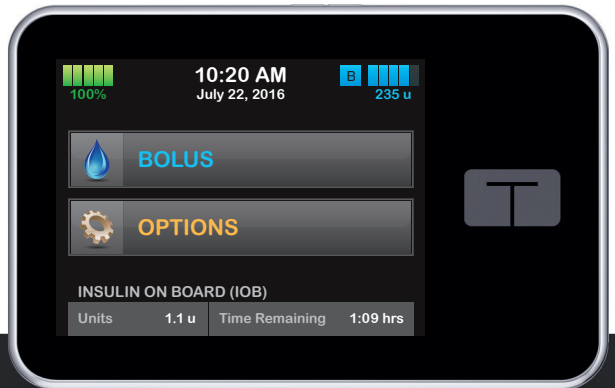
t:slim®
Insulin Pump



User Guide

℞ Only

TANDEM® DIABETES CARE

touch simplicity®

t:slim Insulin Pump User Guide

Software Version: Trestles

Congratulations on the purchase of your new t:slim System. Your decision to use insulin pump therapy is a sign of your commitment to your diabetes care. We recognize and respect the importance of your decision. We also recognize that your t:slim System 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 System. 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 System.

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 System is made up of the t:slim® Insulin Pump and the t:slim 3mL (300 units) cartridge. The t:slim 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 t:slim System is indicated for use in individuals 6 years of age and greater.

The t:slim System is intended for single patient use and requires a prescription.

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

1.2 About this User Guide

This User Guide covers important information on how to operate your t:slim 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 Pump may be referred to as “your pump” or “your t:slim Pump”. The t:slim cartridge may be referred to as “your cartridge.” Together, the t:slim Insulin Pump and the t:slim cartridge may be referred to as “your system”.

The User Guide is organized into sections that allow you to learn to use your t:slim System.

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 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.

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

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 and 11 of this User Guide.

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 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, **DO** turn off the Quick Bolus feature to avoid inadvertent bolus delivery. With the Feature Lock turned on, the Quick Bolus feature is 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 of 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.
Touch Screen	The front glass screen of your pump, which displays all programming, operating, and alarm/alert information.
Tap	Quickly and lightly touch the screen with your finger.
Press	Use your finger to depress a physical button (the Screen On/Quick Bolus Button is the only physical/hardware button on your t:slim Pump).
Hold	Keep pressing a button or touching an icon or menu until its function is complete.
Menu	A list of options on your touch screen that allow you to perform specific tasks.
Icon	An image on your touch screen that indicates an option or item of information, or a symbol on the back of your t:slim Pump or its packaging.

Chapter 2

Important Safety Information

2.1 Indications for Use

Indications for Use

The t:slim® Insulin Delivery System is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 6 years of age and greater. The device is indicated for use with NovoLog or Humalog U-100 insulin.

2.2 Contraindications

Contraindications

The t:slim System 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.

2.3 System Warnings

WARNINGS

DO NOT start to use your t:slim 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 at (877) 801-6901.

DO NOT start to use your t:slim System before you have been appropriately trained on its use by a certified t:slim System trainer. Consult with your healthcare provider for your individual training needs for the t:slim 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. 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 t:slim 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, Inc. 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 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 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, **DO** turn off the Quick Bolus feature to avoid inadvertent bolus delivery. With the Feature Lock turned on, the Quick Bolus feature is 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.

WARNING – Radiology and Medical Procedures and your t:slim System

ALWAYS notify the provider/technician about your diabetes and your t:slim System. If you need to discontinue use of the System 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 t:slim 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.

2.4 System Precautions

PRECAUTIONS

DO NOT open or attempt to repair your System. The System is a sealed device that should be opened and repaired only by Tandem Diabetes Care, Inc. Modification could result in a safety hazard. If your System seal is broken, the System 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 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.

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 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 System'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 System. 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 System and contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

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.

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 System 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 System 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 System.

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 System is not suitable for use in these areas and there is a risk of explosion. Remove your pump if you need to enter these areas.

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 System'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, and infusion sets following the instructions from your healthcare provider. Wash your hands thoroughly after handling used System components.

2.5 Potential Benefits From Using the System

- The t:slim System 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 System 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 System's bolus calculator will recommend a bolus based on the entire amount of carbohydrates entered, which can help eliminate guesswork.

- The System 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.

2.6 Possible Risks From Using the System

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

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

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

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 de-

termine 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.

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 Pump:

- You hear an audible alert
- Your 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.

Chapter 3

Getting to Know Your t:slim System

3.1 What your t:slim System Package Includes

Your t:slim System should include the following items:

1. t:slim Insulin Pump
2. Pump Case
3. t:slim System User Guide
4. t:connect Getting Started Guide
5. USB Cable
6. Wall Power USB Adapter
7. Car Power USB Adapter
8. Cartridge Removal Tool

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

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

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

Supply Reordering

To order cartridges, infusion sets, supplies and accessories, please contact Tandem Diabetes Care, Inc. 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 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 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 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 Pump screen.

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

Units
Units are the measurement for insulin.

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

3.3 Explanation of System Symbols

The following are symbols (and their descriptions), which you may find on your t:slim System and/or its packaging. These symbols tell you about the proper and safe use of the System.

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

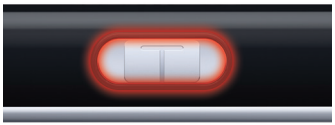
Symbol	Meaning
	Use By Date
	Do Not Re-Use
STERILE R	Sterile by Radiation
PYROGEN	Non Pyrogenic
	Two-sided Temperature Limits
LOT	Lot Number
	Non-ionizing Radiation
	Date of Manufacture
	Two-Sided Humidity Limits

3.4 Explanation of System Icons

The following icons may appear in the status area (to the left or right of the time and date) on your t:slim Pump Home Screen:

Icon	Meaning
	A system reminder, alert, error, or alarm is active.
	Basal insulin is programmed and being delivered.
	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.

3.5 Explanation of System Colors



Red LED

» 1 red blink every 30 seconds indicates a malfunction or alarm condition.

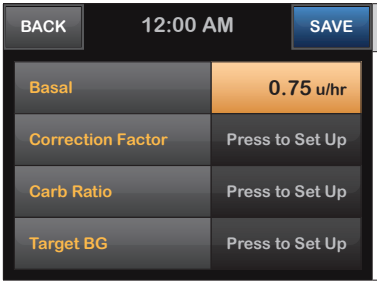
Yellow LED

» 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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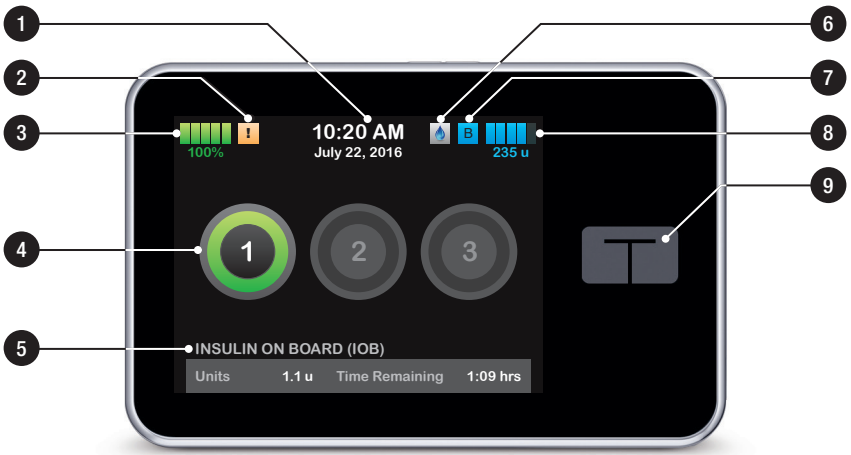
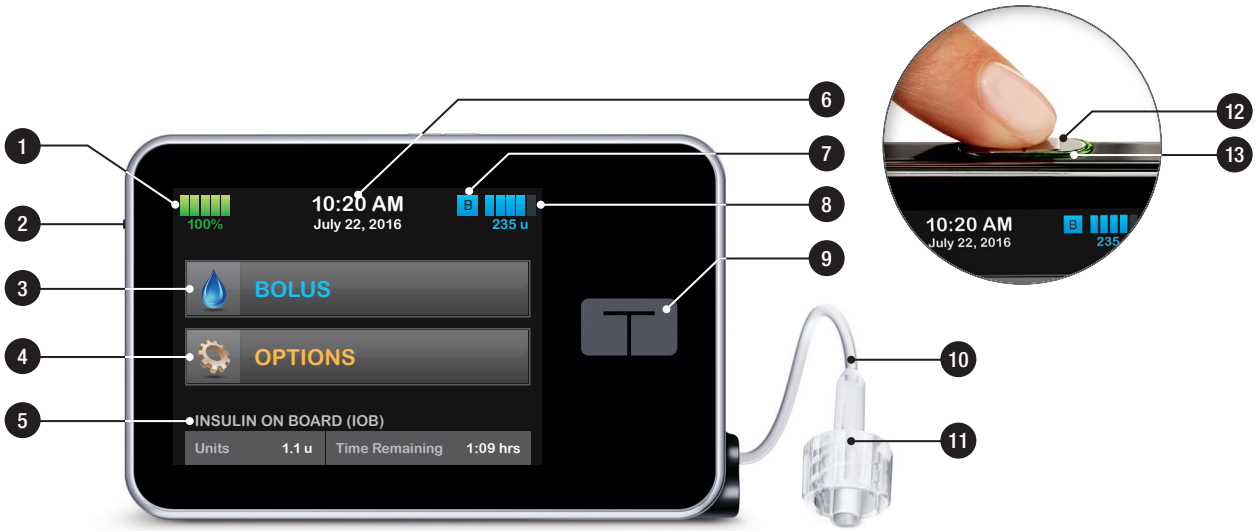
3.6 Screen Lock

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.


