tubing while the tubing is connected to your body. Filling the tubing while it is connected to your body can result in the unintended delivery of insulin.

NOTE

If starting from the Home Screen, tap OPTIONS, tap Load, tap Fill Tubing and then follow the instructions. Insulin delivery will be stopped and must be resumed upon completion.

1. Verify that the infusion set is disconnected from your body.
2. Connect the infusion set tubing to the luer-lock tail of the cartridge:
 - a) 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, discarded properly and use another tubing set.
 - b) Remove the infusion set tubing cap from the luer connector. Be careful to keep the luer connector away from contamination.
 - c) Insert the infusion set tubing to the luer connector on the cartridge tubing ("tail") and twist clockwise to secure it.

Tap **NEXT**.



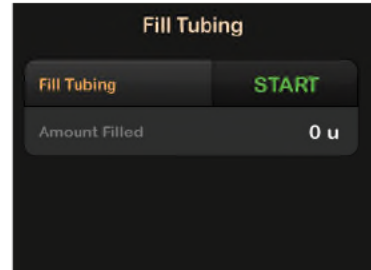
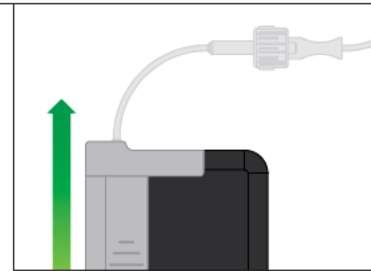
3. Hold the pump vertically (as illustrated to the right) to ensure any air in the cartridge will be dispelled first. Tap **Start**.

▷ Starting Fill screen displayed.

NOTE

The following are approximate amounts of insulin to fill different tubing lengths:

- » 15–20 units for 23 inch tubing
- » 20–25 units for 32 inch tubing
- » 25–30 units for 42 inch tubing

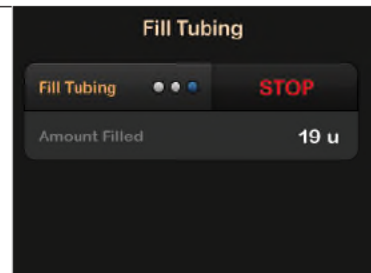


4. Tap **STOP** once 3 drops of insulin are seen at the end of the tubing.

▷ Stopping Fill screen displayed.

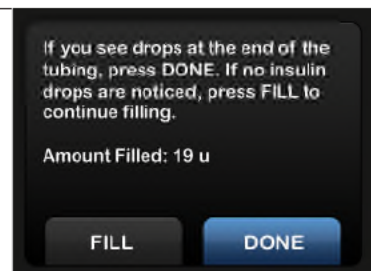
NOTE

During tubing fill, your pump will stop the fill process and notify you if the tubing has been filled with 30 units. You then have the option to continue filling more than this system maximum.

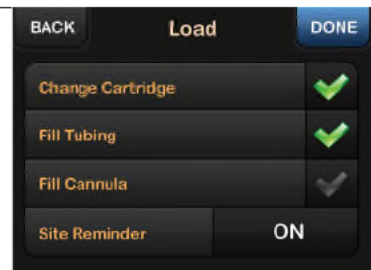


5. Verify that drops are seen and tap **DONE**.

- If you do not see drops, tap **FILL**. The Fill Tubing screen appears, repeat steps 3–5 until you see 3 drops of insulin at the end of the tubing.
- If you did not tap STOP, the “Max fill amount reached!” screen will appear. 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.



6. Fill Tubing is complete.



5.5 Filling Cannula

Filling the Infusion Set Cannula with Insulin

This section describes how to fill the infusion set cannula with insulin.

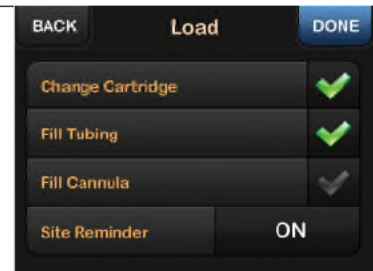
For the correct cannula fill amount, as well as procedures on need/e/cannula insertion and attaching the tubing to your body, refer to the instructions for use included with the infusion set.

To Fill the Cannula

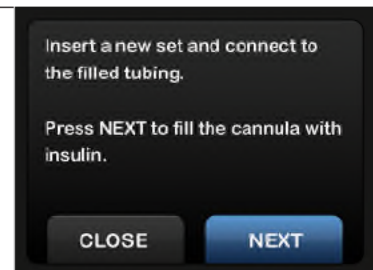
NOTE

- » If starting from the Home Screen, tap OPTIONS, tap Load, tap Fill Cannula and then follow the instructions. Insulin delivery will be stopped and must be resumed upon completion.
- » If using a sterile need/e infusion set, there is no cannula. Skip this section.

1. Tap **Fill Cannula**.



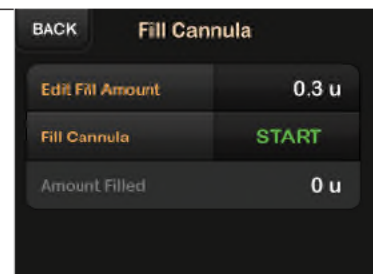
2. Insert a new infusion set and connect tubing to site, then tap **NEXT**.



3. Tap **Edit Fill Amount**.

NOTE

The cannula fill amount displayed is based on your last cannula fill amount. Delivery stops at this amount (unless you tap STOP before this amount is reached).



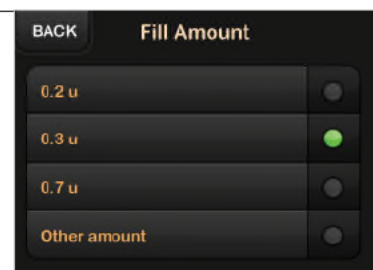
4. Select amount needed for cannula fill.

NOTE

If the amount needed is not listed, tap Other Amount and use the onscreen keypad to enter a value between 0.1 to 1.0 unit.

WARNING

Refer to your infusion set instructions for proper insertion and cannula fill amount.



5. Tap **START**.

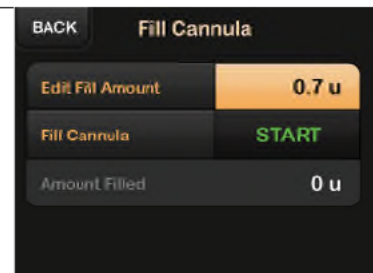
- ▷ Starting Fill screen is displayed.
- ▷ After fill is complete, Stopping Fill screen is displayed.

NOTE

You can tap STOP at any time during the fill process if you want to stop filling the cannula.

NOTE

The screen will return to the Load menu if the Site Reminder is turned OFF. Tap DONE to resume infusion if finished. Or tap Site Reminder to set reminder. If Site Reminder is ON, the pump will automatically display the Site Reminder Screen (refer to next section).



5.6 Setting Site Reminder

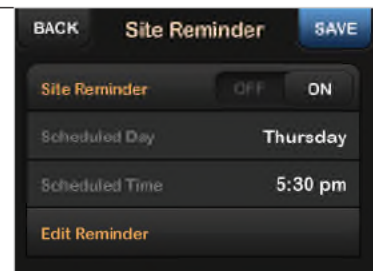
NOTE

If starting from the Home Screen, tap OPTIONS, tap Load, tap Site Reminder then follow the instructions below.

CAUTION

Avoid changing an infusion set before going to bed or if you will not be able to test your BG 1–2 hours after a new set is placed.

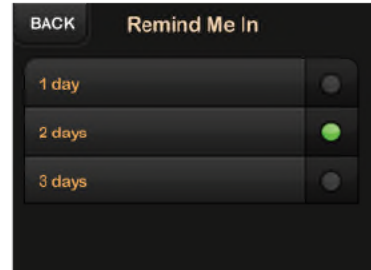
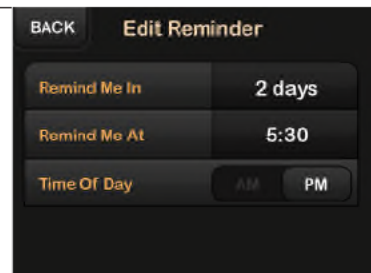
1. Tap **SAVE** if correct. Tap **Edit Reminder** if settings need to be changed.



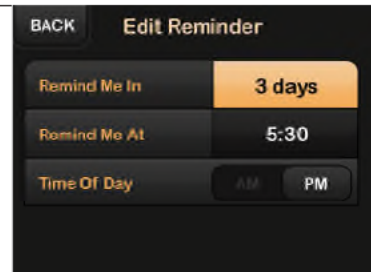
2. Tap **Remind Me In** and select the number of days.

NOTE

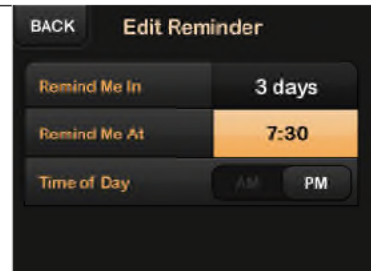
Default reminders set for 3 days.



3. Tap **Remind Me At**. Use the onscreen keypad to enter time and tap **DONE**.

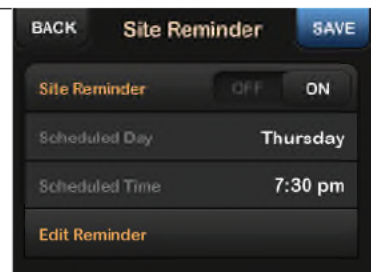


4. Tap **Time of Day** to change AM or PM. Tap **BACK**.



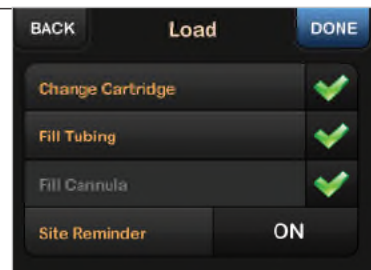
5. Verify Site Reminder is set correctly and tap **SAVE**.

▷ Site Reminder Set screen is displayed.



6. Load screen is displayed. Tap **DONE**.

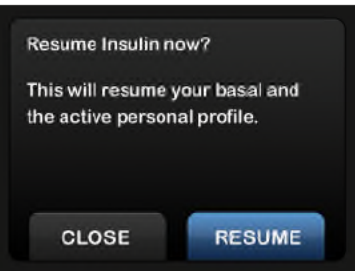
▷ A reminder to test BG in 1–2 hours will display.



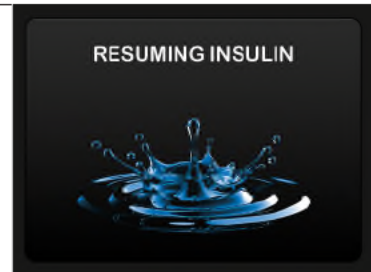
7. Tap **RESUME**.

NOTE

If this is the first time using your t:s m 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.



8. **RESUMING INSULIN** splash screen is displayed.



Chapter 6

Personal Profile

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6.1 Personal Profile Overview

A Personal Profile is a group of settings that define the basal and bolus delivery with specific time segments throughout a 24-hour period. Each profile can be personalized with a name. With a Personal Profile the following can be set:

- **Timed Settings:** Basal Rate, Correction Factor, Carb Ratio and Target BG.
- **Bolus Settings:** Insulin Duration, Max Bolus and Carbohydrates setting (ON/OFF).

The t:sm Pump uses the settings in your currently active profile to calculate the delivery of basal insulin, food boluses and correction boluses based on your Target BG.

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 variables such as schedule, food intake, activity, and exercise, etc.

NOTE

Up to 6 different Personal Profiles can be created and up to 16 different time segments can be set in each Personal Profile. For example, with your "Weekday" profile you might have time segments set up for 12:00 AM, 5:30 AM and 3:00 PM based on your healthcare provider's recommendation.

NOTE

Once defined, a Personal Profile can be viewed by selecting EDIT from the profile menu.

6.2 Creating a New Profile

Creating Personal Profiles

You can create up to 6 Personal Profiles, however; only one can be active at a time. In the Personal Profiles screen, the currently active profile is positioned at the top of the list and is indicated as ON. When you create a Personal Profile, you can define any one of the following Timed Settings:

- Basal (your basal rate in units of insulin per hour)
- Correction Factor (amount BG is lowered by 1 unit of insulin)
- Carb Ratio (number of carbs covered by 1 unit of insulin)
- Target BG (your ideal BG level)

NOTE

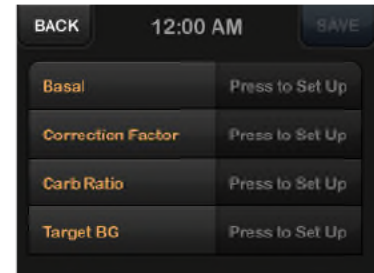
An initial maximum basal rate of 2 units/hr is set for each Personal Profile. If you enter a basal rate greater than 2 units/hr you will be prompted to confirm whether you want to continue with this basal amount. Once basal rates are set in a Personal Profile the maximum basal rate becomes two times the highest basal rate in that Personal Profile. The absolute maximum basal rate is 15 units/hr.

The ranges for Timed Settings (initially inactive) are:

- Basal (range: 0 and 0.1 – 15 units/hr)
- Correction Factor (range: 1 unit:1 mg/dL – 1 unit:600 mg/dL)
- Carb Ratio (range: 1 unit:1 g – 1 unit:300 g)
- Target BG (range: 70 mg/dL – 250 mg/dL)

NOTE

Below a carb ratio of 1:10, increments can be entered in 0.1 g.
For example a carb ratio of 1:8.2 can be programmed.

**In addition, you can define any or all of the following Bolus Settings:**

- Carbs (ON indicates entering grams of Carb; OFF indicates entering units of insulin)
- Insulin Duration (how long a bolus lowers your BG)
- Max Bolus (the maximum amount for a single bolus)

The default settings and ranges for Bolus Settings are as follows:

- Carbs (default: OFF if no Carb Ratio is defined)
- Insulin Duration (default: 5 hrs; range: 2–8 hrs)
- Max Bolus (default: 10 units; range: 1–25 units)

Insulin Duration and Insulin on Board (IOB)

Your t:s m Pump remembers how much insulin you have taken from previous boluses. It does this by relying on the insulin Duration. The insulin Duration affects the amount of time that insulin is actively lowering your BG.

Insulin Duration in your t:s m Pump is set from the factory at 5 hours but can be changed from 2 to 8 hours. Please consult your healthcare provider to accurately set your insulin Duration.

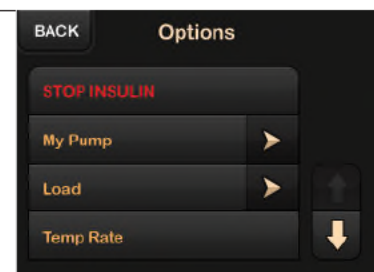
When the insulin Duration setting affects *how long* insulin from previous boluses lowers your BG, the IOB feature affects *how much* insulin is remaining in your body from previous boluses. IOB is always displayed on the Home Screen and is used in bolus delivery calculations when applicable. When a BG is entered during bolus programming, your t:s m Pump will consider any active IOB and calculate an adjusted bolus if necessary.

NOTE

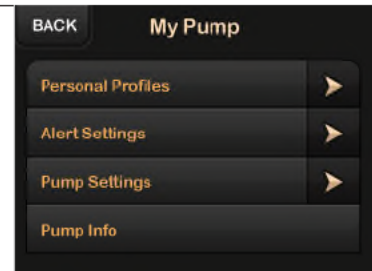
Although you do not need to define every setting, some pump features require certain settings to be defined and activated. During profile setup, your pump prompts you to set up any required settings before you can continue.

1. From the Home Screen, tap **OPTIONS**.

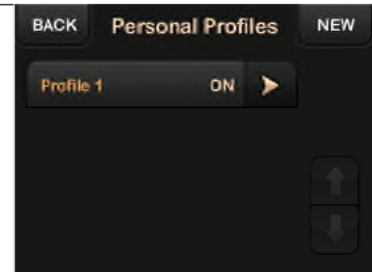
2. Tap **My Pump**.



3. Tap **Personal Profiles**.



4. Tap **NEW** to create a new profile.



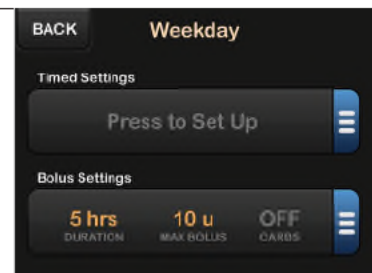
5. Using the onscreen keypad, enter a profile name (up to 16 characters) and tap **SAVE**.

NOTE

Refer to section 3.10 for instructions on using the onscreen keypads.



6. Tap **Press to Setup** to begin setting insulin delivery settings.



6.3 Programming a New Personal Profile

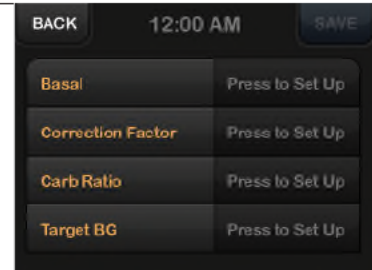
NOTE

- » Once the Personal Profile has been created, the settings must be programmed. The first time segment will start at 12:00 AM (midnight).
- » You must program a basal rate in order to have a valid Personal Profile that you can activate.
- » Be sure to tap SAVE after entering or changing a value.

CAUTION

If you only define a basal rate in Temp Settings your pump will only be able to deliver basal insulin and standard and extended boluses. Your pump will not deliver correction boluses or trigger BG alerts.

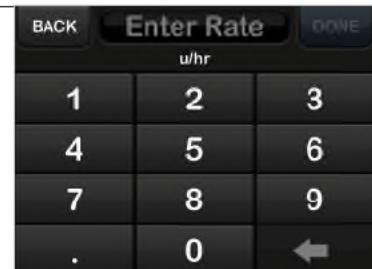
1. Once the new profile has been created, Tap **Basal**.



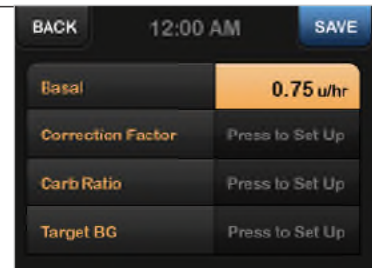
2. Using the onscreen keypad, enter the desired basal rate and tap **DONE**.

CAUTION

Always confirm that the decimal point placement is correct.



3. Tap **Correction Factor**.



4. Using the onscreen keypad, enter the desired correction factor and tap **DONE**.

NOTE

Enter the mg/dL that 1 unit of insulin will lower BG.

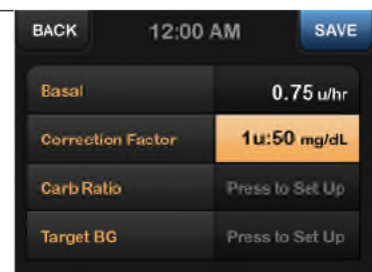


5. Tap **Carb Ratio**.

6. Using the onscreen keypad, enter the desired insulin-to-carbohydrate ratio and tap **DONE**.

NOTE

Enter the grams of carb to be covered by 1 unit of insulin.



7. Tap **Target BG**.

8. Using the onscreen keypad, enter the desired BG target and tap **DONE**.

Basal	0.75 u/hr
Correction Factor	1u:50 mg/dL
Carb Ratio	1u:10 g
Target BG	Press to Set Up

9. Review entered values and tap **SAVE**.

Basal	0.75 u/hr
Correction Factor	1u:50 mg/dL
Carb Ratio	1u:10 g
Target BG	120 mg/dL

10. Confirm Settings.

Tap **YES** if entered data is correct.

Tap **NO** to make changes.

Confirm Settings?	
Basal	0.75 u/hr
Correction Factor	1u:50 mg/dL
Carb Ratio	1u:10 g
Target BG	120 mg/dL
NO YES	

11. Tap **BACK** to set the Bolus Settings.

Tap **ADD** to create additional time settings.

Timed Settings			
12:00 AM			
0.75	1:50	1:10	120
BASAL	CORRECT	CARB	TARGET BG
ADD ↑ ↓			

Adding More Time Segments

NOTE

Any settings that you defined 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 define them all over again.

1. On the Add Segment screen, tap **Start Time**.
2. Using the onscreen keypad, enter the time (hour and minutes) that you want the segment to begin, and tap **DONE**.
3. On the Add Segment screen, tap **Time of Day** to select AM or PM.
4. Tap **NEXT**.
5. Repeat steps 1–10 from the above Programming a New Personal Profile for each segment you want to set up (up to 16).

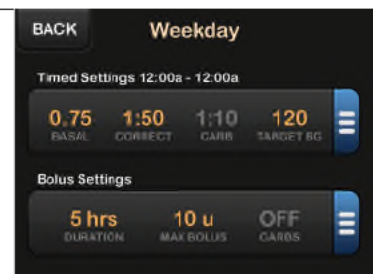
NOTE

Once a time segment is set beyond 12:00 PM, the default will change to PM.

NOTE

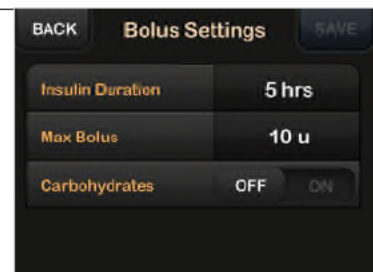
To find time segments in the list that are not displayed on the first screen, tap the scroll arrows.

12. Tap the **Bolus Settings** Panel.



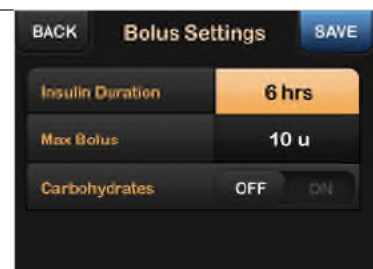
13. Tap **Insulin Duration**.

14. Using the onscreen keypad, enter the desired time for the duration of insulin action and tap **DONE**.



15. Tap **Max Bolus**.

16. Using the onscreen keypad, enter the desired amount for maximum bolus (1–25 units) and tap **DONE**.



17. Tap **Carbohydrates** to activate and use the carb ratio when calculating boluses.

NOTE

If not using a carb ratio, do not turn the Carbohydrates setting to ON.

18. Review entered values and tap **SAVE**.

19. Confirm Settings.

Tap **YES** if entered data is correct.

Tap **NO** to make changes.

20. Tap **Tandem Logo** to return to the Home Screen.

NOTE

Editing, duplicating and renaming an inactive profile will not automatically activate that profile. Refer to section 6.6 for instructions on activating profiles.

Adding More Personal Profiles

NOTE

If starting from the Home Screen, tap OPTIONS, tap My Pump, tap Personal Profiles, tap NEW. Name the new profile and repeat steps 1–10 in section 6.3.

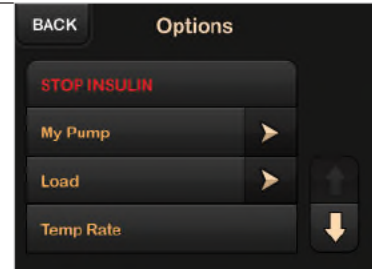
NOTE

If the first profile is programmed using a carb ratio, any new profile will also have the Carbohydrates option turned ON, but a ratio will still need to be defined.

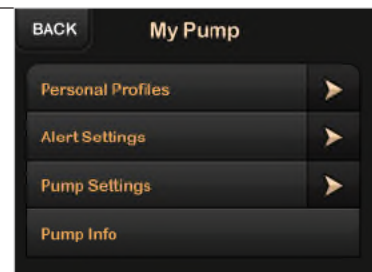
6.4 Editing an Existing Profile

1. From the Home Screen, tap **OPTIONS**.

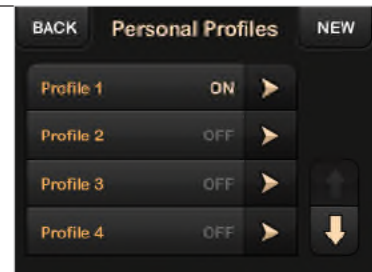
2. Tap **My Pump**.



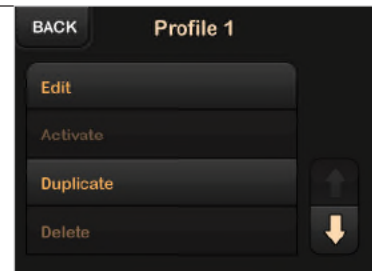
3. Tap **Personal Profiles**.



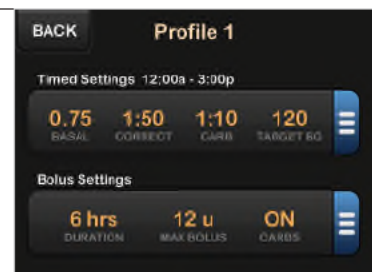
4. Tap the name of the Personal Profile to edit or review.



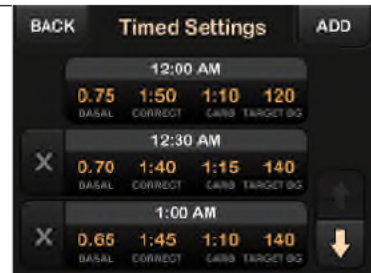
5. Tap **Edit**.



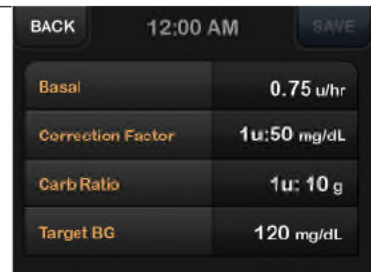
6. Tap **Timed Settings** Panel.



7. Tap the desired time segment to be edited.



8. Tap **Basal**, **Correction Factor**, **Carb Ratio** or **Target BG** to make changes as needed and use the onscreen keypad to enter desired changes. Tap **DONE**.



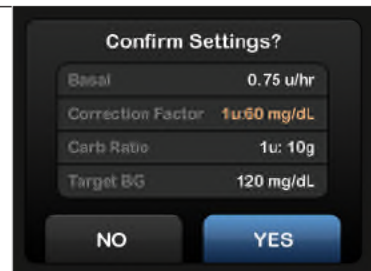
9. View recent changes and tap **SAVE**.



10. Confirm Settings.

Tap **YES** if entered data is correct.

Tap **NO** to make changes.



11. Tap **BACK** after editing all of the time segments.

NOTE

Edit other time segments within the Timed Settings by tapping on them and using the same method described above.

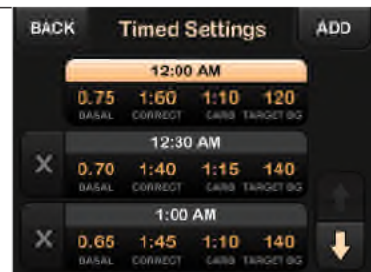
NOTE

To Add a time segment:

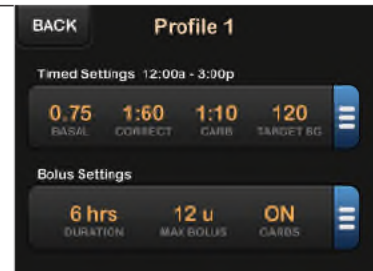
1. Tap ADD.
2. Enter desired start time.

To Delete a time segment:

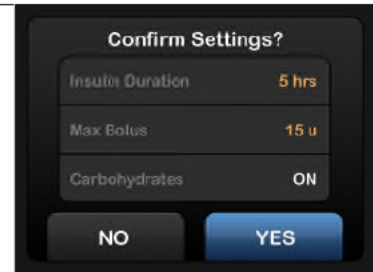
1. Tap on the X to the left of the time segment.
2. Tap YES to confirm.



12. Tap the **Bolus Settings** Panel to change DURATION, MAX BOLUS or CARBS as needed. Use the onscreen keypad to enter desired changes. Tap **SAVE**.



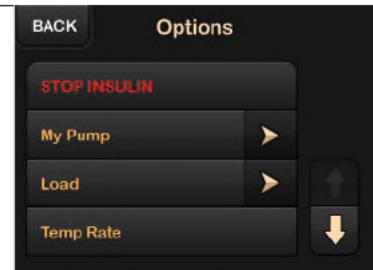
13. Confirm Settings.
Tap **YES** if entered data is correct.
Tap **NO** and make changes.



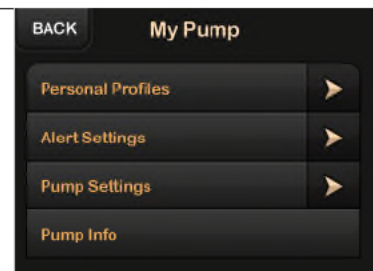
14. Tap **Tandem logo** to return to the Home Screen.

6.5 Duplicating an Existing Profile

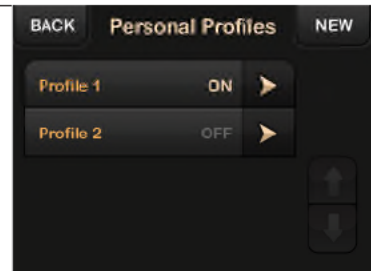
1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.



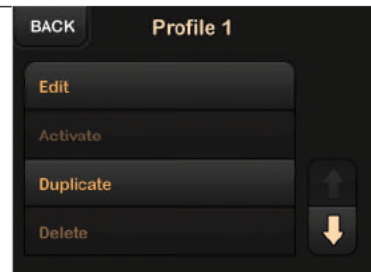
3. Tap **Personal Profiles**.



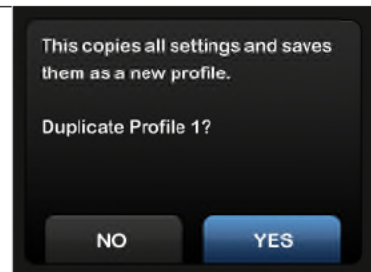
4. Tap the name of the Personal Profile to duplicate.



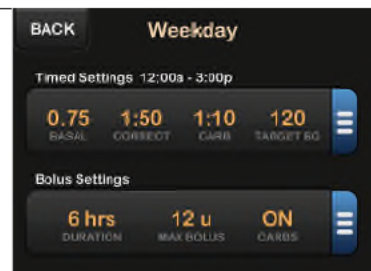
5. Tap **Duplicate**.



6. Confirm profile to duplicate by tapping **YES**.
7. Using the onscreen keypad, enter the name (up to 16 characters) for the new profile and tap **SAVE**.
- ▷ Profile Duplicated screen is displayed.
 - ▷ A new Personal Profile will be created with the same settings as the profile copied.



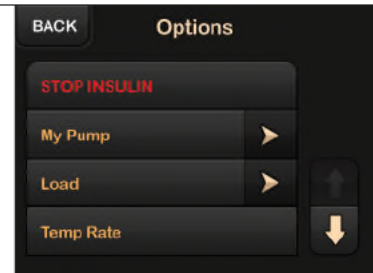
8. Tap the Timed Settings or Bolus Settings Panel to make changes to the new profile.



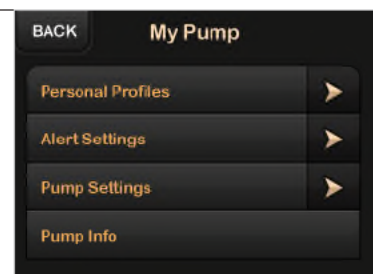
6.6 Activating an Existing Profile

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.



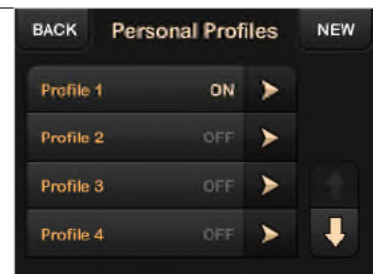
3. Tap **Personal Profiles**.



4. Tap the name of the Personal Profile to be activated.

NOTE

- » The Activate and Delete options are disabled for the currently 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).

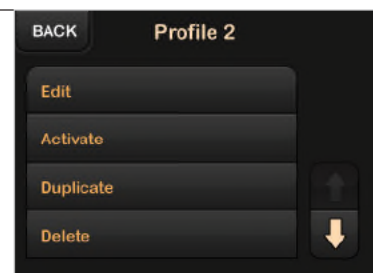


5. Tap **Activate**.

▷ A screen to confirm the activation of the profile is displayed.

6. Tap **YES**.

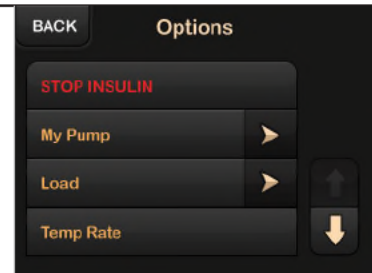
▷ Profile Activated screen is displayed.



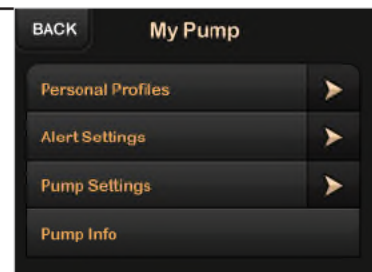
6.7 Renaming an Existing Profile

1. From the Home Screen, tap **OPTIONS**.

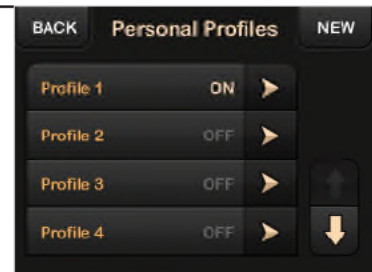
2. Tap **My Pump**.



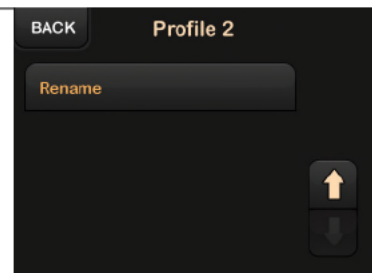
3. Tap **Personal Profiles**.



4. Tap the name of the Personal Profile to be renamed.



5. Tap **Down Arrow**, and then **Rename**.



6. Using the onscreen keypad, rename the profile name (up to 16 characters) and tap **SAVE**.

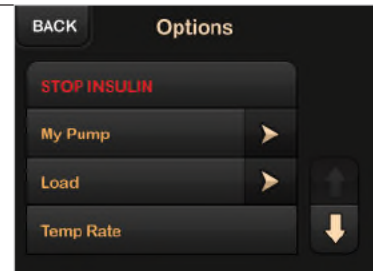
7. Tap **Tandem logo** to return to the Home Screen.



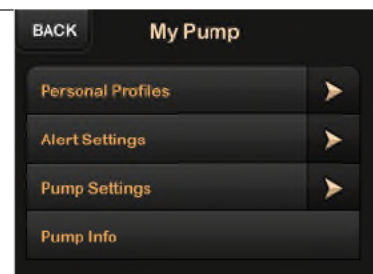
6.8 Deleting an Existing Profile

1. From the Home Screen, tap **OPTIONS**.

2. Tap **My Pump**.



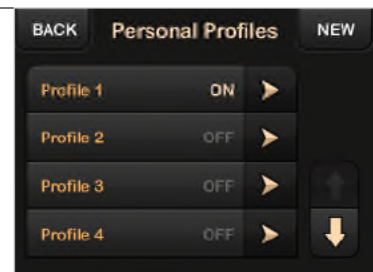
3. Tap **Personal Profiles**.



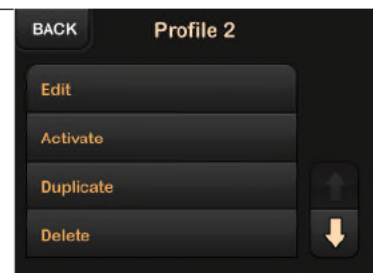
4. Tap the name of the Personal Profile to be deleted.

NOTE

The active Personal Profile cannot be deleted.



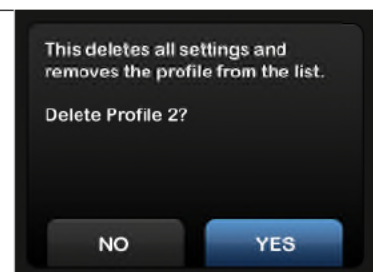
5. Tap **Delete**.



6. Tap **YES**.

▷ Profile Deleted screen is displayed.

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



Chapter 7

Bolus

7.1	Bolus Overview	71
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7.6	Canceling or Stopping a Bolus	78

7.1 Bolus Overview

A bolus is a quick dose of insulin that is usually delivered to cover food eaten or an elevated BG.

Your t:sm 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.

CAUTION

- » Before delivering insulin, always check your pump and infusion set for damage, leaks, or kinks in the tubing, as these problems could restrict or stop insulin delivery and possibly result in under-infusion.
- » If Carbohydrates is turned On in the Bolus Settings of your active Personal Profile, you can deliver boluses only in grams of carbs, not in units of insulin. To deliver in units of insulin, you need to turn off the Carbohydrates setting. Note that the quick bolus delivery setting (grams of carbohydrates or units of insulin) is independent of the active Personal Profile bolus settings.
- » When a standard bolus is being delivered, you cannot initiate another bolus. However, if the DELIVER LATER portion of an extended bolus is being delivered, you can initiate another standard bolus.
- » Only one extended bolus can be running at any given time.
- » When attempting to deliver a bolus that exceeds either your Personal Profile's Max Bolus setting or the pump's maximum bolus amount allowed, a Max Bolus Alert will occur and you will need to make a decision on whether to continue with bolus delivery, adjust the amount, or accept the pump's maximum allowable amount. Refer to Max Bolus Alert in section 15.7.

NOTE

If the max bolus is set at 25 units and the requested bolus is greater than 25 units, after the bolus is delivered a reminder screen will appear. The option of delivering the remaining amount of the bolus of up to an additional 25 units will be given. Refer to Max Bolus Alert in section 15.7.

NOTE

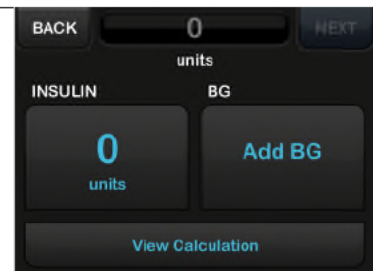
When attempting to deliver a bolus that exceeds the amount of insulin remaining in the cartridge, a message screen appears indicating there is not enough insulin to deliver the requested bolus. You are required to enter a new amount.

7.2 Food Bolus Using Units

NOTE

If bolus using a carb ratio skip to the next section Food Bolus Using Grams.

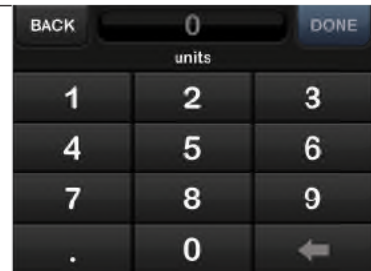
1. From the Home Screen, tap **BOLUS**.
2. Tap **0 units**.



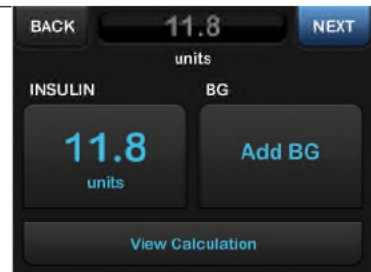
3. Using the onscreen keypad enter desired units of insulin, tap **DONE**.

CAUTION

Always confirm that the decimal placement is correct.



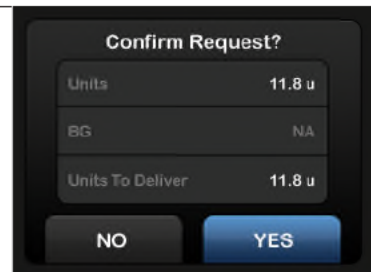
4. Tap **NEXT** to confirm the units of insulin to be delivered.



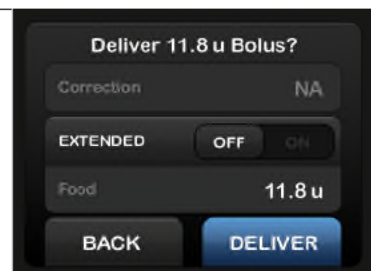
5. Confirm Request.

Tap **YES** if entered data is correct.

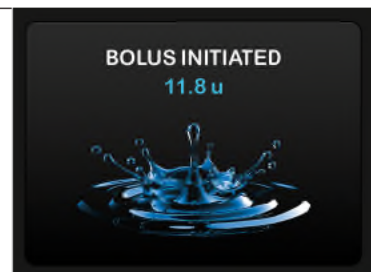
Tap **NO** to go back to make changes or view calculations.



6. Tap **DELIVER**.



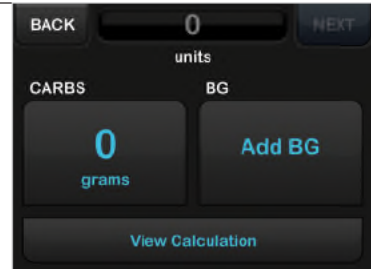
7. The bolus splash is displayed.



7.3 Food Bolus Using Grams

1. From the Home Screen, tap **BOLUS**.

2. Tap **0 grams**.



3. Using the onscreen keypad enter grams of carb and tap **DONE**.

NOTE

- » 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.



