t:slim X2™

Insulin Pump

with Control-IQ+ Technology

Technical User Guide

TANDEM™ Diabetes Care

MG/DL

T:SLIM X2 INSULIN PUMP WITH CONTROL-IQ+ TECHNOLOGY TECHNICAL USER GUIDE
Software Version: Control-IQ+ 7.9

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

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

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

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1 Before You Begin

CHAPTER 1

Introduction

1.1 Conventions of This Guide

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

Formatting Conventions

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

Terminology Definitions

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

Symbol Definitions

Symbol	Definition
	Calls out an important note regarding the use or operation of the system.
	Calls out safety precautions which, if ignored, could result in minor or moderate injury.
	Calls out critical safety information which, if ignored, could result in serious injury or death.
✓	Indicates how the pump or the Tandem t:slim mobile app 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.

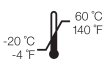
Explanation of t:slim X2 Insulin Pump Symbols

Symbol	Definition
	Caution
	Refer to instruction manual/booklet
	Consult instructions for use or consult electronic instructions for use
	For sale by or on the order of a physician only (United States)
REF	Catalogue number
LOT	Batch code
IP27	Ingress Protection (IP) Code
	Manufacturer

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

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

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

Symbol	Definition
	Authorized representative in Switzerland
	Responsible person in the United Kingdom
	UK Conformity assessed (UKCA) conformity marking
	CE mark
	Regulatory Compliance Mark
	Humidity range
	Temperature range
	Keep Dry
	Outlet Adapter
	Pump Case

1.3 System Description

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

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

The Dexcom G6 CGM, the Dexcom G7 CGM, and the Abbott FreeStyle Libre 2 Plus CGM are each compatible with the t:slim X2 insulin pump with Control-IQ+ technology. The Dexcom G6 transmitter may be referred to as a “transmitter.” The Dexcom G6 sensor may be referred to as a “compatible sensor.” Together, the Dexcom G6 transmitter and Dexcom G6 sensor may be referred to as a “compatible CGM.” The Dexcom G7 sensor and the Abbott FreeStyle Libre 2 Plus sensor each have a built-in transmitter. Each of these will also be referred to as a “compatible CGM.”

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

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

The pump can be used for basal and bolus insulin delivery with or without a CGM. If a CGM is not used, sensor glucose readings will not be sent to the pump display and you will not be able to use Control-IQ+ technology.

The sensor is a disposable device that is inserted under the skin to continuously monitor glucose levels. The Dexcom G6 CGM and the Dexcom G7 CGM each wirelessly send readings to the pump every 5 minutes. The Abbott FreeStyle Libre 2 Plus sensor wirelessly sends readings to the pump every minute. The pump shows sensor glucose readings, a trend graph, as well as the direction and rate of change arrows.

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

The Tandem t:slim mobile app enables you to connect a smartphone to the pump using *Bluetooth*® wireless technology to display your pump information and perform some pump functions on the smartphone as well as display pump notifications. The Tandem t:slim mobile app can transmit pump and therapy data from the pump to the cloud as long as your smartphone is connected to the internet. Download the Tandem t:slim mobile app from Google Play™ or from the App Store® and visit support.tandemdiabetes.com for installation instructions.

NOTE

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

PRECAUTION

Federal (United States) 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 pump. It provides step-by-step instructions to help you properly program, manage, and care for the pump. It also provides important warnings and precautions on proper operation and technical information to ensure your safety.

The user guide is organized into sections. Section 1 provides important information you need to know before you start using the pump. Section 2 covers instructions for using the t:slim X2 pump and using the Tandem t:slim mobile app with the pump. Section 3 covers instructions for using CGM with your pump. Section 4 covers instructions for using Control-IQ+ technology on your pump. Section 5 provides information on the technical specifications of your pump.

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

Product information, including electronic versions of the user guide, Tandem t:slim Getting Started Guide, Tandem t:slim user guides, and a CGM training tutorial, are available at tandemdiabetes.com.

1.5 Indications for Use

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

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

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

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

Control-IQ+ technology is intended for the management of Type 1 diabetes mellitus in persons 2 years of age and greater and of Type 2 diabetes mellitus in persons 18 years of age and greater.

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

1.6 Compatible Insulins

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

- NovoLog U-100 insulin
- Humalog U-100 insulin

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

If you have questions about using other insulins, contact your healthcare provider. Always consult your healthcare provider and refer to the insulin labeling prior to use.

Some insulin products are labeled for use in any pump that is compatible with the insulins listed above. To see if another insulin not listed above can be used, refer to section 2.2 of the prescribing information for that insulin product.

1.7 Compatible iCGMs

Compatible CGMs include the following iCGMs:

- Dexcom G6 CGM
- Dexcom G7 CGM
- Abbott FreeStyle Libre 2 Plus Sensor CGM

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

All CGM components are sold and shipped separately by their respective manufacturers.

NOTE

Your CGM currently allows pairing with one medical device at a time (either the t:slim X2 pump, the Dexcom receiver, or Abbott FreeStyle Libre 2 System Products). Specific manufacturer CGM smartphone app behavior may vary during t:slim X2 use; see Section 20.2 Device Connection Overview.

NOTE

The Mobile Connection setting on your Pump does not relate to the Bluetooth connection between your CGM and Pump. For connecting a CGM to your Pump, see Section 21.1 About Bluetooth Technology. For connecting your Pump to the Tandem t:slim mobile app, see Section 4.3 Connecting to a Smartphone.

NOTE

Product instructions for your CGM Systems include important information on how to use the 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 CGM information when making treatment decisions.

1.8 Important User Information

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

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

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

Whether or not you are using a CGM, it is still very important that you review all instructions in this user guide.

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.

Report any serious incident that occurs in relation to Tandem Diabetes Care products to Tandem Diabetes Care or its local distributor.

1.9 Important Pediatric User Information

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

Younger children may inadvertently press or tap the pump or the Tandem t:slim mobile app, leading to unintentional delivery of insulin.

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

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

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

⚠ WARNING

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

⚠ WARNING

The t:slim X2 insulin pump with Control-IQ+ technology should not be used in children under the age of 2 years old.

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

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

⚠ WARNING
For patients who do not self-manage their disease, the Security PIN function should **ALWAYS** be on when the pump is not being used by a caregiver. The Security PIN function is intended to prevent inadvertent screen taps or button presses that may lead to insulin delivery or changes in the pump settings. These changes can potentially lead to hypoglycemia (low BG) or hyperglycemia (high BG) events. See Section 5.14 Turn Security PIN On or Off for details on how to turn the Security PIN function on.

⚠ WARNING
For patients whose insulin administration is managed by a caregiver, **ALWAYS** turn off the Quick Bolus feature to avoid inadvertent bolus delivery. If the Security PIN is turned on, the Quick Bolus feature is automatically disabled. Inadvertent screen taps, button presses, or tampering with the insulin pump could result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events. See Section 5.14 Turn Security PIN On or Off for details on how to turn the Security PIN function off.

1.10 Emergency Kit

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

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

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

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 pump. Pay attention to other warnings and precautions listed throughout this user guide as they relate to special circumstances, features, or users.

2.1 t:slim X2 Insulin Pump Warnings

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

⚠ WARNING
DO NOT start to use your pump before you have been appropriately trained on its use by a certified trainer or through the training materials available online if you are updating your pump. Consult with your healthcare provider for your individual training needs for the pump. Failure to complete the necessary training on your pump could result in serious injury or death.

⚠ WARNING
ONLY use U-100 insulin analogs that have been tested and found to be compatible for use in the pump, listed in Section 1.6 Compatible Insulins. Only U-100 insulin analogs listed in Section 1.6 Compatible Insulins have been tested and found to be compatible for use in the pump. Use of insulin with greater or lesser concentration can result in an over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING
DO NOT put any other drugs or medications inside your pump cartridge. The pump is designed only for continuous subcutaneous insulin infusion (CSII) with U-100 insulin analogs listed in Section 1.6 Compatible Insulins. Use of other drugs or medications can damage the pump and result in injury if infused.

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

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

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

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

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

you manage your diabetes. Incorrect settings can result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

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

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

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

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

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

⚠ WARNING
ONLY use infusion sets that are 23, 32, or 43 inches in length and approved for use with the t:slim X2 pump. **NEVER** use the 5-inch AutoSoft XC infusion set with the t:slim X2.

⚠ 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 ensure there is a tight connection between the cartridge tubing and the infusion set tubing. A loose connection can cause insulin to leak, resulting in under delivery of insulin. If the connection comes loose, disconnect the infusion set from your body before tightening. This can cause hyperglycemia (high BG).

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

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

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

⚠ WARNING
Delivering large boluses, or delivering multiple boluses back to back may cause hypoglycemia (low BG) events. Pay attention to IOB and the bolus calculator recommended dose before delivering large or multiple boluses.

⚠ WARNING
If you have initiated a bolus and do not see a reduction in BG after an hour or more, it is recommended that you check your infusion set for an occlusion, air bubbles, or for leaks or cannula dislodgement. If the condition persists, call Customer Technical Support or seek medical attention as required.

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

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

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

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

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

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

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

⚠ WARNING
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30.5 cm) to any part of the t:slim X2 pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

⚠ WARNING
Some skin care products such as lotions, sunscreens, and insect repellents can cause cracks in the plastic used to manufacture the pump and cartridge. DO NOT allow these products to come in contact with the pump or cartridge. ALWAYS remove your pump before applying these products and ALWAYS wash your hands before handling your pump or cartridge after using such products. ALWAYS change your cartridge if it becomes exposed to such products and immediately clean your pump. Failure to do so may result in damage to the pump and cartridge and in some cases over or under delivery of insulin.

