

t:slim X2™

Insulin Pump

Dexcom G5™ Mobile CGM Enabled



User Guide

t:slim X2 Insulin Pump with Dexcom G5 Mobile CGM User Guide

Software Version: Pendleton

Congratulations on the purchase of your new t:slim X2™ isystem.

This user guide is designed to assist you with the features and functions of the t:slim X2 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 X2 system.

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

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Please contact Customer Technical Support to obtain a replacement copy of the user guide that is the correct version for your pump. For contact

information in your region see the back cover of this user guide.

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Section 1

Overview





Chapter 1

Introduction

1.1 Conventions of this Guide

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







Formatting Conventions









Convention	Explanation
Bolded Text	Text that is in bold and in a different font than the rest of the sentence or step indicates an on-screen icon or physical button name.
<i>Italic Text</i>	Text that is in italics indicates the name of a screen or menu on the pump display.
Touchscreen	The front glass screen of your pump, which displays all programming, operating, and alarm/alert information.
Tap	Quickly and lightly touch the screen with your finger.
Press	Use your finger to depress a physical button (the Screen On/Quick Bolus button is the only physical/hardware button on your pump).
Hold	Keep pressing a button or touching an icon or menu until its function is complete.
Menu	A list of options on your touchscreen that allow you to perform specific tasks.
Icon	An image on your touchscreen that indicates an option or item of information, or a symbol on the back of your pump or its packaging.
	Calls out an important note regarding the use or operation of the system.
	Calls out safety precautions which, if ignored, could result in minor or moderate injury.
	Calls out critical safety information which, if ignored, could result in serious injury or death.
	Indicates how the pump responds to the previous instruction.

1.2 Explanation of Symbols








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







Explanation of t:slim X2 Insulin Pump Symbols

Symbol	Meaning
	Caution
	Follow Instructions for Use
	Consult instructions for use
R _x Only	For sale by or on the order of a physician only (U.S.)
	Serial number
	Catalogue number
	Batch code
IPX7	International Protection (IP) Code

Symbol	Meaning
	Type BF Applied Part (patient isolation, not defibrillator protected)
	Non-ionizing Radiation
	Medical Device
	Authorized Representative in the European Community
	CE marking of conformity
	Regulatory Compliance Mark
	Humidity limitation
	Temperature limit

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

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Direct Current (DC) voltage
	Separate collection for waste electrical and electronic equipment
	Electric Equipment Designed Primarily for Indoor Use
	IEC Class II Equipment
	Keep Dry

Symbol	Meaning
	Wall Power USB Adapter
	Cartridge Removal Tool
	USB Cable
	Outlet Adapter
	Pump Case
	User Guide

1.3 System Description

The t:slim X2 insulin pump is made up of the t:slim X2 insulin pump, the t:slim 3mL (300 units) cartridge, and a compatible infusion set. In this user guide, the t:slim X2 insulin pump may be referred to as the “pump” or the “t:slim X2 pump.”

The t:slim X2 insulin pump and the Dexcom G5 Mobile continuous glucose monitor (CGM) (sold separately) paired together may be referred to as the “System.”

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

The pump can be used for basal and bolus insulin delivery with or without a CGM.

The Dexcom G5 Mobile transmitter may be referred to as the “transmitter.” The

Dexcom G5 Mobile sensor may be referred to as the “sensor.” Together, the Dexcom G5 Mobile transmitter and Dexcom G5 Mobile sensor may be referred to as the “CGM.”

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

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

The t:slim X2 insulin pump can be used for basal and bolus insulin delivery with or without Dexcom G5 Mobile CGM. If the Dexcom G5 Mobile sensor and transmitter are not used, sensor glucose readings will not be sent to the pump display and you will not receive any sensor glucose alerts.

The Dexcom G5 Mobile sensors and transmitter are sold and shipped separately by Dexcom.

NOTE: Device Connections

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

The t:connect™ mobile app enables you to connect a mobile device to the pump using *Bluetooth* wireless technology to display your pump information on the mobile device. The t:connect mobile app may not yet be available in your region.

⚠ PRECAUTION

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

1.4 About this User Guide

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

The user guide is organized into sections. Section 1 provides important information you need to know before you start using the System. Section 2 covers instructions for using the t:slim X2 pump. Section 3 covers instructions for using CGM with your pump. Section 4 provides information on the technical specifications of your pump and sensor performance characteristics of the Dexcom G5 Mobile CGM.

Pump screens used in this user guide to demonstrate how to use features are

examples only. They should not be considered suggestions for your individual needs.

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

1.5 Indications for Use

The t:slim X2 System consists of the t:slim X2 insulin pump paired with the Dexcom G5 Mobile CGM. The t:slim X2 insulin pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The t:slim X2 insulin pump can be used solely for continuous insulin delivery and as part of the t:slim X2 System.

When used with the Dexcom G5 Mobile CGM, the t:slim X2 System is designed to replace fingerstick blood glucose testing for diabetes treatment decisions. The t:slim X2 system aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the t:slim X2 system results should be based on the trends and patterns seen with several sequential readings over time.

The pump is indicated for use in individuals 6 years of age and greater.

The pump is intended for single patient use. Federal (USA) law restricts this device to sale by or on the order of a physician.

The pump is indicated for use with NovoLog/NovoRapid or Humalog U-100 insulin.

1.6 Contraindications

The t:slim X2 pump, transmitter, and sensor must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. Exposure to MRI, CT, or diathermy treatment can damage the components.

1.7 Important User Information

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

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



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

If you are currently using the pump without Dexcom G5 CGM, or if you are currently using Dexcom G5 CGM, it is still very important that you review all

instructions in this user guide before using the combined System.

NOTE: Use of CGM for Treatment Decisions

Product information for the Dexcom G5 Mobile CGM System includes important information on how to use the Dexcom G5 Mobile CGM information (including sensor glucose readings, trend graph, trend arrow, alarm/alerts) to make treatment decisions. Ensure that you have reviewed this information and discussed it with your healthcare provider, who can guide you in correctly using your Dexcom G5 Mobile CGM information when making treatment decisions.

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

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

1.8 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 Security PIN capabilities of the pump and determining how they best fit with your care plan. These features are detailed in [Chapters 10 Quick Bolus](#) and [11 Device Settings](#).

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

For patients who do not self-manage their disease, the Security PIN function should **ALWAYS** be on when the pump is not being used by a caregiver. The Security PIN function is intended to prevent inadvertent screen taps or button presses that may lead to insulin delivery or changes in the pump settings. These changes can potentially lead to hypoglycemia (low BG) or hyperglycemia (high BG) events. See [Section 11.5 Turn Security PIN On or Off](#) for

details on how to turn the Security PIN function on.

⚠ WARNING

For patients whose insulin administration is managed by a caregiver, **ALWAYS** turn off the Quick Bolus feature to avoid inadvertent bolus delivery. If the Security PIN is turned on, the Quick Bolus feature is automatically disabled. Inadvertent screen taps, button presses, or tampering with the insulin pump could result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events. See [Section 11.5 Turn Security PIN On or Off](#) for details on how to turn the Security PIN function off.

1.9 Emergency Kit

Make sure that you always have an insulin syringe and vial of insulin or a prefilled insulin pen 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:

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

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Section 2

t:slim X2 Insulin Pump

Chapter 2

Important Safety Information

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

2.1 t:slim X2 Insulin Pump Warnings

t:slim X2 Insulin Pump

⚠ WARNING

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

⚠ WARNING

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

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

- » Test blood glucose (BG) levels as recommended by a healthcare provider

- » Demonstrate adequate carbohydrate-counting skills (preferred, not required)
- » Maintain sufficient diabetes self-care skills
- » See a healthcare provider(s) regularly

The user must also have adequate vision and/or hearing in order to recognize pump alerts.

⚠ WARNING

DO NOT start to use your pump before consulting with your healthcare provider to determine which features are most appropriate for you. Only your healthcare provider can determine and help you adjust your basal rate(s), carb ratio(s), correction factor(s), target BG, and duration of insulin action. In addition, only your healthcare provider can determine your CGM settings and how you should use your sensor trend information to help you manage your diabetes. Incorrect settings can result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

ALWAYS be prepared to inject insulin with an alternative method if delivery is interrupted for any reason. Your pump is designed to deliver insulin reliably, but because it uses only rapid-acting insulin, you will not have long-acting

insulin in your body. Failure to have an alternative method of insulin delivery can lead to very high BG or Diabetic Ketoacidosis (DKA).

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

your infusion set from your body before filling the tubing can result in over delivery of insulin. This can cause hypoglycemia (low BG) events.

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

The pump includes parts (such as the USB cable and infusion set tubing) that could pose a

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

If the Security PIN is turned on, the Quick Bolus feature is automatically disabled. Inadvertent screen taps, button presses, or tampering with the insulin pump could result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

Radiology and Medical Procedures and Your t:slim X2 System

⚠ WARNING

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

⚠ WARNING

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

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

⚠ WARNING

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

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

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

⚠ WARNING

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.

⚠ WARNING

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

you have questions, contact Customer Technical Support.

⚠️ WARNING

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

2.2 t:slim X2 Insulin Pump Precautions

⚠️ PRECAUTION

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

⚠️ PRECAUTION

CHANGE your infusion set every 48 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.

⚠️ PRECAUTION

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

⚠️ PRECAUTION

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

⚠️ PRECAUTION

CHECK your infusion set tubing daily for any leaks, air bubbles, or kinks. Air in the tubing, leaks in the tubing, or kinked tubing may restrict

or stop insulin delivery and result in under delivery of insulin.

⚠️ PRECAUTION

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

⚠️ PRECAUTION

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

⚠️ PRECAUTION

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

⚠️ PRECAUTION

CHECK your pump's personal settings regularly to ensure they are correct. Incorrect settings can result in over delivery or under delivery of

insulin. Consult with your healthcare provider as needed.

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠ PRECAUTION

AVOID exposure of your pump to temperatures below 40°F (5°C) or above 99°F (37°C). Insulin

can freeze at low temperatures or degrade at high temperatures. Insulin that has been exposed to conditions outside of the manufacturer's recommended ranges can affect the safety and performance of the pump.

⚠ PRECAUTION

AVOID submerging your pump in fluid beyond a depth of 3 feet (0.91 m) 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 entry. If there are signs of fluid entry, discontinue use of the pump and contact Customer Technical Support.

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠️ PRECAUTION

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

⚠️ PRECAUTION

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

⚠️ PRECAUTION

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

⚠️ PRECAUTION

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

(305 meters). Changes in delivery accuracy can affect insulin delivery and cause injury.

⚠️ PRECAUTION

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

⚠️ PRECAUTION

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

⚠️ PRECAUTION

Interference with your pump's electronics by cell phones can occur if worn in close proximity. It is recommended that your pump and cell phone be worn at least 6.4 inches (16.3 cm) apart.

⚠️ PRECAUTION

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

2.3 Potential Benefits From Using Your Pump

- The pump provides an automated way to deliver basal and bolus insulin. Delivery can be fine-tuned based on up to 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 pump gives you the option of delivering a bolus all at once, or delivering a percentage over an extended period of time without navigating to different menus. You can also program a bolus more discreetly using the Quick Bolus feature, which can be used without

looking at the pump, and can be programmed in increments of either units of insulin or grams of carbohydrate.

- From the bolus screen, the “calculator within a calculator” feature allows you to enter multiple carbohydrate values and add them together. The insulin pump’s bolus calculator will recommend a bolus based on the entire amount of carbohydrates entered, which can help eliminate guesswork.
- The insulin pump keeps track of the amount of active insulin from food and correction boluses (IOB). When programming additional food or correction boluses, the pump will subtract the amount of IOB from the recommended bolus if your BG is below the target set in your active Personal Profile. This can help prevent insulin stacking, which can lead to hypoglycemia (low BG).
- You can program a number of reminders that will prompt you to retest your BG after a low or high BG is entered, as well as a “Missed Meal Bolus Reminder” which will

alert you if a bolus isn’t entered during a specified period of time. If activated, these can help reduce the likelihood that you will forget to check your BG or bolus for meals.

- You have the ability to view a variety of data right on your screen, 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.

2.4 Possible Risks From Using Your Pump

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

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

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

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

Risks that could result from pump failure include the following:

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

hardware defect or software anomaly.

2.5 Working with your Healthcare Provider

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

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

2.6 Verification of Proper Functionality

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

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

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

- Press the **Screen On/Quick Bolus** button to turn the screen on so that you can see the display
- When the display screen is on, the touchscreen responds to your finger tap

PRECAUTION

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

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Chapter 3

Getting to Know Your t:slim X2 Insulin Pump

3.1 What your t:slim X2 Pump Package Includes

Your pump package should include the following items:

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

If any of these items are missing, contact Customer Technical Support.

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

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

Your pump comes with a protective cover in the place where the cartridge is normally inserted. This cover must be

removed and replaced with a cartridge prior to initiating insulin delivery.

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

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

Supply Reordering

To order cartridges, infusion sets, supplies, accessories, screen protectors, please contact Customer Technical Support or your usual supplier of diabetes products.

3.2 Pump Terminology

Basal

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

BG

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

BG Target

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

Bolus

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

Cannula

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

Carb

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

Carb Ratio

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

Correction Bolus

A correction bolus is given to correct high glucose.

Correction Factor

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

Extended Bolus

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

Grams

Grams are the measurement for a carbohydrate.

Insulin Duration

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

Insulin On Board (IOB)

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

Load

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

Personal Profile

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

Quick Bolus

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

Temp Rate

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

Units

Units are the measurement for insulin.










USB Cable










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

3.3 Explanation of t:slim X2 Insulin Pump Icons





The following icons may appear on your pump screen:





Pump Icon Definitions

Symbol	Meaning
	The amount of charge left in the pump battery.
	CGM sensor session is active, and the transmitter is communicating with the pump.
	CGM sensor session is active, but the transmitter is not communicating with the pump.
	CGM calibration is required.
	A system reminder, alert, error, or alarm is active.
	Basal insulin is programmed and being delivered.
	Accept. Tap to continue to the next screen or to answer yes to a message on the pump screen.
	Save. Tap to save settings on the screen.
	New. Tap to add a new item.





Symbol	Meaning
	Amount of insulin remaining in the reservoir.
	A temporary basal rate is active.
	A basal rate of 0 u/hr is active.
	A temporary basal rate of 0 u/hr is active.
	A bolus is being delivered.
	All insulin deliveries are stopped.
	Cancel. Tap to cancel the current operation.
	Decline. Tap to exit the screen or answer no to a message on the pump screen.
	Back. Tap to navigate to the previous screen.

Pump Icon Definitions (Continued)

Symbol	Meaning
	Delete. Tap to delete characters or digits on a keypad.
	Space. Tap to enter a space on the character keypad.
	The associated setting is turned on.
	Bluetooth

Symbol	Meaning
	Total. Tap to total values on a keypad.
	OK. Tap to confirm the current instruction or setting on the screen.
	The associated setting is turned off.
	Security PIN has been enabled. See Section 11.5 Turn Security PIN On or Off .

3.4 Explanation of Pump Colors

	<p>Red LED 1 red blink every 30 seconds indicates a malfunction or alarm condition.</p>
	<p>Yellow LED 1 yellow blink every 30 seconds indicates an alert or reminder condition.</p>
	<p>Green LED</p> <ul style="list-style-type: none"> • 1 green blink every 30 seconds indicates the pump is functioning normally. • 3 green blinks every 30 seconds indicate the pump is charging.
	<p>Orange Highlight When editing settings, changes are highlighted in orange for review before saving.</p>

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3.5 Lock Screen

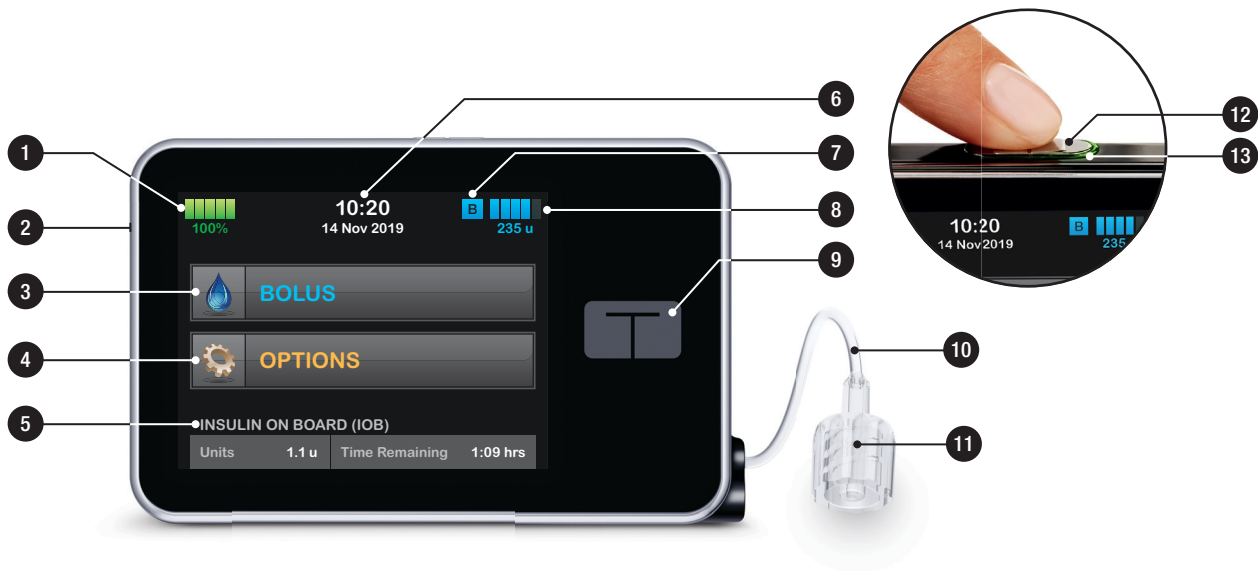
The *Lock* screen appears anytime you turn on the screen. You must tap 1–2–3 in sequential order to unlock the pump.

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



3.6 Home Screen

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



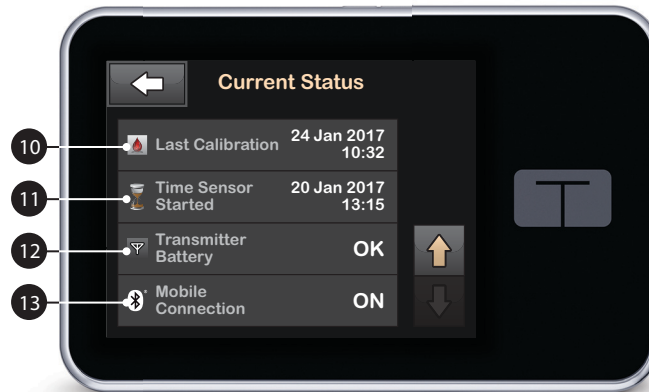
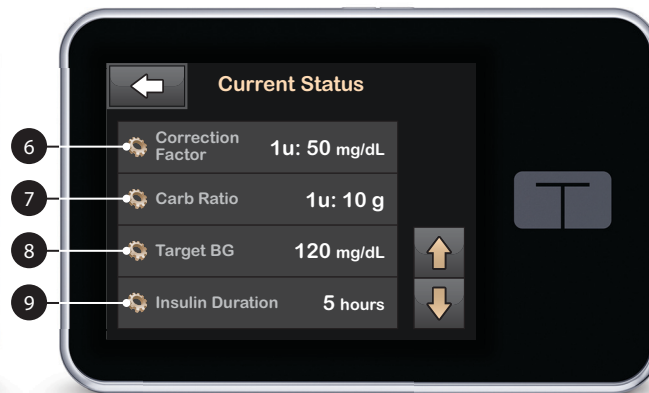
3.7 Status Screen

The *Status* screen can be accessed from the *Lock screen* and the *Home* screen. It is for display only; no changes can be made from this screen.





1. **Profile:** Displays current active Personal Profile.
2. **Basal Rate:** Displays current basal rate being delivered. (If a Temp Rate is active, it is displayed in units/hr.)
3. **Last Bolus:** Displays the amount, date and time of last bolus.
4. **Carbohydrates:** Indicates whether feature is on or off.
5. **Up/Down Arrow:** Indicates there is more information.
6. **Correction Factor:** Displays current correction factor used to calculate a bolus.
7. **Carb Ratio:** Displays current carb ratio used to calculate a bolus.
8. **Target BG:** Displays current BG target used to calculate a bolus.

9. **Insulin Duration:** Displays current insulin duration setting used to calculate insulin on board.
10. **Last Calibration:** Displays date and time of last calibration.
11. **Time Sensor Started:** Displays date and time of last time sensor started.
12. **Transmitter Battery:** Displays transmitter battery status.
13. **Mobile Connection:** Displays whether the mobile connection is turned on or off, whether a mobile device is paired with the pump, and if so whether the mobile device is actively connected to the pump.

The mobile connection may not yet be available in your region.



3.8 Bolus Screen

1. : Returns to the *Home* screen.
2. **Carbs:** Enter grams of carbohydrate. See [Section 10.1 Setting Up Quick Bolus](#) for details on how to set the Increment Type.
3. **Units:** Displays total units calculated. Tap to enter a bolus request or change (override) a calculated bolus.
4. **View Calculation:** Displays how the insulin dose was calculated using the current settings.
5. **Add BG:** Enter blood glucose level. If you have an active CGM session and your CGM value and trend arrow are available, this value is auto-populated.
6. : Moves to next step.
7. : Returns to the *Home* screen.
8. **Insulin:** Enter units of insulin. See [Section 10.1 Setting Up Quick Bolus](#) for details on how to set the Increment Type.
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. : Moves to next step.


Using Grams



Using Units




3.9 Options Screen

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



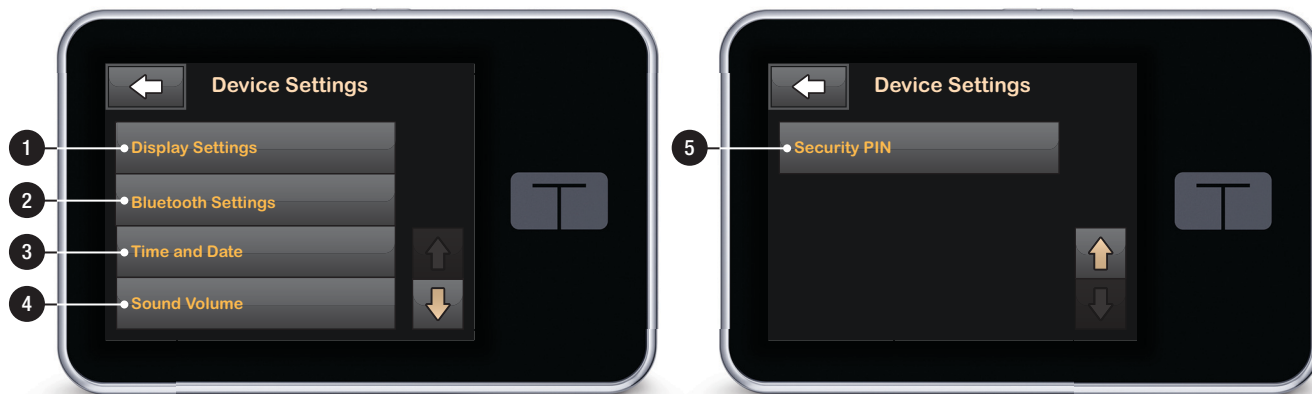
3.10 My Pump Screen

1. : Returns to the *Home* screen.
2. **Personal Profiles:** A group of settings that define basal and bolus delivery.
3. **Alerts & Reminders:** Customize Pump Reminders and Alerts.
4. **Pump Settings:** Customize Quick Bolus.
5. **Pump Info:** Displays pump serial number, Customer Technical Support contact information, website, and other technical information.







3.11 Device Settings Screen

1. **Display Settings:** Customize the Screen Timeout and Language settings.
2. **Bluetooth Settings:** Turn on/off mobile connection. The mobile connection may not yet be available in your region.
3. **Time and Date:** Edit the time and date that will be displayed on the pump.
4. **Sound Volume:** Customize the sound volume for pump alarms, pump alerts, reminders, keypad, bolus, quick bolus, fill tubing, and CGM alerts.
5. **Security PIN:** Turn on/off the Security PIN.







3.12 Number Keypad Screen

1. Value Entered.
2. : 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. : Completes task and saves information entered.
6. Units/Grams: Value of what is entered.
7. : Deletes last number entered.



3.13 Letter Keypad Screen

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



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Chapter 4

Getting Started

4.1 Charging the t:slim X2 Pump

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

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

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

90%, 85%). When the charge amount is less than 5%, it will begin decreasing 1% at a time (for example, you will see 4%, 3%, 2%, 1%).

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

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

PRECAUTION

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

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

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

To charge the pump from an AC Power Outlet:

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

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

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

WARNING

When using an optional Car Power USB Adapter, the charger must be connected to an isolated, battery powered 12 Volt system, such as an

automobile. Connecting the DC vehicle adapter charger to 12 Volt DC that is generated by a power supply connected to alternating current (AC) mains is prohibited.

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

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

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

NOTE: For Customers Using the t:connect Diabetes Management Application

Before using a computer to charge the pump, it is recommended that a driver be installed on the computer by downloading the t:connect uploader software from our website at www.tandemdiabetes.com. This will also allow communication between the pump, the computer, and the t:connect diabetes management application. The t:connect diabetes management application may not yet be available in your region.

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

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

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

PRECAUTION

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

Charging Tips

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

NOTE: 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 touchscreen.


4.2 Using the Touchscreen

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

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

The pump has several safety features to prevent unintentional interaction with the touchscreen. The screen must be unlocked by tapping 1–2–3 in sequence. On all screens, if three non-active areas of the touchscreen are tapped before an active area is tapped, the screen will turn off to prevent accidental screen interactions. There is also a Security PIN feature that can be set up to prevent unintentional access (see [Section 11.5 Turn Security PIN On or Off](#)).

NOTE: Touchscreen Tips

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

4.3 Turning on the t:slim X2 Pump Screen

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

✓ The *Lock* screen will be displayed.

NOTE: Turning off the Pump Screen

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

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

4.4 Unlocking the t:slim X2 Pump Screen

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

1. Press **Screen On/Quick Bolus** button.
 2. Tap 1.
 3. Tap 2.
 4. Tap 3.
- ✓ The pump screen is now unlocked. The last screen that was viewed will be displayed.


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

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

4.5 Selecting Your Language

The language selection screen displays when you unlock the pump screen for the first time, or when you unlock the pump screen after turning the pump off.

To select your language:

1. Tap the circle next to the language you want to display. Tap the down or up arrow to see additional language selections.
2. Tap  to save the selection and continue with pump setup.



4.6 Edit Time


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

⚠ PRECAUTION


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



1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Device Settings**.
4. Tap **Time and Date**.
5. Tap **Edit Time**.
6. Tap **Time**.

7. Using the on-screen keypad, enter the hour and minutes. Verify and tap .
8. Tap **Time of Day** to set AM or PM, or tap **24-hour Time** to toggle that setting on.
9. Verify the correct time is set and tap .

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

4.7 Edit Date

1. From the *Time and Date* screen tap **Edit Date**.
2. Tap **Day**.
3. Using the on-screen keypad enter the current day. Verify and tap .
4. Tap **Month**.
5. Find and tap the current month displayed on the right. Use **Up/Down Arrow** to view months not displayed.
6. Tap **Year**.

7. Using the on-screen keypad enter the current year. Verify and tap .
 8. Verify the correct date is set and tap .
- ✓ Tap the **Tandem logo** to return to the *Home* screen.

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Chapter 5

Infusion Site Care and Loading Cartridge

5.1 Infusion Site Selection and Care

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

⚠ PRECAUTION

CHECK your infusion site daily for proper placement and leaks. **REPLACE** your infusion set if you notice leaks around the site.

Improperly placed sites or leaks around the infusion site can result in under delivery of insulin.

⚠ PRECAUTION

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

General Guidelines

Site Selection

- Your infusion set can be worn anywhere on your body that you would normally inject insulin. Absorption varies from site to site. Discuss options with your healthcare provider.
- The most commonly used sites are the abdomen, upper buttocks, hips, upper arms, and upper legs.
- The abdomen is the most popular site because of access to fatty

tissue. If using the abdominal area, **AVOID**:

- Areas that would constrict the site such as the belt line, waistline, or where you would normally bend.
- Areas 2 inches (5 cm) around your belly button.
- Any scars, moles, stretch marks, or tattoos.
- Areas within 3 inches (7.6 cm) of your CGM sensor site.

Site Rotation

⚠ PRECAUTION

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

- The infusion set must be replaced and rotated every 48–72 hours, or more often if needed.

- With experience, you will find areas that not only provide better absorption, but are more comfortable. Keep in mind, using the same areas may cause scarring or lumps which can affect insulin absorption.
- Consult your healthcare provider to establish a rotation schedule that best fits your needs.

