

t:slim X2™

Insulin Pump

with Basal-IQ™ Technology



User Guide

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t:slim X2 Insulin Pump with Basal-IQ Technology User Guide

Congratulations on the purchase of your new t:slim X2 Insulin Pump with Basal-IQ™ Predictive Low Glucose Suspend (PLGS) Technology. Your decision to use insulin pump therapy with PLGS technology is a sign of your commitment to your diabetes care. We recognize and respect the importance of your decision. We also recognize that your t:slim X2 Insulin Pump with Basal-IQ Technology 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 Technical Support.

This User Guide is designed to assist you with the features and functions of the t:slim X2 Insulin Pump with Basal-IQ Technology. It provides important warnings and cautions on proper operation as well as technical information to ensure your safety. It also provides

step-by-step instructions on how to properly program, manage and care for your t:slim X2 Insulin Pump with Basal-IQ Technology.

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 Technical Support at (877) 801-6901 to obtain a replacement copy of the User Guide that is the correct version for your pump.

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Need help? We are here for you 24 hours a day, 7 days a week at (877) 801-6901.

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Section 1

Before You Begin

Chapter 1

Introduction

1.1 System Description

The t:slim X2™ Insulin Pump is made up of the t:slim X2 Insulin Pump and the t:slim 3mL (300 units) cartridge. The t:slim X2 Insulin Pump delivers insulin in two ways: continuous, or basal insulin delivery, and bolus insulin delivery to cover carbohydrates eaten (food bolus) and to lower high blood glucose (correction bolus). The disposable cartridge is filled with up to 300 units of U-100 insulin and attached to the pump. The cartridge is replaced every few days.

The Dexcom G5 Mobile Sensor is a disposable device that is inserted under the skin to continuously monitor glucose levels for up to 7 days. The Dexcom G5 Mobile Transmitter connects to the sensor pod and wirelessly sends readings to the pump which acts as a receiver for the therapeutic CGM. Every 5 minutes. The display shows sensor glucose readings, trend graph, direction and rate of change arrows. The sensor is discarded after a session of up to 7 days. The transmitter is reusable and is replaced about every 3 months.

The sensor measures glucose in the fluid under the skin—not in blood, and sensor readings are not identical to readings from a blood glucose meter. You still need a blood glucose meter to calibrate your CGM on a regular basis to help ensure the accuracy of sensor glucose readings.

The t:slim X2 Insulin Pump comes pre-loaded with the Basal-IQ™ Technology, or can be updated to include the Basal-IQ Technology. The addition of this feature enables the t:slim X2 System to automatically suspend and resume the delivery of insulin based on Dexcom G5 Mobile CGM sensor readings. The Basal-IQ Technology utilizes the CGM sensor values to calculate a predicted glucose value 30 minutes into the future. If the prediction is less than 80 mg/dL, or the sensor value is less than 70mg/dL, the delivery of insulin will be suspended. The suspension remains in effect until either the actual blood glucose value increases (nadir), or insulin has been suspended for 2 hours in any 2.5 hour period.

Combined, the t:slim X2 Insulin Pump, Dexcom G5 Mobile CGM and the

Basal-IQ Technology may be referred to as the “System.” The t:slim X2 Insulin Pump can be used for basal and bolus insulin delivery with or without Dexcom G5 Mobile CGM. If the Dexcom G5 Mobile Sensor and Transmitter are not used, sensor glucose readings will not be sent to the pump display and you will not be able to use the Basal-IQ Technology.

The Dexcom G5 Mobile Sensors and Transmitter are sold and shipped separately by Dexcom.

NOTE: Device Connections

The Dexcom G5 Mobile CGM only allows pairing with one medical device at a time (either the t:slim X2 Pump or the Dexcom receiver), but you can still use the Dexcom Mobile App and your t:slim X2 Pump simultaneously using the same transmitter ID.

PRECAUTION

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

1.2 About this User Guide

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

In this Guide, the t:slim X2 Pump may be referred to as “your pump” or “your t:slim X2 Pump.” The Dexcom G5 Mobile Transmitter may be referred to as “your transmitter.” The Dexcom G5 Mobile Sensor may be referred to as “your sensor.” Together, the Dexcom G5 Mobile Transmitter and Dexcom G5 Mobile Sensor may be referred to as “your CGM.” The combination of t:slim X2 Pump, CGM and Basal-IQ Technology may be referred to as the “System” or “your System.”

The User Guide is organized into sections. Section 1 provides important information you need to know before you start using the System. Sections 2-4 cover instructions for using the t:slim

X2 Insulin Pump. Sections 5–6 cover instructions for using Dexcom G5 Mobile CGM with your t:slim X2 Insulin Pump and Section 7 covers how the Basal-IQ Technology functions.

Pump screens used in this Guide to demonstrate how to use features are examples only. They should not be considered suggestions for your individual needs.

Product information, including electronic versions of the User Guide, a Guide to Successful Pumping, t:connect Getting Started and User Guides, and a CGM training tutorial, are available at www.tandemdiabetes.com.

1.3 Important User Information

Review all instructions in this User Guide before using the System.

If you are not able to use the System according to the instructions in this User Guide, you may be putting your health and safety at risk.

If you are currently using the t:slim X2 Pump without Dexcom G5 Mobile CGM, or if you are currently using Dexcom G5 Mobile CGM with the Dexcom G5 Mobile Receiver, it is still very important that you review all instructions in this User Guide before using the combined System.

Pay special attention to Warnings and Precautions in this User Guide. Warnings and Precautions are identified with a  symbol.

If you still have questions after reading this User Guide, contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901. We are here for you 24 hours a day, 7 days a week.

1.4 Important Pediatric User Information

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

Younger children may inadvertently press or tap the pump, leading to unintentional delivery of insulin.

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

We recommend reviewing the Quick Bolus and Feature Lock capabilities of the Tandem pump and determining how they best fit with your care plan. These features are detailed in Chapters [10 Quick Bolus](#) and [11 t:slim X2 Pump Settings](#).

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

WARNING

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

WARNING

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

WARNING

For patients who do not self-manage their disease, the Feature Lock function should **ALWAYS** be **ON** when the pump is not being used by a caregiver. The Feature Lock function is intended to prevent inadvertent button presses that may lead to insulin delivery or changes in the pump settings. These changes can potentially lead to hypoglycemic or hyperglycemic events.

WARNING

For patients whose insulin administration is managed by a caregiver, **ALWAYS** turn off the Quick Bolus feature to avoid inadvertent bolus delivery. If the Feature Lock is turned on, the Quick Bolus feature is automatically disabled. Inadvertent button presses or tampering with the insulin pump could result in over delivery or under delivery of insulin. This can cause very low or very high blood glucose which could result in serious injury or death.

1.5 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.
Touchscreen	The front glass screen of your pump, which displays all programming, operating, and alarm/alert information.
Tap	Quickly and lightly touch the screen with your finger.
Press	Use your finger to depress a physical button (the Screen On/Quick Bolus Button is the only physical/hardware button on your t:slim X2 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 X2 Pump or its packaging.

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Chapter 2

Important Safety Information

2.1 Indications for Use

Indications for Use

The System consists of the t:slim X2 Insulin Pump paired with the Dexcom G5 Mobile CGM (Continuous Glucose Monitor), as well as the Basal-IQ Technology.

The t:slim X2 Insulin Pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The t:slim X2 Insulin Pump can be used solely for continuous insulin delivery and as part of the System as the receiver for a therapeutic CGM.

When used with the Dexcom G5 Mobile CGM, the System is designed to replace fingerstick blood glucose testing for diabetes treatment decisions. The System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the System results should be

based on the trends and patterns seen with several sequential readings over time.

The t:slim X2 Insulin Pump running the Basal-IQ Technology can be used to suspend insulin delivery based on CGM sensor readings. In clinical studies, the t:slim X2 Insulin Pump with Basal-IQ Technology demonstrated a reduction of time spent with CGM sensor readings below 70 mg/dL from 65 to 45 minutes per day on average compared to sensor augmented pump therapy alone, importantly, without increasing time spent in hyperglycemia above 180 mg/dL.

The t:slim X2 Insulin Pump with Basal-IQ Technology is indicated for use in individuals 6 years of age and greater.

The t:slim X2 Insulin Pump with Basal-IQ Technology is intended for single patient use and requires a prescription.

The device is indicated for use with NovoLog or Humalog U-100 insulin.

2.2 Contraindications

Contraindications

The t:slim X2 Insulin Pump with Basal-IQ Technology is not intended for anyone unable or unwilling to:

- Test blood glucose (BG) levels as recommended by your healthcare provider
- Demonstrate adequate carbohydrate-counting skills (preferred, 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 System alerts.

The t:slim X2 Pump, Dexcom G5 Mobile Transmitter, and Dexcom G5 Mobile Sensor must be removed before Magnetic Resonance Imaging (MRI),

Computed Tomography (CT) scan, or diathermy treatment. Exposure to MRI, CT, or diathermy treatment can damage the System.

Taking medications with acetaminophen (such as Tylenol) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

2.3 System Warnings



WARNINGS: t:slim X2 Insulin Pump

DO NOT start to use your System before reading the User Guide. Failure to follow the instructions in the User Guide can result in over delivery or under delivery of insulin. This can cause very low or very high blood glucose which could result in serious injury or death. If you have questions or need further clarification on your System use, ask your healthcare provider or call our around-the-clock Customer Technical

Support Department at (877) 801-6901.

DO NOT start to use your System before you have been appropriately trained on its use by a certified System trainer. Consult with your healthcare provider for your individual training needs for the entire System. Failure to complete the necessary training on the System could result in serious injury or death.

DO NOT use any other insulin with your System other than U-100 Humalog or NovoLog. Only Humalog and NovoLog have been tested and found to be compatible for use in the System. Use of insulin with lesser or greater concentration can result in under delivery or over delivery of insulin. This can cause very high or a very low blood glucose.

DO NOT put any other drugs or medications inside your System cartridge. The System is designed only for Continuous Subcutaneous Insulin Infusion (CSII) using Humalog or NovoLog insulin. Use of other drugs or medications can damage the pump and result in injury if infused.

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

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

DO use only FDA cleared insulin infusion sets with a tubing connector and follow their instructions for use. Failure

to do so may result in over delivery or under delivery of insulin and may cause very low or very high blood glucose.

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

DO NOT ignore infusion set cannula fractures. Infusion set cannulas may fracture on rare occasions. If an infusion set cannula breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken infusion set cannula, please report this to Tandem Customer Technical Support at (877) 801-6901.

NEVER fill your tubing while your infusion set is connected to your body. Always ensure that the infusion set is disconnected from your body before filling the tubing. Failure to disconnect your infusion set from your body before

filling the tubing can result in over delivery of insulin. This can cause serious injury or death from very low blood glucose.

DO NOT reuse cartridges or use cartridges other than those manufactured by Tandem Diabetes Care, Inc. Use of cartridges not manufactured by Tandem Diabetes Care or reuse of cartridges may result in over delivery or under delivery of insulin. This can cause very low or very high blood glucose.

ALWAYS twist the tubing connector between the cartridge tubing and the infusion set tubing an extra quarter of a turn to ensure a secure connection. A loose connection can cause insulin to leak, resulting in under delivery of insulin. This can cause high blood glucose.

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

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

DO NOT deliver a bolus until you have reviewed the calculated bolus amount on the pump display. If you dose an insulin amount that is too high or too low, this could cause very high or very low blood glucose. You can always adjust the insulin units up or down before you decide to deliver your bolus.

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

The Insulin Pump includes parts (such as the USB cable and infusion set tubing) that could pose a strangulation or

asphyxiation hazard. **ALWAYS** use the appropriate length of infusion set tubing and arrange cables and tubing to minimize the risk of strangulation. **ENSURE** that these parts are stored in a secure place when not in use.

For patients who do not self-manage their disease, the Feature Lock function should **ALWAYS** be **ON** when the pump is not being used by a caregiver. The Feature Lock function is intended to prevent inadvertent button presses that may lead to insulin delivery or changes in the pump settings. These changes can potentially lead to hypoglycemic or hyperglycemic events.

For patients whose insulin administration is managed by a caregiver, **ALWAYS** turn off the Quick Bolus feature to avoid inadvertent bolus delivery.

If the Feature Lock is turned on, the Quick Bolus feature is automatically disabled. Inadvertent button presses or tampering with the insulin pump could result in over delivery or under delivery of insulin. This can cause very low or very high blood glucose which could result in serious injury or death.



WARNINGS: Radiology and Medical Procedures and your t:slim X2 Insulin Pump

ALWAYS notify the provider/technician about your diabetes and your t:slim X2 Insulin Pump. If you need to discontinue use of the Insulin Pump for medical procedures, follow your healthcare provider's instructions to replace missed insulin when you reconnect to the pump. Check your blood glucose before disconnecting from the pump and again when you reconnect and treat high blood glucose levels as recommended by your healthcare provider.

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

- X-ray
- Computed Tomography (CT) scan
- Magnetic Resonance Imaging (MRI)
- Positron Emission Tomography (PET) scan
- Other exposure to radiation

The System is magnetic resonance (MR) Unsafe. You must take off your pump, transmitter, and sensor and leave them outside the procedure room if you are going to have any of the above procedures.

In addition to the above, **DO NOT** expose your pump, transmitter, or sensor to:

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

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

There are other procedures where you should proceed with caution:

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

can create interference and cause the System to alarm.

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

There is no need to disconnect for electrocardiograms (EKGs) or colonoscopies. If you have questions, contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

DO NOT use the System if you have a condition which, in the opinion of your healthcare provider, would put you at risk including any contraindication to the use of any of the devices in the System per FDA labeling. Examples of individuals who should not use the System include those with uncontrolled thyroid disease, renal failure (e.g. dialysis or eGFR < 30), hemophilia, or another major bleeding disorder, or unstable cardiovascular disease



WARNINGS: Using Dexcom G5 Mobile with your t:slim X2 Insulin Pump

DO NOT ignore symptoms of high and low glucose. If your sensor glucose alerts and readings do not match your symptoms, measure your blood glucose with a blood glucose meter even if your sensor is not reading in the high or low range.

CALIBRATE your CGM at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate and glucose alerts to become unreliable. This could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

DO NOT ignore sensor fractures. Sensors may fracture on rare occasions. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling, or pain—at the insertion site. If you experience a broken sensor, please report

this to Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

DO NOT use Dexcom G5 Mobile CGM in pregnant women or persons on dialysis. The System is **not approved for use** in pregnant women or persons on dialysis and has not been evaluated in these populations. Sensor glucose readings may be inaccurate in these populations and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

DO NOT use Dexcom G5 Mobile CGM in critically ill patients. It is not known how different conditions or medications common to the critically ill population may affect the performance of the System. Sensor glucose readings may be inaccurate in critically ill patients, and solely relying on the sensor glucose alerts and readings for treatment decisions could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

DO NOT insert the sensor in sites other than the abdomen (belly) or upper buttocks (for ages 6–17 only). Other sites have not been studied and are not approved. Use in other sites might cause sensor glucose readings to be inaccurate and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

DO NOT expect CGM alerts until after the 2-hour startup. You will **NOT** get any sensor glucose readings or alerts until after the 2-hour startup ends. During this time you might miss severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

DO NOT use your transmitter if it is damaged/cracked. This could create an electrical safety hazard or malfunction, which might cause electrical shocks.

STORE the Dexcom G5 Mobile CGM sensor at temperatures between 36°F to 77°F for the length of the sensor's shelf life. You may store the sensor in the refrigerator if it is within this tem-

perature range. The sensor should not be stored in a freezer. Storing the sensor improperly might cause the sensor glucose readings to be inaccurate, and you might miss severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

DO NOT allow young children to hold the sensor, transmitter or transmitter kit box without adult supervision. The sensor and transmitter include small parts that may pose a choking hazard. Keep the transmitter kit box away from young children; it contains a magnet that should not be swallowed.

2.4 System Precautions



PRECAUTIONS: t:slim X2 Insulin Pump

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

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

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

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

CHECK your infusion set tubing daily for any leaks, air bubbles, or kinks. Air

Chapter 2 – Important Safety Information

in the tubing, leaks in the tubing, or kinked tubing may restrict or stop insulin delivery and result in under delivery of insulin.

CHECK the tubing connection between your cartridge tubing and infusion set tubing daily to ensure it is tight and secure. Leaks around the tubing connection can result in under delivery of insulin.

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

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

CHECK your insulin pump's personal settings regularly to ensure they are

correct. Incorrect settings can result in over delivery or under delivery of insulin. Consult with your healthcare provider as needed.

ALWAYS make sure that the correct time and date are set on your insulin pump. When editing time, always check 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. Not having the correct time and date setting may affect safe insulin delivery.

CONFIRM that the screen display turns on, you can hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the Screen On Button when you connect a power source to the USB port. These features are used to notify you about alerts, alarms, and other conditions that require your attention. If these features are not working, discontinue use of the pump and contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

CHECK your pump regularly for potential alarm conditions that may display. It

is important to be aware of conditions that may affect insulin delivery and require your attention so you can respond as soon as possible.