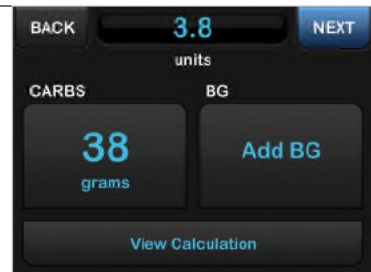
4. Tap **NEXT** to confirm the units of insulin to be delivered.

NOTE

Tap View Calculation to display the Delivery Calculation screen.

NOTE

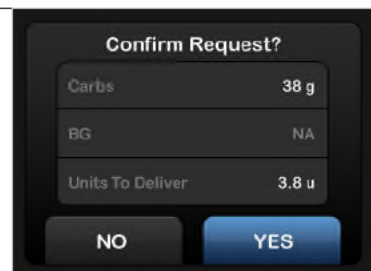
Tap the displayed units calculated to override the amount.



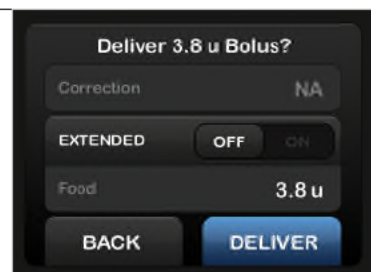
5. Confirm Request.

Tap **YES** if entered data is correct.

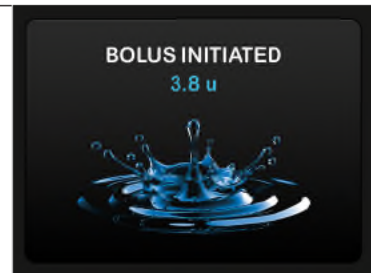
Tap **NO** to go back to make changes or view calculations.



6. Tap **DELIVER**.

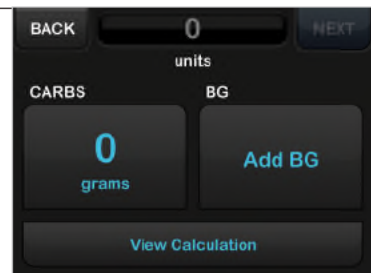


7. The bolus splash screen is displayed.



7.4 Correction Bolus

1. From the Home Screen, tap **BOLUS**.
2. Tap **Add BG**.



3. Using the onscreen keypad, enter BG value and tap **DONE**.



NOTE

Once DONE is tapped, the BG value is saved in pump History whether or not a bolus is delivered.

NOTE

- » If BG is above the Target BG, a message screen will indicate BG is above Target. To add a correction bolus tap YES.
- » If BG is below Target BG, a message screen advises to eat carbs and retest. Tap Close.
- » If BG is at Target BG, it will return to the Bolus Screen with no recommended bolus amount for correction.

NOTE

- » Tap the View Calculation to display the Delivery Calculation screen.
- » If there is OB, the amount will be subtracted from the correction portion of the bolus.
- » Tap the displayed units calculated to override the amount.

NOTE

When your blood glucose is:

- » **Above Target BG:** the insulin for the food bolus and the correction bolus will be added together. If OB is present, it will only be used in the calculation of the correction portion of the bolus.
- » **Between 70 mg/dL and Target BG:** No correction bolus is calculated. No adjustment will be made to the food bolus even if OB is present.
- » **Below 70 mg/dL:** The food bolus will be reduced to correct for the low blood glucose. In addition, if OB is present, it will also be used in the calculation of the food bolus to return your BG to target.

- 4. Tap **NEXT** to confirm the units of insulin to be delivered.**

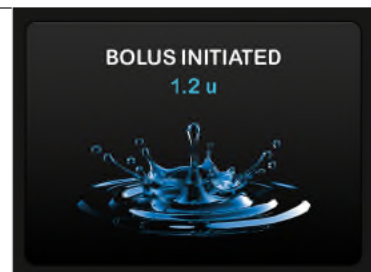
- 5. Confirm Request.**

Tap **YES** if entered data is correct.

Tap **NO** to go back to make changes or view calculations.

- 6. Tap **DELIVER**.**

- 7. The bolus splash screen is displayed.**



7.5 Extended Bolus

1. From the Home Screen, tap **BOLUS**.
2. Tap **0 grams** (or **0 units**).
3. Using the onscreen keypad enter grams of carb (or units of insulin). Tap **DONE**.
4. If desired, tap **Add BG** and using the onscreen keypad enter BG value. Tap **DONE**.

BACK 0 NEXT
units
CARBS BG
0 Add BG
grams
View Calculation

5. Tap **NEXT** to confirm the units of insulin to be delivered.

NOTE

Tap View Calculation to display the Delivery Calculation screen.

BACK 5 NEXT
units
CARBS BG
118 180
grams mg/dL
View Calculation

6. Confirm Request.

Tap **YES** if entered data is correct.

Tap **NO** to go back to make changes or view calculations.

Confirm Request?
Carbs 118 g
BG 180 mg/dL
Units To Deliver 5 u
NO YES

7. Tap **EXTENDED** to turn ON the extended feature, then tap **NEXT**.

Extend Food Bolus?
Correction 1.2 u
EXTENDED OFF ON
Food 3.8 u
BACK NEXT

8. Tap **50%** under DELIVER NOW to adjust the percentage of the food bolus that is to be delivered immediately.

NOTE

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.

BACK 3.8 NEXT
units
DELIVER NOW DELIVER LATER
50 % 50 %
DURATION
2 hrs View Units

NOTE

A correct on bolus will always be given in the DELIVER NOW portion.

9. Use the onscreen keypad to enter the percentage of the bolus to DELIVERED NOW and tap **DONE**.

NOTE

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.

10. Tap **2 hrs** under DURATION.

NOTE

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 will be notified and the duration of the DELIVER LATER portion will be adjusted.

11. Use the onscreen keypad to adjust the length of time the bolus is to be delivered, then tap **DONE**.

12. Tap **NEXT**.

NOTE

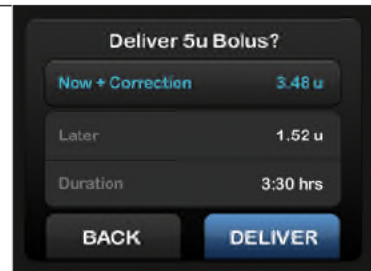
Tap View Units to display the breakdown of units to be delivered NOW versus LATER.

13. Confirm Request.

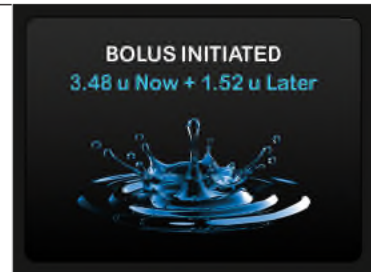
Tap **YES** if entered data is correct.

Tap **NO** to go back to make changes or view calculations.

14. Verify settings and tap **DELIVER**.



15. The bolus splash screen is displayed.



7.6 Canceling or Stopping a Bolus

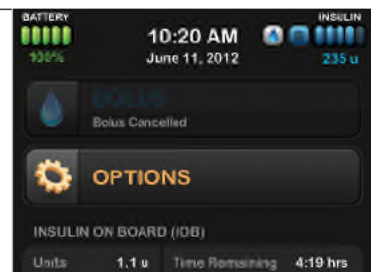
Canceling a Bolus

If delivery **Has Not Started** but has been initiated:

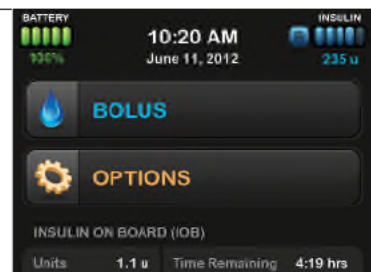
1. Tap red **X** to cancel the bolus.



The bolus button will remain inactive while the bolus is being cancelled.



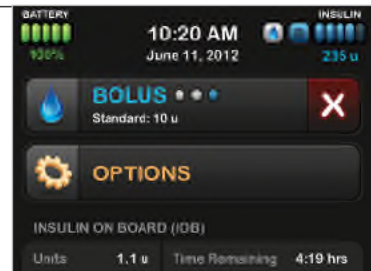
Once cancelled, the bolus button will become active again on the Home Screen.



Stopping a Bolus

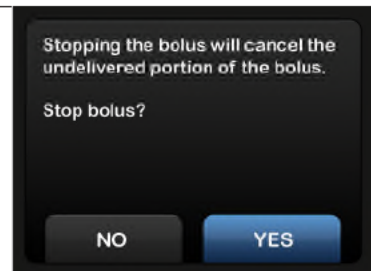
If delivery of the bolus **Has Started**:

1. Tap red **X** to stop delivery.

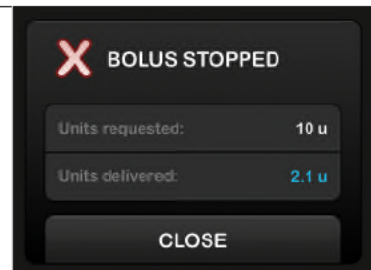


2. Tap **YES**.

▷ The BOLUS STOPPED screen is displayed and the units delivered are calculated.



3. Units requested and delivered are shown. Tap **CLOSE**.



Chapter 8

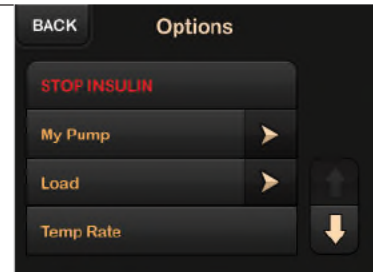
Stop/Resume Insulin

8.1	Stopping Insulin Delivery	81
8.2	Resuming Insulin Delivery	82

8.1 Stopping Insulin Delivery

At any time, even after delivery has started, you can stop all insulin deliveries at once, including basal and any active bolus or temporary deliveries.

1. From the Home Screen, tap **OPTIONS**.
2. Tap **STOP INSULIN**.



3. Tap **STOP**.

- ▷ The All Deliveries Stopped screen appears before returning to the Home Screen showing the status "ALL DELIVERIES STOPPED".

NOTE

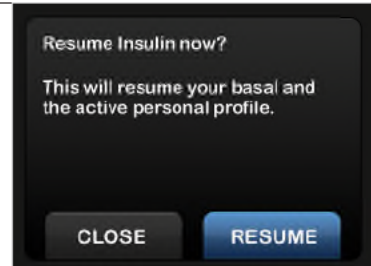
- » When you tap **STOP** on the confirmation screen, any active bolus and any active temporary rate are immediately suspended. If you tap **BACK** on the confirmation screen, bolus delivery continues.
- » No insulin delivery can take place while your pump is stopped.



8.2 Resuming Insulin Delivery

1. If pump screen is not on, press **Screen On/Quick Bolus** Button once to turn on your t:slim Pump screen.

2. Tap **RESUME**.

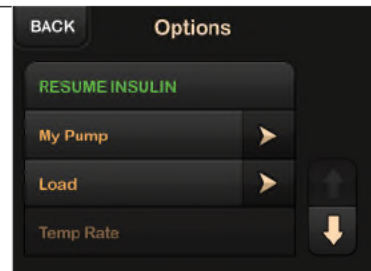


3. The **RESUMING INSULIN** splash screen is displayed.

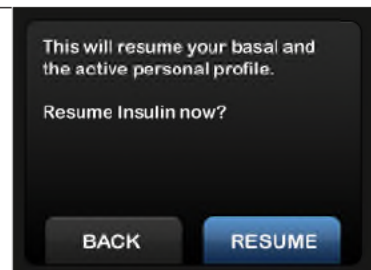


– OR –

1. From the Home Screen, tap **OPTIONS**.
2. Tap **RESUME INSULIN**.



3. Tap **RESUME**.



4. The **RESUMING INSULIN** splash screen is displayed.



Section 3

Additional Pump Operations

Chapter 9

Temporary Basal Rate

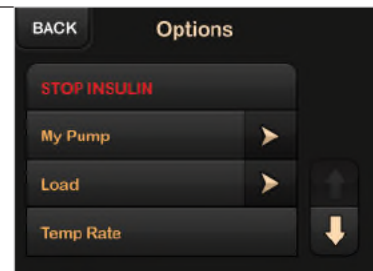
9.1	Setting a Temp Rate	85
9.2	Stopping a Temp Rate	86

9.1 Setting a Temp Rate

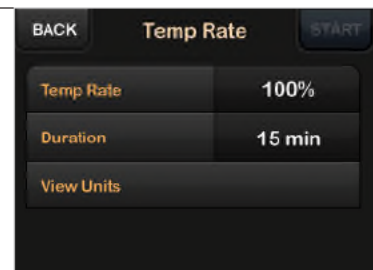
A Temp Rate is used to increase or decrease (by percentage) the current basal rate for a period of time to accommodate special situations. When you enter the Temp Rate screen, the default values are 100% (current basal rate) and a Duration of 0:15 min. The Temp Rate can be set from a minimum of 0% of current basal rate to a maximum of 250% of current basal rate in increments of 1%. If you program a Temp Rate greater than 0% but less than the minimum allowable basal rate of 0.1 units/h, you will be notified that the selected rate is too low and that it will be set to the minimum allowable rate for the day. If you program a Temp Rate more than the maximum allowable basal rate of 15 units/h, you will be notified that the selected rate is too high and that it will be set to the maximum allowable rate for the day. Duration can be set from a minimum of 15 minutes to a maximum of 72 hours in increments of 1 minute.

1. From the Home Screen, tap **OPTIONS**.

2. Tap **Temp Rate**.



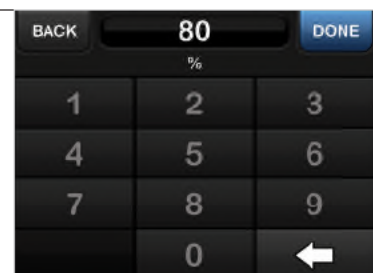
3. Tap **Temp Rate**.



4. Using the onscreen keypad enter desired percentage. Tap **DONE**.

NOTE

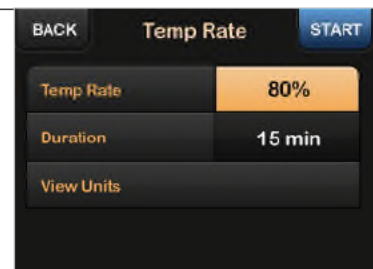
Current rate is 100%. An increase is greater than 100% and decrease is less than 100%.



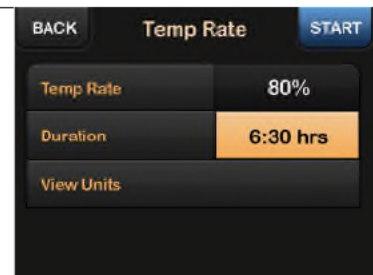
5. Tap **Duration**. Using the onscreen keypad enter desired length of time for temp rate. Tap **DONE**.

NOTE

To see the actual units to be delivered tap View Units.



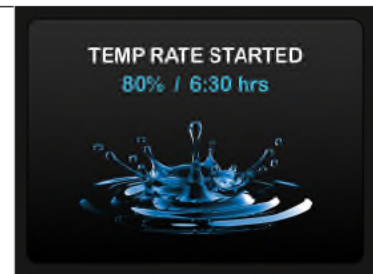
6. Verify settings and tap **START**.



7. The TEMP RATE STARTED splash screen is displayed.

NOTE

If a Temp Rate is currently active, the status of insulin delivery displays an orange "T". If a Temp Rate of 0% is currently active, the status of insulin delivery displays a red "T".

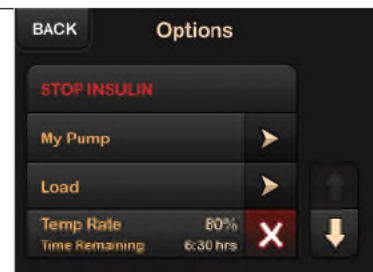


8. The Screen Lock screen will be displayed with the icon indicating a Temp Rate is active.

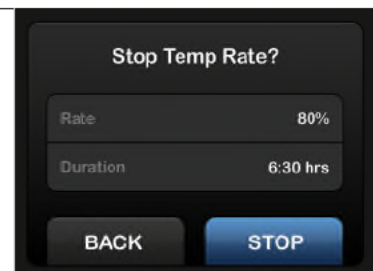
9.2 Stopping a Temp Rate

You can stop a temp rate that is currently being delivered.

1. On the Home Screen, tap **OPTIONS**.
2. On the Options screen, tap **X** (stop icon) on the right side of Temp Rate.



3. On the confirmation screen, tap **STOP**. The TEMP RATE STOPPED screen appears before returning to the Options screen.



Chapter 10

Quick Bolus

10.1	Setting Up Quick Bolus	88
10.2	Delivering Quick Bolus.....	91

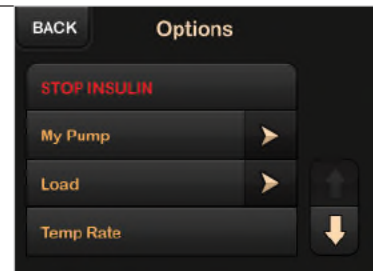
10.1 Setting Up Quick Bolus

Setting up the Quick Bolus function enables you to deliver a bolus by simply pressing a button. It is a way to deliver a bolus by following beep/vibrate commands without navigating through or viewing the pump screen.

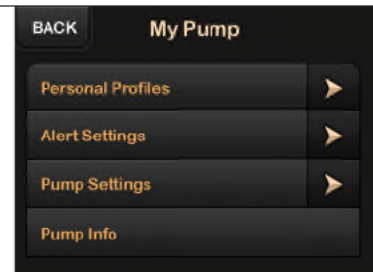
The default of the Quick Bolus function is OFF. Quick Bolus can be set to either units of insulin or grams of carbohydrate. The increment options are 0.5, 1.0, 2.0, and 5.0 units; or 2, 5, 10 and 15 carbs.

1. From the Home Screen, tap **OPTIONS.**

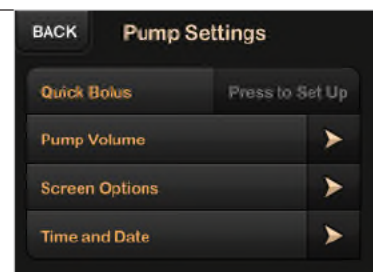
2. Tap **My Pump.**



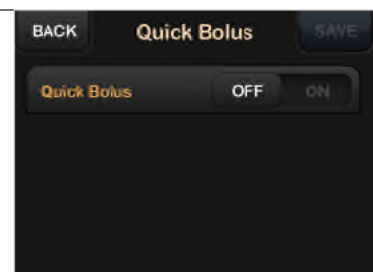
3. Tap **Pump Settings.**



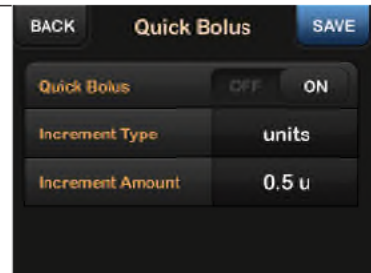
4. Tap **Quick Bolus.**



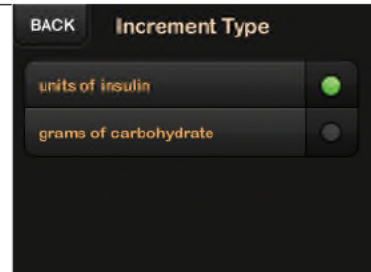
5. Tap **Quick Bolus to turn On.**



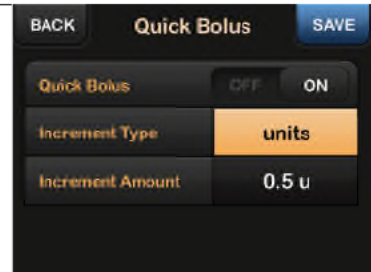
6. Tap **Increment Type**.



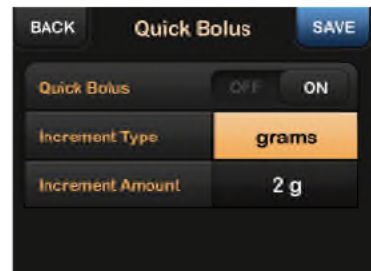
7. Tap **units of insulin** or **grams of carbohydrate**.



8. Tap **Increment Amount**.



Quick Bolus using units



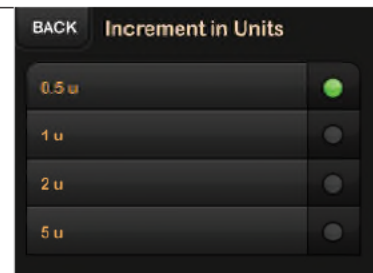
Quick Bolus using grams

- 9.** Select the preferred increment amount.

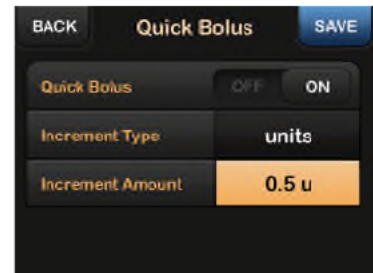
NOTE

The increment amount is added with each press of the Quick Bolus Button when delivering a quick bolus.

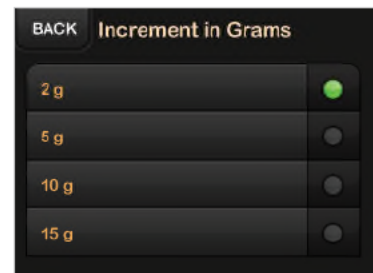
- 10.** Review entered values and tap **SAVE**.



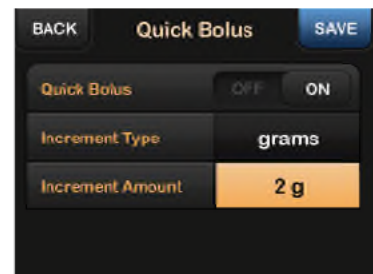
Quick Bolus using units



Quick Bolus using units



Quick Bolus using grams



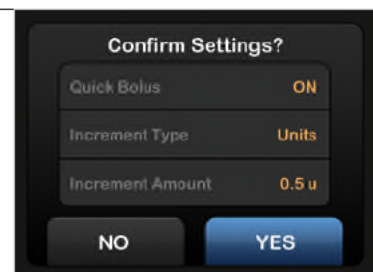
Quick Bolus using grams

- 11.** Confirm Settings.

Tap **YES** if entered data is correct.

Tap **NO** to go back to make changes.

- 12.** Tap **Tandem Logo** to return to the Home Screen.



10.2 Delivering Quick Bolus

If the Quick Bolus function is turned On, you can deliver a bolus without having to look at the insulin Pump's screen. Simply use the Quick Bolus Button to deliver your bolus. Quick bolus uses a delivered as standard boluses (there is no BG entry nor extended delivery capabilities).

CAUTION

When you first use the Quick Bolus feature, you should always look at the screen to confirm correct programming until you are comfortable with this feature.

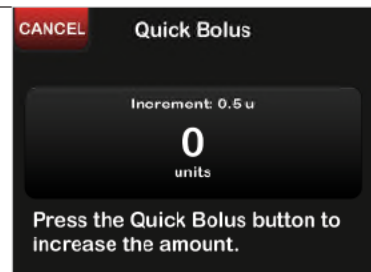
1. Press and hold **Quick Bolus** Button. The Quick Bolus screen will appear. Listen for 2 beeps (if Pump Volume is set to beep) or feel for vibrations (if Pump Volume is set to vibrate).

NOTE

Insulin will beep and vibrate during a Quick Bolus if a beep volume is set. It will only vibrate if the vibrate option is selected.



2. Press **Quick Bolus** Button for each increment until desired amount is reached. The pump will beep/vibrate for each button press.



Quick Bolus using units



Quick Bolus using grams

3. Please wait a few seconds for the pump to beep/vibrate back for each increment pressed to confirm desired amount.
4. After the pump beeps/vibrates, press and hold **Quick Bolus** button to deliver the bolus.

NOTE

- » If more than 5 seconds have passed with no input, the bolus is canceled and never delivered.
- » If you want to cancel the bolus and return to the Home Screen, tap CANCEL on the QUICK BOLUS screen.
- » If the amount you indicated by your button presses exceeds the Max Bolus amount defined in your active Persona Profile, the Quick Bolus Button does not respond to any more button presses.

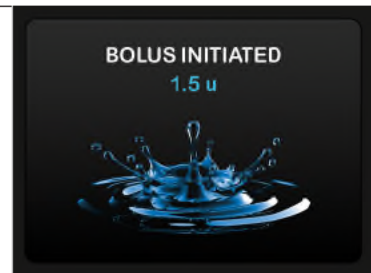


Quick Bolus using units



Quick Bolus using grams of carbs

5. The bolus splash screen is displayed.



Chapter 11

t:slim® Pump Settings

11.1	t:slim Pump Volume	94
11.2	Screen Options	95

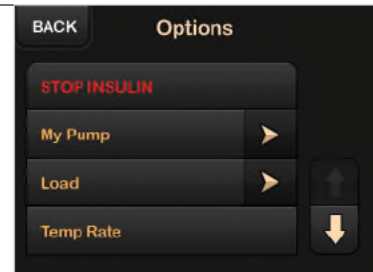
11.1 t:slim Pump Volume

You t:slim Pump is developed from Tandem Diabetes Care, Inc. with the volume pre-set at High. A change to the Pump Volume can be made in Pump Settings.

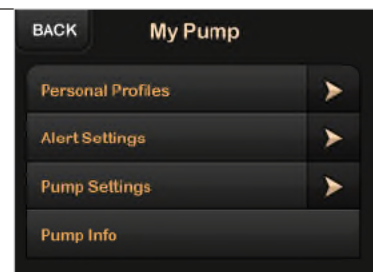
Pump Volume can be personalized for the Buttons, Quick Bolus, Bolus, Reminders, Alerts, and Alarms. Options for Pump Volume include high, medium, low and vibrate.

1. From the Home Screen, tap **OPTIONS**.

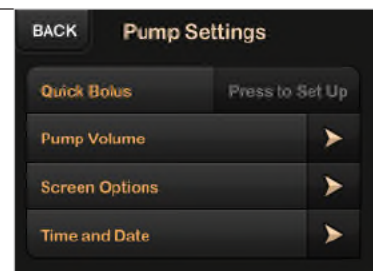
2. Tap **My Pump**.



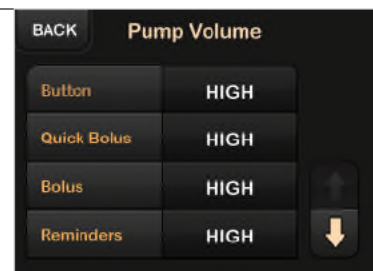
3. Tap **Pump Settings**.



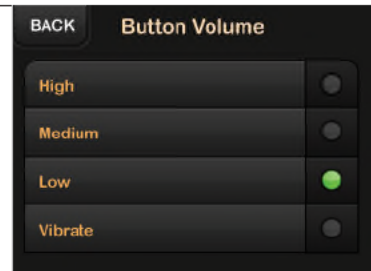
4. Tap **Pump Volume**.



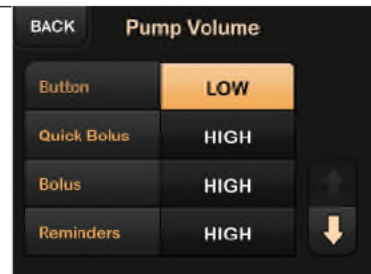
5. Tap desired option.



6. Select preferred volume.



7. Continue to make changes for all Pump Volume options by repeating steps 5 and 6.
8. Tap **Tandem Logo** to return to the Home Screen.



11.2 Screen Options

The Screen Options for your t:slim Pump include Screen Timeout and Feature Lock.

The Screen Timeout can be personalized to the duration the screen stays on without any touch screen interaction. The default for the Screen Timeout is 30 seconds. The recommended options are 15, 30, 60, and 120 seconds.

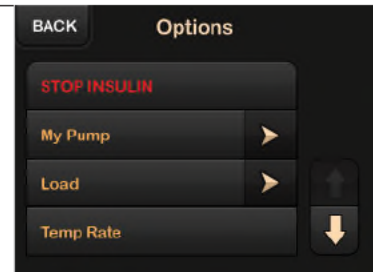
Your t:slim Pump is developed from Tandem Diabetes Care, Inc. with the Feature Lock turned OFF. With the Feature Lock turned ON, you cannot delete a bolus, change any pump settings or access any Personal Profiles.

NOTE

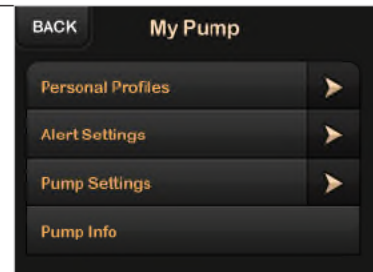
Turn off the pump screen by pressing the Screen On/Quick Bolus button before placing the pump back in its case or any pocket/cloth to prevent unintentional interactions with the touchscreen. A warning post on the pump screen away from the skin when worn under clothing.

1. From the Home Screen, tap **OPTIONS**.

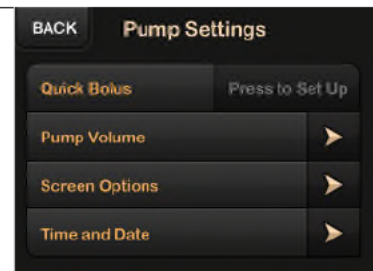
2. Tap **My Pump**.



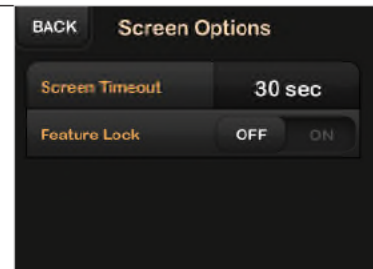
3. Tap **Pump Settings**.



4. Tap **Screen Options**.



5. Tap desired option.

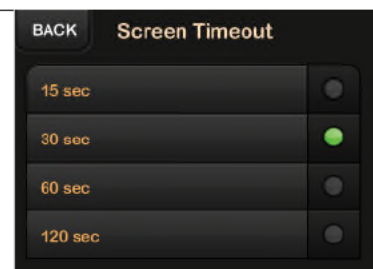


For Screen Timeout

1. Tap **Screen Timeout**.

2. Select preferred time.

3. Tap **Tandem logo** to return to the Home Screen.

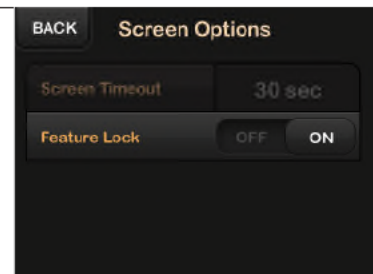


For Feature Lock

1. Tap **Feature Lock** to turn ON or OFF.
 - ▷ A screen to verify that you want to activate the Feature Lock will be displayed.
2. Tap **Tandem logo** to return to the Home Screen.

NOTE

If Feature Lock is turned on, a screen taps will be on a high volume until the Feature Lock is turned off.



To Turn the Feature Lock Off

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Pump Settings**.
4. Tap **Screen Options**.
5. Tap **Feature Lock**.
6. Tap **YES**.

Chapter 12

t:slim[®] Pump Info and History

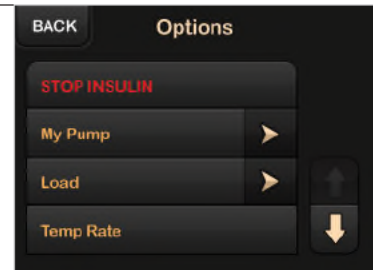
12.1	t:slim Pump Info.....	99
12.2	t:slim Pump History.....	100

12.1 t:slim Pump Info

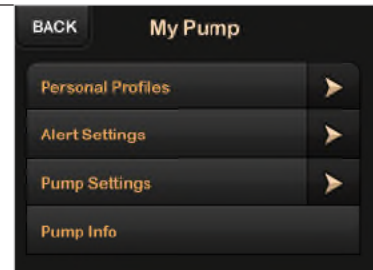
You t:slim Pump allows access to information regarding your pump. In the Pump Info screen you have access to items such as your pump Serial Number, Customer Technical Support telephone number, website, and software/hardware versions.

1. From the Home Screen, tap **OPTIONS**.

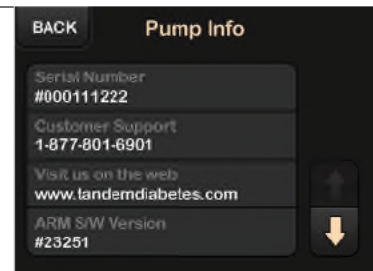
2. Tap **My Pump**.



3. Tap **Pump Info**.



4. Scroll through the Pump Info using the **Up/Down** arrows.
5. Tap **Tandem logo** to return to the Home Screen.



12.2 t:slim Pump History

The History displays the history of pump events. The following history reports can be viewed: Delivery Summary, Bolus, Basal, Load, BG, Alerts and Alarms, and Complete.

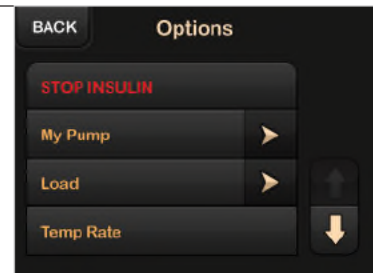
The Delivery Summary breaks down total insulin delivery by basal and bolus types into units and percentages. It can be viewed by the selected time period of: Today, 7 Day, 14 Day and 30 Day Average.

The Bolus, Basal, Load, BG Alerts and Alarms and Complete are categorized by date. The event details in each report are listed by time.

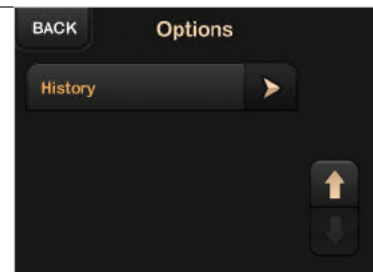
Bolus History shows the bolus start time and the bolus completion time.

1. From the Home Screen, tap **OPTIONS**.

2. Tap the **Down Arrow**.

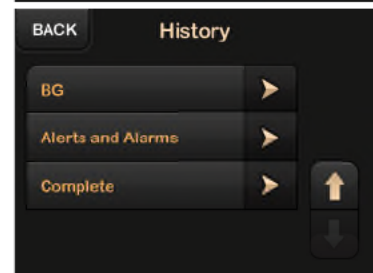
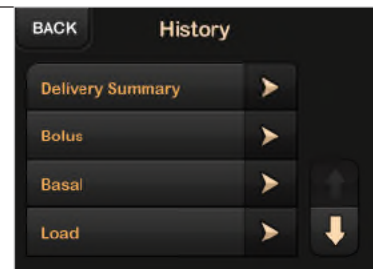


3. Tap **History**.



4. Tap desired option.

5. Tap **Tandem logo** to return to the Home Screen.



Chapter 13

Reminders

13.1	Low BG Reminder.....	102
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13.3	After Bolus BG Reminder.....	106
13.4	Missed Meal Bolus Reminder	108
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Your t:slim Pump has customizable reminders, including:

- Low BG Reminder
- High BG Reminder
- After Bolus BG Reminder
- Missed Meal Bolus Reminder
- Site Reminder

Reminders sound with a single note at the volume/vibe selected in Pump Settings. They repeat at regular intervals until acknowledged. Reminders do not escalate.

13.1 Low BG Reminder

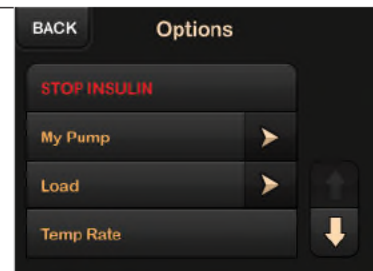
The Low BG Reminder prompts you to re-test your BG after a low BG value is entered. When turning this reminder setting On, you need to specify a low BG value that triggers the reminder, as well as how much time should pass before the reminder occurs. The default values are pre-set to Off, or Off On; Remind Me Below 70 mg/dL, and Remind Me After 15 min, but you can set these values from 70–120 mg/dL and 10–20 min.

NOTE

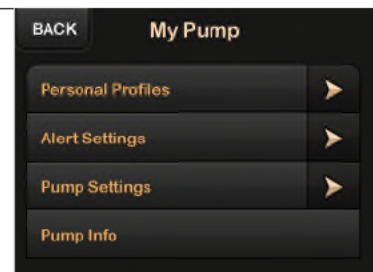
Reminders sound with a single note at the volume selected in Pump Settings. They repeat at regular intervals until acknowledged. Reminders do not escalate.

1. From the Home Screen, tap **OPTIONS.**

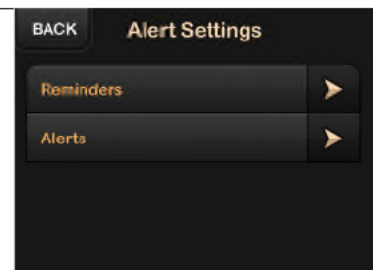
2. Tap **My Pump.**



3. Tap **Alert Settings.**



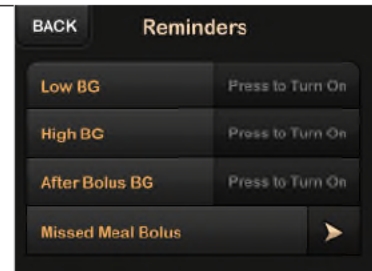
4. Tap **Reminders.**



5. Tap Low BG.

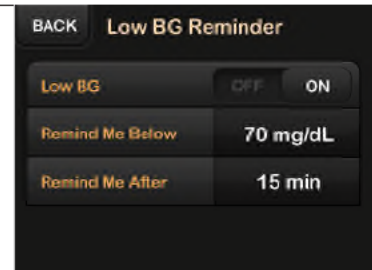
NOTE

If not first-time setup, previous values appear instead of "Press to Turn On."



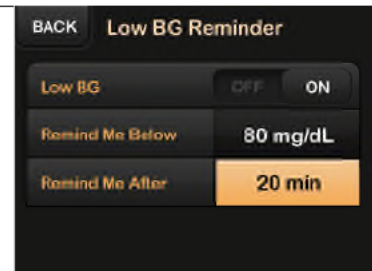
6. Tap Low BG to turn ON or OFF:

- a) Tap **Remind Me Below** and using the onscreen keypad, enter a Low BG value (from 70–120 mg/dL) that you want to trigger the reminder, then tap **SAVE**.
- b) Tap **Remind Me After** and using the onscreen keypad, enter the time duration (from 10–20 min), then tap **SAVE**.



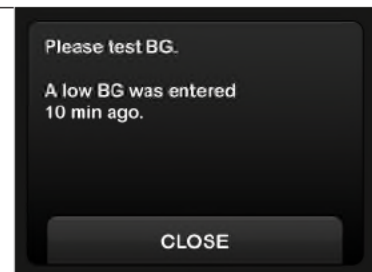
7. Tap BACK on the Low BG Reminder screen to verify your Low BG Reminder setting.

8. Tap Tandem logo to return to the Home Screen.



To Respond to the Low BG Reminder

To clear the reminder and return to whatever activity was in progress when the reminder occurred, tap **CLOSE**.

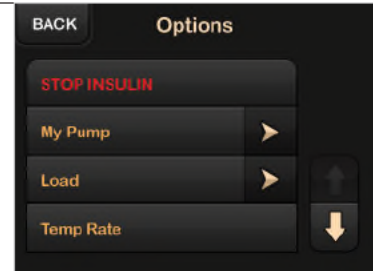


13.2 High BG Reminder

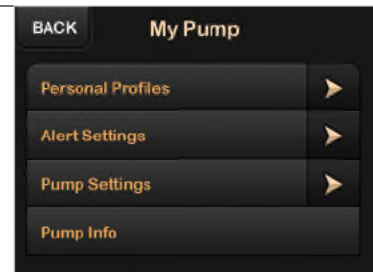
The High BG Reminder prompts you to re-test your BG after a high BG value is entered. When you turn the reminder setting on, you need to specify a high BG value that triggers the reminder, as well as how much time should pass before the reminder occurs. The default values are pre-set to Off, off On, Remind Me Above 200 mg/dL, and Remind Me After 120 min, but you can set these values from 150–300 mg/dL and 1–3 hours.

1. From the Home Screen, tap **OPTIONS**.

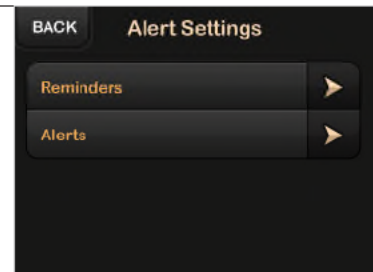
2. Tap **My Pump**.



3. Tap **Alert Settings**.



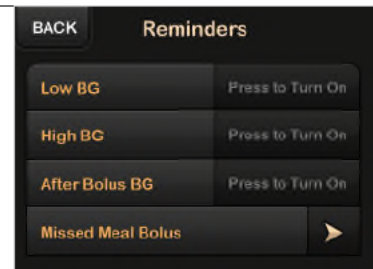
4. Tap **Reminders**.



5. Tap **High BG**.

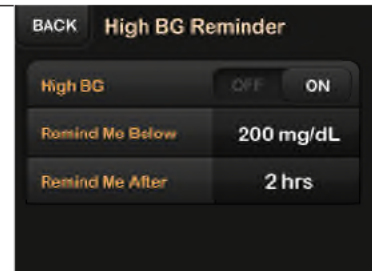
NOTE

If not first-time setup, previous values appear instead of "Press to Turn On".