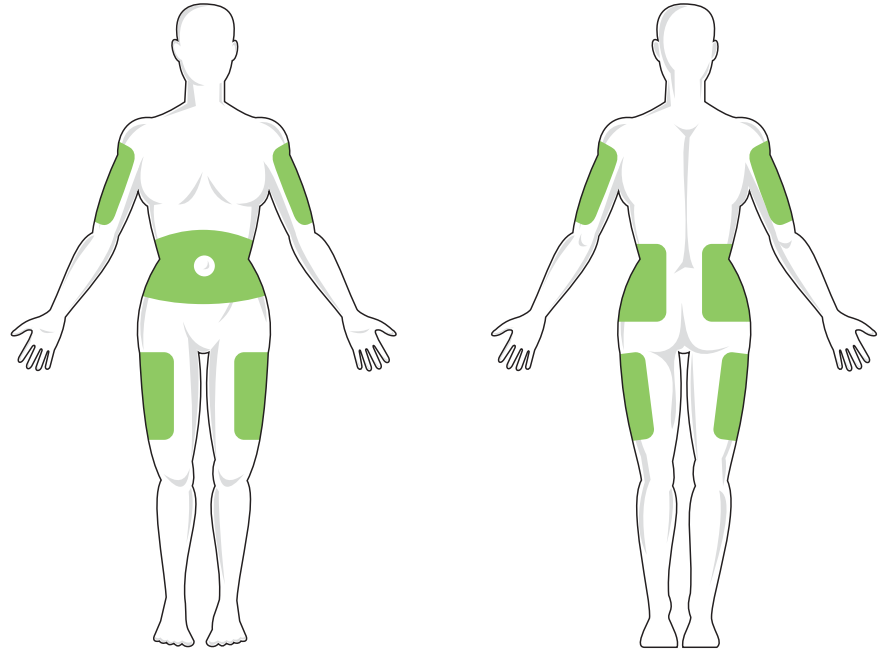
Keep it Clean

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

5.2 Cartridge Instructions for Use

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

Areas of Body for Infusion Set Insertion



5.3 Filling and Loading a t:slim Cartridge

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

⚠ WARNING

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

⚠ WARNING

ALWAYS use cartridges manufactured by Tandem Diabetes Care. Use of any other cartridge brand may result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

DO NOT reuse cartridges. Reuse of cartridges may result in over delivery or under delivery of

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

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

- 1 unopened cartridge
- 3.0 mL syringe and fill needle
- Vial of U-100 Humalog or U-100 NovoLog/NovoRapid insulin
- Alcohol prep swab
- 1 new infusion set
- Infusion set Instructions for Use

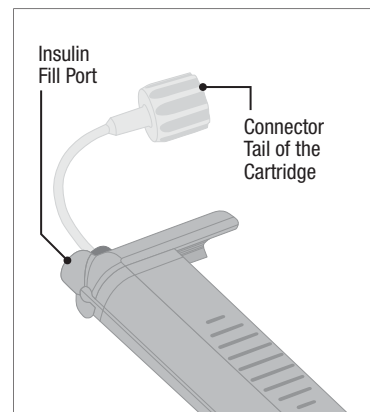
📖 NOTE: Fill Tubing Sound Volume

The pump will beep or vibrate, depending on your pump settings, while the tubing is filling with insulin. To change the Fill Tubing sound setting, see [Section 11.4 Sound Volume](#).

📖 NOTE: Removing the Cartridge

DO NOT remove the used cartridge from the pump during the load process until prompted on the pump screen.

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



⚠ PRECAUTION

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

Instructions for Drawing Insulin from Vial into Syringe

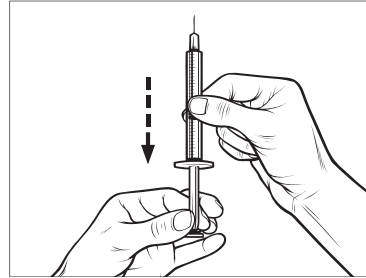
The fill estimate displayed on the pump is the amount of insulin available for delivery. It does not include insulin needed to fill the tubing (up to 30 units) and a small amount of insulin that is not available for delivery. When filling the syringe, add approximately 45 units to the amount of insulin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

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

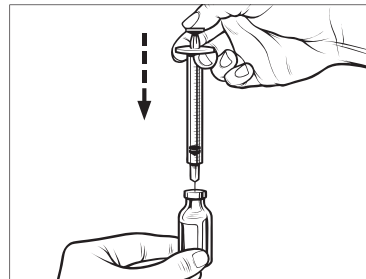
1. Inspect the needle and syringe package for any signs of damage. Discard any damaged product.
2. Wash your hands thoroughly.
3. Wipe the rubber septum of the insulin vial with an alcohol swab.
4. Remove the needle and syringe from their packaging. Securely twist needle onto syringe. Safely remove

protective cap from needle by pulling outward.

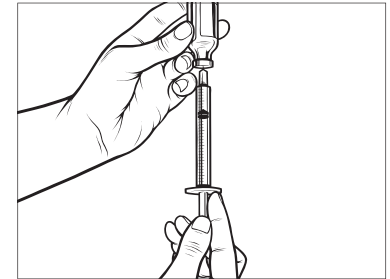
5. Draw air into syringe up to the amount of insulin desired.



6. With insulin vial upright, insert needle into vial. Inject air from syringe into vial. Maintain pressure on syringe plunger.

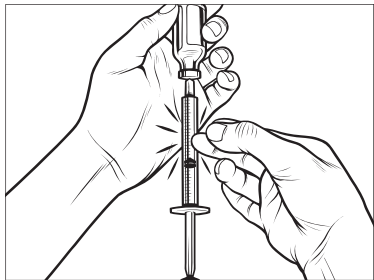


7. With needle still inserted into vial, turn vial and syringe upside down. Release syringe plunger. Insulin will begin to flow from the vial into the syringe.
8. Slowly pull back the plunger to the desired amount of insulin.



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

plunger upwards, forcing any air bubbles back into the vial.



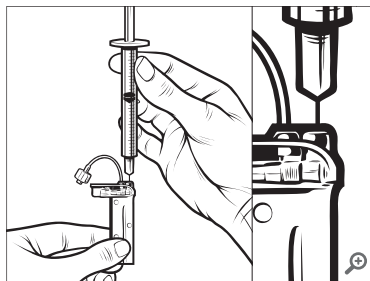
10. Check the syringe for air bubbles and do one of the following:

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

Instructions for Filling the Cartridge

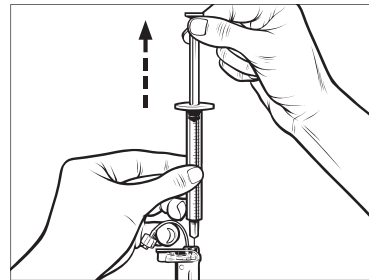
1. Inspect the cartridge package for any signs of damage. Discard any damaged product.
2. Open the package and remove the cartridge.

3. Hold the cartridge upright and gently insert the needle into the white insulin fill port on the cartridge. The needle is not intended to go all the way in, so do not force it.

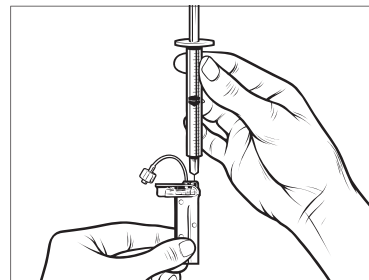


4. Keeping the syringe vertically aligned with the cartridge, and the needle inside the fill port, pull back on the plunger until it is fully retracted. This will remove any residual air from the cartridge.

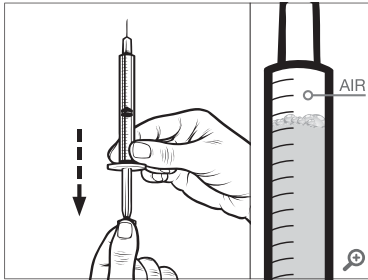
Bubbles will rise toward the plunger.



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

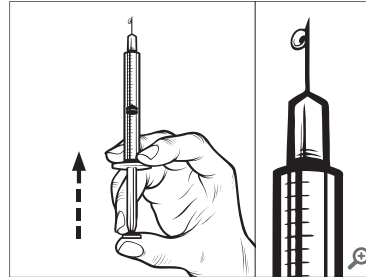


6. Withdraw the needle from the fill port.
7. Turn the syringe upright and pull down on the plunger. Flick the barrel to make sure that any air bubbles rise to the top.

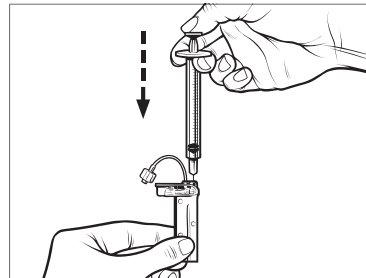


8. Gently press on the plunger to remove air bubbles until insulin fills

the needle hub and you see a drop of insulin at the tip of the needle.



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



10. Maintain pressure on the plunger while you remove the needle from the cartridge. Check the cartridge for leaks. If you detect insulin leaking, discard the cartridge and repeat entire process with a new cartridge.


11. Always dispose of used needles, syringes, cartridges, and infusion sets following the instructions from your healthcare provider.

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  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.

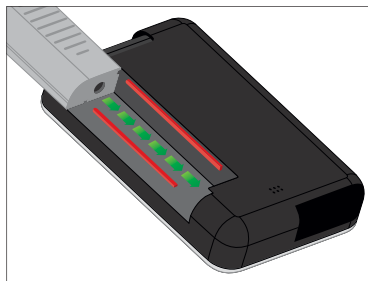
5. Disconnect the infusion set from your body and tap  to continue.

- ✓ *Preparing for Cartridge* screen is displayed.

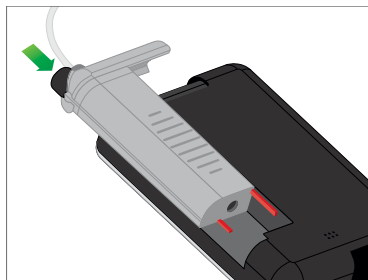
6. Remove the used cartridge. If needed, place the cartridge removal tool or the edge of a coin in the slot at the bottom of the cartridge and twist to aid in the removal of the cartridge.

7. Place bottom of the cartridge at the end of the pump. Make sure

cartridge is lined up to both guide tracks.



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



9. Tap  to continue.

- ✓ *Detecting Cartridge* screen is displayed.
- ✓ After completing the cartridge change, the pump will automatically prompt you to fill the tubing.

WARNING

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

5.4 Filling Tubing

Filling the Infusion Set Tubing with Insulin

WARNING

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

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

NOTE: Fill Tubing Sound Volume

The pump will beep or vibrate, depending on your pump settings, while the tubing is filling with insulin. To change the Fill Tubing sound setting, see [Section 11.4 Sound Volume](#).

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

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

PRECAUTION

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

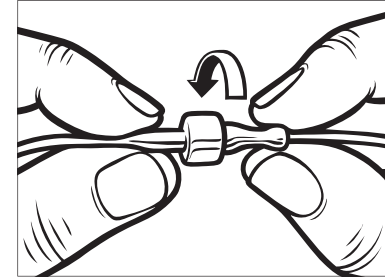
space where insulin should be and can affect insulin delivery.

PRECAUTION

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


1. Verify that the infusion set is disconnected from your body.
2. Ensure that the new infusion set package is not damaged, and remove the sterile tubing from the package. If the package is damaged or opened, discard of properly and use another tubing set.
3. Remove the infusion set tubing cap from the tubing connector. Be careful to keep the tubing connector away from unclean areas.
4. Attach the infusion set tubing to the tubing connector on the cartridge tubing. Twist clockwise until finger tight and then twist another quarter

of a turn to ensure a secure connection.

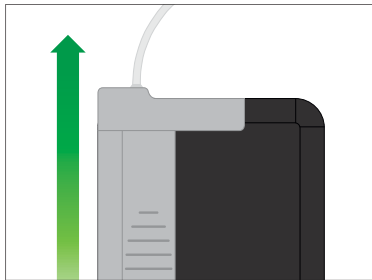


WARNING

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

5. Tap .
6. 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 (60 cm) tubing
 - 20–25 units for 32 inch (80 cm) tubing
 - 25–30 units for 42 inch (110 cm) tubing
7. Tap **STOP** after 3 drops of insulin are seen at the end of the infusion set tubing.

- ✓ *Stopping Fill* screen is displayed.
 - ✓ *Detecting Insulin* screen is displayed.
8. Verify that drops are seen and tap **DONE**.
- If you do not see drops, tap **FILL**. The *Fill Tubing* screen appears, repeat steps 3 to 5 until you see 3 drops of insulin at the end of the tubing.
 - The tubing may be filled with a maximum of 30 units of insulin during each fill cycle. If you do not tap **STOP**, a notification screen will appear letting you know that the maximum amount has been filled. Do one of the following:
 - a. If you are finished filling the tubing, tap **DONE**.
 - b. If you want to fill the tubing with more than 30 units, tap **FILL** to go back to the *Fill Tubing* screen.
- ✓ *Fill Tubing is complete* screen is temporarily displayed.

NOTE: Initial Display of Insulin

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

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

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

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

5.5 Filling Cannula


Filling the Infusion Set Cannula with Insulin

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

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

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

To Fill the Cannula:

1. Tap **Fill Cannula**.
2. Insert a new infusion set and connect filled tubing to site, then tap .
3. Tap **Edit Fill Amount**.
 - ✓ The cannula fill amount displayed is based on your last cannula fill amount. Filling stops at this amount.

4. Select amount needed for cannula fill.
 - See your infusion set instructions for use for proper cannula fill amount.
 - If the amount needed is not listed, tap **Other amount** and use the on-screen keypad to enter a value between 0.1 to 1.0 unit.

5. Tap .


✓ The *STARTING FILL* screen is displayed.

✓ After fill is complete, *STOPPING FILL* screen is displayed.

NOTE: Stopping Fill

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

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





6. Tap  to resume insulin if finished. Or tap **Site Reminder** to set reminder. If Site Reminder is on, the pump will automatically display



the *Site Reminder* screen (see the next section).

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.

1. Tap  if correct. Tap **Edit Reminder** if settings need to be changed.
2. Tap **Remind Me In** and select the number of days (1–3).
 - ✓ The default for the Site Reminder is set for 3 days
3. Tap **Remind Me At**. Use the on-screen keypad to enter time and tap .
4. Tap **Time of Day** to change AM or PM, if applicable. Tap .
5. Verify Site Reminder is set correctly and tap .

- ✓ *Setting Saved* screen is displayed.
- ✓ *Load* screen is displayed.
- 6. Tap .
- ✓ A reminder to test BG in 1 to 2 hours will display.
- 7. Tap .

 **NOTE: First Time Use**

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

- ✓ *RESUMING INSULIN* screen is temporarily displayed.

Chapter 6

Personal Profiles

6.1 Personal Profiles Overview

WARNING

DO NOT start to use your pump before consulting with your healthcare provider to determine which features are most appropriate for you. Only your healthcare provider can determine and help you adjust your basal rate(s), carb ratio(s), correction factor(s), target BG, and duration of insulin action. In addition, only your healthcare provider can determine your CGM settings and how you should use your sensor trend information to help you manage your diabetes. Incorrect settings can result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

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

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

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

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

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

6.2 Creating a New Profile

Creating Personal Profiles

You can create up to six 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 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.

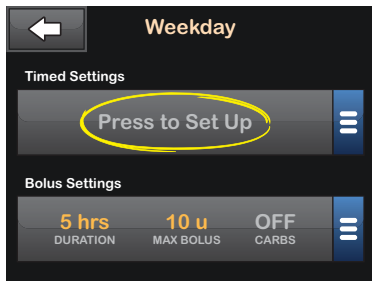
While the insulin duration setting reflects how long insulin from previous boluses lowers your BG, the IOB feature reflects how much insulin is remaining in your body from previous boluses. IOB is always displayed on the *Home* screen and is used in bolus delivery calculations when applicable.

When a glucose value is entered during bolus programming, your 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  to create a new profile.
5. Using the on-screen keypad, enter a profile name (up to 16 characters) and tap .

To use the letter keypad, tap once for first letter displayed, 2 quick taps for middle letter; and 3 quick taps for the third letter.

6. Tap **Press to Set Up** to begin setting insulin delivery settings.



6.3 Programming a New Personal Profile

Once the Personal Profile has been created, the settings must be programmed. The first time segment will start at midnight.

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

PRECAUTION

ALWAYS confirm that the decimal point placement is correct when entering your

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

Timed Settings



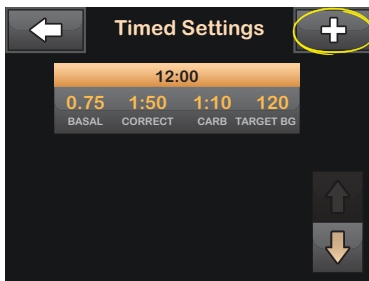
1. Once the new profile has been created, Tap **Basal**.

Using the on-screen keypad, enter your basal rate and tap .

2. Tap **Correction Factor**.
3. Using the on-screen keypad, enter your correction factor (the mg/dL that 1 unit of insulin will lower BG) and tap .
4. Tap **Carb Ratio**.

5. Using the on-screen keypad, enter your insulin-to-carbohydrate ratio (the grams of carbohydrate to be covered by 1 unit of insulin) and tap .
6. Tap **Target BG**.
7. Using the on-screen keypad, enter your target BG and tap .
8. Review entered values and tap .
9. Confirm Settings.
 - Tap if entered data is correct.
 - Tap to make changes.
10. Tap to set the Bolus Settings.

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



Adding More Time Segments

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

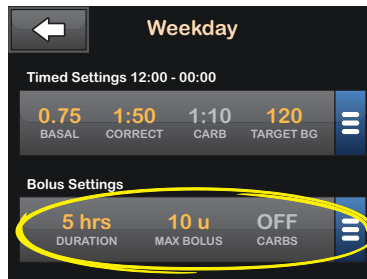
1. On the *Add Segment* screen, tap **Start Time**.
2. Using the on-screen keypad, enter the time (hour and minutes) that you want the segment to begin, and tap **✓**.

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

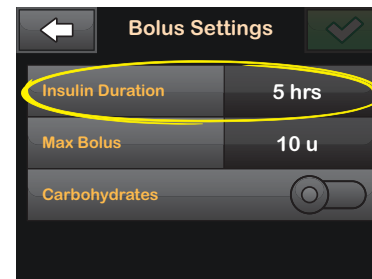
To find time segments in the list that are not displayed on the first screen, tap the **Down Arrow**.

Bolus Settings

1. Tap the **Bolus Settings** panel.






2. Tap **Insulin Duration**.




3. Using the on-screen keypad, enter the desired time for the duration of insulin action (2–8 hrs) and tap **✓**.
4. Tap **Max Bolus**.
5. Using the on-screen keypad, enter the desired amount for maximum bolus (1–25 units) and tap **✓**.

NOTE: 25 Unit Max Bolus

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

6. Tap **Carbohydrates** to turn on and use the carb ratio when calculating boluses.
7. Review entered values and tap .
8. Confirm Settings.
 - Tap  if entered data is correct.
 - Tap  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 .
5. Name the new profile and repeat steps for Timed Settings and Bolus Settings.


NOTE: Carbohydrates Options

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







6.4 Editing or Reviewing an Existing Profile



1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to edit or review.
5. Tap **Edit**.

NOTE: Review Settings

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

6. Tap **Timed Settings** panel.

7. Tap the desired time segment to edit.
8. Tap **Basal, Correction Factor, Carb Ratio** or **Target BG** to make changes as needed and use the on-screen keypad to enter changes. Tap .
9. View recent changes and tap .
10. Confirm Settings.
 - Tap  if entered data is correct.
 - Tap  to make changes.
11. Edit other time segments within the Timed Settings by tapping on them and using the same steps described above.
12. Tap  after editing all of the time segments.
13. Tap the **Bolus Settings** panel to change Insulin Duration, Max Bolus, or Carbohydrates as needed. Use the on-screen keypad to enter desired changes. Tap .
14. Confirm Settings.


- Tap  if entered data is correct.
- Tap  and make changes.

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

NOTE: Adding a Time Segment



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

NOTE: Deleting a Time Segment

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

6.5 Duplicating an Existing Profile


1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to duplicate.
5. Tap **Duplicate**.

6. Confirm profile to duplicate by tapping .
7. Using the on-screen keypad, enter the name (up to 16 characters) for the new profile and tap .
- ✓ *Profile Duplicated* screen is displayed.
- ✓ A new Personal Profile will be created with the same settings as the profile copied.
8. Tap the **Timed Settings** or **Bolus Settings** panel to make changes to the new profile.

6.6 Activating an Existing Profile


1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to be activated.
 - The Activate and Delete options are disabled for the active profile because the profile is already

activated. You cannot delete a profile until you have activated another profile.

- If you have only 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 .
 - ✓ *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**.


- Using the on-screen keypad, rename the profile name (up to 16 characters) and tap .
- Tap **Tandem logo** to return to the *Home* screen.

6.8 Deleting an Existing Profile

- From the *Home* screen, tap **OPTIONS**.
- Tap **My Pump**.
- Tap **Personal Profiles**.
- Tap the name of the Personal Profile to be deleted.

NOTE: Active Personal Profile

The active Personal Profile cannot be deleted.

- Tap **Delete**.
- Tap .
- ✓ *Profile Deleted* screen is displayed.
- Tap the **Tandem logo** to return to the *Home* screen.

Chapter 7

Bolus

7.1 Bolus Overview

⚠ WARNING

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

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

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

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

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

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

⚠ PRECAUTION

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

7.2 Correction Bolus Calculation

Once the pump knows your glucose value, either from the CGM or from manual entry, it will determine whether or not to recommend a correction bolus.

When your glucose value is:

- Above Target BG: the insulin for the food bolus and the correction bolus will be added together. If IOB is present, it 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 lower 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 glucose value. In addition, if IOB is present, it will also be used to reduce the bolus calculation.

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

Glucose Value Auto-Population with CGM

⚠ PRECAUTION

PAY ATTENTION to the trend information on your *Home* screen, as well as your symptoms, before using CGM values to calculate and deliver a correction bolus. Individual CGM values may not be as accurate as blood glucose meter values.

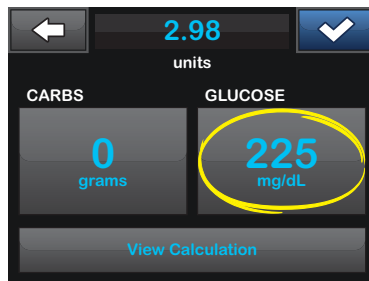
If you have a CGM session active, and if there is both a CGM value and a CGM trend arrow available on the *CGM Home* screen, your glucose value is automatically saved to the pump. To access the *Correction Bolus* screen, tap **BOLUS** from the *CGM Home* screen.

When the CGM reading is automatically populated into the bolus calculator, only the current CGM reading is used to calculate the correction bolus. The trend arrow is not used in the dose calculation. Speak with your healthcare provider for recommendations on how best to utilize the arrows for your correction bolus dosing.

If your healthcare provider has advised you to use the trend arrow to adjust your correction dose, or if you want to change the glucose value used to calculate your correction dose, you can manually override the glucose value auto-populated from your CGM.

To change the glucose value auto-populated from your CGM you can tap

on the glucose value on the *Bolus* screen.



NOTE: Changing the Glucose Value

If the glucose value auto-populated from your CGM was above or below your target BG, your pump will present you with the *Above Target* or *Below Target* correction bolus confirmation screen described later in this section.

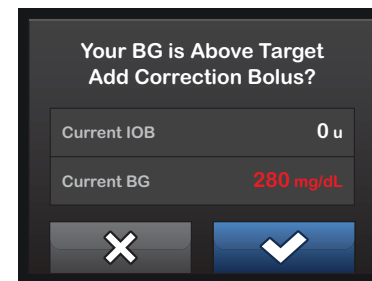
You cannot tap the **Current BG** value on these correction bolus confirmation screens to change the glucose value auto-populated from your CGM.

Tap either or and proceed to the *Bolus* screen to change the glucose value as described above. Once the value is changed, if the manually inputted value is above or below your

Target BG, your pump will again present you with the *Above Target* or *Below Target* confirmation screen where you can choose to accept the correction bolus or decline it.

Above Target

If your glucose value is above your Target BG, the pump presents you with the option for the pump to calculate and add a correction bolus to any other bolus you request.

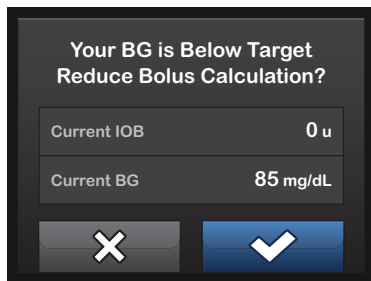


- To accept the correction bolus press . A correction bolus is calculated and will be added to any food bolus you request on the *Bolus* screen.

- To decline the correction bolus, press **X**. No correction bolus will be added to any food bolus you request on the *Bolus* screen.

Below Target

If your glucose value is below your Target BG, the pump presents you with the option for the pump to calculate and subtract a correction bolus from any other bolus you request.



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

be subtracted from any food bolus you request on the *Bolus* screen.

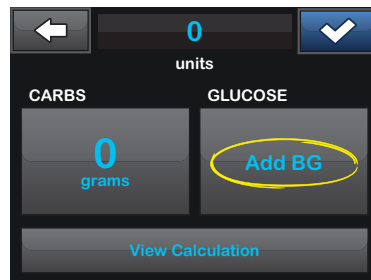
Within Target

If your glucose value is the same value as your Target BG, no *Correction Bolus* screen is displayed.

BG Value Manual Entry

If you do not have a CGM session active, you will need to enter your BG value into the pump manually before advancing to the *Correction Bolus* screens.

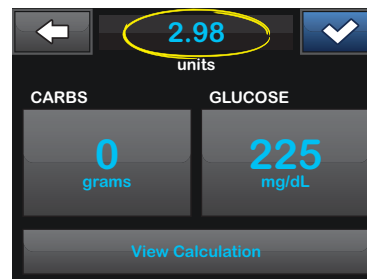
- From the *Home* screen tap **BOLUS**.
- Tap **Add BG**.



- Using the on-screen keypad, enter your BG value and tap **✓**. Once **✓** is tapped, the BG value is saved in your pump history whether or not a bolus is delivered.
- Follow the steps in the appropriate Target section above depending on the results of your BG value.


7.3 Bolus Override

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






7.4 Food Bolus Using Units

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

1. From the *Home* screen, tap **BOLUS**.
2. Tap **0 units**.
3. Using the on-screen keypad enter units of insulin to be delivered, then tap .

WARNING






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

4. Tap  to confirm the units of insulin to be delivered.
5. Confirm Request.
 - Tap  if entered data is correct.
 - Tap  to go back to make changes or view calculations.




6. Tap .

- ✓ The *BOLUS INITIATED* screen is temporarily displayed.

7.5 Food Bolus Using Grams

1. From the *Home* screen, tap **BOLUS**.
2. Tap **0 grams**.
3. Using the on-screen keypad enter grams of carb and tap .
 - To add multiple carb values enter first value, then tap , enter second value, tap . Continue until done.
 - To clear the value entered and start over, tap the  back arrow.
4. Check that the grams of carb are entered in the correct location on the screen.
5. Tap  to confirm the units of insulin to be delivered.

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

6. Confirm Request.
 - Tap  if entered data is correct.
 - Tap  to go back to make changes or view calculations.
 7. Tap .
- ✓ The *BOLUS INITIATED* screen is temporarily displayed.




7.6 Extended Bolus

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

When extending a bolus, any correction bolus amount will always be given in the **DELIVER NOW** portion. Talk with your healthcare provider to determine if this feature is appropriate for you, as well as




for recommendations on the split between now and later and the duration for the later portion.

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 on-screen keypad enter grams of carb (or units of insulin). Tap .
4. If desired, tap **Add BG** and using the on-screen keypad enter a glucose value. Tap .
5. Tap  to confirm the units of insulin to be delivered.


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

6. Confirm Request.

- Tap  if entered data is correct.
 - Tap  to go back to make changes or view calculations.
7. Tap **EXTENDED** to turn on the extended feature, then tap .



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

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




9. Use the on-screen keypad to enter the percentage of the bolus to DELIVER NOW and tap .

For the DELIVER NOW portion, the minimum amount is .05 units. If the DELIVER NOW portion is less than .05 units, you will be notified and the DELIVER NOW portion will be set to .05 units.

The DELIVER LATER portion of the extended bolus also has minimum and maximum rates. If you program a DELIVER LATER rate outside of these limits, you are notified and the duration of the DELIVER LATER portion is adjusted.

10. Tap **2 hrs** under DURATION.
11. Use the on-screen keypad to adjust the length of time the bolus is to be delivered, then tap .
12. Tap .

You can always tap **View Units** to display the breakdown of units to be delivered NOW versus LATER.

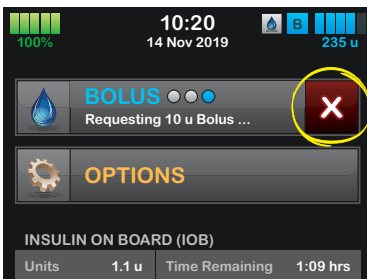
13. Confirm Request.
 - Tap  if entered data is correct.
 - Tap  to go back to make changes or view calculations.
14. Tap .
15. The *BOLUS INITIATED* screen is temporarily displayed.

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.

7.7 Canceling or Stopping a Bolus

Canceling a Bolus If delivery HAS NOT STARTED:



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



- ✓ BOLUS will remain inactive while the bolus is being canceled.

- ✓ Once canceled, BOLUS will become active again on the *Home* screen.

Stopping a Bolus if delivery of the BOLUS HAS STARTED:

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


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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 .

- ✓ 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

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

1. Tap 1–2–3.
2. Tap .

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

– OR –

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

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

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 on-screen keypad enter desired percentage. The current rate is 100%. An increase is greater than 100% and decrease is less than 100%.
5. Tap .
6. Tap **Duration**. Using the on-screen keypad enter desired length of time for Temp Rate. Tap .



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

7. Verify settings and tap .
- ✓ The *TEMP RATE STARTED* screen is temporarily displayed.
 - ✓ The *Lock* screen will be displayed with the icon indicating a Temp Rate is active.

- An T in an orange box means a Temp Rate is active.
- A T in a red box means a Temp Rate of 0 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  (stop icon) on the right side of Temp Rate.
 3. On the confirmation screen, tap .
- ✓ The *TEMP RATE STOPPED* screen appears before returning to the *Options* screen.

Chapter 10

Quick Bolus

10.1 Setting Up Quick Bolus

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

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




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

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Pump Settings**.
4. Tap **Quick Bolus**.
5. Tap **Increment Type**.

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

NOTE: Incrementing Amount

The increment amount is added with each press of the **Screen On/Quick Bolus** button when delivering a quick bolus.

9. Review entered values and tap .
10. Confirm Settings.
 - Tap  if entered data is correct.
 - Tap  to go back to make changes.
11. Tap **Tandem logo** to return to the *Home* screen.

10.2 Delivering Quick Bolus

If the Quick Bolus function is turned On, you can deliver a bolus without having to look at the t:slim X2 pump's screen. Simply use the **Screen On/Quick Bolus**

button to deliver your bolus. Quick boluses are delivered as standard boluses (there is no glucose value entry or extended bolus).