1
2
3
4
5
6
7
8
9
I
100%
10:20 AM
July 22, 2016
B
235 u
1
2
3
INSULIN ON BOARD (IOB)
Units 1.1 u Time Remaining 1:09 hrs

3.7 Home Screen

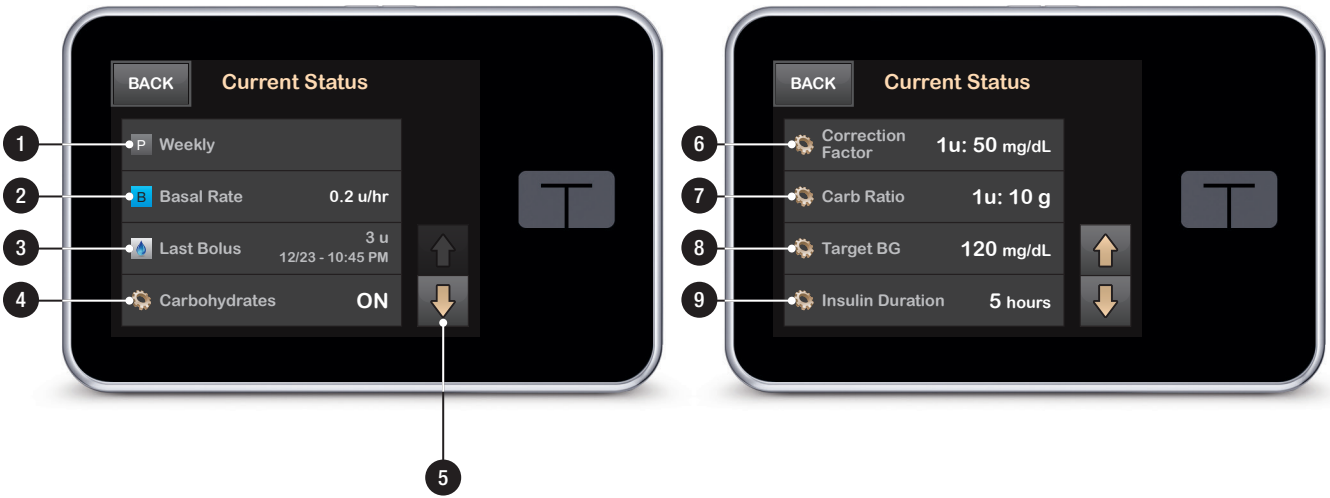
1. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
2. **USB Port:** Port to charge your t:slim Pump battery. Close the cover when not in use.
3. **Bolus:** Program and deliver a bolus.
4. **Options:** Stop/Resume insulin delivery, manage Pump Settings, 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 Connection:** Connects the cartridge tubing to the infusion set tubing.
12. **Screen On/Quick Bolus Button:** Turns the t:slim Pump screen on/off or programs a Quick Bolus (if activated).
13. **LED Indicator:** Illuminates when connected to a power supply and indicates proper functionality.


1
2
3
4
5
6
7
8
9
10
11
12
13
100%
10:20 AM
July 22, 2016
B
235 u
BOLUS
OPTIONS
INSULIN ON BOARD (IOB)
Units
1.1 u
Time Remaining
1:09 hrs
10:20 AM
July 22, 2016
B
235

3.8 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.

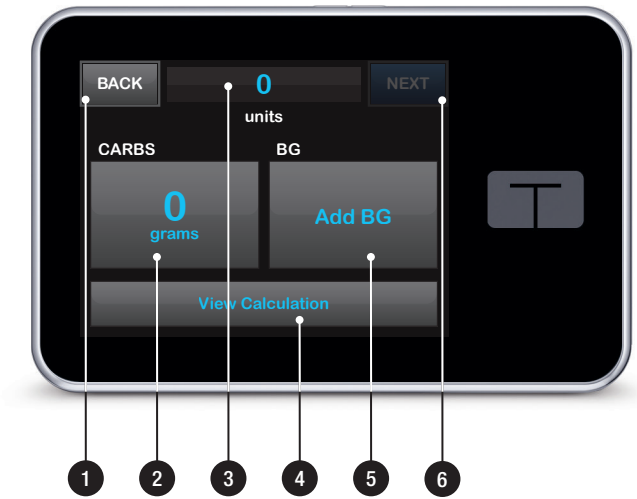
1. **Profile:** Displays current active Personal Profile.
2. **Basal Rate:** Displays current basal rate being delivered. (If a Temp Rate is active, it is displayed in units/hr.)
3. **Last Bolus:** Displays the amount, date and time of last bolus.
4. **Carbohydrates:** Indicates whether feature is on 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.


BACK
Current Status
P Weekly
B Basal Rate 0.2 u/hr
Last Bolus 3 u 12/23 - 10:45 PM
Carbohydrates ON
1
2
3
4
5
BACK
Current Status
Correction Factor 1u: 50 mg/dL
Carb Ratio 1u: 10 g
Target BG 120 mg/dL
Insulin Duration 5 hours
6
7
8
9

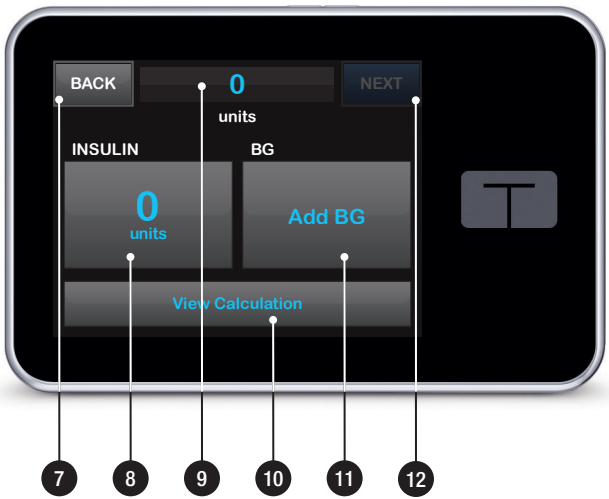
3.9 Bolus Screen

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

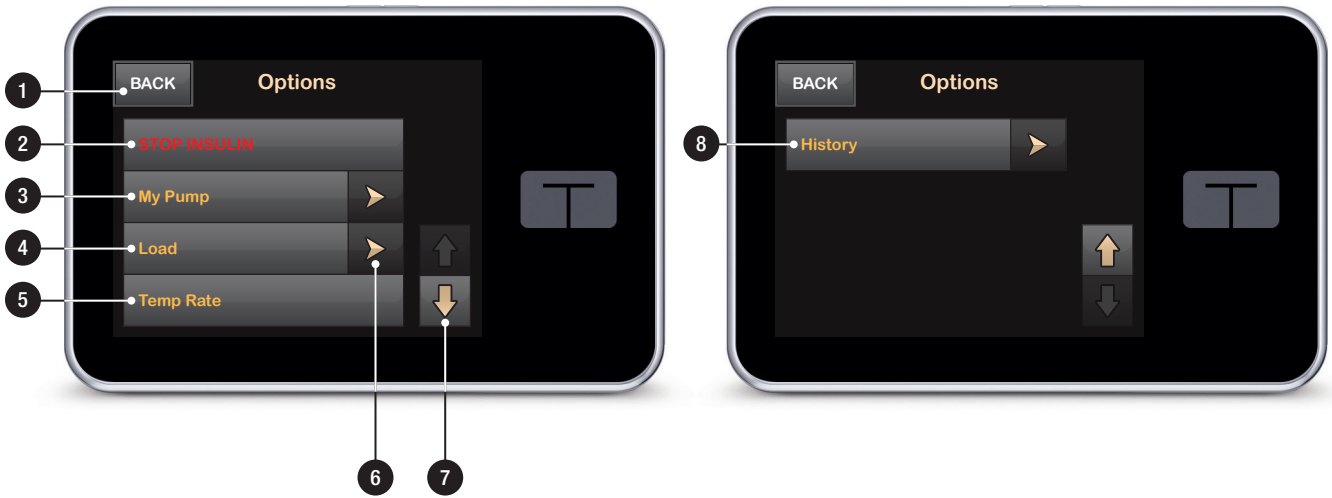


Using Units



3.10 Options Screen

1. **Back:** Returns to the Home Screen.
2. **Stop Insulin:** Stops insulin delivery. If insulin delivery is stopped, RESUME INSULIN will be displayed.
3. **My Pump:** Personal Profiles, Alert Settings, Pump Settings, and Pump Info.
4. **Load:** Change Cartridge, Fill Tubing, Fill Cannula, and Site Reminder.
5. **Temp Rate:** Programs a temporary basal rate.
6. **Menu Arrows:** Indicates additional menu options are available.
7. **Up/Down Arrow:** Indicates there is more information.
8. **History:** Displays historical log of pump events.


1
BACK
Options
2
STOP INSULIN
3
My Pump
4
Load
5
Temp Rate
6
7
8
BACK
Options
History

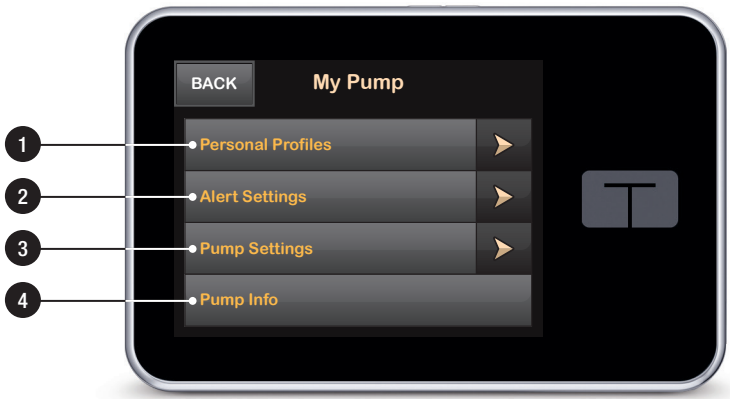
3.11 My Pump Screen

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

2. **Alert Settings:** Customize Pump Reminders and Alerts.

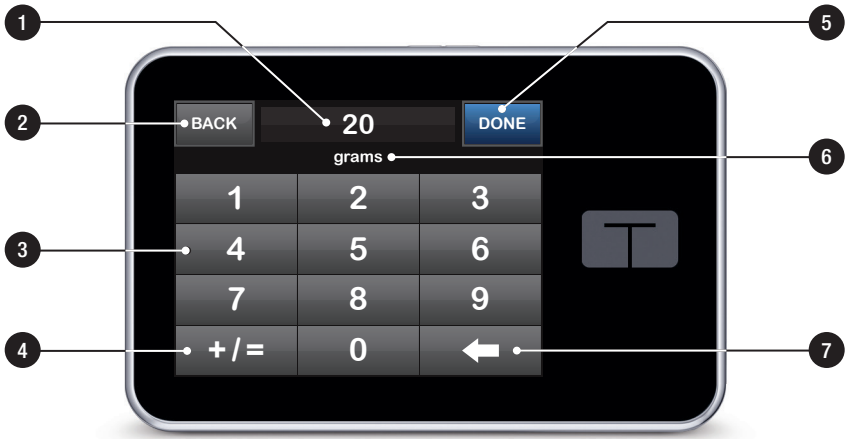
3. **Pump Settings:** Customize Quick Bolus, Pump Volume, Screen Options, and Time and Date.

4. **Pump Info:** Displays t:slim Pump serial number, Tandem Diabetes Care Customer Technical Support phone number, website, and other technical information.


BACK
My Pump
Personal Profiles
Alert Settings
Pump Settings
Pump Info
1
2
3
4

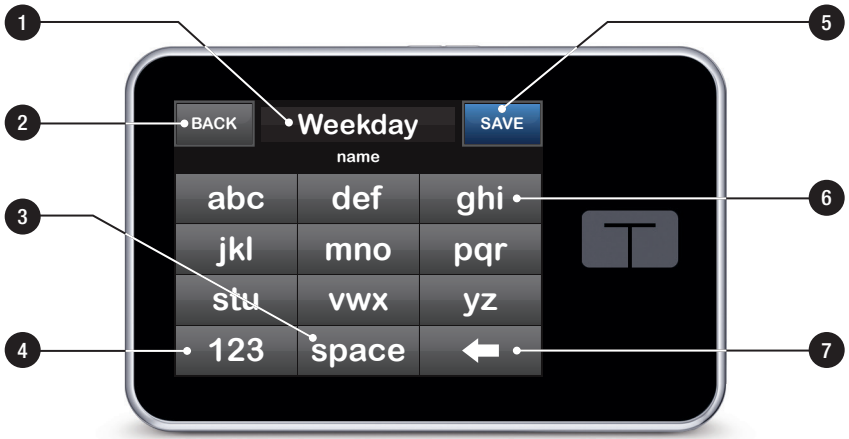
3.12 Number Keypad Screen

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.