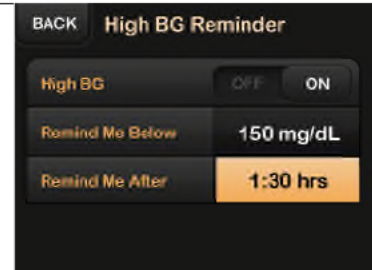
6. Tap High BG to turn ON or OFF.

- a) Tap **Remind Me Above** and using the onscreen keypad, enter a High BG value (from 150–300 mg/dL) that you want to trigger the reminder, then tap **SAVE**.
- b) Tap **Remind Me After** and using the onscreen keypad, enter the time duration (from 1–3 hours), then tap **SAVE**.



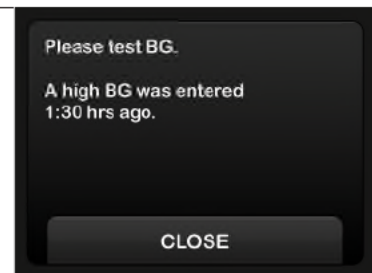
7. Tap BACK on the High BG Reminder screen to verify your High BG Reminder setting.

8. Tap Tandem logo to return to the Home Screen.



To Respond to the High BG Reminder

To clear the reminder and return to whatever activity was in progress when the reminder occurred, tap **CLOSE**.

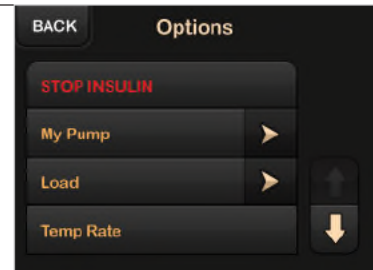


13.3 After Bolus BG Reminder

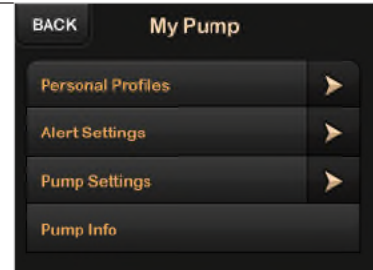
The After Bolus BG Reminder prompts you to test your BG a selected time period after a bolus has been delivered. When turning this reminder on, you need to specify how much time should pass before the reminder occurs. The options include: 1 hour, 1:30 hours, 2 hours and 3 hours.

1. From the Home Screen, tap **OPTIONS**.

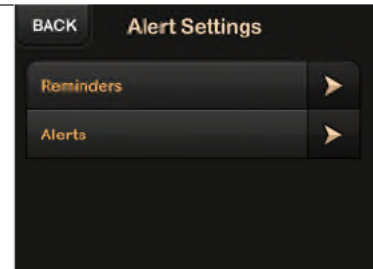
2. Tap **My Pump**.



3. Tap **Alert Settings**.



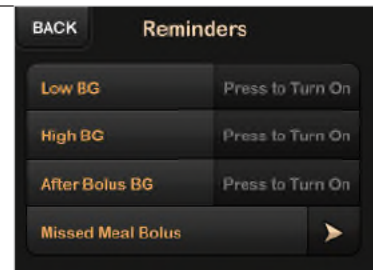
4. Tap **Reminders**.



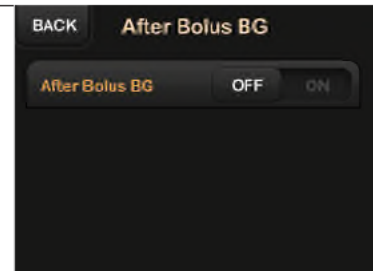
5. Tap **After Bolus BG**.

NOTE

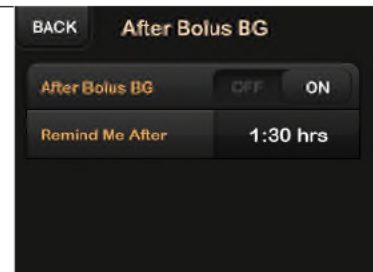
If not first-time setup, previous values appear instead of "Press to Turn On".



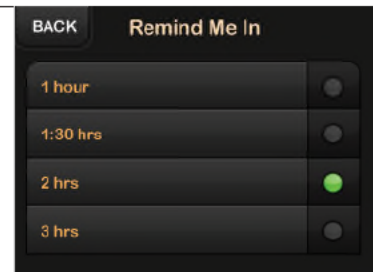
- 6.** Tap **After Bolus BG** to turn ON or OFF.



- 7.** Tap **Remind Me After**.

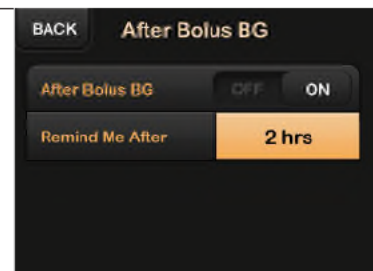


- 8.** Tap the preferred time duration.



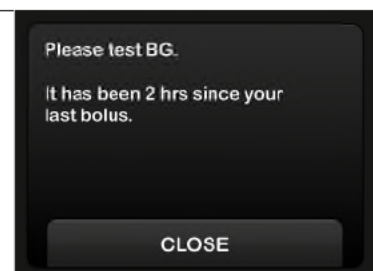
- 9.** Tap **BACK** on the After Bolus BG screen to verify your After BG Reminder setting.

- 10.** Tap **Tandem logo** to return to the Home Screen.



To Respond to the After Bolus BG Reminder

To clear the reminder and return to whatever activity was in progress when the reminder occurred, tap **CLOSE**.

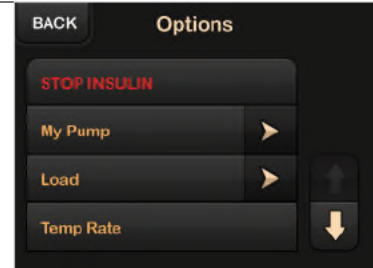


13.4 Missed Meal Bolus Reminder

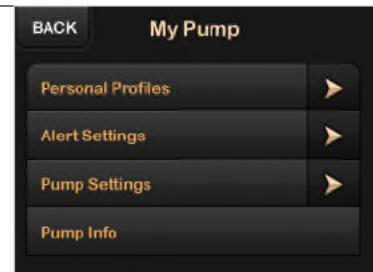
The Missed Meal Bolus Reminder is a personalized reminder that notifies you that a bolus was not delivered during a specified time period. Four separate reminders are available. When programming this reminder, you need to select the Days, the Start Time, and End Time for each reminder.

1. From the Home Screen, tap **OPTIONS**.

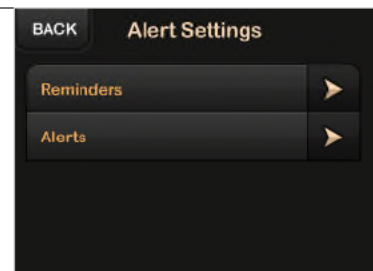
2. Tap **My Pump**.



3. Tap **Alert Settings**.



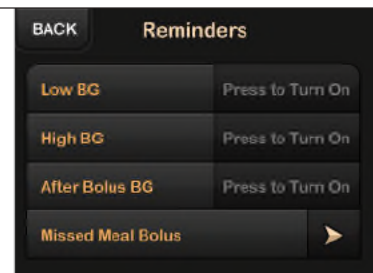
4. Tap **Reminders**.



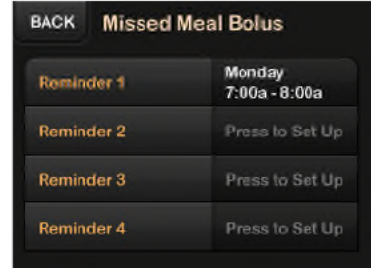
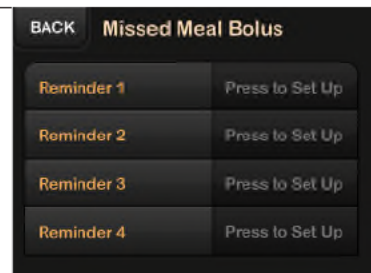
5. Tap **Missed Meal Bolus**.

NOTE

If not first-time setup, previous values appear instead of "Press to Set Up".



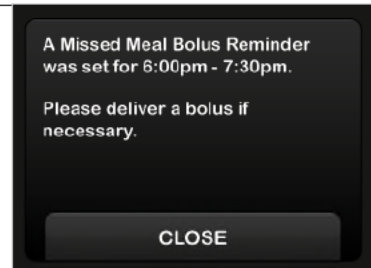
6. On the Missed Meal Bolus screen, tap which reminder you want to set (Reminder 1–4) and do the following:
- Tap **Reminder 1** (options 2, 3, 4).
 - Tap **Reminder 1** (options 2, 3, 4) to set the reminder **ON**.
 - Tap **Selected Days** and tap the desired day(s) you want the reminder to be on, tap **BACK**.
 - Tap **Start Time**, tap **Time** and using the onscreen keypad enter the start time, tap **DONE**.
 - Tap **Time of Day** to select **AM** or **PM**, tap **SAVE**.
 - Tap **End Time**, tap **Time** and using the onscreen keypad enter the end time, tap **DONE**.
 - Tap **Time of Day** to select **AM** or **PM**, tap **SAVE**.
 - Tap **BACK** to return to the Missed Meal Bolus menu to review.



7. Tap **Tandem Logo** to return to the Home Screen.

To Respond to the Missed Meal Bolus Reminder

To clear the reminder and return to whatever activity was in progress when the reminder occurred, tap **CLOSE**.



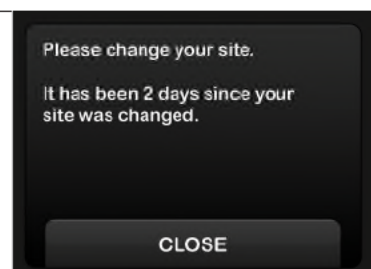
13.5 Site Reminder

The Site Reminder prompts you to change your infusion set. If enabled (default is off), 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, refer to section 5.6.

To Respond to the Site Reminder

To clear the reminder and return to whatever activity was in progress when the reminder occurred, tap **CLOSE**.



Chapter 14

User Settable Alerts and Alarms

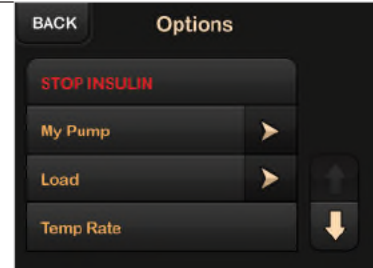
14.1	Low Insulin Alert.....	111
14.2	Auto-Off Alarm	112

14.1 Low Insulin Alert

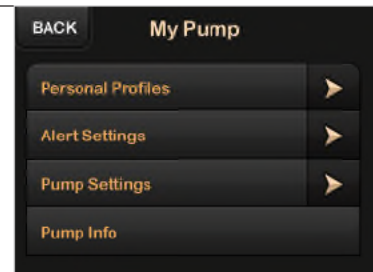
Your insulin Pump continuously tracks how much insulin is emanating in the catheter and alerts you when it is low. You can adjust the Low Insulin Alert setting (the default value is pre-set to 20 units, but it can be set anywhere from 10 to 40 units). When the insulin amount reaches the set value, the Low Insulin Alert beeps/vibrates and appears on the screen.

1. From the Home Screen, tap **OPTIONS**.

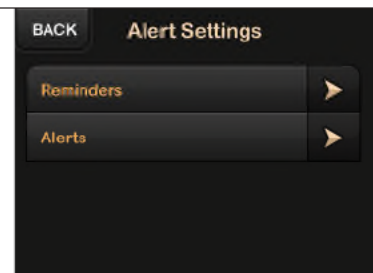
2. Tap **My Pump**.



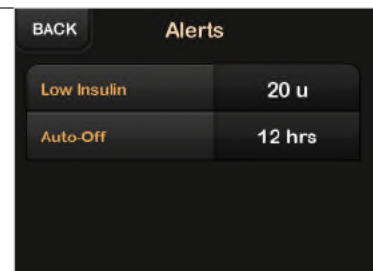
3. Tap **Alert Settings**.



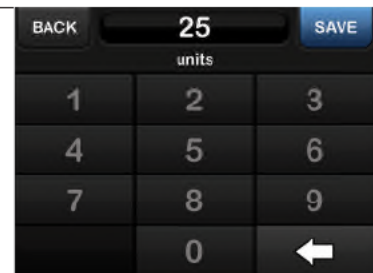
4. Tap **Alerts**.



5. Tap **Low Insulin**.



6. Using the onscreen keypad, enter the number of units (from 10–40 units) that you want the Low Insulin Alert value to be set, and tap **SAVE**.
7. Tap **Tandem logo** to return to the Home Screen.

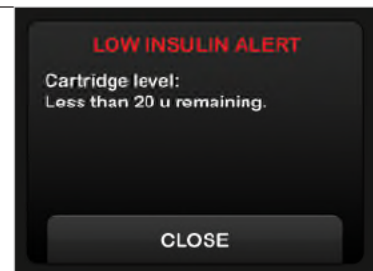


To Respond to the Low Insulin Alert

To clear the message and return to whatever activity was in progress when the message occurred, tap **CLOSE**.

NOTE

Once the LOW INSULIN ALERT occurs, the low insulin indicator (a single red bar on the insulin level) appears in the upper right corner of the Home Screen.

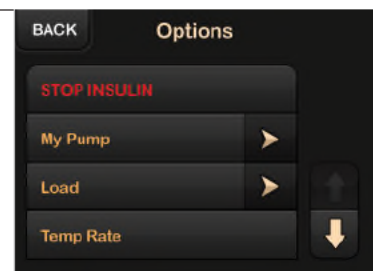


14.2 Auto-Off Alarm

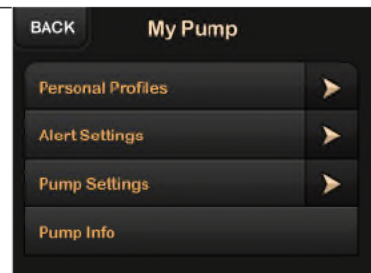
Your Insulin Pump can stop insulin delivery and alert you (or whoever is with you) if there has been no insulin action with the pump within a specified period of time. You can adjust the Auto-Off Alarm setting (the default value is pre-set to 12 hours, but it can be set anywhere from 5 hours to 24 hours, or Off). This alarm notifies you that there has been no insulin action with the pump in the specified number of hours and the pump will shut down after 30 seconds.

When the number of hours since you have tapped on the screen or pressed the Screen On/Quick Bolus Button passes the set value, the Auto-Off Alarm beeps and appears on the screen, and insulin delivery stops.

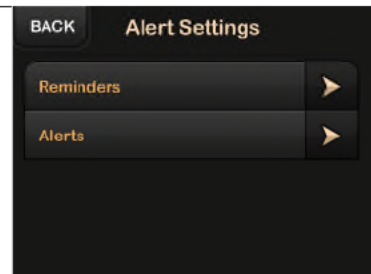
1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.



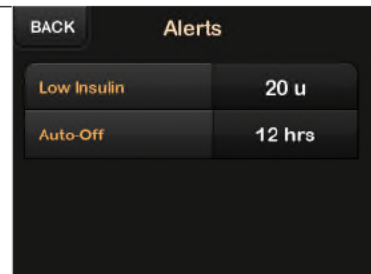
3. Tap **Alert Settings**.



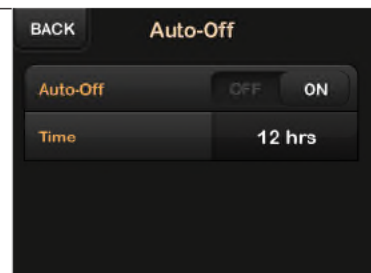
4. Tap **Alerts**.



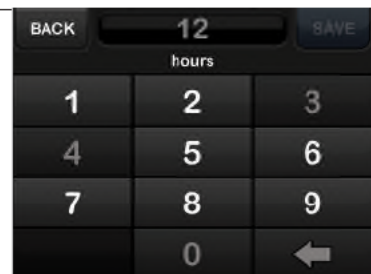
5. Tap **Auto-Off**.



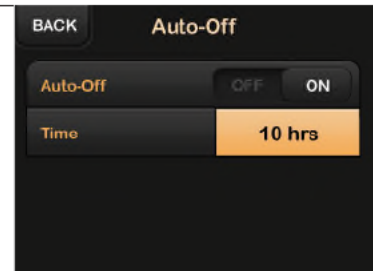
6. Verify **Auto-Off** is set to **ON**, then tap **Time**.



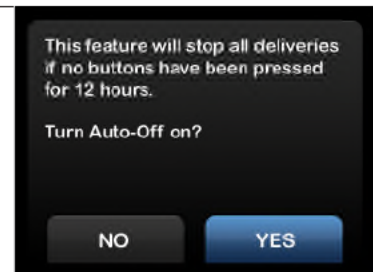
7. Using the onscreen keypad, enter the number of hours (from 5–24 hrs) that you want the Auto-Off Alarm to be triggered, and tap **SAVE**.



8. Tap **BACK** on the Auto-Off screen to verify your Auto-Off Alarm setting.



9. When changing this feature from on to off or from off to on, a confirmation screen will appear. Tap **YES** to change the setting.
10. Tap **Tandem logo** to return to the Home Screen.

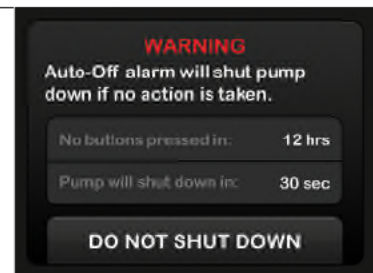


To Respond to Auto-Off Warning

1. Tap **DO NOT SHUT DOWN**.

The alarm clears and the pump returns to normal operation and whatever activity was in progress when the alert occurred.

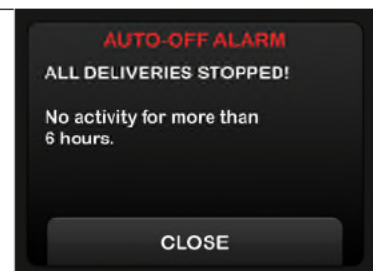
If you do not clear the alarm within the 30-second countdown period, the AUTO-OFF ALARM occurs, accompanied by an audible alarm. This alarm notifies you that your pump has stopped delivering insulin.



Auto-Off Alarm Screen

1. Tap **CLOSE**.

The Home Screen then appears, indicating a status of "All Deliveries Stopped." Resuming insulin delivery must be performed manually (refer to section 8.2).



Section 4

Safety Alerts and Alarms

Chapter 15

Alerts

15.1	Low Power Alert.....	117
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Your t:s m Pump has Alerts that are sounded for an incomplete activity, an impending alarm, or if a maximum has been reached.

Alerts sound with two notes at the volume/volume selected in Pump Settings. They repeat at regular intervals until acknowledged. Alerts do not escalate.

15.1 Low Power Alert

If the t:s m Pump detects a power level of 25% or less remaining, the LOW POWER ALERT occurs. This alert screen displays the level of remaining power. When the pump reaches a 5% battery level, the pump has 30 minutes of remaining battery life.

To Respond to the Low Power Alert

To clear the Alert and return to whatever activity was in progress when the alert occurred, tap **CLOSE**.

NOTE

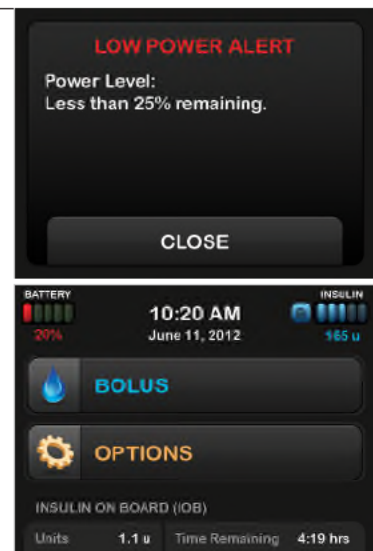
Once the LOW POWER ALERT occurs, the low-power indicator (a single red bar on the battery level) appears on the Home Screen.

NOTE

The battery level will decrease in increments of 5%. At 5% it will decrease in 1% increments.

NOTE

Alerts sound with two notes at the volume selected in Pump Settings. They repeat at regular intervals until acknowledged. Alerts do not escalate.



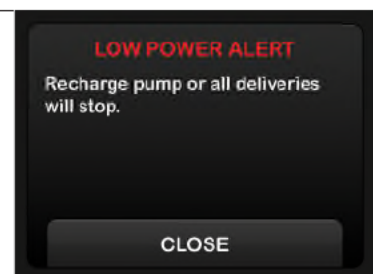
If your t:s m Pump detects a battery level of 5% or less power remaining, a second LOW POWER ALERT occurs, requesting that you recharge your t:s m Pump. The alert will continue until the condition has been corrected. Insulin delivery will continue until the LOW POWER ALARM is triggered and insulin delivery stops.

To Respond to the second Low Power Alert

To temporarily clear the alert and return to whatever activity was in progress when the alert occurred, tap **CLOSE**.

NOTE

Once the second LOW POWER ALERT occurs the low power indicator (a red 5% on the battery level indicator) appears in the upper left corner of the Home Screen.

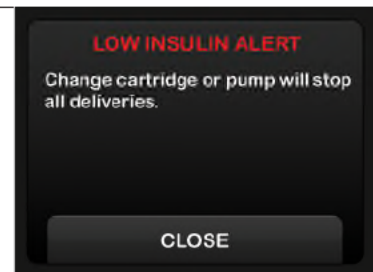


15.2 Low Insulin Alert

If your t:sm Pump detects an insulin level of 5 units or less, the LOW INSULIN ALERT occurs, requesting you to change the cartridge. The alert will continue until the condition has been corrected. Insulin delivery will continue until the EMPTY CARTRIDGE ALARM is triggered and insulin delivery stops.

To Respond to the Low Insulin Alert

To temporarily cease the alert and return to whatever activity was in progress when the alarm occurred, tap **CLOSE**.

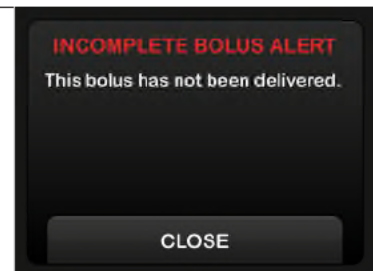


15.3 Incomplete Bolus Alert

If you start to program a bolus but do not complete the request within 90 seconds, the INCOMPLETE BOLUS ALERT occurs. You are prompted to return to the Bolus screen to complete the request.

To Respond to the Incomplete Bolus Alert

Tap **CLOSE** to return to the Bolus screen so that you can complete the bolus request.

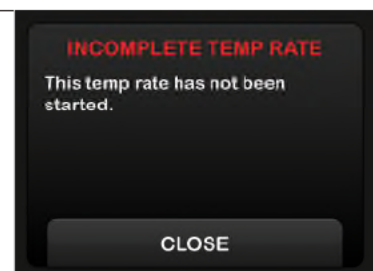


15.4 Incomplete Temp Rate Alert

If you start to set up a temperature rate but do not complete the setup within 90 seconds, the INCOMPLETE TEMP RATE ALERT occurs. You are prompted to return to the Temp Rate screen to complete the setup.

To Respond to the Incomplete Temp Rate Alert

Tap **CLOSE** to return to the Temp Rate screen so that you can complete the temperature rate setup.



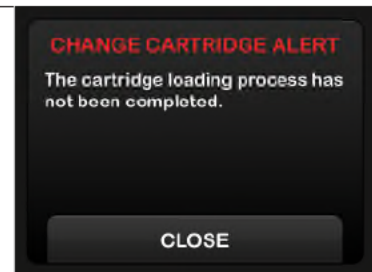
15.5 Incomplete Load Sequence Alerts

Incomplete Cartridge Change Alert

If you begin to change a cartridge but do not complete the process within 3 minutes, the CHANGE CARTRIDGE ALERT occurs.

To Respond to the Incomplete Cartridge Change Alert

Tap **CLOSE** to return to the screen you were on prior to the alert, and complete the cartridge change process.

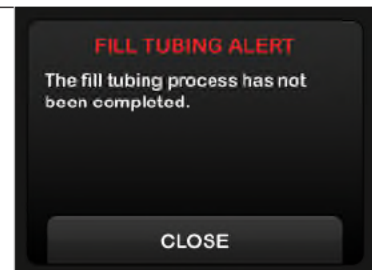


Incomplete Fill Tubing Alert

If you select Fill Tubing from the Load menu but do not complete the process within 3 minutes, the FILL TUBING ALERT occurs.

To Respond to the Incomplete Fill Tubing Alert

Tap **CLOSE** to return to the screen you were on prior to the alert, and complete the tube filling process.

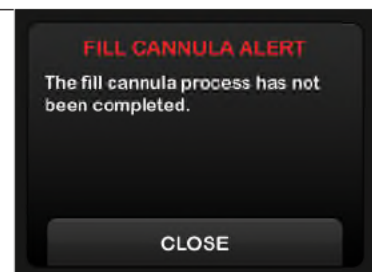


Incomplete Fill Cannula Alert

If you select Fill Cannula from the Load menu but do not complete the process within 3 minutes, the FILL CANNULA ALERT occurs.

To Respond to the Incomplete Fill Cannula Alert

Tap **CLOSE** to return to the screen you were on prior to the alert, and complete the cannula filling process.

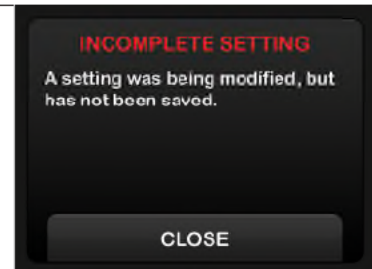


15.6 Incomplete Setting Alert

During the setup of a new Persona Profile if you do not save or complete the programming within 5 minutes, the INCOMPLETE SETTING ALERT occurs.

To Respond to the Incomplete Setting Alert

Tap **CLOSE** to clear the alert and return to the previous screen to finish programming a Persona Profile.

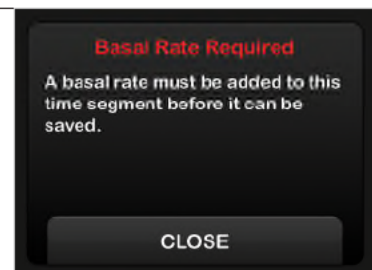


15.7 Basal Rate Required Alert

During the setup of a new time segment in a Persona Profile you must enter a basal rate to have an active profile. If you do not enter a basal rate a BASAL RATE REQUIRED ALERT occurs.

To Respond to the Basal Rate Required Alert

Tap **CLOSE** to clear the alert and to return to the time segment to finish programming a basal rate.



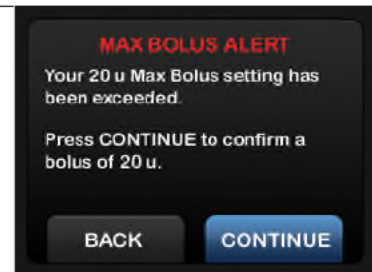
15.8 Max Bolus Alert

If you request a bolus amount that exceeds the Max Bolus setting in the currently active Personal Profile, a MAX BOLUS ALERT occurs. You are prompted to confirm whether you want to deliver the max bolus amount.

To Respond to the Max Bolus Alert

Do one of the following:

- To return to the Bolus screen and adjust the bolus delivery amount, tap **BACK**.
- To deliver the requested bolus tap **CONTINUE**.

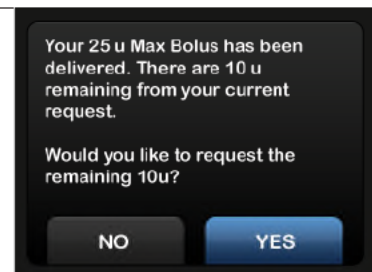


If your Max Bolus amount is defined to be 25 units and you request a bolus that exceeds 25 units, the MAX BOLUS ALERT occurs. If you continue with this max bolus delivery of 25 units, upon completion of this bolus delivery, you will receive a prompt to request the remaining amount of the requested bolus (up to an additional 25 units).

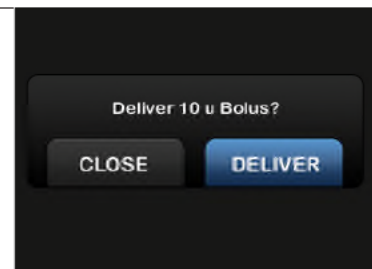
To Respond to Remaining Bolus Request:

Do one of the following:

- Tap **NO**.
 ▷ This returns to the previous screen.



- Tap **YES** to confirm delivery, tap **DELIVER**.



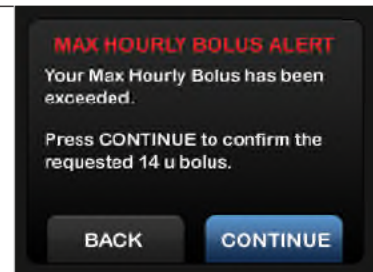
15.9 Max Hourly Bolus Alert

If, within a 60-minute period of time, you request a bolus delivery that is more than 1.5 times your Max Bolus setting, the MAX HOURLY BOLUS ALERT occurs, and you are prompted to confirm whether you want to deliver this bolus amount.

To Respond to the Max Hourly Bolus Alert

Do one of the following:

- To return to the Bolus screen and adjust your bolus amount, tap **BACK**.
- To deliver the bolus, tap **CONTINUE**.



15.10 Max Basal Alert

In either of the following scenarios, if you exceed 2 times the highest basal rate defined in your Personal Profile, the MAX BASAL ALERT occurs:

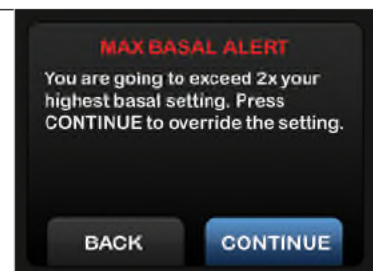
- When defining a basal rate and tapping **SAVE**.
- When requesting a temp rate and tapping **START**.

You are cautioned that you will exceed 2 times your highest basal setting and prompted to confirm whether you want to continue with this basal amount.

To Respond to the Max Basal Alert Before Starting a Temp Rate or Saving a Basal Rate

Do one of the following:

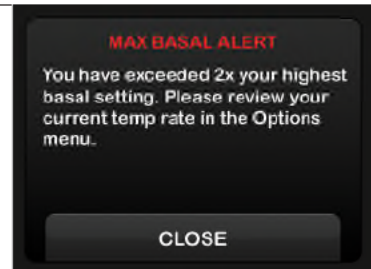
- To return to the previous screen and adjust the amount, tap **BACK**.
- To continue regardless of the excess amount, tap **CONTINUE**.



If you have already started a temp rate and, while the temp rate is running, you activate a new profile that exceeds 2 times your highest basal setting, the MAX BASAL ALERT occurs. You are prompted to review your current temp rate.

To Respond to the Max Basal Alert After the Temp Rate Has Started

1. Tap **CLOSE**.
 - ▷ The Options screen appears, showing the current Temp Rate value.

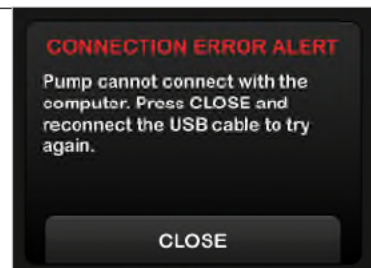


15.11 Connection Error Alert

If you connect your t:s m Pump to a computer via a USB cable in order to sync data and a connection cannot be made, the CONNECTION ERROR ALERT occurs. You are prompted to disconnect and reconnect the USB cable.

To Respond to the Connection Error Alert

1. To clear the alert, tap **CLOSE**.
 - ▷ This returns to the previous screen prior to the alarm.
2. Disconnect and reconnect the USB cable to try again.

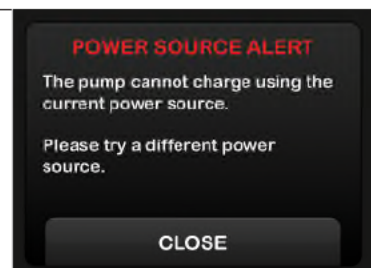


15.12 Power Source Alert

If you attempt to charge your t:s m Pump by connecting to a power source that has insufficient power to charge the t:s m Pump, the POWER SOURCE ALERT occurs. You are prompted to try a different power source.

To Respond to the Power Source Alert

1. To clear the alert, tap **CLOSE**.
 - ▷ This returns to the previous screen prior to the alarm.
2. Disconnect and reconnect to a different power source.

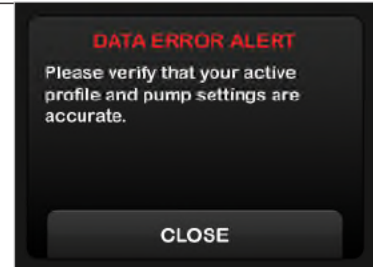


15.13 Data Error Alert

If your t:s m Pump encounters a condition that causes a potential loss of data, the DATA ERROR ALERT occurs. You are prompted to check your active Personal Profile and pump settings.

To Respond to the Data Error Alert

1. To clear the alert, tap **CLOSE**.
 ▶ This returns to the previous screen prior to the alarm.
2. Check your Personal Profiles and pump settings to verify they are accurate (refer to section 6.4).



Chapter 16

Alarms

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Your insulin Pump has an alarm that sounds for potential interruption of insulin delivery.

CAUTION

Monitor your blood glucose (BG) levels frequently with the guidance of your healthcare provider anytime there is an interruption of insulin delivery. Treat elevated blood glucose (BG) levels as recommended by your healthcare provider.

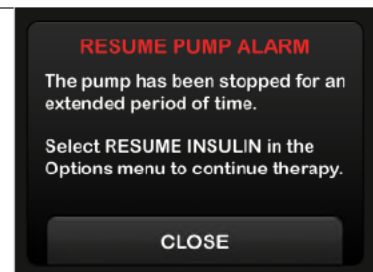
An alarm sounds with three notes at the volume/volume selected in Pump Settings. If not acknowledged, an alarm escalates to highest volume and volume. An alarm repeats at regular intervals until the condition that caused the alarm is resolved.

16.1 Resume Pump Alarm

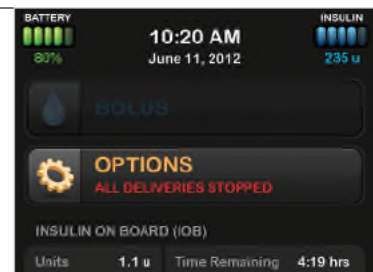
If insulin delivery has stopped for more than 15 minutes, the RESUME PUMP ALARM occurs.

To Respond to the Resume Pump Alarm

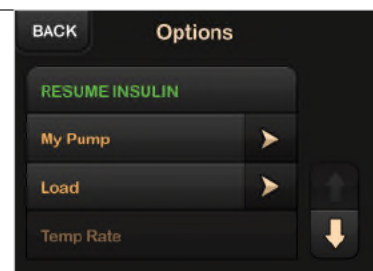
1. Tap **CLOSE** to clear the alarm.



2. From the Home Screen, tap **OPTIONS**.



3. Tap **Resume Insulin**, and tap **Resume**.



16.2 Low Power Alarms

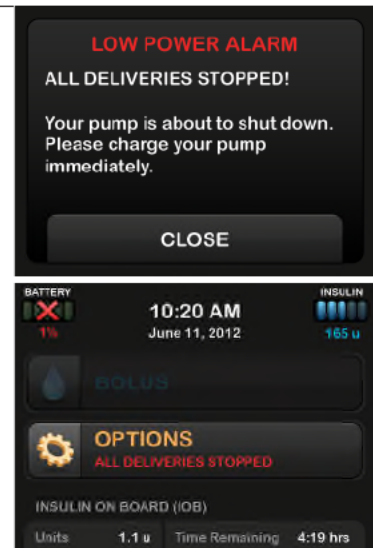
If your t:s m Pump detects a power level of 1% or less power remaining, the LOW POWER ALARM occurs and all insulin deliveries are stopped. You must recharge your t:s m Pump to resume insulin delivery. The alarm will continue until the condition has been corrected or the pump shuts down.

To Respond to the Low Power Alarm

1. To temporarily clear the alarm, tap **CLOSE**.

NOTE

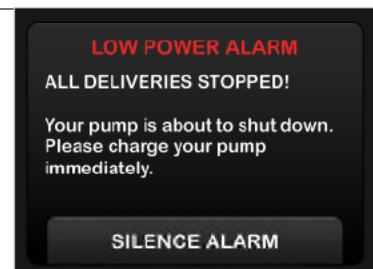
Once the LOW POWER ALARM occurs the low power indicator (a red X and 1% on the battery level indicator) appears in the upper left corner of the Home Screen.



Your t:s m Pump monitors power level in several different ways. If, at any time, your t:s m Pump detects a voltage level too low to ensure normal performance, the LOW POWER ALARM occurs and all insulin deliveries are stopped. You must recharge your t:s m Pump to resume insulin delivery.

To Respond the Low Power Alarm

1. To silence the alarm, tap **SILENCE ALARM**.



16.3 Empty Cartridge Alarm

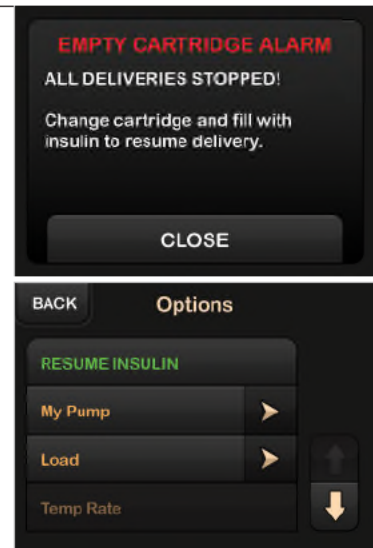
If your insulin Pump detects an insulin level in the cartridge of 1 unit or less, the EMPTY CARTRIDGE ALARM occurs and all insulin deliveries are stopped. You must change the cartridge and fill the new cartridge with insulin before you can resume delivery. The alarm will continue until the condition has been corrected.

To Respond to the Empty Cartridge Alarm

1. Tap **CLOSE**.
 ➤ This returns to the previous screen prior to the alarm.
2. Under OPTIONS, tap **Load** to follow the proper procedure for a cartridge change (refer to section 5.3).

NOTE

Once the EMPTY CARTRIDGE ALARM occurs, the empty cartridge indicator (a red X on the insulin level) appears in the upper right corner of the Home Screen.



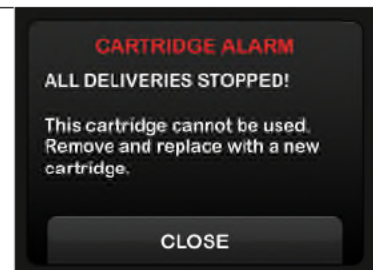
16.4 Cartridge Error Alarm

If any of the following cartridge error scenarios are detected, a CARTRIDGE ALARM occurs and all insulin deliveries stop:

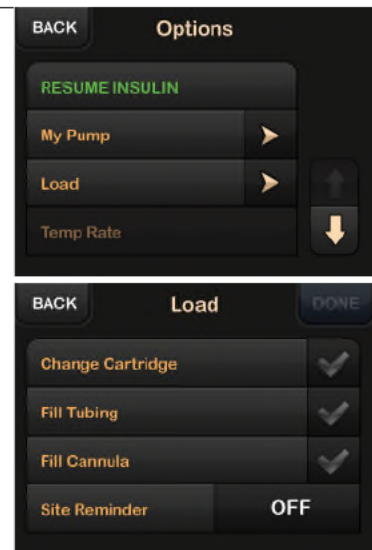
- The pump determines that the loaded cartridge cannot be used (eg, it is defective, etc.).
- The pump detects that you tried to fill the cartridge with insulin without following the proper procedure in the Load menu.
- The pump detects that you have filled the cartridge with more than the maximum amount (300 units) of insulin and therefore the cartridge cannot be used.

To Respond to the Cartridge Alarm

1. To temporarily cease the alarm, tap **CLOSE**.
 ➤ This returns to the previous screen prior to the alarm.



2. Use the Load menu to follow the proper procedure for a cartridge change (refer to section 5.3).

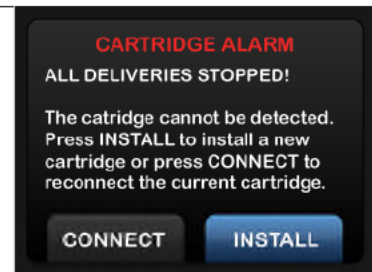


16.5 Cartridge Removal Alarm

If your t:s m Pump detects that the cartridge has been removed, the Cartridge Removal Alarm occurs and all insulin deliveries are stopped.

To Respond to the Cartridge Removal Alarm

1. Tap **CONNECT** to reattach the current cartridge.
2. Tap **INSTALL** to install a new cartridge.

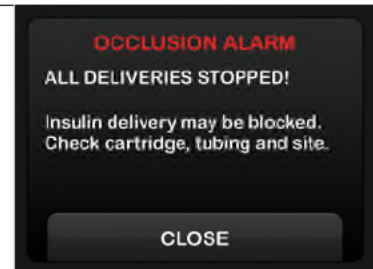


16.6 Occlusion Alarm

If your t:s m Pump detects insulin delivery is blocked, the OCCLUSION ALARM occurs and all insulin deliveries are stopped. Check the cartridge, tubing and cannula to help determine the cause.