PRECAUTION

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

1. Press and hold the **Screen On/Quick Bolus** button. The *Quick Bolus* screen will appear. Listen for 2 beeps (if sound volume is set to beep) or feel for vibrations (if sound volume is set to vibrate).
2. Press the **Screen On/Quick Bolus** button for each increment until desired amount is reached. The pump will beep/vibrate for each button press.
3. Wait for the pump to beep/vibrate once for each increment pressed to confirm desired amount.
4. After the pump beeps/vibrates, press and hold the **Screen On/**

Quick Bolus button for several seconds to deliver the bolus.

 **NOTE: Safety Features**

If you want to cancel the bolus and return to the *Home* screen, tap  on the *Quick Bolus* screen.

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

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 touchscreen to enter bolus information.

- ✓ The *BOLUS INITIATED* screen is temporarily displayed.

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Chapter 11

Device Settings

This chapter contains explanations and instructions for the device settings that are accessible through the *Device Settings* screen.


11.1 Display Settings

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

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

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

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

6. Select preferred time and tap .
7. Tap **Tandem logo** to return to the *Home* screen.

11.2 Mobile Connection

You can connect one mobile device to the pump to display pump information on your mobile device using the t:connect mobile app.

NOTE: Mobile Connection Availability


The t:connect mobile app may not yet be available in your region. Do not turn the mobile connection on if you are not using or do not have access to the t:connect mobile app.

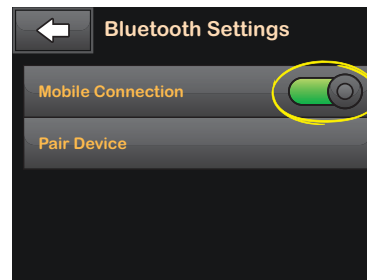
NOTE: CGM Bluetooth Connection



This Mobile Connection setting is not related to your CGM Bluetooth connection. For CGM Bluetooth information, see [Section 23.1 About Bluetooth](#).

Pair a Mobile Device

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

3. Tap **Device Settings**.
4. Tap **Bluetooth Settings**.
5. Tap the on/off toggle next to Mobile Connection and tap  to confirm. **Pair Device** is now displayed.



6. Tap **Pair Device**.
7. A *Mobile App notification* screen is displayed. Tap  to generate your device pairing code.
8. Follow the instructions to enter the pairing code into the t:connect mobile app on your mobile device.
9. Tap  to close the *PAIRING CODE* screen. If the pump has successfully paired with a mobile

device, the *DEVICE PAIRED* screen is displayed.

PRECAUTION

The t:connect mobile app is not a replacement for the information displayed on your insulin pump. The information displayed on the t:connect mobile app may not be identical to the current status of your pump.

11.3 Time and Date

For information on how to set the time and date, see [Sections 4.6 Edit Time](#) and [4.7 Edit Date](#).

11.4 Sound Volume


The Sound Volume is preset to high. A change to the Sound Volume can be made in Device Settings.

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

PRECAUTION

DO NOT use the vibrate feature for alerts and alarms during sleep unless otherwise directed

by your healthcare provider. Having the volume for alerts and alarms set to high will help ensure that you don't miss an alert or alarm.





1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Device Settings**.
4. Tap **Sound Volume**.
5. Tap desired option. Use **Up/Down Arrow** to view additional options.
6. Select preferred volume.
7. Continue to make changes for all Sound Volume options by repeating steps 5 and 6.
8. Tap  when all changes are complete.

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


11.5 Turn Security PIN On or Off

The Security PIN is preset to off. With the Security PIN turned on, you cannot unlock and use the pump without

entering the Security PIN. To turn on the Security PIN, follow these steps.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Device Settings**.
4. Tap the **Down Arrow**.
5. Tap **Security PIN**.
6. Tap **Security PIN** to toggle the feature on.
7. Tap  to create your Security PIN.
8. Using the keypad, enter a number between four and six digits. A PIN may not begin with the number zero.
9. Tap .
10. Tap  to verify your Security PIN.
11. Use the keypad to repeat and verify the new Security PIN.
12. Tap .

✓ A *PIN CREATED* screen is displayed.

13. Tap  to turn the Security PIN on.

14. Tap .

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

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

2. Tap the **Down Arrow**.

3. Tap **Device Settings**.

4. Tap the **Down Arrow**.

5. Tap **Security PIN**.


6. Tap **Change Security PIN**.

7. Tap .

8. Using the keypad, enter the current Security PIN. If you forget your Security PIN, use the override code **314159**.

» The override PIN can be used as many times as needed and never resets or


changes to another PIN. It can be used to unlock the pump when the Security PIN feature is on. If desired, you may use this as a valid Security PIN.

9. Tap  to verify your current Security PIN.

10. Tap .

11. Use the keypad to enter a new Security PIN.

12. Tap .

13. Tap  to verify your new Security PIN.

14. Use the keypad to repeat and verify the new Security PIN.

15. Tap .

✓ A *PIN UPDATED* screen is displayed.

16. Tap .

Chapter 12

t:slim X2 Insulin Pump Information and History

12.1 t:slim X2 Pump Info

Your pump allows access to information about your pump. In the *Pump Info* screen you have access to items such as your pump Serial Number, Customer Technical Support contact information, website, and software/hardware versions.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap the **Down Arrow**.
4. Tap **Pump Info**.
5. Scroll through the Pump Info using the **Up/Down Arrows**.
6. Tap **Tandem logo** to return to the *Home* screen.

12.2 t:slim X2 Pump History

Pump History displays a historical log of pump events. At least 90 days of data can be viewed in History. When the maximum number of events is reached, the oldest events are removed from the

history log and replaced with the most recent events. The following can be viewed in History:

Delivery Summary, Total Daily Dose, Bolus, Basal, Load, BG, Alerts and Alarms, 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 **Pump History**.
5. Tap desired option.
6. Tap **Tandem logo** to return to the *Home* screen.

Chapter 13

t:slim X2 Insulin Pump Reminders

Your pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check 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 acknowledged.

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 Sound 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 glucose value is entered. When turning this reminder on, you need to set a low glucose value that triggers the reminder, as well as how much time should pass before the reminder occurs.

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

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **Low BG**.
6. Low BG is set to on; to turn off, tap **Low BG**.

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

To Respond to the Low BG Reminder



To clear the reminder, tap  and then check your glucose.


13.2 High BG Reminder

The High BG Reminder prompts you to re-test your BG after a high glucose value is entered. When you turn this reminder on, you need to set a high glucose value that triggers the reminder, as well as how much time

should pass before the reminder occurs.


The default for this reminder is preset to off. If on, 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 **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **High BG**.
6. High BG is set to on; to turn off, tap **High BG**.
 - a. Tap **Remind Me Above** and using the on-screen keypad, enter a High BG value (from 150 to 300 mg/dL) that you want to trigger the reminder, then tap .
 - b. Tap **Remind Me After** and using the on-screen keypad, enter the time (from 1 to 3 hours), then tap .

c. Tap  when all changes are complete.

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



To Respond to the High BG Reminder

To clear the reminder tap  and then check your glucose.


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 **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **After Bolus BG**.




6. After Bolus BG is set to on; to turn off, tap **After Bolus BG**.
7. Tap **Remind Me After** and using the on-screen keypad, enter the time (from 1 to 3 hours) that you want to trigger the reminder, then tap .
8. Tap  when all changes are complete.
9. Tap **Tandem logo** to return to the *Home* screen.




To Respond to the After Bolus BG Reminder

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


13.4 Missed Meal Bolus Reminder

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

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **Missed Meal Bolus**.
6. On the Missed Meal Bolus screen, tap which reminder you want to set (Reminder 1 to 4) and do the following:
 - a. Tap **Reminder 1** (or 2, 3, 4).
 - b. Reminder 1 is set to on; to turn off, tap **Reminder 1**.
 - c. Tap **Selected Days** and tap the day(s) you want the reminder to be on, then tap .
 - d. Tap **Start Time**, tap **Time** and using the on-screen keypad enter the start time, then tap .
 - e. Tap **Time of Day** to select AM or PM, if applicable, then tap .

- f. Tap **End Time**, tap **Time** and using the on-screen keypad enter the end time, then tap .
 - g. Tap **Time of Day** to select AM or PM, if applicable, then tap .
 - h. Tap  when all changes are complete.
7. Tap the **Tandem logo** to return to the *Home* screen.

To Respond to the Missed Meal Bolus Reminder


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

13.5 Site Reminder

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

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

To Respond to the Site Reminder


To clear the reminder tap  and change your infusion set.


Chapter 14

User Settable Alerts and Alarms


14.1 Low Insulin Alert

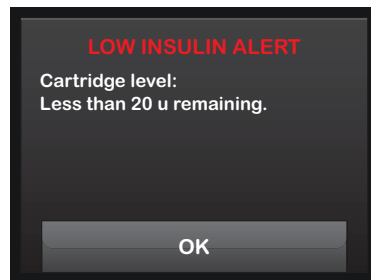
Your t:slim X2 Pump keeps track of how much insulin remains in the cartridge and alerts you when it is low. The default for this alert is preset to 20 units. You can set this alert setting anywhere between 10 and 40 units. When the insulin amount reaches the set value, the Low Insulin Alert beeps/vibrates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

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Alerts**.
5. Tap **Low Insulin**.
6. Using the on-screen keypad, enter the number of units (from 10 to 40 units) that you want the Low Insulin Alert value to be set to, and tap .

7. Tap  when all changes are complete.

To Respond to the Low Insulin Alert




To clear the alert, tap .





14.2 Auto-Off Alarm

Your pump can stop insulin delivery and alert you (or whoever is with you) if there has been no interaction with the pump within a specified period of time. The default for this alarm is preset to 12 hours. You can set it anywhere between 5 and 24 hours, or off. This alarm notifies you that there has been no interaction with the pump in the specified number of hours and the pump will shut down after 30 seconds.

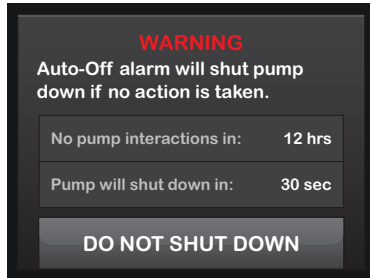
When the number of hours since you have pressed the **Screen On/Quick Bolus** button and tapped any interactive screen option or delivered a Quick Bolus passes the set value, the Auto-Off Alarm beeps and appears on the screen, and insulin delivery stops.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Alerts**.
5. Tap **Auto-Off**.
6. Tap **Auto-Off**. A confirmation screen will appear.
 - Tap  to continue.
 - Tap  to go back.
7. Verify Auto-Off is set to on, then tap **Time**.
8. Using the on-screen keypad, enter the number of hours (from 5 – 24 hours) that you want the Auto-Off Alarm to be triggered, and tap .

9. Tap , then tap  when all changes are complete.
10. Tap **Tandem logo** to return to the *Home* screen.

To Respond to Auto-Off Warning

Tap **DO NOT SHUT DOWN**.

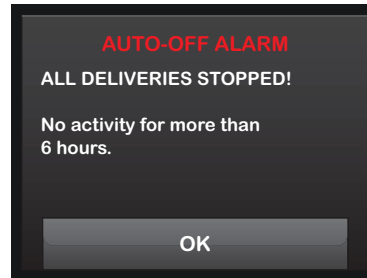


- ✓ The warning clears and the pump returns to normal operation.

If you do not clear the warning within the 30-second countdown period, the **AUTO-OFF ALARM** occurs, accompanied by an audible alarm. This alarm notifies you that your pump has stopped delivering insulin.

Auto-Off Alarm Screen

Tap .



- ✓ The *Home* screen appears, indicating a status of All Deliveries Stopped.

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

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Chapter 15

t:slim X2 Insulin Pump Alerts

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

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

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

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

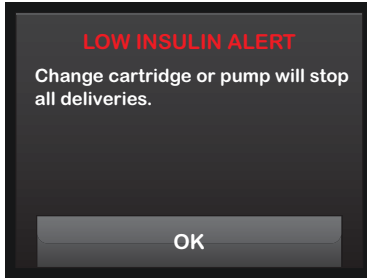
until acknowledged. Alerts do not escalate.

NOTE: CGM Alerts

There is an additional list of alerts and errors related to CGM use in [Chapter 29 CGM Alerts and Errors](#).

15.1 Low Insulin Alert

What will I see on the screen?



What does it mean?

5 units or less of insulin remain in the cartridge.

How will the System notify me?

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

Will the System re-notify me?

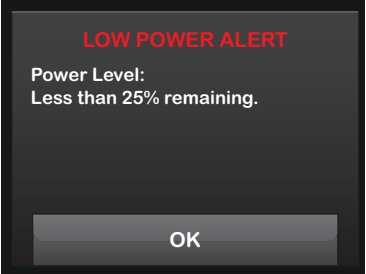
Yes, every 5 minutes until acknowledged.

How should I respond?

Tap **OK**. Change your cartridge as soon as possible to avoid the EMPTY CARTRIDGE ALARM and running out of insulin.

15.2 Low Power Alerts

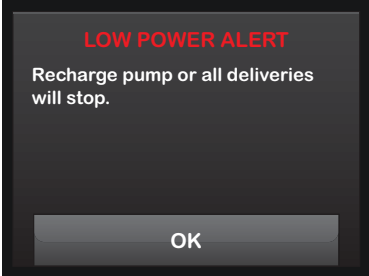
Low Power Alert 1

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

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* and *Lock* screens) appears.

Low Power Alert 2

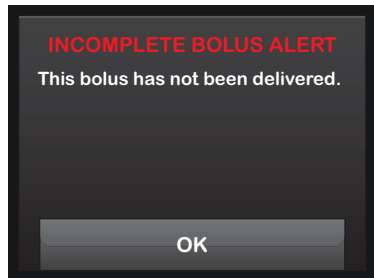
<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>Less than 5% of battery power remains. Insulin delivery will continue for 30 minutes and then the pump will power off and insulin delivery will stop.</p> <p>How will the System notify me?</p> <p>2 sequences of 3 notes or 2 vibrations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

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* and *Lock* screens) 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 Sound Volume.

Will the System re-notify me?

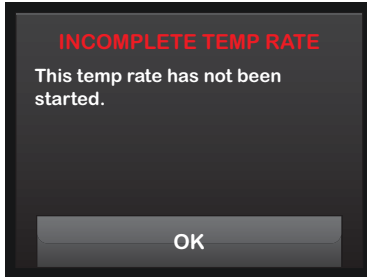
Yes, every 5 minutes until acknowledged.

How should I respond?

1. Tap . The *Bolus* screen will appear. Continue with your bolus request.
2. Tap  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 Sound Volume.

Will the System re-notify me?

Yes, every 5 minutes until acknowledged.

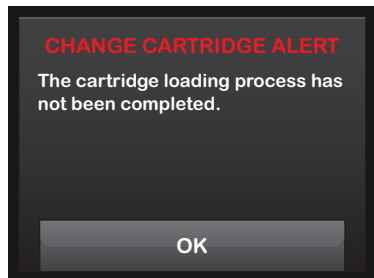
How should I respond?

1. Tap . The *Temp Rate* screen will appear. Continue setting up your temp rate.
2. Tap  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 Sound Volume.

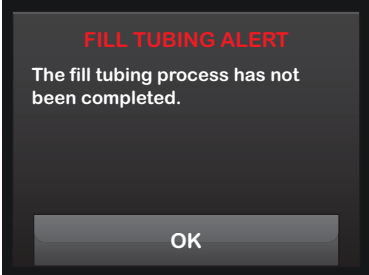

Will the System re-notify me?

Yes, every 5 minutes until acknowledged.

How should I respond?

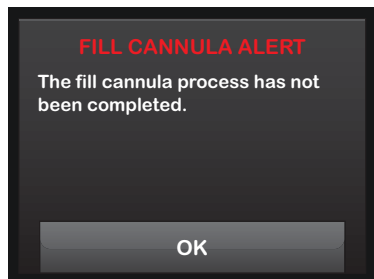
Tap . Complete the cartridge change process.

Incomplete Fill Tubing Alert

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

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 Sound Volume.

Will the System re-notify me?

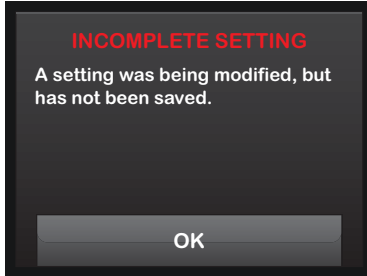
Yes, every 5 minutes until acknowledged.

How should I respond?

Tap . 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 Sound Volume.

Will the System re-notify me?

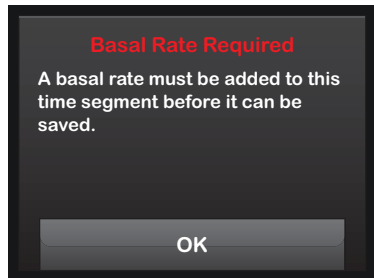
Yes, every 5 minutes until acknowledged.

How should I respond?

Tap . 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?

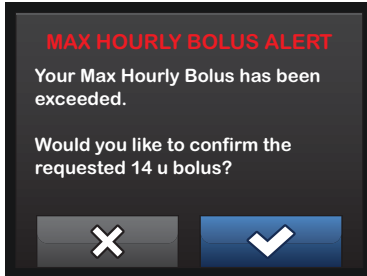
No, a basal rate must be entered to save the time segment.

How should I respond?

Tap **OK**. 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  or  to deliver the bolus.

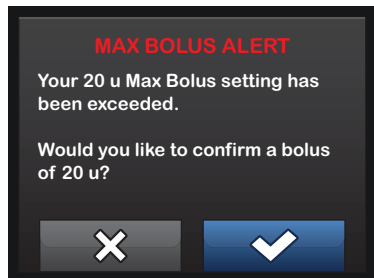
How should I respond?

- Tap  to return to the *Bolus* screen and adjust the bolus delivery amount.
- Tap  to confirm 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?

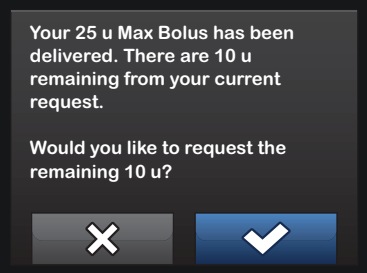




No, you must tap  or  to deliver the bolus.

How should I respond?

- Tap  to return to the *Bolus* screen and adjust the bolus delivery amount.
- Tap  to deliver the amount of your Max Bolus setting.

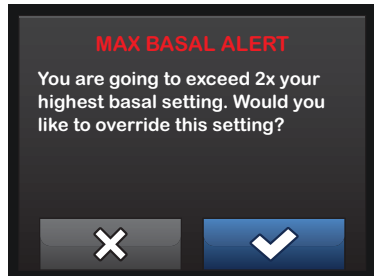
Max Bolus Alert 2

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

<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>Your Max Bolus is set to 25 units and you requested a bolus larger than 25 units.</p> <hr/> <p>How will the System notify me?</p> <p>Prompt screen only.</p> <hr/> <p>Will the System re-notify me?</p> <p>No, you must tap  or  to deliver the remaining amount of the bolus request.</p> <hr/> <p>How should I respond?</p> <p>Before responding to this Alert, always consider whether your bolus insulin needs have changed since you requested the original bolus.</p> <ul style="list-style-type: none"> • Tap  to deliver the remaining amount of the bolus request. A confirmation screen will appear. • Tap  if you do not want to deliver the remaining amount of the bolus request.
--	---

15.10 Max Basal Alert

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.

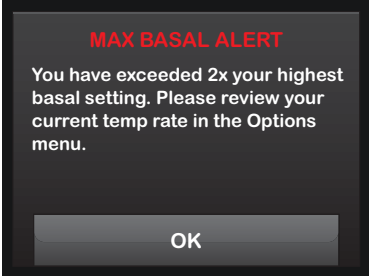

Will the System re-notify me?

No, you must tap  or  to move forward.

How should I respond?

- Tap  to return to the previous screen to adjust the amount.
- Tap  to dismiss the alert and continue with the request.

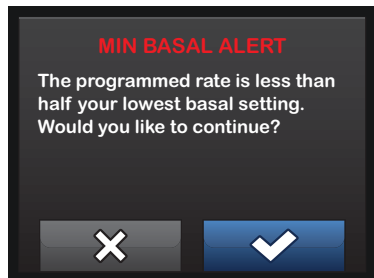
Max Basal Alert 2

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

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.

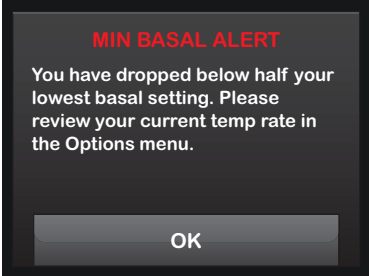

Will the System re-notify me?

No, you must tap  or  to move forward.

How should I respond?

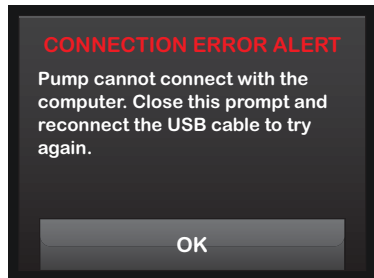
- Tap  to return to the previous screen to adjust the amount.
- Tap  to dismiss the alert and continue with the request.

Min Basal Alert 2

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

15.12 Connection Error Alert

What will I see on the screen?



What does it mean?

You connected pump to a computer with the USB cable to charge it or upload data to the t:connect diabetes management application* and a connection could not be made.

How will the System notify me?

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

Will the System re-notify me?

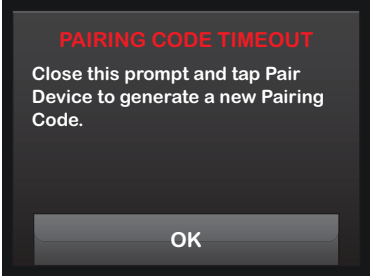

Yes, every 5 minutes until acknowledged.

How should I respond?

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

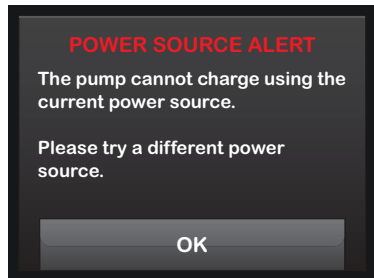
**The t:connect diabetes management application may not yet be available in your region.*

15.13 Pairing Code Timeout

<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>You attempted to connect a mobile device to the pump, but the pairing process took too long (more than 5 minutes) and was unsuccessful.</p> <p>How will the System notify me?</p> <p>2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.</p> <p>Will the System re-notify me?</p> <p>No.</p> <p>How should I respond?</p> <p>Tap . Try to pair the mobile device again.</p>
--	--

15.14 Power Source Alert

What will I see on the screen?



What does it mean?

You connected your pump to a power source that does not have enough power to charge the pump.


How will the System notify me?

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

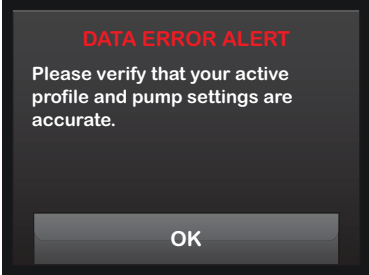
Will the System re-notify me?

Yes, every 5 minutes until acknowledged.

How should I respond?

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

15.15 Data Error Alert

<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>Your pump encountered a condition that could potentially result in a loss of data.</p> <p>How will the System notify me?</p> <p>2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.</p> <p>Will the System re-notify me?</p> <p>Yes, every 5 minutes until acknowledged.</p> <p>How should I respond?</p> <p>Tap OK. Check your Personal Profiles and pump settings to verify that they are accurate. See Section 6.4 Editing or Reviewing an Existing Profile.</p>
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Chapter 16

t:slim X2 Insulin Pump Alarms

PRECAUTION

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

Your 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.

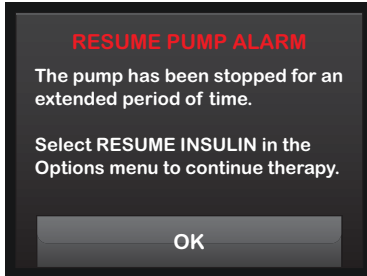
Alarms notify you with 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume. If not acknowledged, alarms escalate to highest volume and vibrate. Alarms repeat regularly until the condition that caused the alarm is corrected.

NOTE: CGM Alerts

There is a list of alerts and errors related to CGM use in [Chapter 29 CGM Alerts and Errors](#).

16.1 Resume Pump Alarm

What will I see on the screen?



What does it mean?



You selected 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 Sound Volume.

Will the System re-notify me?

Yes.

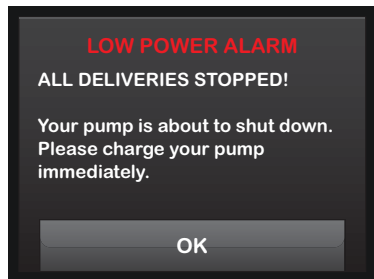
- If not acknowledged by tapping , the System will re-notify you every 3 minutes at highest volume and vibrate.
- If acknowledged by tapping , the System will re-notify you in 15 minutes.

How should I respond?

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

16.2 Low Power Alarm

What will I see on the screen?



What does it mean?

Your pump detected a power level of 1% or less remaining and all deliveries have stopped.

How will the System notify me?

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

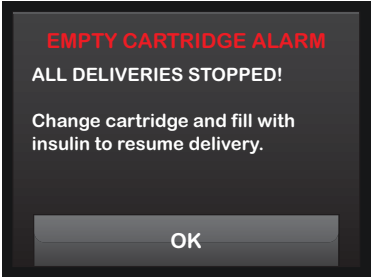
Will the System re-notify me?

Yes, every 3 minutes until no power remains and the pump shuts down.

How should I respond?

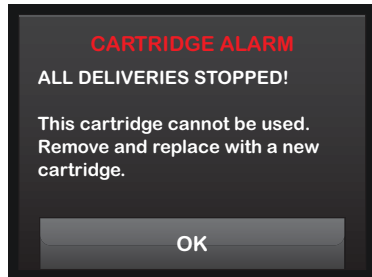
Tap **OK**. Charge your pump immediately to resume insulin delivery.

16.3 Empty Cartridge Alarm

<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>Your pump detected that the cartridge is empty and all deliveries have stopped.</p> <hr/> <p>How will the System notify me?</p> <p>3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.</p> <hr/> <p>Will the System re-notify me?</p> <p>Yes, every 3 minutes until you change the cartridge.</p> <hr/> <p>How should I respond?</p> <p>Tap OK. Change your cartridge immediately by tapping OPTIONS from the <i>Home</i> screen, then Load and follow the instructions in Section 5.3 Filling and Loading a t:slim Cartridge.</p>
--	---

16.4 Cartridge Error Alarm

What will I see on the screen?



What does it mean?

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


How will the System notify me?

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

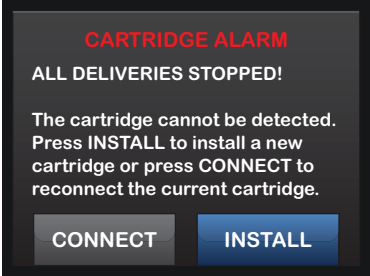
Will the System re-notify me?

Yes, every 3 minutes until you change the cartridge.

How should I respond?

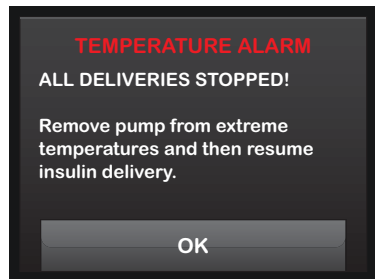
Tap . Change your cartridge immediately by tapping **OPTIONS** from the *Home* screen, then **Load** and follow the instructions in [Section 5.3 Filling and Loading a t:slim Cartridge](#).

16.5 Cartridge Removal Alarm

<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>Your pump detected that the cartridge has been removed and all deliveries have stopped.</p> <hr/> <p>How will the System notify me?</p> <p>3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.</p> <hr/> <p>Will the System re-notify me?</p> <p>Yes, every 3 minutes until you reconnect the current cartridge or change the cartridge.</p> <hr/> <p>How should I respond?</p> <p>Tap CONNECT to reattach the current cartridge. Tap INSTALL to load a new cartridge.</p>
--	--

16.6 Temperature Alarm

What will I see on the screen?



What does it mean?

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

How will the System notify me?

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

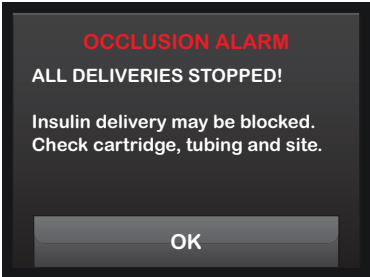
Will the System re-notify me?

Yes, every 3 minutes until a temperature in the operating range is detected.

How should I respond?

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

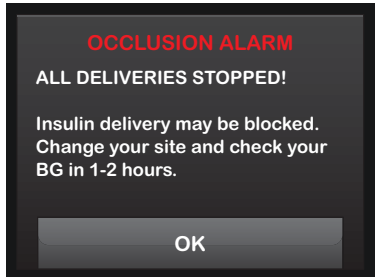
16.7 Occlusion Alarm 1

<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>Your pump detected that insulin delivery is blocked and all deliveries have stopped. See Section 36.4 t:slim X2 Pump Performance Characteristics for more information on how long it can take the system to detect an occlusion.</p> <p>How will the System notify me?</p> <p>3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.</p> <p>Will the System re-notify me?</p> <p>Yes, every 3 minutes until you resume insulin delivery.</p> <p>How should I respond?</p> <p>Tap OK. Check the cartridge, tubing, and infusion site for any sign of damage or blockage and correct the condition. To resume insulin, from the <i>Options</i> menu, tap RESUME INSULIN and tap RESUME to confirm.</p>
--	--

NOTE: Occlusion During Bolus

If the occlusion alarm occurs during bolus delivery, after tapping **OK**, 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.