1
2
3
4
5
6
7
BACK
20
DONE
grams
1
2
3
4
5
6
7
8
9
+/=
0

3.13 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.


1
2
3
4
5
6
7
BACK
Weekday
SAVE
name
abc
def
ghi
jkl
mno
pqr
stu
vwx
yz
123
space

Section 2

Key Pump Features

Chapter 4

Getting Started

4.1 Charging the t:slim Pump

The t:slim Pump is powered by an internal lithium polymer rechargeable battery. A full charge will last up to 7 days with normal use. 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 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 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 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 included Car Power USB Adapter:

1. Plug the USB cable into the included 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 the 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 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 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 System and contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

Charging Tips

Tandem Diabetes Care, Inc. 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 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 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 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 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 Pump Screen

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

▷ The Screen Lock screen will be displayed.

NOTE: 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 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 press 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 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 System. 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 **Time and Date**.
5. Tap **Edit Time**.
6. Tap **Time**.
7. Using the onscreen keypad, enter the hour and minutes. Verify and tap **DONE**.
8. Tap **Time of Day** to set AM or PM.
9. Verify the correct time is set and tap **SAVE**.

   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 connection 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.

⚠ 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

⚠ 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.

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:

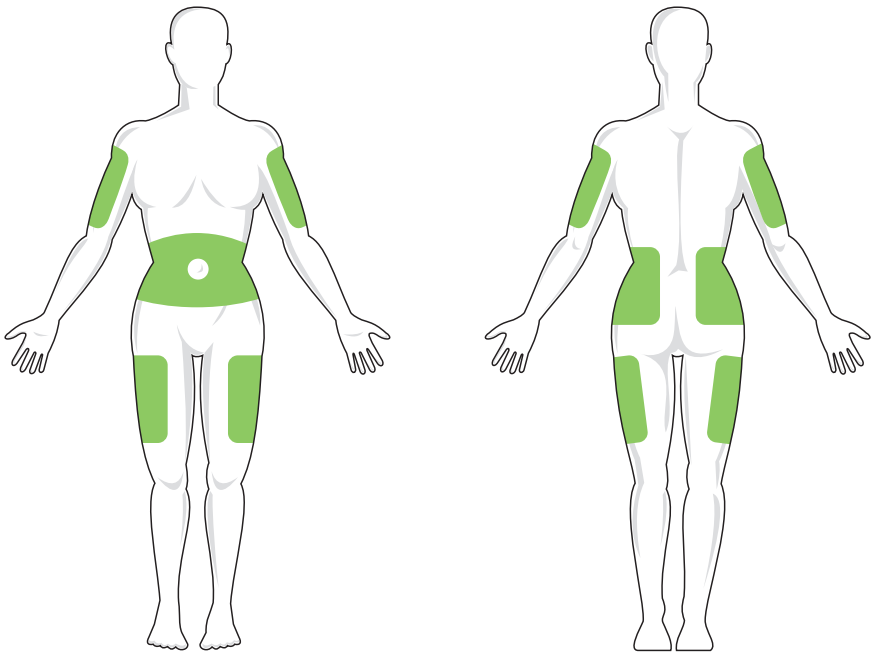
⚠ PRECAUTION
CHANGE your infusion set every 48–72 hours as recommended by your healthcare provider. Wash your hands with anti-bacterial soap before handling the infusion set and thoroughly clean the insertion site on your body to avoid infection. Contact your healthcare provider if you have symptoms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

Areas of Body for Infusion Set Insertion



5.2 Cartridge Instructions for Use

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

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 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 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.

⚠ WARNING

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, Inc. or reuse of cartridges may result in over delivery or under delivery of insulin. This can cause very low or very high blood glucose.

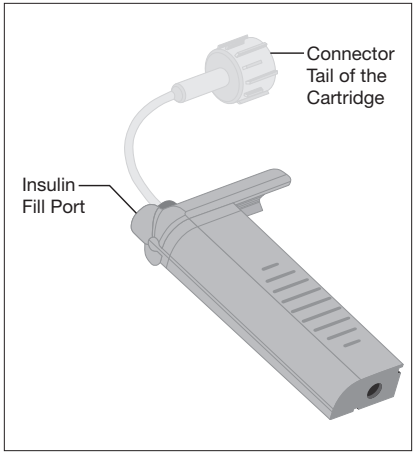
Before you begin, make sure you have the following items:

- 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 Pump screen.

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



Instructions for Drawing Insulin from Vial into Syringe

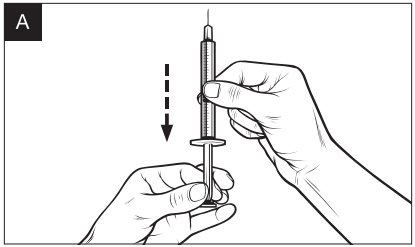
⚠ PRECAUTION

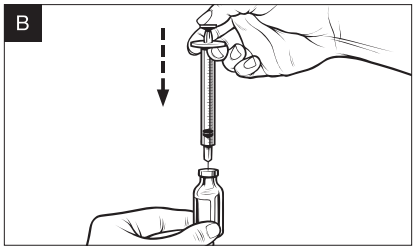
ALWAYS remove all air bubbles from the System before beginning insulin delivery. Ensure there are no air bubbles when drawing insulin into the filling syringe, hold the pump with the white fill port pointed up when filling the tubing, and ensure that there are no air bubbles in the tubing when filling. 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 *(see image A)*.
6. With insulin vial upright, insert needle into vial. Inject air from syringe into vial. Maintain pressure on syringe plunger *(see image B)*.





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.

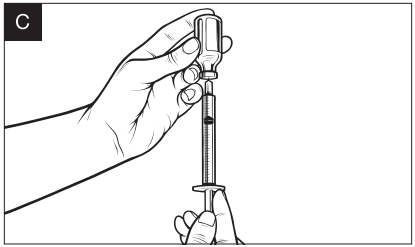
8. Slowly pull back the plunger to the desired amount of insulin *(see image C)*.

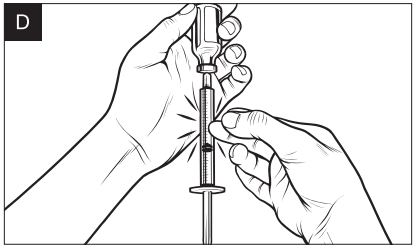
9. While the filling needle is still in the vial and upside down, tap the syringe so that any air bubbles rise to the top *(see image D)*. Then slowly push the plunger upwards, forcing any air bubbles back into the vial.

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.

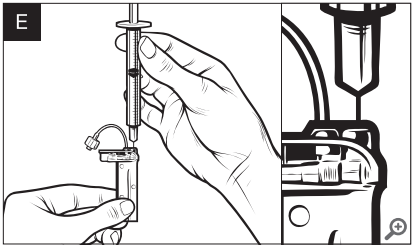
2. Open the package and remove the cartridge.

3. Hold the cartridge upright and gently insert the needle into the white insulin fill port on the cartridge *(see image E)*. 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 *(see image F)*. 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 *(see image G)*.

E



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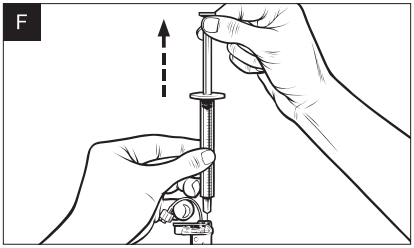
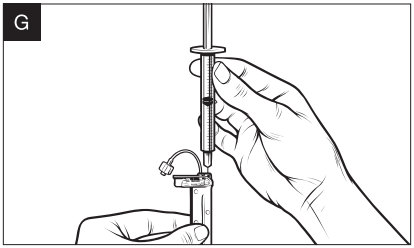


G



6. Withdraw the needle from the fill port.

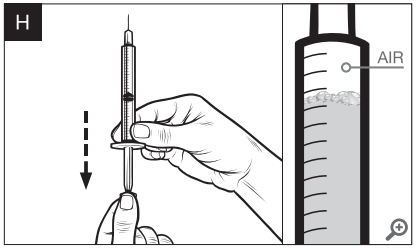
7. Turn the syringe upright and pull down on the plunger *(see image H)*. Flick the barrel to make sure that any air bubbles rise to the top.

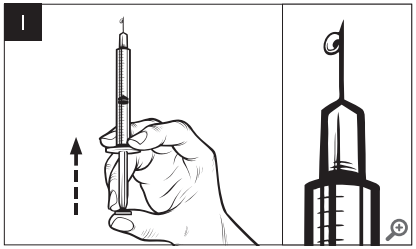
8. Gently press on the plunger to remove air bubbles until insulin fills the needle hub and you see a drop of insulin at the tip of the needle *(see image I)*.

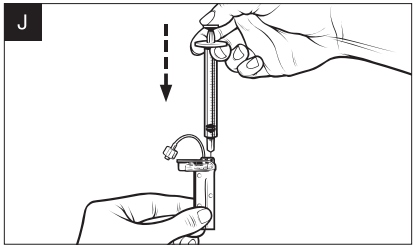
9. Re-insert the needle in the fill port and slowly fill the cartridge with insulin *(see image J)*. It is normal to feel some back pressure as you slowly press on the plunger.

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.







Instructions on How to Install a Cartridge

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

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

   During the load sequence, the Tandem Logo is disabled. Tapping it will not return to the Home Screen.
3. Tap **Change Cartridge**.
4. 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.

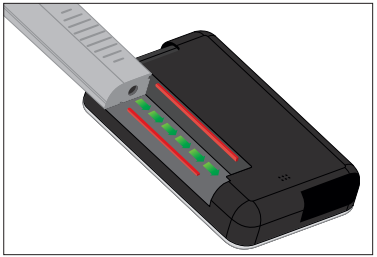
5. Disconnect the infusion set from your body and tap **NEXT** to continue.

▷ "Preparing for Cartridge" screen is displayed.

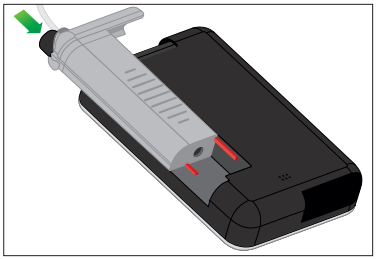
6. Remove the used cartridge.

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

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



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



Tap **UNLOCK** icon when completed.

8. Tap **NEXT** to continue.

▷ "Detecting Cartridge" screen is displayed.