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

ALWAYS look at the screen to confirm correct programming of the bolus amount when you first use the Quick

Bolus feature. Looking at the screen will ensure that you are correctly using the beep/vibration commands to program the intended bolus amount.

DO NOT use your pump if you think it might be damaged due to dropping it or hitting it against a hard surface. Check that the pump is working properly by plugging a power source into the USB port and confirming that the display turns on, you hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the Screen On Button. If you

are unsure about potential damage, discontinue use of the System and contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

AVOID exposure of your pump to temperatures below 40°F (5°C) or above 99°F (37°C). Insulin can freeze at low temperatures or degrade at high temperatures. Insulin that has been exposed to conditions outside of the manufacturer's recommended ranges can affect the safety and performance of the pump.

AVOID submersing your pump in fluid beyond a depth of 3 feet or for more than 30 minutes (IPX7 rating). If your pump has been exposed to fluid beyond these limits, check for any signs of fluid ingress. If there are signs of fluid entry, discontinue use of the pump and contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

AVOID areas where there may be flammable anesthetics or explosive gases. The pump is not suitable for use in these areas and there is a risk of explo-

sion. Remove your pump if you need to enter these areas.

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

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

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

CONSULT your healthcare provider about lifestyle changes such as weight gain or loss, and starting or stopping exercise. Your insulin needs may

change in response to lifestyle changes. Your basal rate(s) and other settings may need adjustment.

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

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

ENSURE that your personal insulin delivery settings are programmed into the pump before you use the System if

you receive a warranty replacement. Failure to enter your insulin delivery settings could result in over delivery or under delivery of insulin. This can cause very low or very high blood glucose which could result in serious injury or death. Consult your healthcare provider as needed.

Interference with your pump's 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.

ALWAYS dispose of used System components such as cartridges, syringes, needles, infusion sets, and CGM sensors following the instructions from your healthcare provider. Wash your hands thoroughly after handling used System components.



**PRECAUTIONS: Using
Dexcom G5 Mobile CGM
with your t:slim X2 Insulin
Pump**

DO NOT open the sensor package until you have washed your hands with soap and water, and let them dry. You may

contaminate the insertion site and suffer an infection if you have dirty hands while inserting the sensor.

DO NOT insert the sensor until you have cleaned the skin with a topical antimicrobial solution, such as isopropyl alcohol, and allowed the skin to dry. Inserting into unclean skin might lead to infection. Do not insert the sensor until the cleaned area is dry so the sensor adhesive will stick better.

AVOID using the same spot repeatedly for sensor insertion. Rotate your sensor placement sites, and do not use the same site for two sensor sessions in a row. Using the same site might cause scarring or skin irritation.

AVOID inserting the sensor in areas that are likely to be bumped, pushed or compressed, or areas of skin with scarring, tattoos, or irritation as these are not ideal sites to measure glucose. Insertion in those areas might affect accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

AVOID injecting insulin or placing an infusion set within 3 inches of the sensor. The insulin might affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

DO NOT use the sensor if its sterile package has been damaged or opened. Using an unsterile sensor might cause infection.

To calibrate the CGM System, **DO** enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Do not enter sensor glucose readings for calibration. Entering incorrect blood glucose values, blood glucose values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

DO NOT calibrate if your blood glucose is changing at a significant rate, typically more than 2 mg/dL per minute. Do not

calibrate when your receiver screen is showing the rising or falling single arrow or double arrow, which indicates that your blood glucose is rapidly rising or falling. Calibrating during significant rise or fall of blood glucose may affect sensor accuracy and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

The CGM System accuracy may be affected when your glucose is changing at a significant rate (i.e., 2 to 3 mg/dL/min or more than 3 mg/dL each minute), such as during exercise or after a meal.

AVOID separating the transmitter and pump by more than 20 feet. The transmission range from the transmitter to the pump is up to 20 feet without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and pump are farther than 20 feet apart or are separated by an obstruction, they might not communicate or the commu-

nication distance may be shorter and result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

DO NOT use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration. Alternative site blood glucose values may be different than those taken from a fingerstick blood glucose value and may not represent the timeliest blood glucose value. Use a blood glucose value taken only from a fingerstick for calibration. Alternative site blood glucose values might affect sensor accuracy and result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

ENSURE that your transmitter ID is programmed into the pump before you use the System if you receive a warranty replacement pump. The pump cannot communicate with the transmitter unless the transmitter ID is entered. If the pump and transmitter are not communicating, you will not receive sensor glucose readings and you might miss severe hypoglycemia (low blood glu-

cose) or hyperglycemia (high blood glucose) events.

DO NOT discard your transmitter. It is reusable. The same transmitter is used for each session until you have reached the end of the transmitter battery life.

The Dexcom G5 Mobile Sensor, Transmitter, and Receiver are not compatible with the SEVEN/SEVEN PLUS Transmitter and Receiver. Different generations will not connect with each other and will not work.

2.5 Potential Benefits From Using the System

- The t:slim X2 Insulin Pump provides an automated way to deliver basal and bolus insulin. Delivery can be fine-tuned based on up to 6 customizable Personal Profiles, each with up to 16 time-based settings for Basal Rate, Carb Ratio, Correction Factor, and Target BG. In addition, the Temp Rate feature allows you to program a temporary basal rate change for up to 72 hours.

- The t:slim X2 Insulin Pump gives you the option of delivering a bolus all at once, or delivering a percentage over an extended period of time without navigating to different menus. You can also program a bolus more discreetly using the Quick Bolus feature, which can be used without looking at the pump, and can be programmed in increments of either units of insulin or grams of carbohydrate.
- From the bolus screen, the “calculator within a calculator” feature allows you to enter multiple carbohydrate values and add them together. The insulin pump’s bolus calculator will recommend a bolus based on the entire amount of carbohydrates entered, which can help eliminate guesswork.
- The insulin pump keeps track of the amount of active insulin from food and correction boluses (IOB). When programming additional food or correction boluses, the pump will subtract the amount of IOB from the recommended bolus if your BG

is below the target set in your active Personal Profile. This can help prevent insulin stacking, which can lead to hypoglycemia.

- You can program a number of reminders that will prompt you to retest your BG after a low or high BG is entered, as well as a “Missed Meal Bolus Reminder” which will alert you if a bolus isn’t entered during a specified period of time. If activated, these can help reduce the likelihood that you will forget to check your blood glucose or bolus for meals.
- You have the ability to view a variety of data right on your screen, including the time and amount of your last bolus, your total insulin delivery by day, as well as broken into basal, food bolus, and correction bolus.
- When paired with Dexcom G5 Mobile Transmitter and Sensor, your t:slim X2 Insulin Pump can receive CGM readings every 5 minutes, which are displayed as a trend graph on the Home Screen.

You can also program your pump to alert you when your CGM readings are above or below a given level, or are rising or falling quickly. Unlike the readings from a standard blood glucose meter, CGM readings allow you to view trends in real time, as well as capture information when you would otherwise be unable to check your blood sugar, such as while you are asleep. This information can be useful for you and your healthcare provider when considering changes to your therapy. In addition, the programmable alerts can help you to spot potential low or high blood glucose sooner than you would using a only a blood glucose meter.

- CGM use has been shown to increase time in your target glucose range, without increasing time spent above or below your target range. Real-time CGM can help improve diabetes control (lower A1C values, reducing glycemic variability and time spent in low and high blood glucose ranges)^{1, 2, 3} which can help reduce diabetes related complications.^{4, 5} These

benefits can be seen especially with using real-time CGM at least 6 days per week² and can be sustained over time.⁶ In some cases, patients perceived an increase in their quality of life and peace of mind when using real-time CGM as well as reporting a high satisfaction with CGM.⁷

¹ Garg S, Zisser H, Schwartz S, Bailey T, Kaplan R, Ellis S, Jovanovic L. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. *Diabetes Care*. 2006; 29:44-50.

² JDRF CGM Study Group. Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes. *NEJM* 2008;359:1464-76.

³ Battelino. Effect of continuous glucose monitoring of hypoglycemia in type 1 diabetes. *Diabetes Care* 2011; 34(4): 795-800.

⁴ The Diabetes Control and Complications Research Group. The effect of intensive treatment of diabetes on the

development and progression of long-term complications of insulin-dependent diabetes mellitus. *N Eng J Med*. 1993; 329:997-1036.

⁵ Ohkubo Y, Kishikawa H, Araki E, et al. Intensive insulin therapy prevents progression of diabetic microvascular complications in Japanese patients with non-insulin dependent diabetes mellitus: a randomized prospective 6-year study. *Diabetes Res Clin Pract*. 1995; 28:103-117.

⁶ JDRF CGM Study Group. Sustained Benefit of Continuous Glucose Monitoring on A1c, Glucose Profiles, and Hypoglycemia in Adults With Type 1 Diabetes. *Diabetes Care* 2009; 32: 2047-2049.

⁷ JDRF CGM Study Group. Quality-of-Life Measures in Children and Adults With Type 1 Diabetes. *Diabetes Care* 2010; 33: 2175-2177.

2.6 Possible Risks From Using the System

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

Risks associated with using the pump functionality of the System

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

There is a remote chance that an infusion set cannula fragment could remain under your skin if the cannula breaks while you are wearing it. If you think a cannula has broken under your skin,

contact your healthcare provider and call Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

Other risks associated with infusion sets include occlusions and air bubbles in the tubing, which can affect insulin delivery.

Risks that could result from pump failure include the following:

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

Risks associated with using the CGM functionality of the System

Inserting the sensor and wearing the adhesive patch might cause infection, bleeding, pain and skin irritations (readi-

ness, swelling, bruising, itching, scarring, or skin discoloration).

There is a remote chance that a sensor fragment could remain under your skin if the sensor breaks while you are wearing it. If you think a sensor has broken under your skin, contact your healthcare provider and call Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

Other risks associated with CGM use include the following:

- You will not get sensor glucose alerts when the alert function is turned off, your transmitter and pump are out of range, or when your pump is not showing sensor glucose readings. You might not notice alerts if you are unable to hear them or feel the vibration.
- There are a number of risks as a result of the fact that the Dexcom G5 Mobile CGM takes readings from fluid below the skin (interstitial fluid) instead of blood. There are differences in how glucose is measured in the blood compared to

how it is measured in interstitial fluid, and glucose is absorbed into the interstitial fluid slower than it is absorbed into the blood, which can cause CGM readings to lag behind readings from a blood glucose meter.

2.7 Working with your Healthcare Provider

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

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 to 8 times daily) in order to detect

hyperglycemia (high blood glucose) and hypoglycemia (low blood glucose) early. Undetected hyperglycemia or hypoglycemia can result without proper monitoring.

Consult your healthcare provider before using the System to determine which features are most appropriate for you. Only your healthcare provider can determine and help you adjust your basal rate(s), insulin-to-carbohydrate ratio(s), correction factor(s), blood glucose (BG) target, and duration of insulin action. In addition, only your healthcare provider can determine your CGM settings and how you should use your sensor trend information to help you manage your diabetes.

2.8 Emergency Kit

Make sure that you always have an insulin syringe and 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 every day:

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

2.9 Verification of Proper Functionality

A power supply (AC adapter with micro-USB connector) is provided as part of the System. Before using your System, ensure that the following occur when you connect a power supply into the USB port of your t:slim X2 Pump:

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

In addition, before using the System, ensure the following:

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

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

PRECAUTION

CONFIRM that the screen display turns on, you can hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the Screen On Button when you connect a power source to the USB port. These features are used to notify you about alerts, alarms, and other conditions that require your attention. If these features are not working, discontinue use of the System and contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

2.10 Wireless Co-existence and Data Security

The System is designed to work safely and effectively in the presence of wireless devices typically found at home, work, retail stores, and places of leisure where daily activities occur. See [Section 33.9 Distances Between the t:slim X2 Pump and RF Equipment](#) for more information.

The System is designed to send and accept Bluetooth® Low Energy (BLE) communication. Communication is not established until you enter the appropriate credentials into your pump.

The System and system components ensure data security via proprietary means and ensure data integrity using error checking processes, such as cyclic redundancy checks.

Chapter 3

Getting to Know Your System

3.1 What your System Package Includes

Your System should include the following items:

1. t:slim X2 Insulin Pump
2. Pump Case
3. t:slim X2 Insulin Pump with Basal-IQ Technology User Guide
4. t:connect® Getting Started Guide
5. USB Cable
6. Wall Power USB Adapter
7. Cartridge Removal Tool

If you use a CGM, the Dexcom G5 Mobile Sensors and Transmitter are sold and shipped separately by Dexcom.

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

Your t:slim X2 Pump is shipped from Tandem Diabetes Care with a clear screen protector. Do not remove the screen protector.

Your t:slim X2 Pump comes from Tandem Diabetes Care with a protective cover in the place where the cartridge is normally inserted. This cover must be removed and replaced with a cartridge prior to initiating insulin delivery.

Your t:slim X2 Pump also includes consumable components that may require replacement during the life of your pump, including:

- Pump case(s)/clip(s)
- Screen protector
- USB rubber door
- USB cable

Supply Reordering

To order cartridges, infusion sets, supplies, accessories, screen protectors, sensors and transmitter, please contact Tandem Diabetes Care at (877) 801-

6901 or your usual supplier of diabetes products.

3.2 System Terminology

Pump 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/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 X2 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 a high BG. With the t:slim X2 Pump it

can be delivered as a Standard, a Correction, an Extended, or a Quick Bolus.

Cannula

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

Carb

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 1 unit of insulin will cover. Also known as insulin-to-carbohydrate ratio.

Correction Bolus

A correction bolus is given to correct high BG.

Correction Factor

A correction factor is the amount of BG that is lowered by 1 unit of insulin. Also known as the Insulin Sensitivity Factor (ISF).

Extended Bolus

An extended bolus is a bolus that is delivered over a period of time. It is commonly used to cover food that takes longer to digest. When administering an extended bolus with your t:slim X2 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).

Insulin On Board (IOB)

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

Load

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

Personal Profile

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

Quick Bolus

Quick bolus (using the Quick Bolus Button) is a way to deliver a bolus by following beep/vibration commands without navigating through or viewing the t:slim X2 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 X2 Pump's micro USB port.

CGM Terminology

Alternate Site BG Testing

Alternate site BG testing is when you take a blood glucose value on your meter using a blood sample from an area on your body other than your fingertip. Do not use alternate site testing to calibrate your sensor.

Applicator

The applicator is a disposable piece that comes attached to the sensor pod and inserts the sensor under the skin. There is a needle inside the applicator that is removed after you insert the sensor.

Calibration

Calibration is when you enter blood glucose values from a blood glucose meter into the System. Calibrations are

needed for your System to show continuous glucose readings and trend information.

CGM

Continuous glucose monitoring.

Glucose Data Gaps

Glucose data gaps occur when your System is unable to provide a sensor glucose reading.

Glucose Trends

Glucose trends let you see the pattern of your glucose levels. The trend graph shows where your glucose levels have been during the time shown on the screen and where your glucose levels are now.

HypoRepeat

HypoRepeat is an optional alert setting that keeps repeating the fixed low alert every 5 seconds until your sensor glucose value rises above 55 mg/dL or you confirm it. This alert can be helpful if you want extra awareness for severe lows.

mg/dL

Milligrams per deciliter. The standard unit of measure for sensor glucose readings in the United States.

Receiver

When the Dexcom G5® Mobile CGM is used with the t:slim X2 Pump to display CGM readings, the insulin pump replaces the receiver. A smartphone with the Dexcom app may be used in addition to the t:slim X2 Insulin Pump to receive sensor readings.

Rise and Fall (Rate of Change) Alerts

Rise and fall alerts occur based on how much and how fast your glucose levels rise or fall.

RF

RF is the abbreviation for radio frequency. RF transmission is used to send glucose information from the transmitter to the pump.

Safety Lock

The safety lock keeps the needle inside the applicator before you are ready to insert the sensor. It also helps you snap the transmitter out of the sensor pod after your sensor session ends.

Sensor

The sensor is the part that includes an applicator and wire. The applicator inserts the wire under your skin, and the wire measures glucose levels in your tissue fluid.

Sensor Pod

The sensor pod is the small plastic base of the sensor attached to your skin that holds the transmitter in place.

Startup Period

The startup period is the 2-hour period after you tell the System you inserted a new sensor. Sensor glucose readings are not provided during this time.

System Reading

A System reading is a sensor glucose reading shown on your pump. This reading is in mg/dL units and is updated every 5 minutes.

Transmitter

The transmitter is the part that snaps into the sensor pod and wirelessly sends glucose information to your pump.

Transmitter ID

The transmitter ID is a series of numbers and/or letters that you enter into your pump to let it communicate with the transmitter.

Transmitter Latch

The transmitter latch is a small disposable piece that snaps the transmitter into the sensor pod. It is removed after the transmitter is snapped in.

Trend (Rate of Change) Arrows

Trend arrows show how fast your glucose levels are changing. There are 7 different arrows that show when your glucose direction and speed change.