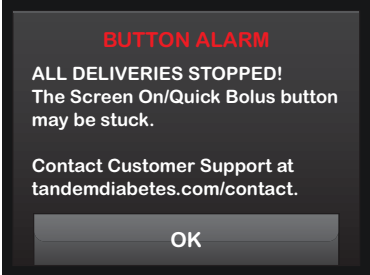

16.8 Occlusion Alarm 2

<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>Your pump detected a second occlusion alarm shortly after the first occlusion alarm and all deliveries have stopped.</p> <hr/> <p>How will the System notify me?</p> <p>3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.</p> <hr/> <p>Will the System re-notify me?</p> <p>Yes, every 3 minutes until you resume insulin delivery.</p> <hr/> <p>How should I respond?</p> <p>Tap OK. Change the cartridge, tubing, and infusion site to ensure proper delivery of insulin. Resume insulin after changing the cartridge, tubing, and infusion site.</p>
--	--

NOTE: Occlusion During Bolus

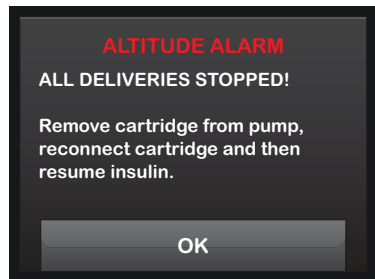
If the second occlusion alarm occurs during bolus delivery, after tapping **OK**, a screen will appear letting you know that the amount of bolus delivery could not be determined and was not added to your IOB.

16.9 Screen On/Quick Bolus Button Alarm

<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>The Screen On/Quick Bolus button (on the top of your pump) is stuck or not functioning properly and all deliveries have stopped.</p> <p>How will the System notify me?</p> <p>3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.</p> <p>Will the System re-notify me?</p> <p>Yes, every 3 minutes until the condition is corrected.</p> <p>How should I respond?</p> <p>Tap . Contact Customer Technical Support.</p>
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16.10 Altitude Alarm

What will I see on the screen?



What does it mean?

Your pump detected a pressure difference between inside the cartridge and the surrounding air within the validated operating range of -1,300 feet to 10,000 feet (-369 meters to 3,048 meters) and all deliveries have stopped.


How will the System notify me?

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

Will the System re-notify me?

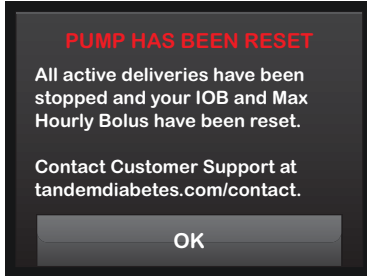
Yes, every 3 minutes until the condition is corrected.

How should I respond?

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

16.11 Reset Alarm

What will I see on the screen?



What does it mean?

Your pump detected that one of 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 Sound Volume.

Will the System re-notify me?

Yes, every 3 minutes until you tap **OK**.

How should I respond?

Tap **OK**. Contact Customer Technical Support.

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Chapter 17

t:slim X2 Insulin Pump Malfunction

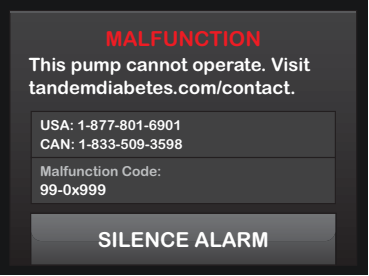
17.1 Malfunction

If your pump detects a system error, the *MALFUNCTION* screen appears and all deliveries are stopped. Contact Customer Technical Support.

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

PRECAUTION

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

<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>Your pump detected a system error and all deliveries have been stopped.</p>
	<p>How will the System notify me?</p> <p>3 sequences of 3 notes at highest volume and 3 vibrations.</p>
	<p>Will the System re-notify me?</p> <p>Yes, every 3 minutes until you acknowledge the malfunction by tapping SILENCE ALARM.</p>
	<p>How should I respond?</p> <ul style="list-style-type: none"> • Write down the Malfunction Code number that appears on the screen. • Tap SILENCE ALARM. The <i>MALFUNCTION</i> screen will remain on the pump even though the alarm is silenced. • Contact Customer Technical Support and provide the Malfunction Code number that you wrote down.

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Chapter 18

Lifestyle Issues and Travel

18.1 Overview

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

⚠ PRECAUTION

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

Physical Activity

The pump can be worn during most forms of exercise, such as running, cycling, hiking, and resistance training. During exercise, the t:slim X2 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 BG levels. Even if you disconnect your tubing from your infusion site, the pump should continue to receive data from the transmitter as long as it is within the 20-foot (6 meter) range without obstruction.

Aquatic Activities

⚠ PRECAUTION

AVOID submerging your pump in fluid beyond a depth of 3 feet (0.91 meters) or for more than 30 minutes (IPX7 rating). If your pump has been exposed to fluid beyond these limits, check for any signs of fluid entry. If there are signs of fluid entry, discontinue use of the pump and contact Customer Technical Support.

Your pump is watertight to a depth of 3 feet (0.91 meters) for up to 30 minutes (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 pump has been tested at altitudes up to 10,000 feet (3,048 meters) at standard operating temperatures.

Extreme Temperatures

You should avoid activities which could expose your pump to temperatures below 41°F (5°C) or above 98.6°F (37°C), as insulin can freeze at low temperatures or degrade at high temperatures.

Other Activities Which Require Removing Your Pump

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

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

Travel

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

- The items listed in the Emergency Kit described in [Section 1.9 Emergency Kit](#).
- A prescription for both rapid-acting and long-acting insulin of the type recommended by your healthcare provider in case you need to take insulin by injection.
- A letter from your healthcare provider explaining the medical need for your insulin pump and other supplies.

Traveling by Air

⚠ PRECAUTION

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

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

The pump is safe for use on commercial airlines. The pump is a Medical Portable Electronic Device (M-PED). The system complies with radiated emissions requirements defined in RTCA/DO-160G, Section 21, Category M. Any M-PED which meet the requirements of this standard in all modes of operation may be used on board aircraft without the need for further testing by the operator.

Pack your pump supplies in your carry-on luggage. **DO NOT** pack your

supplies in checked luggage as it could get delayed or lost.

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

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Chapter 19

Taking Care of Your Pump

19.1 Overview

This section provides information on caring for and maintaining your t:slim X2 pump.

Cleaning Your Pump

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

Wipe the outside of the transmitter with a damp lint-free cloth or isopropyl alcohol wipe between uses.

Inspecting Your Pump for Damage

PRECAUTION

DO NOT use your pump if you think it might be damaged due to dropping it or hitting it against

a hard surface. Check that the pump is working properly by plugging a power source into the USB port and confirming that the display turns on, you hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the **Screen On/Quick Bolus** button. If you are unsure about potential damage, discontinue use of the pump and contact Customer Technical Support.

If you drop your pump or it has been hit against something hard, ensure that it is still working properly. Check that the touchscreen is working and clear, and that the cartridge and infusion set are properly in place. Check for leaks around the cartridge and at the tubing connector to the infusion set. Immediately contact Customer Technical Support if you notice any cracks, chips, or other damage.

Storing Your Pump

If you need to stop using your pump for a long period of time, you can place the pump in storage mode. To place the pump in storage mode, connect the pump to a power source and then press and hold down the **Screen On/Quick Bolus** button for 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 (-20°C) and 140°F (60°C) and at relative humidity levels between 20% and 90%.

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

Disposing of System Components

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

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Section 3

CGM Features

Chapter 20

Important CGM Safety Information

The following includes important safety information related to your CGM its components. The information presented in this chapter does not represent all warnings and precautions related to the CGM. Visit the CGM manufacturer's website for applicable user guides that also present warnings and precautions.

20.1 CGM Warnings

Using Dexcom G5 Mobile with Your t:slim X2 Insulin Pump

⚠ WARNING

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

⚠ WARNING

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

broken sensor wire, please report this to Customer Technical Support.

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

DO NOT insert the sensor in sites other than the abdomen (belly) or upper buttocks (for ages 6–17 only). Other sites have not been studied and

are not approved. Use in other sites might cause sensor glucose readings to be inaccurate and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

STORE the Dexcom G5 Mobile CGM sensor at temperatures between 36°F (2.2°C) to 86°F (30°C) for the length of the sensor's shelf life. You may store the sensor in the refrigerator if it is within this temperature range. The sensor should not be stored in a freezer. Storing the sensor improperly might cause the sensor glucose readings to be inaccurate, and you

might miss severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠️ WARNING

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

20.2 CGM Precautions

Using Dexcom G5 Mobile CGM with Your t:slim X2 Insulin Pump

⚠️ PRECAUTION

DO NOT open the sensor package until you have washed your hands with soap and water, and let them dry. You may contaminate the insertion site and suffer an infection if you have dirty hands while inserting the sensor.

⚠️ PRECAUTION

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

cleaned area is dry so the sensor adhesive will stick better.

⚠️ PRECAUTION

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

⚠️ PRECAUTION

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

⚠️ PRECAUTION

AVOID injecting insulin or placing an infusion set within 3 inches (7.6 cm) of the sensor. The insulin might affect sensor accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠️ PRECAUTION

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

⚠️ PRECAUTION

PAY ATTENTION to the trend information on your *Home* screen, as well as your symptoms, before using CGM values to calculate and deliver a correction bolus. Individual CGM values may not be as accurate as blood glucose meter values.

⚠️ PRECAUTION

To calibrate the Dexcom G5 Mobile CGM, **ALWAYS** enter the exact BG value that your BG meter displays within 5 minutes of a carefully performed BG measurement. Do not enter sensor glucose readings for calibration. Entering incorrect BG values, BG values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠️ PRECAUTION

DO NOT calibrate if your BG is changing at a significant rate, typically more than 2 mg/dL per minute. Do not calibrate when your receiver screen is showing the rising or falling single arrow or double arrow, which indicates that your BG is rapidly rising or falling. Calibrating during significant rise or fall of BG may affect sensor accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠️ PRECAUTION

The Dexcom G5 Mobile CGM accuracy may be affected when your glucose is changing at a significant rate (i.e., 2 to 3 mg/dL/min or more than 3 mg/dL each minute), such as during exercise or after a meal.

⚠️ PRECAUTION

AVOID separating the transmitter and pump by more than 20 feet (6 meters). The transmission range from the transmitter to the pump is up to 20 feet (6 meters) without obstruction. Wireless communication does not work well through water so the range is reduced if you are in a pool, bathtub, or on a water bed, etc. To ensure communication, it is suggested that you face your pump screen out and away from the body, and wear the pump on the same side of the body that you wear your CGM. Types of obstruction differ and have not been tested. If your transmitter and pump are farther than 20 feet (6 meters) apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠️ PRECAUTION

DO NOT use alternative BG site testing (blood from your palm or forearm, etc.) for calibration. Alternative site BG values may be different than

those taken from a fingerstick BG value and may not represent the timeliest BG value. Use a BG value taken only from a fingerstick for calibration. Alternative site BG values might affect sensor accuracy and result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠️ PRECAUTION

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

⚠️ PRECAUTION

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

⚠️ PRECAUTION

The Dexcom G5 Mobile sensor is not compatible with older versions of transmitters or receivers. Do not mix transmitters, receivers, and sensors from different generations.

⚠️ PRECAUTION

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

⚠️ PRECAUTION

Hydroxyurea is a medication used in the treatment of diseases including cancer and sickle cell anemia. It is known to interfere with glucose readings from the sensor. The use of hydroxyurea will result in sensor glucose readings that are higher than actual glucose levels. The level of inaccuracy in sensor glucose readings is based on the amount of hydroxyurea in the body. Relying on sensor glucose results while taking hydroxyurea could result in missed hypoglycemia alerts or errors in diabetes management, such as giving a higher dose of insulin than necessary to correct falsely high sensor glucose values. It can also result in errors when reviewing, analyzing and interpreting historical patterns for assessing glucose control. **DO NOT** use the Dexcom G5 Mobile CGM readings to make diabetes treatment decisions or assess glucose control when taking hydroxyurea.

20.3 Potential Benefits From Using the t:slim X2 System

- When paired with Dexcom G5 Mobile transmitter and sensor, your pump can receive CGM readings every 5 minutes, which are displayed as a trend graph on the Home screen. You can also program your pump to alert you when your CGM readings are above or below a given level, or are rising or falling quickly. Unlike the readings from a standard blood glucose meter, CGM readings allow you to view trends in real time, as well as capture information when you would otherwise be unable to check your blood sugar, such as while you are asleep. This information can be useful for you and your healthcare provider when considering changes to your therapy. In addition, the programmable alerts can help you to spot potential low or high BG sooner than you would using a only a blood glucose meter.

- In some studies, CGM was shown to increase time in the target glucose range, without increasing time above or below the target range. Subjects in these studies had better diabetes control (lowered A1C values, reduced glycemic variability and time spent in low and high BG ranges)^{1, 2, 3} which can help reduce diabetes related complications.^{4, 5} These benefits can be seen especially with using real-time CGM at least 6 days per week² and were sustained over time.⁶ In some cases, patients perceived an increase in their quality of life and peace of mind when using real-time CGM as well as reporting a high satisfaction with CGM.⁷

¹ Garg S, Zisser H, Schwartz S, et al. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. *Diabetes Care*. 2006; 29(1):44-50.

² JDRF CGM Study Group. Continuous glucose monitoring and intensive

treatment of type 1 diabetes. *NEJM*. 2008; 359:1464-76.

³ Battelino T, Phillip M, Bratina N, et al. Effect of continuous glucose monitoring of hypoglycemia in type 1 diabetes. *Diabetes Care* 2011; 34(4):795-800.

⁴ The Diabetes Control and Complications Research Group. The effect of intensive treatment of diabetes on the development and progression of long- term complications of insulin-dependent diabetes mellitus. *NEJM*. 1993; 329:997-1036.

⁵ Ohkubo Y, Kishikawa H, Araki E, et al. Intensive insulin therapy prevents progression of diabetic microvascular complications in Japanese patients with non-insulin dependent diabetes mellitus: a randomized prospective 6-year study. *Diabetes Res Clin Pract*. 1995; 28(2):103-117.

⁶ JDRF CGM Study Group. Sustained benefit of continuous glucose monitoring on A1c, glucose profiles, and hypoglycemia in adults with type 1 diabetes. *Diabetes Care* 2009; 32(11):2047-2049.

7JDRF CGM Study Group. Quality-of-Life measures in children and adults with type 1 diabetes. *Diabetes Care* 2010; 33(10):2175-2177.

20.4 Possible Risks From Using the t:slim X2 System

Inserting the sensor and wearing the adhesive patch might cause infection, bleeding, pain and skin irritations (redness, swelling, bruising, itching, scarring, or skin discoloration).

There is a remote chance that a sensor wire fragment could remain under your skin if the sensor wire breaks while you are wearing it. If you think a sensor wire has broken under your skin, contact your healthcare provider and call Customer Technical Support.

Other risks associated with CGM use include the following:

- You will not get sensor glucose alerts when the alert function is turned off, your transmitter and pump are out of range, or when your pump is not showing sensor glucose readings. You might not

notice alerts if you are unable to hear them or feel the vibration.

- There are a number of risks as a result of the fact that the Dexcom G5 Mobile CGM takes readings from fluid below the skin (interstitial fluid) instead of blood. There are differences in how glucose is measured in the blood compared to how it is measured in interstitial fluid, and glucose is absorbed into the interstitial fluid slower than it is absorbed into the blood, which can cause CGM readings to lag behind readings from a blood glucose meter.

Chapter 21

Getting to Know Your CGM System

21.1 CGM Terminology

Alternate Site BG Testing

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

Applicator

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

Calibration

Calibration is when you enter BG values from a blood glucose meter into the System. Calibrations may be needed for your System to show continuous glucose readings and trend information.

CGM

Continuous glucose monitoring.

Glucose Data Gaps

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

Glucose Trends

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

HypoRepeat

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

mg/dL

Milligrams per deciliter. The standard unit of measure for sensor glucose readings.

Receiver

When the Dexcom G5 Mobile CGM is used with the pump to display CGM readings, the insulin pump replaces the receiver for the therapeutic CGM. A

smartphone with the Dexcom G5 Mobile app may be used in addition to the pump to receive sensor readings.

Rise and Fall (Rate of Change) Alerts

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

RF

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

Safety Lock

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

Sensor

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

Sensor Pod

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

Startup Period

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

System Reading

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

Transmitter

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

Transmitter ID

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

Transmitter Latch

The transmitter latch is a small disposable piece that snaps the

transmitter into the sensor pod. It is removed after the transmitter is snapped in.








Trend (Rate of Change) Arrows







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

21.2 Explanation of CGM Pump Icons

The following CGM icons may appear on your pump screen:

CGM Icon Definitions

Symbol	Meaning
	Unknown sensor reading.
	CGM sensor session is active, but the transmitter is not communicating with the pump.
	The CGM sensor has failed.
	The CGM sensor session has ended.
	Wait 15 minutes calibration error.
	Startup calibration is required (2 BG values).
	Additional startup calibration is required.

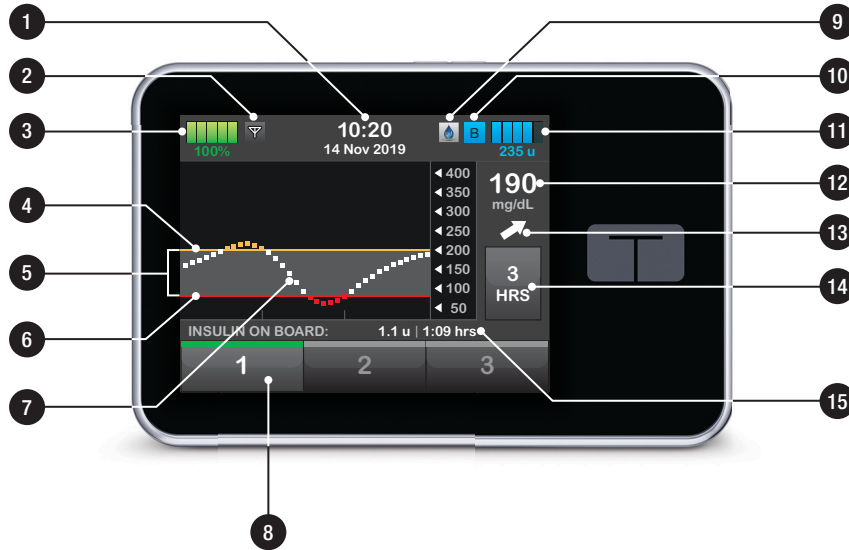
Symbol	Meaning
	Transmitter error.
	Sensor startup 0–30 minutes.
	Sensor startup 31–60 minutes.
	Sensor startup 61–90 minutes.
	Sensor startup 91–119 minutes.
	CGM calibration is required.

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21.3 CGM Lock Screen

The *CGM Lock* screen appears anytime you turn on the screen and you are using your pump with a CGM.

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



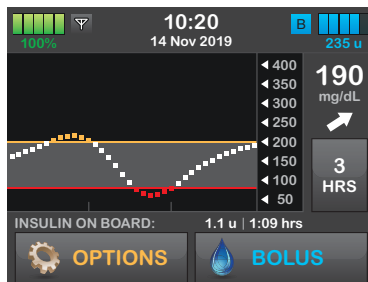
21.4 CGM Home Screen

1. **Time and Date Display:** Displays the current time and date.
2. **Antenna:** Indicates communication status between pump and transmitter.
3. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
4. **High Glucose Alert Setting.**
5. **Glucose Target Range.**
6. **Low Glucose Alert Setting.**
7. **Plot of Most Recent Sensor Glucose Readings.**
8. **Options:** Stop/Resume insulin delivery, manage pump and CGM settings, program a temp rate, load cartridge, and view history.
9. **Bolus:** Program and deliver a bolus.
10. **Status:** Displays current system settings and insulin delivery status.

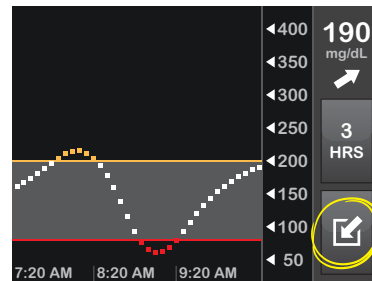
11. **Insulin Level:** Displays the current amount of insulin in the cartridge.
12. **Most Recent 5-Minute Glucose Reading.**
13. **Trend Arrow:** Indicates direction and rate of change.
14. **Trend Graph Time (HRS):** 1, 3, 6, 12 and 24 hour views available.
15. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.

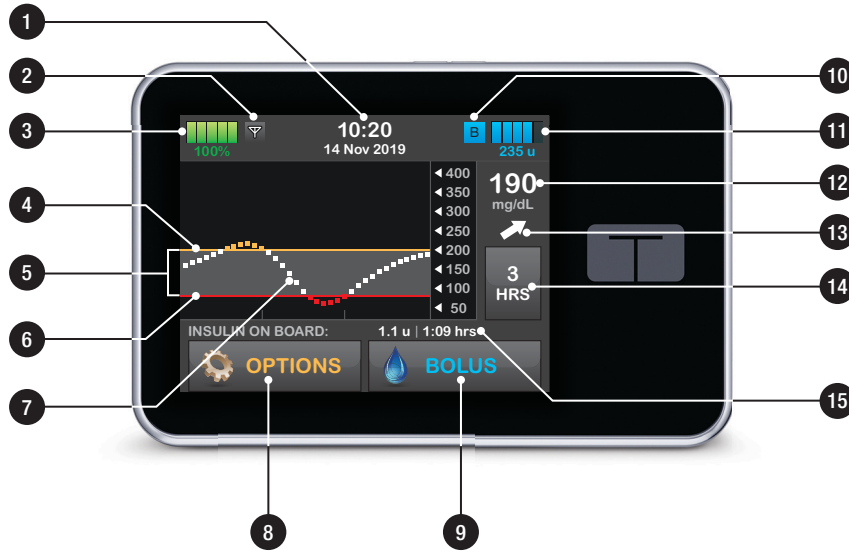
To view CGM information on the full screen:

From the *Home* screen tap anywhere on the CGM trend graph.



Tap the “minimize” icon to return to the *Home* screen.





21.5 My CGM Screen

1. **Start Sensor:** Starts a CGM session. If sensor is active, STOP SENSOR will be displayed.
2. **Calibrate CGM:** Enter a calibration BG value. Only active when sensor session is active.
3. **CGM Alerts:** Customize CGM Alerts.
4. **Transmitter ID:** Enter the transmitter ID.
5. **CGM Info:** View the CGM information.



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Chapter 22

CGM Overview

22.1 CGM Overview

This section of the user guide covers instructions for using a CGM with your t:slim X2 pump. Use of a CGM is optional, and when used, allows readings from your sensor to be displayed on your pump screen. To make treatment decisions during a new sensor startup period, you will also need a commercially available blood glucose meter to use with your System.

As an example, a compatible CGM is the Dexcom G5 Mobile CGM System, which consists of a sensor, transmitter, and a receiver.

NOTE: Device Connections

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

The Dexcom G5 Mobile sensor is a disposable device that is inserted under the skin to continuously monitor glucose levels for up to 7 days. The Dexcom G5 Mobile transmitter

connects to the sensor using Bluetooth wireless technology communication and sends readings to the pump display every 5 minutes. The pump display shows sensor glucose readings, a trend graph, and the direction and rate of change arrows. For information about inserting a Dexcom G5 Mobile CGM sensor, placing a Dexcom G5 Mobile transmitter, and Dexcom G5 Mobile product specifications, visit the manufacturer's website for applicable user guides and training information.

You can also program your pump to alert you when your CGM readings are above or below a given level, or are rising or falling quickly. If CGM readings become 55 mg/dL or lower, the Urgent Low Alert will sound. This alert is not customizable.

Unlike the readings from a standard blood glucose meter, CGM readings allow you to view trends in real time, as well as capture information when you would otherwise be unable to check your BG, such as while you are asleep. This information can be useful for you and your healthcare provider when considering changes to your therapy. In

addition, the programmable alerts can help you to spot potential low or high glucose sooner than you would using a only a blood glucose meter.

22.2 Receiver (t:slim X2 Insulin Pump) Overview

To review the icons and controls displayed on the *Home* screen with CGM enabled, see [Section 21.4 CGM Home Screen](#).

22.3 Transmitter Overview

This section provides information about CGM devices that have a separate transmitter. The information contained in this section is specific to the Dexcom G5 Mobile CGM and is provided as an example. For information about the Dexcom G5 Mobile transmitter, visit the manufacturer's website for applicable user guides.

Snapping into the transmitter holder, the transmitter wirelessly sends glucose information to your pump. If you have a new transmitter, only open the package when you are ready to use it.

Even if you disconnect your tubing from your infusion site, the pump should continue to receive data from the transmitter as long as it is within the 20-foot (6 meter) range without obstruction.

If your transmitter is damaged or cracked, do not use it. Immediately contact Customer Technical Support if you notice any cracks or other damage. Do not use the sensor if its sterile package has been damaged or opened.

Transmitter features:

- Reusable
 - Do not discard after sensor session.
 - Only for you, don't share a transmitter.
- Water resistant
- Can transmit data to your pump for up to 20 feet (6 meters). Range is less if you are in or under water.
- Battery lasts approximately 90 days. Receiver or smart device

prompts you when battery is running low.

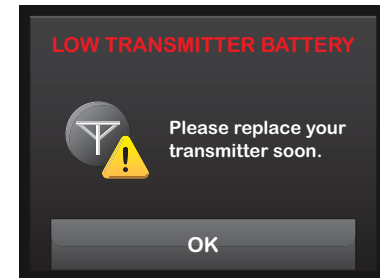
- Serial number is on the back
- M-PED designation
 - Emission levels meet IATA standards.
 - May be used on board aircraft without any further testing by the operator.

⚠ PRECAUTION

DO keep your transmitter and pump within 20 feet (6 meters) with no obstacles (like walls or metal) between them. Otherwise, they may not be able to communicate. If water is between your transmitter and the pump (for example, if you're showering or swimming) keep them closer to each other. The range is reduced because Bluetooth doesn't work as well through water. To ensure communication, it is suggested that you face your pump screen out and away from the body, and wear the pump on the same side of the body that you wear your CGM.



The transmitter battery will last 90 days. Once you see the Low Transmitter Battery Alert, replace the transmitter as soon as possible. Your transmitter battery may drain as quickly as 7 days after this alert occurs.



22.4 Sensor Overview

This section provides information about CGM devices that have a separate sensor. The information contained in this section is specific to the Dexcom G5 Mobile CGM and is provided as an example. For information about the Dexcom G5 Mobile sensor, visit the manufacturer's website for applicable user guides.

The Dexcom G5 Mobile sensor is water resistant when showering, bathing or swimming if the transmitter is fully snapped in. The sensor has been tested to be water resistant when submerged for up to 8 feet (2.4 meters) and up to 24 hours. Underwater use will affect the ability to communicate with the pump, so the range will be much less than during normal use. Extended contact with water could weaken the adhesive used by your infusion sets and Dexcom CGM sensors and cause them to fall off prematurely.

Chapter 23

CGM Settings

23.1 About Bluetooth

Bluetooth Low Energy technology is a type of wireless communication used in cell phones and many other devices. Your t:slim X2 pump and a CGM transmitter wirelessly pair together using Bluetooth wireless technology communication. This allows the pump and transmitter to communicate securely and only with each other.

23.2 Disconnecting from the Dexcom Receiver

The Dexcom G5 Mobile CGM only allows pairing with one medical device at a time. Ensure your transmitter is not connected to the receiver before pairing with the pump by doing the following:

Before entering your CGM transmitter ID into the pump, turn off the Dexcom G5 receiver and wait 15 minutes. This allows the Dexcom G5 Mobile transmitter to forget the connection currently in place with the Dexcom G5 receiver.

NOTE: Turn Receiver Off

It is not enough to Stop the Sensor Session on your Dexcom receiver prior to pairing to the pump. The receiver power must be completely off in order to avoid connection problems.

You may still use a smartphone with the Dexcom G5 Mobile app and your pump simultaneously with the same transmitter ID.

23.3 Entering Your Transmitter ID

To activate the Bluetooth wireless technology communication, you need to enter the unique transmitter ID into your pump. Once the transmitter ID has been entered into your pump, the two devices can be paired, allowing your sensor glucose readings to be displayed on your pump.



If you need to replace your transmitter, you will need to enter the new transmitter ID into your pump. If you need to replace your pump, you will need to re-enter the transmitter ID into your pump.

1. Remove the transmitter from its packaging.

2. From the *Home* screen, tap **OPTIONS**.
3. Tap the **Down Arrow**.
4. Tap **My CGM**.
5. Tap **Transmitter ID**.
6. Using the on-screen keypad, enter the unique transmitter ID.

The transmitter ID can be found on the bottom of your transmitter.

The letters I, O, V, and Z are not used in transmitter IDs and should not be entered. If one of these letters is entered, you will be notified that an invalid ID was entered and prompted to enter a valid ID.

7. Tap .
8. To make sure that the correct transmitter ID is entered, you will be prompted to enter it a second time.
9. Repeat step 6 above, then tap .

If the transmitter IDs you entered do not match you will be prompted to start the process again.

- ✓ Once matching values have been entered, you will be returned to the *CGM Settings* screen and the transmitter ID you entered will be highlighted in yellow.

10. Tap .

23.4 Setting CGM Volume

You can set the sound pattern and volume for CGM alerts and prompts to meet your individual needs. Reminders, alerts, and alarms for pump functions are separate from alerts and errors for CGM functions and do not follow the same pattern and volume.

To set your sound volume, see [Section 11.4 Sound Volume](#).

CGM Volume options:

Vibrate

You can set your CGM to alert you with vibration rather than sound. The only exception to this is the fixed low alert at 55 mg/dL, which alerts you as a vibration first, followed by beeps 5 minutes later if not confirmed.

Soft

When you want your alert to be less noticeable. This sets all alerts and alarms to lower volume beeps.

Normal

The default profile when you receive your pump. This sets all alerts and alarms to higher volume beeps.

HypoRepeat

Very similar to normal profile, but it continuously repeats the fixed low alert every 5 seconds until your sensor glucose reading rises above 55 mg/dL or the alert is confirmed. This can be helpful if you want extra alerts for severe low sensor glucose readings.

The CGM Volume setting that you choose applies to all CGM alerts, errors, and prompts which have their own unique sound pattern, tone and volume. This allows you to identify each alert and error and its meaning.