2.2 Magnetic Resonance Imaging Safety

⚠ WARNING
The pump is magnetic resonance (MR) unsafe. You must take off your pump and leave it outside the procedure room.

2.3 Radiology and Medical Procedures and Your t:slim X2 Pump

Please review your smartphone manufacturer's instructions before using the Tandem t:slim mobile app during any of the radiology or medical procedures listed below.

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

⚠ WARNING
DO NOT expose your pump to:

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

⚠ WARNING
DO NOT expose your pump to:

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

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

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

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

⚠ WARNING
There are other procedures where you should proceed with caution:

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

2.4 Tandem t:slim Mobile App Warnings

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

⚠ WARNING
DO NOT use a smartphone that has been jailbroken or rooted, or with Android developer mode on. Data may become vulnerable if you install the Tandem t:slim mobile app on a smartphone that has been jailbroken or rooted, or uses an unreleased or pre-released operating system. Only download the Tandem t:slim mobile app on Google Play™ or from the App Store®. See Chapter 4 Getting to Know Your Tandem t:slim Mobile App for Tandem t:slim mobile app installation.

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

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

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

⚠ WARNING
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30.5 cm) to any part of the t:slim X2 pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

2.5 t:slim X2 Insulin Pump Precautions

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠ PRECAUTION

CHECK the tubing connection between your cartridge tubing and infusion set tubing daily to ensure it is tight and secure and that there are no cracks, chips, or other damage. Leaks around the tubing connection can result in under delivery of insulin.

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠ PRECAUTION

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

discontinue use of the pump and contact Customer Technical Support.

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

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

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

⚠ 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.

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

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

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

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

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

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

⚠ PRECAUTION
DISCONNECT your infusion set from your body before flying in an aircraft without cabin

pressurization or in planes used for aerobatics or combat simulation (pressurized or not). Rapid changes in altitude or gravity can affect insulin delivery and cause injury.

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠ PRECAUTION

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

⚠ PRECAUTION

The Profile Settings feature is meant to work with TDI based on injection therapy. Do not use the Profile Settings feature if you are coming from pump therapy. Using the Profile Settings feature with a TDI from existing pump therapy can result in under-delivery of insulin and could lead to hyperglycemia (high BG). Always test your BG as needed.

2.6 Tandem t:slim Mobile App Precautions

⚠ PRECAUTION

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

⚠ PRECAUTION

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

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

⚠ PRECAUTION
The Tandem t:slim mobile app receives data from the connected pump via a secure Bluetooth wireless technology connection. If the Bluetooth connection between the pump and the Tandem t:slim mobile app is lost, the Tandem t:slim mobile app will not display current insulin pump information and cannot be used to request a bolus. To help maintain the wireless connection between the insulin pump and the Tandem t:slim mobile app, it is recommended the smartphone running the Tandem t:slim mobile app is within five feet of the compatible insulin pump.

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

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

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

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

⚠ PRECAUTION
ALWAYS rely on your pump for therapy decisions if:

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

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

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

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

⚠ PRECAUTION

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

⚠ PRECAUTION

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

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

2.7 Tandem Cybersecurity Preventative Measures

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

- Keep your pump, smartphone, and Tandem t:slim mobile app in your control or on your person at all times.
- Always disconnect your pump from the computer and USB cable when not using it to upload pump data or perform software updates with the Tandem Device Updater.
- Do not share your pump's serial number or Tandem t:slim mobile app pairing code with any untrusted individual. Do not write these numbers down anywhere they can be accessed by an untrusted individual.
- Do not connect to or allow any third-party devices to pair with your pump that are not included as part of the Tandem system. See Section 1.3 System Description for a full system description.
- Do not use any software or third-party applications which have not been authorized by Tandem as being safe for use with your pump.
- Only attempt to perform software updates using the authorized Tandem Device Updater.
- Contact Tandem's Customer Technical Support if you suspect your pump may have been compromised by any cybersecurity interference or vulnerability.

2.8 Potential Benefits From Using Your Pump

- The pump provides an automated way to deliver basal and bolus insulin. Delivery can be fine-tuned based on up to six customizable Personal Profiles, each with up to 16 time-based settings for basal rate, carb ratio, correction factor, and target BG. In addition, the temp rate feature allows you to program a

temporary Basal Rate change for up to 72 hours.

- The pump gives you the option of delivering a bolus all at once, or delivering a percentage over an extended period of time without navigating to different menus. You can also program a bolus more discreetly using the Quick Bolus feature, which can be used without looking at the pump, and can be programmed in increments of either units of insulin or grams of carbohydrate.
- From the *Bolus* screen, the bolus calculator feature allows you to enter multiple carbohydrate values and add them together. The insulin pump's bolus calculator will recommend a bolus based on the entire amount of carbohydrates entered, which can help eliminate guesswork.
- The pump keeps track of the amount of active insulin from food and correction boluses, or Insulin on Board (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.

2.9 Possible Risks From Using Your Pump

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

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

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

Other risks associated with infusion sets include occlusions and air bubbles in the tubing or dislodged cannula, which can affect insulin delivery. If your BG does not decrease after initiating a bolus, or you have other unexplained high BG, it is recommended that you

check your infusion set for an occlusion or air bubbles, and verify that the cannula has not dislodged. If the condition persists, call Customer Technical Support or seek medical attention as required.

Risks that could result from pump failure include the following:

- possible hypoglycemia (low BG) from over-delivery of insulin due to a hardware defect or software anomaly.
- hyperglycemia (high BG) and ketosis possibly leading to Diabetic Ketoacidosis (DKA) due to pump failure resulting in cessation of insulin delivery due to either a hardware defect, software anomaly, or infusion set failure. Having a backup method of insulin delivery greatly reduces your risk of severe hyperglycemia or DKA.

2.10 Working with Your Healthcare Provider

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

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

2.11 Verification of Proper Functionality

Pump Functionality

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

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

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

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

⚠ PRECAUTION

CONFIRM that the pump screen display turns on, you can hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the **Screen On/Quick Bolus** button when you connect a power source to the USB port. These features are used to notify you about alerts, alarms, and other conditions that

require your attention. If these features are not working, discontinue use of your pump and contact Customer Technical Support.

Tandem t:slim Mobile App Functionality

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

⚠ PRECAUTION

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

CHAPTER 3

Getting to Know Your t:slim X2 Insulin Pump

3.1 What your t:slim X2 Pump Package Includes

Your pump package should include the following items:

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

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

If you use a CGM, the components are sold and shipped separately, directly from the CGM manufacturer.

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

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

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

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

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

Supply Reordering
To order cartridges, infusion sets, supplies, accessories, screen protectors, please contact 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 BG or glucose value goal, an exact number, not a range. When a glucose value is entered in the pump, the calculated insulin bolus will be adjusted up or down as needed to attain this target.

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

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

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

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

Correction Bolus
A correction bolus is given to correct high glucose.

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

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

Grams
Grams are the measurement for a carbohydrate.

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

Pairing Code
A unique, temporary code generated by the t:slim X2 pump used to pair the pump with a single smartphone. The code is valid for 5 minutes. This pairing code is not related to the CGM pairing code.

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.

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

3.3 Explanation of t:slim X2 Insulin Pump Icons

The following icons may appear on your pump:

Pump Icon Definitions

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

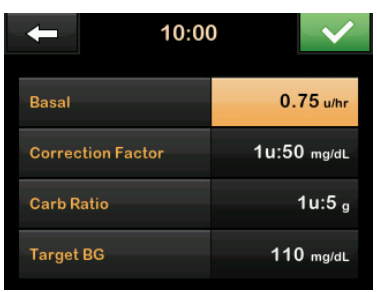
Symbol	Definition
	The amount of insulin remaining in the cartridge.
	A temporary basal rate is active.
	A basal rate of 0 u/hr is active.
	A temporary basal rate of 0 u/hr is active.
	A bolus is being delivered.
	Cancel. Tap to cancel the current operation.
	Decline. Tap to exit the screen or answer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

Pump Icon Definitions (Continued)

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

Symbol	Definition
	Security PIN has been enabled. See Section 5.14 Turn Security PIN On or Off.
	The associated setting is turned on.
	The associated setting is turned off.
	Tandem logo. When the pump screen is turned on and unlocked, tap to return to the *Home* screen.

3.4 Explanation of Pump Colors

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

3.5 Pump Back Side

1. t:slim X2 Cartridge: A single-use disposable cartridge can hold up to 300 units (3.0 mL) of insulin.