3.3 Explanation of System Symbols

The following are symbols (and their descriptions), which you may find on your System and/or its packaging. These symbols tell you about the proper and safe use of the System. Some of these symbols may not have meaning in the United States, and are listed for informational purposes only.

Symbol	Meaning
	Caution; Consult Manual for Important Safety Documentation
	See Instructions for Use
	Serial Number of Device
	Part Number
IPX7	Watertight Equipment (protected against the effects of temporary immersion in water)
	Type BF Applied Part (patient isolation, not defibrillator protected)
	Manufacturer
R_x Only	For sale by or on the order of a physician only (U.S.)

Symbol	Meaning
	Use By Date
	Do Not Re-Use
	Sterile by Radiation
	Non Pyrogenic
	Two-sided Temperature Limits
	Lot Number
	Non-ionizing Radiation
	Date of Manufacture

Explanation of System Symbols (Part 1 of 2)

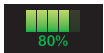
Symbol	Meaning
	Direct Current (DC) voltage
	Alternating Current
	Temporary Submersion
	Vertically Falling Drops
	Two-Sided Humidity Limits
	European Union WEEE Directive 2006/66/EC
	Electrical Equipment Designed Primarily for Indoor Use
	Keep Dry

Symbol	Meaning
	Class II Equipment
	Authorized Representative in the European Community
	Marking Certifies That the Device Meets the European Council Directive 93/42/EEC
	Do Not Use if Package is Damaged
	Ship By Date
	MR Unsafe
	Input
	Bluetooth

Explanation of System Symbols (Part 2 of 2)

3.4 Explanation of System Icons

The following icons may appear on your t:slim X2 Pump screen:

Symbol	Meaning
	The amount of charge left in the pump battery.
	CGM sensor session is active, and the transmitter is communicating with the pump.
	CGM sensor session is active, but the transmitter is not communicating with the pump.
	CGM calibration is required.
	A system reminder, alert, error, or alarm is active.
	Basal insulin is programmed and being delivered.
	CGM sensor session is active, but the transmitter is not communicating with the pump.
	The CGM sensor has failed. See Section 24.4 Additional CGM Status Symbols .
	The CGM sensor session has ended. See Section 24.4 Additional CGM Status Symbols .

Symbol	Meaning
	Amount of insulin remaining in the reservoir.
	A temporary basal rate is active.
	A basal rate of 0 u/hr is active.
	A temporary basal rate of 0 u/hr is active.
	A bolus is being delivered.
	All insulin deliveries are stopped.
	Transmitter error.
	Sensor startup 0–30 minutes.
	Sensor startup 31–60 minutes.

Pump Icon Definitions (Part 1 of 2)

Symbol	Meaning
	Wait 15 minutes calibration error.
	Startup calibration is required (2 BG values).
	Additional startup calibration is required.

Symbol	Meaning
	Sensor startup 61–90 minutes.
	Sensor startup 91–119 minutes.
	CGM calibration is required.

Pump Icon Definitions (Part 2 of 2)

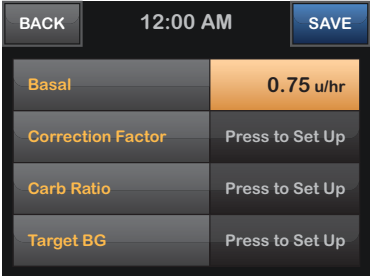
If you have a CGM session active and are using the Basal-IQ Technology, you may see the following additional icons on your pump screen:

Symbol	Meaning
	The Basal-IQ Technology is enabled and delivering the active Personal Profile basal rate.
	The Basal-IQ Technology is currently active. All insulin deliveries have been suspended.

Symbol	Meaning
	The Basal-IQ Technology is active: all insulin deliveries have been suspended.

Basal-IQ Icon Definitions

3.5 Explanation of System Colors

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

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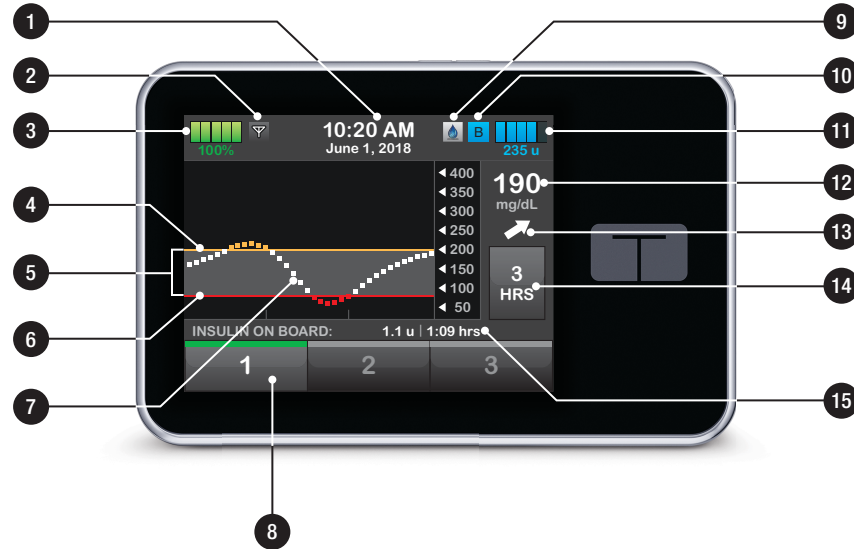
3.6 Screen Lock

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



3.7 CGM Screen Lock

1. **Time and Date Display:** Displays the current time and date.
2. **Antenna:** Indicates communication status between pump and transmitter.
3. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
4. **High Glucose Alert Setting.**
5. **Glucose Target Range.**
6. **Low Glucose Alert Setting.**
7. **Plot of Most Recent Sensor Glucose Readings.**
8. **1–2–3:** Unlocks pump screen.
9. **Active Bolus Icon:** Indicates a bolus is active.
10. **Status:** Displays current system settings and insulin delivery status.
11. **Insulin Level:** Displays the current amount of insulin in the cartridge.
12. **Most Recent 5-Minute Glucose Reading.**
13. **Trend Arrow:** Indicates direction and rate of change.
14. **Trend Graph Time (HRS):** 1, 3, 6, 12 and 24 hour views available.
15. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.



3.8 Basal-IQ Screen Lock

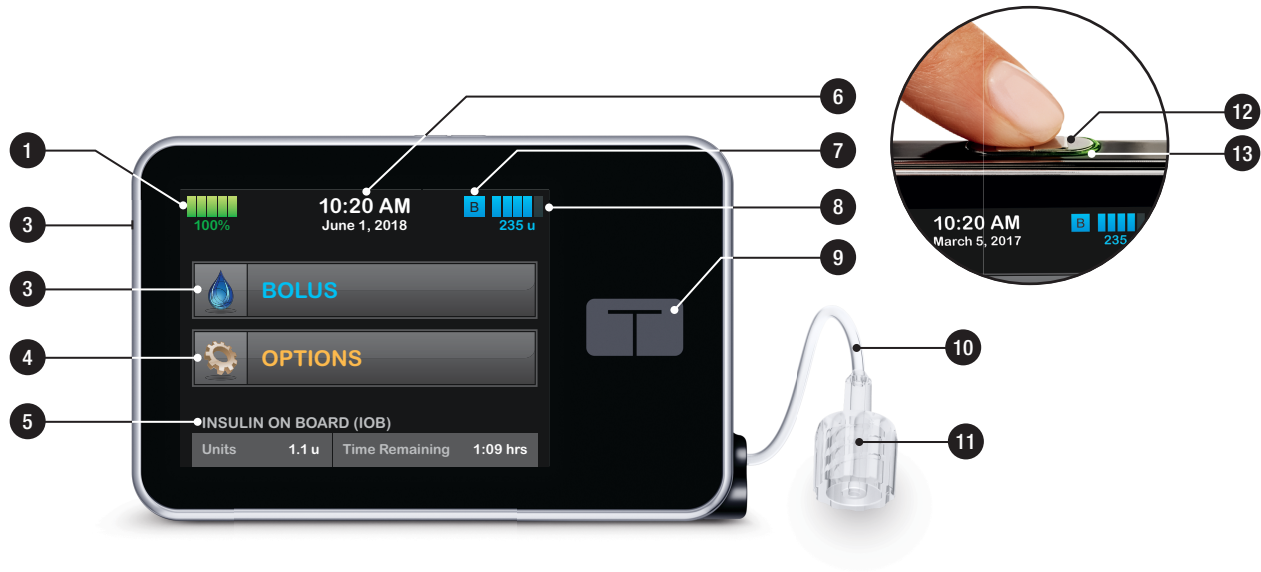
The screen with Screen Lock and Basal-IQ Technology turned on is the same as the CGM Screen Lock, with the following additions.

1. **Basal-IQ Technology Status:**
Indicates the status of the Basal-IQ Technology.
2. **CGM Graph Shading:** Red shading indicates the Basal-IQ Technology is, or was, active for the period indicated.



3.9 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 X2 Pump battery. Close the cover when not in use.
3. **Bolus:** Program and deliver a bolus.
4. **Options:** Stop/Resume insulin delivery, manage Pump and CGM Settings, program a Temp Rate, Load cartridge, and view History.
5. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.
6. **Time and Date Display:** Displays the current time and date.
7. **Status:** Displays current system settings and insulin delivery status.
8. **Insulin Level:** Displays the current amount of insulin in the cartridge.
9. **Tandem Logo:** Returns to the Home Screen.
10. **Cartridge Tubing:** Tubing that is attached to the cartridge.
11. **Tubing Connector:** Connects the cartridge tubing to the infusion set tubing.
12. **Screen On/Quick Bolus Button:** Turns the t:slim X2 Pump screen on/off or programs a Quick Bolus (if activated).
13. **LED Indicator:** Illuminates when connected to a power supply and indicates proper functionality.

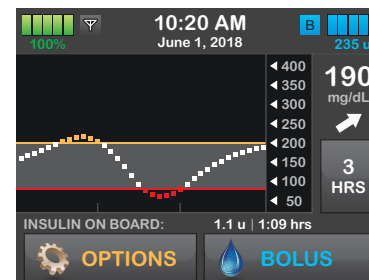


3.10 CGM Home Screen

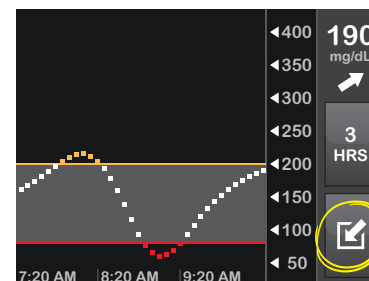
1. **Time and Date Display:** Displays the current time and date.
2. **Antenna:** Indicates communication status between pump and transmitter.
3. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
4. **High Glucose Alert Setting.**
5. **Glucose Target Range.**
6. **Low Glucose Alert Setting.**
7. **Plot of Most Recent Sensor Glucose Readings.**
8. **Options:** Stop/Resume insulin delivery, manage Pump and CGM Settings, program a Temp Rate, Load cartridge, and view History.
9. **Bolus:** Program and deliver a bolus.
10. **Status:** Displays current system settings and insulin delivery status.
11. **Insulin Level:** Displays the current amount of insulin in the cartridge.
12. **Most Recent 5-Minute Glucose Reading.**
13. **Trend Arrow:** Indicates direction and rate of change.
14. **Trend Graph Time (HRS):** 1, 3, 6, 12 and 24 hour views available.
15. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.

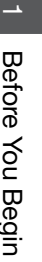
To view CGM information on the full screen:

From the Home Screen tap anywhere on the CGM trend graph.



Tap the “minimize” icon to return to the Home Screen.





3.11 Basal-IQ Home Screen

The home screen with Basal-IQ Technology turned on is identical to the CGM Home Screen, with the following additions:

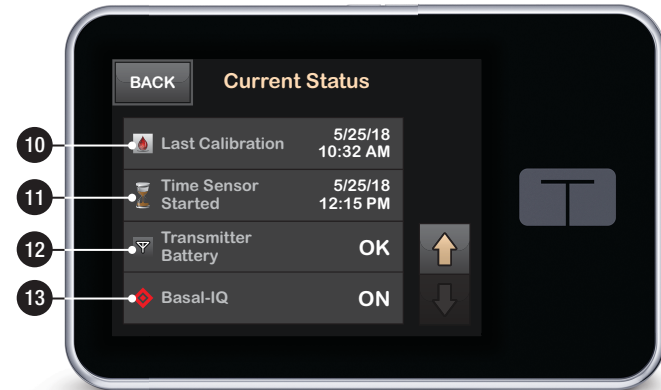
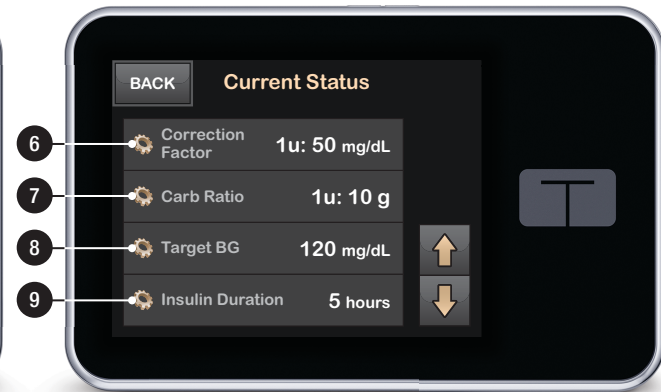
1. **Basal-IQ Technology Status:**
Indicates the status of the Basal-IQ Technology.
2. **CGM Graph Shading:** Red shading indicates the Basal-IQ Technology is, or was, active for the period indicated.



3.12 Status Screen

The status screen can be accessed from the lock screen and the Home Screen. It is for display only; no changes can be made from this screen.

1. **Profile:** Displays current active Personal Profile.
2. **Basal Rate:** Displays current basal rate being delivered. (If a Temp Rate is active, it is displayed in units/hr.)
3. **Last Bolus:** Displays the amount, date and time of last bolus.
4. **Carbohydrates:** Indicates whether feature is on or off.
5. **Up/Down Arrow:** Indicates there is more information.
6. **Correction Factor:** Displays current correction factor used to calculate a bolus.
7. **Carb Ratio:** Displays current carb ratio used to calculate a bolus.
8. **Target BG:** Displays current BG target used to calculate a bolus.
9. **Insulin Duration:** Displays current insulin duration setting used to calculate insulin on board.
10. **Last Calibration:** Displays date and time of last calibration.
11. **Time Sensor Started:** Displays date and time of last time sensor started.
12. **Transmitter Battery:** Displays transmitter battery status.
13. **Basal-IQ Status:** Displays the Basal-IQ Technology status.



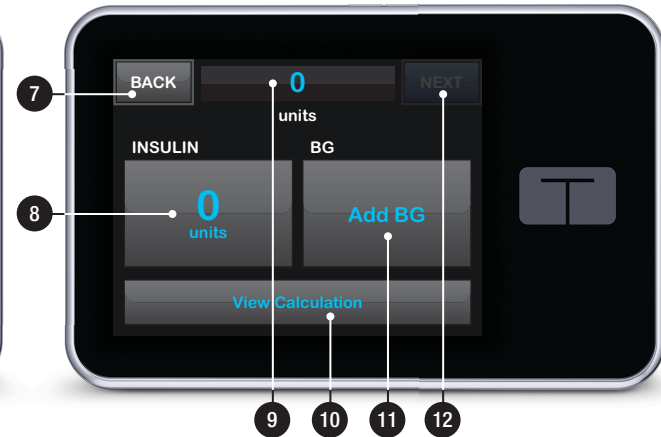
3.13 Bolus Screen

1. **Back:** Returns to the Home Screen.
2. **Carbs:** Enter grams of carb.
3. **Units:** Displays total units calculated. Tap to enter a bolus request or change (override) a calculated bolus.
4. **View Calculation:** Displays how the insulin dose was calculated using the current settings.
5. **Add BG:** Enter blood glucose level.
6. **Next:** Moves to next step.
7. **Back:** Returns to the Home Screen.
8. **Insulin:** Enter units of insulin.
9. **Units:** Displays total units calculated. Tap to enter a bolus request or change (override) a calculated bolus.
10. **View Calculation:** Displays how the insulin dose was calculated using the current settings.
11. **Add BG:** Enter blood glucose level.
12. **Next:** Moves to next step.