To Respond to the Occlusion Alarm

1. To temporarily clear the alarm, tap **CLOSE**.
 ▷ This returns to the previous screen prior to the alarm.
2. Check the cartridge, tubing, and cannula and correct the condition.
3. Resume insulin delivery (refer to section 8.2)

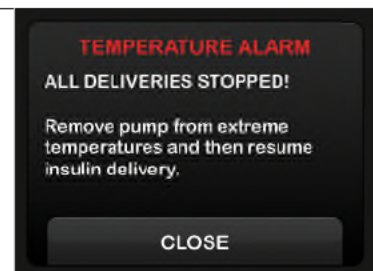


16.7 Temperature Alarm

If your t:s m Pump detects a temperature outside of the normal operating range, the TEMPERATURE ALARM occurs and all insulin deliveries are stopped.

To Respond to the Temperature Alarm

1. To temporarily clear the alarm, tap **CLOSE**.
 ▷ This returns to the previous screen prior to the alarm.
2. Remove the pump from the extreme temperature.
3. Resume insulin delivery (refer to section 8.2).

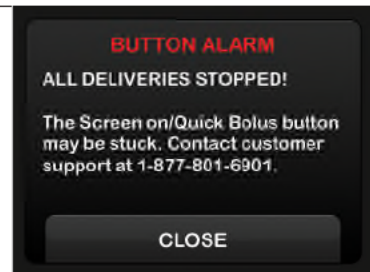


16.8 Screen On/Quick Bolus Button Alarm

If the Screen On/Quick Bolus Button (on the top of your t:s m Pump) is stuck or not functioning properly, the BUTTON ALARM occurs and all insulin deliveries are stopped. Contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901.

To Respond to the Button Alarm

1. To temporarily clear the alarm, tap **CLOSE**.
 ▷ This returns to the previous screen prior to the alarm.
2. Contact Customer Technical Support at 1-877-801-6901.

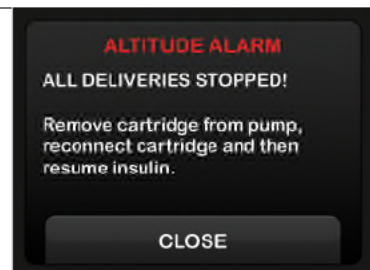


16.9 Altitude Alarm

If your t:s m Pump detects a pressure change outside of the operating range, the ALTITUDE ALARM occurs and all insulin deliveries are stopped.

To Respond to the Altitude Alarm

1. To temporarily clear the alarm, tap **CLOSE**.
 ▷ This returns to the previous screen prior to the alarm.
2. Remove cartridge from the pump and reconnect the cartridge.
3. Resume insulin delivery (refer to section 8.2).

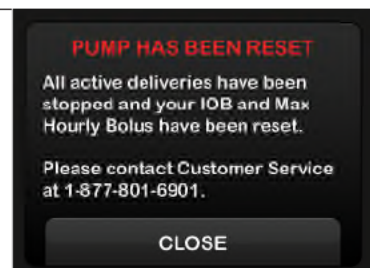


16.10 Reset Alarm

If your t:s m Pump detects that one of its micro-processors has experienced a reset, the PUMP RESET screen appears and all insulin deliveries are stopped.

To Respond to the Reset Alarm

1. To temporarily clear the alarm, tap **CLOSE**.
2. Contact Customer Service at 1-877-801-6901.
3. Do not resume insulin before speaking with a Customer Service representative.



Chapter 17

Malfunction

17.1	Malfunction	133
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17.1 Malfunction

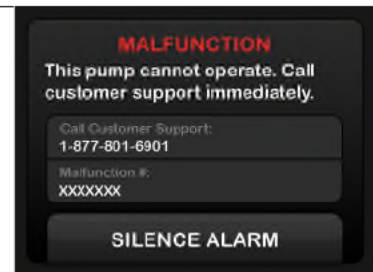
If your t:sm Pump detects a system error, the MALFUNCTION ALARM occurs and an insulin delivery is stopped. Malfunctions sound with three notes at the highest volume and vibrate. They repeat at regular intervals until acknowledged. Malfunctions cannot be resolved.

CAUTION

Monitor your blood glucose (BG) levels frequently with the guidance of your healthcare provider anytime there is an interruption of insulin delivery. If pump therapy can not be resumed start backup plan per your healthcare provider.

To Respond to the Malfunction Alarm

1. Write down the Malfunction Code number that appears on the screen.
2. Tap **SILENCE ALARM**. The alarm is silenced and the screen times out. Press the Screen On/Quick Bolus Button to see the screen again. The MALFUNCTION screen appears but the alarm is silenced.
3. Contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901 and provide the Malfunction Code number you wrote down.



Section 5

Care and Maintenance

Chapter 18

Taking Care of your t:slim® Pump

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18.1 Overview

This section provides information on caring for and maintaining your t:slim Pump.

Cleaning Your t:slim 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.

Inspecting Your t:slim Pump for Damage

If you drop your t:slim Pump or it has been hit against something hard, ensure that it is still working properly. Check that the touch screen is working and clear, and that the catheter and infusion set are properly in place. Check for leaks around the catheter and at the tube connector to the infusion set. Immediately contact Tandem Diabetes Care Customer Technical Support at 1-877-801-6901 if you notice any cracks, chips, or other damage.

Disposing of t:slim Pump Accessories

Regulations require controlled disposal of devices such as insulin infusion pumps and related disposables, so ask your Tandem Diabetes Care, Inc. representative or healthcare provider about local regulations regarding disposal of catheters, infusion sets, and other disposable accessories.

Section 6

Technical Specifications

Chapter 19

Technical Specifications

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19.1 Overview

This appendix provides tables of technical specifications, options, settings, and electrical magnet component information for the t:s m Pump. The specifications in this appendix meet the international standards set forth in EC 60601-1 and EC 60601-2-24.

19.2 t:slim Pump Specifications

The following table lists the t:s m Pump specifications and the related details.

Specification Type	Specification Details
Classification	External PSU Class infusion Pump internally-powered equipment type BF applied part The risk of ignition of flammable anesthetics and explosive gases by the pump's remote While this risk is remote, it is not recommended to operate the t:s m 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 Temperature Range	41°F and 98.6°F 5°C and 37°C at maximum relative humidity of 90% non-condensing
Storage Temperature Range	-4°F and 140°F -20°C to 60°C at maximum relative humidity of 90% non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa (equivalent from sea level up to 10,000 ft)
Reservoir Volume	30 mL or 300 units
Cannula Flow Amount	0.1 to 1.0 units of infusion
Infusion Concentration	U-100
Alarm type	Visual and audible and vibratory
Baseline Delivery Accuracy at Flow Rates (tested per EC 60601-2-24)	±5% *
Bolus Delivery Accuracy at Volumes (tested per EC 60601-2-24)	±5% *

* In extreme pressure environments, delivery accuracy may vary up to ±15%. Extreme pressure environments include any rapid elevation change of 1,000 ft.

Time to Occlusion Alarm

Operating Rate	Typical	Maximum
Bolus (3 units or Greater)	21 Seconds	23 Seconds
Baseline (2 units/hr)	1 Hour 4 Minutes	1 Hour 10 Minutes
Baseline (1 unit/hr)	1 Hour 57 Minutes	2 Hours 7 Minutes
Baseline (0.1 unit/hr)	19 Hours 43 Minutes	25 Hours 30 Minutes

19.3 t:slim Pump Options and Settings

The following table lists the t:slim Pump options and settings, and the related details.

Option/Setting Type	Option/Setting Details
Time	12-hour clock
Maximum Basal Rate	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 Range 0%–250%
Bolus Setup	Can be set based on carbohydrate (grams) or insulin input (units) Default units (the range for carbs is 1–999 grams the range for insulin is 0.05–25 units)
Insulin-to-Carb (C) Ratio	16 time segments per 24-hour period Ratio 1 unit of insulin per x grams of carbs 1:1 to 1:300 (resolution is 1 above 10 and 0.1 below 10)
BG Correction Target Value	16 time segments 70 to 250 mg/dL in 1 mg/dL increments
Insulin Sensitivity Factor (SF)	16 time segments Ratio 1 unit of insulin reduces glucose x mg/dL 1:1 to 1:600 (1 mg/dL increments)
Duration of Insulin Action	1 time segment 2–8 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 0.5 1 2 5 units (default is 0.5 units) or when set to grams/carbs 2 5 10 15 grams (default is 2 g)
Maximum Extended Bolus Time	8 hours
Maximum Bolus Size	25 units
Low Reservoir Volume Indicator	Status indicator (visible on home screen) Low insulin Alert (user adjustable 10–40 units)
Auto-Off Alarm	On or Off (default is On) user-adjustable (5–24 hours default is 12 hours which you can change when options set to On)
History Storage	Up to 90 days of data (11,000 events)
Language	English
Feature Lock	Blocks access to insulin delivery screens and pump setting screens (default is Off)
Screen Lock	Protects from unintentional taps
Site Reminder	Prompts user to change infusion set Can be set for 1–3 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
After Bolus Reminder	Prompts user to test BG at a selected time period after a Bolus has been delivered increment options of 1 hr 1.30 hrs 2 hrs and 3 hrs
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
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

19.4 Additional t:slim Pump Specifications

The following table lists additional t:slim Pump specifications and the related details.

Specification Type	Specification Details
Patent Protection from Arterial 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 Occurs on Alarm Threshold.	30 PS
Rate of delivery during Bolus	Bolus > 3 units Approximate 2 units/min Bolus ≤ 3 units Approximate 1.6 units/min
Rate of delivery during Prime	Approximate 7 units/min
Bolus Duration	Bolus > 3 units duration Approximate 30 seconds/unit Bolus ≤ 3 units duration Approximate 37 seconds/unit
Frequency of Basal Delivery	5 minutes for a Basal Rate
Retention time of Electronic Memory when Internal System Batteries Fully Discharged	Greater than 30 days
Infusion Set used for testing	Unomed ca Comfort™ Infusion Set
Statement of Meaning of the Clinical Ingress Protection (IP) Classification	IPX7 – watertight to a depth of 3 feet for up to 30 minutes
Internal System Battery	Rechargeable Lithium Polymer
Internal System Battery Life	4 years minimum under normal use conditions
Typical Operating time when System is Operating at Intermed Rate	During normal use, the intermed rate is 2 units/hr. Battery charge can be reasonably expected to last up to 7 days (depending on the pump settings) from a fully charged state to a totally discharged state.
Handling of Over-infusion or Under-infusion	The method of delivery isolates the infusion 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 continuous self-tests, layering of redundancies and confirmations, and numerous other safeguard alarms. Users are required to review and confirm the details of a bolus delivery, 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 pre-defined period of time. Under-infusion is mitigated by occlusion detection and blood glucose monitoring as blood glucose entries are recorded. Users are prompted to treat high blood glucose conditions with a correction bolus.
Bolus Volume at Release of Occlusion	0.4–0.6 units at 2 units per hour with Unomed ca Comfort™ (60cm) Infusion Set

19.5 Electromagnetic Compatibility

The information contained in this section is specific to the t:s m Pump. This information provides a reasonable assurance of normal operation, but does not guarantee such under all conditions. If the t:s m Pump must be used in close proximity with other electronic equipment, the pump should be observed in this environment to verify normal operation. Specific precautions for electromagnetic compatibility must be taken when using medical electronic equipment. The system shall be placed into service with adherence to the EMC information provided here. Using cables and accessories not specified in this Use Guide may adversely impact safety, performance, and electromagnetic compatibility, including increased emissions and/or decreased immunity.

This section contains the following tables of information:

- Electromagnetic Emissions
- Electromagnetic Immunity
- Distances Between the t:slim pump and RF Equipment

19.6 Electromagnetic Emissions

The t:s m Pump is intended for use in the electromagnetic environment specified below. A user must make sure that the pump 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 pump 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 pump 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, EC 61000-3-2	N/A	
Voltage Fluctuations/Flicker Emissions, EC 61000-3-3	N/A	

19.7 Electromagnetic Immunity

The t:s m Pump s ntended fo use n the e ect omagnet c env onment spec fied be ow. A ways make su e that the pump s used n such an env onment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 6 000 4 2	8 kV contact 5 kV air	8 kV contact 5 kV air	Floors should be wood concrete or ceramic tile If floors are covered with synthetic material the relative humidity should be at least 30%
Electrical Fast Transient/burst IEC 6 000 4 4	2 kV for power supply lines kV for input/ output lines	2 kV for power supply lines kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 6 000 4 5	kV differential mode 2 kV common mode	kV differential mode 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage Dips Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 6 000 4	<5% Ur (>95% dip in Ur) for 0.5 cycle 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (30% dip in Ur) for 25 cycles <5% Ur (>95% dip in Ur) for 5 sec	<5% Ur (>95% dip in Ur) for 0.5 cycle 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (30% dip in Ur) for 25 cycles <5% Ur (>95% dip in Ur) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment If the user of the pump requires continued operation during power mains interruptions it is recommended that the pump be powered from an uninterruptible power supply or a battery NOTE Ur is the a c mains voltage prior to application of the test level
Power Frequency (50/60 Hz) Magnetic Field IEC 6 000 4 8	3 A/m	400 A/m (IEC 60601-2-24)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Conducted RF IEC 6 000 4 6	3 Vrms 50 kHz to 80 MHz	0 V	Portable and mobile RF communications equipment should be used no closer to any part of the pump including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance $d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.2\sqrt{P}$ 800 MHz to 2.5 GHz $d = 0.23\sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m) Field strengths from fixed RF transmitters as determined by an electromagnetic site survey should be less than the compliance level in each frequency range ^b Interference may occur in the vicinity of equipment marked with the following symbol 
Radiated RF IEC 6 000 4 3	3 V/m 80 MHz to 2.5 GHz	30 V/m	

NOTE At 80 MHz and 800 MHz the higher frequency range applies

NOTE 2 These guidelines may not apply in all situations Electromagnetic propagation is affected by absorption and reflection from structures objects and people

Field strengths from fixed transmitters such as base stations for radio (cellular/cordless) telephones and land mobile radios amateur radio AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy To assess the electromagnetic environment due to fixed RF transmitters an electromagnetic site survey should be considered If the measured field strength in the location in which the pump is used exceeds the applicable RF compliance level above the pump should be observed to verify normal operation If abnormal performance is observed additional measures may be necessary such as reorienting or relocating the pump

^b Over the frequency range 50 kHz to 80 MHz field strengths should be less than 0 V/m

19.8 Distances Between the t:slim Pump and RF Equipment

The t:slim Pump is intended for use in an electromagnetic environment typically found in the home, at work, restaurants, and places of business, where daily activities occur. The chart below can be used as a guide to determine the recommended minimum distance to maintain between a radio frequency (RF) transmitter and the t:slim Pump. For specific concerns about a particular RF transmitter interfacing with your Pump's operation, please contact the transmitter manufacturer for its rated power and frequency.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the t:slim Pump			
The t:slim Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the t:slim Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pump as recommended below according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter in Watts	Separation Distance According to Frequency of Transmitter <i>inches or feet (m)</i>		
	150 kHz to 80 MHz (d <i>in meters</i> = $0.35\sqrt{P}$)	80 MHz to 800 MHz (d <i>in meters</i> = $0.12\sqrt{P}$)	800 MHz to 2.5 GHz (d <i>in meters</i> = $0.23\sqrt{P}$)
0.01	<u>1.6 in</u> (0.04)	<u>0.12 in</u> (0.012)	<u>0.9 in</u> (0.023)
0.1	<u>4.3 in</u> (0.11)	<u>1.5 in</u> (0.038)	<u>2.9 in</u> (0.073)
1	<u>1.1 ft</u> (0.35)	<u>4.7 in</u> (0.120)	<u>9.0 in</u> (0.23)
10	<u>3.6 ft</u> (1.11)	<u>14.9 in</u> (0.379)	<u>2.39 ft</u> (0.727)
100	<u>11.5 ft</u> (3.50)	<u>3.94 ft</u> (1.20)	<u>7.54 ft</u> (2.3)
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be determined using the equation applicable to the frequency of the transmitter where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

The table below provides a list of typical devices for various levels of transmitter power and frequency, and the recommended separation distances from the transmitter and the pump.

Rated Maximum Output Power of Transmitter in Watts	Typical Devices	Recommended Separation Distance <i>Inch (Meters)</i>	
0.001W	Bluetooth Class 3 (standard 1 meter range) Commonly used as Bluetooth headset	0.3 in (0.007 m)	
0.01W	Internet to music adaptor Commonly used for FM wireless music streaming	0.5 in (0.013 m)	
0.1W	Bluetooth Class 1 (100 meter range) Wireless router (WiFi)	2.9 in (0.073 m)	
0.5W	Typical cellular/smart phone *	6.4 in (0.163 m)	
1W	Typical microwave oven RF leakage	9 in (0.23 m)	

** Caution: Interference with pump electronics by cell phones can occur if worn in close proximity. It is recommended that your pump and cell phone be worn at least 6.4 inches apart.*

19.9 FCC Notice Concerning Interference

The t:s m Pump complies with FCC/ C RF exposure limits for general population/uncontrolled exposure.

t:s m Pumps equipped with a Bluetooth® RF option transmit at a maximum effective radiated power of 3.4 mW in the 2.4 GHz ISM band, which covers the frequency range from 2.40 GHz to 2.50 GHz.

The t:slim Pump 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

Compliance with these guidelines provides reasonable protection against harmful interference in a normal residential environment. The t:s m Pump generates, uses, and can radiate radio frequency energy, and may cause harmful interference to radio communications. There is no guarantee that interference will not occur in a particular installation. If the t:s m Pump does cause harmful interference to radio or television reception, the interference may be corrected by one of the following measures:

- Move or relocate the t:slim Pump
- Increase the distance between the t:slim Pump and the other device that is emitting or receiving interference

Changes or modifications not expressly approved by Tandem Diabetes Care, Inc. could void the user's authority to operate the equipment.

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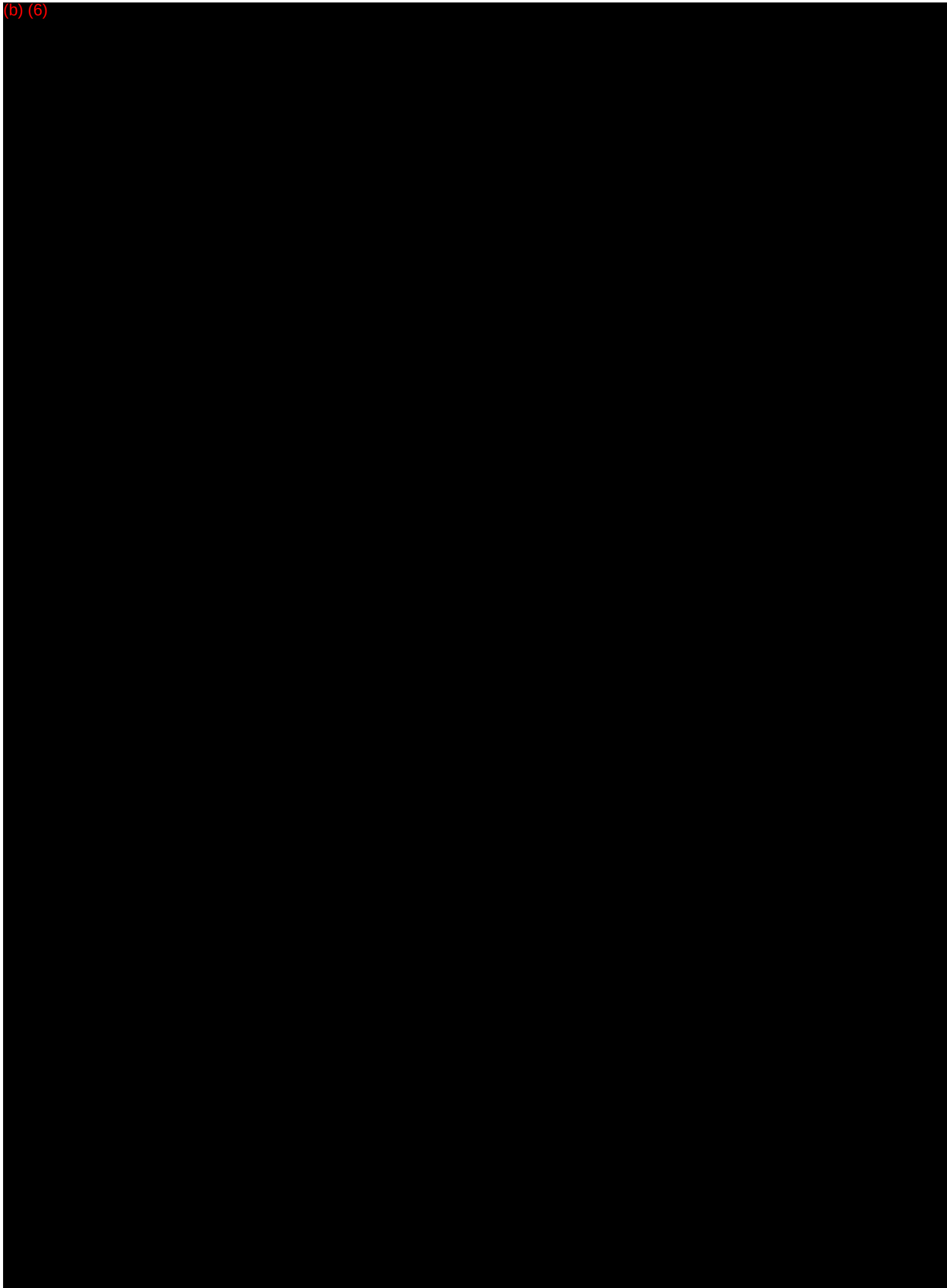
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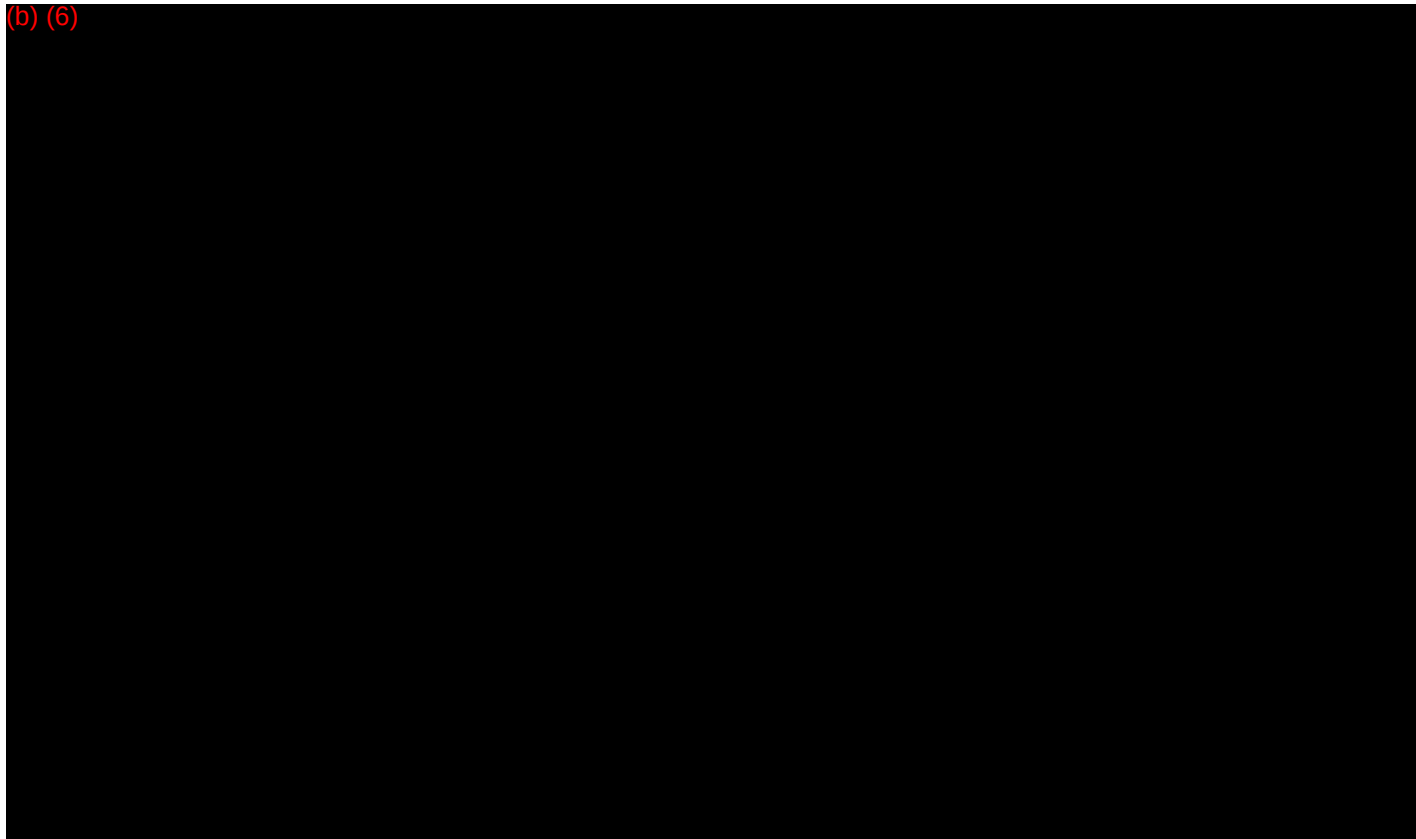
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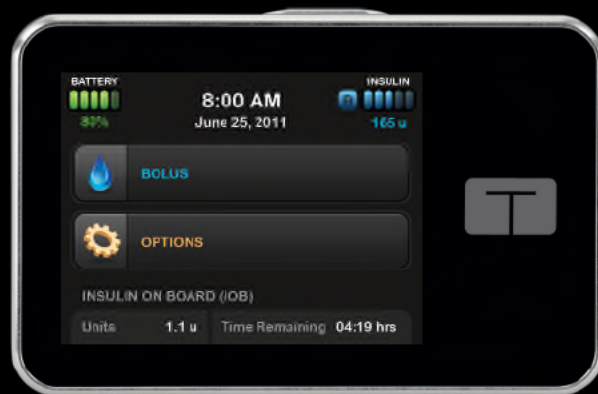
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t:slim™



User Guide

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t:slim™ Insulin Delivery System Version 4.3 User Guide

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t:slim Pump User Guide

At Tandem Diabetes Care, Inc. we listen closely to the diabetes community in order to understand your needs. We recognize and respect the importance of your decision to begin insulin pump therapy as a member of our family. We also recognize that your pump purchase is only the beginning of your relationship with Tandem. Our commitment goes much deeper than simply supplying products to help you in your diabetes management. We pledge to be here to support you with training and education through our network of Clinical Diabetes Specialists. We also pledge to be here to support you with our dedicated Customer Support.

This t:slim User Guide is designed to assist you with the features and functions of the t:slim Pump (t:slim) and cartridge. It provides important warnings and cautions on proper operation to ensure your safety, as well as technical information. It also provides step-by-step illustrative instructions on how to properly program, manage and care for t:slim.

Need help? We are here for you 24 hours a day, 7 days a week at 1-877-801-6901.

Changes in equipment, software, or procedures occur periodically; information describing these changes will be included in future editions of this User Guide. Please contact Tandem Diabetes Care Customer Support at 1-877-801-6901 to obtain a replacement copy of the User Guide that is the correct version for your pump.

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1.1 Purpose of this Guide

This guide is for users of the t:slim Insulin Delivery System (t:slim System). The intended use of the t:slim System is for the Continuous Subcutaneous Insulin Infusion (CSII), at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater.

WARNING

United States (U.S.) Federal law restricts this device to sale by or on the order of a physician.

If you are unable to use the t:slim System according to the instructions in this Guide, you may be putting your health and safety at risk. Be sure to speak with your healthcare provider if you have questions or concerns about using your pump properly.

CAUTION

The first time you start insulin infusion therapy using your t:slim Pump, you must be under the supervision of your healthcare provider.

Read **all** of the instructions provided in this User Guide before using your t:slim Pump, and monitor your blood glucose (BG) with the guidance of your healthcare provider. According to the American Association of Diabetes Educators' white paper **Insulin Pump Therapy: Guidelines for Successful Outcomes**, patients should routinely check their BG levels at **least 4 times daily** (optimally 6-8 times daily) in order to detect hyperglycemia and hypoglycemia early. Undetected hyperglycemia or hypoglycemia can result without proper monitoring.

1.2 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 insulin infusion therapy. Your healthcare provider can help you establish diabetes management guidelines that best fit your lifestyle and needs.

Your needs will influence how your healthcare provider helps you enter your initial pump settings. If you have any questions about diabetes management after you start using your t:slim Pump, do not hesitate to contact your healthcare provider.

1.3 Important Safety Information

This section covers important safety information, including indications for use and contraindications, what to keep in an emergency kit, and warnings and precautions. In case of an emergency, call 911 (U.S. only).

CAUTION

Before using your t:slim Pump, ensure that you have been appropriately trained on its use or that you are with a certified t:slim Pump trainer. Incorrect use of your t:slim Pump or failure to follow the appropriate instructions in this User Guide can lead to serious injury or even death. If you have questions or need further clarification on your t:slim Pump use, ask your healthcare provider or call our around-the-clock Customer Support Department at 1-877-801-6901.

Your t:slim Pump is designed only for the Continuous Subcutaneous Insulin Infusion (CSII) of U-100 insulin; it is not intended for use with any other delivery substance. Consult your healthcare provider before using your t:slim Pump to determine which programming features are most appropriate for you. Only your healthcare provider can determine your basal rate, insulin-to-carbohydrate ratios, correction factors, BG target ranges, and duration of insulin action. Additionally:

- Ensure that any small components on your t:slim Pump and its accessories are kept away from small children who could potentially ingest them.
- Avoid changing your infusion set before bedtime or if you will not be able to test your BG at least 1-2 hours after a new set is placed.
- Always check that your cartridge has insulin to last through the night.
- Unless otherwise recommended by your healthcare provider, do not use the vibrate feature during sleep; rather, set the volume to high for all alarms and warnings.
- Since air bubbles can compromise delivery accuracy, always remove all bubbles when drawing insulin into syringe; always hold the pump with the cartridge white insulin fill port pointed up when filling cartridge; and always ensure that there are no air bubbles in the tubing when priming.
- Ensure that the t:slim Pump you use for therapy has all your personal settings programmed with your specific treatment plan.
- If you damage or drop your t:slim Pump, ensure that it is still working properly. If you are unsure as to potential damage, call Tandem Diabetes Care Customer Support at 1-877-801-6901.

1.4 Emergency Kit

Make sure that you always have an insulin syringe and a vial of insulin with you as a backup for emergency situations. You should also always have an appropriate emergency kit with you. Talk with your healthcare provider regarding what items this kit should include.

CAUTION

- » Your t:slim 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. In order to prevent Diabetic Ketoacidosis (DKA) or a very high BG, you must be prepared to inject insulin if delivery is interrupted for any reason. Only use U-100 insulin, as any lesser or greater concentration can result in serious health consequences. Never fill your tubing while your infusion set is connected to your body. Doing so can result in unintended delivery of insulin, which can result in serious injury or death.
- » If you have any questions regarding these cautions, call your healthcare provider or Tandem Diabetes Care Customer Support at 1-877-801-6901.
- » 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 compensate for missed basal and/or bolus insulin. Check your blood glucose level at minimum before disconnecting from the pump and again when you reconnect.

1.5 Indications for Use and Contraindications

Indications for Use

The t:slim™ Insulin Delivery System is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater.

Contraindications

The t:slim Pump is not intended for anyone unable or unwilling to:

- Test BG levels as recommended by your healthcare provider
- Demonstrate adequate carbohydrate-counting skills (preferred, but not required)
- Maintain sufficient diabetes self-care skills
- See your healthcare provider(s) regularly

You must also have adequate vision and/or hearing in order to recognize your t:slim Pump alerts.

1.6 Verification of Proper Functionality

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

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

In addition, before using your t:slim Pump, ensure the following:

- Press the Screen On/Quick Bolus Button to illuminate the screen so that you can easily read the display
- When the screen is illuminated, the touch screen responds to your finger tap

CAUTION

If any of these conditions fail to occur, do NOT use the t:slim Pump, as this may be an indication that the pump's alarms, alerts, and other built-in safety features may not be working properly. If the pump is connected to your body, disconnect the infusion set from your body and contact Tandem Diabetes Care Customer Support at 1-877-801-6901.

1.7 Warnings and Precautions

When using your t:slim Pump, always take precautions regarding the following:

- Radiology and Medical Procedures
- Extreme Temperatures

- Amusement Park Rides
- Aircraft Without Cabin Pressurization
- Small Parts Potentially Ingestible by Children
- Do Not Use in the Presence of Flammable Anesthetics or Explosive Gases
- Air Travel
- Other Precautions

Radiology and Medical Procedures

If you are going to have an X-ray, computerized tomography (CAT) scan, magnetic resonance imaging (MRI), or other exposure to radiation, take off your t:slim Pump and remove it from the procedure room. If you have questions, contact Tandem Diabetes Care Customer Support at 1-877-801-6901. Your t:slim Pump, however, has been designed to withstand common electromagnetic interference, including airport and department store security systems. Refer to Electromagnetic Compatibility in section 19.5 for more detailed information.

In addition to radiological procedures, there are a number of other medical procedures which will require you to remove your t:slim Pump, most notably:

- **Pacemaker/Implantable Cardioverter Defibrillator (AICD)** – Disconnect your t:slim Pump and leave it outside the procedure room during the insertion of the pacemaker device and reprogramming (the infusion set can remain in place).
- **Cardiac Catheterization** – Disconnect your t:slim Pump and leave it outside the procedure room.
- **Nuclear Stress Test** – Disconnect your t:slim Pump and leave it outside the procedure room during the scan (it can remain connected during the injection of radioisotopes).

There are also other procedures where you should proceed with caution, most notably:

- **Laser Surgery** – Your t:slim Pump and infusion set can usually be worn during the procedure. However, some lasers can create interference and cause your t:slim Pump to set off an alarm.
- **General Anesthesia** – Depending on the equipment being used, you may or may not need to remove your t:slim Pump. Be sure to ask your healthcare provider.

There is no need to disconnect for electrocardiograms (EKGs) or colonoscopies.

Extreme Temperatures

Avoid exposure of your t:slim Pump to temperatures below 40° F (5° C) or above 99° F (37° C), as insulin solutions can freeze at low temperatures or degrade at high temperatures. Do not steam, sterilize, or autoclave your t:slim Pump at any time.

Amusement Park Rides

Very powerful electromagnets are sometimes used on “free-fall” or thrill rides. Remove your t:slim Pump and do not take it on these types of rides. Also, on high-speed/high-gravity roller coasters, you should disconnect (NOT stop or suspend) your pump as well.

Aircraft Without Cabin Pressurization

Disconnect (NOT stop or suspend) your t:slim Pump before flying in an aircraft without cabin pressurization or in planes used for aerobatics or combat simulation (pressurized or not).

Small Parts Potentially Ingestible by Children

Insulin pumps, including the t:slim Pump, include small parts (such as pieces of the infusion set, rubber USB port cover, and cartridge components) that could be ingested by children. Therefore, keep your t:slim Pump and accessories out of the reach of children.

Do Not Use in the Presence of Flammable Anesthetics or Explosive Gases

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 Pump in the presence of flammable anesthetics or explosive gases.

Air Travel

Follow TSA and airline guidelines whenever traveling with medical equipment. For further information, contact Tandem Diabetes Care Customer Support at 1-877-801-6901.

Other Precautions

Be sure to heed these other important precautions regarding your t:slim Pump:

- If your t:slim Pump is damaged or shows any signs of fluid entry, disconnect the set from your body, and contact Tandem Diabetes Care Customer Support at 1-877-801-6901.
- Always follow proper clean technique when handling your pump and cartridge:
 - » Wash your hands with anti-bacterial soap before handling.
 - » Use only sterile, unopened products, such as needles, cartridges, and infusion sets.
 - » Thoroughly clean the insertion site on your body.
- Your t:slim Pump is a sealed device that should be opened and repaired only by the manufacturer. If your t:slim Pump seal is broken or the back label is removed or damaged, the warranty is voided and your t:slim Pump is no longer watertight.
- Conduct regular checks of your t:slim Pump and infusion set, particularly:
 - » Check your infusion site for proper placement and leaks. Improperly placed sites or leaks around the infusion site can result in under-infusion.
 - » Check your infusion set tubing for any damage, leaks, or kinks while using your t:slim Pump. Damaged, leaking, or kinked tubing may restrict or stop insulin delivery and result in under-infusion.
 - » Check your t:slim Pump's personal settings to ensure that they are correct.
 - » Check your t:slim Pump's audible tones and vibratory alerts to ensure they are easily detectable.
- Use only single-use, disposable t:slim cartridges. The efficacy of your t:slim Pump cannot be guaranteed if cartridges other than those manufactured by Tandem Diabetes Care, Inc. are used or if cartridges are filled more than once. Use of cartridges not manufactured by Tandem Diabetes Care, Inc. or reuse of cartridges may result in over-infusion or under-infusion and may cause serious injury or death.

- Use only FDA cleared infusion sets with a standard luer lock connection and consult its instructions for use. Failure to do so may result in over-infusion or under-infusion and may cause serious injury or death. Change your infusion set every 48-72 hours. Consult your healthcare provider for more information.
- Always dispose of used cartridges and infusion sets following your community's regulations. Insulin can be absorbed through the skin, so wash your hands thoroughly after handling any insulin-holding device.
- Regularly check your t:slim Pump screen for rare but potential failure conditions that may display.
- Everyone who connects additional equipment to the pump configures a medical system, and is therefore responsible to ensure that the system complies with the requirements of standard IEC60601-1-1.

1.8 Conventions of this Guide

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

Convention	Explanation
Bolded Text	Text that is in bold and in a different font than the rest of the sentence or step indicates an onscreen or physical button name.
Touch Screen	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 t:slim Pump).
Hold	Keep pressing a button or touching an icon or menu until its function is complete.
Menu	A list of options on your touch screen that allow you to perform specific tasks.
Icon	An image on your touch screen that indicates an option or item of information, or a symbol on the back of your t:slim Pump or its packaging.

2

Introduction

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2.2	What your t:slim Insulin Delivery System Package Includes	16
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2.1 Welcome

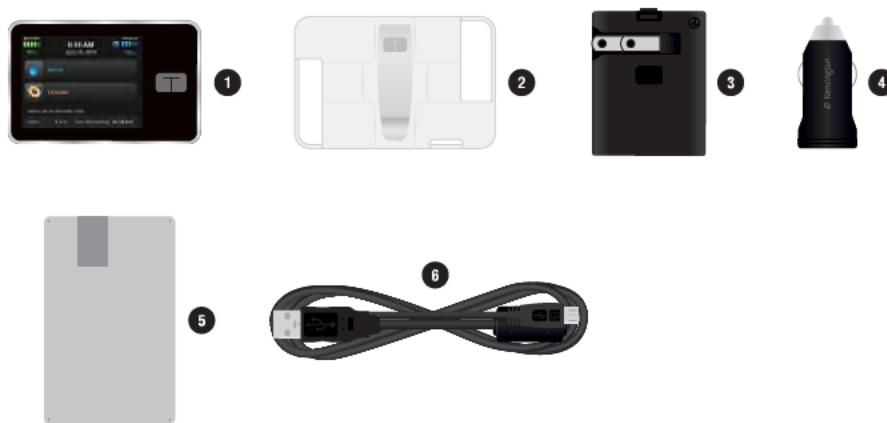
Congratulations on the purchase of your new t:slim System. Your decision to use insulin pump therapy is a sign of your commitment to your diabetes care. The t:slim Pump is designed using the latest technology. The following pages provide step-by-step illustrative instructions on how to properly program, manage, and care for your pump.

2.2 What your t:slim Insulin Delivery System Package Includes

Your t:slim System should contain the following items:

1. t:slim Pump
2. t:slim Belt Clip
3. AC power charger, USB
4. DC vehicle adapter charger, USB
5. The t:slim User Guide (available on USB card in a printable format)
6. USB cable, A to Micro B, 2 meter

If any of these items are missing, contact Tandem Diabetes Care Customer Support at 1-877-801-6901.



NOTE

Your t:slim Pump is shipped from Tandem Diabetes Care, Inc. with a clear screen protector. Do not remove the screen protector. Additional screen protectors can be ordered by contacting Tandem Diabetes Care Customer Support at 1-877-801-6901.

NOTE

Your t:slim Pump is shipped from Tandem Diabetes Care, Inc. 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 therapy.

2.3 Explanation of Symbols

The following are symbols (and their descriptions), which you may find on your t:slim Pump and/or its packaging:

	Caution; Consult Manual for Important Safety Documentation		Type BF Applied Part (patient isolation, not defibrillator protected)
	Consult Instructions for Use		Manufacturer
	Serial Number of device		For sale by or on the order of a physician only (U.S.)
	Part Number		Direct Current (DC) voltage
	Water-tight Equipment (protected against the effects of temporary immersion in water)		

2.4 Warranty Information

At Tandem Diabetes Care, Inc. we are committed to ensuring your complete satisfaction with our products. Our Customer Support Department is available 24 hours a day via phone at 1-877-801-6901 or via email at technicalsupport@tandemdiabetes.com. Your t:slim System's 4-year warranty covers the pump. The warranty period begins upon the date of purchase.