2. Vent Holes: Vent holes help the pump function correctly. It is important that these vents remain uncovered.

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


t:slim X2
Insulin Pump
U-100 INSULIN
2797
0086
Tandem Diabetes Care, Inc. • tandemdiabetes.com
12400 High Bluff Dr. • San Diego, California 92130 • USA
1
2

3.6 Lock Screen

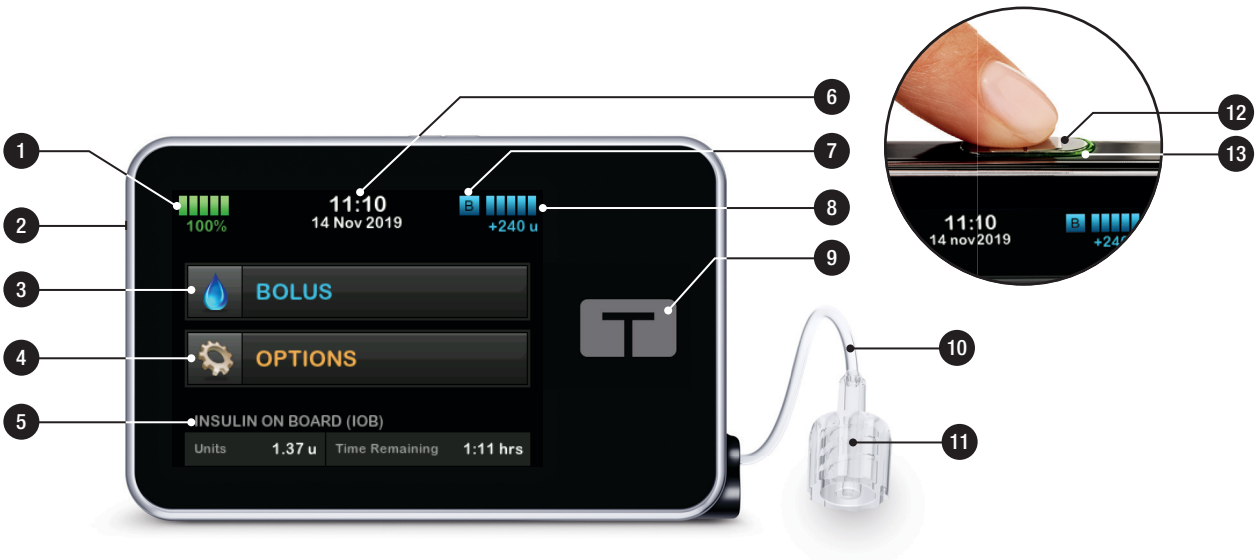
The *Lock* screen appears anytime you turn on the screen. You must tap **1–2–3** in sequential order to unlock the pump.

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


1
2
3
4
5
6
7
8
10:20
14 Nov 2019
100%
235 u
1
2
3
INSULIN ON BOARD (IOB)
Units 1.1 u
Time Remaining 1:09 hrs

3.7 Home Screen

1. Battery Level: Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
2. USB Port: Port to charge your pump battery. Close the cover when not in use.
3. Bolus: Program and deliver a bolus.
4. Options: Stop/Resume insulin delivery, manage pump and CGM settings, start/stop activities, load a cartridge, and view history.
5. Insulin On Board (IOB): Amount and time remaining of any active insulin on board.
6. Time and Date Display: Displays the current time and date.
7. Status: Displays current pump settings and insulin delivery status.
8. Insulin Level: Displays the current amount of insulin in the cartridge.
9. Tandem Logo: Returns to the *Home* screen.
10. Cartridge Tubing: Tubing that is attached to the cartridge.
11. 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.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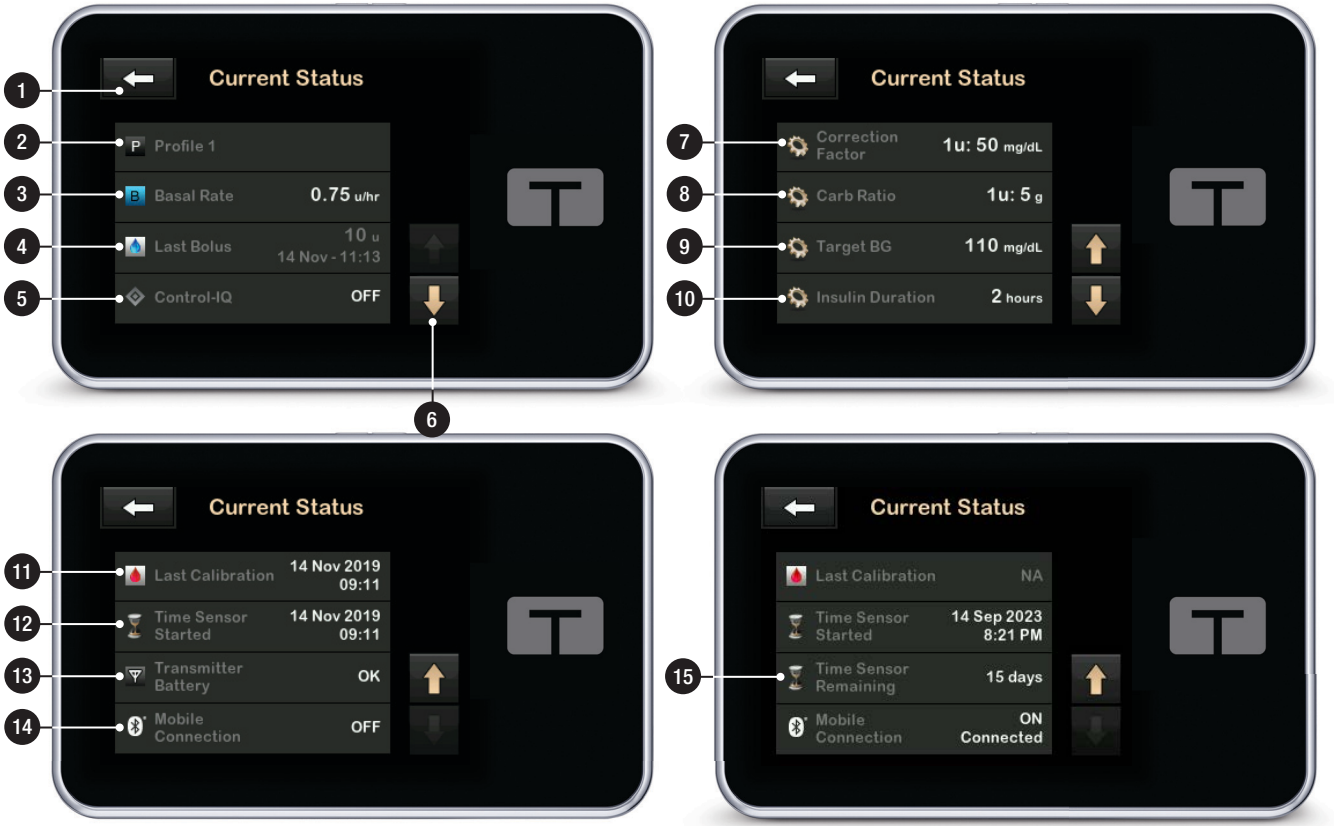
7
8
9
10
11
12
13
100%
11:10
14 Nov 2019
+240 u
BOLUS
OPTIONS
INSULIN ON BOARD (IOB)
Units
1.37 u
Time Remaining
1:11 hrs
11:10
14 nov2019

3.8 Current Status Screen

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

1.  : Returns to the *Home* screen.
2. Profile: Displays current active Personal Profile.
3. Basal Rate: Displays current basal rate being delivered in units/hr. If a temp rate is active, this row will change to display current temp rate being delivered in units/hr.
4. Last Bolus: Displays amount, date and time of last bolus.
5. Control-IQ Status: Displays Control-IQ+ technology status.
6. Up/Down Arrow: Indicates there is more information.
7. Correction Factor: Displays current correction factor used to calculate a bolus.
8. Carb Ratio: Displays current carb ratio used to calculate a bolus.
9. Target BG: Displays current BG target used to calculate a bolus.
10. Insulin Duration: Displays current insulin duration setting used to calculate insulin on board.
11. Last Calibration (Dexcom only): Displays date and time of last calibration.
12. Time Sensor Started: Displays date and time of last time sensor started.
13. Transmitter Battery (Dexcom G6 only): Displays CGM transmitter battery status.
14. Mobile Connection: Displays whether the mobile connection is turned on or off, whether a smartphone is paired with the pump, and if so whether the smartphone is actively connected to the pump.
15. Time Sensor Remaining (Abbott FreeStyle Libre 2 Plus Sensor only): Displays time remaining in the current CGM sensor session.


Current Status
1
2
P
Profile 1
3
B
Basal Rate
0.75 u/hr
4
Last Bolus
10 u
14 Nov - 11:13
5
Control-IQ
OFF
6
Current Status
7
Correction Factor
1u: 50 mg/dL
8
Carb Ratio
1u: 5 g
9
Target BG
110 mg/dL
10
Insulin Duration
2 hours
Current Status
11
Last Calibration
14 Nov 2019 09:11
12
Time Sensor Started
14 Nov 2019 09:11
13
Transmitter Battery
OK
14
Mobile Connection
OFF
Current Status
Last Calibration
NA
Time Sensor Started
14 Sep 2023 8:21 PM
15
Time Sensor Remaining
15 days
Mobile Connection
ON
Connected

3.9 Bolus Screen

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

1.  : Returns to the *Home* screen.

2. **Insulin:** Enter units of insulin. You may change this setting to use grams of carb. See Section 6.3 Creating a New Profile for details on how to set the Increment Type.

3. **Units:** Displays total units calculated. Tap to enter a bolus request or change (override) a calculated bolus.