⚠ WARNING

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

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

5.4 Filling Tubing

Filling the Infusion Set Tubing with Insulin

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

To fill the tubing without changing the cartridge, from the Home Screen tap OPTIONS, tap Load, tap Fill Tubing and then follow the instructions. Tap NEW if you installed a new cartridge. Tap FILL if you did not install a new cartridge and want to continue with filling the tubing.

⚠ 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.

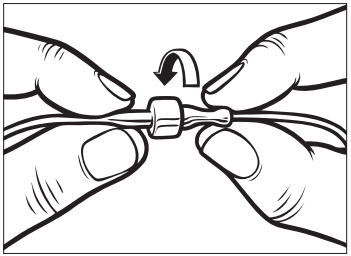
1. Verify that the infusion set is disconnected from your body.

2. Connect the infusion set tubing to the tubing connector on the cartridge:

   a. Ensure that the new infusion set package is not damaged, and remove the sterile tubing from the package. If the package is damaged or opened, discard of properly and use another tubing set.

   b. Remove the infusion set tubing cap from the tubing connector. Be careful to keep the connector away from unclean areas.

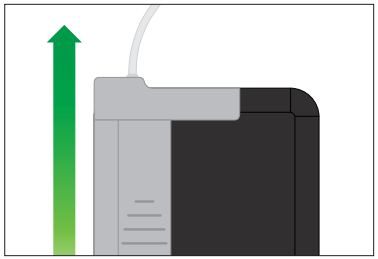
   c. Attach the infusion set tubing to the tubing connector on the cartridge tubing. Twist clockwise until finger tight and then twist another quarter of a turn to ensure a secure connection.



⚠ WARNING
ALWAYS twist the tubing connection 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.

Tap **NEXT**.

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



▷ "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

4. 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.

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

- If you do not see drops, tap **FILL**. The Fill Tubing screen appears, repeat steps 3 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.

6. Fill Tubing is complete.

NOTE: Initial Display of Insulin Level

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 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. 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 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 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.

6. Load screen is displayed. 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 Pump and a Personal Profile has not been defined, a screen will notify you that a profile must be activated to resume insulin. Tap CLOSE.

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

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Chapter 6

Personal Profile

6.1 Personal Profile 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. 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 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 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.

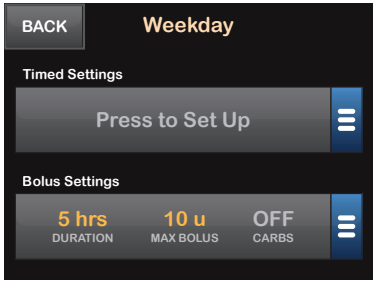
Consult your healthcare provider to accurately set your Insulin Duration.

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 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

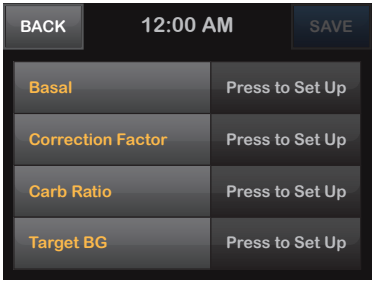
Once the Personal Profile has been created, the settings must be programmed. The first time segment will start at 12:00 AM (midnight).

- 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 prescibed 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**.

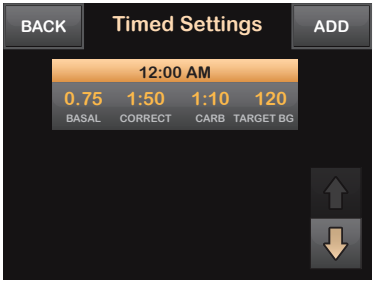
10. Confirm Settings.

    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.

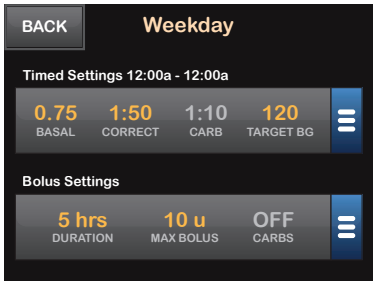
4. Tap **NEXT**.

5. Repeat steps 1 to 10 from the “Programming a New Personal Profile” section above for each segment you want to set up (up to 16).

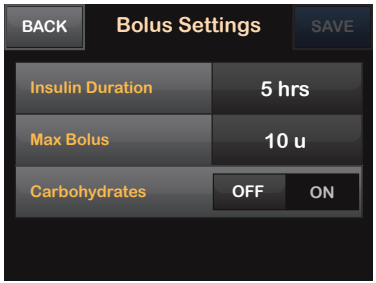
   To find time segments in the list that are not displayed on the first screen, tap the Down Arrow.

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 (refer to Max Bolus Alert in chapter 15.9).

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.

   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**.
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 or Deleting Time Segments

To Add a time segment:

» Tap ADD.

» Enter desired start time.

To Delete a time segment:

» Tap on the X to the left of the time segment.

» 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.

   The active Personal Profile cannot be deleted.
5. Tap **Delete**.
6. Tap **YES**.

▷ "Profile Deleted" screen is displayed.

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

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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 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.

You can always override the calculated bolus by tapping the area above "units" located at the top of the bolus screen between BACK and NEXT. The override function is always active.

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

⚠ PRECAUTION

CHECK your System'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 Food Bolus Using Units

If bolusing using a carb ratio skip to the next chapter, Food Bolus Using Grams.

1. From the Home Screen, tap **BOLUS**.
2. Tap **0 units**.
3. 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 healthcare provider has prescribed for you.
4. Tap **NEXT** to confirm the units of insulin to be delivered.
5. Confirm Request.

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

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

6. Tap **DELIVER**.

7. The bolus initiated screen is temporarily displayed.

7.3 Food Bolus Using Grams

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

2. Tap **0 grams**.

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

   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**.

8. The bolus initiated screen is temporarily displayed.

7.4 Correction Bolus

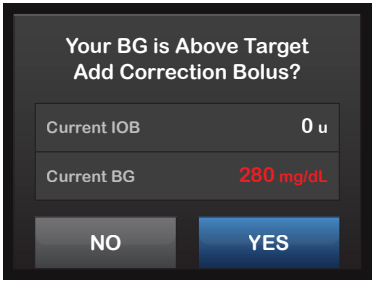
1. From the Home Screen, tap **BOLUS**.

2. Tap **Add BG**.

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

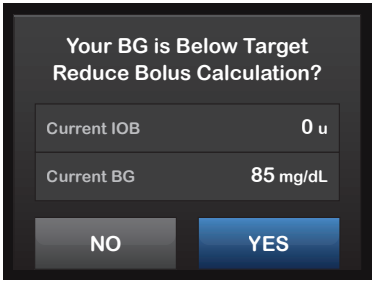
   Once DONE is tapped, the BG value is saved in pump History whether or not a bolus is delivered.

If BG is above the Target BG, a message screen will indicate BG is above Target.



To add a correction bolus tap YES.

If BG is below Target BG, a message screen will indicate BG is below Target.



To reduce bolus calculation tap YES.

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.

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

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

5. Confirm Request.

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

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

6. Tap **DELIVER**.

7. The bolus initiated screen is temporarily displayed.

7.5 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 our 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**.

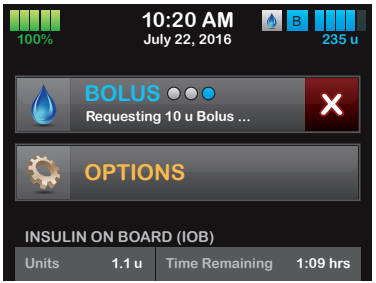
15. The bolus initiated screen is temporarily displayed.

7.6 Canceling or Stopping a Bolus

Canceling a Bolus If delivery <u>Has Not Started</u>

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 <u>Has Started</u>:

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.

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

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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.

8.2 Resuming Insulin Delivery

1. If pump screen is not on, press **Screen On/Quick Bolus Button** once to turn on your t:slim Pump screen.
2. Tap **1–2–3** to access the Home Screen.
3. Tap **RESUME**.
4. The RESUMING INSULIN screen is temporarily displayed.

– OR –

1. From the Home Screen, tap **OPTIONS**.
2. Tap **RESUME INSULIN**.
3. Tap **RESUME**.
4. 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.

1. From the Home Screen, tap **OPTIONS**.
2. Tap **Temp Rate**.
3. Tap **Temp Rate**.
4. Using the onscreen keypad enter desired percentage. The current rate is 100%. An increase is greater than 100% and decrease is less than 100%. 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**.
7. The “TEMP RATE STARTED” screen is temporarily displayed.
8. 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.

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
   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 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 **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 **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 **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.

5. The bolus initiated screen is temporarily displayed.

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Chapter 11

t:slim Pump Settings

11.1 t:slim Pump Volume

Pump Volume is pre-set 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.

   Tap **SAVE** when all changes are complete.
8. Tap **Tandem Logo** to return to the Home Screen.

11.2 Screen Options

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

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.

Feature Lock is pre-set 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.

For Feature Lock

1. 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.

2. Tap **YES** to confirm.
3. Tap **SAVE**.
4. 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.

To Turn the Feature Lock Off

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

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Chapter 12

t:slim Pump Info and History

12.1 t:slim Pump Info

Your t:slim 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 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, 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.

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

Chapter 13

t:slim Pump Reminders

Your t:slim 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 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 pre-set 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 pre-set 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**.
   a. 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**.
7. Tap **SAVE** when all changes are complete.
8. 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. 4 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 **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 pre-set 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, refer to Chapter 5.6.

To Respond to the Site Reminder

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

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Chapter 14

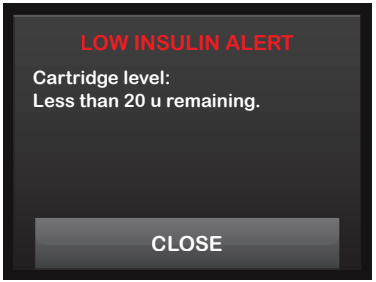
User Settable Alerts and Alarms

14.1 Low Insulin Alert

Your t:slim Pump keeps track of how much insulin remains in the cartridge and alerts you when it is low. The default for this alert is pre-set 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, 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 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 pre-set 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.

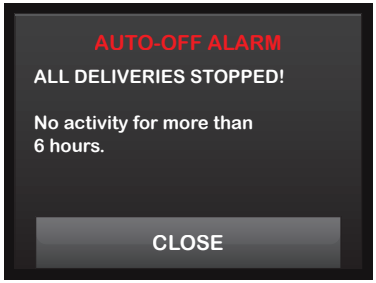
To Respond to Auto-Off Warning

1. 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



1. Tap **CLOSE**. The Home Screen then appears, indicating a status of “All Deliveries Stopped.” You must resume delivery to continue therapy, (refer to Chapter 8.2).

Section 4

t:slim Pump Safety Alerts and Alarms

Chapter 15

t:slim Pump Alerts

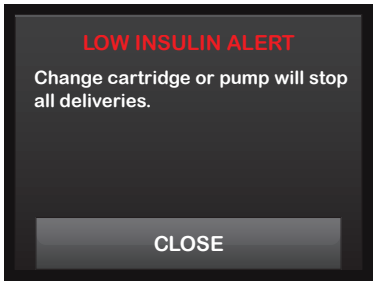
Your t:slim Pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check you BG after a bolus). Alerts display automatically to notify you about safety conditions that 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.