The fixed low alert at 55 mg/dL cannot be turned off or changed.

The Soft, Normal, and HypoRepeat options have the following sequence:


- The first alert is vibrate only.

- If the alert is not confirmed in 5 minutes, the system vibrates and beeps.
- If the alert is not confirmed in 5 more minutes, the system vibrates and beeps louder. This continues at the same volume every 5 minutes until confirmed.
- If the alert is confirmed and your sensor glucose readings continue to be at or below 55 mg/dL your system repeats the alert sequence in 30 minutes (HypoRepeat option only).

Sound Option Descriptions

CGM Volume	Vibrate	Soft	Normal	HypoRepeat
High Alert	2 long vibrates	2 long vibrates + 2 low beeps	2 long vibrates + 2 medium beeps	2 long vibrates + 2 medium beeps
Low Alert	3 short vibrates	3 short vibrates + 3 low beeps	3 short vibrates + 3 medium beeps	3 short vibrates + 3 medium beeps
Rise Alert	2 long vibrates	2 long vibrates + 2 low beeps	2 long vibrates + 2 medium beeps	2 long vibrates + 2 medium beeps
Fall Alert	3 short vibrates	3 short vibrates + 3 low beeps	3 short vibrates + 3 medium beeps	3 short vibrates + 3 medium beeps
Out of Range Alert	1 long vibrate	1 long vibrate + 1 low beep	1 long vibrate + 1 medium beep	1 long vibrate + 1 medium beep
Fixed Low Alert	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps + pause + repeat sequence
All Other Alerts	1 long vibrate	1 long vibrate + 1 low beep	1 long vibrate + 1 medium beep	1 long vibrate + 1 medium beep

To Select Your CGM Volume:

1. From the *Home* screen, tap **OPTIONS**.
 2. Tap the **Down Arrow**.
 3. Tap **Device Settings**.
 4. Tap **Sound Volume**.
 5. Tap the **Down Arrow**.
 6. Tap **CGM Alerts**.
 7. Tap **Vibrate, Soft, Normal** or **HypoRepeat** to select.
- ✓ Once a value is selected, the pump will return to the previous screen.
8. Tap .

You can view this information at any time.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap the **Down Arrow**.
5. Tap **CGM Info**.

23.5 CGM Info

CGM Info contains important information about your device. The following can be found in CGM Info:

- Firmware Revision
- Hardware Revision

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Chapter 24

Setting CGM Alerts

Setting Your CGM Alerts

You can create personal settings for how and when you want the System to tell you what is happening.

The High and Low Alerts tell you when your sensor glucose readings are outside your target glucose range.

Rise and Fall (rate of change) Alerts let you know when your glucose levels are changing fast.

The System also has a 55 mg/dL Fixed Low Alert that cannot be changed or turned off. This safety feature tells you your glucose level may be dangerously low.

The Out of Range Alert notifies you when the transmitter and pump are not communicating. Keep the transmitter and the pump within 20 feet (6 meters) of each other without obstruction. When the transmitter and the pump are too far apart, you will not get sensor glucose readings or alerts.

High and Low Glucose Alerts

You can personalize the High and Low Alerts which tell you when your sensor

glucose readings are outside of your target glucose range. When you have both your High and Low Alerts turned on, a grey zone on your trend graph shows your target range. The default for the High Alert is on, 200 mg/dL. The default for the Low Alert is on, 80 mg/dL. Consult with your healthcare provider before setting the High and Low Glucose Alert setting.


24.1 Setting Your High Glucose Alert and Repeat Feature

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap **CGM Alerts**.
5. Tap **High and Low**.
6. To Set the High Alert, tap **High Alert**.
7. Tap **Alert Me Above**.

The default setting for the High Alert is 200 mg/dL.

NOTE: Turning the Alert Off

To turn off the High Alert, tap the on/off toggle. The screen will indicate that off is selected.

8. Using the on-screen keypad, enter the value above which you want to be notified. It can be set between 120 and 400 mg/dL in 1 mg/dL increments.
9. Tap .


The repeat feature allows you to set a time for the High Alert to sound again and display on your pump as long as your sensor glucose reading remains above the High Alert value. The default value is: Never (the alert will not sound again). You can set the repeat feature to sound again every 15 minutes, 30 minutes, 1 hour, 2 hours, 3 hours, 4 hours, or 5 hours when your sensor glucose reading remains above the High Alert value.

To Set Up the Repeat Feature:

10. Tap **Repeat**.

- To select the repeat time, tap the time you want the alert to sound again. For instance, if you select 1 hr, the alert will sound every hour as long as your sensor glucose reading remains above the High Alert value.

Use the up and down arrows to view all Repeat options.

- ✓ Once a value is selected, the pump will return to the previous screen.
- Tap .


24.2 Setting Your Low Glucose Alert and Repeat Feature

- From the *Home* screen, tap **OPTIONS**.
- Tap the **Down Arrow**.
- Tap **My CGM**.
- Tap **CGM Alerts**.
- Tap **High and Low**.
- To Set the Low Alert, tap **Low Alert**.
- Tap **Alert Me Below**.

The default setting for the Low Alert is 80 mg/dL.


NOTE: Turning the Alert Off

To turn off the Low Alert, tap the on/off toggle. The screen will indicate that off is selected.

- Using the on-screen keypad, enter the value below which you want to be notified. It can be set between 60 and 100 mg/dL in 1 mg/dL increments.
- Tap .

The repeat feature allows you to set a time for the Low Alert to sound again and display on your pump as long as your sensor glucose reading remains below the Low Alert value. The default value is: Never (the alert will not sound again). You can set the repeat feature to sound again every 15 minutes, 30 minutes, 1 hour, 2 hours, 3 hours, 4 hours, or 5 hours when your sensor glucose reading remains below the Low Alert value.

To Set Up the Repeat Feature:

- Tap **Repeat**.
 - To select the repeat time, tap the time you want the alert to sound again. For instance, if you select 1 hr, the alert will sound every hour as long as your sensor glucose reading remains below the Low Alert Value.
- Use the up and down arrows to view all repeat options.
- ✓ Once a value is selected, the pump will return to the previous screen.
- Tap .

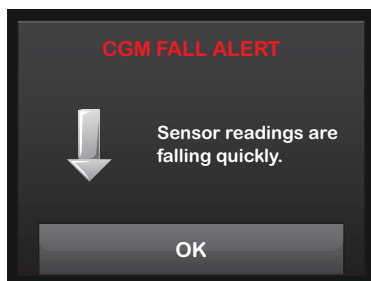
24.3 Rate Alerts

Rate alerts tell you when your glucose levels are rising (Rise Alert) or falling (Fall Alert) and by how much. You can choose to be alerted when your sensor glucose reading is rising or falling 2 mg/dL or more per minute, or 3 mg/dL or more per minute. The default value for both the Fall Alert and the Rise Alert is off. When turned on, the default is 3 mg/dL. Consult with your healthcare

provider before setting the Rise and Fall Alerts.

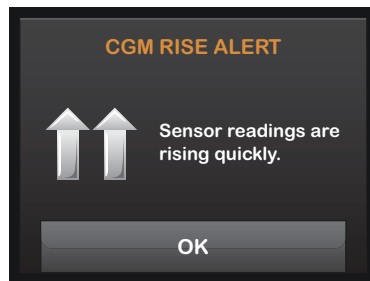
Examples

If you set your Fall Alert to 2 mg/dL per minute and your sensor glucose readings fall at this rate or faster, the CGM FALL ALERT with one arrow pointing down shows. The pump vibrates or beeps according to your CGM Volume selection.




If you set your Rise Alert to 3 mg/dL per minute and your sensor glucose readings rise at this rate or faster, the CGM RISE ALERT with two arrows pointing up shows. The pump vibrates

or beeps according to your CGM Volume selection.




24.4 Setting Your Rise Alert

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the Down Arrow.
3. Tap My CGM.
4. Tap CGM Alerts.
5. Tap Rise and Fall.
6. Tap Rise Alert.
7. To select the default of 3 mg/dL/min, tap .


To change your selection, tap **Rate**.

NOTE: Turning the Alert Off

To turn off the Rise Alert, tap the on/off toggle.


8. Tap 2 mg/dL/min to select.
- ✓ Once a value is selected, the pump will return to the previous screen.
9. Tap .

24.5 Setting Your Fall Alert

1. From the *Home* screen, tap **OPTIONS**.
 2. Tap the Down Arrow.
 3. Tap My CGM.
 4. Tap CGM Alerts.
 5. Tap Rise and Fall.
 6. Tap Fall Alert.
 7. To select the default of 3 mg/dL/min, tap .
- To change your selection, tap **Rate**.

NOTE: Turning the Alert Off

To turn off the Fall Alert, tap the on/off toggle.

8. Tap 2 mg/dL/min to select.
- ✓ Once a value is selected, the pump will return to the previous screen.
9. Tap .

24.6 Setting Your Out of Range Alert

The range from the transmitter to the pump is up to 20 feet (6 meters) without obstruction.


The Out of Range Alert lets you know when your transmitter and pump are not communicating with each other. Keep the transmitter and the pump within 20 feet (6 meters) of each other without obstruction. To ensure communication, it is suggested that you face your pump screen out and away from the body, and wear the pump on the same side of the body that you wear your CGM. When the transmitter and pump are not communicating, you will not get sensor glucose readings or

alerts. The default value is off; 30 minutes if turned on.

The Out Of Range symbol appears on the pump *Home* screen and on the *Out of Range Alert* screen (if turned on) when the transmitter and pump are not communicating. The amount of time out of range also shows on the alert screen. It will continue to re-alert until the transmitter and pump are back in range.

To Set Your Out of Range Alert:

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap **CGM Alerts**.
5. Tap **Out of Range**.
The default is set off; 30 minutes if turned on.
6. To change the time, tap **Alert After**.
7. Using the on-screen keypad, enter the time after which you want to be alerted (between 20 minutes and 3

hours and 20 minutes) then tap .

8. Tap .

⚠ PRECAUTION

We recommend that you enable the CGM Out of Range Alert to notify you if your CGM is disconnected from your pump whenever you are not actively monitoring your pump status.

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Chapter 25

Starting a CGM Sensor Session

25.1 Start the Sensor

To start a CGM session, follow the steps below.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap **START SENSOR**.
 - ✓ Once you start a sensor session, the **START SENSOR** option is replaced with **STOP SENSOR**.
 - ✓ The *SENSOR STARTED* screen will appear to let you know your sensor startup has begun.
 - ✓ Your pump will return to the *CGM Home* screen with the 3 hour trend graph displayed.
5. Check your pump *CGM Home* screen 10 minutes after starting your sensor session to make sure your pump and transmitter are communicating. The antenna symbol should be to the right of the battery indicator and should be white.
 6. If you see the out of range symbol below the insulin level indicator, and the antenna symbol is grayed out, follow these troubleshooting tips:
 - a. Make sure your pump and transmitter are within 20 feet (6 meters) of each other without obstruction. Re-check in 10 minutes to see if the out of range symbol is still active.
 - b. If the pump and transmitter are still not communicating, check the *My CGM* screen to make sure the correct transmitter ID is entered.
 - c. If the correct transmitter ID is entered and the pump and transmitter are still not communicating, contact Customer Technical Support.

25.2 Sensor Startup Period

As an example, the Dexcom G5 Mobile CGM sensor needs a 2-hour startup period to adjust to being under your skin. You will not get sensor glucose readings or alerts until the 2-hour startup period ends and you complete your first calibrations. For information about Dexcom G5 Mobile CGM sensor startup periods, visit the manufacturer's website for applicable user guides.

During the startup period, the *CGM Home* screen on your pump shows a 2-hour countdown symbol in the upper right portion of the screen. The countdown symbol fills in over time to show that you are getting closer to the end of the startup period.



⚠ WARNING

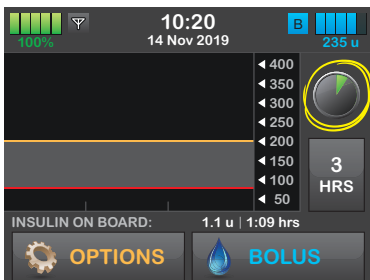
Continue to use a blood glucose meter and test strips in order to make treatment decisions during the 2-hour startup period.

📖 NOTE:

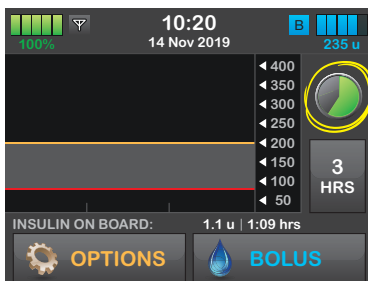
Once your sensor session has completed, you must end the current session before you can start a new session.

Examples

For example, if you started your sensor session 20 minutes ago, you would see this countdown symbol on the *CGM Home* screen.



If you started your sensor session 90 minutes ago, you would see this countdown symbol on the *CGM Home* screen.



At the end of the 2-hour startup period, then you will be prompted to enter 2 calibration values. 2 blood drops will appear in the place where the countdown symbol was. If you entered a sensor code, the countdown symbol will be replaced with the current CGM reading.



If you did not enter a sensor code, then follow the instructions in the next section to calibrate your sensor. Skip the calibration instructions if you entered a sensor code. You may enter a calibration into the System at any time. Pay attention to your symptoms, and if they do not match the current CGM readings, you may choose to enter a calibration.

NOTE:

Once your sensor session has completed, you must end the current session before you can start a new session.

Chapter 26

Calibrating Your CGM System

26.1 Calibration Overview

Your CGM System need calibrations using BG values obtained from a commercially available blood glucose meter to display continuous sensor glucose readings and trend information. There are important times when you must calibrate:

- 2-hour startup: 2 hours after you start your sensor session
- 12-hour update: every 12 hours after the 2 hour start up calibration
- More information is needed for other reasons

On the first day of your sensor session, you must enter 2 BG values into your pump to calibrate. You must enter 1 BG value to calibrate every 12 hours after your first startup calibration. The pump will remind you when the System needs these calibrations. In addition, you may be prompted to enter additional BG values to calibrate as needed.

⚠ WARNING

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

⚠ PRECAUTION

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

⚠ PRECAUTION

DO NOT calibrate if your BG is changing at a significant rate, typically more than 2 mg/dL per minute. Do not calibrate when your receiver screen is showing the rising or falling single arrow, which indicates that your BG is rapidly rising or falling. Calibrating during significant rise or fall of BG may affect sensor accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

When calibrating, you must enter your BG values into the pump by hand. You can use any commercially available

blood glucose meter. You must calibrate with accurate blood glucose meter values to get accurate sensor glucose readings.

Follow these important instructions when obtaining BG values for calibration:


- BG values used for calibration must be between 40 to 400 mg/dL and must have been taken within the past 5 minutes.
- Your sensor cannot be calibrated if the glucose value from your meter is less than 40 mg/dL. For safety reasons, if your BG is low, first treat your low BG.
- Make sure a sensor glucose reading shows in the upper right portion of the *CGM Home* screen before calibrating.
- Make sure the antenna symbol is visible to the right of the battery indicator on the *CGM Home* screen and is active (white, not greyed out) before calibrating.
- Always use the same meter to calibrate that you routinely use to

measure your BG. Do not switch your meter in the middle of a sensor session. Blood glucose meter and strip accuracy vary between blood glucose meter brands.

- The accuracy of the blood glucose meter used for calibration may affect the accuracy of sensor glucose readings. Follow your blood glucose meter manufacturer's instructions for BG testing.

26.2 Startup Calibration

2 hours after you start the sensor session, the *CALIBRATE CGM* screen will appear, letting you know that 2 separate BG values from your meter must be entered. You will not see sensor glucose readings until the pump accepts the BG values.

1. From the *CALIBRATE CGM* screen, Tap .
- ✓ The *CGM Home* screen will appear with two blood drops in the upper right portion of the screen. The two blood drops will stay on the screen

until you enter 2 separate BG values to calibrate.

2. Wash and dry your hands, make sure your glucose test strips are not expired and have been stored properly, and make sure your meter is properly coded (if required).
3. Take a BG measurement using your blood glucose meter. Carefully apply the blood sample to the test strip following your meter manufacturer's instructions.




PRECAUTION

DO use fingertips to calibrate from your meter. Blood from other places may be less accurate and not as timely.

4. Tap **OPTIONS**.
5. Tap the **Down Arrow**.
6. Tap **My CGM**.
7. Tap **Calibrate CGM**.
8. Using the on-screen keypad, enter the BG value from your blood glucose meter.

PRECAUTION


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

9. Tap .
10. Tap  to confirm the calibration. Tap  if the BG value does not exactly match the reading from your blood glucose meter. The on-screen keypad will reappear. Enter the exact reading from your meter.
 - ✓ The *CALIBRATION ACCEPTED* screen will appear.
 - ✓ The *My CGM* screen will appear.
11. Tap **Calibrate CGM** to enter your second BG value.
 - ✓ The on-screen keypad will appear.

12. Wash and dry your hands, make sure your glucose test strips are not expired and have been stored properly, and make sure your meter is properly coded (if required).
13. Take a BG measurement using your blood glucose meter. Carefully apply the blood sample to the test strip following your meter manufacturer's instructions.
14. Follow steps 8–10 to enter your second BG value.

26.3 Calibration BG Value and Correction Bolus

Your t:slim X2 pump uses the BG value entered for calibration to determine if a correction bolus is needed, or to provide other important information about your insulin on board and BG.

- If you enter a calibration value that is above your Target BG in Personal Profiles, a message screen will indicate “YOUR BG IS ABOVE TARGET”. To add a correction bolus, tap . Follow the instructions in [Section 7.2](#)

[Correction Bolus Calculation](#) to deliver a correction bolus.

- If you enter a calibration value that is below your Target BG in Personal Profiles, a message screen will indicate “YOUR BG IS BELOW TARGET”, and other important information will appear on the screen.
- If you enter your Target BG as a calibration value, the pump will return to the *CCM Home* screen.

26.4 24 Hour Calibration Update

Calibrate your CGM System when prompted. If you did not enter the sensor code during sensor session start, then calibration will be at least every 24 hours after your first day of calibrations to make sure your sensor glucose readings remain accurate and close to your BG values. You can enter BG values sooner than 24 hours if you want. If you have not entered any BG values in the past 24 hours, the pump will ask you to enter a BG value to update its calibration.

The *CALIBRATE CGM* screen will appear, letting you know that a BG value from your blood glucose meter must be entered to calibrate. In addition, a blood drop will appear to the right of the antenna symbol and will remain there until a BG value is entered to calibrate.

1. From the *CALIBRATE CGM* Screen, Tap .

PRECAUTION




DO use fingertips to calibrate from your meter. Blood from other places may be less accurate and not as timely.

2. Tap **OPTIONS**.
3. Tap the **Down Arrow**.
4. Tap **My CGM**.
5. Tap **Calibrate CGM**.
6. Using the on-screen keypad, enter the BG value from your blood glucose meter.

PRECAUTION

DO enter the exact BG value displayed on your meter within 5 minutes of using your

meter. Don't enter the Dexcom G5 reading for calibration.

7. Tap .
 8. Tap  to confirm the calibration.
Tap  if the BG value does not exactly match the reading from your meter. The on-screen keypad will appear. Enter the exact reading from your meter.
- ✓ The *CALIBRATION ACCEPTED* screen will appear, followed by the *CGM Home* screen.

BG value to calibrate in either 15 minutes or 1 hour, depending on the error.

26.5 Other Reasons You May Need to Calibrate

You may need to calibrate when your System did not accept the last calibration, or when the BG value you entered for calibration is very different from the sensor glucose reading.

When you see the *CALIBRATE CGM* screen, calibrate using the instructions in the previous chapters.

If you see the *CALIBRATION ERROR* screen, you will be prompted to enter a

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Chapter 27

Viewing CGM Data on Your t:slim X2 Insulin Pump

27.1 Overview

⚠ WARNING

DO NOT ignore how you feel. If your glucose alerts and readings do not match what you're feeling, use your blood glucose meter to make diabetes treatment decisions or, if needed, seek immediate medical attention.

During an active sensor session, CGM readings are sent to your pump every 5 minutes. This section teaches you how to view your sensor glucose readings and trend information. The trend graph provides additional information that your blood glucose meter does not. It shows your current glucose value, the direction it is changing and how fast it is changing. The trend graph can also show you where your glucose has been over time.

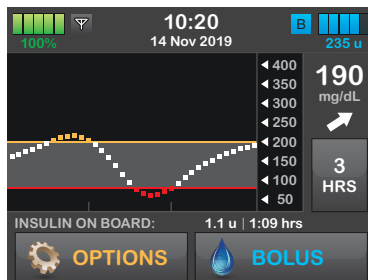
Your blood glucose meter measures glucose in your blood. Your sensor measures glucose from interstitial fluid (the fluid under your skin). Because glucose from different fluids is measured, readings from your blood glucose meter and sensor may not match.

The greatest benefit you get from using continuous glucose monitoring will come from trending information. It is important that you focus on the trends and rate of change on your receiver rather than the exact glucose reading.

⚠ PRECAUTION

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

Press the **Screen On/Quick Bolus** button to turn the screen on. If a CGM session is active, you will see the *CGM Home* screen with the 3 hour trend graph displayed.



- The current time and date are shown at the top of the screen in the middle.
- Each “dot” on the trend graph is a sensor glucose reading reported every 5 minutes.
- Your High Alert setting shows as an orange line across the trend graph.
- Your Low Alert setting shows as a red line across the trend graph.
- The gray zone highlights your target glucose range, between your High and Low Alert settings.
- Sensor glucose readings are shown in milligrams per deciliter (mg/dL).
- If your sensor glucose reading is between your High and Low Alert settings, it is shown in white.
- If your sensor glucose reading is above your High Alert setting, it is shown in orange.
- If your sensor glucose reading is below your Low Alert setting, it is shown in red.

- If the Low Alert is not set and your glucose reading is 55 mg/dL or lower, it is shown in red.
- The dots on the trend graph display as different colors based on your High and Low Alert settings: white if between High and Low Alert settings, orange if above High Alert settings, red if below Low Alert setting.

27.2 CGM Trend Graphs

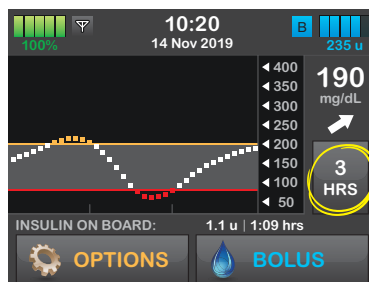
You can view your past sensor glucose trend information on your *CGM Home* screen.

1, 3, 6, 12, and 24 hour trend views can be seen. The 3 hour Trend Graph is the default view and will be shown on the *Home* screen even if a different trend graph was shown when the screen turned off.

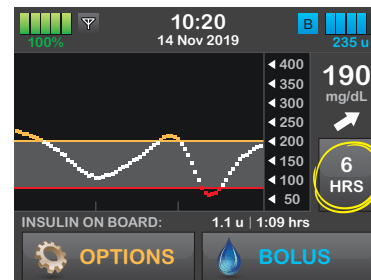
Sensor glucose information is only reported for values between 40 and 400 mg/dL. Your trend graph shows a flat line or dots at 40 or 400 mg/dL when your glucose is outside this range.

To view different Trend Graph times, tap on the Trend Graph Time (HRS) to cycle through the options.

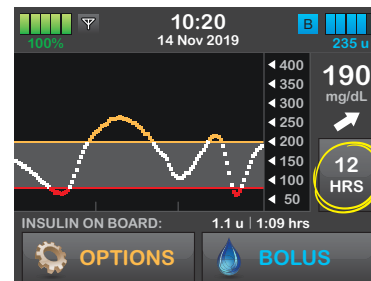
3 Hour Trend Graph (default view) shows you your current glucose reading along with the last 3 hours of sensor glucose readings.



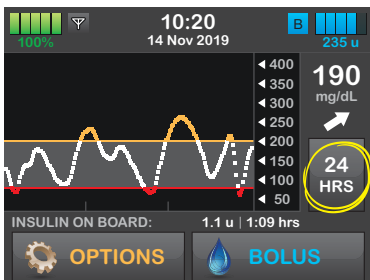
6 Hour Trend Graph shows you your current glucose reading along with the last 6 hours of sensor glucose readings.



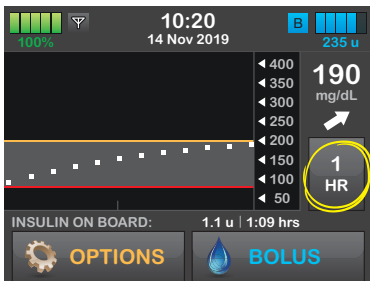
12 Hour Trend Graph shows you your current glucose reading along with the last 12 hours of sensor glucose readings.



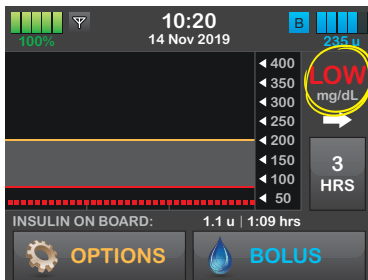
24 Hour Trend Graph shows you your current glucose reading along with the last 24 hours of sensor glucose readings.



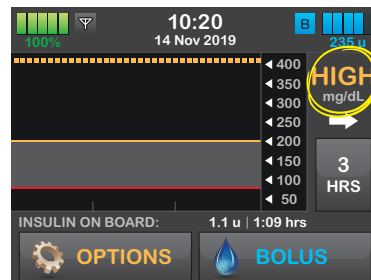
1 Hour Trend Graph shows you your current glucose reading along with the last 1 hour of sensor glucose readings.



LOW shows when your most recent sensor glucose reading is less than 40 mg/dL.



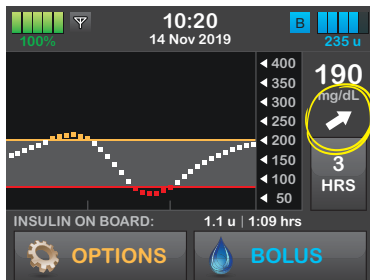
HIGH shows when your most recent sensor glucose reading is greater than 400 mg/dL.



27.3 Rate of Change Arrows

Your rate of change arrows add detail about the direction and speed of glucose change over the last 15–20 minutes.

The trend arrows show below your current sensor glucose reading.










Do not overreact to the rate of change arrows. Consider recent insulin dosing, activity, food intake, your overall trend graph and your BG value before taking action.

If there are missed communications between the sensor and your pump during the last 15–20 minutes due to being out of range or due to an error condition, an arrow may not display. If the trend arrow is missing, and you are concerned that your BG level may be rising or falling, take a BG measurement using your blood glucose meter.

The table below shows the different trend arrows your receiver displays:

Trend Arrow Definitions

	Constant: Your glucose is steady (not increasing/decreasing more than 1 mg/dL each minute). Your glucose could increase or decrease by up to 15 mg/dL in 15 minutes.
	Slowly rising: Your glucose is rising 1–2 mg/dL each minute. If it continued rising at this rate, your glucose could increase up to 30 mg/dL in 15 minutes.
	Rising: Your glucose is rising 2–3 mg/dL each minute. If it continued rising at this rate, your glucose could increase up to 45 mg/dL in 15 minutes.
	Rapidly rising: Your glucose is rising more than 3 mg/dL each minute. If it continued rising at this rate, your glucose could increase more than 45 mg/dL in 15 minutes.

	Slowly falling: Your glucose is falling 1–2 mg/dL each minute. If it continued falling at this rate, your glucose could decrease up to 30 mg/dL in 15 minutes.
	Falling: Your glucose is falling 2–3 mg/dL each minute. If it continued falling at this rate, your glucose could decrease up to 45 mg/dL in 15 minutes.
	Rapidly falling: Your glucose is falling more than 3 mg/dL each minute. If it continued falling at this rate, your glucose could decrease more than 45 mg/dL in 15 minutes.
No Arrow	No rate of change information: The System cannot calculate how fast your glucose is rising or falling at this time.

27.4 CGM History

CGM History displays the historical log of CGM events. At least 90 days of data can be viewed in History. When the maximum number of events is reached, the oldest events are removed from the history log and replaced with the most recent events. The following history sections can be viewed:

- Sessions and Calibrations
- Alerts and Errors
- Complete

Each section above is organized by date. If there are no events associated with a date, the day will not be shown in the list.

The Sessions and Calibrations section includes the start time and date for each Sensor Session, the stop time and date for each Sensor Session, and all calibration BG values entered.

The Alerts and Errors section includes the date and time for all Alerts and Errors that occurred. The letter “D” (D: Alert) before an Alert or Alarm indicates

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

The Complete section includes all information from the Sessions and Calibrations and Alerts and Errors sections as well as any changes to Settings.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **History**.
4. Tap **CGM History**.
5. Tap section you want to view. Each section is organized by date. Tap the date to view events from that day. Use the **Down Arrow** to scroll to more dates.

27.5 Missed Readings

If your pump misses CGM readings for a period of time, you will see three dashes where the CGM reading typically displays on the *CGM Home*

screen and on the *CGM Lock* screen. The system will automatically attempt to backfill missing data points up to 6 hours in the past when connectivity is restored and readings begin to appear. If the sensor glucose number or trend arrow is missing, and you are concerned that your BG level may be rising or falling, take a BG measurement using your blood glucose meter..

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Chapter 28

Ending Your CGM Sensor Session

Ending Your Sensor Session


When the sensor session ends, you will need to replace the sensor and start a new sensor session. In some cases your sensor session may end early. You may also choose to end the sensor session early.

Glucose alerts and alarms do not work after the sensor session ends.


28.1 Automatic Sensor Shut-Off

Your t:slim X2 Pump tells you how much time you have left until your sensor session is complete. The *SENSOR EXPIRING SOON* screen shows at 6 hours remaining, 2 hours remaining, and 30 minutes remaining before your 7 day session ends. You will continue to receive sensor glucose readings after each reminder.

When you see the *SENSOR EXPIRING SOON* screen:

1. Tap  to return to the previous screen.
- ✓ The *SENSOR EXPIRING SOON* screen will show again when there

are 2 hours remaining, and when there are 30 minutes remaining.