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

5. **Glucose:** Enter BG or sensor glucose level. This value is populated automatically if each of the following conditions are true:

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

   NOTE

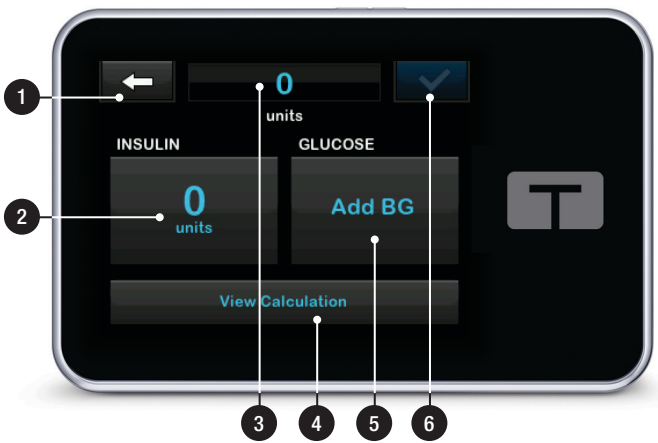
   For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's product instructions. You can also see Section 25.3 Rate of Change Arrows.

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

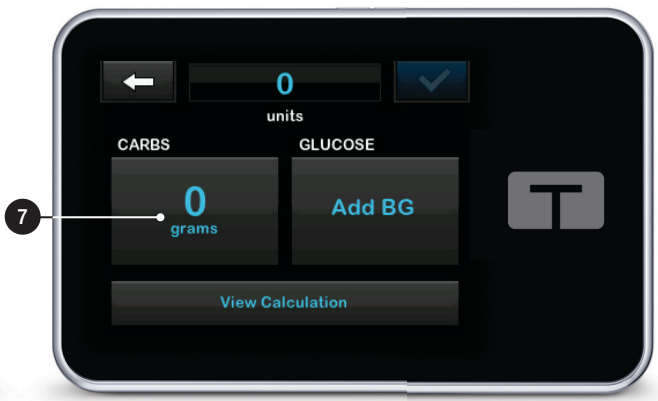
6.  : Moves to next step.

7. **Carbs:** Enter grams of carbohydrate. You may change this setting to use units of insulin. See Section 6.3 Creating a New Profile for details on how to set the Increment Type.

Using Units

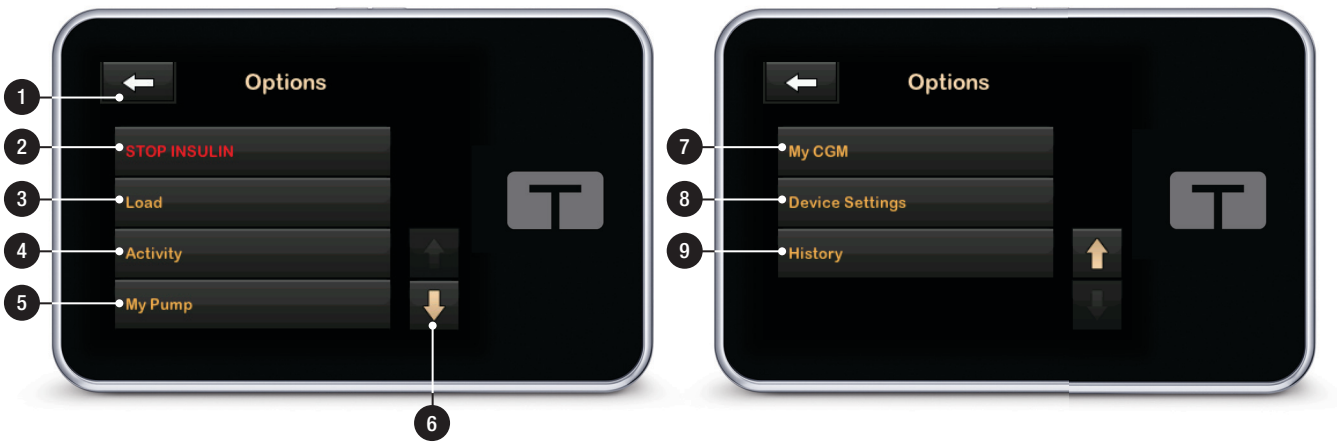


Using Grams



3.10 Options Screen

1.  : Returns to the *Home* screen.
2. Stop Insulin: Stops insulin delivery. If insulin delivery is stopped, RESUME INSULIN will be displayed.
3. Load: Change Cartridge, Fill Tubing, Fill Cannula, and Site Reminder.
4. Activity: Programs on Exercise, Sleep, and temporary Basal Rates.
5. My Pump: Personal Profiles, Control-IQ, Alerts & Reminders, and Pump Info.
6. Up/Down Arrow: Indicates there is more information.
7. My CGM: Displays options to configure and use a compatible CGM.
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.


Options
STOP INSULIN
Load
Activity
My Pump
1
2
3
4
5
6
Options
My CGM
Device Settings
History
7
8
9

3.11 My Pump Screen

1.  : Returns to the *Options* screen.

2. Personal Profiles: A group of settings that define basal and bolus delivery.

3. Control-IQ: Turn on/off Control-IQ+ technology and enter required values.

4. Alerts & Reminders: Customize Pump Reminders and Pump Alerts.

5. Pump Info: Displays pump serial number, Customer Technical Support service contact information website, and other technical information.


My Pump
1
2
Personal Profiles
3
Control-IQ
4
Alerts & Reminders
5
Pump Info

3.12 Device Settings Screen

1.  : Returns to the *Options* screen.

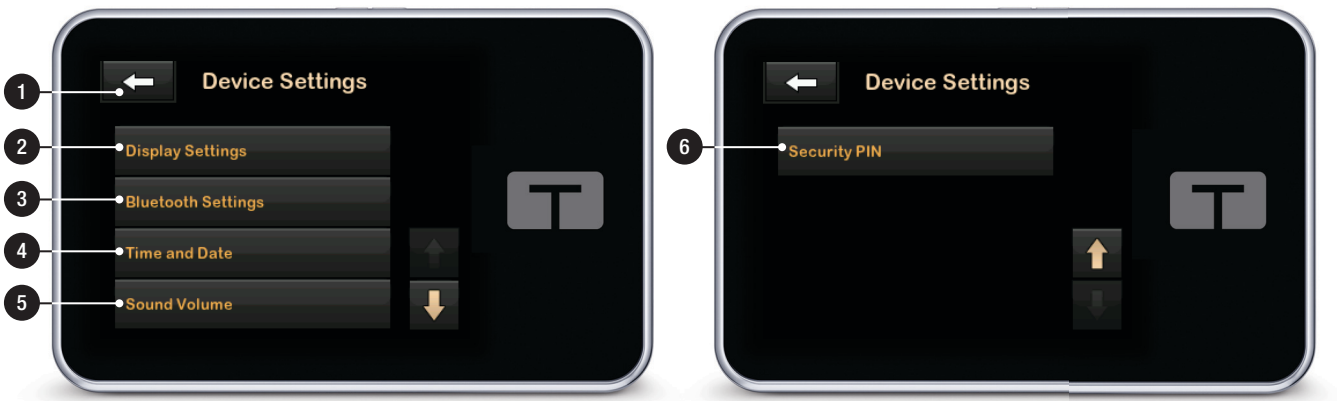
2. **Display Settings:** Customize the Screen Timeout settings.

3. **Bluetooth Settings:** Turn on/off Mobile Connection.

4. **Time and Date:** Edit the time and date that will be displayed on the pump.

5. **Sound Volume:** Customize the sound volume for pump alarms, pump alerts, reminders, keypad, bolus, quick bolus, fill tubing, and CGM alerts.

6. **Security PIN:** Turn on/off the Security PIN.


1
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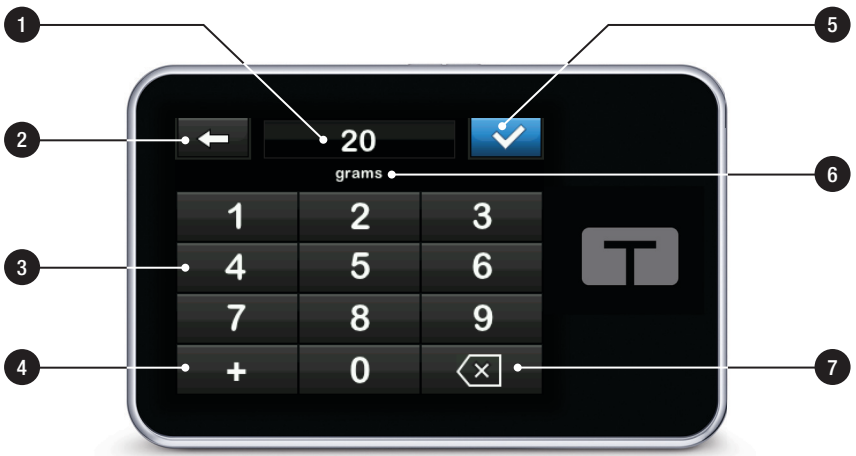
5
6
Device Settings
Display Settings
Bluetooth Settings
Time and Date
Sound Volume
Device Settings
Security PIN

3.13 Number Keypad Screen

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


1
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3
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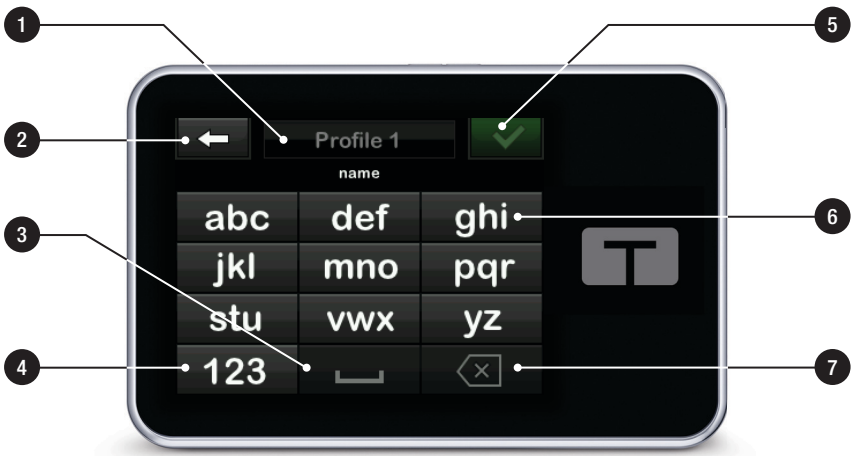
5
6
7
20
grams
1
2
3
4
5
6
7
8
9
+
0

3.14 Letter Keypad Screen

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


1
2
3
4
5
6
7
Profile 1
name
abc
def
ghi
jkl
mno
pqr
stu
vwx
yz
123

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CHAPTER 4

Getting to Know Your Tandem t:slim Mobile App

4.1 Overview

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

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

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

NOTE

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

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

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

⚠ WARNING

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

⚠ PRECAUTION

ALWAYS rely on your pump for therapy decisions when:

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

⚠ PRECAUTION

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

⚠ PRECAUTION

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

request or control a bolus from the Tandem t:slim mobile app.