3

t:slim Overview

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3.1 t:slim Pump Overview

Your t:slim Pump uses touch screen technology. To activate and interact with your t:slim Pump, use the pad of your finger to quickly and lightly tap on the screen. Do not use your finger nail or another object to interact with the screen. It will not activate the screen or its functions.

Your t:slim 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.

3.2 t:slim System Terminology

Basal

Basal is a slow continuous delivery of insulin, which keeps BG levels stable between meals and during sleep. It is measured in units per hour (u/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 blood glucose goal, an exact number, not a range. When a BG is entered in the t:slim 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 an elevated BG. With t:slim Pump it can be delivered as a Standard, a Correction, an Extended, or a Quick Bolus.

Cannula

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

Carbohydrate

Carbohydrates are sugars and starches that the body breaks down into glucose, which is then used as an energy source. It is measured in grams.

Carbs

Abbreviation for carbohydrates.

Carb Ratio

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

Correction Bolus

A correction bolus is given to correct elevated BG.

Correction Factor

A correction factor is the amount of BG that is lowered by one 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 t:slim Pump, enter the DELIVER NOW portion to dose a percentage of insulin immediately and the remaining percentage over a period time.

Grams

Grams are a unit of measurement for carbohydrates.

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).

IOB

IOB is the abbreviation for Insulin on Board. It is insulin that is still active (has the ability to continue to lower the BG) in the body from a previous bolus delivery.

Load

Load refers to the process of removing, replacing and filling 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 Quick Bolus Button) is a fast and discreet way of programming and delivering a bolus without having to look at the pump screens.

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.

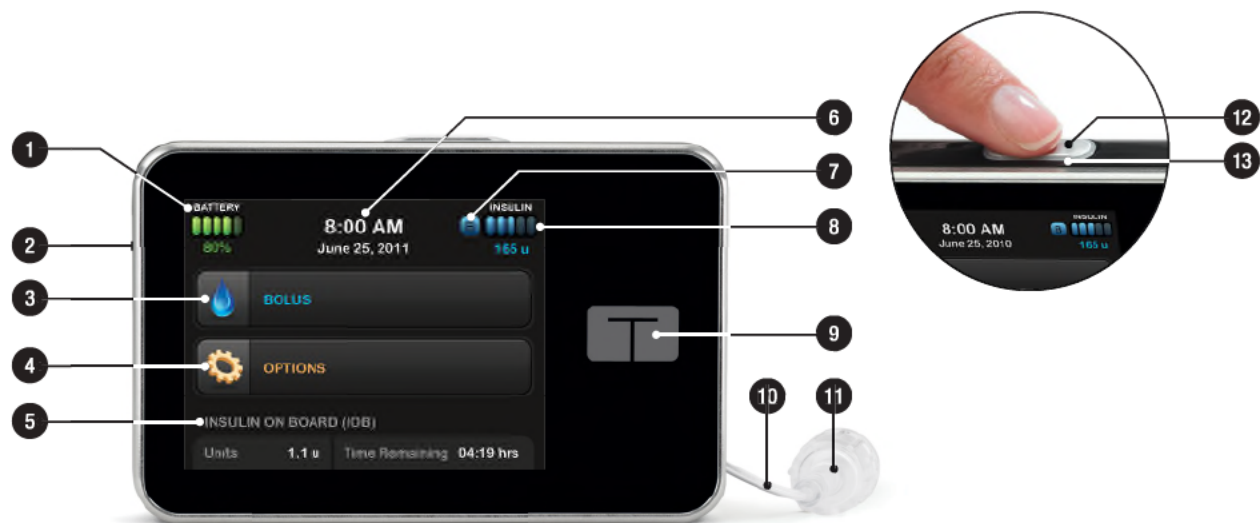
Units

Units are the measurement for insulin.

USB Cable

USB is the abbreviation for Universal Serial Bus. The cord connects into the t:slim Pump's micro USB port.

3.3 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 t:slim Pump battery. Close the cover when not in use.

3. **BOLUS:** Program and deliver a bolus.

4. **OPTIONS:** Stop/Resume insulin delivery, manage Pump Settings, Load cartridge, program a Temp Rate, and view History.

5. **INSULIN ON BOARD (IOB):** Amount and time remaining of any active insulin on board.

6. **Time & Date Display:** Displays the current time and date. Tap to set the time and date.

7. **Status:** Displays current pump settings and insulin delivery status.

8. **INSULIN Level:** Displays the current amount of insulin in the cartridge.

9. **Tandem Logo:** Returns to Home Screen.

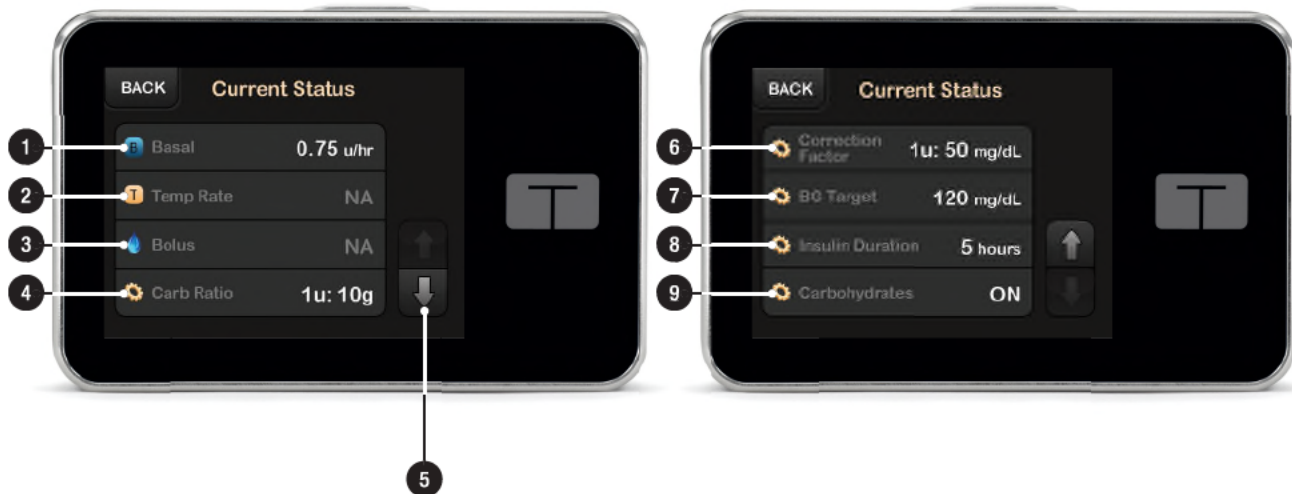
10. **Cartridge Tubing:** Tubing that is attached to the cartridge.

11. **Luer Lock Connection:** Connects the cartridge tubing to the infusion set tubing.

12. **Screen On/Quick Bolus Button:** Turns on the t:slim Pump screen or programs a quick bolus (if activated).

13. **LED Indicator:** Illuminates when connected to a power supply and indicates proper functionality.

3.4 Status Screen



1. **Active Basal Rate:** Displays current basal rate being delivered.

2. **Temp Rate:** If active this is displayed in u/hr.

3. **Active Bolus:** Displays bolus amount when bolus delivery is active.

4. **Carb Ratio:** Displays current carb ratio used to calculate bolus.

5. **Up/Down Arrow:** Indicates there is more information.

6. **Correction Factor:** Displays current correction factor used to calculate bolus.

7. **BG Target:** Displays current BG target used to calculate bolus.

8. **Insulin Duration:** Displays current insulin duration used to calculate insulin on board.

9. **Carbohydrates:** Indicates whether feature is On or Off.

NOTE

The status screen is for display only, no changes can be made from this screen.

3.5 Bolus Screen

Using Grams



1. **BACK:** Returns to Home Screen.
2. **CARBS:** Enter grams of carb to be consumed.
3. **Units:** Displays total units calculated.
4. **View Calculation:** Displays how the insulin dose was calculated using the current settings.
5. **BG:** Enter blood glucose level.
6. **NEXT:** Moves to next step.

Using Units



1. **BACK:** Returns to Home Screen.
2. **INSULIN:** Enter units of insulin.
3. **Units:** Displays total units calculated.
4. **View Calculation:** Displays how the insulin dose was calculated using the current settings.
5. **BG:** Enter blood glucose level.
6. **NEXT:** Moves to next step.

3.6 Options Screen



1. **BACK:** Returns to Home Screen.

2. **STOP INSULIN:** Stops insulin delivery. If insulin delivery is stopped, Resume Insulin will be displayed.

3. **My Pump:** Personal Profiles, Alert Settings, Pump Settings, and Pump Info.

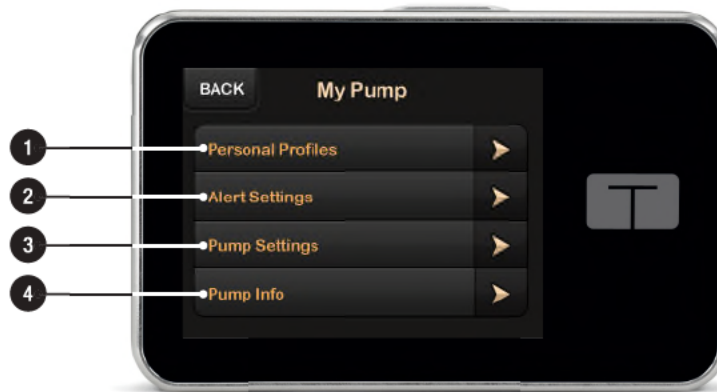
4. **Load:** Change Cartridge, Fill Tubing, Fill Cannula, and Site Reminder.

5. **Temp Rate:** Programs a temporary basal rate.

6. **Menu Arrows:** Indicates additional menu options are available.

7. **History:** Displays historical log of pump events.

3.7 My Pump Screen



1. Personal Profiles: A group of settings that defines basal and bolus delivery.

2. Alert Settings: Customize Reminders and Alerts.

3. Pump Settings: Customize Quick Bolus, Pump Volume, Screen Lock, and Feature Lock.

4. Pump Info: Displays t:slim Pump serial number, Customer Support phone number and website.

3.8 Keypad Numbers Screen



1. Value Entered.

2. BACK: Returns to previous screen.

3. Keypad Numbers.

4. +/=: Allows numbers to be added on gram screen. If in units, this displays as a decimal point.

5. DONE: Completes task and saves information entered.

6. Units/Grams: Value of what is entered.

7. DEL: Deletes last number entered.

NOTE

If changing an existing number, begin by tapping the numbers on the keypad to override the current value.

3.9 Keypad Letters Screen



1. Name of Profile.

2. BACK: Returns to previous screen.

3. Space: Enters a space.

4. 123: Changes keypad mode from letters (ABC) to numbers (123).

5. SAVE: Saves entered information.

6. Letters: Tap once for first letter displayed, two quick taps for middle letter, and three quick taps for third letter.

7. DEL: Deletes last letter or number entered.

NOTE

If changing an existing name, begin by tapping the letters on the keypad to enter new text. The maximum number of characters is 16.

Basic Pump Operations

Section 2

4

Getting Started

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WARNING

Before you can safely and effectively use your t:slim Pump, it is very important that you carefully follow the procedures in these sections.

The t:slim Pump continues to operate normally while charging and full pump functionality is available, therefore, the patient does not need to interrupt therapy.

If you choose to disconnect 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 compensate for missed basal and/or bolus insulin. Check your blood glucose level at minimum before disconnecting from the pump and again when you reconnect.

4.1 Charging t:slim Pump

Your t:slim Pump is shipped in a factory set state for minimal battery usage. The pump can only be switched from the original state to an operational state by charging the pump.

The t:slim Pump is powered by an internal Lithium Polymer rechargeable battery. Included with the pump are accessories for charging from AC, automobile outlets, or a PC USB port. Upon receipt of the pump, you should charge it using the AC charger for at least 2.5 hours to ensure a full charge.

WARNING

In order to maintain compliance with the IEC 60601-1 safety standard, the pump must be charged with a power supply that conforms to either IEC 60601-1 or IEC 60950-1, or an equivalent safety standard, when connected to an AC mains power source.

To Charge the Pump

1. Plug the 2-prong end of the AC charger into a grounded AC electrical outlet.
2. Plug the USB cable into the AC charger and the other end into the Micro USB port of your t:slim Pump. The screen illuminates.

You may also charge the pump by connecting the supplied charge adapter to an auxiliary power outlet and the USB cable to the pump, or connect the pump to a USB port on a PC that complies with IEC 60950 (or equivalent) safety standard.

WARNING

When using the DC vehicle adapter charger, 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 AC mains is prohibited.

CAUTION

When connected to a charging source, always take precaution to detach the USB cable from the pump prior to moving distances further than the length of the USB cable. Failure to do so may result in the cannula becoming dislodged at the infusion site. For this reason it is recommended not to charge the pump while sleeping.

When you charge the t:slim Pump, the following should occur:

- The screen illuminates
- An audible alert
- The LED (edge around the Screen On/Quick Bolus Button) illuminates
- A vibrating alert
- A charge (lightning bolt) symbol on the battery indicator appears

CAUTION

If any of these conditions fail to occur, do NOT use the t:slim Pump, as this may be an indication that the pump's alarms, alerts, and other built-in safety features may not be working properly. If the t:slim Pump is connected to your body, disconnect the set from your body and contact Tandem Diabetes Care Customer Support at 1-877-801-6901.

Charging Tips

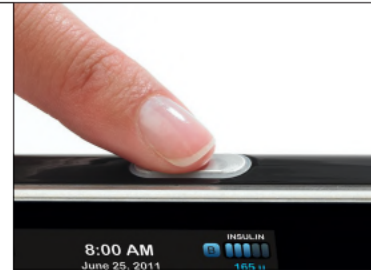
Tandem Diabetes Care, Inc. recommends periodically checking the power-level indicator, charging the pump approximately 30 minutes each day, and also avoiding frequent full discharges.

4.2 Turning On t:slim Pump Screen

1. To turn on your t:slim Pump screen, press the **Screen On/Quick Bolus** Button, located on the top of the pump, once.
 - ▷ The Home Screen or the last screen that was viewed will be displayed.

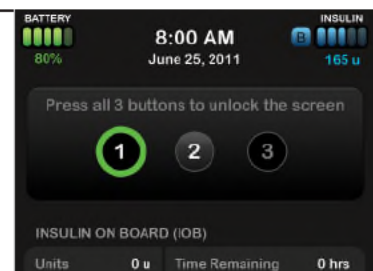
NOTE

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

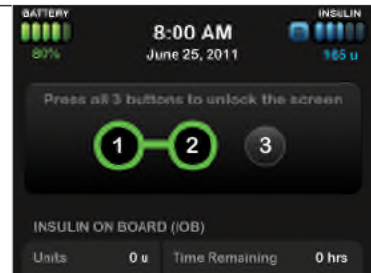


4.3 Unlocking Pump Screen

1. Press **Screen On/Quick Bolus** Button.
2. Tap 1.

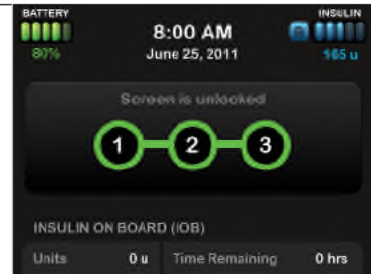


3. Tap 2.



4. Tap 3.

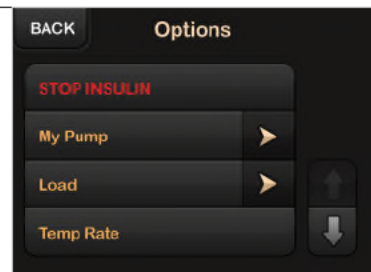
- ▷ The pump screen is now unlocked. The last screen that was viewed will be displayed.



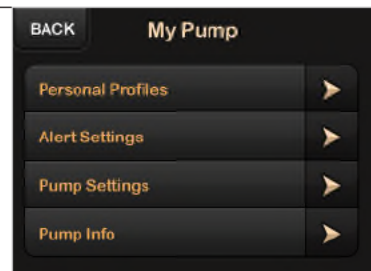
4.4 Enabling/Disabling Screen Lock Setting

1. From Home Screen, tap **OPTIONS**.

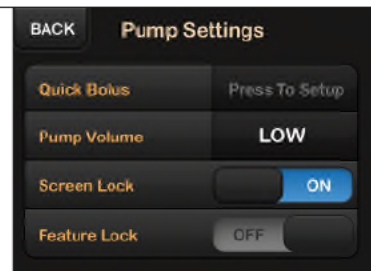
2. Tap **My Pump**.



3. Tap **Pump Settings**.



4. Tap **Screen Lock** to turn ON or OFF.



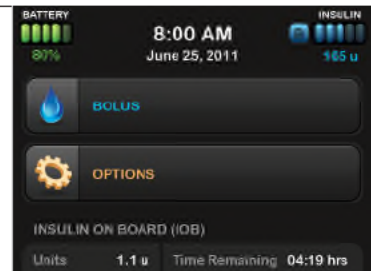
4.5 Editing Time

After powering up your t:slim 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.

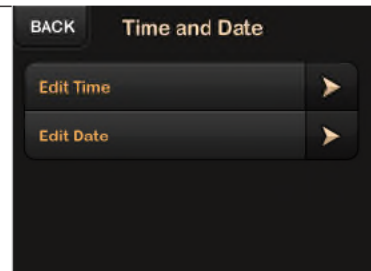
CAUTION

It is very important to set the current time and date accurately to ensure precise settings, and thus, facilitate safe insulin delivery. When editing time, always ensure that the AM/PM setting is accurate. AM is to be used from midnight until 11:59 AM. PM is to be used from noon until 11:59 PM.

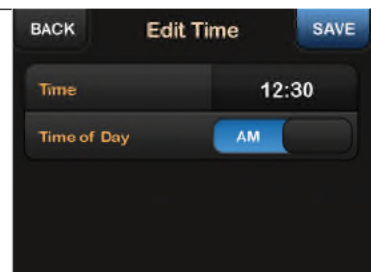
1. From Home Screen, tap time/date.



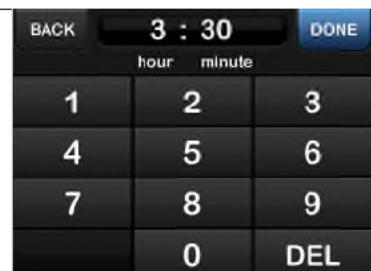
2. Tap **Edit Time**.



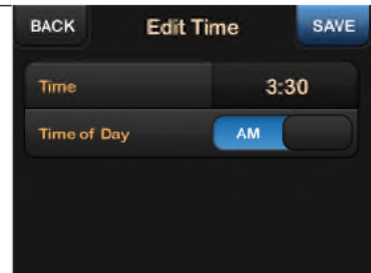
3. Tap **Time**.



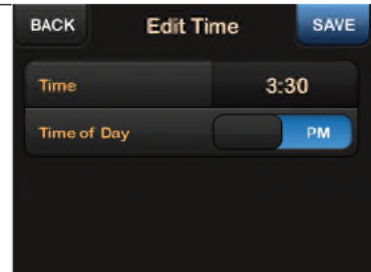
4. Using the onscreen keypad, enter the hour and minutes. Verify and tap **DONE**.



5. Tap **Time of Day** to set **AM** or **PM**.

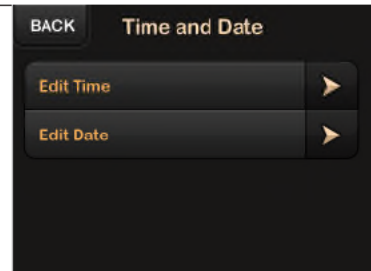


6. Verify the correct time is set and tap **SAVE**.

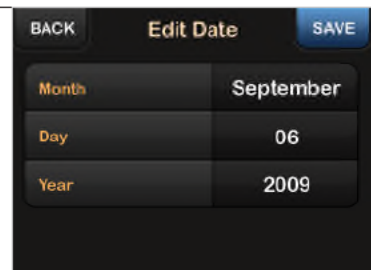


4.6 Editing Date

1. From Time and Date screen tap **Edit Date**.



2. Tap **Month**. Find and tap current month display on the right. Use Up/Down Arrow to view months not displayed.



3. Tap **Day**. Using the onscreen keypad enter the current day. Verify and tap **DONE**.
4. Tap **Year**.

The screenshot shows the 'Edit Date' screen with a 'BACK' button on the left and a 'SAVE' button on the right. The date is displayed as June 06, 2009. The fields are labeled 'Month', 'Day', and 'Year'.

5. Using the onscreen keypad enter the current year. Verify and tap **DONE**.

The screenshot shows a numeric keypad for selecting the year. The year '2010' is entered and displayed at the top. The keypad has buttons for digits 1-9, 0, and a 'DEL' button. There are 'BACK' and 'DONE' buttons at the top.

6. Verify the correct date is set and tap **SAVE**.

The screenshot shows the 'Edit Date' screen with the date set to June 21, 2010. The 'Month' field shows 'June', the 'Day' field shows '21', and the 'Year' field shows '2010'. The 'SAVE' button is highlighted in blue.

5

Infusion Site Care and Loading Cartridge

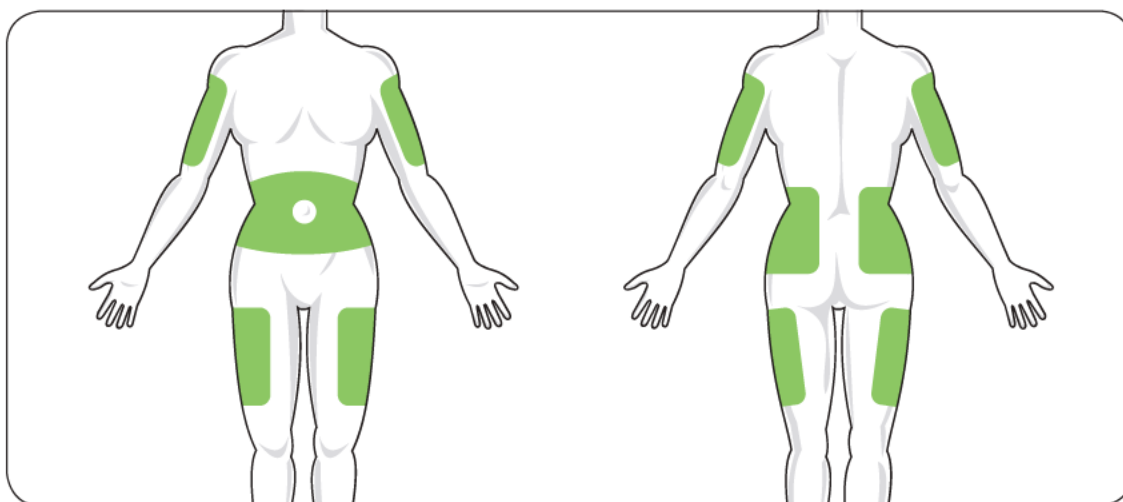
5.1	Infusion Site Selection and Care.....	37
5.2	Cartridge Instructions for Use.....	38
5.3	Loading and Filling a t:slim Cartridge	39
5.4	Filling Tubing	43
5.5	Filling Cannula	45
5.6	Setting Site Reminder	47

5.1 Infusion Site Selection and Care

WARNING

- » Use only FDA cleared insulin infusion sets with a standard luer lock connection and consult its instructions for use. Failure to do so may result in over-infusion or under-infusion and may cause serious injury or death. Change your infusion set every 48-72 hours. Consult your healthcare provider for more information.
- » Use only single-use disposable cartridges. Failure to do so may result in over-infusion or under-infusion and may cause serious injury or death.
- » Use only Humalog® or NovoLog® U-100 insulin. Failure to do so may result in serious health consequences.

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.
 - » Area 2 inches around your bellybutton.
 - » Any scars, moles, or stretch marks.

Site Rotation

- The infusion set must be replaced and rotated every two to three days.
- It is very likely you will find areas that not only provide better absorption, but are more comfortable. Keep in mind, using the same areas can cause scarring or lumps which can affect insulin absorption.
- Consult your healthcare provider to establish a rotation schedule.

Keep it clean

- When changing your infusion set, use clean technique to avoid infection.
- Wash hands, use IV prep, and keep area clean to avoid contamination.
- IV prep that has both an antiseptic and an adhesive is encouraged.

5.2 Cartridge Instructions for Use

Symbols

	Use By Date (MM/DD/YYYY)		Model Number
	Do Not Re-Use		No Latex
	See Instructions for Use		Non Pyrogenic
	Method of Sterilization: Gamma		Temperature Limits -4°F (-20°C) to 140°F (+60°C)

t:slim 3mL cartridge (300 units)
REF: 003380 (10 pack) / REF: 003379

Indications for Use

The cartridge is indicated as a reservoir for the delivery of rapid-acting insulin with the t:slim Pump. Humalog® and NovoLog® have been tested by Tandem Diabetes Care, Inc. and found to be safe for use in the t:slim Pump. Humalog® was tested for up to 48 hours as labeled, NovoLog® was tested for up to 72 hours.

WARNING

United States (U.S.) Federal law restricts this device to sale by or on the order of a physician.

Contraindications

The cartridge is contraindicated for use with products other than Humalog® and NovoLog®.

WARNING

- » The cartridge is sterile, non-pyrogenic, and for single-use only.
- » Do not use if package has been opened or damaged.
- » Dispose of filling syringe and needle safely in a sharps container.
- » Failure to remove air from filling syringe and tubing may result in inaccurate delivery of medication.
- » Always disconnect infusion set from body when filling cartridge with insulin or while priming tubing.
- » Refer to the insulin manufacturer's package insert for proper handling.

CAUTION

- » Insulin should be at room temperature before filling cartridge.
- » Do not store filled cartridges.
- » Check for leaks regularly after changing cartridge and infusion set.
- » The first set-up should be done in the presence of your healthcare provider.
- » Attach only FDA cleared insulin infusion sets compatible with luer connectors to the cartridge.
- » Minimize contact with insulin. Wash hands thoroughly after handling any device that contains insulin.

5.3 Loading and Filling a t:slim Cartridge

This section describes how to load the cartridge into your t:slim Pump and fill the cartridge with insulin. The single-use, disposable cartridge can hold up to 300 units (3.0 mL) of insulin.

CAUTION

Inspect the cartridge to ensure that there is no damage. Never use a cartridge that is damaged (cracks, dislodged tip connectors, etc). If there is damage, call Tandem Diabetes Care Customer Support at 1-877-801-6901 to request a replacement cartridge.

CAUTION

Before you begin, verify that the infusion set is NOT connected to your body.

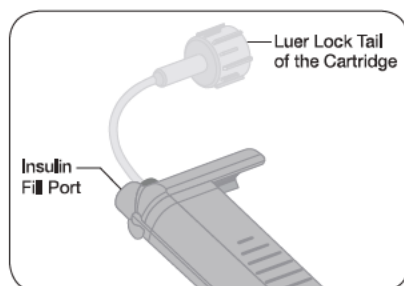
Before you begin, make sure you have the following items:

- 1 unopened, disposable, sterile, single-use cartridge
- Vial of Humalog® or NovoLog® insulin
- 3.0 mL syringe and fill needle
- Alcohol prep swab
- 1 new infusion set

NOTE

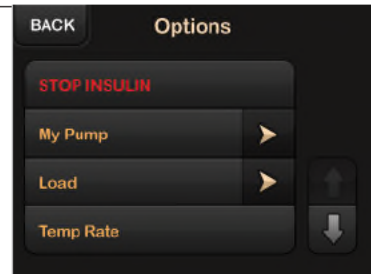
Do NOT remove the cartridge during the Load process until prompted on the t:slim screen.

The illustration below identifies the luer lock and insulin fill port used in the cartridge filling process

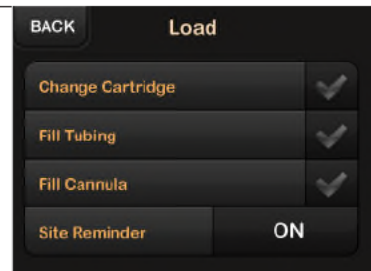


1. From Home Screen tap **OPTIONS**.

2. Tap **Load**.



3. Tap **Change Cartridge**.

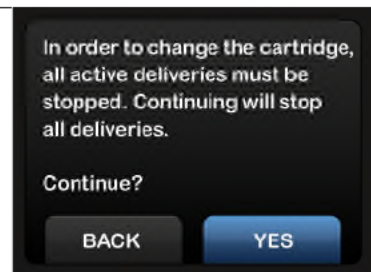


4. Screen will display that all insulin deliveries will be stopped. Tap **YES**.

▷ Stopping All Deliveries screen is displayed.

NOTE

If needed, place the edge of a coin in the slot at the bottom of the cartridge and twist to aid in the removal of the cartridge.

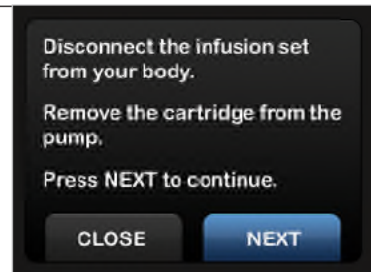


5. Remove used cartridge and tap **NEXT**.

▷ Preparing for cartridge screen is displayed.

CAUTION

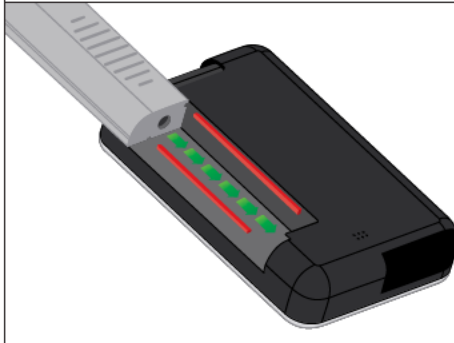
- » If this is the very first time you are loading the cartridge, remove the shipping canister (which is not for human use, as indicated on its label) from the back of the pump.
- » Do not fill the cartridge until you load it into your pump.



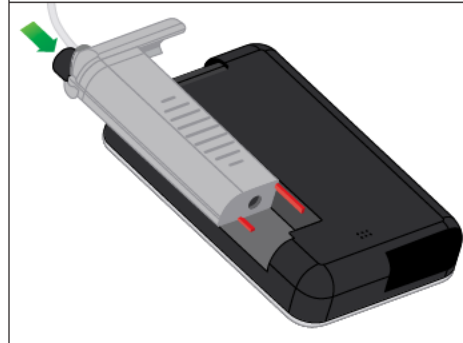
Instructions on How to Load a Cartridge

1. Inspect cartridge package for any indication of damage. Discard any damaged product.
2. Open package and remove cartridge.

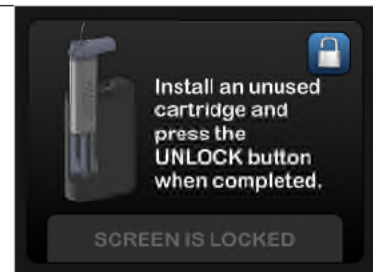
3. Place bottom of the cartridge at the end of the pump. Make sure cartridge is lined up to both guide tracks.



4. Push on the circular fill port next to the cartridge tubing to slide the cartridge onto the pump.



6. After the cartridge is installed tap **Unlock**.



7. Tap **NEXT**.

▷ Detecting Cartridge screen is displayed.

CAUTION

Use only the syringe and needle provided by Tandem Diabetes Care, Inc. to fill the cartridge. After filling the cartridge and before connecting and filling the tubing, reduce the possibility of trapped air in the cartridge by holding your t:slim Pump vertically with the cartridge insulin fill port on top.

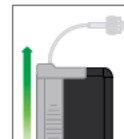


Instructions for Drawing Insulin from Vial into Syringe

1. Wash your hands and remove the needle and syringe from their package. Securely twist needle onto syringe.
2. Safely remove protective cap from needle by pulling outward.
3. Draw air into syringe up to the amount of insulin desired (3mL maximum).
4. Wipe the rubber septum of the insulin vial with an alcohol swab.
5. With insulin vial upright, insert needle into vial. Inject air from syringe into vial. Maintain pressure on syringe plunger.
6. With needle still inserted into vial, turn vial and syringe upside down. Release syringe plunger. Pressure will push plunger and let the insulin flow from vial into syringe.
7. Release the pressure on the plunger and slowly withdraw the desired amount of insulin (equal to the amount of air you filled previously) from the vial into the syringe.
8. While the filling needle is still in the vial and upside down, tap the syringe and slowly push its plunger upwards, forcing any air bubbles back into the vial.
9. Check the syringe for air bubbles and do one of the following:
 - » If there are air bubbles present, repeat step 8.
 - » If no air bubbles are present, remove the filling needle from the vial.

Instructions for Filling the Cartridge

1. When prompted on the pump screen, gently insert needle straight down into white insulin fill port of a new cartridge loaded onto t:slim Pump. The screen will automatically lock during this sequence.
2. Hold the pump upright (as illustrated to the right). Slowly depress the syringe plunger to inject insulin into the cartridge. Note: While filling a cartridge, a back pressure is felt and the pressure increases as the amount of insulin dispensed into the cartridge increases.
3. While maintaining pressure on the plunger, remove the syringe needle from the cartridge. Check the area around the white insulin fill port for leaks. If you detect insulin is leaking from the white insulin fill port, discard the cartridge and repeat entire process with a new cartridge. If you need a replacement cartridge, call Tandem Diabetes Care Customer Support at 1-877-801-6901.
4. Dispose of used needles in a labeled sharps container in accordance with local requirements.



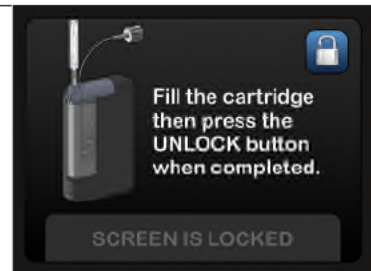
CAUTION

The minimum cartridge fill is 45 units. The maximum cartridge fill is 300 units. Do not overfill or 'top off' when filling the cartridge as the additional amount cannot be delivered. This can lead to a cartridge error, which will require a new cartridge.

WARNING

Do not remove insulin from a filled cartridge.

8. After the cartridge is filled, tap **Unlock**.



9. Tap **NEXT**. The pump takes a few seconds to detect insulin before the **FILLED AMOUNT** screen appears, displaying the total amount of insulin added to the cartridge. (If necessary, you can tap **BACK** to return to the Fill Cartridge screen to continue filling the cartridge).

▷ Detecting Insulin screen is displayed.

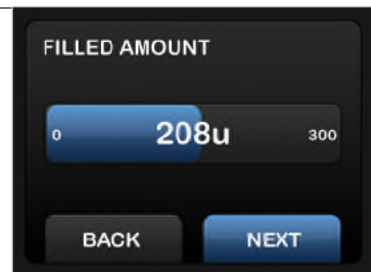


10. View **Filled Amount** and tap **NEXT**.

▷ Cartridge Changed screen will display.

NOTE

After completing the cartridge change, the pump will automatically prompt you to fill tubing.



5.4 Filling Tubing

Filling the Infusion Set Tubing with Insulin

This section describes how to fill (or “prime”) the infusion set tubing with insulin.

WARNING

Never fill the infusion set tubing while the tubing is connected to your body. Filling the tubing while it is connected to your body can result in the unintended delivery of insulin.

NOTE

If starting from the Home Screen, tap **OPTIONS**, tap **Load**, tap **Fill Tubing** and then follow the instructions. Insulin delivery will be stopped and then resumed upon completion.

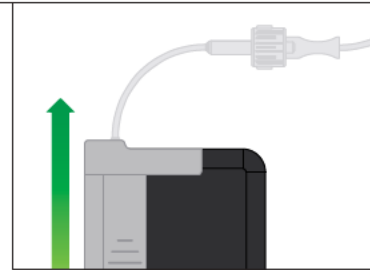
1. Verify that the infusion set is disconnected from your body and tap **NEXT**.

Disconnect the infusion set from your body and press **NEXT** to fill your tubing with insulin.

NEXT

2. Holding the pump vertically (as illustrated to the right), connect the infusion set tubing to the luer lock tail of the cartridge:

- a) 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 of properly and use another tubing set.
- b) Remove the infusion set tubing cap from the luer connector. Be careful to keep the luer connector away from unsanitary areas.
- c) Insert the female luer connector on the infusion set tubing to the male luer connector on the cartridge tubing ("tail") and twist clockwise to secure it.



3. Tap **Start**.

▷ Starting Fill screen is displayed.

Fill Tubing

Fill Tubing

START

Amount Filled

0 u

4. Tap **STOP** once 3 drops of insulin are seen at the end of the tubing.

▷ Stopping Fill screen is displayed.

Fill Tubing

Fill Tubing

STOP

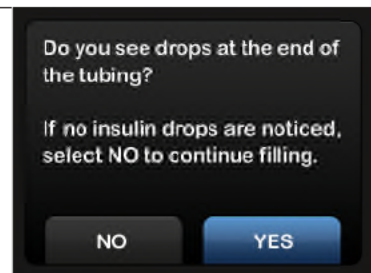
Amount Filled

19 u

NOTE

During tube filling, your pump will stop the fill process and notify you when the tubing has been filled with 30 units. You then have the option to continue filling more than this system max fill amount.

5. Verify that drops are seen and tap **YES**.
 - ▷ Fill Tubing screen is displayed.
6. If you do not see drops, tap **NO**. The Fill Tubing screen appears, repeat steps 4-6 until you see 3 drops of insulin at the end of the tubing.
7. If you did not tap STOP in step 5, the "Max fill amount reached!" screen will appear. 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.

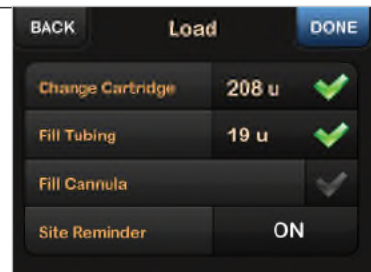


8. Fill Tubing is complete.

NOTE

The following are approximate amounts of insulin to fill different tubing lengths:

- » 16-19 units for 23 inch tubing
- » 20-23 units for 36 inch tubing
- » 24-27 units for 42 inch tubing



5.5 Filling Cannula

Filling the Infusion Set Cannula with Insulin

This section describes how to fill (or "prime") the infusion set cannula with insulin.

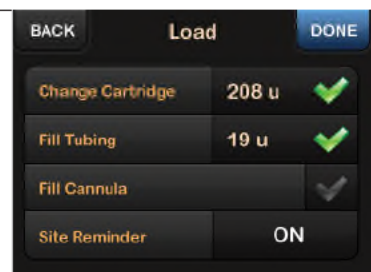
For the correct cannula fill amount, as well as procedures on needle/cannula insertion and attaching the tubing to your body, refer to the instructions for use included with the infusion set.

To Fill the Cannula

NOTE

- » If starting from the Home Screen, tap OPTIONS, tap Load, tap Fill Cannula and then follow the instructions. Insulin delivery will be stopped and then resumed upon completion.
- » If using a steel needle infusion set, there is no cannula. Skip this Section.

1. Tap **Fill Cannula**.



2. Insert a new infusion set and connect tubing to site, then tap **NEXT**.

Insert a new set and connect to the tubing.

Press NEXT to fill the cannula with insulin.

BACK

NEXT

3. Tap **Edit Fill Amount**.

NOTE

The cannula fill amount displayed is based on your last cannula fill amount. Delivery stops at this amount (unless you tap Stop before this amount is reached).

4. Select amount needed for cannula fill.

NOTE

If the amount needed is not listed, tap Other Amount and use the onscreen keypad to enter a value between 0.1 to 1.0 unit.

WARNING

Refer to your infusion set instructions for proper cannula fill amount.

5. Tap **START**.

- ▷ Starting Fill screen is displayed.
- ▷ Cannula Filled screen is displayed. The Amount Filled will be displayed.

NOTE

You can tap STOP at any time during the fill process if you want to stop filling the cannula.

NOTE

If Site Reminder is turned OFF, this is indicated on the screen. Tap DONE 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 (refer to next section).

5.6 Setting Site Reminder

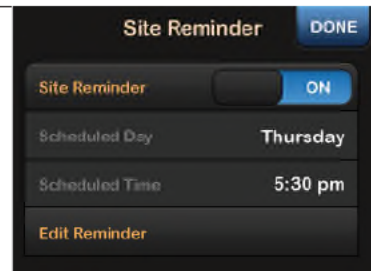
NOTE

If starting from the Home Screen, tap OPTIONS, tap Load, tap Site Reminder then follow the instructions below.

CAUTION

Avoid changing an infusion set before going to bed or if you will not be able to test your BG 1-2 hours after a new set is placed.

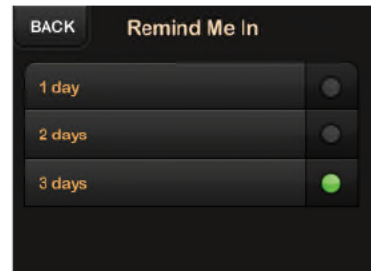
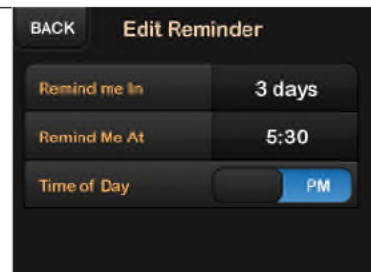
1. Tap **Edit Reminder** if settings need to be changed.