Using Grams



Using Units



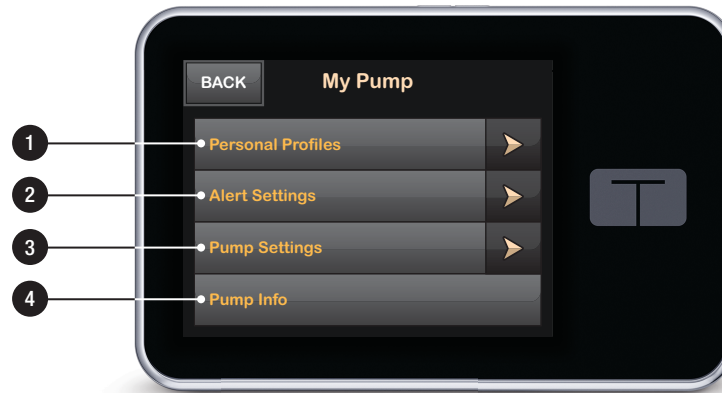
3.14 Options Screen

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. **My CGM:** Start/Stop Sensor, Calibrate CGM, CGM Alerts, and CGM Settings.
5. **Temp Rate:** Programs a temporary basal rate.
6. **Up/Down Arrow:** Indicates there is more information.
7. **Load:** Change Cartridge, Fill Tubing, Fill Cannula, and Site Reminder.
8. **Pump History:** Displays historical log of pump events.
9. **CGM History:** Displays historical log of CGM events.
10. **Basal-IQ:** Turn on/off Basal-IQ Technology, and Basal-IQ Alerts.
11. **Menu Arrows:** Indicates additional menu options are available.



3.15 My Pump Screen

1. **Personal Profiles:** A group of settings that define basal and bolus delivery.
2. **Alert Settings:** Customize Pump Reminders and Alerts.
3. **Pump Settings:** Customize Quick Bolus, Pump Volume, Screen Options, and set Time and Date.
4. **Pump Info:** Displays t:slim X2 Pump serial number, Tandem Diabetes Care Customer Technical Support phone number, website, and other technical information.



3.16 My CGM Screen

1. **Start Sensor:** Starts a CGM session. If sensor is active, STOP SENSOR will be displayed.
2. **Calibrate CGM:** Enter a calibration blood glucose value. Only active when sensor session is active.
3. **CGM Alerts:** Customize CGM Alerts.
4. **CGM Settings:** Enter transmitter ID, customize CGM volume, and view CGM information.



3.17 Basal-IQ Screen

1. **Basal-IQ Technology on/off:** Turns on, or off, the Basal-IQ Technology.
2. **Suspend Alert on/off:** Turns on, or off, the alert indicating when insulin has been suspended.
3. **Resume Alert on/off:** Turns on, or off, the alert indicating when insulin has been resumed after a suspension.

NOTE: Basal-IQ Technology Off by Default

If this is the first time using your t:slim X2 Insulin Pump with the Basal-IQ Technology, you must have an active sensor session before using the Basal-IQ Technology. The alerts settings are not available until after the Basal-IQ Technology is turned on.

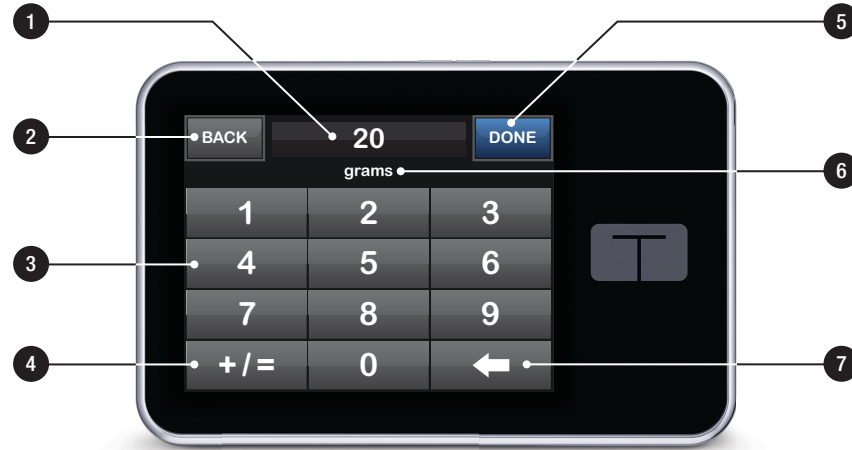
NOTE: Suspend/Resume Alerts

Once the Basal-IQ Technology is turned on, the Suspend and Resume Alerts are turned off by default.



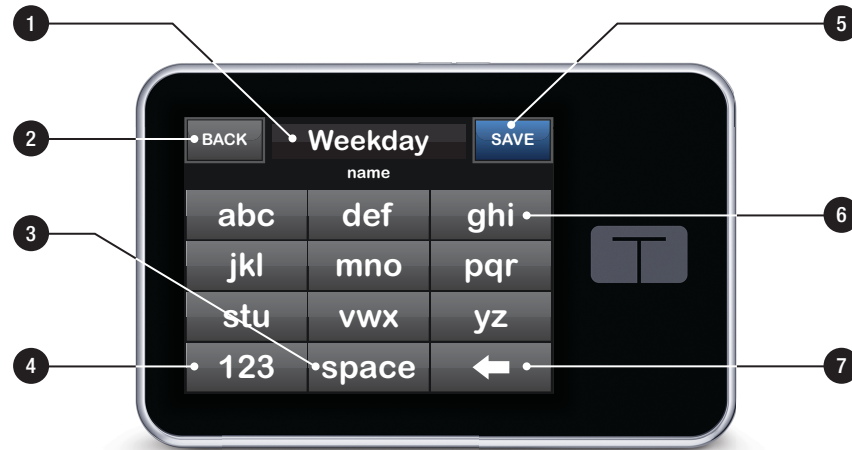
3.18 Number Keypad Screen

1. **Value Entered.**
2. **Back:** Returns to previous screen.
3. **Keypad Numbers.**
4. **+/=:** Allows numbers to be added on gram screen. If 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. **←:** Deletes last number entered.



3.19 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, 2 quick taps for middle letter, and 3 quick taps for third letter.
7. **←:** Deletes last letter or number entered.



Section 2

Key Pump Features

Chapter 4

Getting Started

4.1 Charging the t:slim X2 Pump

The t:slim X2 Pump is powered by an internal lithium polymer rechargeable battery. A full charge will last up to 7 days with average use, or 5 days when using CGM with average use. Please be aware that the battery life on a single charge can vary considerably depending on individual usage, including insulin delivered, display-on time, and frequency of reminders, alerts and alarms.

Accessories for charging from wall and automobile outlets, as well as from a PC USB port, are included with the pump. Use only the accessories provided with the System to charge your t:slim X2 Pump. If you lose any of the accessories, or need a replacement, contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

The battery level indicator is displayed in the upper left portion of the Home Screen. The charge amount will increase or decrease by 5% at a time (for example, you will see 100%, 95%, 90%, 85%). When the charge amount

is less than 5%, it will begin decreasing 1% at a time (for example, you will see 4%, 3%, 2%, 1%).

When you first receive your t:slim X2 Pump, you will need to connect it to a charging source before it can be used. Charge the pump until the battery level indicator on the upper left portion of the Home Screen reads 100% (initial charge can take up to 2.5 hours).

The t:slim X2 Pump continues to operate normally while charging. You do not need to disconnect from the pump while charging.

PRECAUTION

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

If you choose to disconnect from the pump while charging, check with your healthcare provider for specific guidelines. Depending on the length of time you are disconnected, you may need to

replace missed basal and/or bolus insulin. Check your blood glucose before disconnecting from the pump and again when you reconnect.

To charge the pump from an AC Power Outlet:

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

To charge the pump using the optional Car Power USB Adapter:

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

⚠ WARNING

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

To charge the pump using a USB port on a Personal Computer (PC):

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

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

Before using a Mac® or PC to charge the t:slim X2 Pump, it is recommended that a driver be installed on the computer by downloading the t:connect Uploader Software from our website at www.tandemdiabetes.com. This will also allow communication between the pump, the PC, and the t:connect Application. Depending on your computer,

charging time will vary. The pump will display a CONNECTION ERROR ALERT message if it is not charging properly.

When you charge the t:slim X2 Pump, you will notice the following:

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

⚠ PRECAUTION

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

Customer Technical Support at (877) 801-6901.

Charging Tips

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

■ NOTE: Fully Discharged Battery

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

4.2 Using the Touch Screen

To turn on your t:slim X2 Pump screen, first press the Screen On/Quick Bolus Button, then use the pad of your finger to quickly and lightly tap on the screen. Do not use your finger nail or other object to interact with the screen. It will not activate the screen or its functions.

Your t:slim X2 Pump is designed to give you quick and easy access to the functions that you will use in your day-to-day diabetes management whether basic or advanced.

The t:slim X2 Pump 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, if 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: Touch Screen Tips

When using the t:slim X2 Pump, tap the Tandem Logo to return to the Home Screen or tap BACK to return to the previous screen.

4.3 Turning on the t:slim X2 Pump Screen

To turn on your t:slim X2 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: Turning off the Pump Screen

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

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

4.4 Unlocking the t:slim X2 Pump Screen

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

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

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

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

4.5 Edit Time

After powering up your t:slim X2 Pump for the first time, set the current time and date. Refer back to this section if you need to edit the time for either traveling in a different time zone or adjusting for Daylight Savings Time.

PRECAUTION

ALWAYS make sure that the correct time and date are set on your pump. When editing time, always check 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. Not having the correct time and date setting may affect safe insulin delivery.

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

2. Tap **My Pump**.
3. Tap **Pump Settings**.
4. Tap the **Down Arrow**.
5. Tap **Time and Date**.
6. Tap **Edit Time**.
7. Tap **Time**.
8. Using the onscreen keypad, enter the hour and minutes. Verify and tap **DONE**.
9. Tap **Time of Day** to set AM or PM.
10. Verify the correct time is set and tap **SAVE**.

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

4.6 Edit Date

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

3. Find and tap the 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.

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Chapter 5

Infusion Site Care and Loading Cartridge

5.1 Infusion Site Selection and Care

WARNING

DO use only FDA cleared insulin infusion sets with a tubing connector and follow their instructions for use. Failure to do so may result in over delivery or under delivery of insulin and may cause very low or very high blood glucose.

WARNING

DO NOT ignore infusion set cannula fractures. Infusion set cannulas may fracture on rare occasions. If an infusion set cannula breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken infusion set cannula, please report this to Tandem Customer Technical Support at (877) 801-6901.

WARNING

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

PRECAUTION

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

General Guidelines

Site Selection

- Your infusion set can be worn anywhere on your body that you would normally inject insulin. Absorption varies from site to site. Discuss options with your healthcare provider.
- The most commonly used sites are the abdomen, upper buttocks, hips, upper arms, and upper legs.
- The abdomen is the most popular site because of access to fatty tissue. If using the abdominal area, AVOID:
 - Areas that would constrict the site such as the belt line, waistline, or where you would normally bend.

- Areas 2 inches around your belly button.
- Any scars, moles, stretch marks, or tattoos.
- Areas within 3 inches of your CGM sensor site.

Site Rotation

PRECAUTION

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

- The infusion set must be replaced and rotated every 48–72 hours, or more often if needed.
- With experience, you will find areas that not only provide better absorption, but are more comfortable. Keep in mind, using the same areas may cause scarring

or lumps which can affect insulin absorption.

- Consult your healthcare provider to establish a rotation schedule that best fits your needs.

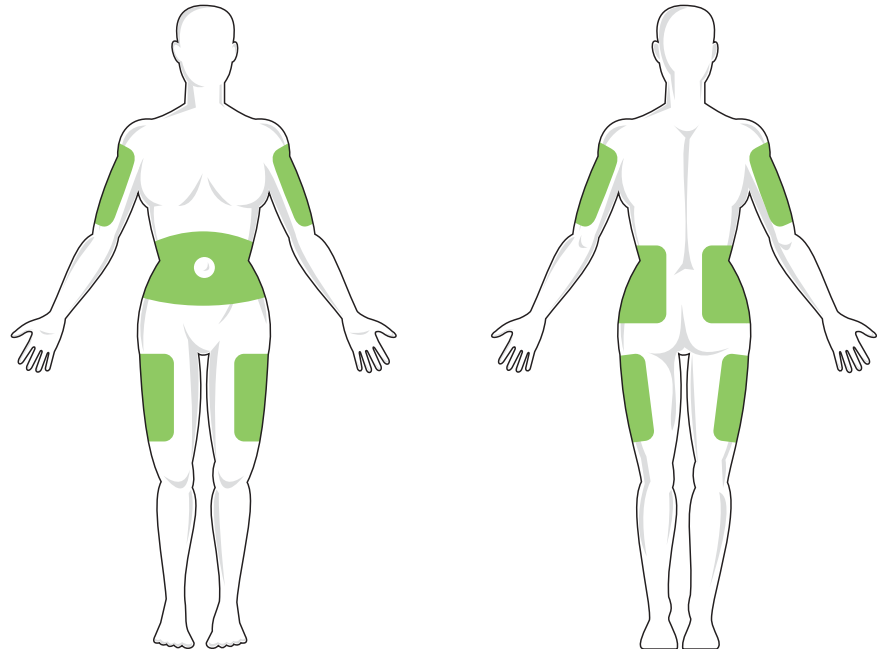
Keep it Clean

- When changing your infusion set, use clean techniques to avoid an infection.
- Wash your hands, use antiseptic wipes or infusion site preparation products, and keep the area clean.
- Site preparation products that have both an antiseptic and an adhesive are encouraged.

5.2 Cartridge Instructions for Use

For complete cartridge labeling, consult the Cartridge Instructions for Use included in the t:slim® Cartridge box.

Areas of Body for Infusion Set Insertion



5.3 Filling and Loading a t:slim Cartridge

This section describes how to fill the cartridge with insulin and load the cartridge into your t:slim X2 Pump. The single-use disposable cartridge can hold up to 300 units (3.0 mL) of insulin.

⚠ WARNING

DO NOT use any other insulin with your System other than U-100 Humalog or NovoLog. Only Humalog and NovoLog have been tested and found to be compatible for use in the Pump. Use of insulin with lesser or greater concentration can result in under delivery or over delivery of insulin. This can cause very high or a very low blood glucose.

⚠ WARNING

DO NOT reuse cartridges or use cartridges other than those manufactured by Tandem Diabetes Care. Use of cartridges not manufactured by Tandem Diabetes Care or reuse of cartridges may result in over delivery or under delivery of insulin. This can cause very low or very high blood glucose.

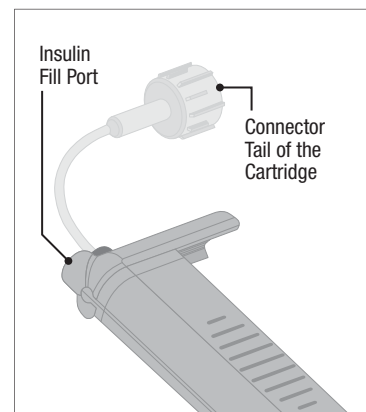
Before you begin, make sure you have the following items:

- 1 unopened cartridge
- 3.0 mL syringe and fill needle
- Vial of Humalog or NovoLog insulin
- Alcohol prep swab
- 1 new infusion set
- Infusion set Instructions for Use

📘 NOTE: Removing the Cartridge

DO NOT remove the used cartridge from the pump during the load process until prompted on the t:slim X2 Pump screen.

The illustration identifies the connector and insulin fill port used in the cartridge filling process.



⚠ PRECAUTION

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

Instructions for Drawing Insulin from Vial into Syringe

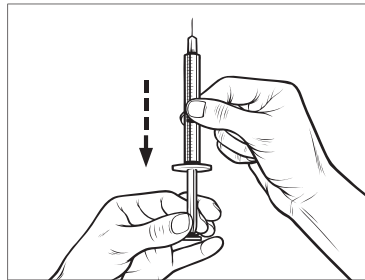
⚠ PRECAUTION

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

The fill estimate displayed on the pump is the amount of insulin available for delivery. It does not include insulin needed to fill the tubing (up to 30 units) and a small amount of insulin that is not available for delivery. When filling the syringe, add approximately 45 units to the amount of insulin you want available for delivery.

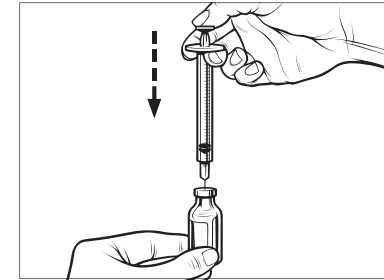
For example, the pump requires a minimum of 50 units available for delivery after fill tubing has been completed. Fill the syringe with approximately 95 units to have enough to fill your tubing and still have 50 units available for delivery.

1. Inspect the needle and syringe package for any signs of damage. Discard any damaged product.
2. Wash your hands thoroughly.
3. Wipe the rubber septum of the insulin vial with an alcohol swab.
4. Remove the needle and syringe from their packaging. Securely twist needle onto syringe. Safely remove protective cap from needle by pulling outward.
5. Draw air into syringe up to the amount of insulin desired.



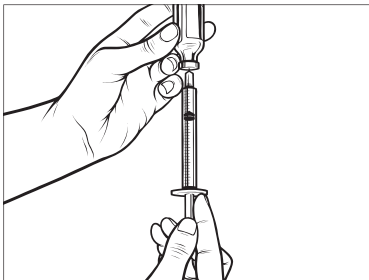
6. With insulin vial upright, insert needle into vial. Inject air from

syringe into vial. Maintain pressure on syringe plunger.