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

4.2 Install the Tandem t:slim Mobile App

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

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

Supported mobile devices are compliant with appropriate electrical safety standards (IEC 60950-1, IEC 62368-1, or equivalent).

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

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

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

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

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

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

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

If you are a new user:

1. Tap **Get Started**.

2. Enter your account information, including name, account type, and login information.

   NOTE

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

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

   NOTE

   We encourage you to discuss these values with your healthcare provider before setting them. You can leave the fields blank during account set-up and enter them later. Setting or changing these values will not change any settings in the pump itself.

Update the Tandem t:slim Mobile App

When updates to the Tandem t:slim mobile app are available on Google Play or from the App Store, do not uninstall the app. When you download and install an update, your Tandem t:slim mobile app will still be connected to your Tandem t:slim account, the smartphone will still be paired with your pump, and your app settings will remain the same.

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

Updating Your Smartphone

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

⚠ PRECAUTION

DO NOT update your smartphone operating system prior to confirming that it is compatible with the Bolus Delivery plus Display and Data Upload feature of the Tandem t:slim mobile app. If you update to an incompatible operating system version, you will lose the ability to request or control a bolus from the Tandem t:slim mobile app. For more information, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the Tandem t:slim mobile app *Settings* screen, then tap **App Guide**.

4.3 Connecting to a Smartphone

You can connect one compatible smartphone to the pump to display pump information and perform some

pump functions on that smartphone using the Tandem t:slim mobile app.

NOTE

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

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

NOTE

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

Pair a Smartphone

NOTE

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

NOTE

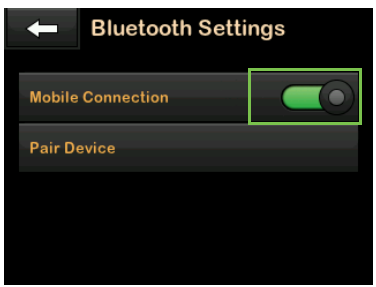
We strongly suggest that you upload pump data to the Tandem t:slim web application or the Tandem Source platform using the USB cable provided with your pump before you complete the pairing process to ensure all your pump data is uploaded as quickly as possible to the Tandem cloud. The first time you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

Pair the Tandem t:slim mobile app with your pump as follows:

1. From your smartphone, open the Tandem t:slim mobile app.
   - » If you have an existing Tandem t:slim account, log in using your credentials.
   - » If you are a new user, create an account as shown in Section 4.2 Install the Tandem t:slim Mobile App.

✓ The Tandem t:slim mobile app will prompt you to begin the pairing process.

2. From your pump's *Home* screen:
   a. Tap **OPTIONS**.
   b. Tap the **Down Arrow**.
   c. Tap **Device Settings**.
   d. Tap **Bluetooth Settings**.
   e. Tap the on/off toggle next to Mobile Connection and tap ✓ to confirm. **Pair Device** is now displayed.



3. From the Tandem t:slim mobile app on your smartphone:
   a. Tap **Begin** in the Tandem t:slim mobile app. A confirmation prompt will appear.

b. Choose the appropriate pump serial number on the *Select your pump* screen and tap **Next**.

NOTE

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

4. From your pump's *Bluetooth Settings* screen, tap **Pair Device**.

5. Your pump will display a *Mobile App notification* screen. Tap ✓ to generate your device pairing code.

✓ Your pump will display a unique pairing code.

NOTE

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

NOTE

DO NOT tap ✕ on your pump. Tapping ✕ will return you to the Bluetooth Settings screen to repeat step 4.

6. From your smartphone, enter the pairing code generated in Step 5 into the Tandem t:slim mobile app and tap **Pair with pump**.

✓ Your pump will display a confirmation screen.

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

NOTE

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

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

Your Tandem t:slim mobile app will remain synchronized with your pump as long as a Bluetooth connection is established. The Tandem t:slim mobile app uploads your pump's data into the Tandem cloud approximately once per hour whenever it is connected to wi-fi or cellular data, depending on your data use settings. This allows you and your healthcare provider easy access to your data via the Tandem t:slim web application or the Tandem Source platform without requiring access to your pump or connection cables.

⚠ PRECAUTION

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

Unpair a Smartphone

You can disconnect a smartphone from a pump:

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

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

Unpair a smartphone from your pump as follows:

1. From the Tandem t:slim mobile app:
    a. Tap **Settings** on the *Navigation* bar.
    b. Tap **Paired Pump**.
    c. Tap **Unpair pump**. A confirmation prompt will appear.
    d. Tap **Unpair**. The Tandem t:slim mobile app displays a banner confirming that your pump has been unpaired and returns you to the pairing screen.
2. From your pump's *Home* screen, disable your pump's **Mobile Connection** toggle:
    a. Tap **Options**.
    b. Tap **Device Settings**.
    c. Tap **Bluetooth Settings**.
    d. Tap the on/off toggle next to **Mobile Connection** and tap  to confirm. **Pair Device** will disappear.
3. From your smartphone, remove your pump from your smartphone's Bluetooth device list.

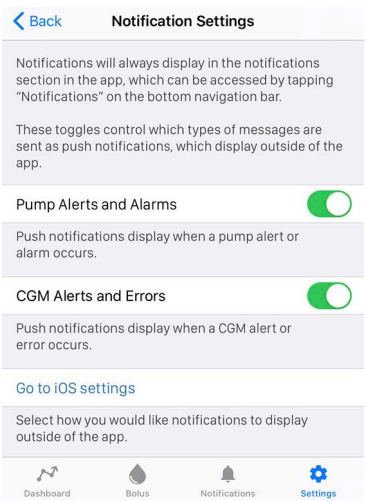
If your pump is malfunctioning, or you otherwise don't have access to your pump (e.g., the pump has been lost or returned to Tandem), use your Tandem t:slim mobile app to unpair your smartphone from your pump as follows:

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

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

4.4 Set Mobile Notifications

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



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

- Tandem t:slim mobile app notifications
- Bluetooth

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

⚠ PRECAUTION

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

⚑ NOTE

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

4.5 Mobile Connection Security

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

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

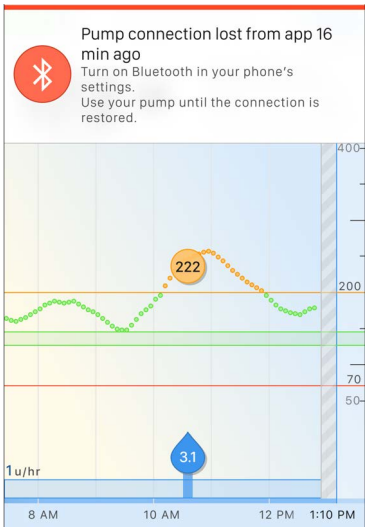
4.6 Lost Pump Connection

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

⚠ PRECAUTION

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

The *Pump Connection Lost* notification banner replaces the current pump status until you re-establish the Bluetooth connection.

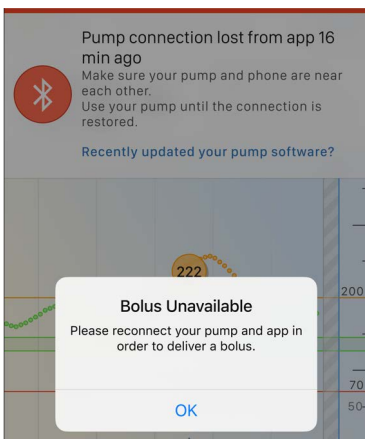


You will also see a gray shaded area on the graph since no data can be displayed when the connection is lost. When the connection is lost, use the pump to administer therapy while troubleshooting the loss of connection.

⚠ PRECAUTION

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

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



Reconnect Bluetooth

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

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

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

1. Force quit or close the Tandem t:slim mobile app.
2. Open the Tandem t:slim mobile app.
3. If your connection is lost again, disable your smartphone's Bluetooth connection.
4. Enable your smartphone's Bluetooth connection.
5. If your connection is lost again, sign out of your Tandem t:slim account.
6. Pair your smartphone with your pump as described in Section 4.3 Connecting to a Smartphone.