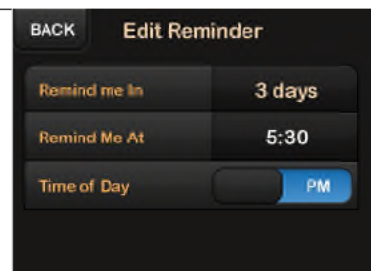
2. Tap **Remind Me In** and select the number of days.

NOTE

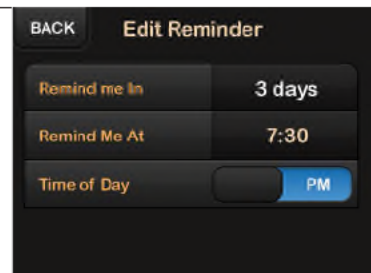
Default reminder is set for 3 days.



3. Tap **Remind Me At**. Use the onscreen keypad to enter time and tap **DONE**.

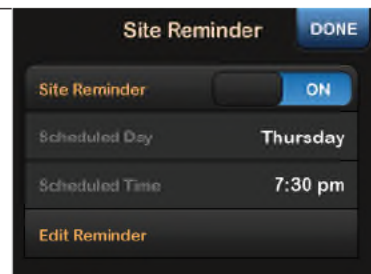


4. Tap **Time of Day** to change AM or PM. Tap **BACK**.



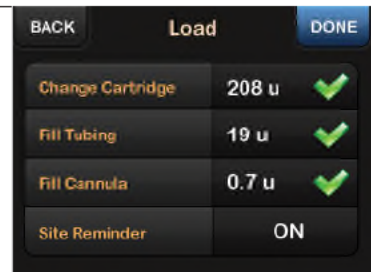
5. Verify site reminder is set correctly and tap **DONE**.

▷ Site Reminder Set screen is displayed.

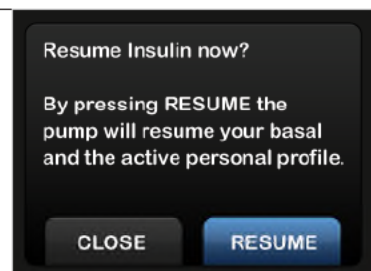


6. Load screen is displayed. Tap **DONE**.

▷ A reminder to test BG in 1-2 hours will display.



7. Tap **RESUME**.



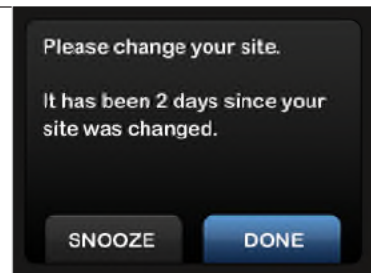
8. **RESUMING INSULIN** splash screen is displayed.



To Respond to the Site Change Reminder

Do one of the following:

1. To acknowledge the alarm but delay it, tap **Snooze**.
The reminder will then re-alarm in 10 minutes.
2. To acknowledge the alarm and move back to the Home Screen, tap **DONE**.



6

Personal Profile

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6.1 Personal Profile Overview

A Personal Profile is a group of settings that define the 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, Carbohydrates setting (ON/OFF) and Max Bolus.

The t:slim Pump uses the settings in your currently active profile to calculate the delivery of basal insulin, food boluses and correction boluses based on your Target BG.

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 variables such as schedule, food intake, activity, and exercise, etc.

NOTE

Up to 6 different Personal Profiles can be created and up to 16 different Time Segments can be set in each Personal Profile. For example, within your "Weekday" profile you might have Time Segments set up for 12:00 AM, 5:30 AM and 3:00 PM based on your healthcare providers recommendation.

NOTE

Once defined, a Personal Profile can be viewed by selecting EDIT from the profile menu.

6.2 Creating a New Profile

Creating Personal Profiles

You can create up to 6 Personal Profiles, however; only one can be active at a time. In the Personal Profiles screen, the currently active profile is positioned at the top of the list and is indicated as ON. When you create a Personal Profile, you can define any or all of the following Timed Settings:

- Basal (your basal rate in units of insulin per hour)
- Correction Factor (amount BG drops per 1 u of insulin)
- Carb Ratio (number of carbs covered by 1 u of insulin)
- Target BG (your ideal BG level)

NOTE

An initial maximum basal rate of 2 u/hr is set for each Personal Profile. If you enter a basal rate greater than 2 u/hr you will be prompted to confirm whether you want to continue with this basal amount. Once basal rates are set in a Personal Profile the maximum basal rate becomes two times the highest basal rate in that Personal Profile. The absolute maximum basal rate is 15 u/hr.

The ranges for Timed Settings (initially inactive) are:

- Basal (range: 0 and 0.1 – 15 u/hr)
- Correction Factor (range: 1 u:1 mg/dL – 1 u:600 mg/dL)
- Carb Ratio (range: 1 u:1 g – 1 u:300 g)
- Target BG (range: 60 mg/dL – 250 mg/dL)

NOTE

A Basal Rate must be defined to have a valid Personal Profile. Other settings are optional.

In addition, you can define any or all of the following Bolus Settings:

- Insulin Duration (how long a bolus lowers your BG)
- Carbohydrates (instead of units for bolus deliveries)
- Max Bolus (the maximum amount of bolus insulin to deliver in a single bolus)

The default settings and ranges for Bolus Settings are as follows:

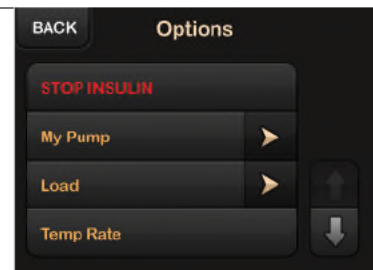
- Insulin Duration (default: 5 hrs; range: 2-8 hrs)
- Carbohydrates (default: OFF if no Carb Ratio is defined; ON if Carb Ratio is defined)
- Max Bolus (default: 10 u; range: 1-25 u)

NOTE

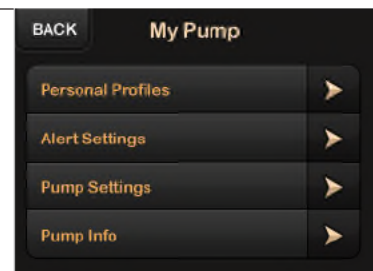
Although you do not need to define every setting, some pump features require certain settings to be defined and activated. During profile setup, your pump prompts you to set up any required settings before you can continue.

1. From Home Screen, tap **OPTIONS**.

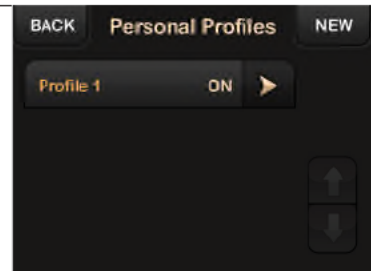
2. Tap **My Pump**.



3. Tap **Personal Profiles**.



4. Tap **NEW** to create a new profile.



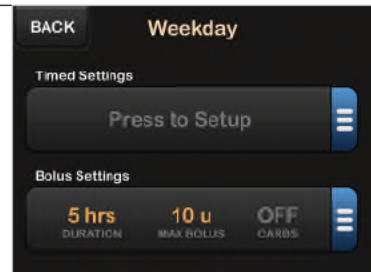
5. Using the onscreen keypad, enter a profile name (up to 16 characters) and tap **SAVE**.

NOTE

Refer to section 3.9 for instructions on using the onscreen keypads.



6. Tap **Press to Setup** to begin setting insulin delivery settings.



6.3 Programming a New Personal Profile

NOTE

- » Once the Personal Profile has been created, the settings must be programmed. The first Time Segment will start at 12:00 AM (midnight).
- » There is always at least one (default) Time Segment at 12:00 AM (midnight). If the settings in this segment are not yet defined, you must at least set a Basal value in order to have a valid Personal Profile that you can activate.
- » For settings that require keypad entry, be sure to tap SAVE after entering or changing a value.

CAUTION

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. However, your pump will not deliver correction boluses, track IOB, or trigger BG alerts.

1. Once the new profile has been created, Tap **Basal**.

2. Using the onscreen keypad, enter the desired basal rate and tap **SAVE**.

CAUTION

Always confirm that the decimal point placement is correct.

3. Tap **Correction Factor**.

4. Using the onscreen keypad, enter the desired correction factor and tap **SAVE**.

NOTE

Enter the mg/dL that 1 unit of insulin will lower BG.

5. Tap **Carb Ratio**.

6. Using the onscreen keypad, enter the desired insulin-to-carbohydrate ratio and tap **SAVE**.

NOTE

Enter the grams of carb to be covered by 1 unit of insulin.

7. Tap Target BG.

8. Using the onscreen keypad, enter the desired BG target and tap **SAVE.**

9. Review entered values and tap **SAVE if correct.**

10. Confirm Settings.

Tap **YES** if entered data is correct.

Tap **NO** to go back and make changes.

11. Tap the **Bolus Settings Panel.**

12. Tap **Insulin Duration.**

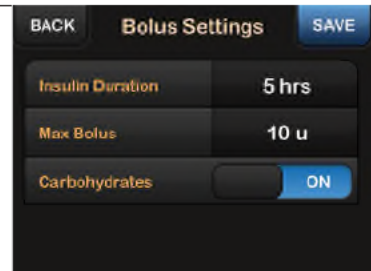
Using the onscreen keypad, enter the desired time for the duration of insulin action and tap **DONE**.

13. Tap **Max Bolus.** Using the onscreen keypad, enter the desired amount for maximum bolus and tap **DONE**.

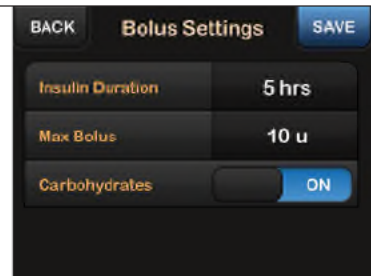
14. Tap **Carbohydrates** to activate and use the carb ratio when calculating boluses.

NOTE

If not using a carb ratio, do not turn the Carbohydrates setting to ON.



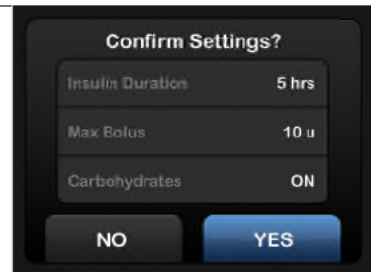
15. Review entered values and tap **SAVE** if correct.



16. Confirm Settings.

Tap **YES** if entered data is correct.

Tap **NO** to go back and make changes.



Adding More Time Segments

NOTE

- » Any settings that you defined in the previous Time Segment also appears in the new segment. This allows you to simply adjust only the specific settings you want to, rather than have to define them all over again.
- » In addition, any settings you define in the new segment that were not defined in the previous segment now appear in the previous segment (for consistency across all segments).

NOTE

If starting from Home Screen, tap OPTIONS, tap My Pump, tap Personal Profiles, tap the profile name, tap Edit, tap Timed Settings then follow the instructions below.

1. On the Timed Settings screen (listing the existing Time Segments), tap **ADD**.
2. On the Add Segment screen, tap **Start Time**.
3. Using the onscreen keypad, enter the time (hour and minutes) that you want the segment to begin, and tap **DONE**.
4. On the Add Segment screen, tap **Time of Day** to select AM or PM.
5. Tap **SAVE**.
6. Repeat steps 1-9 from the above Programming a New Personal Profile for each segment you want to set up (up to 16).

NOTE

To find Time Segments in the list that are not displayed on the first screen, tap scroll arrows.

17. Once all segments are defined, tap **Tandem Logo** to return to Home Screen.

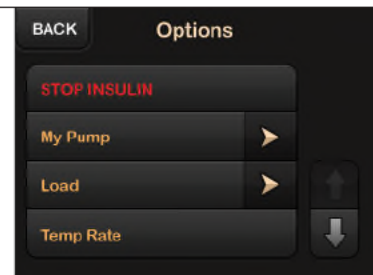
NOTE

Editing, duplicating and renaming an inactive profile will not automatically activate that profile. Refer to section 6.6 for instructions on activating profiles.

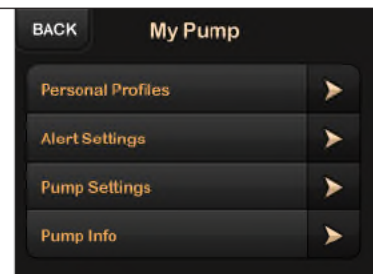
6.4 Editing an Existing Profile

1. From Home Screen tap **OPTIONS**.

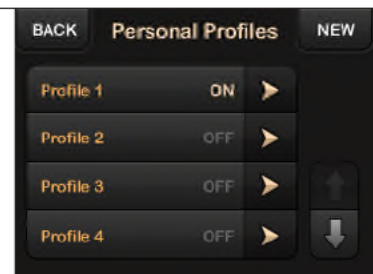
2. Tap **My Pump**.



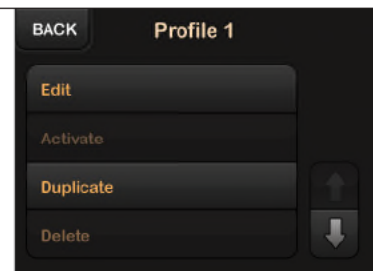
3. Tap **Personal Profiles**.



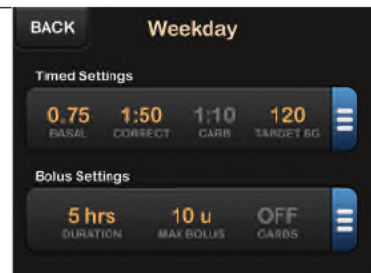
4. Tap profile name to edit.



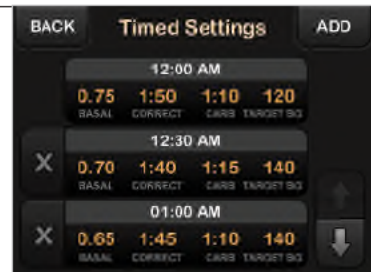
5. Tap **Edit**.



6. Tap **Timed Settings** Panel.



7. Tap the desired timed setting to be edited.



8. Tap **Basal**, **Correction Factor**, **Carb Ratio** or **Target BG** to make changes as needed and use the onscreen keypad to enter desired changes. Tap **SAVE**.



9. Confirm Settings.

Tap **YES** if entered data is correct.

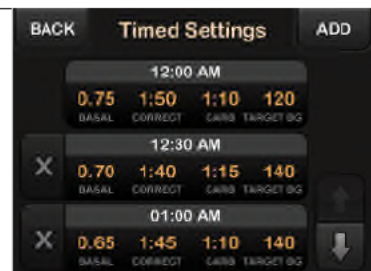
Tap **NO** to go back and make changes.



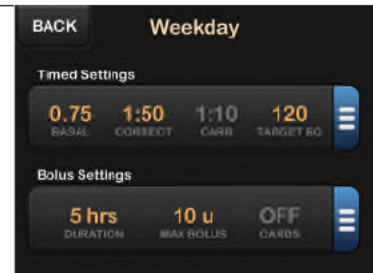
10. Tap **BACK** after editing all of the time segments.

NOTE

Edit other Time Segments within the Timed Settings by tapping on them and using the same method described above.



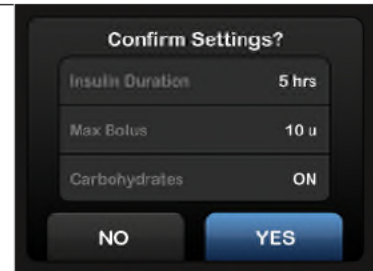
11. Tap the **Bolus Settings** Panel to change DURATION, MAX BOLUS or CARBS as needed and use the onscreen keypad to enter desired changes. Tap **SAVE**.



12. Confirm Settings.

Tap **YES** if entered data is correct.

Tap **NO** to go back and make changes.



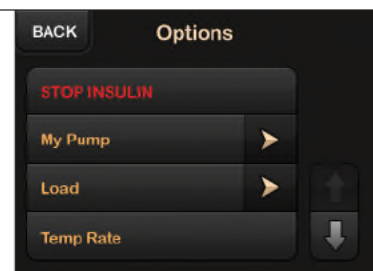
13. Tap **BACK** to Edit, Activate, Duplicate, Delete or Rename if desired. Or tap **Tandem Logo** to return to Home Screen.

To delete a Time Segment:

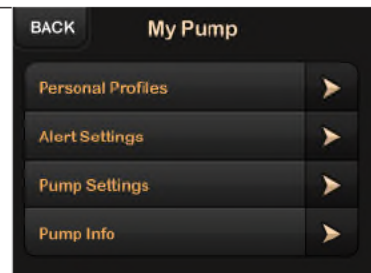
1. Tap on the **X** to the left of the Time Segment.
2. Tap **YES** to confirm.

6.5 Duplicating an Existing Profile

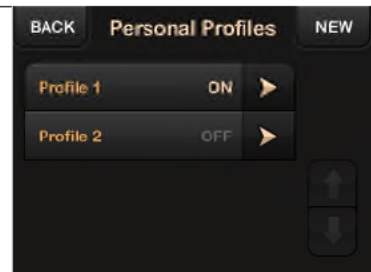
1. From Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.



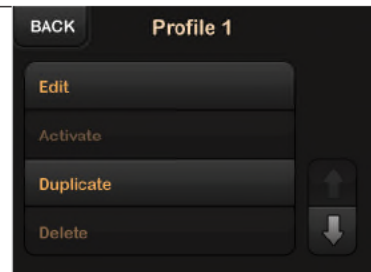
3. Tap **Personal Profiles**.



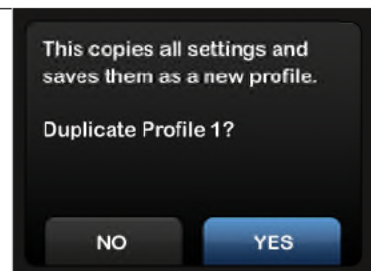
4. Tap the name of the Personal Profile to duplicate.



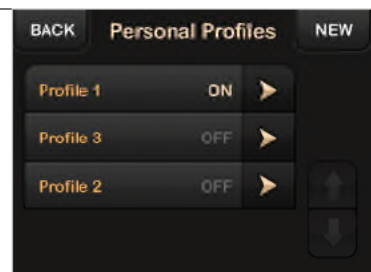
5. Tap **Duplicate**.



6. Confirm profile to duplicate by tapping **YES**.
7. Using the onscreen keypad, enter the name (up to 16 characters) for the new profile and tap **SAVE**.
8. A new Personal Profile will be created with the same settings as the profile copied.



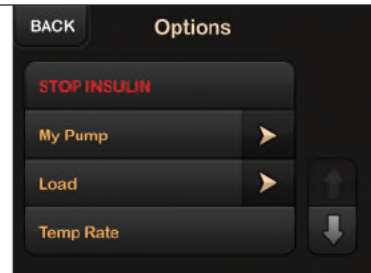
9. Tap the name of the new Personal Profile that was created to **Edit**, **Activate**, **Duplicate**, **Delete** or **Rename** this profile.



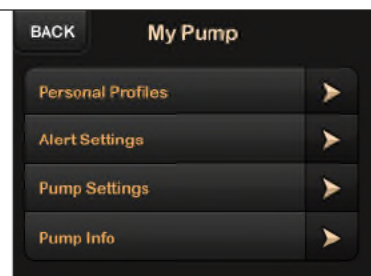
6.6 Activating an Existing Profile

1. From Home Screen tap **OPTIONS**.

2. Tap **My Pump**.



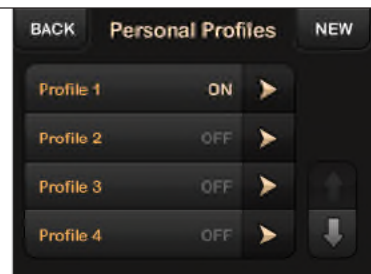
3. Tap **Personal Profiles**.



4. Tap the profile name to be activated.

NOTE

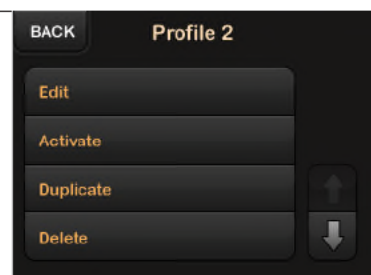
- » The Activate and Delete options are disabled for the currently active profile because the profile is already activated and you cannot delete a profile until you have deactivated it and activated another profile.
- » If you have only one profile defined, you do not need to activate it (that profile is automatically activated).



5. Tap **Activate**.

▷ A screen to confirm the activation of the profile is displayed.

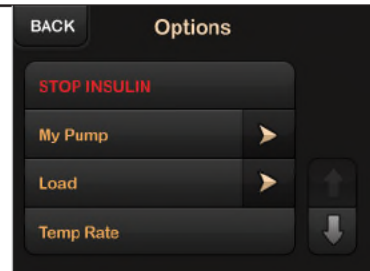
6. Tap **YES**.



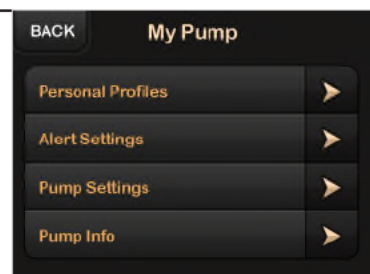
6.7 Renaming an Existing Profile

1. From Home Screen tap **OPTIONS**.

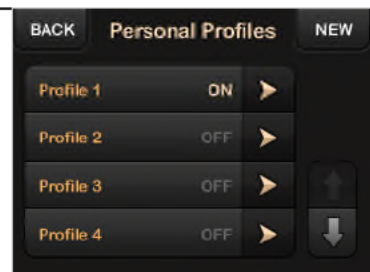
2. Tap **My Pump**.



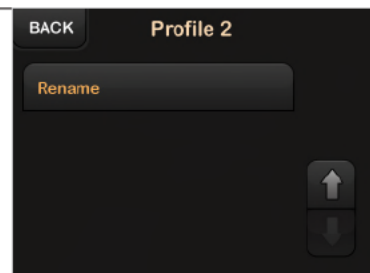
3. Tap **Personal Profiles**.



4. Tap the profile name to be renamed.



5. Tap **Down Arrow**, and then **Rename**.



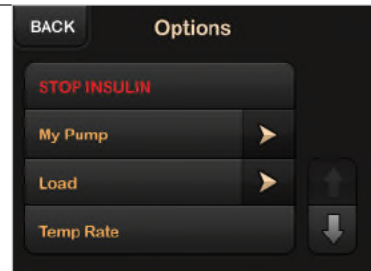
6. Using the onscreen keypad, rename the profile name (up to 16 characters) and tap **SAVE**.



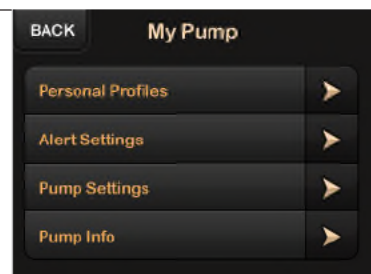
6.8 Deleting an Existing Profile

1. From Home Screen tap **OPTIONS**.

2. Tap **My Pump**.



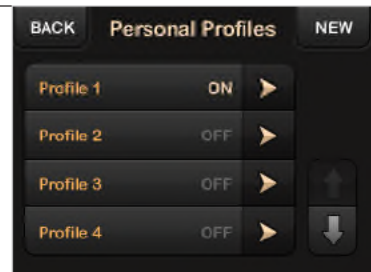
3. Tap **Personal Profiles**.



4. Tap the profile name to be deleted.

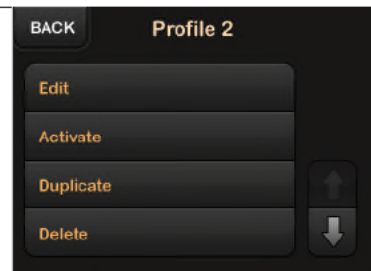
NOTE

The active Personal Profile can not be deleted.

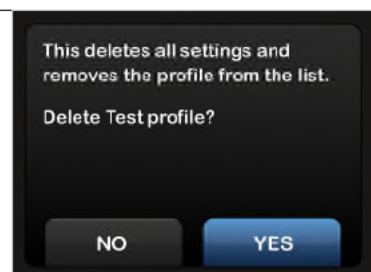


5. Tap **Delete**.

➤ A screen to confirm the deletion of the profile is displayed.



6. Tap **YES**.



7

Bolus

7.1	Bolus Overview	65
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7.1 Bolus Overview

A bolus is a quick dose of insulin that is usually delivered to cover food eaten or an elevated BG.

Your t:slim Pump offers you the ability to deliver different boluses to cover carbohydrate intake (food bolus) and bring your BG back to target range (correction bolus).

Food and correction boluses can also be programmed together.

Your t:slim Pump uses touch screen technology to help you program different bolus types.

In addition, by tapping View Calculation on the Bolus screen, you can always see how your t:slim Pump calculated your suggested bolus.

CAUTION

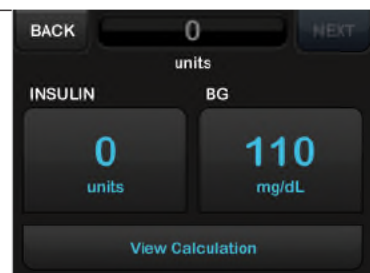
- » Before delivering insulin, always check your pump and infusion set for damage, leaks, or kinks in the tubing, as these problems could restrict or stop insulin delivery and possibly result in under-infusion.
- » If Carbohydrates is turned On in the Bolus Settings of your active Personal Profile, you can deliver boluses only in grams of carbs, not in units of insulin. To deliver in units of insulin, you need to turn off the Carbohydrates setting. Note that the quick bolus delivery setting (grams of carbohydrates or units of insulin) is independent of the active Personal Profile bolus settings.
- » When a standard bolus is being delivered, initiation of another bolus is locked out. However, if an extended bolus is being delivered, initiation of a standard bolus is not locked out (but initiation of a second extended bolus is locked out and you cannot stack a standard bolus on top of the "now" portion of the extended bolus).
- » When attempting to deliver a bolus that exceeds either your Personal Profile's Max Bolus setting or the pump's maximum bolus amount allowed, a Max Bolus Alert will occur and you will need to make a decision on whether to continue with bolus delivery, adjust the amount, or accept the pump's maximum allowable amount. Refer to Max Bolus Alerts in section 15.10.

7.2 Food Bolus Using Units

NOTE

If bolusing using a carb ratio skip to the next section Food Bolus Using Grams.

1. From Home Screen tap **BOLUS**.
2. Tap **0 units**.



3. Using the onscreen keypad enter desired units of insulin, tap **DONE**.

CAUTION

Always confirm that the decimal point placement is correct.

4. Tap **NEXT** to confirm the units of insulin to be delivered.

NOTE

You can tap View Calculation to display the Delivery Calculation screen.

5. Confirm Request.

Tap **YES** if entered data is correct.

Tap **NO** to go back to make changes or view calculations.

6. Tap **DELIVER**.

7. The bolus splash screen will be displayed to confirm delivery.

7.3 Food Bolus Using Grams

1. From Home Screen tap **BOLUS**.

2. Tap **0 grams**.

BACK 0 NEXT
units
CARBS BG
0 110
grams mg/dL
View Calculation

3. Using the onscreen keypad enter grams of carb and tap **DONE**.

NOTE

- » To add multiple carb values enter first value, then tap +/-, enter second value, tap +/-, Continue until done.
- » To clear last carb value entered, tap CLR.

BACK Enter Carbs DONE
grams
1 2 3
4 5 6
7 8 9
+ / = 0 DEL

4. Tap **NEXT** to confirm the units of insulin to be delivered.

NOTE

You can tap View Calculation to display the Delivery Calculation screen.

BACK 11.8 NEXT
units
CARBS BG
118 110
grams mg/dL
View Calculation

5. Confirm Request.

Tap **YES** if entered data is correct.

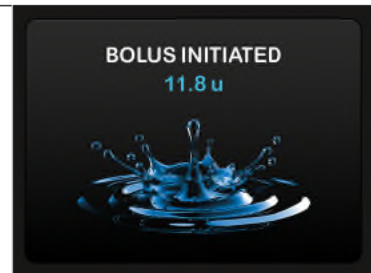
Tap **NO** to go back to make changes or view calculations.

Confirm Request?
Carbs 118 g
BG 110 mg/dL
Units To Deliver 11.8 u
NO YES

6. Tap **DELIVER**.

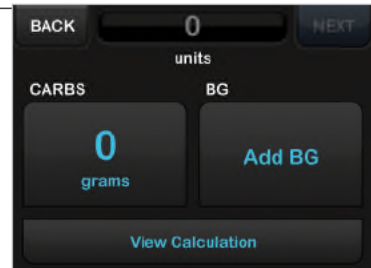
Deliver 11.8 u Bolus?
Correction NA
EXTENDED OFF
Food 11.8 u
BACK DELIVER

7. The bolus splash screen will be displayed to confirm delivery.



7.4 Correction Bolus

1. From Home Screen tap **BOLUS**.
2. Tap **Add BG**.



3. Using the onscreen keypad enter BG value and tap **DONE**.

NOTE

Once DONE is tapped, the BG value is saved whether or not a bolus is delivered.

NOTE

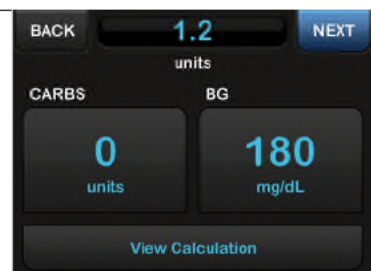
- » If BG is above the Target BG, a message screen will indicate BG is above Target. To add a correction bolus tap YES.
- » If BG is below Target BG, a message screen advises to eat carbs and retest. Tap Close.
- » If BG is at Target BG, it will return to the Bolus Screen with no recommended bolus amount for correction.



4. Tap **NEXT** to confirm the units of insulin to be delivered.

NOTE

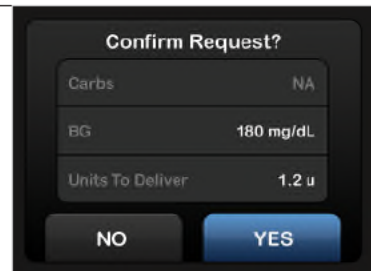
You can tap View Calculation to display the Delivery Calculation screen.



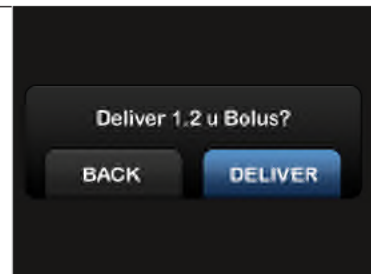
5. Confirm Request.

Tap **YES** if entered data is correct.

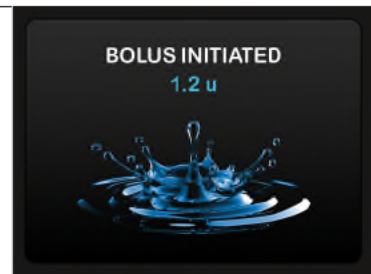
Tap **NO** to go back to make changes or view calculations.



6. Tap **DELIVER**.



7. The bolus splash screen will be displayed to confirm delivery.



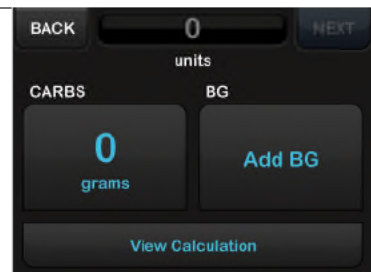
7.5 Extended Bolus

1. From Home Screen tap **BOLUS**.

2. Tap **0 grams** (or **0 units**).

3. Using the onscreen keypad enter grams of carb (or units of insulin). Tap **DONE**.

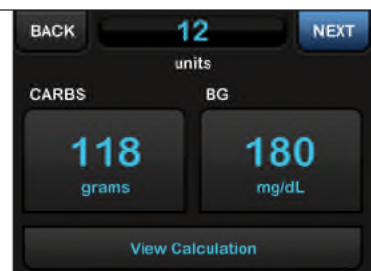
4. If desired, tap **Add BG** and using the onscreen keypad enter BG value. Tap **DONE**.



5. Tap **NEXT** to confirm the units of insulin to be delivered.

NOTE

You can tap View Calculation to display the Delivery Calculation screen.



6. Confirm Request.

Tap **YES** if entered data is correct.

Tap **NO** to go back to make changes or view calculations.

Confirm Request?

Carbs	118 g
BG	180 mg/dL
Units To Deliver	12 u

NO YES

7. Tap **EXTENDED** to turn on the extended feature, then tap **NEXT**.

NOTE

A correction bolus will always be given in the DELIVER NOW portion.

Deliver 12 u Bolus?

Correction	1.2 u
EXTENDED	OFF
Food	11.8 u

BACK DELIVER

8. Tap **50%** under DELIVER NOW to adjust the percentage of the food bolus that is to be delivered immediately.

BACK 12 units NEXT

DELIVER NOW	DELIVER LATER
50 %	50 %
DURATION	
2:00 hrs	View Units

9. Use the onscreen keypad to enter the percentage of the bolus to be delivered NOW and tap **DONE**.

NOTE

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.

BACK 50 % DONE

1	2	3
4	5	6
7	8	9
	0	DEL

10. Tap **2 hrs** under DURATION.

BACK 12 units NEXT

DELIVER NOW	DELIVER LATER
60 %	40 %
DURATION	
2:00 hrs	View Units

11. Use the onscreen keypad to adjust the length of time the bolus is to be delivered, then tap **DONE**.

12. Tap **NEXT**.

NOTE

Tap View Units to display the breakdown of units to be delivered NOW versus LATER.

13. Confirm Request.

Tap **YES** if entered data is correct.

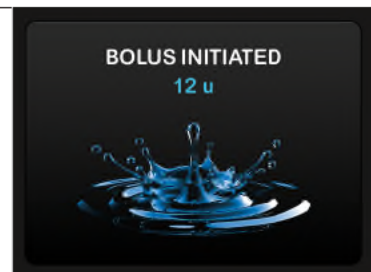
Tap **NO** to go back to make changes or view calculations.

14. Verify settings and tap **DELIVER**.

15. The bolus splash screen will be displayed to confirm delivery.

NOTE

To cancel all of the extended bolus (NOW and LATER), cancel the bolus and then cancel the extended bolus.



7.6 Insulin Duration and Insulin on Board (IOB)

Your t:slim Pump remembers how much insulin you have taken from previous boluses. It does this by relying on the Insulin Duration setting when calculating a correction bolus. The Insulin Duration reflects the amount of time that insulin is actively lowering your BG.

Insulin Duration in your t:slim Pump is set from the factory at 5 hours but can be changed from 2 to 8 hours. Please consult your healthcare provider to accurately set your Insulin Duration.

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 always considered in bolus delivery calculations when a BG is entered. When a BG is entered during bolus programming your t:slim Pump will consider any active IOB and calculate a decreased bolus dose as an option.

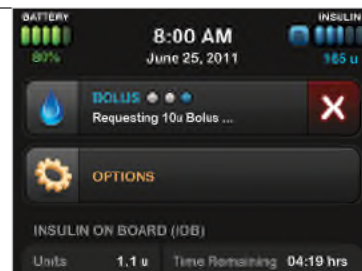
NOTE

If there is IOB, the amount will be subtracted from the correction portion of the bolus first. If the IOB is greater than the correction portion the remainder of the IOB amount will be subtracted from the food portion of the bolus.

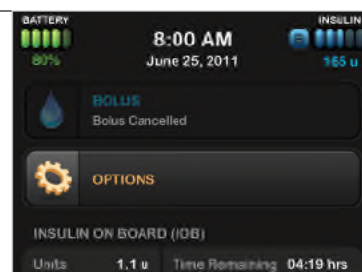
7.7 Canceling or Stopping a Bolus

If delivery has NOT started but has been initiated:

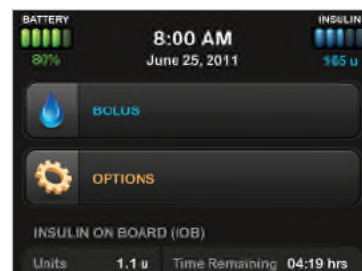
1. Tap red X to cancel the bolus.



The following screen will be displayed for three seconds indicating the bolus has been cancelled.

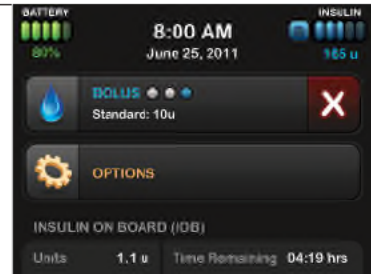


It will then return to the Home Screen.



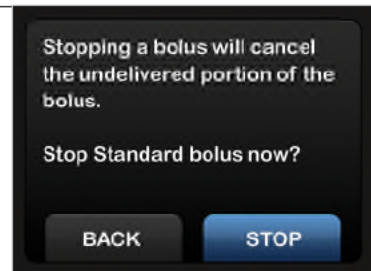
If delivery of the bolus HAS started:

1. Tap red **X** to stop delivery.

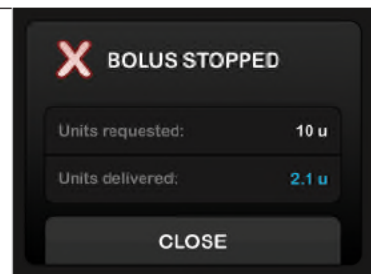


2. Tap **STOP**.

- ▷ The BOLUS STOPPED screen is momentarily displayed while the units delivered is calculated.



3. Units requested and delivered are shown. Tap **CLOSE**.



8

Stop/Resume Insulin

8.1	Stopping Insulin Delivery	75
8.2	Resuming Insulin Delivery	76

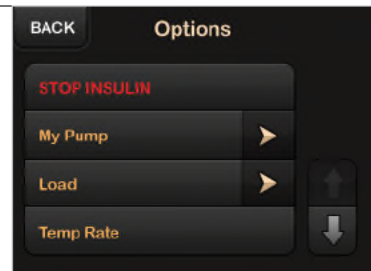
8.1 Stopping Insulin Delivery

At any time, even after delivery has started, you can stop all insulin deliveries at once, including basal and any active bolus or temp rate deliveries.

While the pump is in stop mode, the screen is blank until you press the Screen On/Quick Bolus Button, at which time you are prompted to resume insulin. You must resume operation of the pump in order to restart delivery of basal insulin.

1. From Home Screen tap **OPTIONS**.

2. Tap **STOP INSULIN**.

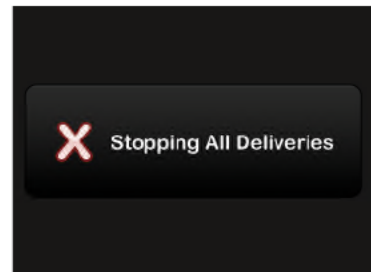


3. Tap **STOP**.

- ▷ The STOPPING ALL DELIVERIES screen appears for 3 seconds before returning to the Home Screen showing the status "ALL DELIVERIES STOPPED".

NOTE

- » When you tap **STOP** on the confirmation screen, any active bolus and any active temp rate are immediately suspended. If you tap **BACK** on the confirmation screen, bolus delivery continues.
- » No insulin delivery can take place while your pump is stopped.



8.2 Resuming Insulin Delivery

1. If pump is asleep, press **Screen On/Quick Bolus** Button once to turn on your t:slim Pump screen.

2. Tap **RESUME**.

By pressing RESUME the pump will resume your basal and the active personal profile.

Resume Insulin now?

BACK

RESUME

3. The **RESUMING INSULIN** splash screen will be displayed.

RESUMING INSULIN



– OR –

1. From Home Screen tap **OPTIONS**.

2. Tap **RESUME INSULIN**.

BACK

Options

RESUME INSULIN

My Pump



Load



Temp Rate



3. Tap **RESUME**.

By pressing RESUME the pump will resume your basal and the active personal profile.

Resume Insulin now?

BACK

RESUME

4. The **RESUMING INSULIN** splash screen will be displayed to confirm delivery.

RESUMING INSULIN



Additional Pump Operations

Section 3

9

Temporary Basal Rate

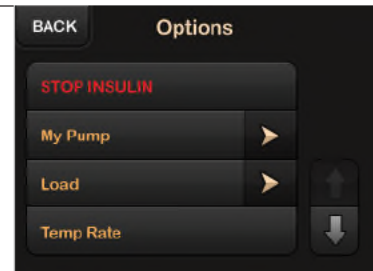
9.1	Setting a Temp Rate	79
9.2	Stopping a Temp Rate	80

9.1 Setting a Temp Rate

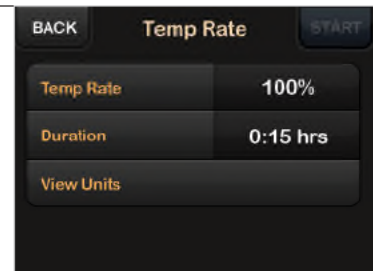
A Temp Rate sets either an increase or decrease (by percentage) to your basal rate for a pre-determined period of time. The Temp Rate feature is selectable from the Options menu. When you enter the Temp Rate screen, the default values are 100% (current basal rate) and a Duration of 0:15 hrs. The Temp 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.