- ✓ After the final 30 minutes, the *REPLACE SENSOR* screen is displayed.
2. Tap .
- ✓ The *Home* screen will appear with the Replace Sensor icon in the place where sensor glucose readings normally show.

New sensor glucose readings do not show on your pump after your sensor session ends. You must remove your sensor and insert a new sensor.

28.2 Ending a Sensor Session Before Automatic Shut-Off

You can end your sensor session at any time before the automatic sensor shutdown. To end your sensor session early:

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

4. Tap **STOP SENSOR**.
5. Tap  to confirm.
- ✓ The *SENSOR STOPPED* screen is temporarily displayed.
- ✓ The *Home* screen will appear with the Replace Sensor icon in the place where sensor glucose readings normally show.

New sensor glucose readings do not show on your pump after your sensor session ends. You must remove your sensor and insert a new sensor.

28.3 Removing the Sensor and Transmitter

WARNING

DO NOT ignore broken or detached sensor wires. A sensor wire could remain under your skin. If a sensor wire breaks off under your skin and you can't see it, don't try to remove it. Contact your healthcare provider. Also seek professional medical help if you have symptoms of infection or inflammation (redness, swelling, or pain) at the insertion site. If you experience a broken sensor, please report this to Customer Technical Support.

For information about removing the Dexcom G5 Mobile sensor and Dexcom G5 Mobile transmitter, visit the manufacturer's website for applicable user guides.

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Chapter 29

CGM Alerts and Errors

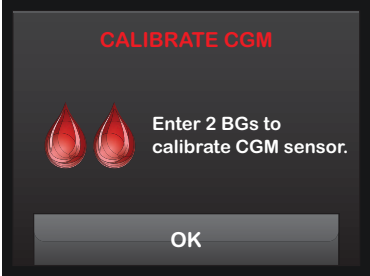
This section describes CGM alerts and errors that appear on your *Home* screen. It applies only to the CGM portion of your System. CGM alerts and errors do not follow the same pattern of vibration and beeps as insulin delivery reminders, alerts, and alarms.

For information on insulin delivery reminders, alerts, and alarms, see [Chapters 15 t:slim X2 Insulin Pump Alerts](#), [16 t:slim X2 Insulin Pump Alarms](#), and [17 t:slim X2 Insulin Pump Malfunction](#).

PRECAUTION

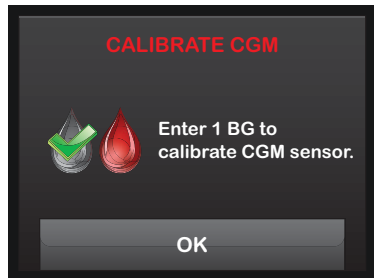
You must customize the CGM alert settings on your t:slim X2 pump and the Dexcom G5 Mobile app separately. The alert settings apply to the phone and pump separately.

29.1 Startup Calibration Alert

<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>2-hour CGM startup period is complete. This will only appear if you did not enter a sensor code.</p> <hr/> <p>How will the System notify me?</p> <p>1 vibration, then vibration/beep every 5 minutes until confirmed.</p> <hr/> <p>Will the System re-notify me?</p> <p>Yes, every 15 minutes until you calibrate.</p> <hr/> <p>How should I respond?</p> <p>Tap OK and enter 2 separate BG values to calibrate the system and start your CGM session.</p>
--	--

29.2 Second Startup Calibration Alert

What will I see on the screen?



What does it mean?

The System needs an additional BG value to complete startup calibration. This will only appear if you did not enter a sensor code.

How will the System notify me?

1 vibration, then vibration/beep every 5 minutes until confirmed.

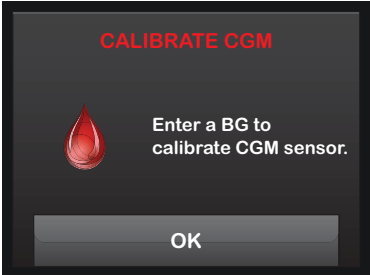
Will the System re-notify me?

Yes, every 15 minutes until second calibration is entered.

How should I respond?

Tap **OK** and enter a BG value to calibrate the System and start your CGM session.

29.3 12 Hour Calibration Alert

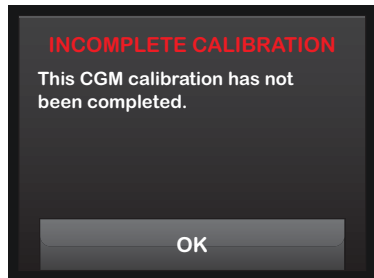
<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>The System needs a BG value to calibrate. This will only appear if you did not enter a sensor code.</p> <p>How will the System notify me?</p> <p>On screen only with no vibration or beep.</p> <p>Will the System re-notify me?</p> <p>Yes, every 15 minutes.</p> <p>How should I respond?</p> <p>Tap OK and enter a BG value to calibrate the system.</p>
--	--

⚠ WARNING

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

29.4 Incomplete Calibration

What will I see on the screen?



What does it mean?

If you start to enter a calibration value using the keypad and do not complete the entry within 90 seconds, this screen appears.

How will the System notify me?

2 beeps or vibrations depending on Sound Volume selected.

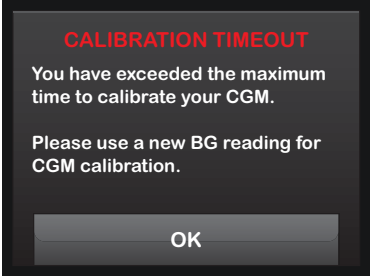
Will the System re-notify me?

Yes, every 5 minutes until confirmed.

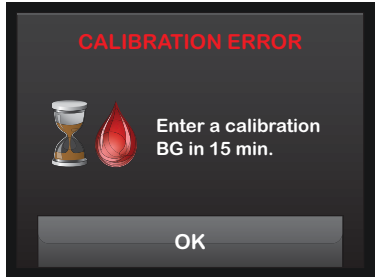
How should I respond?

Tap **OK** and complete your calibration by entering the value using the on-screen keypad.

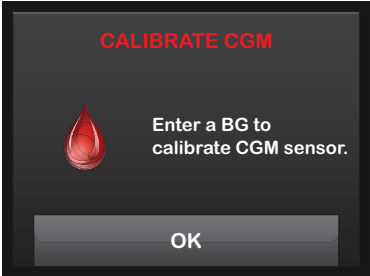
29.5 Calibration Timeout

<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>If you start to enter a calibration value using the keypad and do not complete the entry within 5 minutes, this screen appears.</p> <hr/> <p>How will the System notify me?</p> <p>2 beeps or vibrations depending on Sound Volume selected.</p> <hr/> <p>Will the System re-notify me?</p> <p>Yes, every 5 minutes until confirmed.</p> <hr/> <p>How should I respond?</p> <p>Tap OK and obtain a new BG value using your meter. Enter the value using the on-screen keypad to calibrate the System.</p>
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29.6 Wait 15 Minute Calibration Error Alert

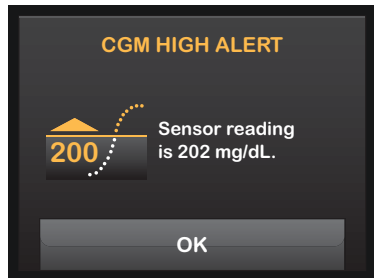
<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>The sensor cannot calibrate.</p> <p>How will the System notify me?</p> <p>1 vibration, then vibration/beep every 5 minutes until confirmed.</p> <p>Will the System re-notify me?</p> <p>No.</p> <p>How should I respond?</p> <p>Tap OK to confirm. Wait 15 minutes then enter 1 more BG value. Wait 15 more minutes. If error screen still appears, enter 1 more BG value. Wait 15 minutes. If no sensor glucose readings appear, the sensor needs to be replaced.</p>
--	--

29.7 Calibration Required Alert

<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>The System needs a BG value to calibrate. Sensor glucose readings will not be displayed at this time.</p> <p>How will the System notify me?</p> <p>1 vibration, then vibration/beep every 5 minutes until confirmed.</p> <p>Will the System re-notify me?</p> <p>Yes, every 15 minutes.</p> <p>How should I respond?</p> <p>Tap OK and enter a BG value to calibrate the System.</p>
--	--

29.8 CGM High Alert

What will I see on the screen?



What does it mean?

Your most recent sensor glucose reading is at or above the High Alert setting.

How will the System notify me?

2 vibrations, then 2 vibrations/beeps every 5 minutes until confirmed or your glucose value drops below the Alert level.

Will the System re-notify me?

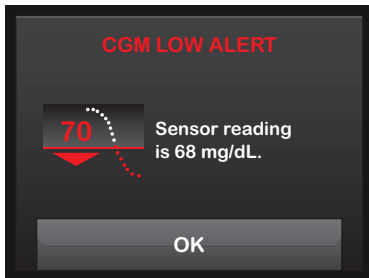
Only if you have turned on the Repeat feature.

How should I respond?

Tap  to confirm.

29.9 CGM Low Alert

What will I see on the screen?



What does it mean?

Your most recent sensor glucose reading is at or below the Low Alert setting.

How will the System notify me?

3 vibrations, then 3 vibrations/beeps every 5 minutes until confirmed or your glucose value goes above the Alert level.

Will the System re-notify me?

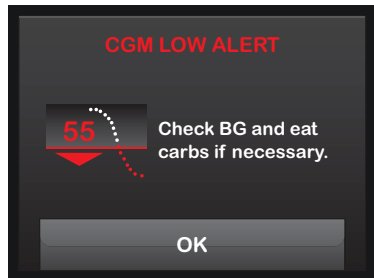
Only if you have turned on the Repeat feature.

How should I respond?

Tap  to confirm.

29.10 CGM Fixed Low Alert

What will I see on the screen?



What does it mean?

Your most recent sensor glucose reading is at or below 55 mg/dL.

How will the System notify me?

4 Vibrations, then 4 vibrations/beeps every 5 minutes until confirmed or your glucose value goes above 55 mg/dL.

Will the System re-notify me?

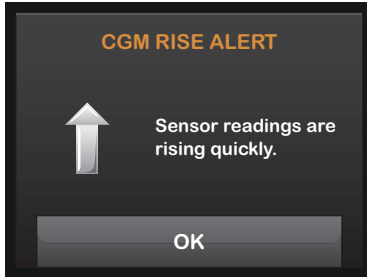
Yes, 30 minutes after each confirmation until your glucose value goes above 55 mg/dL.

How should I respond?

Tap to confirm.

29.11 CGM Rise Alert

What will I see on the screen?



What does it mean?

Your glucose levels are rising at 2 mg/dL per minute or faster (at least 30 mg/dL in 15 minutes).

How will the System notify me?

2 vibrations, then 2 vibrations/beeps every 5 minutes or until confirmed.

Will the System re-notify me?

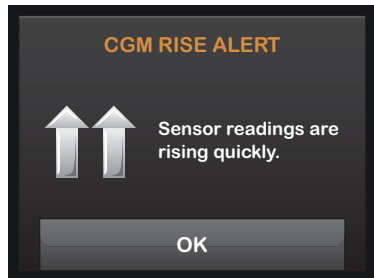
No.

How should I respond?

Tap  to confirm.

29.12 CGM Rapid Rise Alert

What will I see on the screen?



What does it mean?

Your glucose levels are rising at 3 mg/dL per minute or faster (at least 45 mg/dL in 15 minutes).

How will the System notify me?

2 vibrations, then 2 vibrations/beeps every 5 minutes or until confirmed.

Will the System re-notify me?

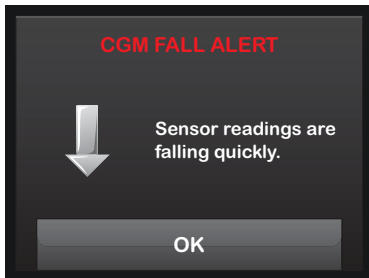
No.

How should I respond?

Tap **OK** to confirm.

29.13 CGM Fall Alert

What will I see on the screen?



What does it mean?

Your glucose levels are falling at 2 mg/dL per minute or faster (at least 30 mg/dL in 15 minutes).

How will the System notify me?

3 vibrations, then 3 vibrations/beeps every 5 minutes or until confirmed.

Will the System re-notify me?

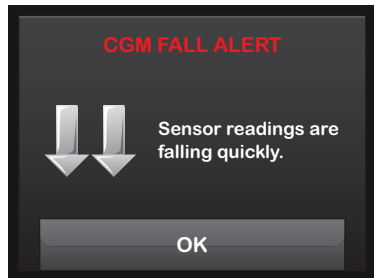
No.

How should I respond?

Tap **OK** to confirm.

29.14 CGM Rapid Fall Alert

What will I see on the screen?



What does it mean?

Your glucose levels are falling at 3 mg/dL per minute or faster (at least 45 mg/dL in 15 minutes).

How will the System notify me?

3 vibrations, then 3 vibrations/beeps every 5 minutes or until confirmed.

Will the System re-notify me?

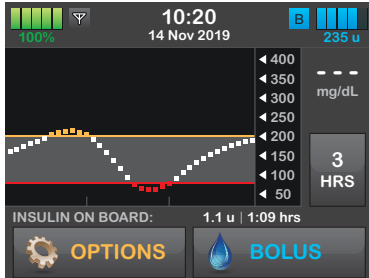
No.

How should I respond?

Tap **OK** to confirm.

29.15 Unknown Sensor Reading

What will I see on the screen?



What does it mean?

The sensor is sending sensor glucose readings that the System does not understand. You will not receive sensor glucose readings.

How will the System notify me?

On screen only with no vibration or beep.

Will the System re-notify me?

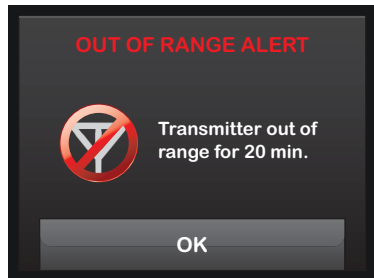
The 3 dashes will remain on the screen until a new glucose reading is received and displayed in their place.

How should I respond?

Wait 30 minutes for more information from the system. Do not enter BG values for calibration. The system will not use BG values for calibration when “- - -” appears on the screen.

29.16 Out of Range Alert

What will I see on the screen?



What does it mean?

The transmitter and pump are not communicating and you will not receive sensor glucose readings.

How will the System notify me?

1 vibrate, then vibration/beep every 5 minutes until the transmitter and pump are back in range.

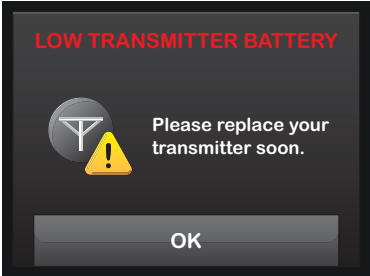
Will the System re-notify me?

Yes, if the transmitter and pump remain out of range.

How should I respond?

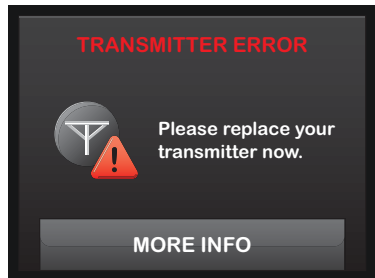
Tap **OK** to confirm and move the transmitter and pump closer together, or remove the obstruction between them.

29.17 Low Transmitter Battery Alert

<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>Transmitter battery is low.</p> <p>How will the System notify me?</p> <p>1 vibration, then vibration/beep every 5 minutes until confirmed.</p> <p>Will the System re-notify me?</p> <p>Yes, the alarm will notify you when there are 21, 14, and 7 days of transmitter battery life remaining.</p> <p>How should I respond?</p> <p>Tap OK to confirm. Replace the transmitter as soon as possible.</p>
--	--

29.18 Transmitter Error

What will I see on the screen?



What does it mean?

The transmitter has failed and the CGM session has stopped.

How will the System notify me?

1 vibration, then vibration/beep every 5 minutes.

Will the System re-notify me?

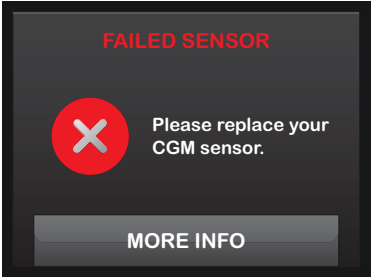
No.

How should I respond?

Tap **MORE INFO**. A screen notifying you that your CGM session has stopped but insulin delivery continues will appear.

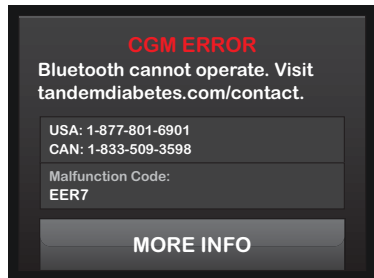
Replace the transmitter immediately.

29.19 Failed Sensor Error

<p>What will I see on the screen?</p> 	<p>What does it mean?</p> <p>The sensor is not working properly and the CGM session has stopped.</p> <p>How will the System notify me?</p> <p>1 vibration, then vibration/beep every 5 minutes.</p> <p>Will the System re-notify me?</p> <p>No.</p> <p>How should I respond?</p> <p>Tap MORE INFO. A screen notifying you that your CGM session has stopped but insulin delivery continues will appear.</p> <p>Replace the sensor and begin a new CGM session.</p>
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29.20 CGM System Error

What will I see on the screen?



What does it mean?

Your CGM System is not working properly; the CGM session has stopped and the CGM can no longer be used.

How will the System notify me?

1 vibration, then vibration/beep every 5 minutes.

Will the System re-notify me?

No.

How should I respond?

Tap MORE INFO. A screen notifying you that your CGM System cannot operate but insulin delivery continues will appear. Call Customer Technical Support.

Chapter 30

CGM Troubleshooting

This chapter provides helpful tips and instructions to help you fix issues you may have while using the CGM portion of your System.

If the troubleshooting steps in this chapter do not fix your issue, contact Customer Technical Support.

The following tips are specific to troubleshooting the Dexcom G5 Mobile CGM connected to your pump. For more information about Dexcom G5 Mobile CGM troubleshooting, visit the manufacturer's website for applicable user guides.

30.1 CGM Pairing Troubleshooting

Possible issue:

Difficulty pairing your Dexcom G5 Mobile CGM with your t:slim X2 insulin pump.

Troubleshooting tip:

The Dexcom G5 Mobile CGM only allows pairing with one medical device at a time. Ensure your CGM is not connected to the Dexcom receiver before pairing with the pump. You may

still use a smartphone with the Dexcom G5 Mobile app and your t:slim X2 insulin pump simultaneously with the same transmitter ID. See [Section 23.2 Disconnecting from the Dexcom Receiver](#).

30.2 Calibration Troubleshooting

To ensure proper calibration of your CGM, follow these important tips.

Before you take a BG value for calibration, wash your hands, make sure your glucose test strips have been stored properly and are not expired and make sure that your meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions that came with your meter or test strips.

Do not calibrate if you see the Out of Range symbol in the place where your sensor glucose readings are normally shown on the screen.

Do not calibrate if you see “- - -” in the place where you sensor glucose readings are normally shown on the screen.

Do not calibrate if your BG value is below 40 mg/dL or above 400 mg/dL.

Make sure you have not taken any medications containing acetaminophen/paracetamol.

30.3 Unknown Sensor Reading Troubleshooting

When your CGM cannot provide a sensor glucose reading “- - -” shows in the place where your sensor glucose is normally shown on the screen. This means that the System does not understand the sensor signal temporarily.

Often the System can correct the problem and continue providing sensor glucose readings. If it has been at least 3 hours since your last sensor glucose reading, contact Customer Technical Support.

Do not enter any BG values for calibration when you see “- - -” on your screen. The System will not use a BG value for calibration when this symbol is on your screen.

If you see “- -” often during a sensor session, follow the troubleshooting tips below before inserting another sensor.

- Make sure your sensor is not expired.
- Make sure your sensor pod is not dislodged or peeling up.
- Make sure your transmitter is snapped in completely.
- Make sure nothing is rubbing the sensor pod (e.g., clothing, seat belts, etc.).
- Make sure to select a good insertion site.
- Make sure your insertion site is clean and dry before sensor insertion.
- Wipe the bottom of the transmitter with a damp cloth or isopropyl alcohol wipe. Place the transmitter on a clean, dry cloth and air dry for 2–3 minutes.

30.4 Out of Range/No Antenna Troubleshooting

PRECAUTION

AVOID separating the transmitter and receiver by more than 20 feet (6 meters). The transmission range from the transmitter to the receiver is up to 20 feet (6 meters) without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and receiver are farther than 20 feet (6 meters) apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

If you see the Out of Range icon on your screen in the place where your sensor glucose reading normally shows, then your t:slim X2 pump is not communicating with your transmitter and sensor glucose readings will not show on your screen. Each time you start a new sensor session, wait 10 minutes for your t:slim X2 pump to start communicating with your transmitter.

When a sensor session is active, you may sometimes experience loss of communication for 10 minutes at a time. This is normal.

If you see the Out of Range icon for more than 10 minutes, move your t:slim X2 Pump and CGM transmitter closer together and remove any obstructions. Wait 10 minutes and communication should be restored.

You must enter your transmitter ID correctly into your pump to receive sensor glucose readings (see [Section 23.3 Entering Your Transmitter ID](#)). Make sure you have removed your sensor and stopped your sensor session before checking or changing your transmitter ID. You cannot change your transmitter ID during a sensor session.

If you are still having trouble getting sensor glucose readings, contact Customer Technical Support.

30.5 Failed Sensor Troubleshooting

The System may detect issues with your sensor where it cannot determine your glucose reading. The sensor session ends and the *FAILED SENSOR* screen shows on your t:slim X2 pump. If you see this screen, it means your CGM session has ended.

- Remove your sensor and insert a new sensor.
- To help improve future sensor performance, follow the troubleshooting tips below.
- Make sure your sensor is not expired.
- Make sure your sensor pod is not dislodged or peeling up.
- Make sure your transmitter is snapped in completely.
- Make sure nothing is rubbing the sensor pod (e.g., clothing, seat belts, etc.).

- Make sure you have selected a good insertion site.

30.6 Sensor Inaccuracies

Inaccuracies are usually related to your sensor only and not to your transmitter or pump. Your sensor glucose readings are meant to be used for trending purposes only. The sensor measures glucose in the fluid under the skin—not in blood, and sensor glucose readings are not identical to readings from your blood glucose meter.

WARNING

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

PRECAUTION

To calibrate the System, **DO** enter the exact BG value that your blood glucose meter displays within 5 minutes of a carefully performed BG measurement. Do not enter sensor glucose values for calibration. Entering incorrect BG

values, BG values obtained more than 5 minutes before entry, or sensor glucose readings might affect sensor accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

If the difference between your sensor glucose reading and BG value is greater than 20% of the BG value for sensor readings > 80 mg/dL or greater than 20 mg/dL for sensor readings < 80 mg/dL, wash your hands and take another BG measurement. If the difference between this second BG measurement and the sensor is still greater than 20% for sensor readings > 80 mg/dL or greater than 20 mg/dL for sensor readings < 80 mg/dL, recalibrate your sensor using the second BG value. The sensor glucose reading will correct over the next 15 minutes. If you see differences between your sensor glucose readings and BG values outside of this acceptable range, follow the troubleshooting tips below before inserting another sensor:

- Make sure your sensor is not expired.

- Make sure you do not calibrate when “- - -” or the Out of Range icon are on the screen.
- Do not use alternative BG site testing (blood from your palm or forearm, etc.) for calibration as alternative site readings may be different than those from a BG value. Use a BG value only from your fingers for calibration.
- Use only BG values between 40–400 mg/dL for calibration. If one or more of your values is outside of this range, the receiver will not calibrate.
- Use the same meter you routinely use to measure your BG to calibrate. Do not switch your meter in the middle of a sensor session. Blood glucose meter and strip accuracy vary between blood glucose meter brands.
- Before taking a BG measurement for calibration, wash your hands, make sure your glucose test strips have been stored properly and are not expired and make sure that your meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions provided with your meter or test strips.
- Make sure you are using your blood glucose meter following the manufacturer’s instructions to get accurate BG values for calibration.
- Make sure you have not taken any medications containing acetaminophen/paracetamol to ensure you are getting accurate blood glucose values for calibration.

Section 5

Technical Specifications and Warranty

Chapter 36

Technical Specifications

36.1 Overview

This section provides tables of technical specifications, performance characteristics, options, settings, and electromagnetic compliance information for the t:slim X2 pump. The specifications in this section meet the international standards set forth in IEC 60601-1 and IEC 60601-2-24.

36.2 t:slim X2 Pump Specifications

t:slim X2 Pump Specifications

Specification Type	Specification Details
Classification	External PSU: Class II, Infusion Pump. Internally-powered equipment, Type BF applied part. The risk of ignition of flammable anesthetics and explosive gases by the pump is remote. While this risk is remote, it is not recommended to operate the t:slim X2 pump in the presence of flammable anesthetics or explosive gases.
Size	3.13" x 2.0" x 0.6" (L x W x H) - (7.95 cm x 5.08 cm x 1.52 cm)
Weight (with full disposable)	3.95 ounces (112 grams)
Operating Conditions	Temperature: 41°F (5°C) to 98.6°F (37°C) Humidity: 20% to 90% RH non-condensing
Storage Conditions	Temperature: -4°F (-20°C) to 140°F (60°C) Humidity: 20% to 90% RH non-condensing
Atmospheric Pressure	-1,300 feet to 10,000 feet (-369 meters to 3,048 meters)
Moisture Protection	IPX7: Watertight to a depth of 3 feet (0.91 meters) 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

t:slim X2 Pump Specifications (Continued)

Specification Type	Specification Details
Basal Delivery Accuracy at all Flow Rates (tested per IEC 60601-2-24)	±5% The pump is designed to vent automatically when there is a pressure difference between inside the cartridge and the surrounding air. In certain conditions, such as a gradual elevation change of 1,000 feet (305 meters), the pump may not vent immediately and delivery accuracy can vary up to 15% until 3 units have been delivered or elevation changes by more than 1,000 feet (305 meters).
Bolus Delivery Accuracy at all Volumes (tested per IEC 60601-2-24)	±5%
Patient Protection from Air Infusion	The pump provides subcutaneous delivery into interstitial tissue and does not deliver intravenous injections. Clear tubing aids in detecting air.
Maximum Infusion Pressure Generated and Occlusion Alarm Threshold	30 PSI
Frequency of Basal Delivery	5 minutes for all Basal Rates
Retention Time of Electronic Memory when Internal System Battery is Fully Discharged (including Alarm Settings and Alarm History)	Greater than 30 days
Infusion Set used for Testing	Unomedical Comfort™ Infusion Set
Typical Operating Time when System is Operating at Intermediate Rate	During normal use, the intermediate rate is 2 units/hr; battery charge can be reasonably expected to last up to 7 days (5 days if using CGM) from a fully charged state to a totally discharged state

t:slim X2 Pump Specifications (Continued)

Specification Type	Specification Details
Handling of Over-Infusion or Under-Infusion	<p>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.</p> <p>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 predefined period of time.</p> <p>Under-infusion is mitigated by occlusion detection and BG monitoring as BG entries are recorded. Users are prompted to treat high BG conditions with a correction bolus.</p>
Bolus Volume at Release of Occlusion (2 units per hour Basal)	Less than 3 units with Unomedical Comfort (110cm) Infusion Set
Residual Insulin Remaining in the Cartridge (unusable)	Approximately 15 units
Minimum Audible Alarm Volume	45 dBA at 1 meter

NOTE: Delivery Accuracies

Accuracies stated in this table are valid for all Tandem Diabetes Care, Inc. branded infusion sets including: AutoSoft™ 90, AutoSoft™ XC, AutoSoft™ 30, VariSoft™, TruSteel™, Comfort™, Contact, t:90™, Inset™, and t:30™ branded infusion sets.

USB Charging/Download Cable Specifications

Specification Type	Specification Detail
Tandem P/N	004113
Length	6 feet (2 meters)
Type	USB A to USB Micro B

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

Specification Type	Specification Detail
Tandem P/N	007866
Input	100 to 240 Volts AC, 50/60 Hz
Output Voltage	5 Volts DC
Max Output Power	5 Watts
Output Connector	USB type A

Car Adapter (sold separately), Specifications

Specification Type	Specification Detail
Tandem P/N	003934
Input	12 Volts DC

Car Adapter (sold separately), Specifications (Continued)

Specification Type	Specification Detail
Output Voltage	5 Volts DC
Max Output Power	5 Watts minimum
Output Connector	USB type A

PC, USB Connector, Specifications

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

Requirements for Charging from a Computer

The t:slim X2 pump is designed to be connected to a host computer for battery charging and data transfer. The following minimum characteristics are required of the host computer:

- USB 1.1 port (or later)
- Computer compliant with 60950-1 or equivalent safety standard

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

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

36.3 t:slim X2 Pump Options and Settings

t:slim X2 Pump Options and Settings

Option/Setting Type	Option/Setting Detail
Time	May be set to 12-hour or 24-hour clock (default is 12-hour clock)
Maximum Basal Rate	0.1 – 15 units/hr
Insulin Delivery Profiles (Basal and Bolus)	6
Basal Rate Segments	16 per delivery profile
Basal Rate Increment	0.001 at 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). 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
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)

tslim X2 Pump Options and Settings (Continued)

Option/Setting Type	Option/Setting Detail
Maximum Extended Bolus Time	8 hours
Maximum Bolus Size	25 units
Low Reservoir Volume Indicator	Status indicator visible on <i>Home</i> screen; Low Insulin Alert is user adjustable from 10 to 40 units (default is 20 units).
Auto-Off Alarm	On or Off (default is on); user-adjustable (5 to 24 hours; default is 12 hours, which you can change when option is set to on).
History Storage	At least 90 days of data
Language	Dependent on region of use. May be set to English, Czech, Danish, Dutch, French, German, Italian, Norwegian, Spanish, or Swedish (default is English).
Security PIN	Protects from unintentional access, and blocks access to quick bolus when enabled (default is off).
Screen Lock	Protects from unintentional screen interactions.
Site Reminder	Prompts user to change infusion set. Can be set for 1 to 3 days at a time selected by user (default is off).
Missed Meal Bolus Reminder	Prompts user if a bolus has not occurred during the period of time the reminder is set for. 4 reminders available (default is off).
After Bolus Reminder	Prompts user to test BG at a selected time period after a Bolus has been delivered. Can be set between 1 to 3 hours (default is off).
High BG Reminder	Prompts user to retest BG after a High BG has been entered. User selects High BG value and time for reminder. (default is off).
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).