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

4.7 Restart the Tandem t:slim Mobile App

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

For iOS devices:

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

For Android devices:

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

⚠ PRECAUTION

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

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

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

2. Tap **Paired Pump**.

3. Tap **Unpair Pump**.

4. Repeat the pairing process as shown in Section 4.3 Connecting to a Smartphone.

4.8 Tandem t:slim Mobile App Dashboard

1. Pump Battery Level: Displays the level of pump battery power remaining. When the pump is connected for charging, the charging icon (lightning bolt) will display.

2. Most Recent Glucose Reading and Trend Arrow.

3. BG Entry: Your BG value at the moment you entered it into your bolus calculator.

4. Graph of Most Recent Glucose Readings: Displays CGM sensor readings for the last 24 hours. You may swipe left and right to see all 24-hours in the graph. This graph also includes blood glucose (BG) readings entered into the bolus calculator.

5. Delivered Bolus: The amount of bolus insulin actually delivered for a given bolus event.

6. Delivered Basal: The amount of insulin delivered as basal for the past 24-hour period. This includes changes in insulin delivery related to use of Control-IQ+™ technology.

7. Status: Displays current pump settings and insulin delivery status. Swipe up to scroll down in the Tandem t:slim mobile app and see complete Status information. This screen may vary slightly depending on the type of CGM you are using.

8. Navigation Bar: Displays icons representing each mobile app page. The icon for the active Tandem t:slim mobile app page is highlighted blue.

9. Insulin Level: Displays the current amount of insulin in the cartridge. You can also tap the Insulin Level Icon to automatically scroll down and see complete Status information.

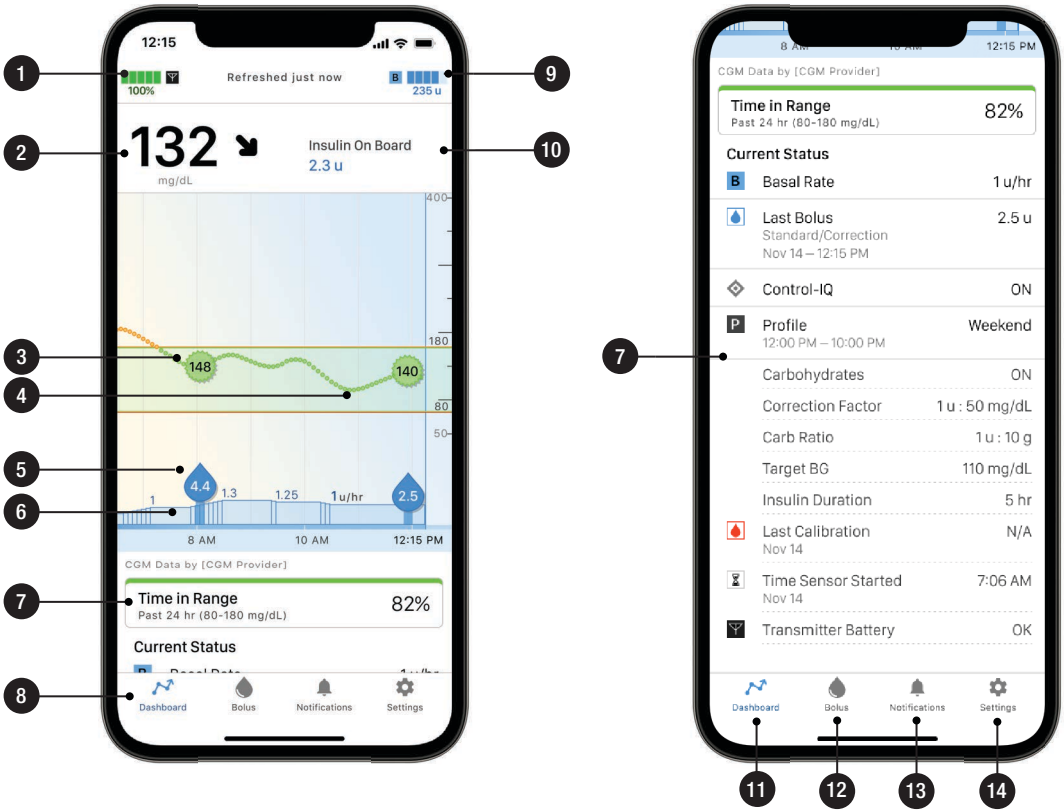
10. Insulin On Board (IOB): Amount and time remaining of any active insulin on board.

11. Dashboard: Displays pump status bar, current glucose reading, IOB status, CGM graph, time in range information, and current status.

12. Bolus: Navigate to the *Bolus* screen to program and deliver a bolus (only available with compatible devices).

13. Notifications: Displays active pump alerts, alarms, reminders, and malfunctions. See Section 4.4 Set Mobile Notifications for more information.

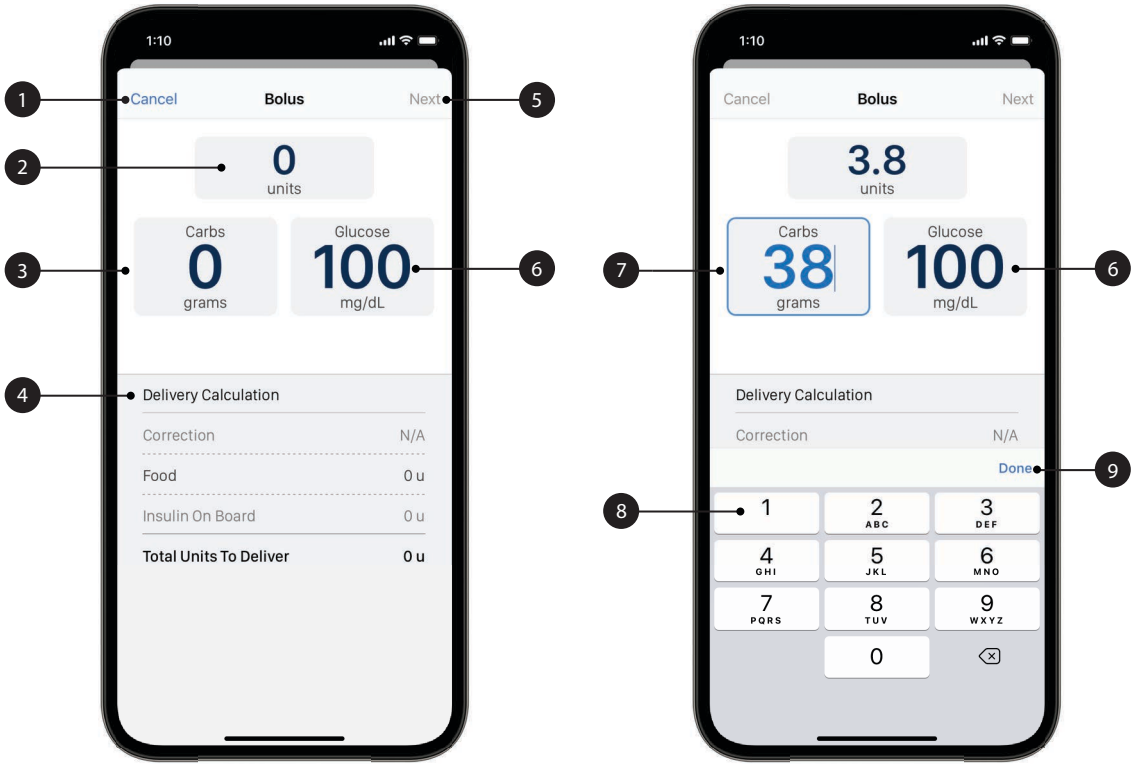
14. Settings: Navigate to the settings screen, including Glucose Thresholds for Display, App Notification Settings, Data Control settings, Tandem account information, pump pairing and unpairing, About, and Help.


12:15
100%
Refreshed just now
235 u
132
mg/dL
Insulin On Board
2.3 u
400
180
80
50
148
140
4.4
1.3
1.25
1 u/hr
2.5
1
8 AM
10 AM
12:15 PM
CGM Data by [CGM Provider]
Time in Range
Past 24 hr (80-180 mg/dL)
82%
Current Status
Dashboard
Bolus
Notifications
Settings
1
2
3
4
5
6
7
8
9
10
CGM Data by [CGM Provider]
Time in Range
Past 24 hr (80-180 mg/dL)
82%
Current Status
Basal Rate
1 u/hr
Last Bolus
Standard/Correction
Nov 14 – 12:15 PM
2.5 u
Control-IQ
ON
Profile
12:00 PM – 10:00 PM
Weekend
Carbohydrates
ON
Correction Factor
1 u : 50 mg/dL
Carb Ratio
1 u : 10 g
Target BG
110 mg/dL
Insulin Duration
5 hr
Last Calibration
Nov 14
N/A
Time Sensor Started
Nov 14
7:06 AM
Transmitter Battery
OK
Dashboard
Bolus
Notifications
Settings
7
11
12
13
14

4.9 Tandem t:slim Mobile App Bolus Screen

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

   NOTE
   For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's user guide. You can also see Section 25.3 Rate of Change Arrows.
7. Carbs: Enter grams of carbohydrate. You may change this setting on the pump to use units of insulin. See Section 8.9 Quick Bolus for more information.
8. Keypad Numbers.
9. Done: Completes task and saves information entered.