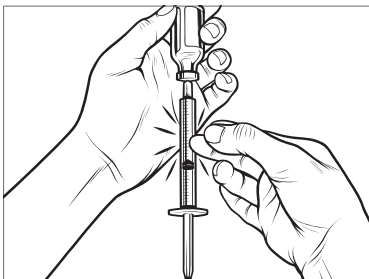


7. With needle still inserted into vial, turn vial and syringe upside down. Release syringe plunger. Insulin will begin to flow from the vial into the syringe.

8. Slowly pull back the plunger to the desired amount of insulin.



9. While the filling needle is still in the vial and upside down, tap the syringe so that any air bubbles rise to the top. Then slowly push the plunger upwards, forcing any air bubbles back into the vial.

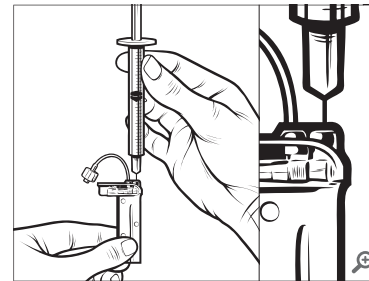


10. Check the syringe for air bubbles and do one of the following:

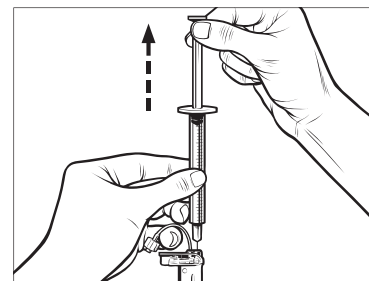
- If there are air bubbles present, repeat step 9.
- If no air bubbles are present, remove the filling needle from the vial.

Instructions for Filling the Cartridge

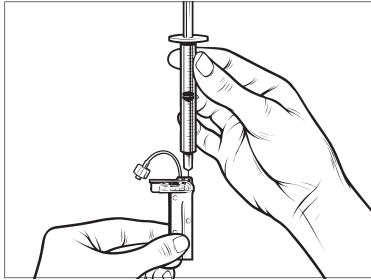
1. Inspect the cartridge package for any signs of damage. Discard any damaged product.
2. Open the package and remove the cartridge.
3. Hold the cartridge upright and gently insert the needle into the white insulin fill port on the cartridge. The needle is not intended to go all the way in, so do not force it.



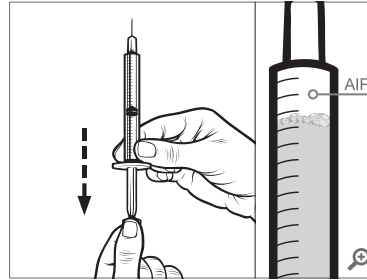
4. Keeping the syringe vertically aligned with the cartridge, and the needle inside the fill port, pull back on the plunger until it is fully retracted. This will remove any residual air from the cartridge. Bubbles will rise toward the plunger.



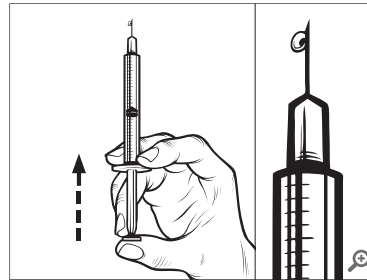
5. Make sure the needle is still in the fill port and release the plunger. Pressure will pull the plunger to its neutral position but it will **NOT** push any air back inside the cartridge.



6. Withdraw the needle from the fill port.
7. Turn the syringe upright and pull down on the plunger. Flick the barrel to make sure that any air bubbles rise to the top.

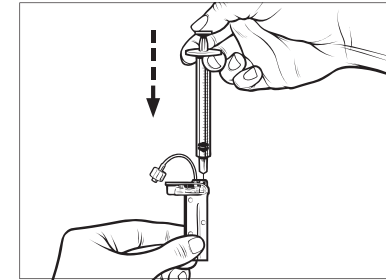


8. Gently press on the plunger to remove air bubbles until insulin fills the needle hub and you see a drop of insulin at the tip of the needle.



9. Re-insert the needle in the fill port and slowly fill the cartridge with insulin. It is normal to feel some

back pressure as you slowly press on the plunger.



10. Maintain pressure on the plunger while you remove the needle from the cartridge. Check the cartridge for leaks. If you detect insulin leaking, discard the cartridge and repeat entire process with a new cartridge.
11. Always dispose of used needles, syringes, cartridges, and infusion sets following the instructions from your healthcare provider.

Chapter 5 – Infusion Site Care and Loading Cartridge

Instructions on How to Install a Cartridge

If this is the very first time you are loading the cartridge, remove the shipping canister (which is not for human use) from the back of the pump.

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

2. Tap the **Down Arrow**.

3. Tap **Load**.

- ✓ During the load sequence, the Tandem Logo is disabled.

Tapping it will not return to the Home Screen.

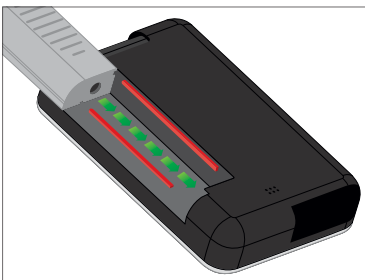
4. Tap **Change Cartridge**.

5. Screen will display that all insulin deliveries will be stopped. Tap **YES** to continue.

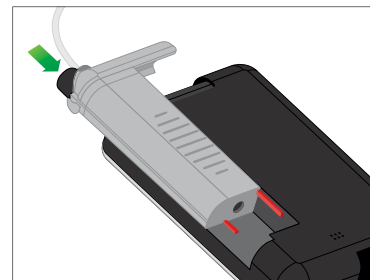
NOTE: First Time Use

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

6. Disconnect the infusion set from your body and tap **NEXT** to continue.
- ✓ “Preparing for Cartridge” screen is displayed.
7. Remove the used cartridge. If needed, place the cartridge removal tool or the edge of a coin in the slot at the bottom of the cartridge and twist to aid in the removal of the cartridge.
8. Place bottom of the cartridge at the end of the pump. Make sure cartridge is lined up to both guide tracks.



9. Push on the circular fill port next to the cartridge tubing to slide the cartridge onto the pump. Tap **UNLOCK** when completed.



10. Tap **NEXT** to continue.

- ✓ Detecting Cartridge screen is displayed.

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

WARNING

DO NOT remove or add insulin from a filled cartridge after loading onto the pump. This will result in an inaccurate display of the insulin level on the Home Screen and you could run out of insulin before the pump detects an empty car-

tridge. This can cause very high blood glucose, or Diabetic Ketoacidosis (DKA).

5.4 Filling Tubing

Filling the Infusion Set Tubing with Insulin

This section describes how to fill the infusion set tubing with insulin after you change the cartridge.

To fill the tubing without changing the cartridge, from the Home Screen tap **OPTIONS**, tap **Down Arrow**, tap **Load**, tap **Fill Tubing** and then follow the instructions.

- Tap **NEW** if you installed a new cartridge.
- Tap **FILL** if you did not install a new cartridge and want to continue with filling the tubing.

⚠ WARNING

NEVER fill your tubing while your infusion set is connected to your body. Always ensure that the infusion set is disconnected from your body before filling the tubing. Failure to disconnect

your infusion set from your body before filling the tubing can result in over delivery of insulin. This can cause serious injury or death from very low blood glucose.

⚠ PRECAUTION

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

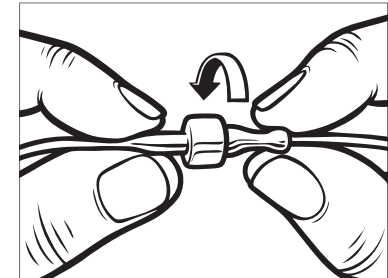
⚠ PRECAUTION

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

1. Verify that the infusion set is disconnected from your body.
2. Ensure that the new infusion set package is not damaged, and remove the sterile tubing from the package. If the package is

damaged or opened, discard of properly and use another tubing set.

3. Remove the infusion set tubing cap from the tubing connector. Be careful to keep the tubing connector away from unclean areas.
4. Attach the infusion set tubing to the tubing connector on the cartridge tubing. Twist clockwise until finger tight and then twist another quarter of a turn to ensure a secure connection.



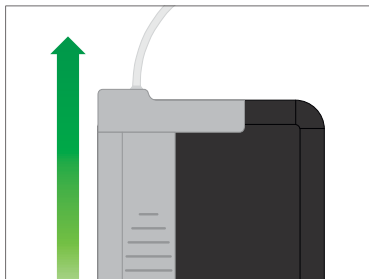
⚠ WARNING

ALWAYS twist the tubing connector between the cartridge tubing and the infu-

Chapter 5 – Infusion Site Care and Loading Cartridge

sion set tubing an extra quarter of a turn to ensure a secure connection. A loose connection can cause insulin to leak, resulting in under delivery of insulin. This can cause high blood glucose.

5. Tap **NEXT**.
6. Hold the pump vertically to ensure any air in the cartridge will be expelled first. Tap **START**. The pump will beep and vibrate regularly while the tubing is being filled.



- ✓ “Starting Fill” screen is displayed.

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
7. Tap **STOP** after 3 drops of insulin are seen at the end of the infusion set tubing.
 - ✓ Stopping Fill screen is displayed.
 - ✓ Detecting Insulin screen is displayed.
 8. Verify that drops are seen and tap **DONE**.
 - If you do not see drops, tap **FILL**. The Fill Tubing screen appears, repeat steps 3 to 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.

- ✓ Fill Tubing is complete.

NOTE: Initial Display of Insulin

After tubing fill is complete, when the pump returns to the Home Screen, an estimate of how much insulin is in the cartridge is displayed in the upper right portion of the screen. You will see one of the following on the screen:

+ 40 u	More than 40 units detected in the cartridge
+ 60 u	More than 60 units detected in the cartridge
+ 120 u	More than 120 units detected in the cartridge
+ 180 u	More than 180 units detected in the cartridge
+ 240 u	More than 240 units detected in the cartridge

After 10 units are delivered, an actual number of units remaining in the cartridge will be displayed on the Home Screen

The amount of insulin remaining displayed on the Home Screen will decrease 5 units at a time (for example, you will see 140, 135, 130, 125). When less than 40 units remain, it will begin decreasing 1 unit at a time (for example, you will see 40, 39, 38, 37) until there is 1 unit remaining.

5.5 Filling Cannula

Filling the Infusion Set Cannula with Insulin

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

To fill the cannula without filling the tubing, from the Home Screen, tap **OPTIONS**, tap **Down Arrow**, tap **Load**, tap **Fill Cannula** and then follow the instructions below.

If you are using a steel needle infusion set, there is no cannula; skip this section.

To Fill the Cannula:

1. Tap **Fill Cannula**.

2. Insert a new infusion set and connect filled tubing to site, then tap **NEXT**.
3. Tap **Edit Fill Amount**.
 - ✓ The cannula fill amount displayed is based on your last cannula fill amount. Filling stops at this amount.
4. Select amount needed for cannula fill.
 - Refer to your infusion set instructions for use for proper cannula fill amount.
 - 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.
5. Tap **START**.
 - ✓ “Starting Fill” screen is displayed.
 - ✓ After fill is complete, “Stopping Fill” screen is displayed.

NOTE: Stopping Fill

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

- ✓ The screen will return to the Load menu if the Site Reminder is turned off.
6. Tap **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

This section describes how to set the Site Reminder after you fill the cannula.

To set the Site Reminder without filling the cannula, from the Home Screen, tap **OPTIONS**, tap **Down Arrow**, tap **Load**, tap **Site Reminder** then follow the instructions below.

PRECAUTION

DO NOT change your infusion set before bedtime or if you will not be able to test your blood

Chapter 5 – Infusion Site Care and Loading Cartridge

glucose 1–2 hours after the new infusion set is placed. It is important to confirm that the infusion set is inserted correctly and delivering insulin. It is also important to respond quickly to any problems with the insertion to ensure continued insulin delivery.

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 (1–3).
 - ✓ The default for the Site 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 **DONE**.
5. Verify Site Reminder is set correctly and tap **SAVE**.
 - ✓ “Setting Saved” screen is displayed.
 - ✓ Load screen is displayed.

6. Tap **DONE**.

- ✓ A reminder to test BG in 1 to 2 hours will display.

7. Tap **RESUME**.

NOTE: First Time Use

If this is the first time using your t:slim X2 Pump and a Personal Profile has not been defined, a screen will notify you that a profile must be activated to resume insulin. Tap **CLOSE**.

- ✓ **RESUMING INSULIN** screen is temporarily displayed.

Chapter 6

Personal Profiles

6.1 Personal Profiles Overview

WARNING

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

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

- **Timed Settings:** Basal Rate, Correction Factor, Carb Ratio and Target BG.

- **Bolus Settings:** Insulin Duration, Max Bolus and Carbohydrates setting (on/off).

The t:slim X2 Pump uses the settings in your active profile to calculate the delivery of basal insulin, food boluses and correction boluses based on your Target BG. If you only define a basal rate in Timed Settings, your pump will only be able to deliver basal insulin and standard and extended boluses. Your pump will not calculate correction boluses.

Up to 6 different Personal Profiles can be created and up to 16 different time segments can be set in each Personal Profile. Having several Personal Profiles provides more flexibility for your body and lifestyle. For example, you could have “Weekday” and “Weekend” profiles if you have different insulin delivery needs on weekdays and weekends, based on schedule, food intake, activity, and exercise, etc.

6.2 Creating a New Profile

Creating Personal Profiles

You can create up to 6 Personal Profiles; however, only 1 can be active at a time. In the Personal Profiles screen, the active profile is positioned at the top of the list and is marked as **ON**. When you create a Personal Profile, you can set any or all of the following Timed Settings:

- Basal Rate (your basal rate in units/hr)
- Correction Factor (amount 1 unit of insulin lowers BG)
- Carb Ratio (grams of carbs covered by 1 unit of insulin)
- Target BG (your ideal BG level, measured in mg/dL)

Although you do not need to define every setting, some pump features require certain settings to be defined and activated. When you are creating a new profile, your pump prompts you to

set up any required settings before you can continue.

The ranges you can set for Timed Settings are:

- Basal (range: 0 and 0.1 to 15 units/hr)
- Correction Factor (range: 1 unit:1 mg/dL to 1 unit:600 mg/dL)
- Carb Ratio (range: 1 unit:1 gram to 1 unit:300 grams)

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

- Target BG (range: 70 mg/dL to 250 mg/dL)

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

- 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 to 8 hrs)
- Max Bolus (default: 10 units; range: 1 to 25 units)

Insulin Duration and Insulin on Board (IOB)

Your t:slim X2 Pump remembers how much insulin you have taken from previous boluses. It does this by relying on the Insulin Duration. The Insulin Duration reflects the amount of time that insulin is actively lowering your BG.

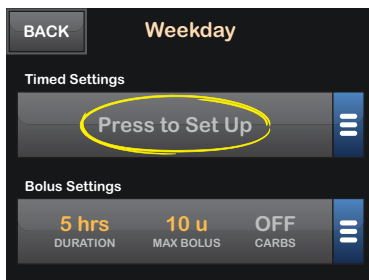
Consult your healthcare provider to accurately set your Insulin Duration.

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 used in bolus delivery calculations when applicable. When a BG is entered during bolus programming, your t:slim X2 Pump will consider any active IOB and calculate an adjusted bolus if necessary.

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**.

Tap once for first letter displayed, 2 quick taps for middle letter; and 3 quick taps for the third letter.

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



6.3 Programming a New Personal Profile

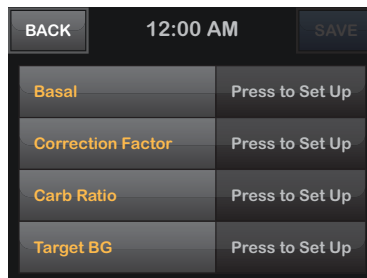
Once the Personal Profile has been created, the settings must be programmed. The first time segment will start at 12:00 AM (midnight).

- You must program a basal rate in order to have a Personal Profile that you can activate.
- Be sure to tap **SAVE** after entering or changing a value.

⚠ PRECAUTION

ALWAYS confirm that the decimal point placement is correct when entering your Personal Profile information. Incorrect decimal point placement can prevent you from getting the proper insulin amount that your healthcare provider has prescribed for you.

Timed Settings

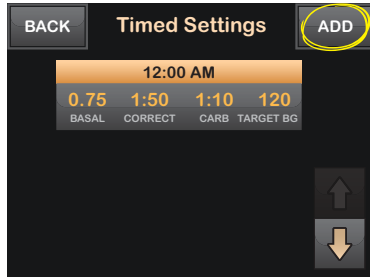


1. Once the new profile has been created, Tap **Basal**.
2. Using the onscreen keypad, enter your basal rate and tap **DONE**.
3. Tap **Correction Factor**.
4. Using the onscreen keypad, enter your correction factor (the mg/dL

that 1 unit of insulin will lower BG) and tap **DONE**.