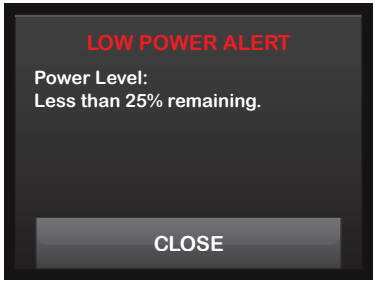
15.1 Low Insulin Alert

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?

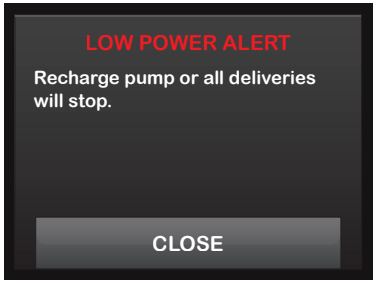
Tap **CLOSE**. Charge your pump as soon as possible to avoid the second LOW POWER ALERT.

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

What will I see on the Screen?



What does it mean?

Less than 5% of battery power remains. Insulin delivery will continue for 30 minutes and then the pump will power off and insulin delivery will stop.

How will the System notify me?

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

Will the System re-notify me?

Yes, every 5 minutes until acknowledged.

How should I respond?

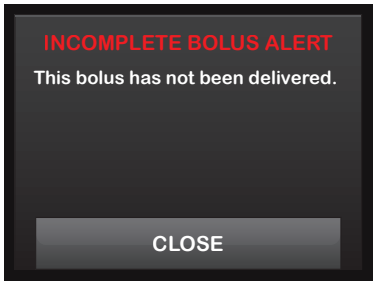
Tap CLOSE. Charge your pump immediately to avoid the LOW POWER ALARM and system power off.

NOTE: Low Battery Display

Once the second LOW POWER ALERT occurs, the low-power indicator (a red 5% 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?

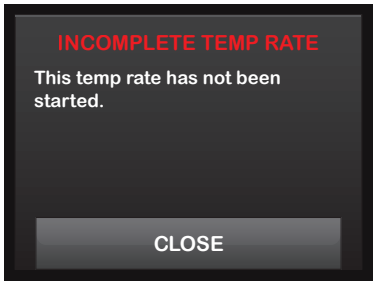
Yes, every 5 minutes until acknowledged.

How should I respond?

Tap CLOSE. The Bolus screen will appear. Continue with your bolus request, or 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.

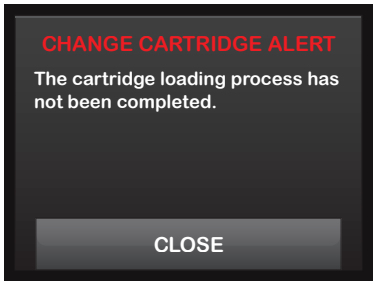
How should I respond?

Tap CLOSE. The Temp Rate screen will appear. Continue setting up your temp rate, or tap BACK if you do not want to continue setting up your temp rate.

15.5 Incomplete Load Sequence Alerts

Incomplete Cartridge Change Alert

What will I see on the Screen?



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?

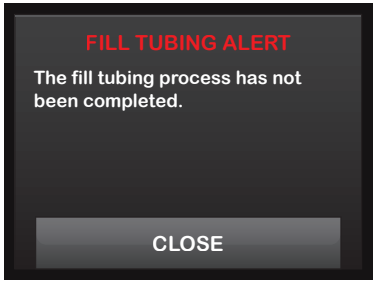
Yes, every 5 minutes until acknowledged.

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?

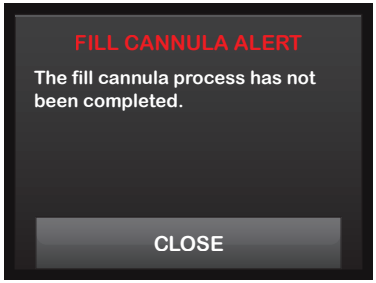
Yes, every 5 minutes until acknowledged.

How should I respond?

Tap CLOSE. Complete the fill tubing process.

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?

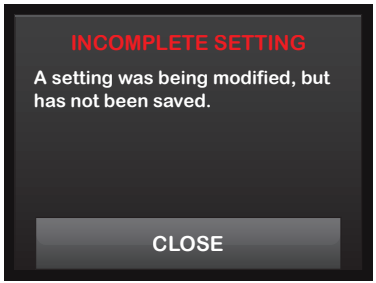
Yes, every 5 minutes until acknowledged.

How should I respond?

Tap CLOSE. Complete the cannula fill process.

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?

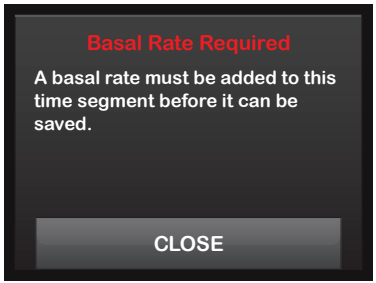
Yes, every 5 minutes until acknowledged.

How should I respond?

Tap CLOSE. Complete programming the Personal Profile.

15.7 Basal Rate Required Alert

What will I see on the Screen?



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?

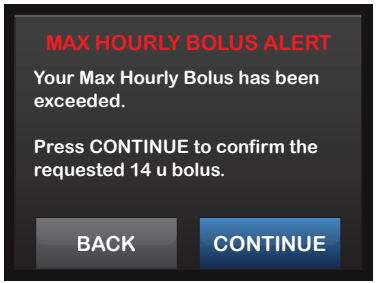
No. A basal rate must be entered to save the time segment.

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.

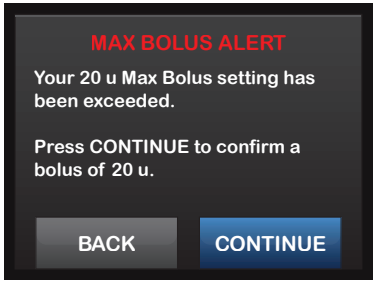
How should I respond?

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?



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.

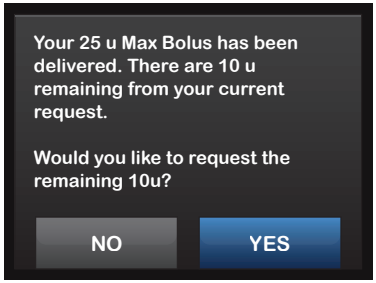
How should I respond?

Tap BACK to return to the Bolus screen and adjust the bolus delivery amount, or tap CONTINUE to deliver the amount of your Max Bolus setting.

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.

Max Bolus Alert 2

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 if your bolus insulin needs have changed since you requested the original bolus.

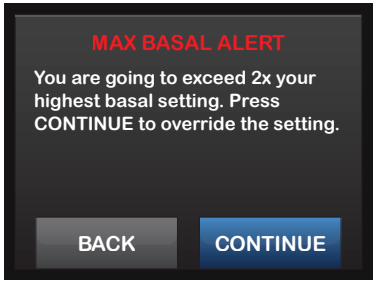
Tap YES to deliver the remaining amount of the bolus request. A confirmation screen will appear.

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?



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?

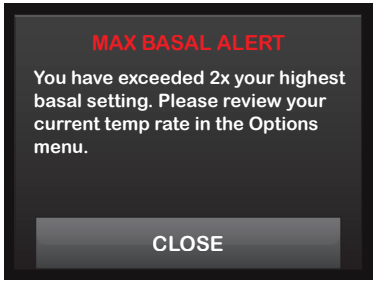
No. You must tap BACK or CONTINUE to move forward.

How should I respond?

Tap BACK to return to the previous screen to adjust the amount, or tap CONTINUE to dismiss the alert and continue with the request.

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.

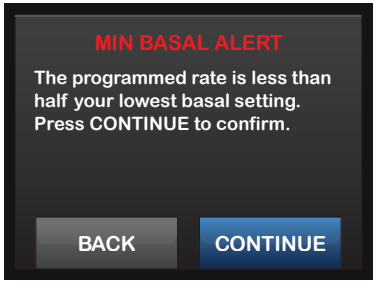
How should I respond?

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?



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?

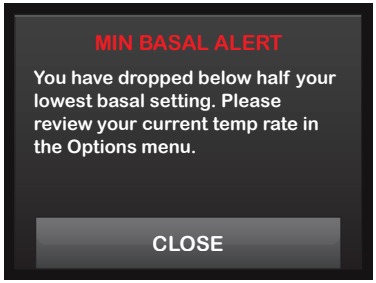
No. You must tap BACK or CONTINUE to move forward.

How should I respond?

Tap BACK to return to the previous screen to adjust the amount, or tap CONTINUE to dismiss the alert and continue with the request.

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 Settings.

Will the System re-notify me?

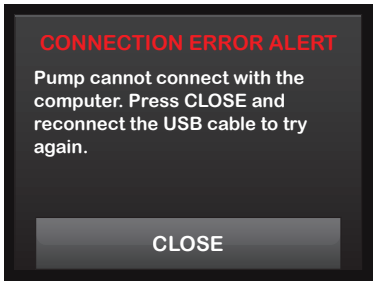
Yes, every 5 minutes until acknowledged.

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?



What does it mean?

You connected your t:slim 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 Settings.

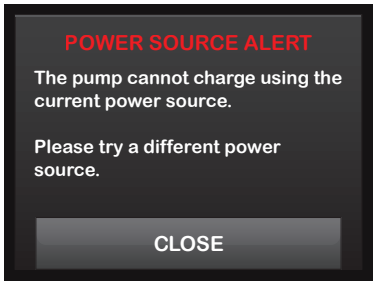
Will the System re-notify me?

Yes, every 5 minutes until acknowledged.

How should I respond?

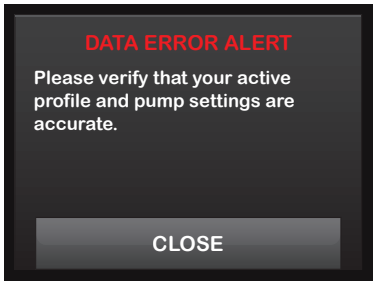
Tap CLOSE. Disconnect and reconnect the USB cable to try again.

15.13 Power Source Alert

What will I see on the Screen?	What does it mean?
	You connected your t:slim 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 Settings.
	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?



What does it mean?

Your t:slim 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 Settings.

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 (refer to Chapter 6.4).

Chapter 16

t:slim 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 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.

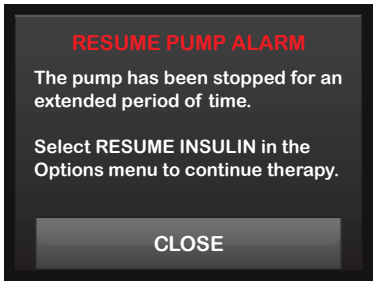
If multiple Reminders, Alerts, and Alarms happen at the same time, Alarms will be displayed first, Alerts will be displayed second, and Reminders will be displayed third. Each must be confirmed separately until all have been confirmed.