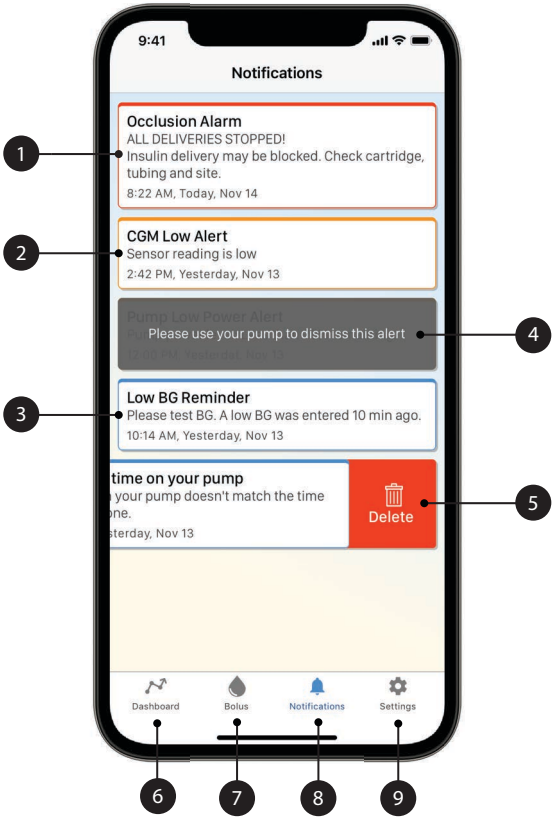

1:10
Cancel
Bolus
Next
0
units
Carbs
0
grams
Glucose
100
mg/dL
Delivery Calculation
Correction
N/A
Food
0 u
Insulin On Board
0 u
Total Units To Deliver
0 u
1
2
3
4
5
6
1:10
Cancel
Bolus
Next
3.8
units
Carbs
38
grams
Glucose
100
mg/dL
Delivery Calculation
Correction
N/A
Done
1
2 ABC
3 DEF
4 GHI
5 JKL
6 MNO
7 PQRS
8 TUV
9 WXYZ
0
6
7
8
9

4.10 Tandem t:slim Mobile App Notifications Screen

⚠ PRECAUTION

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

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


9:41
Notifications
Occlusion Alarm
ALL DELIVERIES STOPPED!
Insulin delivery may be blocked. Check cartridge, tubing and site.
8:22 AM, Today, Nov 14
CGM Low Alert
Sensor reading is low
2:42 PM, Yesterday, Nov 13
Please use your pump to dismiss this alert
Low BG Reminder
Please test BG. A low BG was entered 10 min ago.
10:14 AM, Yesterday, Nov 13
Delete
Dashboard
Bolus
Notifications
Settings
1
2
3
4
5
6
7
8
9

4.11 Tandem t:slim Mobile App Settings

1. CGM: View CGM information for the current sensor session.

2. Alerts & Sounds: Turn push notifications on or off (e.g., pump alerts and alarms, CGM alerts and errors) and directly access smartphone operating system settings relevant to the Tandem t:slim mobile app (e.g., whether to allow cellular data use to upload data).

3. App: View account information, paired pump information, data control, graph display settings, pump and CGM history, and additional information about Tandem and corporate policies.

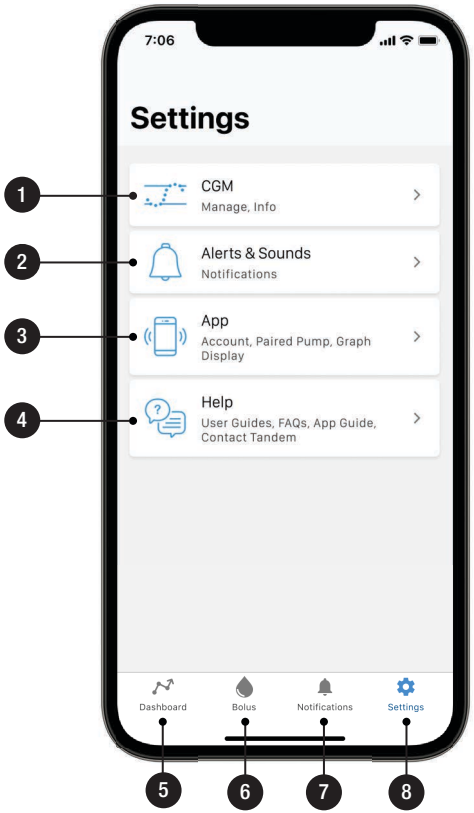
4. Help: Access in-app help information, including FAQs, the pump user guide, an Icons and Graphics Glossary, and an App Guide that includes information on smartphone compatibility, setting up your smartphone, and troubleshooting information.

5. Dashboard: Displays pump status bar, current glucose reading, IOB status, CGM graph, time in range information, and current status.

6. Bolus: Navigate to the *Bolus* screen to program and deliver a bolus (only available with compatible devices).

7. Notifications: Displays active pump alerts, alarms, reminders, and malfunctions. See Section 4.4 Set Mobile Notifications for more information.

8. Settings: Navigate to the *settings* screen, including CGM information, app notification settings, settings related to the Tandem t:slim mobile app itself, and Help.


7:06
Settings
CGM
Manage, Info
Alerts & Sounds
Notifications
App
Account, Paired Pump, Graph Display
Help
User Guides, FAQs, App Guide, Contact Tandem
Dashboard
Bolus
Notifications
Settings
1
2
3
4
5
6
7
8

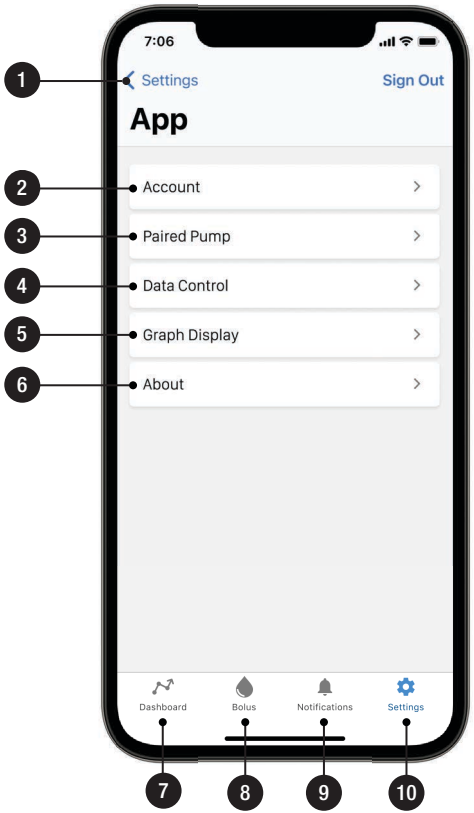
4.12 Tandem t:slim Mobile App Settings – App Screen

1. Settings: Return to the *Settings* screen.
2. Account: Update account information, including your name, date of birth, email address, and security question.
3. Paired Pump: View and manage which pump is paired with your Tandem t:slim mobile app.

   NOTE

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

4. Data Control: Control Tandem t:slim mobile app data usage.
5. Graph Display: Update glucose charting targets as well as cartridge and infusion set change frequency.
6. About: Access additional information, including various product identifiers, links to important safety information, consent statements, and instructions for use.
7. Dashboard: Displays pump status bar, current glucose reading, IOB status, CGM graph, time in range information, and current status.
8. Bolus: Navigate to the *Bolus* screen to program and deliver a bolus (only available with compatible devices).
9. Notifications: Displays active pump alerts, alarms, reminders, and malfunctions. See Section 4.4 Set Mobile Notifications for more information.
10. Settings: Navigate to the *settings* screen, including CGM information, app notification settings, settings related to the Tandem t:slim mobile app itself, and Help.


7:06
Settings
Sign Out
App
Account
Paired Pump
Data Control
Graph Display
About
Dashboard
Bolus
Notifications
Settings
1
2
3
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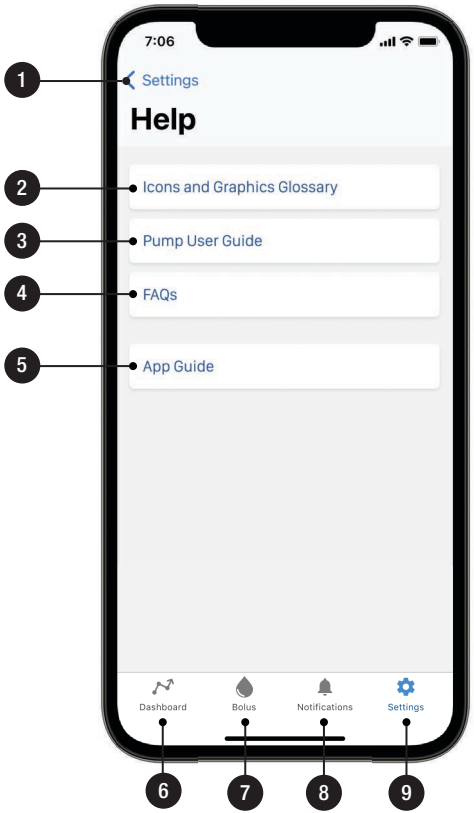
9
10

4.13 Tandem t:slim Mobile App Settings – Help Screen

1. Settings: Return to the *Settings* screen.
2. Icons and Graphics Glossary: View a glossary of icons and symbols you may find in the Tandem t:slim mobile app.
3. Pump User Guide Control: View the latest pump user guide in a separate browser window.
4. FAQs: View mobile app help articles in a separate browser window.
5. App Guide: View app usage information, including smartphone compatibility, setting up your smartphone, and troubleshooting information.
6. Dashboard: Displays pump status bar, current glucose reading, IOB status, CGM graph, time in range information, and current status.
7. Bolus: Navigate to the *Bolus* screen to program and deliver a bolus (only available with compatible devices).
8. Notifications: Displays active pump alerts, alarms, reminders, and malfunctions. See Section 4.4 Set Mobile Notifications for more information.
9. Settings: Navigate to the *settings* screen, including CGM information, app notification settings, settings related to the Tandem t:slim mobile app itself, and Help.