1. From Home Screen tap **OPTIONS**.

2. Tap **Temp Rate**.



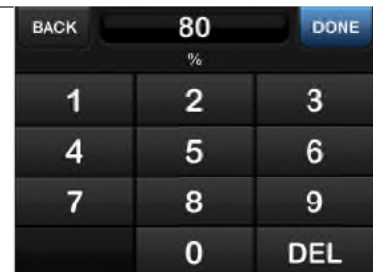
3. Tap **Temp Rate**.



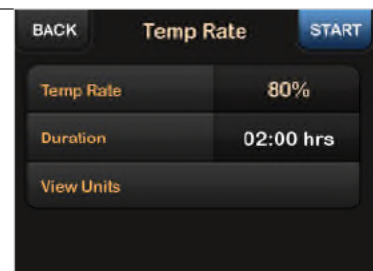
4. Using the onscreen keypad enter desired percentage. Tap **DONE**.

NOTE

Current rate is 100%. An increase is greater than 100% and decrease is less than 100%.



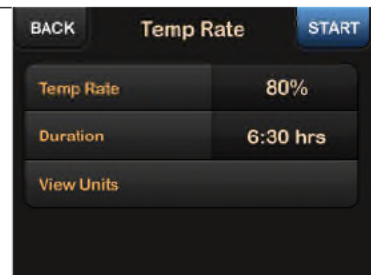
5. Tap **Duration**. Using the onscreen keypad enter desired length of time for temp rate. Tap **DONE**.



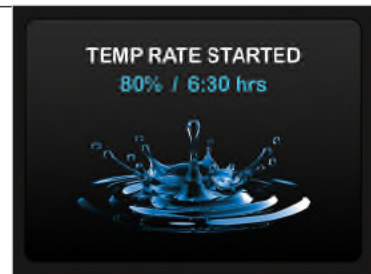
6. Verify settings and tap **START**.

NOTE

To see the actual units to be delivered tap View Units.



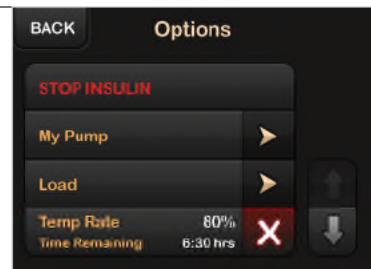
7. The TEMP RATE STARTED splash screen will be displayed to confirm delivery.



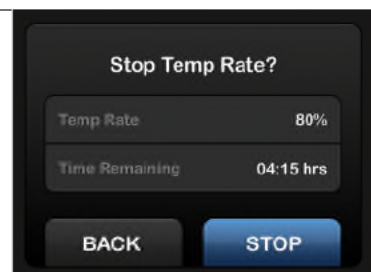
9.2 Stopping a Temp Rate

You can stop a temp rate that is currently being delivered.

1. On the Home Screen, tap **OPTIONS**.
2. On the Options screen, tap **X** (stop icon) on the right side of **Temp Rate**.



3. On the confirmation screen, tap **STOP**. The TEMP RATE STOPPED screen appears for 3 seconds before returning to the Options screen.



10

Quick Bolus

10.1	Setting Up Quick Bolus	82
10.2	Delivering Quick Bolus.....	84

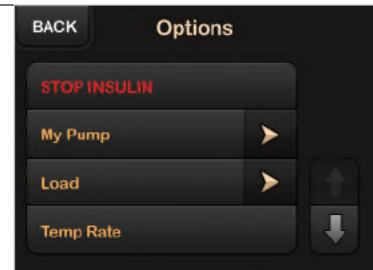
10.1 Setting Up Quick Bolus

Setting up the Quick Bolus function enables you to deliver a bolus by simply pressing a button.

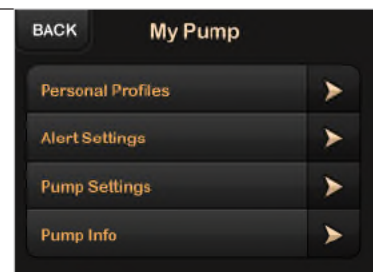
The default state of the Quick Bolus function is OFF. Quick Bolus can be set to either units of insulin or grams of carbohydrate. The increment options are 0.5, 1.0, 2.0, and 5.0 units; or 2, 5, 10 and 15 carbs.

1. From Home Screen, tap **OPTIONS**.

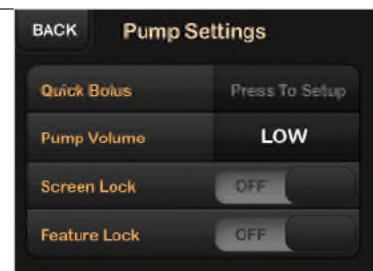
2. Tap **My Pump**.



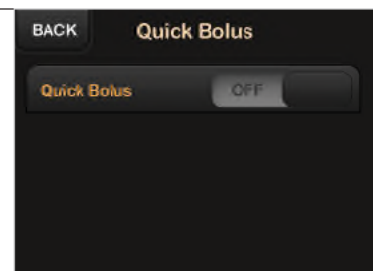
3. Tap **Pump Settings**.



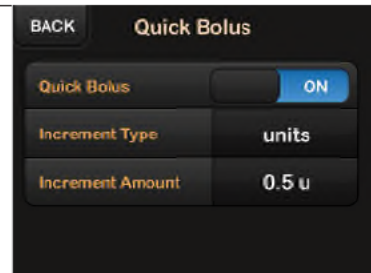
4. Tap **Quick Bolus**.



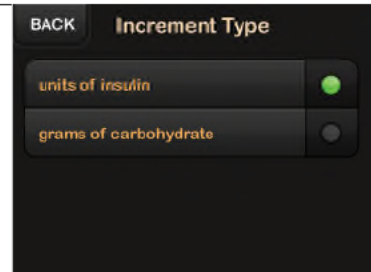
5. Tap **Quick Bolus**.



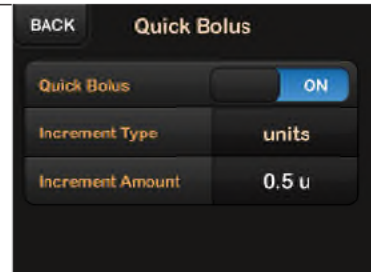
6. Tap **Increment Type** to set Units or Grams.



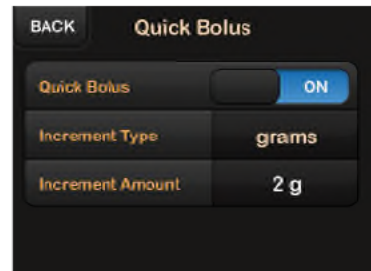
7. Tap **Units of Insulin** or **Grams of Carbohydrate**.



8. Tap **Increment Amount**.



Quick Bolus using units



Quick Bolus using grams

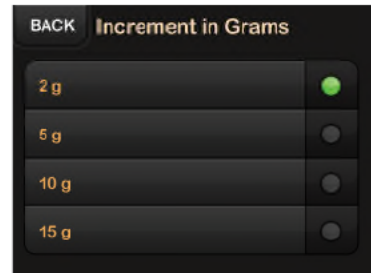
9. Select the preferred Increment amount.

NOTE

The increment amount is added with each press of the Quick Bolus Button when delivering a quick bolus.

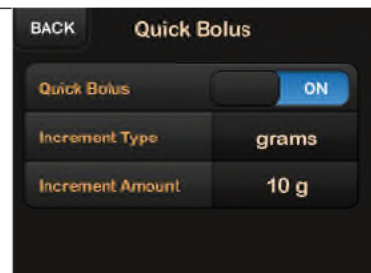


Quick Bolus using units



Quick Bolus using grams

10. Verify settings and tap **Tandem Logo** to return to Home Screen.



10.2 Delivering Quick Bolus

If the Quick Bolus function is turned On and set up, you can deliver a bolus without having to look at the t:slim Pump's screen (although the screen does display Quick Bolus status). Simply use the Quick Bolus Button to deliver your bolus. Quick boluses are delivered as standard boluses (there is no BG entry nor extended delivery capabilities).

NOTE

The Quick Bolus function is only available when the last screen accessed prior to the screen timing out was the Home Screen or the Screen Lock screen.

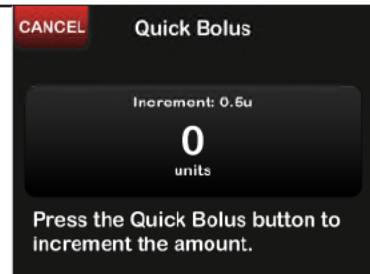
CAUTION

When you first use the Quick Bolus feature, you should always look at the screen to confirm correct programming until you are comfortable with this feature.

1. Press and hold **Quick Bolus** Button.



2. The Quick Bolus screen will appear. Listen for 2 beeps (if Pump Volume is set to beep) or feel for vibrations (if Pump Volume is set to vibrate).
3. Press **Quick Bolus** Button for each increment until desired amount is reached. The pump will beep/vibrate for each button press.



Quick Bolus using units



Quick Bolus using grams

4. Please wait a few seconds for the pump to beep/vibrate back for each increment pressed to confirm desired amount.
5. After the beeps/vibrate press and hold **Quick Bolus** Button to deliver a bolus.

NOTE

If you delay 10 or more seconds in pressing the button after the function is activated, the function is cancelled.

NOTE

- » If you delay 5 or more seconds in pressing the button after pump response, the bolus is cancelled.
- » If, at any time during this procedure, you want to cancel the bolus and return to the Home Screen, tap CANCEL on the QUICK BOLUS screen.
- » If the amount you indicated by your button presses exceeds the Max Bolus amount defined in your active personal profile, the Quick Bolus Button does not respond to any more button presses.

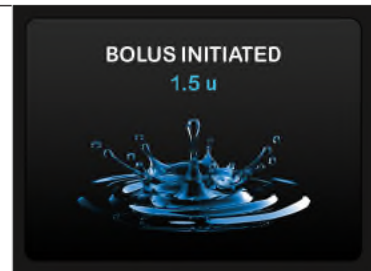


Quick Bolus using units



Quick Bolus using grams of carb

6. The bolus splash screen will be displayed to confirm delivery.



11

Pump Settings

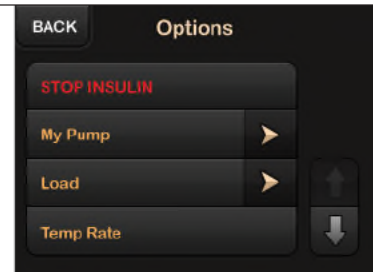
11.1	Pump Volume.....	88
11.2	Screen Lock.....	89
11.3	Feature Lock.....	89

11.1 Pump Volume

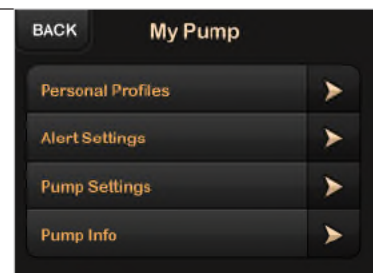
Your t:slim Pump is delivered from Tandem Diabetes Care, Inc. with the volume pre-set at High. A change to the Pump Volume can be made in Pump Settings.

1. From the Home Screen tap **OPTIONS**.

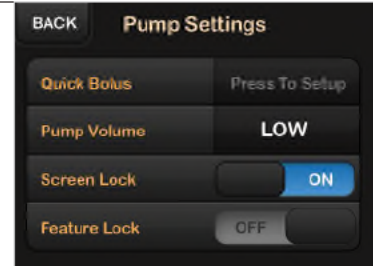
2. Tap **My Pump**.



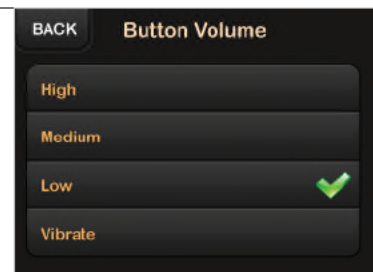
3. Tap **Pump Settings**.



4. Tap **Pump Volume**.



5. Select **High**, **Medium**, **Low** or **Vibrate** and tap **BACK** to return to the My Pump menu.



11.2 Screen Lock

Your t:slim Pump is delivered from Tandem Diabetes Care, Inc. with the Screen Lock activated. The Screen Lock can be turned off in Pump Settings. With the screen lock on, no screens can be accessed.

For detailed information on the screen lock feature, refer to sections 4.3 and 4.4.

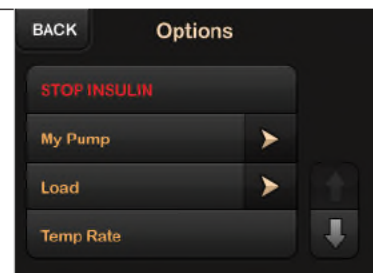
11.3 Feature Lock

Your t:slim Pump is delivered from Tandem Diabetes Care, Inc. with the Feature Lock turned off. The Feature Lock can be turned on in Pump Settings. With the Feature Lock turned on, you cannot deliver a bolus, change any pump settings or access any Personal Profiles.

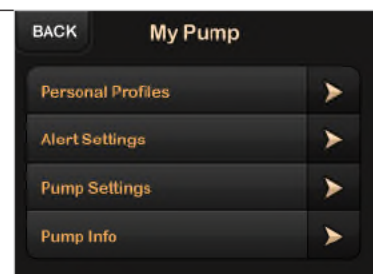
To Turn the Feature Lock On

1. From the Home Screen tap **OPTIONS**.

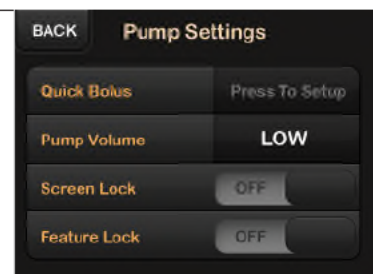
2. Tap **My Pump**.



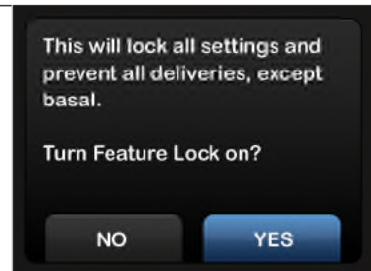
3. Tap **Pump Settings**.



4. Tap **Feature Lock**.



5. Tap **YES** and tap **BACK** after making your change to go back to the My Pump Menu.



To Turn the Feature Lock Off

1. From the Home Screen tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Pump Settings**.
4. Tap **Feature Lock**.
5. Tap **YES** and tap **BACK** after making your change to go back to the My Pump menu.

12

Pump Info and History

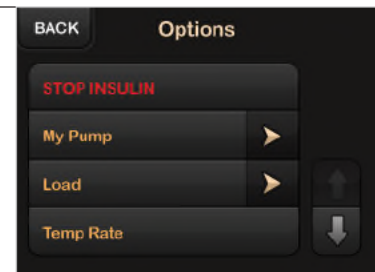
12.1	Pump Info	92
12.2	Pump History	92

12.1 Pump Info

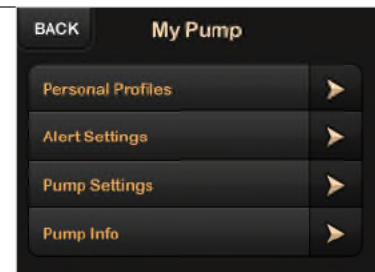
Your t:slim Pump allows access to information regarding your pump. In the Pump Info screen you have access to items such as the toll free Customer Support telephone number, your serial number and software/hardware versions.

1. From the Home Screen tap **OPTIONS**.

2. Tap **My Pump**.

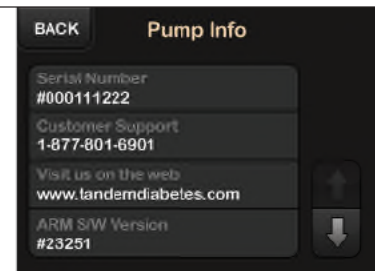


3. Tap **Pump Info**.



4. Scroll through the Pump Info using the **Up/Down** arrows.

Tap **BACK** after reviewing the information to go to the My Pump menu, or tap **Tandem Logo** to return to Home Screen.

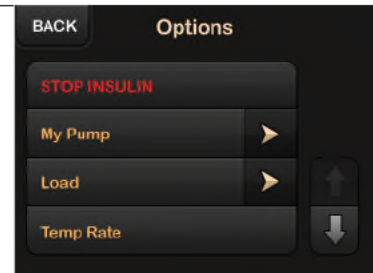


12.2 Pump History

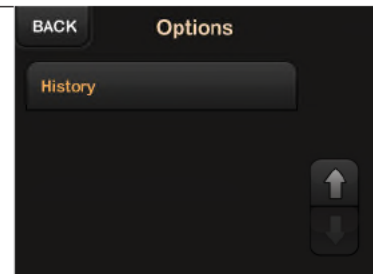
Your t:slim Pump allows access to its complete history of events.

1. From the Home Screen tap **OPTIONS**.

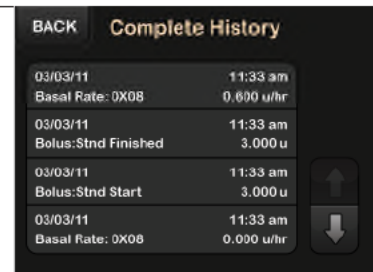
2. Tap the **Down Arrow**.



3. Tap **History**.



4. Scroll through the Complete History using the **Up/Down** arrows.
5. Tap **BACK** to go back to the Options screen, or tap **Tandem Logo** to return to Home Screen.



13

Reminders

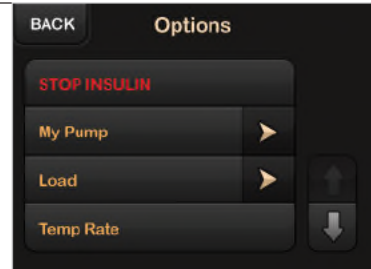
13.1	Low BG Reminder.....	95
13.2	High BG Reminder	96
13.3	After Bolus BG Reminder.....	97
13.4	Missed Meal Bolus Reminder	100
13.5	Site Reminder	101

13.1 Low BG Reminder

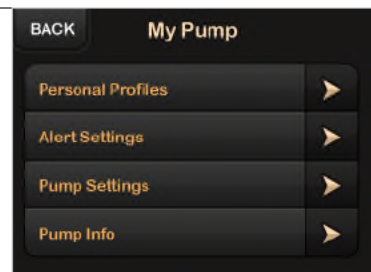
When turned on and set up in the My Pump settings, the Low BG Reminder prompts you to re-test your BG after a low BG value is entered. When turning this reminder setting on, you need to specify a low BG value that triggers the reminder, as well as how much time should pass before the reminder occurs. The default values are pre-set to Off, or if On; Remind me Below 70 mg/dL, and Remind me After 15 min, but you can set these values from 60-120 mg/dL and 10-20 min.

1. From the Home Screen tap **OPTIONS**.

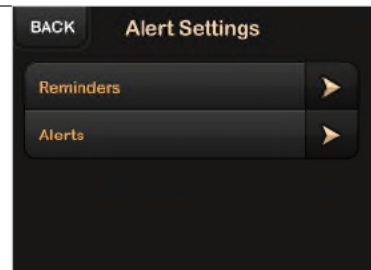
2. Tap **My Pump**.



3. Tap **Alert Settings**.



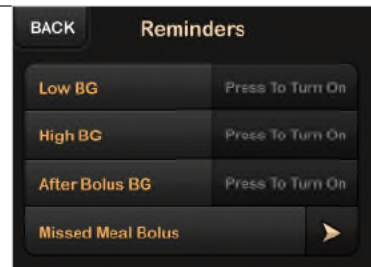
4. Tap **Reminders**.



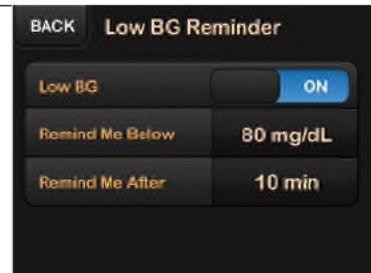
5. Tap **Low BG**.

NOTE

If not first-time setup, previous values appear instead of "Press to Turn On."



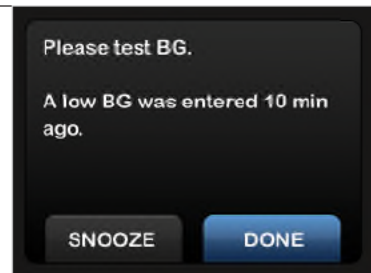
6. On the Low BG Reminder screen, do the following:
 - a) Tap **Low BG** to set the reminder **ON**.
 - b) Tap **Remind Me Below** and, using the onscreen keypad, enter a Low BG value (from 60-120 mg/dL) that you want to trigger the reminder, then tap **SAVE**.
 - c) Tap **Remind Me After** and, in the onscreen keypad, enter the time duration (from 10-20 min) after your pump detects a Low BG level that you want to trigger the reminder, then tap **SAVE**.
7. Tap **BACK** on the Low BG Reminder screen to check your Low BG Reminder setting.



To Respond to the Low BG Reminder

Do one of the following:

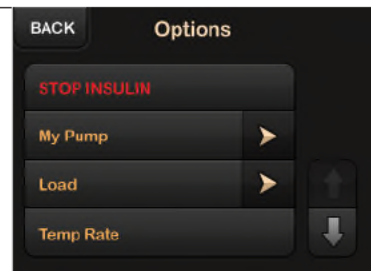
1. To temporarily clear the reminder (recurs in 10 minutes), tap **SNOOZE**. You can continue tapping **SNOOZE** every 10 minutes, indefinitely.
2. To return to normal operation (whatever activity was in progress when the reminder occurred), tap **DONE**.



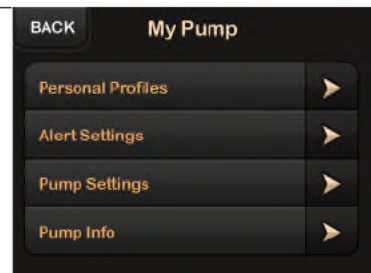
13.2 High BG Reminder

When turned on and set up in the My Pump settings, the High BG Reminder prompts you to re-test your BG after a high BG value is entered. When you turn this reminder setting on, you need to specify a high BG value that triggers the reminder, as well as how much time should pass before the reminder occurs. The default values are pre-set to Off, Remind me Above 200 mg/dL, and Remind me After 120 min, but you can set these values from 150-300 mg/dL and 60-180 min.

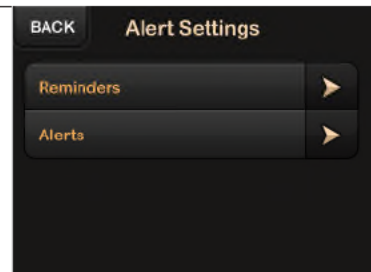
1. From the Home Screen tap **OPTIONS**.
2. Tap **My Pump**.



3. Tap **Alert Settings**.



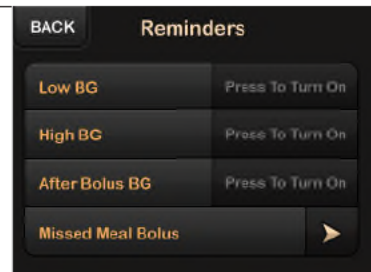
4. Tap **Reminders**.



5. On the Reminders screen, tap **High BG**.

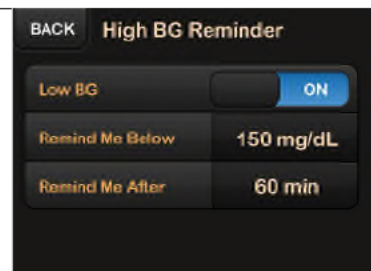
NOTE

If not first-time setup, previous values appear instead of "Press to Turn On".



6. On the High BG Reminder screen, do the following:

- Tap **High BG** to set the reminder **ON**.
- Tap **Remind Me Above** and, using the onscreen keypad, enter a High BG value (from 150-300 mg/dL) that you want to trigger the reminder, then tap **SAVE**.
- Tap **Remind Me After** and, using the onscreen keypad, enter the time duration (from 60-180 min) after your pump detects a High BG level that triggers the reminder, then tap **SAVE**.

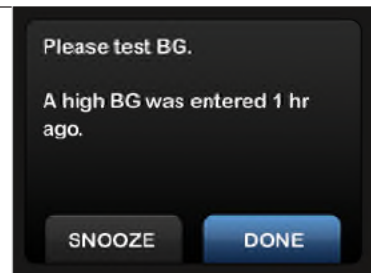


7. Tap **BACK** on the High BG Reminder screen to check your High BG Reminder setting.

To Respond to the High BG Reminder

Do one of the following:

1. To temporarily clear the reminder (recurs in 10 minutes), tap **SNOOZE**. You can continue tapping **SNOOZE** every 10 minutes, indefinitely.
2. To return to normal operation (whatever activity was in progress when the reminder occurred), tap **DONE**.

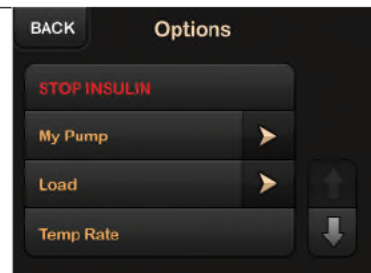


13.3 After Bolus BG Reminder

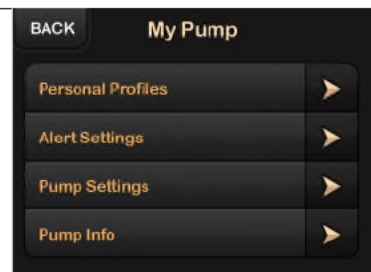
When turned on and set up in the My Pump Alert Settings, the After Bolus BG Reminder prompts you to test your BG a selected time period after a bolus has been delivered. When turning this reminder on you need to select the time from the options in the Remind Me In menu. These options include: 1 hour, 1:30 hrs, 2 hrs and 3 hrs.

1. From the Home Screen tap **OPTIONS**.

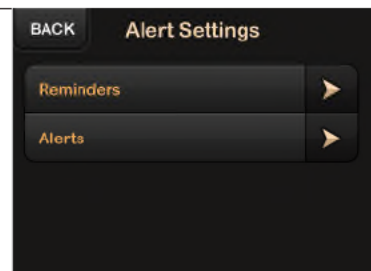
2. Tap **My Pump**.



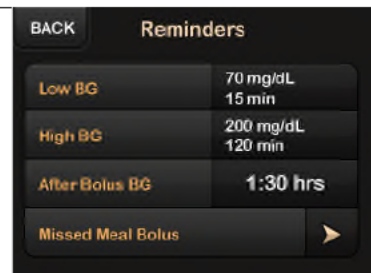
3. Tap **Alert Settings**.



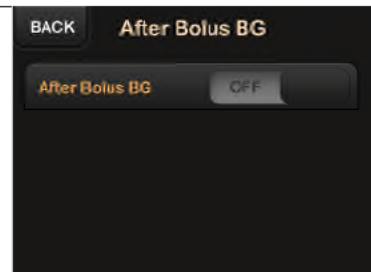
4. Tap **Reminders**.



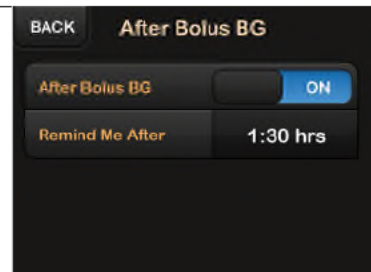
5. Tap **After Bolus BG**.



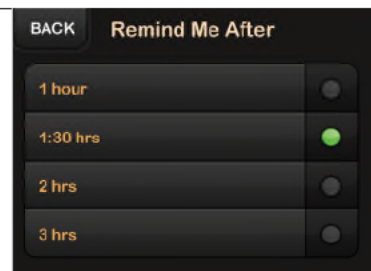
6. Tap **After Bolus BG** to set the reminder **ON**.



7. Tap **Remind Me After**.



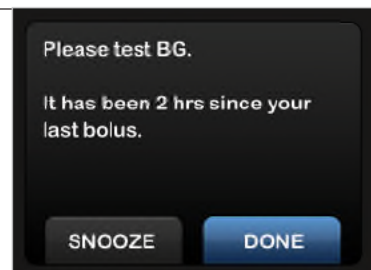
8. Tap the duration of time, then tap **BACK** to return to the Reminders menu.



To Respond to the After Bolus BG Reminder

Do one of the following:

1. To temporarily clear the reminder (recurs in 10 minutes), tap **SNOOZE**. You can continue tapping **SNOOZE** every 10 minutes, indefinitely.
2. To return to normal operation (whatever activity was in progress when the reminder occurred), tap **DONE**.

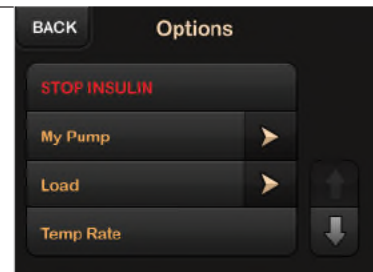


13.4 Missed Meal Bolus Reminder

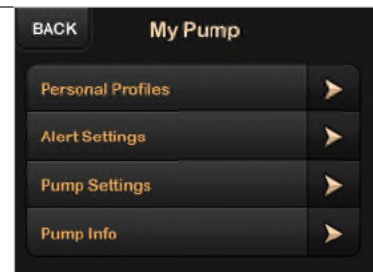
When turned on and set up in the My Pump Alert Settings, the Missed Meal Bolus Reminder is prompted based on the time period selected. Four separate reminders are available. When turning this reminder on you need to select the Days, the Start Time, and End Time for the given reminder.

1. From the Home Screen tap **OPTIONS**.

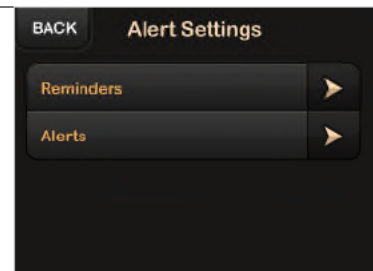
2. Tap **My Pump**.



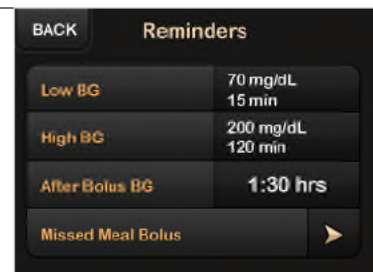
3. Tap **Alert Settings**.



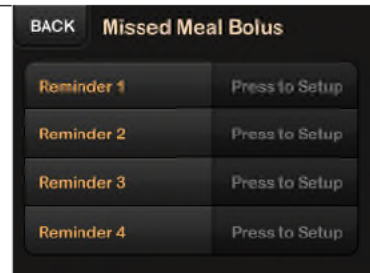
4. Tap **Reminders**.



5. Tap **Missed Meal Bolus**.



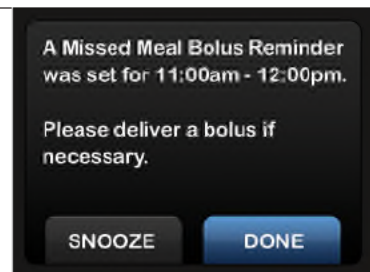
6. On the Missed Meal Bolus screen, tap which reminder you want to set (Reminder 1-4) and do the following:
 - a) Tap **Reminder 1** (or 2, 3, 4) to set the reminder **ON**.
 - b) Tap **Selected Days** and tap the desired days you want the reminder to be on, tap **BACK**.
 - c) Tap **Start Time**, tap **Time** to select the start time, tap **DONE**.
 - d) Tap **Time of Day** to **select AM** or **PM**, tap **SAVE**.
 - e) Tap **End Time**, tap **Time** to select the end time, tap **DONE**.
 - f) Tap **Time of Day** to **select AM** or **PM**, tap **SAVE**.
 - g) Tap **BACK** to return to the Missed Meal Bolus menu to review.
 - h) Tap **Tandem Logo** to return to the Home Screen.



To Respond to the Missed Meal Bolus Reminder

Do one of the following:

1. To temporarily clear the reminder (recurs in 10 minutes), tap **SNOOZE**. You can continue tapping **SNOOZE** every 10 minutes, indefinitely.
2. To return to normal operation (whatever activity was in progress when the reminder occurred), tap **DONE**.



13.5 Site Reminder

You can program your t:slim Pump to remind you to change your infusion set. If enabled (default is off), it will prompt you to change your infusion set. The reminder can be set for 1-3 days at a time selected by you.

For detailed information on the Site Reminder feature, refer to section 5.6.

14

User Settable Alerts and Alarms

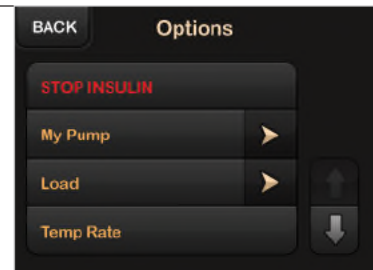
14.1	Low Insulin Alert.....	103
14.2	Auto-Off Alarm	104

14.1 Low Insulin Alert

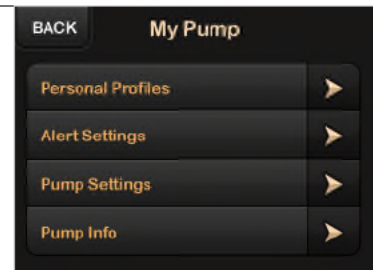
Your t:slim Pump continually tracks how much insulin is remaining in the cartridge and alerts you when it is low. You can adjust the Low Insulin Alert setting (the default value is pre-set to 20 u, but it can be set anywhere from 5 u to 50 u). When the insulin amount reaches the set value, the Low Insulin Alert beeps and appears on the screen.

1. From the Home Screen tap **OPTIONS**.

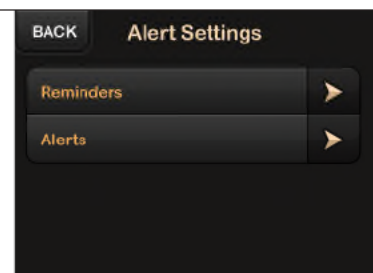
2. Tap **My Pump**.



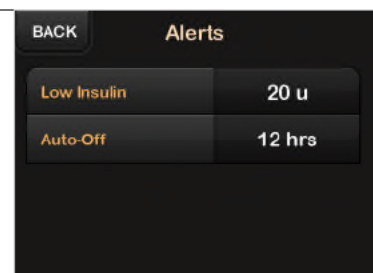
3. Tap **Alert Settings**.



4. Tap **Alerts**.



5. Tap **Low Insulin**.



6. Using the onscreen keypad, enter the number of units (from 5-50 u) that you want the Low Insulin alert triggered at, and tap **SAVE**.

To Respond to the Low Insulin Alert

1. Tap **CLOSE**.

The alert clears and your pump returns to normal operation (whatever activity was in progress when the alert occurred).

NOTE

Once the LOW INSULIN ALERT occurs, the low insulin indicator (a single red bar on the insulin indicator) appears in the upper-right corner of the Home Screen.

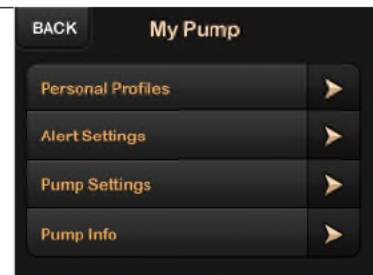
14.2 Auto-Off Alarm

Your t:slim Pump can stop insulin delivery and alert you (or whoever is with you) if you have not responded to the pump within a specified period of time. You can adjust the Auto-Off alarm limit setting (the default value is pre-set to 12 hrs, but you can set it anywhere from 5 hrs to 24 hrs, or Off).

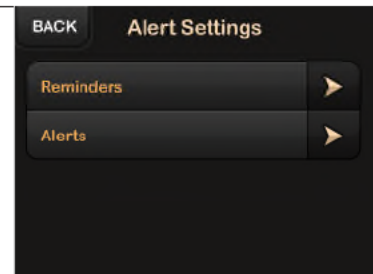
When the number of hours since you have tapped on the screen or pressed the Screen On/Quick Bolus Button passes a set value, the Auto-Off alarm beeps and appears on the screen, and insulin delivery stops.

1. From the Home Screen tap **OPTIONS**.
2. Tap **My Pump**.

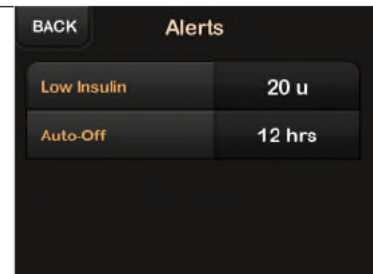
3. Tap **Alert Settings**.



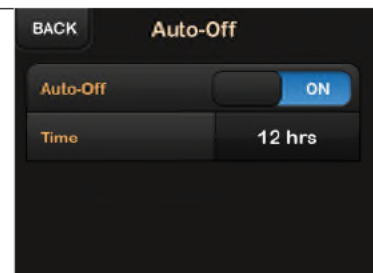
4. Tap **Alerts**.



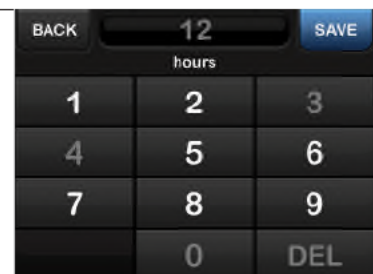
5. Tap **Auto-Off**.



6. Make sure **Auto-Off** is set to **ON**, then tap **Time**.



7. Using the onscreen keypad, enter the number of hours (from 5-24 hrs) that you want the Auto-Off alarm triggered at, and tap **SAVE**.



To Respond to Auto-Off

Auto-Off Warning

If the Auto-Off alarm is set to ON in the My Pump settings, and the number of hours since you tapped on the screen or pressed the Screen On/Quick Bolus Button passes the set value, insulin delivery stops and the Auto-Off (WARNING!) alarm occurs.

This alarm notifies you that there has been no interaction with the pump in the set number of hours and that the pump will shut down after 30 seconds.

1. Tap **DO NOT SHUT DOWN**.

The alarm clears and the pump returns to normal operation (whatever activity was in progress when the alert occurred). If you do not clear the alarm within the 30-second countdown period, the EMERGENCY! screen appears, accompanied by an audible alarm. This alarm notifies you that your pump has stopped delivering insulin.

In case of an emergency situation, information is provided on this screen so that someone can help you by calling 911.

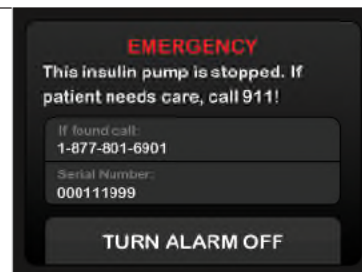


Auto-Off Emergency Screen

1. Tap **TURN ALARM OFF**.

The Emergency condition clears and the alarm is turned off.

The Home Screen then appears, indicating a status of "All Deliveries Stopped." Resuming insulin delivery must be performed manually (refer to section 8.2).



Safety Alerts and Alarms

Section 4

15

Alerts

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15.1 Low Power Alert

If the t:slim Pump detects a power level of 20% or less remaining, the LOW POWER ALERT occurs. This alert screen displays the level of remaining power.

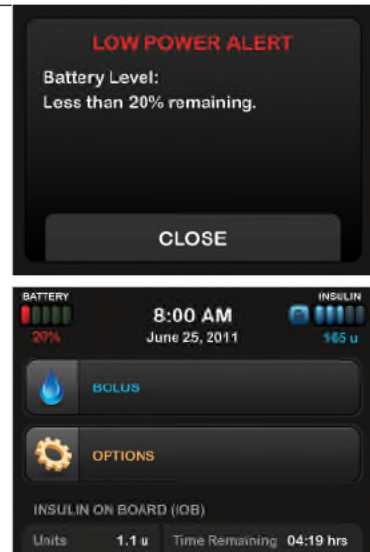
To Respond to the Low Power Alert

1. Tap **CLOSE**.

The alert clears and your pump returns to normal operation (whatever activity was in progress when the alert occurred).

NOTE

- » Once the LOW POWER ALERT occurs, the low-power indicator (a single red bar on the power indicator) appears on the Home Screen.
- » Thereafter, the same alert recurs after every 5% drop in power level until the LOW POWER ALARM occurs (at 5% remaining).



15.2 Incomplete Bolus Alert

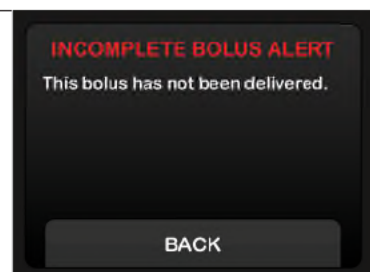
If you start to program a bolus but do not complete the setup within 1 minute, the INCOMPLETE BOLUS ALERT occurs. You are prompted to return to the Bolus screen to complete the setup.

NOTE

This alert does not appear if you tap BACK instead of DELIVER on the Bolus set up screen.