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 vibe. Alarms repeat regularly until the condition that caused the alarm is corrected.

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.

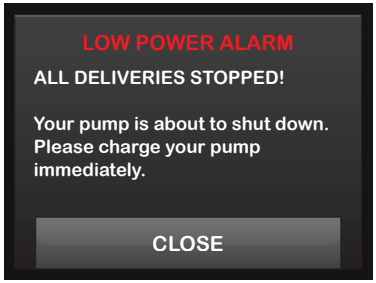
How should I respond?

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?



What does it mean?

Your t:slim 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?

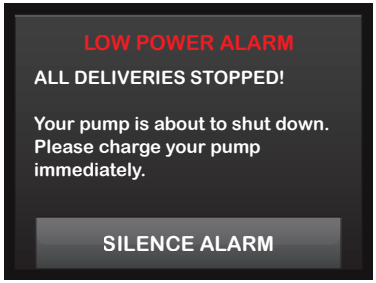
Yes, the System will re-notify you every 3 minutes until no power remains and the pump shuts down.

How should I respond?

Tap CLOSE. Charge your pump immediately to resume insulin delivery.

Low Power Alarm 2

What will I see on the Screen?



What does it mean?

Your t:slim 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?

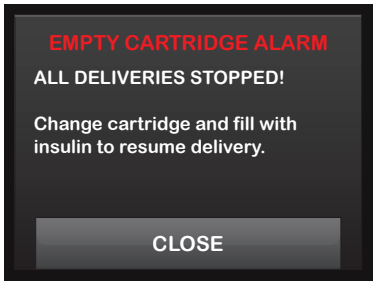
The pump will power back on once it has been plugged into a charging source and has reached an adequate level of charge.

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 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 Chapter 5.3.

16.4 Cartridge Error Alarm

What will I see on the Screen?

What does it mean?

Your t:slim 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?

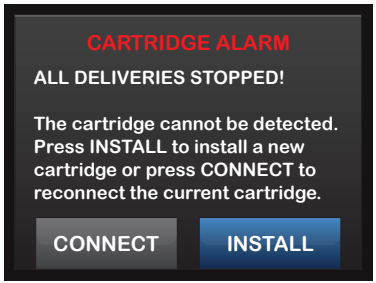
Yes. The system will re-notify you every 3 minutes until you change the cartridge.

How should I respond?

Tap CLOSE. Change your cartridge immediately by tapping OPTIONS from the Home Screen, then Load and follow the instructions in Chapter 5.3.

16.5 Cartridge Removal Alarm

What will I see on the Screen?



What does it mean?

Your t:slim 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.

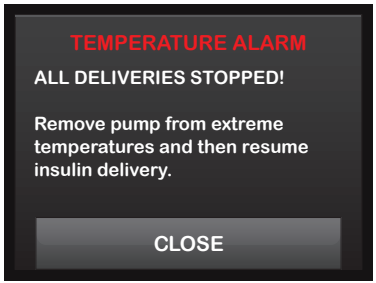
Will the System re-notify me?

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.

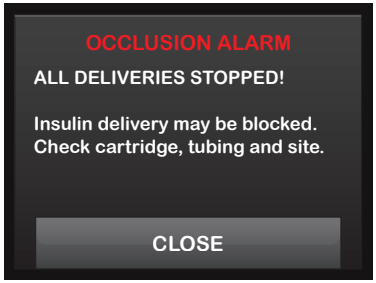
16.6 Temperature Alarm

What will I see on the Screen?	What does it mean?
	Your t:slim 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 Alarms

Occlusion Alarm 1

What will I see on the Screen?



What does it mean?

Your t:slim Pump detected that insulin delivery is blocked 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 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.

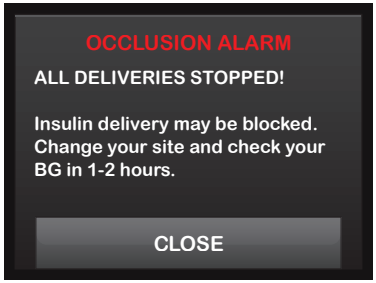
** See Section 20.4 for more information on how long it can take the system to detect an occlusion.*

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.

Occlusion Alarm 2

What will I see on the Screen?



What does it mean?

Your t:slim Pump detected a second occlusion alarm shortly after the first occlusion alarm and all deliveries have stopped.

How will the System notify me?

3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in 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?

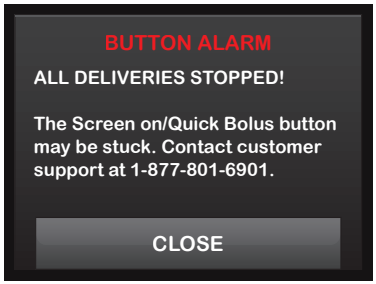
Tap CLOSE. Change the cartridge, tubing, and infusion site to ensure proper delivery of insulin. Resume insulin after changing the cartridge, tubing, and infusion site.

NOTE: Occlusion During Bolus

If the second occlusion alarm occurs during bolus delivery, after tapping CLOSE, a screen will appear letting you know that the amount of bolus delivery could not be determined and was not added to your IOB.

16.8 Screen On/Quick Bolus Button Alarm

What will I see on the Screen?



What does it mean?

The Screen On/Quick Bolus Button (on the top of your t:slim Pump) is stuck or not functioning properly and all deliveries have stopped.

How will the System notify me?

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

Will the System re-notify me?

Yes. The System will re-notify you every 3 minutes until the condition is corrected.

How should I respond?

Tap **CLOSE**. Contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

16.9 Altitude Alarm

What will I see on the Screen?

What does it mean?

Your t:slim Pump detected a pressure difference between inside the cartridge and the surrounding air within the validated operating range of -1,300 feet to 10,000 feet 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?

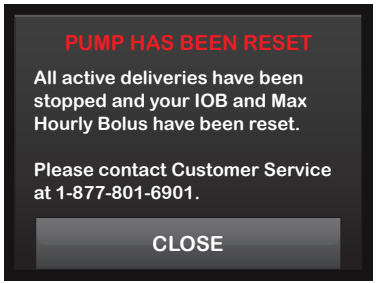
Yes. The System will re-notify you every 3 minutes until the condition is corrected.

How should I respond?

Tap CLOSE. Remove the cartridge from the pump (this will allow the cartridge to fully vent) and then reconnect the cartridge.

16.10 Reset Alarm

What will I see on the Screen?



What does it mean?

Your t:slim Pump detected that one if its micro-processors experienced a reset and all deliveries have been stopped.

How will the System notify me?

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

Will the System re-notify me?

Yes. The System will re-notify you every 3 minutes until you tap CLOSE.

How should I respond?

Tap **CLOSE**. Contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

Chapter 17

t:slim Pump Malfunction

17.1 Malfunction

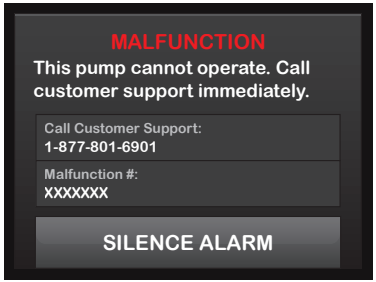
If your t:slim Pump detects a system error, the MALFUNCTION screen appears and all deliveries are stopped. Contact Tandem Diabetes Care Customer Technical Support.

Malfunctions notify you with 3 sequences of 3 notes at highest volume and 3 vibrations. They repeat at regular intervals until acknowledged by tapping SILENCE ALARM.

⚠ PRECAUTION

ALWAYS check with your healthcare provider for specific guidelines if you want or need to disconnect from the pump for any reason. Depending on the length of time and reason you are disconnecting, you may need to replace missed basal and/or bolus insulin. Check your 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.

What will I see on the Screen?



What does it mean?

Your t:slim Pump detected a system error and all deliveries have been stopped.

How will the System notify me?

3 sequences of 3 notes at highest volume and 3 vibrations.

Will the System re-notify me?

Yes, the System will notify you every 3 minutes until you acknowledge the malfunction by tapping SILENCE ALARM.

How should I respond?

Write down the Malfunction Code number that appears on the screen.

Tap SILENCE ALARM. The MALFUNCTION screen will remain on the pump even though the alarm is silenced.

Contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901 and provide the Malfunction Code number that you wrote down.

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Section 5

Living With and Caring for Your t:slim System

Chapter 18

Lifestyle Issues and Travel

18.1 Overview

While the convenience and flexibility of the t:slim System allow most users to participate in a variety of activities, some lifestyle changes may be required. Additionally, your insulin needs may change in response to lifestyle changes.

⚠ PRECAUTION

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

Physical Activity

The t:slim System can be worn during most forms of exercise, such as running, cycling, hiking, and resistance training. During exercise, the pump can be worn in the provided case, your pocket, or other third-party "sport cases." For activities where contact is a concern, such as baseball, hockey, martial arts, or basketball, you can disconnect from your pump for short periods of time. If planning to disconnect from your pump, discuss a plan with your healthcare provider to compensate for any basal insulin delivery you miss while disconnected, and be sure to continue to check your blood glucose levels.

Aquatic Activities

⚠ PRECAUTION

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.

Your t:slim Pump is watertight to a depth of 3 feet for up to 30 minutes (IPX7 rating), but it is not waterproof. Your pump should not be worn while swimming, scuba diving, surfing, or during any other activities that could submerge the pump for an extended period of time. Your pump should not be worn in hot tubs or Jacuzzis.

Extreme Altitudes

Some activities, such as hiking, skiing or snowboarding, could expose your pump to extreme altitudes. The t:slim Pump has been tested at altitudes up to 10,000 feet at standard operating temperatures.

Extreme Temperatures

You should avoid activities which could expose your System to temperatures below 40˚F (5˚C) or above 99˚F (37˚C), as insulin can freeze at low temperatures or degrade at high temperatures.

Other Activities Which Require Removing Your Pump

There are other activities, such as bathing and intimacy, when it may be more convenient for you to remove your pump. It is safe to do so for short periods of time. If planning to disconnect from your pump, discuss a plan with your health care provider for compensating for any basal delivery

you miss while disconnected, and be sure to check your blood glucose levels frequently. Missing basal delivery could cause your blood sugar to rise.

Travel

The flexibility afforded by an insulin pump can simplify some aspects of travel, but it still requires planning. Be sure to order your pump supplies before your trip so that you have enough supplies with you while you're away from home. In addition to pump supplies, you should also always bring the following items:

- The items listed in the Emergency Kit described in Section 2.8.
- A prescription for both rapid-acting and long-acting insulin of the type recommended by your healthcare provider in case you need to take insulin by injection.
- A letter from your HCP explaining the medical need for your insulin pump and other supplies.

Traveling by Air

⚠ PRECAUTION

DO NOT expose your System to X-ray screening used for carry-on and checked luggage. Newer full body scanners used in airport security screening are also a form of X-ray and your System should not be exposed to them. Notify the Transportation Security Administration (TSA) Agent that your System cannot be exposed to X-ray machines and request an alternate means of screening.