36.4 t:slim X2 Pump Performance Characteristics

Rate of Delivery

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

Bolus Duration

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

Time to Occlusion Alarm*

Operating Rate	Typical	Maximum
Bolus (3 units or Greater)	1 minute 2 seconds	3 Minutes
Basal (2 units/hr)	1 Hour 4 Minutes	2 Hours
Basal (0.1 units/hr)	19 Hours 43 Minutes	36 Hours
<p><i>*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.</i></p>		

36.5 Dexcom G5 Mobile CGM Sensor Performance Characteristics

We recommend that you review the information in this chapter with your healthcare provider to understand how well Dexcom G5 Mobile CGM performs.

Dexcom G5 Mobile CGM uses a glucose sensor to continuously measure and monitor your glucose levels. The sensor is “calibrated” using a commercially available blood glucose meter; Once calibrated, the CGM reports glucose readings up to every 5 minutes. The CGM was evaluated in a clinical study in which CGM sensor readings were compared to blood glucose values to assess its performance and how well the CGM readings compare to a laboratory test method that measures blood glucose values. Additionally, patients performed self-monitoring blood glucose meter tests at home to assess the CGM performance in real use environment.

Although the performance characteristics of the CGM are presented in the following, there is no commonly accepted statistical approach for capturing performance of continuous glucose monitors (CGMs), such as the Dexcom G5 Mobile CGM System.

Clinical Study Overview

The CGM performance was evaluated in four separate prospective clinical studies. In all four studies, subjects were required to confirm glucose readings with their SMBG meter before making any treatment decisions. Two studies included adults, and two studies included pediatrics. In the following sections and tables, the studies will be identified as follows:

Adult Studies (18 years and older)

Original Adult Study: the Receiver included software version SW10050

Software 505 Adult Study: the Receiver included software version SW10505

Pediatric Studies (2 to 17 years)

Original Pediatric Study: the Receiver included software version SW10050

Software 505 Pediatric Study: the Receiver included software version SW10505

The Dexcom G5 Mobile CGM System incorporates the algorithm from software version SW10505 and has a new software number.

Overview of Adult Studies

The CGM performance for adults was evaluated in two separate prospective clinical studies:

Original Adult Study (software SW10050) and the **Software 505 Adult Study** (software SW10505).

Differences between the studies include the number of subjects enrolled, the number of sensors worn by each participant, the SMBG meter used, and the number of clinic days each subject participated in during the study. An

overview of each study is provided here.

The **Original Adult Study** enrolled 72 subjects, and the **Software 505 Adult Study** enrolled 51 subjects. All subjects had Type 1 or Type 2 diabetes mellitus, and required insulin or oral medication to manage their diabetes. In the **Original Adult Study**, 83% of subjects had Type 1 diabetes, and 17% of subjects had Type 2 diabetes. In the **Software 505 Adult Study**, 86% of subjects had Type 1 diabetes, and 14% of subjects had Type 2 diabetes. Both studies included subjects greater than 18 years of age.

Subjects in both studies used the CGM for 7 days. In the **Original Adult Study**, thirty-six subjects each wore 2 sensors; in the **Software 505 Adult Study**, all subjects wore 1 sensor only. Throughout the 7-day wear period, the sensor was calibrated with an average of 2 fingersticks per day (approximately once every 12 hours). In the **Original Adult Study**, subjects used the LifeScan® OneTouch® Ultra® 2 meter and in the **Software 505 Adult Study**,

subjects used Bayer's CONTOUR® NEXT USB meter.

In the **Original Adult Study**, all subjects were evaluated in a controlled clinic environment on all three clinic days:

Day 1, Day 4, and Day 7 of the 7-day wear period. In the **Software 505 Adult Study**, subjects were evaluated in one of the three clinic days so there are fewer data samples than in the **Original Adult Study**. While using the CGM in the clinic, subjects had their blood glucose measured every 15 minutes with a reliable laboratory method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer.

This instrument is referred to as the "YSI." Readings from the CGM were reported every 5 minutes and paired with YSI values in order to characterize how well the CGM readings agreed with laboratory standard blood glucose results. The remainder of the study took place at home, and the CGM performance was also paired with the comparative meter results, referred to as the "SMBG."

Overview of Pediatric Studies

The CGM performance for children and adolescents was evaluated in two separate prospective clinical studies: the **Original Pediatric Study** (SW10050) and the **Software 505 Pediatric Study** (SW10505). Differences between the studies include the number of subjects enrolled, the number of CGMs worn by each participant, the SMBG meter used, the length of time subjects were evaluated in a controlled clinic environment and whether or not subjects ages 13-17 had their glucose levels intentionally manipulated during the study. An overview of each study is provided here.

The **Original Pediatric Study** enrolled 176 subjects, with 16% of subjects younger than 6-years old, and the **Software 505 Pediatric Study** enrolled 79 subjects, with 20% of subjects younger than 6-years old. All subjects had Type 1 or Type 2 diabetes mellitus and required insulin or oral medication to manage their diabetes. In the **Original Pediatric Study**, about 99% of subjects had Type 1 diabetes and 1%

had Type 2 diabetes. In the **Software 505 Pediatric Study**, all subjects had Type 1 diabetes. Sensors were inserted in either the abdomen or upper buttocks.

Subjects in all studies used the CGM for 7 days. In the **Original Pediatric Study**, all subjects wore 2 sensors; in the **Software 505 Pediatric Study**, all subjects wore 1 sensor only. Throughout the 7-day wear period, the sensors were calibrated with an average of 2 fingersticks per day (approximately once every 12 hours), using self-monitoring blood glucose (SMBG) meter values. The **Original Pediatric Study** used the LifeScan® OneTouch® Verio® IQ meter; the **Software 505 Pediatric Study** used Bayer's CONTOUR® NEXT USB meter. All subjects were evaluated in a controlled clinic environment on Day 1, Day 4 or Day 7 of the 7-day wear period. While using the CGM in the clinic, subjects provided at least two fingerstick measurements per hour, and subjects ages 6-17 also provided venous blood for comparison to a laboratory method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose

Analyzer. This instrument is referred to as the "YSI." In the **Original Pediatric Study**, subjects' glucose levels were not intentionally manipulated during this study; in the **Software 505 Pediatric Study**, subjects ages 13-17 had their glucose levels intentionally manipulated during the clinic session. Readings from the CGM were reported every 5 minutes and paired with YSI values collected every 15 minutes in order to characterize how well the CGM readings agreed with laboratory standard blood glucose results. The remainder of the study took place at home, and the CGM performance was also paired with the comparative meter results, referred to as the "SMBG.

Table 1-A. Agreement to YSI within CGM Glucose Ranges (Adult)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent Greater than 40/40% YSI
Overall	Original	9152	71%	82%	92%	3%
	Software 505	2263	86%	93%	98%	1%
40–60	Original	512	67%	78%	88%	6%
	Software 505	120	89%	94%	98%	0%
61–80	Original	781	73%	85%	94%	2%
	Software 505	226	91%	96%	99%	0%
81–180	Original	3853	67%	78%	91%	3%
	Software 505	738	84%	92%	98%	1%
181–300	Original	2784	72%	84%	93%	4%
	Software 505	798	86%	93%	98%	1%
301–350	Original	775	82%	91%	97%	2%
	Software 505	229	86%	94%	98%	1%
351–400	Original	447	74%	84%	91%	5%
	Software 505	152	80%	92%	97%	0%

1. CGM readings are within 40–400 mg/dL, inclusive.

2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 1-B. Agreement to YSI within CGM Glucose Ranges (Pediatric)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent Greater than 40/40% YSI
Overall	Original	2922	55%	68%	85%	7%
	Software 505	2262	81%	91%	96%	2%
40–60	Original	19	63%	74%	79%	21%
	Software 505	86	54%	74%	91%	3%
61–80	Original	76	61%	82%	92%	4%
	Software 505	142	77%	82%	90%	3%
81–180	Original	1155	56%	69%	84%	6%
	Software 505	805	78%	88%	97%	1%
181–300	Original	1380	55%	68%	85%	7%
	Software 505	957	89%	96%	99%	1%
301–350	Original	206	48%	62%	80%	11%
	Software 505	209	81%	91%	94%	5%
351–400	Original	86	48%	61%	79%	12%
	Software 505	63	64%	81%	83%	8%

1. CGM readings are within 40–400 mg/dL, inclusive.

2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Agreement Relative to YSI

Agreement between the CGM and blood glucose values is characterized using paired CGM and YSI values. The CGM and YSI results were compared by pairing the YSI blood glucose value to a CGM glucose reading that occurred immediately after the YSI was collected.

The agreement of the CGM to blood glucose values was assessed by calculating the percentage of CGM readings that were within 15%, 20%, 30% and greater than 40% of the YSI values. For readings less than or equal to 80 mg/dL the absolute difference in mg/dL between the two glucose results was calculated. For values greater than 80 mg/dL the absolute percent difference (%) from the YSI values was calculated. The percentages of total readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30% or greater than 40 mg/dL or 40% are provided in Tables 1-A and 1-B. The tables are categorized within CGM glucose ranges. When you see a CGM reading on your receiver, this table shows you how likely that reading

matches your blood glucose level (measured by YSI in the study).

For example, in the **SW10505 Adult Study** (Table 1-A), the total number of data pairs considered in the analysis was 2263. Of these, 93% of the CGM readings fall within ± 20 mg/dL of the YSI blood glucose values 80 mg/dL and within $\pm 20\%$ of YSI blood glucose values > 80 mg/dL.

Table 2-A. Number and Percentage of YSI Values When CGM Readings are “Low” or “High” (Adult)

			YSI (mg/dL)					Total
CGM Readings	Study ¹	CGM-YSI Pairs	< 55	< 60	< 70	< 80	> 80	
“LOW”	Original	n	66	84	123	142	13	155
		Cumulative Percent	42%	54%	79%	92%	8%	--
	Software 505	n	11	16	17	18	0	18
		Cumulative Percent	61%	89%	94%	100%	0%	--

			YSI (mg/dL)					Total
CGM Readings	Study ¹	CGM-YSI Pairs	> 340	> 320	> 280	> 240	≤ 240	
“HIGH”	Original	n	189	220	238	246	2	248
		Cumulative Percent	76%	89%	96%	99%	1%	--
	Software 505	n	40	43	45	45	0	45
		Cumulative Percent	89%	96%	100%	100%	0%	--

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 2-B. Number and Percentage of YSI Values When CGM Readings are “Low” or “High” (Pediatric)

			YSI (mg/dL)					Total
CGM Readings	Study ¹	CGM-YSI Pairs	< 55	< 60	< 70	< 80	> 80	
“LOW”	Original	n	0	0	0	0	13	13
		Cumulative Percent	0%	0%	0%	0%	100%	--
	Software 505	n	3	5	10	15	1	16
		Cumulative Percent	19%	31%	63%	94%	6%	--

			YSI (mg/dL)					Total
CGM Readings	Study ¹	CGM-YSI Pairs	> 340	> 320	> 280	> 240	≤ 240	
“HIGH”	Original	n	38	51	68	69	1	70
		Cumulative Percent	54%	73%	97%	99%	1%	--
	Software 505	n	14	19	22	23	1	24
		Cumulative Percent	58%	79%	92%	96%	4%	--

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Agreement When CGM Reads “LOW” or “HIGH”

The CGM reports glucose readings between 40 and 400 mg/dL. When the CGM determines the glucose reading is below 40 mg/dL, it displays “LOW” on the pump home screen. When the CGM determines that the glucose level is above 400 mg/dL, it displays “HIGH” on the pump home screen. Because the CGM does not display glucose values below 40 mg/dL or above 400 mg/dL, the comparisons to the actual blood glucose levels (as determined by the YSI analyzer) when CGM is classified as “LOW” or “HIGH” are included separately in Tables 2-A and 2-B. The tables include the numbers and the cumulative percentages when YSI values were less than certain glucose levels (for “LOW”), and when YSI values were greater than certain glucose levels (for “HIGH”).

For example, in the **Software 505 Adult Study** (Table 2-A), when the CGM displayed “LOW” (18 occasions), 100% (18 out of 18) of the YSI values were less than 80 mg/dL, and 94% (17 out of 18) of the YSI values were less than 70

mg/dL. When the CGM displayed “HIGH” (45 occasions), 100% (45 out of 45) of the YSI values were greater than 240 mg/dL, and 100% (45 out of 45) of the YSI values were greater than 280 mg/dL.

Table 3-A. Concurrence of CGM Readings and YSI Values (Original Adult Study)

CGM mg/dL	YSI (mg/dL) Row Percentage of Matched Pairs in Each CGM Glucose Range											Number of Paired CGM-YSI
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	
< 40	6%	48%	37%	7%	1%	0%	0%	0%	0%	0%	0%	155
40-60	4%	49%	36%	11%	1%	0%	0%	0%	0%	0%	0%	512
61-80	0%	22%	51%	24%	1%	0%	0%	0%	0%	0%	0%	781
81-120	0%	2%	17%	66%	13%	1%	0%	0%	0%	0%	0%	1706
121-160	0%	0%	1%	25%	60%	13%	2%	0%	0%	0%	0%	1492
161-200	0%	0%	0%	2%	28%	53%	16%	2%	0%	0%	0%	1240
201-250	0%	0%	0%	0%	3%	21%	51%	21%	3%	1%	0%	1181
251-300	0%	0%	0%	0%	0%	4%	19%	49%	24%	3%	0%	1018
301-350	0%	0%	0%	0%	0%	0%	3%	28%	51%	16%	1%	775
351-400	0%	0%	0%	0%	0%	0%	3%	10%	43%	38%	7%	447
> 400	0%	0%	0%	0%	0%	0%	1%	6%	21%	57%	15%	248

Table 3-B. Concurrence of CGM Readings and YSI Values (Software 505 Adult Study)

CGM mg/dL	YSI (mg/dL) Row Percentage of Matched Pairs in Each CGM Glucose Range											Number of Paired CGM- YSI
	< 40	40- 60	61- 80	81- 120	121- 160	161- 200	201- 250	251- 300	301- 350	351- 400	> 400	
< 40	6%	83%	11%	0%	0%	0%	0%	0%	0%	0%	0%	18
40–60	2%	74%	22%	3%	0%	0%	0%	0%	0%	0%	0%	120
61–80	0%	19%	68%	13%	0%	0%	0%	0%	0%	0%	0%	226
81–120	0%	0%	19%	72%	8%	1%	0%	0%	0%	0%	0%	347
121–160	0%	0%	0%	17%	72%	11%	0%	0%	0%	0%	0%	246
161–200	0%	0%	0%	0%	25%	59%	16%	0%	0%	0%	0%	286
201–250	0%	0%	0%	0%	0%	16%	70%	13%	1%	0%	0%	376
251–300	0%	0%	0%	0%	0%	2%	16%	61%	14%	7%	0%	281
301–350	0%	0%	0%	0%	0%	0%	2%	28%	59%	10%	1%	229
351–400	0%	0%	0%	0%	0%	0%	0%	4%	47%	45%	5%	152
> 400	0%	0%	0%	0%	0%	0%	0%	0%	20%	38%	42%	45

Table 3-C. Concurrence of CGM Readings and YSI Values (Original Pediatric Study)

CGM mg/dL	YSI (mg/dL) Row Percentage of Matched Pairs in Each CGM Glucose Range											Number of Paired CGM-YSI
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	
< 40	0%	0%	0%	54%	31%	15%	0%	0%	0%	0%	0%	13
40-60	0%	21%	58%	16%	5%	0%	0%	0%	0%	0%	0%	19
61-80	0%	21%	45%	30%	4%	0%	0%	0%	0%	0%	0%	76
81-120	0%	1%	20%	66%	12%	1%	0%	0%	0%	0%	0%	338
121-160	0%	0%	1%	36%	54%	7%	1%	0%	0%	0%	0%	511
161-200	0%	0%	0%	4%	40%	48%	6%	1%	0%	0%	0%	596
201-250	0%	0%	0%	1%	9%	44%	41%	5%	0%	0%	0%	658
251-300	0%	0%	0%	0%	2%	7%	50%	36%	3%	0%	2%	432
301-350	0%	0%	0%	0%	0%	2%	18%	59%	21%	0%	0%	206
351-400	0%	0%	0%	0%	0%	0%	3%	28%	50%	16%	2%	86
> 400	0%	0%	0%	0%	0%	0%	1%	14%	41%	36%	7%	70

Table 3-D. Concurrence of CGM Readings and YSI Values (Software 505 Pediatric Study)

CGM mg/dL	YSI (mg/dL) Row Percentage of Matched Pairs in Each CGM Glucose Range											Number of Paired CGM- YSI
	< 40	40- 60	61- 80	81- 120	121- 160	161- 200	201- 250	251- 300	301- 350	351- 400	> 400	
< 40	6%	25%	63%	6%	0%	0%	0%	0%	0%	0%	0%	16
40–60	0%	33%	60%	6%	1%	0%	0%	0%	0%	0%	0%	86
61–80	0%	8%	64%	26%	2%	0%	0%	0%	0%	0%	0%	142
81–120	0%	1%	15%	69%	13%	1%	1%	0%	0%	0%	0%	314
121–160	0%	0%	0%	15%	66%	18%	1%	0%	0%	0%	0%	313
161–200	0%	0%	0%	1%	18%	66%	15%	0%	0%	0%	0%	355
201–250	0%	0%	0%	0%	1%	17%	68%	14%	0%	0%	0%	444
251–300	0%	0%	0%	0%	0%	0%	26%	58%	16%	0%	0%	336
301–350	0%	0%	0%	0%	0%	0%	4%	40%	46%	9%	0%	209
351–400	0%	0%	0%	0%	0%	0%	3%	14%	62%	21%	0%	63
> 400	0%	0%	0%	0%	0%	0%	4%	13%	29%	38%	17%	24

Concurrence of CGM and Laboratory Reference

Table 3-A (Original Adult Study), 3-B (Software 505 Adult Study), 3-C (Original Pediatric Study) and 3-D (Software 505 Pediatric Study) are categorized by ranges of CGM glucose readings. These tables describe, for each range of CGM glucose readings, what percentage of paired YSI values were in the same glucose range (shaded) or in glucose ranges above and below the paired CGM readings.

For example, based on the **Software 505 Adult Study**, when CGM readings are within 81 to 120 mg/dL, you can expect your blood glucose levels are within 81 to 120 mg/dL 72% of time.

Table 4-A. Difference to YSI within CGM Glucose Ranges (Adult)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of paired CGM-YSI	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	9152	2.9%	1.7%	13.3%	9.8%
	Software 505	2263	2.5%	2.4%	9.0%	7.0%
*40–60	Original	512	-10.0	-8.2	13.5	9.7
	Software 505	120	-3.3	-2.1	6.9	4.8
*61–80	Original	781	-2.4	-0.4	11.4	8.6
	Software 505	226	0.8	1.4	6.7	5.4
81–180	Original	3853	4.8%	3.0%	13.8%	9.8%
	Software 505	738	3.9%	4.1%	9.6%	8.2%
181–300	Original	2784	2.1%	0.0%	11.9%	9.2%
	Software 505	798	0.6%	0.4%	8.0%	6.1%
301–350	Original	775	3.8%	2.8%	9.8%	7.9%
	Software 505	229	4.1%	3.4%	8.0%	5.8%
351–400	Original	447	10.4%	7.7%	12.8%	9.1%
	Software 505	152	7.2%	6.3%	9.2%	7.2%

1. CGM readings are within 40–400 mg/dL, inclusive. 2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

* For CGM ≤ 80 mg/dL, the difference and absolute difference in mg/dL are included instead of percent differences (%).

Table 4-B. Difference to YSI within CGM Glucose Ranges (Pediatric)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of paired CGM-YSI	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	2922	13.5%	11.6%	17.4%	13.5%
	Software 505	2262	1.8%	1.2%	10.4%	7.9%
*40–60	Original	19	-18.1	-9.1	19.2	9.1
	Software 505	86	-15.3	-13.2	16.1	13.2
*61–80	Original	76	-3.7	-2.3	13.4	10.6
	Software 505	142	-4.8	-1.0	11.8	7.7
81–180	Original	1155	11.9%	9.7%	17.0%	13.0%
	Software 505	805	1.9%	0.7%	10.6%	8.1%
181–300	Original	1380	14.8%	12.4%	17.4%	13.3%
	Software 505	957	2.2%	1.0%	8.1%	6.5%
301–350	Original	206	19.2%	15.9%	19.4%	15.9%
	Software 505	209	7.8%	6.5%	11.0%	7.9%
351–400	Original	86	18.5%	15.5%	19.1%	15.5%
	Software 505	63	14.9%	11.6%	15.2%	11.6%

1. CGM readings are within 40–400 mg/dL, inclusive. 2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

* For CGM ≤ 80 mg/dL, the difference and absolute difference in mg/dL are included instead of percent differences (%).

Accuracy Relative to YSI

Accuracy between matched pairs was also estimated by calculating the percent difference between the CGM reading and the YSI value. For example, if the YSI value is 100 mg/dL and the CGM reading is 90 mg/dL, a 10% difference between the CGM and the YSI is reported. The CGM and YSI values were compared by pairing the CGM reading that fell immediately after the YSI value was collected.

In the example above, the CGM reading is less than the YSI value, so the percent difference reading is negative. The mean percent difference is the average of all positive and negative percent differences between the two devices; it tells you if the CGM reads higher or lower on average than the YSI within each glucose range.

Another estimate used to show the accuracy of the CGM is the absolute percent difference. The absolute percent difference tells you the percent difference or “distance” between the CGM and YSI values, but does not tell you whether the CGM is reading, on

average, higher or lower than the YSI laboratory standard. The mean absolute percent difference is the average “distance” (regardless if positive or negative) between CGM readings and YSI values.

Accuracy measures in differences for both the **Original Adult** and **Software 505 Adult Studies** are summarized in Table 4-A. Accuracy measures in differences for both the **Original Pediatric** and **Software 505 Pediatric Studies** are summarized in Table 4-B. Tables 4-A and 4-B are categorized within CGM glucose ranges.

For example, in the **Software 505 Adult Study** (Table 4-A), overall, on average, the CGM reads 2.5% different (Mean Percent Difference) than the reference and 9.0% absolute different (Mean Absolute Difference) than the reference values. The Median Percent Difference shows that half of the time the CGM reads 2.4% or less than the YSI blood glucose values and the Median Absolute Percent Difference shows that half of the time the CGM reads about 7.0% or less than the YSI blood glucose values.

Table 5-A. Hypoglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Adult)

Hypoglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	50%	50%	71%	29%
	Software 505	71%	29%	68%	32%
60	Original	64%	36%	75%	25%
	Software 505	85%	15%	83%	17%
70	Original	79%	21%	83%	17%
	Software 505	92%	8%	91%	9%
80	Original	87%	13%	86%	14%
	Software 505	95%	5%	90%	10%
90	Original	90%	10%	89%	11%
	Software 505	96%	4%	94%	6%

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 5-B. Hypoglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Pediatric, Ages 6-17 Years)

Hypoglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	0%	100%	0%	100%
	Software 505	22%	78%	75%	25%
60	Original	11%	89%	25%	75%
	Software 505	42%	58%	78%	23%
70	Original	47%	53%	50%	50%
	Software 505	68%	32%	75%	25%
80	Original	55%	45%	55%	45%
	Software 505	86%	14%	91%	9%
90	Original	69%	31%	62%	38%
	Software 505	90%	10%	93%	7%
100	Original	75%	25%	62%	38%
	Software 505	91%	9%	93%	7%

1. Both sets of study data are presented and are labeled as *Original* (SW10050) or *Software 505* (SW10505).

Table 5-C. Hypoglycemic Alert and Detection Rate Evaluation in Reference to SMBG 30 Minutes Before and After (Pediatric, Ages 2-5 Years)

Hypoglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	3%	97%	57%	43%
	Software 505	25%	75%	100%	0%
60	Original	11%	89%	62%	38%
	Software 505	20%	80%	100%	0%
70	Original	29%	71%	77%	23%
	Software 505	20%	80%	100%	0%
80	Original	35%	65%	85%	15%
	Software 505	61%	39%	100%	0%
90	Original	51%	49%	89%	11%
	Software 505	78%	22%	100%	0%
100	Original	64%	36%	91%	9%
	Software 505	82%	18%	100%	0%

1. Both sets of study data are presented and are labeled as *Original* (SW10050) or *Software 505* (SW10505).

Low and High Glucose Alerts

The ability of the CGM to detect high and low glucose levels is assessed by comparing CGM results to YSI results at low and high blood glucose levels and determining if the alert may have sounded. The CGM and YSI values were compared by pairing the CGM reading that occurred immediately after the YSI value was collected. We suggest that you ask your doctor what alert settings would be best for you.

The Low Glucose Alert

Estimates of how well the adjustable Low Glucose Alert performs are presented in Tables 5-A, 5-B and 5-C. Table 5-A represents the hypoglycemic alert evaluation within 15 minutes of the YSI value in the adult studies. Table 5-B represents the alert evaluation within 15 minutes of the YSI value for a subset of the pediatric population—subjects age 6 to 17 years who had YSI measurements every 15 minutes. Table 5-C represents the alert evaluation within 30 minutes of an SMBG reading for 2- to 5-year old subjects in the pediatric studies.

Hypoglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or below the alert setting within 15 or 30 minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the blood glucose level was above the alert setting within 15 or 30 minutes before or after the device alarmed.

For example, if you set the Low Glucose Alert to 70 mg/dL and your alarm sounds, how often can you expect your blood sugar to actually be low? In the **Software 505 Adult Study** (Table 5-A), when your alarm sounds, you can expect your blood sugar to be below 70 mg/dL approximately 92% of the time and above 70 mg/dL approximately 8% of the time within the 15 minute period before or after your alarm sounds.

Hypoglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to

an episode of hypoglycemia or how often it misses such an event. The Hypoglycemia Detection Rate is the % of time the blood glucose level was at or below the alert setting and device alarmed within 15 or 30 minutes before or after the blood glucose was at or below the alert settings. The Hypoglycemia Missed Detection Rate is the % of time the blood glucose was at or below the alert setting, but the device did not alarm within 15 or 30 minutes before or after the blood glucose was at or below the alert setting.

For example, if you set the Low Glucose alert to 70 mg/dL, how often will your alarm alert you if your blood glucose goes below 70 mg/dL? In the **Software 505 Adult Study** (Table 5-A), when your blood sugar goes below 70 mg/dL, you can expect your alarm to sound 91% of the time and not to sound approximately 9% of time within the 15 minute period before or after your blood sugar goes below 70 mg/dL.

Table 6-A. Hyperglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Adult)

Hyperglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	95%	5%	98%	2%
	Software 505	98%	2%	100%	0%
140	Original	94%	6%	97%	3%
	Software 505	97%	3%	99%	1%
180	Original	92%	8%	97%	3%
	Software 505	97%	3%	99%	1%
200	Original	92%	8%	97%	3%
	Software 505	96%	4%	98%	2%
220	Original	91%	9%	95%	5%
	Software 505	94%	6%	98%	2%
240	Original	91%	9%	94%	6%
	Software 505	93%	7%	95%	5%
300	Original	82%	18%	86%	14%
	Software 505	86%	14%	90%	10%

1. Both sets of study data are presented and are labeled as *Original* (SW10050) or *Software 505* (SW10505).

Table 6-B. Hyperglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Pediatric, Ages 6-17 Years)

Hyperglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	91%	9%	98%	2%
	Software 505	98%	2%	99%	1%
140	Original	87%	13%	99%	1%
	Software 505	97%	3%	98%	2%
180	Original	75%	25%	99%	1%
	Software 505	94%	6%	98%	2%
200	Original	71%	29%	98%	2%
	Software 505	94%	6%	97%	3%
220	Original	67%	33%	97%	3%
	Software 505	93%	7%	96%	4%
240	Original	62%	38%	96%	4%
	Software 505	88%	12%	94%	6%
300	Original	43%	57%	93%	7%
	Software 505	69%	31%	84%	16%

1. Both sets of study data are presented and are labeled as *Original (SW10050)* or *Software 505 (SW10505)*.

Table 6-C. Hyperglycemic Alert and Detection Rate Evaluation in Reference to SMBG 30 Minutes Before and After (Pediatric, Ages 2-5 Years)

Hyperglycemic Alert Level (mg/dL)	Study ¹	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	92%	8%	98%	2%
	Software 505	97%	3%	99%	1%
140	Original	90%	10%	98%	2%
	Software 505	98%	2%	100%	0%
180	Original	87%	13%	96%	4%
	Software 505	99%	1%	93%	7%
200	Original	85%	15%	96%	4%
	Software 505	98%	2%	93%	7%
220	Original	81%	19%	95%	5%
	Software 505	100%	0%	97%	3%
240	Original	80%	20%	95%	5%
	Software 505	99%	1%	98%	2%
300	Original	71%	29%	90%	10%
	Software 505	95%	5%	96%	4%

1. Both sets of study data are presented and are labeled as *Original (SW10050)* or *Software 505 (SW10505)*.

The High Glucose Alert

Estimates of how well the adjustable High Glucose Alert performs are presented in Tables 6-A, 6-B and 6-C. Table 6-A represents the hyperglycemic alert evaluation within 15 minutes of the YSI value in the adult studies. Table 6-B represents the alert evaluation within 15 minutes of the YSI value for a subset of the pediatric population—subjects age 6 to 17 years who had YSI measurements every 15 minutes. Table 6-C represents the alert evaluation within 30 minutes of an SMBG reading for 2- to 5-year old subjects in the pediatric studies.

Hyperglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or above the alert setting within 15 or 30 minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the blood glucose level was below the alert setting within 15 or 30 minutes before or after the device alarmed.

For example, if you set the High Glucose alert to 200 mg/dL and your alarm sounds, how often can you expect your blood sugar to actually be high? In the **Software 505 Adult Study** (Table 6-A), when your alarm sounds, you can expect your blood sugar to be at or above 200 mg/dL approximately 96% of the time and not be above 200 mg/dL approximately 4% of the time within the 15 minute period before or after your alarm sounds.

Hyperglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hyperglycemia or how often it misses such an event. The Hyperglycemia Detection Rate is the % of time the blood glucose level was at or above the alert setting and the device alarmed within 15 or 30 minutes before or after the blood glucose was at or above the alert settings. The Hyperglycemia Missed Detection Rate is the % of time the blood glucose was at or above the alert setting, but the device did not alarm within 15 or 30 minutes before or after the blood

glucose was at or above the alert setting.

For example, if you set your High Glucose alert to 200 mg/dL, how often will your alarm alert you if your blood glucose goes at or above 200 mg/dL? In the **Software 505 Adult Study** (Table 6-A), when your blood sugar goes above 200 mg/dL, you can expect your alarm to sound 98% of the time and not to sound approximately 2% of time within the 15 minute period before or after your blood sugar goes above 200 mg/dL.

Table 7-A. Percentage of CGM Readings¹ Within YSI Values With Data Stratified in 2-Hour Increments After Calibration (Adult)

Time From Calibration	Study ²	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent Greater than 40/40% YSI
0-2 hours	Original	1929	78%	88%	96%	2%
	Software 505	469	93%	97%	99%	0%
2-4 hours	Original	1516	69%	81%	91%	4%
	Software 505	389	90%	97%	99%	0%
4-6 hours	Original	1547	69%	79%	91%	5%
	Software 505	383	85%	91%	97%	2%
6-8 hours	Original	1520	68%	79%	92%	3%
	Software 505	380	79%	90%	97%	2%
8-10 hours	Original	1555	71%	82%	92%	4%
	Software 505	347	83%	92%	98%	0%
10-12 hours	Original	1068	65%	77%	91%	4%
	Software 505	295	80%	90%	98%	0%
12-14 hours	Original	17	65%	76%	82%	12%
	Software 505	0	--	--	--	--

1. CGM readings are within 40–400 mg/dL, inclusive.

2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 7-B. Percentage of CGM Readings¹ Within YSI Values With Data Stratified in 2-Hour Increments After Calibration (Pediatric)

Time From Calibration	Study ²	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent Greater than 40/40% YSI
0-2 hours	Original	648	65%	75%	87%	7%
	Software 505	545	83%	91%	97%	1%
2-4 hours	Original	649	51%	67%	86%	7%
	Software 505	460	72%	89%	96%	2%
4-6 hours	Original	630	51%	61%	80%	10%
	Software 505	428	77%	88%	95%	2%
6-8 hours	Original	409	52%	68%	85%	5%
	Software 505	325	88%	92%	94%	3%
8-10 hours	Original	296	53%	69%	84%	7%
	Software 505	305	86%	93%	97%	1%
10-12 hours	Original	253	58%	74%	89%	5%
	Software 505	198	89%	94%	98%	0%
12-14 hours	Original	37	32%	38%	65%	22%
	Software 505	1	100%	100%	100%	0%

1. CGM readings are within 40–400 mg/dL, inclusive.

2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Calibration Stability

The CGM must be calibrated every 12 hours. To demonstrate performance of the CGM over a 12-hour calibration period, sensors were evaluated to verify that performance remains consistent over the 12-hour calibration period.

CGMs were evaluated in 2-hour increments after calibration.

Performance was estimated at each 2-hour interval and stratified by glucose values by calculating the percentage of CGM readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30%, 40 mg/dL or 40% and greater than 40 mg/dL or 40% of the YSI values in Tables 7-A and 7-B.

Table 8-A. Sensor Stability Relative to YSI (Accuracy Over Time¹) - (Adult)

Day of Wear	Study ²	Number of paired CGM-YSI	Mean Absolute Percent Difference	Median Absolute Percent Difference	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent Greater than 40/40% YSI
Day 1	Original	3023	16.7%	13.2%	59%	71%	86%	6%
	Software 505	680	10.7%	7.9%	77%	84%	96%	2%
Day 4	Original	3108	11.4%	8.2%	77%	87%	95%	2%
	Software 505	777	8.0%	6.4%	89%	96%	99%	0%
Day 7	Original	3021	11.9%	8.9%	76%	87%	95%	2%
	Software 505	806	8.5%	7.2%	90%	97%	99%	0%

1. CGM readings are within 40–400 mg/dL, inclusive.

2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 8-B. Sensor Stability Relative to YSI (Accuracy Over Time¹) - (Pediatric, Ages 6-17 Years)

Day of Wear	Study ²	Number of paired CGM-YSI	Mean Absolute Percent Difference	Median Absolute Percent Difference	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent Greater than 40/40% YSI
Day 1	Original	1016	21.2%	15.8%	48%	61%	78%	15%
	Software 505	740	12.7%	8.5%	75%	83%	91%	4%
Day 4	Original	810	16.0%	13.9%	52%	66%	87%	3%
	Software 505	795	8.1%	6.7%	89%	97%	100%	0%
Day 7	Original	1096	15.1%	11.3%	63%	76%	89%	4%
	Software 505	727	10.4%	8.4%	80%	91%	98%	1%

1. CGM readings are within 40–400 mg/dL, inclusive.

2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 8-C. Sensor Stability Relative to SMBG (Accuracy Over Time¹) - (Pediatric, Ages 2-17 Years)

Day of Wear	Study ²	Number of paired CGM-SMBG	Mean Absolute Percent Difference	Median Absolute Percent Difference	Percent within 15/15% SMBG	Percent within 20/20% SMBG	Percent within 30/30% SMBG	Percent Greater than 40/40% SMBG
Day 1	Original	3216	18.8%	14.2%	53%	65%	81%	10%
	Software 505	893	14.8%	10.7%	64%	79%	91%	5%
Day 2	Original	2148	16.2%	12.4%	60%	74%	87%	6%
	Software 505	436	13.2%	10.4%	69%	81%	95%	3%
Day 3	Original	1977	15.2%	11.0%	63%	76%	89%	5%
	Software 505	441	13.8%	11.3%	66%	77%	91%	2%
Day 4	Original	2830	14.0%	10.9%	66%	79%	91%	4%
	Software 505	850	10.7%	8.5%	79%	91%	97%	1%
Day 5	Original	1768	15.4%	10.7%	67%	78%	90%	5%
	Software 505	374	11.4%	8.7%	74%	86%	96%	1%
Day 6	Original	1704	14.3%	9.8%	68%	79%	90%	4%
	Software 505	410	12.3%	9.2%	72%	80%	93%	2%
Day 7	Original	2675	12.4%	9.2%	72%	83%	94%	3%
	Software 505	860	11.3%	8.6%	79%	90%	96%	2%

1. CGM readings are within 40–400 mg/dL, inclusive.

2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Sensor Stability

Relative to YSI

Sensors can be worn for up to 7 days. Performance was estimated by calculating the percentage of CGM readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30%, 40 mg/dL or 40% and greater than 40 mg/dL or 40% of the YSI values at the beginning (Day 1), middle (Day 4) and end (Day 7) of the CGM lifecycle. The average and median of the absolute percent differences are included in Tables 8-A and 8-B showing consistent accuracy and sensor stability over the 7-day life of the sensor.

Relative to SMBG (Pediatric Study)

Performance was also estimated by calculating the percentage of CGM readings within various percentages of the SMBG values at each day of the sensor wear period (Table 8-C). The average and median of the absolute percent differences are included in the table.

Precision of Sensor Readings

A subset of subjects wore two sensors at the same time. This was to look at how similarly two sensors function on the same subject (sensor precision). Precision was evaluated by comparing the glucose readings from the two sensors worn on the same subject at the same time.

In the **Original Adult Study**, 36 subjects wore two sensors. Results showed that sensor readings from the two sensors generally agreed with each other within 9% (absolute percent difference) with a 7% coefficient of variation. In the **Original Pediatric Study**, all subjects wore two sensors. Results showed that sensor readings from the two sensors generally agreed with each other within 10% (absolute percent difference) with a 7% coefficient of variation. Only one sensor was worn in the **Software 505 Adult** and **Software 505 Pediatric Studies** so precision data was not collected.

Sensor Life

Sensors may be worn for up to 7 days (168 hours). To estimate how long a sensor will work over 7 days, all sensors worn were evaluated to determine how many days/hours of readings each sensor provided.

In the **Original Adult Study**, 108 sensors were evaluated. Ninety-four percent (94%) of the sensors lasted until Day 7 (145-168 hours). There were 6 (6%) sensors that ended early, four of which lasted more than 3 days.

In the **Software 505 Adult Study**, 51 sensors were evaluated. Ninety-eight percent (98%) of the sensors lasted until Day 7 (145-168 hours). There was 1 (2%) sensor that ended early, which lasted until day 5 of the sensor wear.

In the **Original Pediatric Study**, 351 sensors were evaluated. Eighty-five percent (85%) of the sensors lasted until Day 7 (145-168 hours).

In the **Software 505 Pediatric Study**, 77 sensors were evaluated. Ninety-four

percent (94%) of the sensors lasted until Day 7 (145-168 hours).

Table 9-A. Number of Readings Provided by Each Sensor Over 7-Days (Adult)

% of Total Possible Readings Provided	Study ¹	Total Readings Provided (Min-Max)	% of Systems Providing That Number of Readings
0–25%	Original	167–491	2%
	Software 505	0	0%
26–50%	Original	719–914	4%
	Software 505	856–856	2%
51–75%	Original	1267–1267	1%
	Software 505	1253–1253	2%
76–100%	Original	1811–1992	94%
	Software 505	1497–1992	96%

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 9-B. Number of Readings Provided by Each Sensor Over 7-Days (Pediatric)

% of Total Possible Readings Provided	Study ¹	Total Readings Provided (Min-Max)	% of Systems Providing That Number of Readings
0–25%	Original	103–427	3%
	Software 505	60–223	4%
26–50%	Original	569–954	3%
	Software 505	877–891	3%
51–75%	Original	1006–1484	9%
	Software 505	1131–1342	3%
76–100%	Original	1518–1992	86%
	Software 505	1623–1990	91%

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 10-A. CGM Readings Within Wear Days (Adult)

Statistic	Study¹	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	All Days²
Mean	Original	98%	98%	98%	98%	97%	99%	95%	97%
	Software 505	98%	99%	98%	98%	96%	99%	97%	98%
Median	Original	100%	100%	100%	100%	100%	100%	100%	100%
	Software 505	99%	100%	100%	100%	100%	100%	100%	100%
Standard Deviation	Original	5%	3%	9%	8%	10%	3%	11%	8%
	Software 505	3%	2%	8%	11%	15%	2%	13%	9%

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

2. A total of 108 sensors were included with the Original Study and 51 sensors were included with the Software 505 Study.

Table 10-B. CGM Readings Within Wear Days (Pediatric)

Statistic	Study ¹	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	All Days ²
Mean	Original	97%	96%	96%	95%	94%	94%	92%	97%
	Software 505	96%	96%	95%	96%	93%	95%	93%	96%
Median	Original	99%	99%	99%	99%	99%	99%	98%	99%
	Software 505	99%	98%	99%	99%	97%	97%	98%	99%
Standard Deviation	Original	6%	10%	9%	12%	14%	14%	17%	6%
	Software 505	9%	6%	12%	10%	15%	7%	12%	9%

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

2. A total of 108 sensors were included with the Original Study and 77 sensors were included with the Software 505 Study.

Number of Readings Provided

The CGM is capable of providing a reading up to every 5 minutes, or up to 288 readings per day. For a variety of reasons, the CGM may not display a glucose reading and readings are “skipped.” Tables 9-A and 9-B estimate the number of readings you can expect to receive from the CGM over the entire 7-day period after calibration. Tables 10-A and 10-B show the number of readings you can expect to receive from the sensor within each system wear day.

For the **Software 505 Adult Study** (SW10505), 96% of CGM provided between 1,497 and 1,992 valid glucose readings (or more than 75% of the expected number of readings) as seen in Table 9-A. Adjusted within each sensor wear-day, the CGM in the **Software 505 Adult Study** provided an average of 98% of all expected glucose readings (288) as seen in Table 10-A.

Table 11-A. Agreement to SMBG within CGM Glucose Ranges (Adult)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of paired CGM-SMBG	Percent within 15/15% SMBG	Percent within 20/20% SMBG	Percent within 30/30% SMBG	Percent Greater than 40/40% SMBG
Overall	Original	7508	69%	81%	94%	2%
	Software 505	2992	77%	87%	96%	1%
40–60	Original	731	75%	84%	92%	4%
	Software 505	221	73%	80%	87%	7%
61–80	Original	968	78%	86%	95%	1%
	Software 505	336	77%	85%	95%	1%
81–180	Original	3141	65%	78%	93%	2%
	Software 505	1362	74%	85%	96%	1%
181–300	Original	1960	68%	81%	94%	3%
	Software 505	826	80%	90%	97%	1%
301–350	Original	450	77%	88%	98%	1%
	Software 505	161	83%	93%	99%	0%
351–400	Original	258	75%	85%	95%	2%
	Software 505	86	90%	93%	98%	1%

1. CGM readings are within 40–400 mg/dL, inclusive.

2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 11-B. Agreement to SMBG within CGM Glucose Ranges (Pediatric)

CGM Glucose Range ¹ (mg/dL)	Study ²	Number of paired CGM-SMBG	Percent within 15/15% SMBG	Percent within 20/20% SMBG	Percent within 30/30% SMBG	Percent Greater than 40/40% SMBG
Overall	Original	16318	64%	76%	89%	5%
	Software 505	4264	73%	84%	94%	2%
40–60	Original	487	44%	55%	68%	19%
	Software 505	240	54%	71%	86%	7%
61–80	Original	1340	59%	70%	85%	7%
	Software 505	399	64%	76%	92%	2%
81–180	Original	7084	62%	74%	90%	5%
	Software 505	1650	72%	84%	95%	2%
181–300	Original	5627	69%	80%	90%	5%
	Software 505	1526	79%	89%	97%	2%
301–350	Original	1176	65%	77%	90%	4%
	Software 505	319	72%	83%	94%	2%
351–400	Original	604	58%	72%	86%	6%
	Software 505	130	69%	79%	86%	8%

1. CGM readings are within 40–400 mg/dL, inclusive.

2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 12-A. CGM Difference to SMBG Within CGM Glucose Ranges (Adult)

CGM Glucose Ranges ¹ (mg/dL)	Study ²	Number of Paired CGM-SMBG	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	7508	-0.4%	-1.4%	14.0%	11.0%
	Software 505	2992	-2.6%	-2.7%	11.3%	8.6%
*40–60	Original	731	-9.3	-8.0	11.7	8.0
	Software 505	221	-10.3	-6.0	13.0	8.0
*61–80	Original	968	-1.0	1.0	10.7	8.0
	Software 505	336	-4.0	-2.0	10.1	7.0
81–180	Original	3141	1.4%	0.0%	14.2%	11.0%
	Software 505	1362	-2.6%	-3.1%	11.4%	8.9%
181–300	Original	1960	-0.7%	-2.8%	13.0%	10.3%
	Software 505	826	-1.4%	-2.0%	9.5%	7.4%
301–350	Original	450	-0.7%	-2.6%	10.5%	8.6%
	Software 505	161	0.0%	0.0%	8.3%	6.0%
351–400	Original	258	5.0%	3.0%	11.9%	8.6%
	Software 505	7508	-0.4%	-1.4%	14.0%	11.0%

1. CGM readings are within 40–400 mg/dL, inclusive. 2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

* For CGM ≤ 80 mg/dL, the differences in mg/dL are included instead of percent differences (%).

Table 12-B. CGM Difference to SMBG Within CGM Glucose Ranges (Pediatric)

CGM Glucose Ranges ¹ (mg/dL)	Study ²	Number of Paired CGM-SMBG	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	7508	-0.4%	-1.4%	14.0%	11.0%
	Software 505	2992	-2.6%	-2.7%	11.3%	8.6%
*40–60	Original	731	-9.3	-8.0	11.7	8.0
	Software 505	221	-10.3	-6.0	13.0	8.0
*61–80	Original	968	-1.0	1.0	10.7	8.0
	Software 505	336	-4.0	-2.0	10.1	7.0
81–180	Original	3141	1.4%	0.0%	14.2%	11.0%
	Software 505	1362	-2.6%	-3.1%	11.4%	8.9%
181–300	Original	1960	-0.7%	-2.8%	13.0%	10.3%
	Software 505	826	-1.4%	-2.0%	9.5%	7.4%
301–350	Original	450	-0.7%	-2.6%	10.5%	8.6%
	Software 505	161	0.0%	0.0%	8.3%	6.0%
351–400	Original	258	5.0%	3.0%	11.9%	8.6%
	Software 505	7508	-0.4%	-1.4%	14.0%	11.0%

1. CGM readings are within 40–400 mg/dL, inclusive. 2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

* For CGM ≤ 80 mg/dL, the differences in mg/dL are included instead of percent differences (%).

Agreement and Accuracy Relative to SMBG

Agreement between the CGM and blood glucose values is also characterized using paired CGM and SMBG results (Tables 11-A/B to 12-A/B).

The CGM and SMBG values were compared by pairing the comparative SMBG value to a CGM glucose reading that occurred immediately after the SMBG was collected. These results characterize the performance subjects expect during real-time use of the CGM in their daily diabetes management when comparing the CGM readings to their home blood glucose meter results. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the two glucose results was calculated. For values greater than 80 mg/dL, the absolute percent difference (%) from the SMBG values was calculated. The percentages of total readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30%, 40 mg/dL or 40% or greater than 40 mg/dL or 40% were then calculated.

For example, if the CGM reads 100 mg/dL, it is between 81-180 mg/dL range and you can expect the CGM readings to be within 20% of the SMBG values 85% of the time for the **Software 505 Adult Study**, as seen in Table 11-A.

Overall, the CGM in the Software 505 Adult Study reads, on average, 2.6% lower (Mean Percent Difference) than SMBG values and 11.3% absolute different (Mean Absolute Percent Difference) than the SMBG values. The Median Percent Difference shows that half of the time the CGM reads lower in 2.7% or less than the SMBG values and the Median Absolute Percent Difference shows that half of the time the CGM reads about 8.6% or less different than SMBG values, as seen in Table 12-A.

Adverse Events

No serious adverse events or device-related serious adverse events occurred during the studies. Mild to moderate skin irritation, such as erythema or edema, occurred at the sensor needle insertion area or around the adhesive area. No infection, bruising, or bleeding occurred at the

sensor needle insertion area or the adhesive area.

36.6 Electromagnetic Compatibility

The information contained in this section is specific to the System. This information provides reasonable assurance of normal operation, but does not guarantee such under all conditions. If the System must be used in close proximity with other electrical equipment, the System should be observed in this environment to verify normal operation. Special precautions for electromagnetic compatibility must be taken when using medical electrical equipment. The System 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 System is defined as follows:

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

This section contains the following tables of information:

- Electromagnetic Emissions
- Electromagnetic Immunity
- Distances Between the System and RF Equipment

36.7 Wireless Co-existence and Data Security

The System is designed to work safely and effectively in the presence of wireless devices typically found at home, work, retail stores, and places of leisure where daily activities occur. See [Section 36.10 Distances Between the t:slim X2 Pump and RF Equipment](#) for more information.

The System is designed to send and accept Bluetooth wireless technology communication. Communication is not established until you enter the appropriate credentials into your pump.

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

36.8 Electromagnetic Emissions

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

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

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

36.9 Electromagnetic Immunity

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


Guidance and Manufacturer's Declaration – Electromagnetic 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 (100 kHz repetition frequency)	± 2 kV for power supply lines ± 1 kV for input/output lines (100 kHz repetition frequency)	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.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	70% UR (30% dip in Ur) for 25 cycles 0% Ur (100% dip in Ur) for 1 cycle at 0 degrees 0% Ur (100% dip in Ur) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% Ur (100% dip in Ur) for 250 cycles	70% UR (30% dip in Ur) for 25 cycles 0% Ur (100% dip in Ur) for 1 cycle at 0 degrees 0% Ur (100% dip in Ur) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% Ur (100% dip in Ur) for 250 cycles	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	30 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.

Guidance and Manufacturer’s Declaration – Electromagnetic Immunity (Continued)

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 Vrms	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: 150 MHz to 80MHz, $d = 1.20\sqrt{P}$ 80 MHz to 800 MHz, $d = 1.20\sqrt{P}$ 800 MHz to 2.5GHz, $d = 2.30\sqrt{P}$ 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*, should be less than the compliance level in each frequency range**. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	30 V/m	
Proximity Field from Wireless Transmitters	385 MHz: 27 V/m @ 18 Hz Pulse modulation 450 MHz: 28 V/m @ FM modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz Pulse modulation 810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz Pulse modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz Pulse Modulation 2450 MHz: 28 V/m @ 217 Hz Pulse modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz Pulse modulation	385 MHz: 27 V/m @ 18 Hz Pulse modulation 450 MHz: 28 V/m @ FM modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz Pulse modulation 810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz Pulse modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz Pulse Modulation 2450 MHz: 28 V/m @ 217 Hz Pulse modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz Pulse modulation	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
<p><i>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</i></p> <p><i>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</i></p> <p><i>*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.</i></p> <p><i>**Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.</i></p>			

36.10 Distances Between the t:slim X2 Pump and RF Equipment

The 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 System. For specific concerns about a particular RF transmitter interfering with your System’s operation, please contact the CGM transmitter manufacturer for its rated power and frequency.

Recommended Distances Between the System and a Radio Frequency Transmitter

Rated Maximum Output Power of Transmitter in Watts	Separation Distance According to Frequency of Transmitter in meters		
	150 kHz to 80 MHz ($d = 1.20\sqrt{P}$)	80 MHz to 800 MHz ($d = 1.20\sqrt{P}$)	800 MHz to 2.5 GHz ($d = 2.30\sqrt{P}$)
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23





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.

Recommended Distances Between the System and Devices

Rated Maximum Output Power of Transmitter in Watts	Typical Devices	Recommended Separation Distance in Inches (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 adapter. Commonly used for FM wireless music streaming	0.5 in (0.013 m)	
0.1W	Bluetooth Class 1 (100 meter range). Wireless router (WiFi). Typical cellular/smart phone*	2.9 in (0.073 m)	
1W	Typical microwave oven RF leakage.	9.0 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 (0.163 meters) apart.*

36.11 Quality of Wireless Service

The manufacturer defines the quality of service of the System as the percent of readings successfully received by the display, where the CGM transmitter and display attempt to communicate every 5 minutes. One of the System's essential performance requirements states that the System will not discontinue reporting data and/or information from the Dexcom G5 Mobile transmitter to the user without notification.

The System notifies the user of a missed reading, or when the transmitter and pump are out of range of one another in several ways. The first is when a dot is missed on the CGM graph which will occur within five minutes of the previous reading. The second indication occurs after 10 minutes when the Out of Range icon is displayed on the *Home* screen. The third is a user settable alert that will notify the user when the pump and CGM transmitter is out of range of one another. Setting this alert is defined in

Section 24.6 Setting Your Out of Range Alert.

The System performance requirements state that 90% of readings will be successfully transferred to the display while the transmitter and display are within 20 feet (6 meters) of each other, and no more than 12 consecutive readings (1 hour) will be missed.

To improve quality of service when other devices operating in the 2.4 GHz band are around, the t:slim X2 insulin pump uses the built-in coexistence features provided by Bluetooth wireless technology.

36.12 FCC Notice Concerning Interference

The transmitter covered by this User Guide has been certified under FCC ID: PH29433.

Although the transmitter has been approved by the United States Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular

transmission from the transmitter will be free from interference.

Compliance Statement (Part 15.19)

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Warning (Part 15.21)

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC Interference Statement (Part 15.105 (b))

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part

15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

- Consult the dealer or an experienced radio/TV technician for help.

This portable transmitter with its antenna complies with FCC/IC RF exposure limits for general population/uncontrolled exposure.

36.13 Warranty Information

The following represents the warranty information applicable only to customers in the United States. For warranty information for regions outside the United States, visit www.tandemdiabetes.com/warranty.

Warranty t:slim X2 Insulin Pump

This warranty is valid only in the United States.

Tandem Diabetes Care, Inc. (“Tandem”) warrants the t:slim X2 Insulin Pump against defects in materials and workmanship, under normal use, for the period of 4 years from the original date of shipment of the pump to the original end use purchaser (the

“Warranty Period”). For any defective t:slim X2 Pump covered by the foregoing warranty, Tandem will, at its discretion, repair the pump or replace it with a new or refurbished t:slim X2 Pump, subject to the conditions and exclusions stated herein. Repair or replacement of a t:slim X2 Pump will not extend the original 4 year warranty, which will continue to apply. If your t:slim X2 Pump is replaced, then you must return your original pump to Tandem in accordance with Tandem’s instructions. In the event the defective t:slim X2 Pump is not returned, then this warranty shall be void and you will not be entitled to future pump replacement or repairs.

The warranty is valid only if the t:slim X2 Pump is used in accordance with Tandem’s instructions for use and this user guide and will not apply if:

- damage results from changes or modifications made to the t:slim X2 Insulin Pump by the user or third persons after the date of manufacture;

- damage results from service or repairs performed to any part of the t:slim X2 Pump by any person or entity other than Tandem;
- the t:slim X2 Pump seal is broken;
- a non-Tandem cartridge is used with the t:slim X2 Pump;
- damage consists of scratches and wear to surfaces and other externally exposed parts due to wear and tear;
- damage results from an event or accident beyond the control of Tandem; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse.

From time-to-time Tandem may offer software updates for your t:slim X2 Pump to help to ensure the up-to-date functionality of your pump or software that are intended to add new features to your t:slim X2 Pump. Tandem reserves the right to offer those updates,

if any, in its sole discretion either at no charge or for an additional fee to be determined at a future date. To the extent that an update is offered at no charge, it is considered to be included in the original cost of your pump. Any future software updates will be subject to your acceptance of other terms and conditions that may be applicable at that time, including additional terms that may modify or limit the terms of this Warranty.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the t:slim X2 Pump covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate.

This warranty only applies to the t:slim X2 Pump and does not apply to other products or accessories. This warranty is valid only in the United States. No employee of Tandem or any other party is authorized to make any warranty in addition to those made in this Warranty.

The remedies provided for in this warranty are the exclusive remedies

available for any warranty claims. 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

This warranty is valid only in the United States.

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

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

- the cartridge has been used for more than a single-time use by a single end-user;
- damage results during the improper opening of the sterile package not in conformance with the procedures outlined in the associated Instructions for Use;
- the sterile package is compromised while in the control of the user by any means other than purposeful opening by the user at the time of intended product use;
- damage results from changes or modifications made to the cartridge by the user or third persons after the date of manufacture;
- damage results from service or repairs performed to any part of the cartridge by any person or entity other than Tandem;

- damage is caused by use of the cartridge with any non-Tandem insulin pump;
- damage results from an event or accident beyond the control of Tandem; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty does not apply to insulin pumps and other accessories. This warranty is valid only in the United States. No employee of Tandem or any other party is authorized to make any warranty in addition to those made in this Warranty.

The remedies provided for in this warranty are the exclusive remedies available for any warranty claims.

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

Warranty t:lock Infusion Sets Luer Infusion Sets

This warranty is valid only in the United States.

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

the conditions and exclusions stated herein.

The warranty is valid only if the infusion sets are used in accordance with the accompanying instructions for use and user guide provided with your insulin pump and will not apply if:

- the infusion set has been used for more than a single-time use by a single end-user;
- the sterile package is compromised while in the control of the user by any means other than purposeful opening by the user at the time of intended product use;
- damage results during the improper opening of the sterile package not in conformance with the procedures outlined in the accompanying instructions for use;
- damage results from changes or modifications made to the infusion set by the user or third persons after the date of manufacture;
- damage results from service or repairs performed to any part of the

infusion set by any person or entity other than Tandem;

- damage is caused by use of the t:lock infusion set with any non-Tandem insulin pump;
- damage results from an event or accident beyond the control of Tandem; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty does not apply to insulin pumps and other accessories. No employee of Tandem or any other party, including without limitation any authorized distributor, is authorized to make any warranty in addition to those made in this warranty.

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

CGM Warranty

Tandem Diabetes Care does not sell CGM sensors or transmitters and therefore provides no warranty for CGM sensors or transmitters used with the t:slim X2 insulin pump. For more information about CGM warranty information, visit the manufacturer's website.

36.14 Returned Goods Policy

The following represents the returned goods policy applicable

only to customers in the United States. For information on the returned goods policy for your region, visit www.tandemdiabetes.com/warranty.

Any insulin pump product (“Pump”) that was originally purchased from Tandem Diabetes Care, Inc. (“Tandem”) or one of its authorized distributors within the United States may be returned to Tandem only for the following reasons: (1) during the applicable Warranty Period, if the customer experiences an issue with the Pump that is covered by the Warranty, then Tandem will repair or replace the Pump as provided under the Warranty above, or (2) during the 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 authorized distributor will accept the return of the Pump and provide a refund to the customer and/or its insurance company for the amount actually paid for the Pump. Tandem will not accept or be

obligated to accept for return any Pump for any other reason. To assure prompt handling when returning a Pump, the customer must first obtain a returned materials authorization (RMA) number from Tandem’s or its authorized distributor’s Customer Service Department. This RMA number must be clearly written on the outer box. If Tandem provides a label, the label must be attached or taped to the outer box. If no label is provided, Tandem recommends shipping via insured ground service with a tracking number. Tandem is not responsible for lost or damaged packages.

To obtain an RMA number and shipping address, please contact Tandem Customer Technical Support. Returns pre-authorized by Tandem’s authorized distributors should be sent to the distributor authorizing the return, unless other instructions are provided. Returns made without the RMA number will be returned to the customer, freight

collect. This policy is subject to applicable law.

36.15 t:slim X2 Insulin Pump Event Data (Black Box)

Your t:slim X2 pump’s event data is monitored and logged on the pump. The information stored on the may be obtained and used by Customer Technical Support for troubleshooting purposes when a pump is uploaded to a data management application that supports use of the t:slim X2 pump, or if the pump is returned for any reason. Others who may assert a legal right to know, or who obtain your consent to know such information may also have access to read and use this data.

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