To Respond to the Incomplete Bolus Alert

1. Tap **BACK** to return to the Bolus screen so that you can complete the bolus setup.



15.3 Incomplete Temp Rate Alert

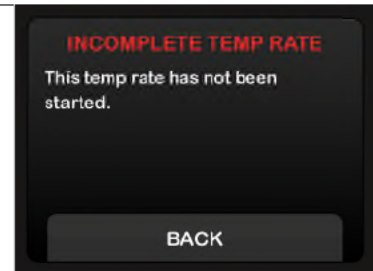
If you start to set up a temp rate but do not complete the setup within 1 minute, the INCOMPLETE TEMP RATE ALERT occurs. You are prompted to return to the Temp Rate screen to complete the setup.

NOTE

This alert does not appear if you tap BACK instead of DELIVER on the Temp Rate set up screen.

To Respond to the Incomplete Temp Rate Alert

1. Tap **BACK** to return to the Temp Rate screen so that you can complete the temp rate setup.



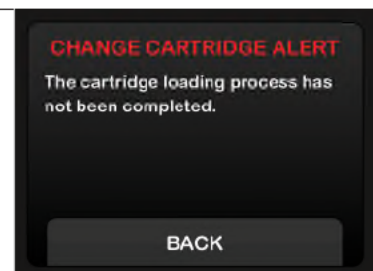
15.4 Incomplete Load Sequence Alerts

Incomplete Cartridge Change Alert

If you begin to change a cartridge but do not complete the process (and 2 or more minutes have passed since your last pump interaction) the CHANGE CARTRIDGE ALERT occurs.

To Respond to the Incomplete Cartridge Change Alert

1. Tap **BACK** to return to the screen you were on prior to the alert, and complete the cartridge changing process.

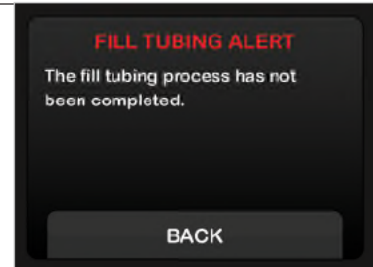


Incomplete Tubing Fill Alert

If you select **Fill Tubing** from the Load menu but do not complete the process (and 2 or more minutes have passed since your last pump interaction) the **FILL TUBING ALERT** occurs.

To Respond to the Incomplete Fill Tubing Alert

1. Tap **BACK** to return to the screen you were on prior to the alert, and complete the tube filling process.

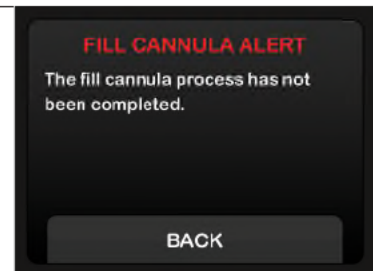


Incomplete Cannula Fill Alert

If you select **Fill Cannula** from the Load menu but do not complete the process (and 2 or more minutes have passed since your last pump interaction) the **FILL CANNULA ALERT** occurs.

To Respond to the Incomplete Cannula Fill Alert

1. Tap **BACK** to return to the screen you were on prior to the alert, and complete the cannula filling process.

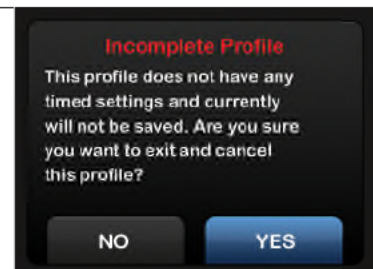


15.5 Incomplete Personal Profile Setting Alert

During the setup of a new **Personal Profile**, if you enter a number key pad screen to change a **value** but do not tap **Save** (and 5 or more minutes have passed since your last pump interaction) you will be prompted with an **INCOMPLETE PERSONAL PROFILE SETTING ALERT**.

Do one of the following:

1. Tap **NO** and you will be able to set up the Timed Settings fields.
2. Tap **YES** and you will exit the Timed Setting screen and cancel the set up of this new profile.

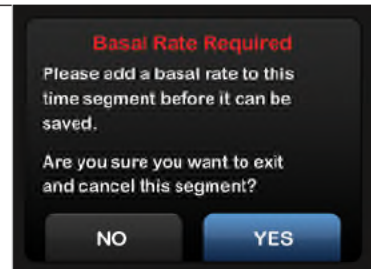


15.6 Basal Rate Required Alert

During the setup of a new Personal Profile you must enter a Basal Rate to have an active profile. If you do not enter a Basal Rate you will be prompted with a BASAL RATE REQUIRED ALERT.

Do one of the following:

1. Tap **NO** and you will return to the previous screen where you can enter a Basal Rate.
2. Tap **YES** and you will exit to the Timed/Bolus Settings screen.

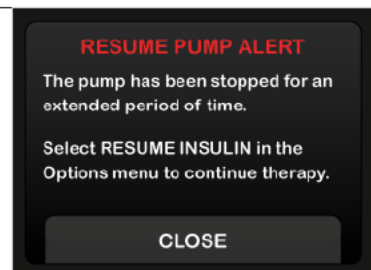


15.7 Resume Pump Alert

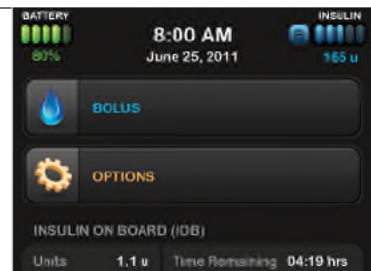
If insulin delivery has stopped for more than 15 minutes, the RESUME PUMP ALERT occurs. You are prompted to go to the Options menu to resume insulin delivery.

To Respond to the Resume Pump Alert

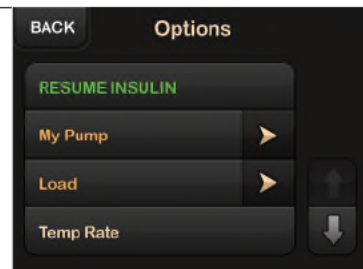
1. Tap **CLOSE** to clear the alert and return to the screen you were on prior to the alert.
2. Tap **Home** to go to the Home Screen.



3. Tap **OPTIONS** to go to the Options screen.



4. Tap **RESUME INSULIN** on the Options screen.



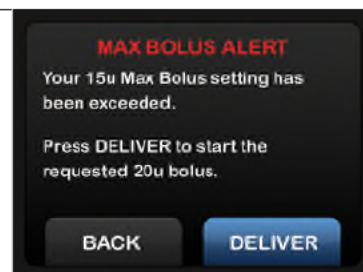
15.8 Max Bolus Alert

If you request a bolus amount that exceeds the Max Bolus setting in the currently active personal profile, but the amount does not exceed the pump's system-defined Max Bolus, a MAX BOLUS ALERT occurs. You are prompted to confirm whether you want to deliver this bolus amount.

To Respond to the Max Bolus Alert When Your Profile's Max Bolus Setting is Exceeded

Do one of the following:

1. To return to the Bolus screen and adjust the bolus delivery amount, tap **BACK**.
2. To deliver the requested bolus regardless of the excess amount, tap **DELIVER**.

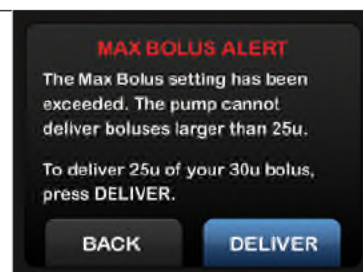


If you request a bolus amount that exceeds the pump's system-defined Max Bolus amount of 25 units, a MAX BOLUS ALERT occurs. You are prompted to confirm whether you want to instead deliver the pump's max-allowed bolus amount (25 units).

To Respond to the Max Bolus Alert When the Pump's Max Bolus Amount is Exceeded

Do one of the following:

1. To return to the Bolus screen and adjust the bolus delivery amount, tap **BACK**.
2. To deliver the system's max-allowed bolus amount (25 units), tap **DELIVER**.



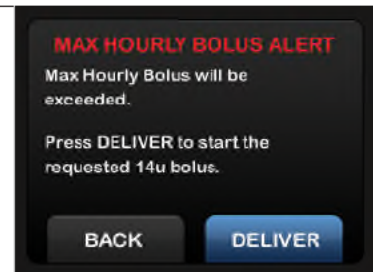
15.9 Max Hourly Bolus Alert

If, within a 60-minute period of time, you request a bolus delivery that is more than 1.5 times your Max Bolus setting, the MAX HOURLY BOLUS ALERT occurs, and you are prompted to confirm whether you really want to deliver this bolus amount.

To Respond to the Max Hourly Bolus Alert

Do one of the following:

1. To return to the Confirm Bolus screen and adjust your insulin delivery amount, tap **BACK**.
2. To deliver the bolus regardless of the excess amount, tap **DELIVER**.



15.10 Max Basal Alert

In either of the following scenarios, if you exceed 2 times the highest basal rate defined in your personal profile, the MAX BASAL ALERT occurs:

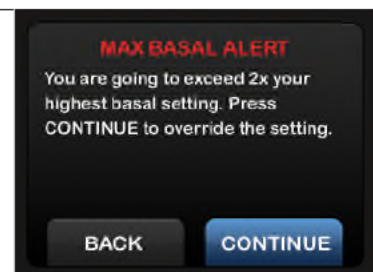
- When defining a basal rate and tapping **SAVE** on the basal rate keypad screen
- When requesting a temp rate and tapping **START** at the Temp Rate screen

You are cautioned that you will exceed 2 times your highest basal setting and prompted to confirm whether you want to continue with this basal amount.

To Respond to the Max Basal Alert Before Starting a Temp Rate or Saving a Basal Rate

Do one of the following:

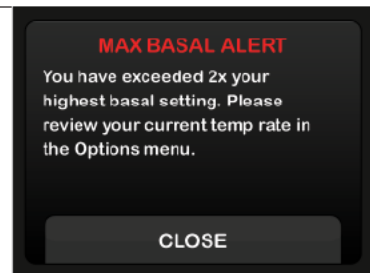
1. To return to the previous screen and adjust the basal amount, tap **BACK**.
2. To dismiss the alert and continue regardless of the excess amount, tap **CONTINUE**.



If you have already started a temp rate and, while the temp rate is running, you activate a new profile that exceeds 2 times your highest basal setting, the MAX BASAL ALERT occurs. You are prompted to review your current temp rate.

To Respond to the Max Basal Alert After the Temp Rate Has Started**1. Tap CLOSE.**

- ▷ The Options screen appears, showing the current Temp Rate value.

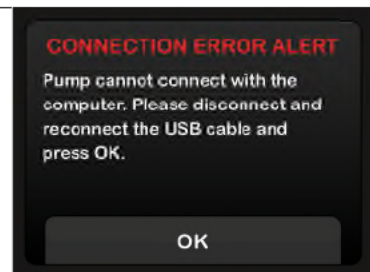


15.11 Connection Error Alert

If you connect the pump to a computer via a USB cable in order to sync data, and for some reason a connection cannot be made, the CONNECTION ERROR ALERT occurs. You are prompted to disconnect and reconnect the USB cable.

To Respond to the Connection Error Alert

1. Tap **OK** to clear the alert and return to the screen you were on prior to the alert.
2. Try disconnecting and reconnecting the USB cable.

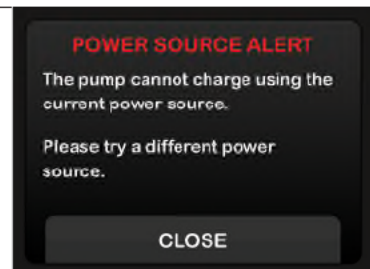


15.12 Power Source Alert

If you try to charge the pump by connecting it to a power source, and this source does not have enough power to sufficiently charge the pump, the POWER SOURCE ALERT occurs. You are prompted to try connecting to a different power source.

To Respond to the Power Source Alert

1. Tap **CLOSE** to clear the alert and return to the screen you were on prior to the alert.
2. Try connecting the pump to a different power source.

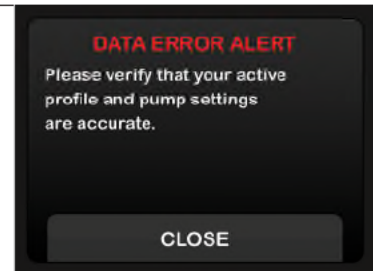


15.13 Data Error Alert

If your pump encounters a condition that causes a potential loss of data, the DATA ERROR ALERT occurs. You are prompted to verify that your active profile is accurate.

To Respond to the Data Error Alert

1. Tap **CLOSE** to clear the alert and return to the screen you were on prior to the alert.
2. Verify that the insulin delivery settings in your active personal profile are accurate (refer to section 6.4).



16

Alarms

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16.8	Screen On/Quick Bolus Button Alarm	123

16.1 Low Power Alarm

If your t:slim Pump detects a power level of 5% or less of power remaining, the LOW POWER ALARM occurs, requesting that you recharge your pump. The alarm and insulin delivery continue for 30 minutes until the SHUTDOWN ALARM triggers and insulin delivery stops.

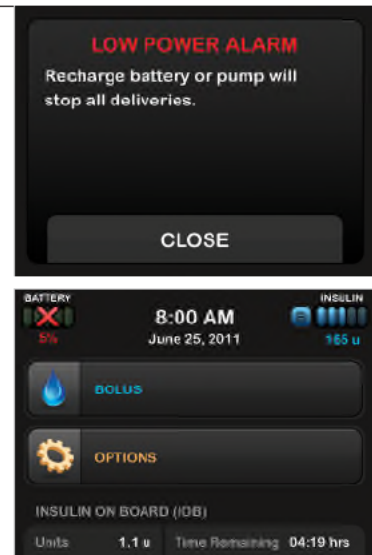
To Respond to the Low Power Alarm

1. Tap **CLOSE**. The alarm temporarily clears and your pump returns to normal operation (whatever activity was in progress when the alarm occurred).

The alarm then repeats at every 1% drop in remaining power level, until finally your pump shuts down due to depleted power and all insulin deliveries stop.

NOTE

Once the LOW POWER ALARM occurs, the near-empty power indicator (a red X on the power indicator) appears in the upper-left corner of the Home Screen.



16.2 Shutdown Alarm

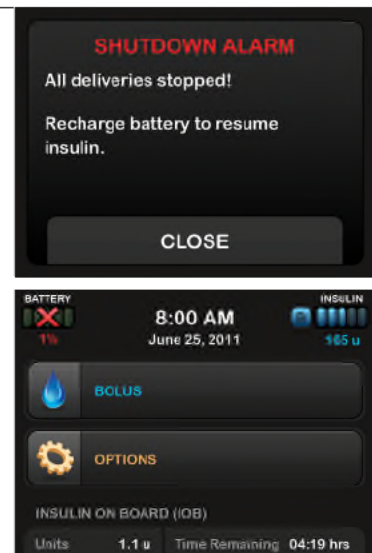
If your t:slim Pump detects a power level of 1% or less of power remaining, the SHUTDOWN ALARM occurs. This alarm indicates that all insulin deliveries have stopped and states that you must recharge your pump to resume insulin delivery. If you do not clear the alarm, it continues until you clear it or until 5 minutes have elapsed, in which case your pump shuts down.

To Respond to the Shutdown Alarm

1. Tap **CLOSE**. The alarm temporarily clears and your pump returns to normal operation (whatever activity was in progress when the alarm occurred).
2. Recharge your pump (refer to section 4.1).

NOTE

Once the SHUTDOWN ALARM occurs, the empty-power indicator (a red X and 1% on the power indicator) appears in the upper-left corner of the Home Screen.



16.3 Low Insulin Alarm

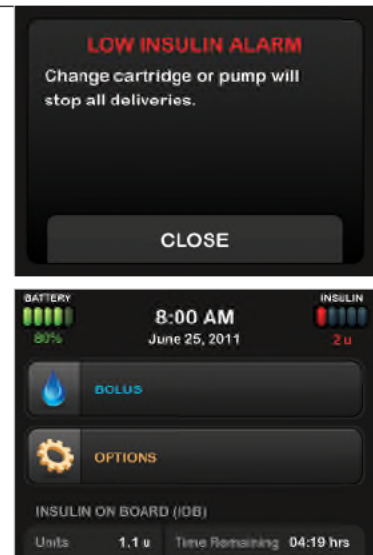
If your t:slim Pump detects an insulin level at or below 5 units, the LOW INSULIN ALARM occurs. You are prompted to change the cartridge; otherwise all insulin deliveries will stop. If you do not clear the alarm, it continues until you clear it or until the EMPTY CARTRIDGE ALARM occurs.

To Respond to the Low Insulin Alarm

1. Tap **CLOSE**. The alarm clears and your pump returns to normal operation (whatever activity was in progress when the alarm occurred).

NOTE

Once the LOW INSULIN ALARM occurs, the low insulin indicator (a single red bar on the insulin indicator) appears in the upper-right corner of the Home Screen.



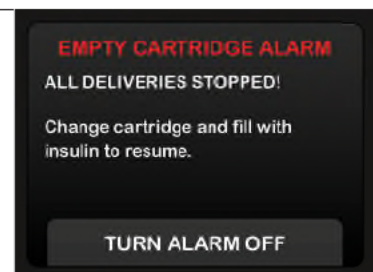
16.4 Empty Cartridge Alarm

If your t:slim Pump detects no cartridge or an insulin level at or below 1 unit, the EMPTY CARTRIDGE ALARM occurs, and all insulin delivery stops. This alarm requests that you change the cartridge and fill it with insulin before you can resume delivery.

If you do not clear the alarm, it continues until you clear it or basal delivery of insulin is depleted, or you change the cartridge. Once the alarm occurs, you cannot deliver a bolus.

To Respond to the Empty Cartridge Alarm

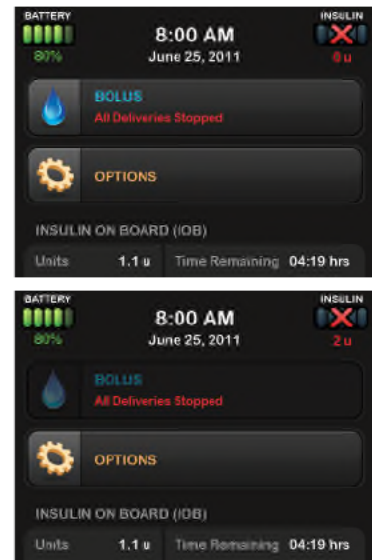
1. Remove the empty cartridge from the pump.
2. Tap **TURN ALARM OFF**.
 - ▷ The alarm clears and the Change Cartridge screen appears.



3. Change the cartridge (refer to section 5.3).

NOTE

Once the alarm occurs, the empty cartridge indicator (a red X and 0 u on the insulin indicator) appears in the upper-right corner of the Home Screen.



16.5 Cartridge Error Alarm

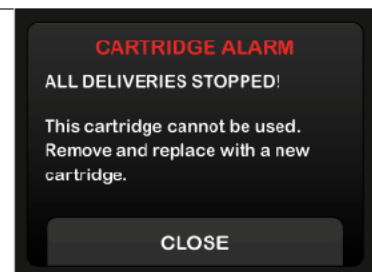
If any of the following cartridge error scenarios are detected, a CARTRIDGE ALARM occurs and insulin deliveries stop:

- The pump determines that the loaded cartridge cannot be used (eg, it is defective, etc).
- The pump detects that you tried to fill the cartridge with insulin without following the proper procedure using the Load menu.
- The pump detects that you have filled the cartridge with more than the recommended amount of insulin, and therefore the cartridge cannot be used.

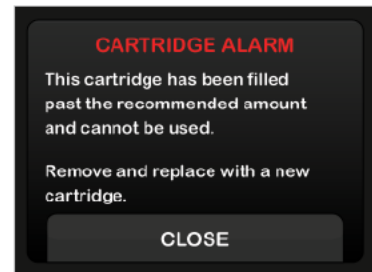
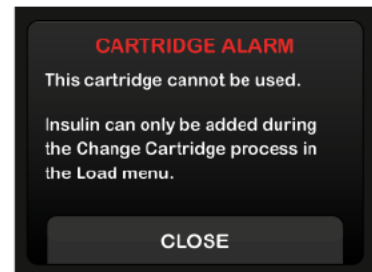
Depending on the scenario, you are prompted to replace the cartridge with a new one and/or use the Load menu to fill the cartridge.

To Respond to Cartridge Alarms

1. Tap **CLOSE** to clear the alert and return to the screen you were on prior to the alarm. The alarm continues every 5 minutes until you replace the cartridge.
2. Do one of the following:
 - a) Remove the cartridge from the pump and replace it with a new one.
 - b) Use the Load menu to fill the cartridge.



For detailed procedures on these tasks, refer to section 5.3.

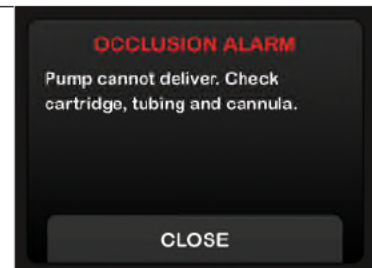


16.6 Occlusion Alarm

If your t:slim Pump detects an insulin occlusion, the OCCLUSION ALARM occurs, and all deliveries are stopped. You are asked to check the cartridge, tubing, and cannula.

To Respond to the Occlusion Alarm

1. Tap **CLOSE** to clear the alarm and return to the Home Screen.
2. Check the cartridge, tubing, and cannula to determine what might be causing the occlusion.
3. Resume insulin (refer to section 8.2).



CAUTION

If an occlusion occurs, there is a possibility of a delay in insulin delivery. Please check with your healthcare provider for recommendations on how to compensate for missed basal insulin delivery. If the occlusion is due to a kink in the infusion set tubing, when the kink is corrected and the occlusion is cleared it may result in a bolus of insulin. Appropriate blood glucose monitoring and/or adjustments in subsequent bolus delivery should be considered.

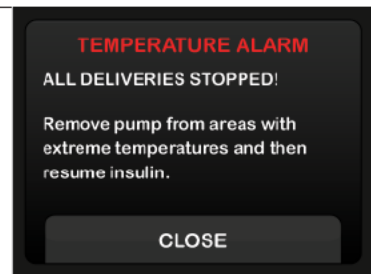
16.7 Temperature Alarm

If your t:slim Pump detects a temperature outside of the normal operating range, the TEMPERATURE ALARM occurs.

You are asked to remove the pump from the area of extreme temperature and then resume insulin delivery.

To Respond to the Temperature Alarm

1. Tap **CLOSE** to clear the alarm and return to the Home Screen.
2. Remove the pump from the area of extreme temperature and resume insulin delivery (refer to section 8.2).

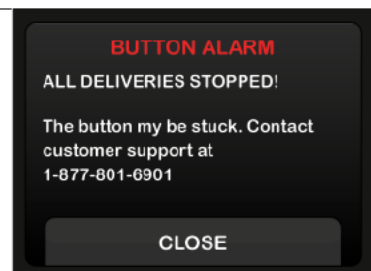


16.8 Screen On/Quick Bolus Button Alarm

If the Screen On/Quick Bolus Button (on the top of your pump) is stuck or not functioning properly, the BUTTON ALARM occurs. All insulin deliveries stop and you are asked to contact Tandem Diabetes Care Customer Support at 1-877-801-6901.

To Respond to the Button Alarm

1. Tap **CLOSE** to clear the alarm and return to the screen you were on prior to the alarm.
2. Contact Customer Support at 1-877-801-6901.



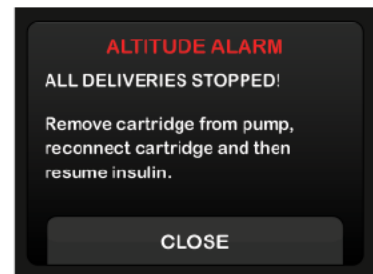
16.9 Altitude Alarm

If your t:slim Pump detects a pressure change outside of the operating range, the ALTITUDE ALARM occurs.

You are asked to remove and reconnect the cartridge and then resume insulin.

To Respond to the Altitude Alarm

1. Tap **CLOSE** to clear the alarm and return to the screen you were on prior to the alarm.
2. Remove and immediately reconnect the cartridge.
3. Resume insulin (refer to section 8.2).



17

Malfunction

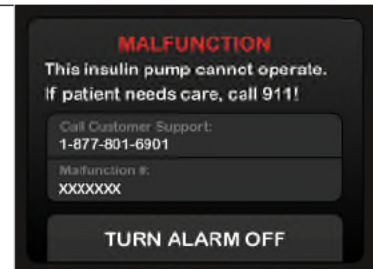
17.1	Malfunction	125
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17.1 Malfunction

If your t:slim Pump detects a system error, the MALFUNCTION alarm occurs.

To Respond to the Malfunction Alarm

1. Write down the code number that appears on the screen.
2. Tap **TURN ALARM OFF**. The alarm is silenced and the screen times out. You can press the Screen On/Quick Bolus Button to turn the screen back on (the MALFUNCTION screen reappears but there is no audible alarm).
3. Contact Tandem Diabetes Care Customer Support at 1-877-801-6901 and provide the code you wrote down.



Care and Maintenance

Section 5

18

Taking Care of your t:slim

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18.1 Overview

This section provides information on caring for and maintaining your t:slim Pump.

Cleaning Your t:slim 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.

Inspecting Your t:slim Pump for Damage

If you drop your t:slim Pump or it has been hit against something hard, ensure that it is still working properly. Check that the touch screen is working and clear, and that the cartridge and infusion set are properly in place. Check for leaks around the cartridge and at the luer connector to the infusion set. Immediately contact Tandem Diabetes Care Customer Support at 1-877-801-6901 if you notice any cracks, chips, or other damage.

Disposing of t:slim Pump Accessories

Regulations require controlled disposal of devices such as insulin infusion pumps, so ask your Tandem Diabetes Care, Inc. representative or healthcare provider about local regulations regarding disposal of cartridges, infusion sets, and other disposable accessories.

Technical Specifications

Section 6

19

Technical Specifications

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19.1 Overview

This appendix provides tables of technical specifications, options, settings, and electromagnetic compliance information for the t:slim Pump. The specifications in this appendix meet the international standards set forth in IEC 60601-1 and IEC 60601-2-24.

19.2 t:slim Pump Specifications

The following table lists the t:slim Pump specifications and their related details.

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 Pump in the presence of flammable anesthetics or explosive gases.
Size	L x W x H – 3.13 L x 2.0 W x .6 H (7.95 cm L x 5.08 cm W x 1.52 cm H)
Weight (with full disposable)	4.05 ounces (115 grams)
Operating Temperature Range	41°F and 98.6°F, 5°C and 37°C at maximum relative humidity of 90% non-condensing
Storage Temperature Range	-4°F and 140°F -20°C to 60°C at maximum relative humidity of 90% non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa (equivalent from sea level up to 10,000 ft.)
Reservoir Volume	3.0 mL or 300 units
Cannula Fill Amount	0.1 to 1.0 units of insulin
Insulin Concentration	U-100
Alarm Type	Audible and vibratory
Basal Delivery Accuracy at all Flow Rates (tested per IEC 60601-2-24)	±5% *
Bolus Delivery Accuracy at all Volumes (tested per IEC 60601-2-24)	±5% *

* In extreme pressure environments, delivery accuracy may vary up to ±15%. Extreme pressure environments include any rapid elevation change of 1,000 ft. or more. In these extreme pressure environments, the system can be manually vented by removing, then reconnecting the cartridge and resuming insulin.

Time to Occlusion Alarm

	Typical	Maximum
Bolus (3u or Greater)	21 Seconds	23 Seconds
Basal (2u/hr)	1 Hour 4 Minutes	1 Hour 10 Minutes
Basal (1u/hr)	1 Hour 57 Minutes	2 Hours 7 Minutes
Basal (0.1u/hr)	19 Hours 43 Minutes	25 Hours 30 Minutes

19.3 t:slim Pump Options and Settings

The following table lists the t:slim Pump options and settings and their related details.

Option/Setting Type	Option/Setting Details
Time	12-hour clock
Maximum Basal Rate	15 u/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 u/hr
Temp Basal Rate	15 minutes to 72 hours with 1 minute resolution Range: 0%-250%
Bolus Setup	Can deliver based on carb input (grams) or insulin input (units); Default is units. (The range for carbs is 1-999 grams; the range for insulin is 0.05-25 units)
Insulin-to-Carb (IC) Ratio	16 time segments per 24-hour period; Ratio: 1u of insulin per x grams of carbs; 1:1 to 1:300
BG Correction Target Value	16 time segments. 60 to 250 mg/dL in 1 mg/dL increments
Insulin Sensitivity Factor (ISF)	16 time segments; Ratio: 1u of insulin reduces glucose x mg/dL; 1:1 to 1:600 (1 mg/dL increments)
Duration of Insulin Action	1 time segment; 2-8 hours in 1-minute increments (default is 5 hrs)
Bolus Increment	0.05 units
Quick Bolus Increments	When set to units: 0.5, 1, 2, 5 units (default is 0.1 u); or When set to grams/carbs: 2, 5, 10, 15 grams (default is 1 g)
Maximum Extended Bolus Time	8 hours
Maximum Bolus Size	25 units
Low Reservoir Volume Indicator	Status indicator (always visible); Low Insulin Alert (user adjustable: 5-50 units)
Auto-Off Alert	On or Off (default is On); user-adjustable (5-24 hours; default is 12 hours, which you can change when option is set to On)
History Storage	Up to 90 days of data (11,000 events)
Language	English
Feature Lock	Blocks access to insulin delivery screens and pump setting screens (default is Off)
Screen Lock	Protects from unintentional taps (default is On)
Site Reminder	Prompts user to change infusion set. Can be set for 1-3 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.
After Bolus Reminder	Prompts user to test BG at a selected time period after a Bolus has been delivered. Increments options of 1 hr, 1:30 hrs, 2 hrs and 3 hrs.
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.
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.

19.4 Additional t:slim Pump Specifications

The following table lists additional the t:slim Pump specifications and their related details.

Specification Type	Specification Details
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
Rate of delivery during Bolus and Prime	Approximately 6.67 Units/min for Bolus, 8 Units/min for Prime
Bolus Duration	Approximately 9 seconds/unit
Frequency of Basal Delivery	5 minutes for all Basal Rates
Retention Time of Electronic Memory when Internal System Battery is Fully Discharged	Greater than 30 days
Infusion Set used for Testing	Unomedical Comfort Infusion Set
Statement of Meaning of the Claimed Ingress Protection (IP) Classification	IPX7: watertight to a depth of 3 feet for up to 30 minutes
Internal System Battery	Rechargeable Lithium Polymer
Internal System Battery Life	4 years minimum under normal use conditions
Typical Operating Time when System is Operating at Intermediate Rate	During normal use, the intermediate rate is 2 u/hr; battery charge can be reasonably expected to last up to 7 days (depending on the pump settings) from a fully charged state to a totally discharged state
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 continuous self-tests, 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 pre-defined period of time. Under-infusion is mitigated by occlusion detection and blood glucose monitoring as blood glucose entries are recorded. Users are prompted to treat high blood glucose conditions with a correction bolus.
Bolus Volume at Release of Occlusion	0.4-0.6 units at 2 units per hour with Unomedical Comfort (60cm) Infusion Set

19.5 Electromagnetic Compatibility

The information contained in this section is specific to the t:slim Pump. This information provides reasonable assurance of normal operation, but does not guarantee such under all conditions. If the t:slim Pump must be used in close proximity with other electrical equipment, the pump 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 shall be placed into service with adherence to the EMC information provided here. Using cables and accessories not specified in this User Guide may adversely impact safety, performance, and electromagnetic compatibility, including increased emissions and/or decreased immunity.

This section contains the following tables of information:

- Electromagnetic Emissions
- Electromagnetic Immunity
- Distances Between the pump and RF Equipment

19.6 Electromagnetic Emissions

The t:slim Pump is intended for use in the electromagnetic environment specified below. Always make sure that the pump 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 pump 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 pump 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	

19.7 Electromagnetic Immunity

The t:slim Pump is intended for use in the electromagnetic environment specified below. Always make sure that the pump is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	<5% Ur (>95% dip in Ur) for 0,5 cycle 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (30% dip in Ur) for 25 cycles <5% Ur (>95% dip in Ur) for 5 sec	<5% Ur (>95% dip in Ur) for 0,5 cycle 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (30% dip in Ur) for 25 cycles <5% Ur (>95% dip in Ur) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the pump requires continued operation during power mains interruptions, it is recommended that the pump be powered from an uninterruptible power supply or a battery. NOTE: Ur is the a.c. mains voltage prior to application of the test level.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	400 A/m (IEC 60601-2-24)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 V	Portable and mobile RF communications equipment should be used no closer to any part of the pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 0.35\sqrt{P}$ 80 MHz to 800 MHz, $d = 0.12\sqrt{P}$ 800 MHz to 2,5GHz, $d = 0.23\sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	30 V/m	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the pump is used exceeds the applicable RF compliance level above, the pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the pump.			
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.			

19.8 Distances Between the Pump and RF Equipment

The t:slim Pump is intended for use in an electromagnetic environment typically found in the home, at work, retail stores, and places of leisure, where daily activities occur. The chart below can be used as a guideline for determining the recommended minimum distance to maintain between a radio frequency (RF) transmitter and the t:slim Pump. For specific concerns about a particular RF transmitter interfering with your Pump's operation, please contact the transmitter manufacturer for its rated power and frequency.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the t:slim Pump			
The t:slim Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the t:slim Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pump as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter in Watts	Separation Distance According to Frequency of Transmitter <i>in or ft (m)</i>		
	150 kHz to 80 MHz (<i>d in meters = $0.35\sqrt{P}$</i>)	80 MHz to 800 MHz (<i>d in meters = $0.12\sqrt{P}$</i>)	800 MHz to 2.5 GHz (<i>d in meters = $0.23\sqrt{P}$</i>)
0.01	<u>1.6 in</u> (0.04)	<u>0.12 in</u> (0.012)	<u>0.9 in</u> (0.023)
0.1	<u>4.3 in</u> (0.11)	<u>1.5 in</u> (0.038)	<u>2.9 in</u> (0.073)
1	<u>1.1 ft</u> (0.35)	<u>4.7 in</u> (0.120)	<u>9.0 in</u> (0.23)
10	<u>3.6 ft</u> (1.11)	<u>14.9 in</u> (0.379)	<u>2.39 ft</u> (0.727)
100	<u>11.5 ft</u> (3.50)	<u>3.94 ft</u> (1.20)	<u>7.54 ft</u> (2.3)
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

The table below provides a list of typical devices for various levels of transmitter power and frequency, and the recommended separation distances from the transmitter and the pump.

Rated Maximum Output Power of Transmitter in Watts	Typical Devices	Recommended Separation Distance <i>Inch (Meters)</i>	
0.001W	Bluetooth Class 3 (standard 1 meter range) Commonly used as bluetooth headset	0.3 in (0.007 m)	
0.01W	Internet to music adaptor Commonly used for FM wireless music streaming	0.5 in (0.013 m)	
0.1W	Bluetooth Class 1 (100 meter range) Wireless router (WiFi)	2.9 in (0.073 m)	
0.5W	Typical cellular/smart phone *	6.4 in (0.163 m)	
1W	Typical microwave oven RF leakage	9 in (0.23 m)	

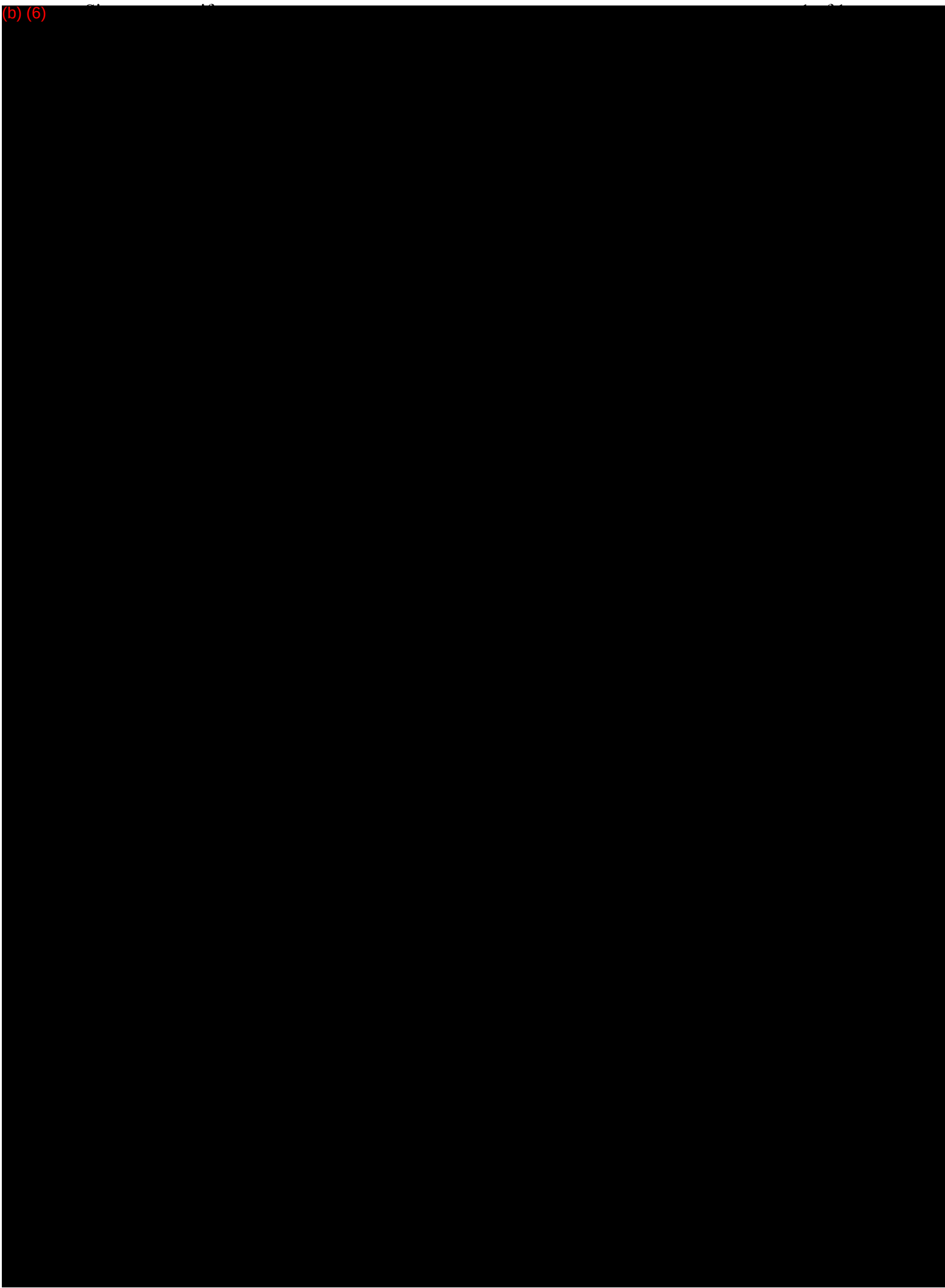
* Caution: Interference with pump electronics by cell phones can occur if worn in close proximity. It is recommended that your pump and cell phone be worn at least 6.4 inches apart.



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003732 Rev. E



K133 593/S002

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San Diego, California 92121
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February 27, 2013

By Messenger510(k) 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

FDA CDRH DMC

FEB 28 2014

Received

Attention: Alan Stevens, General Hospital Devices Branch (WO66-2561)

**Re: Response to FDA's January 22, 2014 K133593, Additional Information
(AI) Request for Tandem Diabetes Care™, Inc.'s t:slim™ Insulin
Delivery System (K133593)**

Dear Mr. Stevens:

Tandem Diabetes Care, Inc. ("Tandem" or the "Company"), is responding to the Food and Drug Administration's ("FDA" or the "Agency") Additional Information Request issued on January 22, 2014, regarding the company's t:slim™ Insulin Delivery System ("t:slim") Special 510(k) premarket notification (K133593). For FDA's convenience of review, each of the issues raised in the FDA's email correspondence is listed in the attachment, followed by the company's response.

Per FDA's request, two copies of the response are included herein, including 1 paper copy and 1 electronic copy ("eCopy"). According to the instructions on the FDA website, the eCopy provided with this submission is an exact duplicate of the paper copy.

Tandem believes that the information provided with this response adequately address each of FDA's January 22, 2014, requests for additional information concerning the t:slim Special 510(k). If you have any additional questions regarding the 510(k) notice, please contact me at the number below or Janice Hogan, Hogan Lovells US LLP, at (267) 675-4600. Upon clearance of the device, please fax the substantial equivalence letter to me at (858) 362-7070 or to Janice Hogan at (267) 675-4601.

Sincerely,

John Sheridan
EVP and Chief Operating OfficerJSheridan@tandemdiabetes.com
(858) 255-6345**Attachments**cc: Janice Hogan, Hogan Lovells US LLP
Susan Tiedy-Stevenson, Hogan Lovells US LLP
Eva Nalian, Tandem Diabetes Care



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February 27, 2013

By Messenger

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Sincerely,

A handwritten signature in blue ink that reads 'John Sheridan'.

John Sheridan
EVP and Chief Operating Officer

JSheridan@tandemdiabetes.com
(858) 255-6345

Attachments

cc: Janice Hogan, Hogan Lovells US LLP
Susan Tiedy-Stevenson, Hogan Lovells US LLP
Eva Nalian, Tandem Diabetes Care