5. Tap **Carb Ratio**.
6. Using the onscreen keypad, enter your insulin-to-carbohydrate ratio (the grams of carb to be covered by 1 unit of insulin) and tap **DONE**.
7. Tap **Target BG**.
8. Using the onscreen keypad, enter your target BG and tap **DONE**.
9. Review entered values and tap **SAVE**.
10. Confirm Settings.
 - Tap **YES** if entered data is correct.
 - Tap **NO** to make changes.
11. Tap **BACK** to set the Bolus Settings.

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



Adding More Time Segments

When adding more time segments, any settings that you entered in the previous time segment are copied and appear in the new segment. This allows you to simply adjust only the specific settings you want, rather than have to enter them all over again.

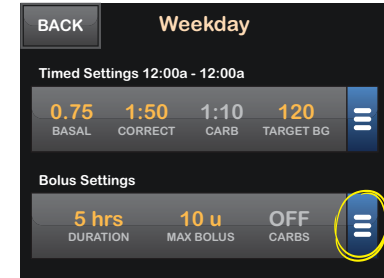
1. On the Add Segment screen, tap **Start Time**.
2. Using the onscreen keypad, enter the time (hour and minutes) that you want the segment to begin, and tap **DONE**.

3. On the Add Segment screen, tap **Time of Day** to select AM or PM.
- ✓ Once a time segment is set beyond 12:00 PM, the default will change to PM.
4. Tap **NEXT**.
5. Repeat steps 1 to 6 from the [Creating a New Profile](#) section above for each segment you want to create (up to 16).

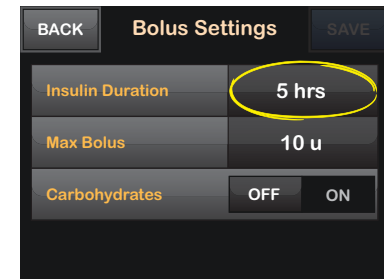
To find time segments in the list that are not displayed on the first screen, tap the **Down Arrow**.

Bolus Settings

1. Tap the **Bolus Settings** Panel.



2. Tap **Insulin Duration**.



3. Using the onscreen keypad, enter the desired time for the duration of insulin action (2–8 hrs) and tap **DONE**.

4. Tap **Max Bolus**.
5. Using the onscreen keypad, enter the desired amount for maximum bolus (1–25 units) and tap **DONE**.

NOTE: 25 Unit Max Bolus

If you set the max bolus to 25 units and a bolus larger than 25 units is calculated using your Carb Ratio or Correction Factor, after the bolus is delivered a reminder screen will appear. The option of delivering the remaining amount of the bolus up to an additional 25 units will be given (see Section 15.9 [Max Bolus Alerts](#)).

6. Tap **Carbohydrates** to turn on and use the carb ratio when calculating boluses.
7. Review entered values and tap **SAVE**.
8. Confirm Settings.
 - Tap **YES** if entered data is correct.
 - Tap **NO** to make changes.

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

Adding More Personal Profiles

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap **NEW**.
5. Name the new profile and repeat steps for Timed Settings and Bolus Settings.

NOTE: Carbohydrates Options

If the first profile you created 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 or Reviewing an Existing Profile

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

2. Tap **My Pump**.

3. Tap **Personal Profiles**.

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

5. Tap **Edit**.

NOTE: Review Settings

To review settings but bypass editing the settings, skip the remaining steps in this section. You can tap **BACK** to navigate to the Personal Profiles list or tap the Tandem Logo to return to the Home Screen.

6. Tap **Timed Settings Panel**.
7. Tap the desired time segment to edit.
8. Tap **Basal, Correction Factor, Carb Ratio or Target BG** to make changes as needed and use the onscreen keypad to enter 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. Edit other time segments within the Timed Settings by tapping on them and using the same steps described above.

12. Tap **BACK** after editing all of the time segments.13. Tap the **Bolus Settings Panel** to change DURATION, MAX BOLUS or CARBS as needed. Use the onscreen keypad to enter desired changes. Tap **SAVE**.

14. Confirm Settings.

- Tap **YES** if entered data is correct.
- Tap **NO** and make changes.

15. Tap **Tandem Logo** to return to the Home Screen. **NOTE: Adding a Time Segment**

To Add a time segment, tap **ADD** and enter the desired start time.

 NOTE: Deleting a Time Segment

To Delete a time segment, tap on the X to the left of the time segment and tap **YES** to confirm.

6.5 Duplicating an Existing Profile

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to duplicate.
5. Tap **Duplicate**.
6. Confirm profile to duplicate by tapping **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.
 - The Activate and Delete options are disabled for the active profile because the profile is already activated. You cannot delete a profile until you have activated another profile.

- If you have only 1 profile defined, you do not need to activate it (that profile is automatically activated).

5. Tap **Activate**.

- ✓ A screen to confirm the activation request is displayed.

6. Tap **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: Active Personal Profile

The active Personal Profile cannot be deleted.

5. Tap **Delete**.
 6. Tap **YES**.
- ✓ Profile Deleted screen is displayed.

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

Chapter 7

Bolus

7.1 Bolus Overview

WARNING

DO NOT deliver a bolus until you have reviewed the calculated bolus amount on the pump display. If you dose an insulin amount that is too high or too low, this could cause very high or very low blood glucose. You can always adjust the insulin units up or down before you decide to deliver your bolus.

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

The minimum bolus size is 0.05 units. The maximum bolus size is 25 units. If you attempt to deliver a bolus that is larger than the amount of insulin in the cartridge, a message screen appears indicating that there is not enough insulin to deliver the bolus.

Your t:slim X2 Pump offers you the ability to deliver different boluses to cover carbohydrate intake (food bolus) and bring your BG back to target (correction bolus). Food and correction boluses can also be programmed together.

If Carbohydrates is turned on in your active personal profile, you will enter grams of carbohydrate and the bolus will be calculated using your Carb Ratio.

If Carbohydrates is turned off in your active personal profile, you will enter units of insulin to request the bolus.

If the Basal-IQ Technology is turned on and has suspended insulin delivery during a normal bolus, all bolus deliveries will continue until completed. A new bolus cannot be started until insulin is resumed.

PRECAUTION

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

7.2 BG Entry and Correction Bolus Calculation

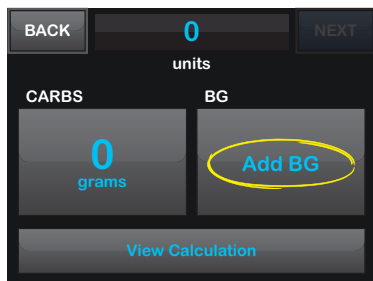
When your blood glucose is:

- Above Target BG: the insulin for the food bolus and the correction bolus will be added together. If IOB is present, it will only be used in the calculation of the correction portion of the bolus.
- Between 70 mg/dL and Target BG: You will be given an option to reduce the food bolus to correct for the low blood glucose. In addition, if IOB is present, it will also be used to reduce the bolus calculation.
- Below 70 mg/dL: The food bolus will be reduced to automatically correct for the low blood glucose. In addition, if IOB is present, it will also be used to reduce the bolus calculation.

Always treat hypoglycemia (low blood glucose) with fast-acting carbohydrates according to the instructions of your healthcare provider and then re-test your blood glucose to ensure that the treatment was successful.

BG Value Manual Entry

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

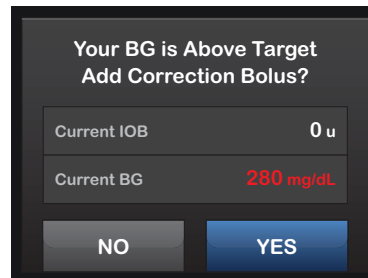


3. Using the onscreen keypad, enter your BG value and tap **DONE**. Once **DONE** is tapped, the BG value is saved in pump History whether or not a bolus is delivered.

BG Above Target

If your BG is above your Target BG, the pump presents you with the option for the pump to calculate and add a cor-

rection bolus to any other bolus you request.

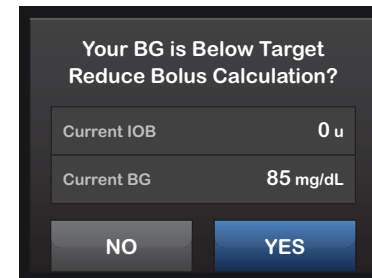


- To accept the correction bolus press **YES**. A correction bolus is calculated and will be added to any food bolus you request on the Bolus Screen.
- To decline the correction bolus, press **NO**. No correction bolus will be added to any food bolus you request on the Bolus Screen.

BG Below Target

If your BG is below your Target BG, the pump presents you with the option for the pump to calculate and subtract a

correction bolus from any other bolus you request.



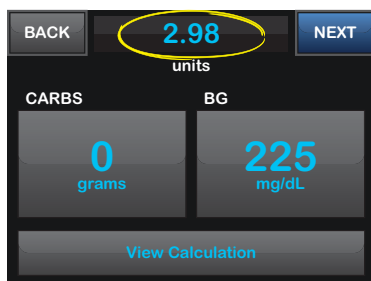
- To accept the correction bolus press **YES**. A correction bolus is calculated and will be subtracted from any food bolus you request on the Bolus Screen.
- To decline the correction bolus, press **NO**. No correction bolus will be subtracted from any food bolus you request on the Bolus Screen.

BG Within Target

If your BG is within your target range, no correction bolus screen is displayed.

7.3 Bolus Override

You can override the calculated bolus by tapping on the calculated units value and entering the units of insulin you want delivered. The bolus override is always active.



7.4 Food Bolus Using Units

If bolusing using a carb ratio, skip to the section [7.5 Food Bolus Using Grams](#).

1. From the Home Screen, tap **BOLUS**. Tap 0 units.
2. Using the onscreen keypad enter units of insulin to be delivered, then tap **DONE**.

⚠ PRECAUTION

ALWAYS confirm that the decimal point placement is correct when entering bolus information. Incorrect decimal point placement can prevent you from getting the proper amount of insulin that your health-care provider has prescribed for you.

3. Tap **NEXT** to confirm the units of insulin to be delivered.
 4. Confirm Request.
 - Tap **YES** if entered data is correct.
 - Tap **NO** to go back to make changes or view calculations.
 5. Tap **DELIVER**.
- ✓ The bolus initiated screen is temporarily displayed.

7.5 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**.
 - To add multiple carb values enter first value, then tap **+/=**, enter second value, tap **+/=**. Continue until done.
 - To clear the value entered and start over, tap the **←** back arrow.
 4. Check that the grams of carb are entered in the correct location on the screen.
 5. Tap **NEXT** to confirm the units of insulin to be delivered.
- You can always tap **View Calculation** to display the Delivery Calculation screen.
6. Confirm Request.

- Tap **YES** if entered data is correct.
 - Tap **NO** to go back to make changes or view calculations.
7. Tap **DELIVER**.

- ✓ The bolus initiated screen is temporarily displayed.

7.6 Extended Bolus

The Extended Bolus feature allows you to deliver part of the bolus now and part of the bolus slowly over a period of up to 8 hours. This can be helpful for high fat meals such as pizza or if you have gastroparesis (delayed stomach emptying).

When using extended bolus, any correction bolus amount will always be given in the DELIVER NOW portion. Talk with your healthcare provider to determine if this feature is appropriate for you, as well as for recommendations on the split between now and later and the duration for the later portion.

Only 1 extended bolus can be active at any given time. However, if the DELIVER LATER portion of an extended bolus is active, you can request another standard bolus.

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

You can always tap **View Calculation** to display the Delivery Calculation screen.

6. Confirm Request.
 - Tap **YES** if entered data is correct.
 - Tap **NO** to go back to make changes or view calculations.
7. Tap **EXTENDED** to turn on the extended feature, then tap **NEXT**.
8. Tap **50%** under DELIVER NOW to adjust the percentage of the food

bolus that is to be delivered immediately.

The percentage value for DELIVER LATER is automatically calculated by the pump. The default is 50% NOW and 50% LATER. The default for DURATION is 2 hours.

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

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.

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**.

You can always 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. Tap **DELIVER**.

15. The bolus initiated screen is temporarily displayed.

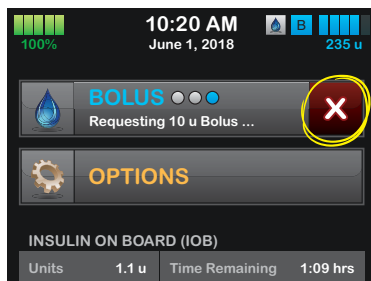
NOTE: Extended Bolus During Insulin Suspension

If the Basal-IQ Technology is on and has suspended insulin delivery during an extended bolus, all remaining bolus insulin will be canceled. If desired, a new bolus must be initiated after insulin delivery has been resumed.

7.7 Canceling or Stopping a Bolus

Canceling a Bolus If delivery HAS NOT STARTED:

1. Tap 1–2–3 to access the Home Screen.
2. Tap X (stop icon) to cancel the bolus.



- ✓ The bolus button will remain inactive while the bolus is being canceled.
- ✓ Once canceled, the bolus button will become active again on the Home Screen.

Stopping a Bolus if delivery of the BOLUS HAS STARTED:

1. Tap 1–2–3 to access the Home Screen.
 2. Tap X (stop icon) to stop delivery.
 3. Tap YES.
- ✓ The BOLUS STOPPED screen is displayed and the units delivered are calculated.
 - ✓ Units requested and delivered are shown.
4. Tap CLOSE.

Chapter 8

Stop/Resume Insulin

8.1 Stopping Insulin Delivery

You can stop all insulin delivery at any time. When you stop all insulin delivery, any active bolus and any active temp rate are immediately stopped. No insulin delivery can take place while your pump is stopped.

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**. A red exclamation mark icon also appears to the right of the time and date.

NOTE: Manually Stopping Insulin and Basal-IQ

If you manually stop insulin delivery, you must manually resume insulin delivery. The Basal-IQ™ Technology does not automatically resume insulin if you decide to stop it manually.

8.2 Resuming Insulin Delivery

If pump screen is not on, press Screen On/Quick Bolus Button once to turn on your t:slim X2 Pump screen.

1. Tap **1–2–3** to access the Home Screen.
 2. Tap **RESUME**.
- ✓ The **RESUMING INSULIN** screen is temporarily displayed.

– OR –

1. From the Home Screen, tap **OPTIONS**.
 2. Tap **RESUME INSULIN**.
 3. Tap **RESUME**.
- ✓ The **RESUMING INSULIN** screen is temporarily displayed.

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Section 3

Additional Pump Operations

Chapter 9

Temporary Basal Rate

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. This feature can be helpful for situations such as exercise or illness.

When you enter the Temp Rate screen, the default values are 100% (current basal rate) and a Duration of 0:15 min. The Temp Rate can be set from a minimum of 0% of current basal rate to a maximum of 250% of current basal rate in increments of 1%.

Duration can be set from a minimum of 15 minutes to a maximum of 72 hours in increments of 1 minute.

If you program a Temp Rate greater than 0% but less than the minimum allowable basal rate of 0.1 units/hr, you will be notified that the selected rate is too low and that it will be set to the minimum allowable rate for delivery.

If you program a Temp Rate more than the maximum allowable basal rate of 15 units/hr, you will be notified that the

selected rate is too high and that it will be set to the maximum allowable rate for delivery.

NOTE: Temp Rate with Basal-IQ

When you start a Temp Rate while using the Basal-IQ Technology, the Temp Rate persists, even if Basal-IQ Technology suspends insulin delivery, unless you manually stop the Temp Rate.

1. From the Home Screen, tap **OPTIONS**.
2. Tap **Temp Rate**.
3. Using the onscreen keypad enter desired percentage. The current rate is 100%. An increase is greater than 100% and decrease is less than 100%.
4. Tap **DONE**.
5. Tap **Duration**. Using the onscreen keypad enter desired length of time for Temp Rate. Tap **DONE**.

You can always tap **View Units** to see the actual units to be delivered.

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

- ✓ The **TEMP RATE STARTED** screen is temporarily displayed.
- ✓ The Screen Lock screen will be displayed with the icon indicating a Temp Rate is active.
 - An orange “T” means a Temp Rate is active.
 - A red “T” means a Temp Rate of 0 is active.

NOTE: Temp Rate After Insulin Resumption

If the Basal-IQ Technology is on and has suspended insulin delivery while a Temp Rate is active, the temp rate timer will remain active. The Temp Rate will be resumed when insulin delivery is resumed as long as the Temp Rate is still active.

9.2 Stopping a Temp Rate

To stop an active temp rate:

1. From 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.

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Chapter 10

Quick Bolus

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/vibration commands without navigating through or viewing the pump screen.

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

The quick bolus delivery setting (grams of carbohydrate or units of insulin) is independent of the active Personal Profile bolus setting.

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Pump Settings**.
4. Tap **Quick Bolus**.

5. Tap **Increment Type**.
6. Tap **units of insulin** or **grams of carbohydrate** to select.
7. Tap **Increment Amount**.
8. Select the preferred increment amount.