Visit TSA's website if you have any questions or concerns.

www.tsa.gov
Email:
TSA-ContactCenter@tsa.dhs.gov
Phone:
1-866-289-9673.

Your System has been designed to withstand common electromagnetic interference including airport metal detectors.

Pack your pump supplies in your carry-on luggage. DO NOT pack your supplies in checked luggage as it could get delayed or lost.

If traveling internationally, contact Tandem Diabetes Care Customer Support prior to your trip to obtain a travel loaner pump in case your pump malfunctions outside of Tandem's replacement area.

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Chapter 19

Taking Care of Your t:slim System

19.1 Overview

This section provides information on caring for and maintaining your System.

Cleaning Your System

When cleaning your t:slim Pump, use a damp lint-free cloth. Do not use household or industrial cleaners, solvents, bleach, scouring pads, chemicals, or sharp instruments. Never submerge the pump in water or use any other liquid to clean it. Do not place the pump in the dishwasher or use hot water to clean it. If needed, use only a very mild detergent, such as a bit of liquid soap with warm water. When drying your pump, use a soft towel; never place your pump in a microwave oven or baking oven to dry it.

Inspecting Your System for Damage

⚠ PRECAUTION

DO NOT use your pump if you think it might be damaged due to dropping it or hitting it against a hard surface. Check that the System 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.

If you drop your t:slim Pump or it has been hit against something hard, ensure that it is still working properly. Check that the touch screen is working and clear, and that the cartridge and infusion set are properly in place. Check for leaks around the cartridge and at the tubing connector to the infusion set. Immediately contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901 if you notice any cracks, chips, or other damage.

Storing Your System

If you need to stop using your t:slim Pump for a long period of time, you can place the pump in storage mode. To place the pump in storage mode, connect the pump to a power source and then press and hold down the Screen On/Quick Bolus Button for 25 seconds. The pump will beep 3 times before going into storage mode. Disconnect the pump from the power source.

Keep the pump protected when not in use. Store at temperatures between -4°F and 140°F and at relative humidity levels between 20% and 90%.

To bring the pump out of storage mode, simply connect the pump to a power source.

Disposing of System Components

Consult your healthcare provider for instructions for disposal of devices containing electronic waste such as your pump and for instructions for disposal of potentially bio-hazardous materials such as used cartridges, needles, syringes, and infusion sets.

Section 6

Technical Specifications and Warranty

Chapter 20

Technical Specifications

20.1 Overview

This section provides tables of technical specifications, performance characteristics, options, settings, and electromagnetic compliance information for the t:slim System. The specifications in this section meet the international standards set forth in IEC 60601-1 and IEC 60601-2-24.

20.2 t:slim System Specifications

t:slim Pump Specifications

Specification Type	Specification Details
Classification	External PSU: Class II, Infusion Pump. Internally-powered equipment, Type BF applied part. The risk of ignition of flammable anesthetics and explosive gases by the pump is remote. While this risk is remote, it is not recommended to operate the t:slim Pump in the presence of flammable anesthetics or explosive gases.
Size	3.13″ x 2.0″ x 0.6″ (L x W x H) - (7.95 cm x 5.08 cm x 1.52 cm)
Weight (with full disposable)	3.95 ounces (112 grams)
Operating Conditions	Temperature: 41°F (5°C) to 98.6°F (37°C) Humidity: 20% to 90% RH non-condensing
Storage Conditions	Temperature: -4°F (-20°C) to 140°F (60°C) Humidity: 20% to 90% RH non-condensing
Atmospheric Pressure	-1,300 feet to 10,000 feet
Moisture Protection	IPX7: Watertight to a depth of 3 feet for up to 30 minutes
Reservoir Volume	3.0 mL or 300 units
Cannula Fill Amount	0.1 to 1.0 units of insulin
Insulin Concentration	U-100
Alarm Type	Visual, audible, and vibratory

table continued on next page …

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Specification Type	Specification Details
Basal Delivery Accuracy at all Flow Rates (tested per IEC 60601-2-24)	±5% **The System is designed to vent automatically when there is a pressure difference between inside the cartridge and the surrounding air. In certain conditions, such as a gradual elevation change of 1,000 feet, the System may not vent immediately and delivery accuracy can vary up to 15% until 3 units have been delivered or elevation changes by more than 1,000 feet.**
Bolus Delivery Accuracy at all Volumes (tested per IEC 60601-2-24)	±5%
Patient Protection from Air Infusion	The pump provides subcutaneous delivery into interstitial tissue and does not deliver intravenous injections. Clear tubing aids in detecting air.
Maximum Infusion Pressure Generated and Occlusion Alarm Threshold	30 PSI
Frequency of Basal Delivery	5 minutes for all Basal Rates
Retention Time of Electronic Memory when Internal System Battery is Fully Discharged (including Alarm Settings and Alarm History)	Greater than 30 days
Infusion Set used for Testing	Unomedical Comfort™ Infusion Set

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Specification Type	Specification Details
Internal System Battery Life	4 years minimum under normal use conditions
Typical Operating Time when System is Operating at Intermediate Rate	During normal use, the intermediate rate is 2 units/hr; battery charge can be reasonably expected to last up to 7 days from a fully charged state to a totally discharged state
Handling of Over-Infusion or Under-Infusion	The method of delivery isolates the insulin chamber from the patient and the software performs frequent monitoring of system status. Multiple software monitors provide redundant protection against unsafe conditions. Over-infusion is mitigated by continuous self-tests, layering of redundancies and confirmations, and numerous other safeguard alarms. Users are required to review and confirm the details of all bolus deliveries, basal rates, and temp rates to ensure certainty before initiating a delivery. In addition, once bolus deliveries are confirmed, the user is given 5 seconds to cancel the delivery before it is started. An optional Auto-Off alarm triggers when the user has not interacted with the pump's user interface for a pre-defined period of time. Under-infusion is mitigated by occlusion detection and blood glucose monitoring as blood glucose entries are recorded. Users are prompted to treat high blood glucose conditions with a correction bolus.
Bolus Volume at Release of Occlusion (2 units per hour Basal)	Less than 3 units with Unomedical Comfort™ (110cm) Infusion Set
Residual Insulin Remaining in the Cartridge (unusable)	Less than 10 units
Minimum Audible Alarm Volume	45 dBA at 1 meter

USB Charging/Download Cable Specifications

Tandem P/N	004113
Length	6 feet
Type	USB A to USB Micro B

Power Supply/Charger, AC, Wall Mount, USB Specifications

Tandem P/N	03933
Input	100 to 240 Volts AC, 50/60 Hz
Output Voltage	5 Volts DC
Max Output Power	5 Watts
Output Connector	USB type A

Power Supply/Charger, DC, Vehicle adapter, USB Specifications

Tandem P/N	003934
Input	12 Volts DC
Output Voltage	5 Volts DC
Max Output Power	5 Watts minimum
Output Connector	USB type A

PC, USB Connector, Specifications

Output Voltage	5 Volts DC
Output Connector	USB type A
Safety Standard Compliance	60950-1 or 60601-1 or equivalent

The t:slim System is designed to be connected to a host PC for battery charging and data transfer to t:connect. The following minimum characteristics are required of the host PC:

- USB 1.1 port (or later)
- t:connect Uploader Software (available for download at www.tandemdiabetes.com)
- PC compliant with 60950-1 or equivalent safety standard

Connecting the t:slim System to a host PC that is attached to other equipment could result in previously unidentified risks to the patient, operator, or a third party. The user should identify, analyze, evaluate, and control these risks.

Subsequent changes to the host PC could introduce new risks and require additional analysis. These changes can include but are not limited to changing the configuration of the PC, connecting additional items to the PC, disconnecting items from the PC, and updating or upgrading equipment connected to the PC.

20.3 t:slim Pump Options and Settings

Option/Setting Type	Option/Setting Details
Time	12-hour clock
Maximum Basal Rate	15 units/hr
Insulin Delivery Profiles (Basal and Bolus)	6
Basal Rate Segments	16 per delivery profile
Basal Rate Increment	0.001 at programed rates equal to or greater than 0.1 units/hr
Temp Basal Rate	15 minutes to 72 hours with 1 minute resolution with a range of 0% to 250%
Bolus Setup	Can deliver based on carb input (grams) or insulin input (units). Default is units. (The range for carbs is 1 to 999 grams; the range for insulin is 0.05 to 25 units)
Insulin-to-Carb (IC) Ratio	16 time segments per 24-hour period; Ratio: 1 unit of insulin per x grams of carbs; 1:1 to 1:300 (can be set by 0.1 below 10)
BG Correction Target Value	16 time segments. 70 to 250 mg/dL in 1 mg/dL increments
Insulin Sensitivity Factor (ISF)	16 time segments; Ratio: 1 unit of insulin reduces glucose x mg/dL; 1:1 to 1:600 (1 mg/dL increments)
Duration of Insulin Action	1 time segment; 2 to 8 hours in 1-minute increments (default is 5 hrs)
Bolus Increment	0.01 at volumes greater than 0.05 units

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Option/Setting Type	Option/Setting Details
Quick Bolus Increments	When set to units: 0.5, 1, 2, 5 units (default is 0.5 units); or when set to grams/carbs: 2, 5, 10, 15 grams (default is 2 g)
Maximum Extended Bolus Time	8 hours
Maximum Bolus Size	25 units
Low Reservoir Volume Indicator	Status indicator visible on Home Screen; Low Insulin Alert is user adjustable from 10 to 40 units (default is 20 units).
Auto-Off Alarm	On or Off (default is On); user-adjustable (5 to 24 hours; default is 12 hours, which you can change when option is set to On).
History Storage	At least 90 days of data
Language	English
Feature Lock	Blocks access to insulin delivery screens and pump setting screens (default is Off).
Screen Lock	Protects from unintentional taps.
Site Reminder	Prompts user to change infusion set. Can be set for 1 to 3 days at a time selected by user (default is Off).
Missed Meal Bolus Reminder	Prompts user if a bolus has not occurred during the period of time the reminder is set for. 4 reminders available (default is Off).
After Bolus Reminder	Prompts user to test BG at a selected time period after a Bolus has been delivered. Can be set between 1 to 3 hours (default is Off).
High BG Reminder	Prompts user to retest BG after a High BG has been entered. User selects High BG value and time for reminder. (default is Off).
Low BG Reminder	Prompts user to retest BG after a Low BG has been entered. User selects Low BG value and time for reminder. (default is Off).

20.4 t:slim Pump Performance Characteristics

Rate of Delivery

25 Unit Bolus Delivery Speed	2.97 Units/min Typical
2.5 Unit Bolus Delivery Speed	1.43 Units/min Typical
20 Unit Prime	9.88 Units/min Typical

Bolus Duration

25 Unit Bolus Duration	8 minutes 26 seconds Typical
2.5 Unit Bolus Duration	1 minute 45 seconds Typical

Time to Occlusion Alarm

Operating Rate	Typical	Maximum
Bolus (3 units or Greater)	21 Seconds	3 Minutes
Basal (2 units/hr)	1 Hour 4 Minutes	2 Hours
Basal (0.1 units/hr)	19 Hours 43 Minutes	36 Hours

The time to occlusion alarm is based on insulin volume not delivered. During an occlusion event, boluses of less than 3 units may not trigger an occlusion alarm if no basal insulin is being delivered. The bolus amount will reduce the time to occlusion depending on the basal rate.