NOTE: Incrementing Amount

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

9. Review entered values and tap **SAVE**.
10. Confirm Settings.
 - Tap **YES** if entered data is correct.
 - Tap **NO** to go back to make changes.
11. 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 t:slim X2 Pump's screen. Simply use the Quick Bolus Button to deliver your bolus. Quick boluses are delivered as standard boluses (there is no BG entry or extended bolus).

PRECAUTION

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

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

3. The pump will beep/vibrate once for each increment pressed to confirm desired amount.
4. After the pump beeps/vibrates, press and hold the **Quick Bolus Button** to deliver the bolus.

NOTE: Safety Features

If you want to cancel the bolus and return to the Home Screen, tap **CANCEL** on the QUICK BOLUS screen.

If more than 10 seconds have passed with no input, the bolus is canceled and never delivered.

You cannot exceed the Max Bolus setting defined in your active Personal Profile when using the Quick Bolus feature. Once you reach the Max Bolus amount, a different tone will sound to notify you (if Quick Bolus is set to vibrate, the pump will stop vibrating in response to additional button presses to notify you). Look at the screen to confirm the bolus amount.

You cannot exceed 20 button presses when using the Quick Bolus feature. Once you reach 20 button presses, a different tone will sound to notify you (if Quick Bolus is set

to vibrate, the pump will stop vibrating in response to additional button presses to notify you). Look at the screen to confirm the bolus amount.

If you hear a different tone at any point during programming or the pump stops vibrating in response to button presses, look at the screen to confirm the bolus amount. If the Quick Bolus screen does not display the correct bolus amount, use the touch screen to enter bolus information.

- ✓ The bolus initiated screen is temporarily displayed.

NOTE: Quick Bolus During Insulin Suspension

If the Basal-IQ Technology is on and has suspended insulin delivery during a Quick Bolus, all remaining bolus insulin will be delivered.

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Chapter 11

t:slim X2 Pump Settings

This chapter contains explanations and instructions for Pump Settings that are not covered in other chapters.

11.1 t:slim X2 Pump Volume

Pump Volume is preset to high. A change to the Pump Volume can be made in Pump Settings.

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

PRECAUTION

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

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

4. Tap **Pump Volume**.
5. Tap desired option. Use **Up/Down Arrow** to view additional options.
6. Select preferred volume.
7. Continue to make changes for all Pump Volume options by repeating steps 5 and 6.
8. Tap **SAVE** when all changes are complete.
9. Tap **Tandem Logo** to return to the Home Screen.

11.2 Screen Options

The Screen Options for your t:slim X2 Pump include Screen Timeout and Feature Lock.

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

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

11.3 Turn Feature Lock ON or OFF

Feature Lock is preset to off. With the Feature Lock turned on, you cannot deliver a bolus, change any pump settings or access any Personal Profiles.

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 and tap **SAVE**.

3. Tap **Tandem Logo** to return to the Home Screen.
4. Tap **Feature Lock** to turn On or Off and tap **SAVE**.
- ✓ A screen to verify that you want to activate the Feature Lock will be displayed.
5. Tap **YES** to confirm.
6. Tap **SAVE**.
7. Tap **Tandem Logo** to return to the Home Screen.

 NOTE: Pump Volume

When Feature Lock is turned on, Pump Volume will be set to high until the Feature Lock is turned off.

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Chapter 12

t:slim X2 Pump Info and History

12.1 t:slim X2 Pump Info

Your t:slim X2™ Pump allows access to information about your pump. In the Pump Info screen you have access to items such as your pump Serial Number, Tandem Diabetes Care 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 X2 Pump History

Pump History displays a historical log of pump events. At least 90 days of data can be viewed in History. When the

maximum number of events is reached, the oldest events are removed from the history log and replaced with the most recent events. The following can be viewed in History:

Delivery Summary, Total Daily Dose, Bolus, Basal, Load, BG, Alerts and Alarms, Basal-IQ, and Complete.

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

Total Daily Dose breaks down basal and bolus delivery into units and percentages for each individual day. You can scroll through each individual day to see your total insulin delivery.

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

The letter “D” (D: Alert) before an Alert or Alarm indicates the time it was

declared. The letter “C” (C: Alert) indicates the time it was cleared.

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

The Basal-IQ™ history shows the historical log of the Basal-IQ Technology. status, including when the feature is enabled or disabled, as well as the time that insulin suspended and resumed.

1. From the Home Screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Pump History**.
4. Tap desired option.
5. Tap **Tandem Logo** to return to the Home Screen.

Chapter 13

t:slim X2 Pump Reminders

Your t:slim X2 Pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check your BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

If multiple Reminders, Alerts, and Alarms happen at the same time, Alarms will be displayed first, Alerts will be displayed second, and Reminders will be displayed third. Each must be confirmed separately until all have been confirmed.

Information in this section will help you learn how to respond to Reminders.

Reminders notify you with a single sequence of 3 notes or a single vibration depending on the volume/vibrate setting in Pump Volume. They repeat

every 10 minutes 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 on, you need to set a low BG value that triggers the reminder, as well as how much time should pass before the reminder occurs.

The default for this reminder is preset to off. If on, Remind Me Below 70 mg/ dL, and Remind Me After 15 min, but you can set these values from 70 to 120 mg/dL and 10 to 20 min.

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alert Settings**.
4. Tap **Pump Reminders**.
5. Tap **Low BG**.

6. Low BG is set to on; to turn off, tap **LOW BG**.

- a. Tap **Remind Me Below** and using the onscreen keypad, enter a Low BG value (from 70 to 120 mg/dL) that you want to trigger the reminder, then tap **DONE**.
- b. Tap **Remind Me After** and using the onscreen keypad, enter the time (from 10 to 20 min), then tap **DONE**.
- c. Tap **SAVE** when all changes are complete.
- d. Tap **Tandem Logo** to return to the Home Screen.

To Respond to the Low BG Reminder

To clear the reminder, tap **CLOSE** and then check BG using your blood glucose meter.

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 this reminder on, you need to set a high BG value that triggers the reminder, as well as how much time should pass before the reminder occurs.

The default for this reminder is preset to off. If on, Remind Me Above 200 mg/dL, and Remind Me After 120 min, but you can set these values from 150 to 300 mg/dL and 1 to 3 hrs.

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alert Settings**.
4. Tap **Pump Reminders**.
5. Tap **High BG**.
6. High BG is set to on; to turn off, tap **High BG**.

- a. Tap **Remind Me Above** and using the onscreen keypad, enter a High BG value (from 150 to 300 mg/dL) that you want to trigger the reminder, then tap **DONE**.
- b. Tap **Remind Me After** and using the onscreen keypad, enter the time (from 1 to 3 hours), then tap **DONE**.
- c. Tap **SAVE** when all changes are complete.

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

To Respond to the High BG Reminder

To clear the reminder tap **CLOSE** and then check BG using your blood glucose meter.

13.3 After Bolus BG Reminder

The After Bolus BG Reminder prompts you to test your BG at a selected time after bolus delivery. When turning this

reminder on, you need to set how much time should pass before the reminder occurs. The default is 1 hour and 30 minutes. It can be set from 1 to 3 hours.

1. From the Home Screen, tap **OPTIONS**
2. Tap **My Pump**.
3. Tap **Alert Settings**.
4. Tap **Pump Reminders**.
5. Tap **After Bolus BG**.
6. After Bolus BG is set to on; to turn off, tap **After Bolus BG**.
7. Tap **Remind Me After** and using the onscreen keypad, enter the time (from 1 to 3 hours) that you want to trigger the reminder, then tap **DONE**.
8. Tap **SAVE** when all changes are complete.
9. Tap **Tandem Logo** to return to the Home Screen.

To Respond to the After Bolus BG Reminder

To clear the reminder tap **CLOSE** and then check BG using your blood glucose meter.

13.4 Missed Meal Bolus Reminder

The Missed Meal Bolus Reminder lets you know if a bolus was not delivered during a specified time period. Four separate reminders are available. When programming this reminder you need to select the Days, the Start Time, and End Time for each reminder.

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alert Settings**.
4. Tap **Pump Reminders**.
5. Tap **Missed Meal Bolus**.
6. On the Missed Meal Bolus screen, tap which reminder you want to set

(Reminder 1 to 4) and do the following:

- a. Tap **Reminder 1** (or 2, 3, 4).
- b. Reminder 1 is set to on; to turn-off, tap **Reminder 1**.
- c. Tap **Selected Days** and tap the day(s) you want the reminder to be on, then tap **BACK**.
- d. Tap **Start Time**, tap **Time** and using the onscreen keypad enter the start time, then tap **DONE**.
- e. Tap **Time of Day** to select AM or PM, then tap **DONE**.
- f. Tap **End Time**, tap **Time** and using the onscreen keypad enter the end time, then tap **DONE**.
- g. Tap **Time of Day** to select AM or PM, then tap **DONE**.
- h. Tap **SAVE** when all changes are complete.

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

To Respond to the Missed Meal Bolus Reminder

To clear the reminder tap **CLOSE** and deliver a bolus if necessary.

13.5 Site Reminder

The Site Reminder prompts you to change your infusion set. The default for this reminder is preset to off. If on, the reminder can be set for 1 to 3 days and at a time of day selected by you.

For detailed information on the Site Reminder feature, see [Section 5.6 Setting Site Reminder](#).

To Respond to the Site Reminder

To clear the reminder tap **CLOSE** and change your infusion set.

Chapter 14

User Settable Alerts and Alarms

14.1 Low Insulin Alert

Your t:slim X2™ Pump keeps track of how much insulin remains in the cartridge and alerts you when it is low. The default for this alert is preset to 20 units. You can set this alert setting anywhere between 10 and 40 units. When the insulin amount reaches the set value, the Low Insulin Alert beeps/ vibrates and appears on the screen. After the alert is cleared, the low insulin indicator (a single red bar on the insulin level display on the Home Screen appears).

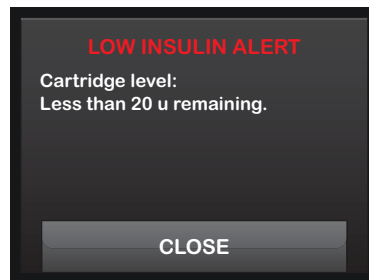
1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alert Settings**.
4. Tap **Pump Alerts**.
5. Tap **Low Insulin**.
6. Using the onscreen keypad, enter the number of units (from 10 to 40 units) that you want the Low Insulin

Alert value to be set to, and tap **DONE**.

7. Tap **SAVE** when all changes are complete.

To Respond to the Low Insulin Alert

To clear the alert, tap **CLOSE**.



14.2 Auto-Off Alarm

Your t:slim X2 Pump can stop insulin delivery and alert you (or whoever is with you) if there has been no interaction with the pump within a specified period of time. The default for this alarm is preset to 12 hours. You can set it anywhere between 5 and 24 hours, or

off. This alarm notifies you that there has been no interaction with the pump in the specified number of hours and the pump will shut down after 30 seconds.

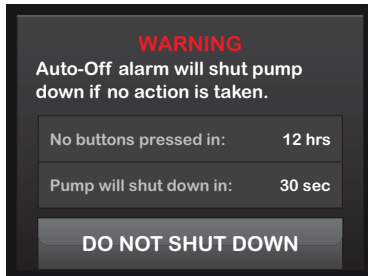
When the number of hours since you have pressed the Screen On/Quick Bolus Button and tapped any interactive screen option or delivered a Quick Bolus passes the set value, the Auto-Off Alarm beeps and appears on the screen, and insulin delivery stops.

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alert Settings**.
4. Tap **Pump Alerts**.
5. Tap **Auto-Off**. A confirmation screen will appear.
 - Tap **YES** to continue.
 - Tap **NO** to go back.

6. Verify Auto-Off is set to on, then tap **Time**.
7. Using the onscreen keypad, enter the number of hours (from 5 to 24 hrs) that you want the Auto-Off Alarm to be triggered, and tap **DONE**.
8. Tap **DONE**, then tap **SAVE** when all changes are complete.
9. Tap **Tandem Logo** to return to the Home Screen.

To Respond to Auto-Off Warning

Tap **DO NOT SHUT DOWN**.

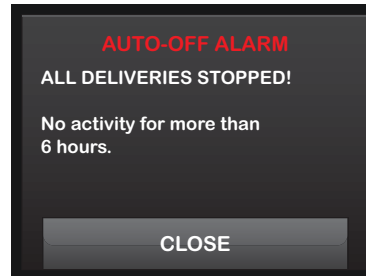


- ✓ The warning clears and the pump returns to normal operation.

If you do not clear the warning within the 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

Tap **CLOSE**.



- ✓ The Home Screen appears, indicating a status of "All Deliveries Stopped."

You must resume delivery to continue therapy, refer to [Section 8.2 Resuming Insulin Delivery](#).

Section 4

Pump Safety Alerts and Alarms

Chapter 15

t:slim X2 Pump Alerts

Your t:slim X2™ Pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check you BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

If multiple Reminders, Alerts, and Alarms happen at the same time, Alarms will be displayed first, Alerts will be displayed second, and Reminders will be displayed third. Each must be confirmed separately until all have been confirmed.

Information in this section will help you learn how to respond to Alerts.

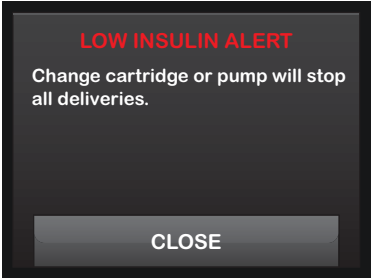
Alerts notify you with 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume. They repeat regularly

until acknowledged. Alerts do not escalate.

NOTE: CGM Alerts

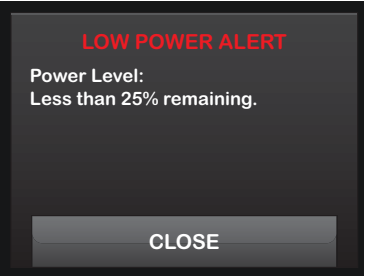
There is an additional list of Alerts and Errors related to CGM use in [Chapter 26 CGM Alerts and Errors](#).

15.1 Low Insulin Alert

What will I see on the screen? 	What does it mean? 5 units or less of insulin remain in the cartridge. How will the System notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume. Will the System re-notify me? Yes, every 5 minutes until acknowledged. How should I respond? Tap CLOSE. Change your cartridge as soon as possible to avoid the EMPTY CARTRIDGE ALARM and running out of insulin.
--	---

15.2 Low Power Alerts

Low Power Alert 1

What will I see on the screen? 	What does it mean? Less than 25% of battery power remains.
	How will the System notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the System re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap CLOSE. Charge your pump as soon as possible to avoid the second LOW POWER ALERT.

 NOTE: Low Battery Display

Once the LOW POWER ALERT occurs, the low-power indicator (a single red bar on the battery level display on the Home Screen) appears.

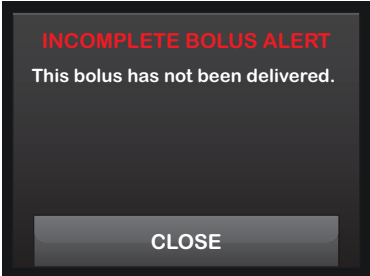
Low Power Alert 2

LOW INSULIN ALERT Change cartridge or pump will stop all deliveries. CLOSE	What does it mean? Less than 5% of battery power remains. Insulin delivery will continue for 30 minutes and then the pump will power off and insulin delivery will stop.
	How will the System notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the System re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap CLOSE . Charge your pump immediately to avoid the LOW POWER ALARM and system power off.

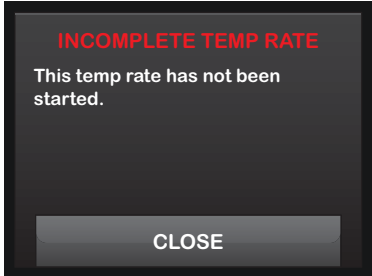
NOTE: Low Battery Display

Once the LOW POWER ALERT occurs, the low-power indicator (a single red bar on the battery level display on the Home Screen) appears.

15.3 Incomplete Bolus Alert

What will I see on the screen? 	What does it mean? You started a bolus request but did not complete the request within 90 seconds.
	How will the System notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the System re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? • Tap CLOSE. The Bolus screen will appear. Continue with your bolus request. • Tap BACK if you do not want to continue your bolus request.

15.4 Incomplete Temp Rate Alert

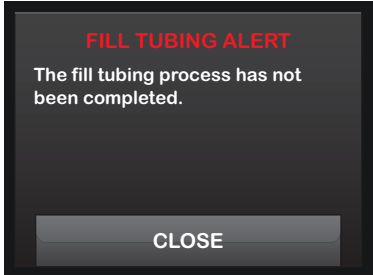
What will I see on the screen? 	What does it mean? You started to set up a temp rate but did not complete the request within 90 seconds. How will the System notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume. Will the System re-notify me? Yes, every 5 minutes until acknowledged. How should I respond? • Tap CLOSE. The Temp Rate screen will appear. Continue setting up your temp rate. • Tap BACK if you do not want to continue setting up your temp rate.
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15.5 Incomplete Load Sequence Alerts

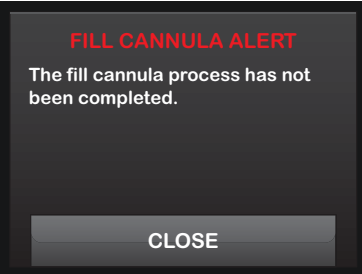
Incomplete Cartridge Change Alert

What will I see on the screen? CHANGE CARTRIDGE ALERT The cartridge loading process has not been completed. CLOSE	What does it mean? You selected Change Cartridge from the Load menu but did not complete the process within 3 minutes.
	How will the System notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the System re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap CLOSE. Complete the cartridge change process.

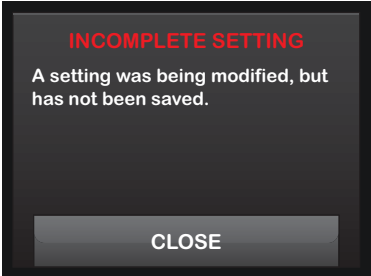
Incomplete Fill Tubing Alert

What will I see on the Screen? 	What does it mean? You selected Fill Tubing from the Load menu but did not complete the process within 3 minutes. How will the System notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume. Will the System re-notify me? Yes, every 5 minutes until acknowledged. How should I respond? Tap CLOSE. Complete the fill tubing process.
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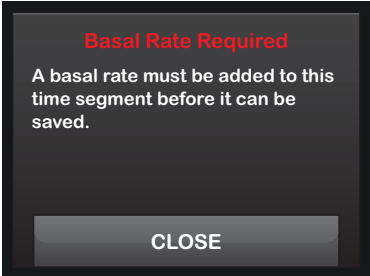
Incomplete Fill Cannula Alert

What will I see on the Screen? 	What does it mean? You selected Fill Cannula from the Load menu but did not complete the process within 3 minutes. How will the System notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume. Will the System re-notify me? Yes, every 5 minutes until acknowledged. How should I respond? Tap CLOSE. Complete the cannula fill process.
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15.6 Incomplete Setting Alert

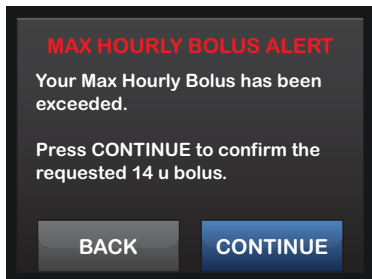
What will I see on the screen? 	What does it mean? You started to set up a new Personal Profile but did not save or complete the programming within 5 minutes. How will the System notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume. Will the System re-notify me? Yes, every 5 minutes until acknowledged. How should I respond? Tap CLOSE. Complete programming the Personal Profile.
--	--

15.7 Basal Rate Required Alert

What will I see on the screen? A screenshot of a mobile device screen showing a dark background with the text "Basal Rate Required" in red at the top. Below it, in white, is the message "A basal rate must be added to this time segment before it can be saved." At the bottom, there is a grey button with the word "CLOSE" in white capital letters.	What does it mean? You did not enter a basal rate in a time segment in Personal Profiles. A basal rate must be entered in each time segment (rate can be 0 u/hr).
	How will the System notify me? Prompt screen only.
	Will the System re-notify me? No. A basal rate must be entered to save the time segment.
	How should I respond? Tap CLOSE. Enter a basal rate in the time segment.

15.8 Max Hourly Bolus Alert

What will I see on the screen?



What does it mean?

In the previous 60 minutes, you requested total bolus delivery that is more than 1.5 times your Max Bolus setting.

How will the System notify me?

Prompt screen only.

Will the System re-notify me?

No. You must tap **BACK** or **CONTINUE** to deliver the bolus.

How should I respond?

- Tap **BACK** to return to the Bolus screen and adjust the bolus delivery amount.
- Tap **CONTINUE** to deliver the bolus.

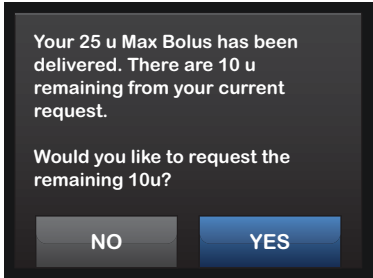
15.9 Max Bolus Alerts

Max Bolus Alert 1

What will I see on the screen? MAX BOLUS ALERT Your 20 u Max Bolus setting has been exceeded. Press CONTINUE to confirm a bolus of 20 u. BACK CONTINUE	What does it mean? You requested a bolus larger than the Max Bolus setting in your active Personal Profile. How will the System notify me? Prompt screen only. Will the System re-notify me? No. You must tap BACK or CONTINUE to deliver the bolus. How should I respond? • Tap BACK to return to the Bolus screen and adjust the bolus delivery amount. • Tap CONTINUE to deliver the amount of your Max Bolus setting.
--	--

Max Bolus Alert 2

The following applies only if you have Carbs turned on in your active Personal Profile and your Max Bolus amount is set to 25 units.

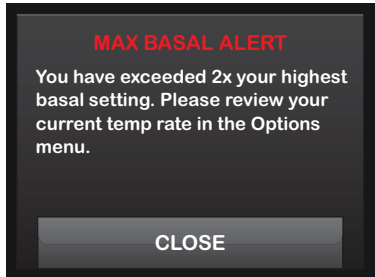
What will I see on the screen? 	What does it mean? Your Max Bolus is set to 25 units and you requested a bolus larger than 25 units. How will the System notify me? Prompt screen only. Will the System re-notify me? No. You must tap NO or YES to deliver the remaining amount of the bolus request. How should I respond? Before responding to this Alert, always consider whether your bolus insulin needs have changed since you requested the original bolus. • Tap YES to deliver the remaining amount of the bolus request. A confirmation screen will appear. • Tap NO if you do not want to deliver the remaining amount of the bolus request.
--	---

15.10 Max Basal Alerts

Max Basal Alert 1

What will I see on the screen? MAX BASAL ALERT You are going to exceed 2x your highest basal setting. Press CONTINUE to override the setting. BACK CONTINUE	What does it mean? When entering a basal rate or requesting a temp rate, you requested a basal rate more than 2 times the highest basal rate defined in your Personal Profile. How will the System notify me? Prompt screen only. Will the System re-notify me? No. You must tap BACK or CONTINUE to move forward. How should I respond? • Tap BACK to return to the previous screen to adjust the amount. • Tap CONTINUE to dismiss the alert and continue with the request.
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Max Basal Alert 2

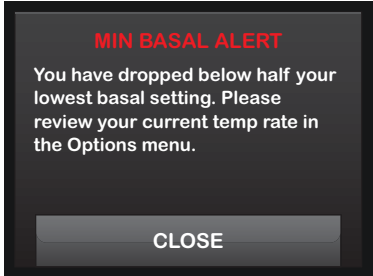
What will I see on the screen? 	What does it mean? An active temp rate exceeded 2 times your highest basal setting defined in your Personal Profile. How will the System notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume. Will the System re-notify me? Yes, every 5 minutes until acknowledged. How should I respond? Tap CLOSE and review your current temp rate in the Options menu.
--	--

15.11 Min Basal Alerts

Min Basal Alert 1

What will I see on the screen? MIN BASAL ALERT The programmed rate is less than half your lowest basal setting. Press CONTINUE to confirm. BACK CONTINUE	What does it mean? When entering a basal rate or requesting a temp rate, you requested a basal rate less than half of the lowest basal rate defined in your Personal Profile. How will the System notify me? Prompt screen only. Will the System re-notify me? No. You must tap BACK or CONTINUE to move forward. How should I respond? • Tap BACK to return to the previous screen to adjust the amount. • Tap CONTINUE to dismiss the alert and continue with the request.
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Min Basal Alert 2

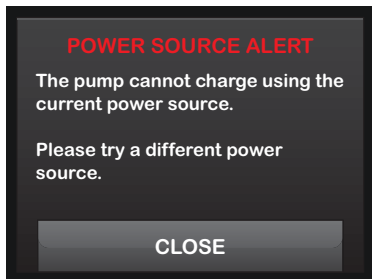
What will I see on the screen? 	What does it mean? An active temp rate dropped below half of your lowest basal setting defined in your Personal Profile. How will the System notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume. Will the System re-notify me? Yes, every 5 minutes until acknowledged. How should I respond? Tap CLOSE and review your current temp rate in the Options menu.
--	--

15.12 Connection Error Alert

What will I see on the screen? CONNECTION ERROR ALERT Pump cannot connect with the computer. Press CLOSE and reconnect the USB cable to try again. CLOSE	What does it mean? You connected your t:slim X2 Pump to a computer with the USB cable to charge it or upload data to t:connect and a connection could not be made. How will the System notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume. Will the System re-notify me? Yes, every 5 minutes until acknowledged. How should I respond? Tap CLOSE. Disconnect and reconnect the USB cable to try again.
--	--

15.13 Power Source Alert

What will I see on the screen?



What does it mean?

You connected your t:slim X2 Pump to a power source that does not have enough power to charge the pump.

How will the System notify me?

2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.

Will the System re-notify me?

Yes, every 5 minutes until acknowledged.

How should I respond?

Tap CLOSE. Connect the pump to a different power source to charge.

15.14 Data Error Alert	
What will I see on the screen? DATA ERROR ALERT Please verify that your active profile and pump settings are accurate. CLOSE	What does it mean? Your t:slim X2 Pump encountered a condition that could potentially result in a loss of data.
	How will the System notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the System re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap CLOSE. Check your Personal Profiles and pump settings to verify that they are accurate. See Section 6.4 Editing or Reviewing an Existing Profile.

Chapter 16

t:slim X2 Pump Alarms

PRECAUTION

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

Your t:slim X2 Pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check you BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

If multiple Reminders, Alerts, and Alarms happen at the same time, Alarms will be displayed first, Alerts will be displayed second, and Reminders will be displayed third. Each must be confirmed separately until all have been confirmed.

Information in this section will help you learn how to respond to Alarms.

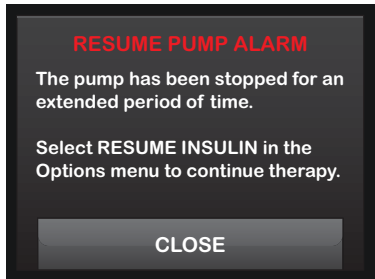
Alarms notify you with 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume. If not acknowledged, alarms escalate to highest volume and vibrate. Alarms repeat regularly until the condition that caused the alarm is corrected.

NOTE: CGM Alerts and Errors

There is an additional list of Alerts and Errors related to CGM use in Chapter [26 CGM Alerts and Errors](#).

16.1 Resume Pump Alarm

What will I see on the screen?



What does it mean?

You tapped STOP INSULIN in the Options menu and insulin delivery has been stopped for more than 15 minutes.

How will the System notify me?

3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.

Will the System re-notify me?

Yes.

- If not acknowledged by tapping CLOSE, the system will re-notify you every 3 minutes at highest volume and vibrate.
- If acknowledged by tapping CLOSE, the system will re-notify you in 15 minutes.

How should I respond?

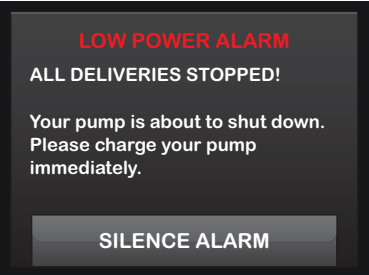
To resume insulin, from the Options menu, tap RESUME INSULIN and tap RESUME to confirm.

16.2 Low Power Alarms

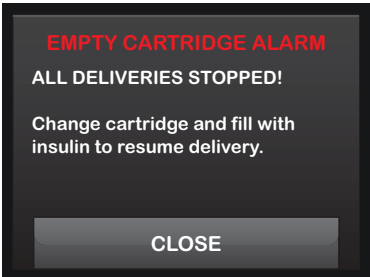
Low Power Alarm 1

What will I see on the screen? LOW POWER ALARM ALL DELIVERIES STOPPED! Your pump is about to shut down. Please charge your pump immediately. CLOSE	What does it mean? Your t:slim X2 Pump detected a power level of 1% or less remaining and all deliveries have stopped.
	How will the System notify me? 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the System re-notify me? Yes, the System will re-notify you every 3 minutes until no power remains and the pump shuts down.
	How should I respond? Tap CLOSE. Charge your pump immediately to resume insulin delivery.

Low Power Alarm 2

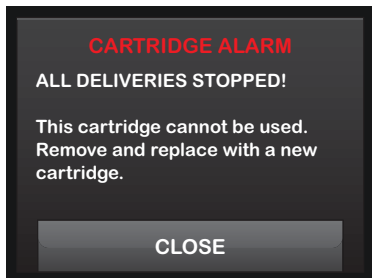
	What does it mean? Your t:slim X2 Pump detected a voltage level too low to ensure normal performance and all deliveries have stopped. How will the System notify me? A series of rapid beeps at maximum volume for at least 20 seconds before the System shuts down. Will the System re-notify me? The pump will power back on once it has been plugged into a charging source and has reached an adequate level of charge. How should I respond? Tap SILENCE ALARM. Charge your pump immediately to resume insulin delivery.
---	--

16.3 Empty Cartridge Alarm

What will I see on the screen? 	What does it mean? Your t:slim X2 Pump detected that the cartridge is empty and all deliveries have stopped. How will the System notify me? 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume. Will the System re-notify me? Yes. The system will re-notify you every 3 minutes until you change the cartridge. How should I respond? Tap CLOSE. Change your cartridge immediately by tapping OPTIONS from the Home Screen, then Load and follow the instructions in section 5.3 Filling and Loading a t:slim Cartridge.
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16.4 Cartridge Error Alarm

What will I see on the screen?



What does it mean?

Your t:slim X2 Pump detected that the cartridge could not be used and all deliveries have stopped. This can be caused by cartridge defect, not following the proper procedure to load the cartridge, or over filling the cartridge (with more than 300 units of insulin).

How will the System notify me?

3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.

Will the System re-notify me?

Yes. The system will re-notify you every 3 minutes until you change the cartridge.

How should I respond?

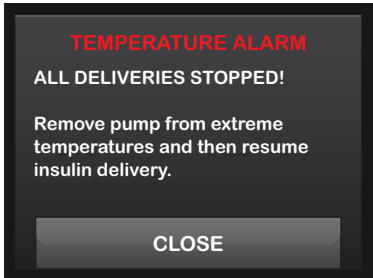
Tap **CLOSE**. Change your cartridge immediately by tapping **OPTIONS** from the Home Screen, then **Load** and follow the instructions in section 5.3 [Filling and Loading a t:slim Cartridge](#).

16.5 Cartridge Removal Alarm

What will I see on the screen? CARTRIDGE ALARM ALL DELIVERIES STOPPED! The cartridge cannot be detected. Press INSTALL to install a new cartridge or press CONNECT to reconnect the current cartridge. CONNECT INSTALL	What does it mean? Your t:slim X2 Pump detected that the cartridge has been removed and all deliveries have stopped. How will the System notify me? 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume. Will the System re-notify me? Yes. The system will re-notify you every 3 minutes until you reconnect the current cartridge or change the cartridge. How should I respond? Tap CONNECT to reattach the current cartridge. Tap INSTALL to load a new cartridge.
--	---

16.6 Temperature Alarm

What will I see on the screen?



What does it mean?

Your t:slim X2 Pump detected an internal temperature below 35°F (2°C) or above 113°F (45°C) or a battery temperature below 35°F (2°C) or above 125°F (52°C) and all deliveries have stopped.

How will the System notify me?

3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.

Will the System re-notify me?

Yes. The system will re-notify you every 3 minutes until a temperature in the operating range is detected.

How should I respond?

Tap **CLOSE**. Remove the pump from the extreme temperature and then resume insulin delivery.

16.7 Occlusion Alarm 1	
What will I see on the screen? OCCLUSION ALARM ALL DELIVERIES STOPPED! Insulin delivery may be blocked. Check cartridge, tubing and site. CLOSE	What does it mean? Your t:slim X2 Pump detected that insulin delivery is blocked and all deliveries have stopped. See Section 30.4 t:slim X2 Pump Performance Characteristics for more information on how long it can take the system to detect an occlusion.
	How will the System notify me? 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the System re-notify me? Yes. The System will re-notify you every 3 minutes until you resume insulin delivery.
	How should I respond? Tap CLOSE. Check the cartridge, tubing, and infusion site for any sign of damage or blockage and correct the condition. To resume insulin, from the Options menu, tap RESUME INSULIN and tap RESUME to confirm.

NOTE: Occlusion During Bolus

If the occlusion alarm occurs during bolus delivery, after tapping **CLOSE** a screen will appear letting you know how much of the requested bolus was delivered before the occlusion alarm. When the occlusion is cleared, some or all of the previously requested insulin volume may be delivered. Test your BG at the time of alarm and follow your healthcare provider's instructions for managing potential or confirmed occlusions.