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20.5 Electromagnetic Compatibility

The information contained in this section is specific to the t:slim System. This information provides reasonable assurance of normal operation, but does not guarantee such under all conditions. If the t:slim System must be used in close proximity with other electrical equipment, the System should be observed in this environment to verify normal operation. Special precautions for electromagnetic compatibility must be taken when using medical electrical equipment. The System shall be placed into service with adherence to the EMC information provided here. Using cables and accessories not specified in this User Guide may adversely impact safety, performance, and electromagnetic compatibility, including increased emissions and/or decreased immunity.

For IEC 60601-1 testing, Essential Performance for the t:slim System is defined as follows:

- The System will not over deliver a clinically significant amount of insulin.
- The System will not under deliver a clinically significant amount of insulin without notification to the user.
- The System will not deliver a clinically significant amount of insulin after occlusion release.

This section contains the following tables of information:

- Electromagnetic Emissions
- Electromagnetic Immunity
- Distances Between the t:slim System and RF Equipment

20.6 Electromagnetic Emissions

The t:slim System is intended for use in the electromagnetic environment specified below. Always make sure that the System is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions, CISPR 11	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions, CISPR 11	Class B	The System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions, IEC 61000-3-2	N/A	
Voltage Fluctuations/Flicker Emissions, IEC 61000-3-3	N/A	

20.7 Electromagnetic Immunity

The t:slim System is intended for use in the electromagnetic environment specified below. Always make sure that the System is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	<5% Ur (>95% dip in Ur) for 0,5 cycle 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (30% dip in Ur) for 25 cycles <5% Ur (>95% dip in Ur) for 5 sec	<5% Ur (>95% dip in Ur) for 0,5 cycle 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (30% dip in Ur) for 25 cycles <5% Ur (>95% dip in Ur) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the pump requires continued operation during power mains interruptions, it is recommended that the pump be powered from an uninterruptible power supply or a battery. NOTE: Ur is the a.c. mains voltage prior to application of the test level.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	400 A/m (IEC 60601-2-24)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 V	Portable and mobile RF communications equipment should be used no closer to any part of the pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 0.35\sqrt{P}$ 80 MHz to 800 MHz, $d = 0.12\sqrt{P}$ 800 MHz to 2.5GHz, $d = 0.23\sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	30 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the pump is used exceeds the applicable RF compliance level above, the pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

20.8 Distances Between the t:slim Pump and RF Equipment

The t:slim System is intended for use in an electromagnetic environment typically found in the home, at work, retail stores, and places of leisure, where daily activities occur. The chart below can be used as a guideline for determining the recommended minimum distance to maintain between a radio frequency (RF) transmitter and the t:slim System. For specific concerns about a particular RF transmitter interfering with your System's operation, please contact the transmitter manufacturer for its rated power and frequency.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the t:slim System

The t:slim System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the t:slim System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter in Watts	Separation Distance According to Frequency of Transmitter *inches or feet* (m)		
	150 kHz to 80 MHz (d *in meters* = 0.35√P)	80 MHz to 800 MHz (d *in meters* = 0.12√P)	800 MHz to 2.5 GHz (d *in meters* = 0.23√P)
0.01	1.6 in (0.04)	0.12 in (0.012)	0.9 in (0.023)
0.1	4.3 in (0.11)	1.5 in (0.038)	2.9 in (0.073)
1	1.1 ft (0.35)	4.7 in (0.120)	9.0 in (0.23)
10	3.6 ft (1.11)	14.9 in (0.379)	2.39 ft (0.727)
100	11.5 ft (3.50)	3.94 ft (1.20)	7.54 ft (2.3)

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

The table below provides a list of typical devices for various levels of transmitter power and frequency, and the recommended separation distances from the transmitter and the System.

Rated Maximum Output Power of Transmitter in Watts	Typical Devices	Recommended Separation Distance *Inch (Meters)*	
0.001W	Bluetooth Class 3 (standard 1 meter range) Commonly used as bluetooth headset	0.3 in (0.007 m)	
0.01W	Internet to music adaptor Commonly used for FM wireless music streaming	0.5 in (0.013 m)	
0.1W	Bluetooth Class 1 (100 meter range) Wireless router (WiFi)	2.9 in (0.073 m)	
0.5W	Typical cellular/smart phone*	6.4 in (0.163 m)	
1W	Typical microwave oven RF leakage	9 in (0.23 m)	

* Caution: Interference with pump electronics by cell phones can occur if worn in close proximity. It is recommended that your pump and cell phone be worn at least 6.4 inches apart.

20.9 FCC Notice Concerning Interference

The t:slim Pump complies with FCC/IC RF exposure limits for general population/uncontrolled exposure.

t:slim Pumps equipped with a Bluetooth® RF option transmit at a maximum effective radiated power of 3.4 mW in the 2.4 GHz ISM band, which covers the frequency range from 2.40 GHz to 2.50 GHz.

The t:slim Pump complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and;

2. This device must accept any interference received, including interference that my cause undesired operation

Compliance with these guidelines provides reasonable protection against harmful interference in a normal residential environment. The t:slim Pump generates, uses, and can radiate radio frequency energy, and may cause harmful interference to radio communications. There is no guarantee that interference will not occur in a particular installation. If the t:slim Pump does cause harmful interference to radio or television reception, the interference may be corrected by one of the following measures:

- Move or relocate the t:slim Pump

- Increase the distance between the t:slim Pump and the other device that is emitting or receiving interference

Changes or modifications not expressly approved by Tandem Diabetes Care, Inc. could void the user's authority to operate the equipment.

20.10 Warranty Information

Warranty

t:slim Insulin Pump

Tandem Diabetes Care, Inc. ("Tandem") warrants the t:slim Insulin Pump against defects in materials and workmanship, under normal use, for the period of 4 years from the original date of shipment of the pump to the original end use purchaser (the "Warranty Period"). For any defective t:slim Pump covered by the foregoing warranty, Tandem will, at its discretion, repair the pump or replace it with a new or refurbished t:slim Pump, subject to the conditions and exclusions stated herein. Repair or replacement of a t:slim Pump will not extend the original 4 year warranty, which will continue to apply. If your t:slim Pump is replaced, then you must return your original pump to Tandem in accordance with Tandem's instructions. In the event the defective t:slim Pump is not returned, then this warranty shall be void and you will not be entitled to future pump replacement or repairs.

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

- damage results from changes or modifications made to the t:slim Insulin Pump by the user or third persons after the date of manufacture;
- damage results from service or repairs performed to any part of the t:slim Pump by any person or entity other than Tandem;
- the t:slim Pump seal is broken;
- a non-Tandem cartridge is used with the t:slim Pump;
- damage consists of scratches and wear to surfaces and other externally exposed parts due to wear and tear;
- damage results from an event or accident beyond the control of Tandem; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse.

From time-to-time Tandem may offer software updates for your t:slim Pump to help to ensure the up-to-date functionality of your pump or software that are intended to add new features to your t:slim Pump. Tandem reserves the right to offer those updates, if any, in its sole discretion either at no charge or for an additional fee to be determined at a future date. To the extent that an update is offered at no charge, it is considered to be included in the original cost of your pump. Any future software updates will be subject to your acceptance of other terms and conditions that may be applicable at that time, including additional terms that may modify or limit the terms of this Warranty.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the t:slim Pump covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty only applies to the t:slim Pump and does not apply to other products or accessories. This warranty is valid only in the United States. No

employee of Tandem or any other party is authorized to make any warranty in addition to those made in this Warranty.

The remedies provided for in this warranty are the exclusive remedies available for any warranty claims. Neither Tandem nor its suppliers or distributors shall be liable for losses, liabilities, claims or damages of any kind or nature whatsoever, including, without limitation, any indirect, incidental, consequential, or special damages of any kind caused by or arising out of a defect in the product. All other warranties, express or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

Warranty

t:slim Cartridges

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

The warranty is valid only if the cartridges are used in accordance with the accompanying instructions for use and user guide and will not apply if:

- the cartridge has been used for more than a single-time use by a single end-user;
- damage results during the improper opening of the sterile package not in conformance with the procedures outlined in the associated Instructions for Use;
- the sterile package is compromised while in the control of the user by any means other than purposeful opening by the user at the time of intended product use;
- damage results from changes or modifications made to the cartridge by the user or third persons after the date of manufacture;
- damage results from service or repairs performed to any part of the cartridge by any person or entity other than Tandem;
- damage is caused by use of the cartridge with any non-Tandem insulin pump;
- damage results from an event or accident beyond the control of Tandem; or
- damage results from negligence or improper use, including but not limited to improper storage or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This war-

ranty does not apply to insulin pumps and other accessories. This warranty is valid only in the United States. No employee of Tandem or any other party is authorized to make any warranty in addition to those made in this Warranty.

The remedies provided for in this warranty are the exclusive remedies available for any warranty claims. Neither Tandem nor its suppliers or distributors shall be liable for losses, liabilities, claims or damages of any kind or nature whatsoever, including, without limitation, any indirect, incidental, consequential, or special damages of any kind caused by or arising out of a defect in the product. All other warranties, express or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

20.11 Returned Goods Policy

Any insulin pump product ("Pump") that was originally purchased from Tandem Diabetes Care®, Inc. ("Tandem") or one of its authorized distributors may be re-turned to Tandem only for the following reasons: (1) during the applicable warranty period (which is set forth in the user guide for the Pump), the customer experiences an issue with the Pump that is covered by the warranty set forth in the user guide for the Pump, then Tandem will repair or replace the Pump as provided under the applicable warranty above, and (2) during the thirty (30) day period after the shipment of the Pump, if the customer discovers that the Pump is not suited for the customer based on a valid, good faith medical reason which has been confirmed by the customer's physician, then Tandem or the autho-rized distributor will accept the return of the Pump and provide a refund to the customer and/or its insurance company for the amount actually paid for the Pump. Tandem will not accept or be obligated to accept for return any Pump that is not based on one of the two reasons. To assure prompt handling when returning a Pump, the customer must first obtain a returned materials authorization (RMA) number from Tandem's or its authorized distributor's Customer Service Department. This returned materials authorization number must be clearly written on the outer box. If Tandem or the authorized distributor provides a label, the label must be attached or taped to the outer box. If no label is provided, Tandem recommends shipping via insured ground service with a tracking number. Tandem is not responsible for lost or damaged packages.

To obtain a returned materials authorization (RMA) number and shipping address, please contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

Returns pre-authorized by Tandem's authorized distributors should be sent to the distributor authorizing the return, unless other instructions are provided.

Returns made without the returned materials authorization number will be returned to the customer, freight col-

lect. This policy is subject to applicable law.

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