7:06
Settings
Help
Icons and Graphics Glossary
Pump User Guide
FAQs
App Guide
Dashboard
Bolus
Notifications
Settings
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CHAPTER 5

Getting Started

5.1 Charging the t:slim X2 Pump

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

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

⚠ WARNING

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

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

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

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

⚑ NOTE

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

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

⚠ PRECAUTION

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

⚑ NOTE

Keep the charging cable aligned with the pump USB port during charging. Tension on the charging cable could damage the pump.

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. Align the Tandem logo on the cable with the Tandem logo on the pump.

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

⚠ WARNING

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

1. Plug the USB cable into the car power USB adapter.

2. Plug the car power USB adapter into a grounded auxiliary power outlet.

3. Plug the other end of the cable into the micro USB port on the pump. Align the Tandem logo on the cable with the Tandem logo on the pump.

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

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

1. Plug the included USB cable into your computer.

2. Plug the other end of the cable into the micro USB port on the pump. Align the Tandem logo on the cable with the Tandem logo on the pump.

⚑ NOTE

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

Depending on your computer, charging time will vary. The pump will display a Connection Error Alert message if it is not charging properly.

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

⚠ WARNING

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

1. Plug the USB cable into the car power USB adapter.

2. Plug the car power USB adapter into a grounded auxiliary power outlet.

3. Plug the other end of the cable into the micro USB port on the pump. Align the Tandem logo on the cable with the Tandem logo on the pump.

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

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

⚠ PRECAUTION

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

5.2 Turning the Pump On

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

5.3 Using the Touchscreen

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

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

The pump has several safety features to prevent unintentional interaction with the touchscreen. The screen must be unlocked by tapping **1–2–3** in sequence. On all screens, if three non-active areas of the touchscreen are tapped before an active area is tapped, the screen will turn off to prevent accidental screen interactions. There is also a Security PIN feature that can be set up to prevent unintentional access. See Section 5.14 Turn Security PIN On or Off.

⚑ NOTE

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

5.4 Turning the t:slim X2 Pump Screen On

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

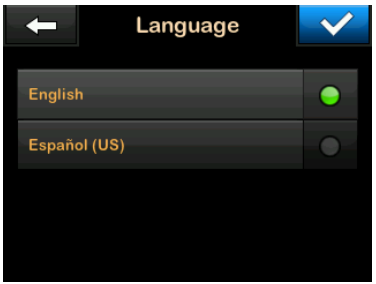
✓ The *Lock* screen will be displayed.

5.5 Selecting Your Language

The *Language Selection* screen displays when you unlock the pump screen for the first time, or when you unlock the screen after turning the pump off.

To select your language:

1. Tap the circle next to the language you want to display.



2. Tap ✓ to save the selection and continue with pump setup.

5.6 Turning the Pump Screen Off

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

NOTE

Always turn off the pump screen before placing the pump back in its case or any pocket/clothing. Always position the pump screen away from the skin.

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

5.7 Turning the Pump Off

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

5.8 Unlocking the t:slim X2 Pump Screen

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

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

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

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

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

5.9 Edit Time

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

⚠ PRECAUTION

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

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

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

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

5.10 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  .

5.11 Basal Limit

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

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

NOTE

If you are setting your Basal Limit after you have set any of your Personal Profiles, you cannot set your Basal Limit lower than any of your existing basal rates. See Section 6.3 Creating a New Profile.

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

5. Tap **Basal Limit**.

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

✓ A *SETTING SAVED* screen is temporarily displayed.

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

NOTE

When Control-IQ+™ technology is turned on, the Basal Limit may be exceeded if Control-IQ+ technology predicts that you will require more insulin to stay in your target range. Setting the Basal Limit does not affect the functionality of Control-IQ+ technology.

5.12 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 ✓.

5.13 Sound Volume

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

⚠ PRECAUTION

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

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

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

5.14 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  .

10. Tap  to enter a new Security PIN.

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

12. Tap  .

13. Tap  to verify your new Security PIN.

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

15. Tap  .

✓ A *PIN UPDATED* screen is displayed.

16. Tap  .

5.15 Mobile Connection

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

See Section 4.3 Connecting to a Smartphone for detailed instructions to pair or unpair your smartphone and your pump.

NOTE

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

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CHAPTER 6

Insulin Delivery Settings

6.1 Personal Profiles Overview

⚠ WARNING

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

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

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

⚑ NOTE

In order to turn on Control-IQ+™ technology, the Timed Settings must be complete for every time segment, and the Carbohydrates setting must be turned on in the Bolus Settings.

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

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

⚑ NOTE

Some of the Personal Profile settings are overridden when Control-IQ+ technology is turned on. See Chapter 30 Introduction to Control-IQ+ Technology.

When you create a Personal Profile, you can set any or all of the following Timed Settings:

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

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

The ranges you can set for Timed Settings are:

- Basal (range: 0 and 0.1 to 15 units/hour)

  ⚠ WARNING
  Control-IQ+ technology reverts to your normal basal rate when the pump has not received a CGM reading for 20 minutes. For example, when the pump and CGM are out of range, during the sensor startup period, when a sensor session ends, or when there is a transmitter or sensor error.

  ⚑ NOTE
  The Basal Rate may not exceed the Basal Limit set in Pump Settings (Section 5.11 Basal Limit). If you are setting your Basal Limit after you have set any of your Personal Profiles, you cannot set your Basal Limit lower than any of your existing Basal Rates.

- Correction Factor (range: 1 unit:1 mg/dL to 1 unit:600 mg/dL)
- Carb Ratio (range: 1 unit:1 gram to 1 unit:300 grams)

  Below a Carb Ratio of 1:10, increments can be entered in 0.1 gram. For example a Carb Ratio of 1:8.2 can be programmed.

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

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

- Insulin Duration (amount of time that insulin is active and available in the body after a bolus has been delivered)
- Carbs (ON indicates entering grams of Carb; OFF indicates entering units of insulin)

  ⚑ NOTE
  Changing the Carbs setting on the pump changes the bolus calculators on both the pump and the Tandem t:slim™ mobile app.

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

- Insulin Duration (default: 5 hours; range: 2 to 8 hours)

  ⚑ NOTE
  When using Control-IQ+ technology, the insulin duration is set to five hours and cannot be changed. This duration is used for all bolus deliveries as well as for basal adjustments made by Control-IQ+ technology.

- Carbs (default: dependent on pump history)

  ⚑ NOTE
  If you received a new pump with Control-IQ+ technology, the default setting will be on. If you updated your pump, the default setting will be the same as what you set up on your pump previously. Check to ensure that the Carbs setting is on in order to use Control-IQ+ technology.

Insulin Duration and Insulin on Board (IOB)

Your pump remembers how much insulin your pump has delivered from boluses. It does this by relying on the insulin duration. The insulin duration reflects the amount of time that insulin is actively lowering your BG.

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

delivery calculations when applicable. When a glucose value is entered during bolus programming, your pump will consider any active IOB and adjusts the calculated bolus if necessary.

The insulin duration time is displayed on the *Home* screen when Control-IQ+ technology is not enabled.

Consult your healthcare provider to accurately set your insulin duration.

If you have Control-IQ+ technology enabled, IOB includes all basal delivered above and below the programmed Basal Rate, in addition to all bolus insulin delivered. The insulin duration time is not displayed on the *Home* screen.

Insulin duration is set to 5 hours when Control-IQ+ technology is enabled and cannot be changed.

6.2 Creating Your First Profile

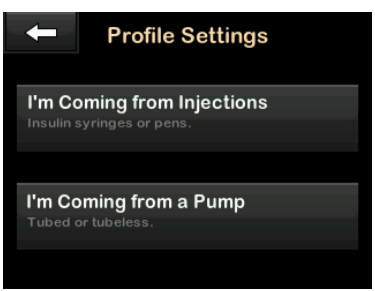
If you are currently using insulin injections, you can create your starting profile using the Profile Settings calculator. The Profile Settings calculator uses your weight and your Total Daily Insulin to create your profile.

NOTE

The Profile Settings calculator is only available for first time set-up of a new pump. This feature cannot be accessed after initial profile set-up.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap + to create a new profile.

✓ The *Profile Settings* screen appears.

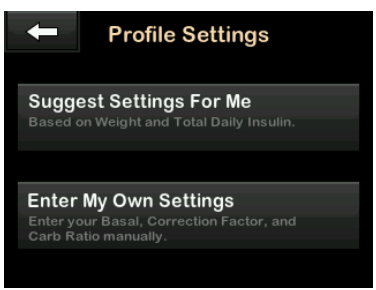


- If you tap **I'm Coming from Injections**, you can either create your own profile by tapping **Enter My Own Settings** or use the pump's default settings by tapping **Suggest Settings for Me**.
- If you tap **I'm Coming from a Pump**, you will create and enter your first profile as described in Section 6.3 Creating a New Profile.

Profile Settings

To use the Profile Settings calculator to create your first profile:

1. Tap **Suggest Settings for Me**.



2. Using the on-screen keypad, enter a profile name (up to 16 characters) and tap ✓.
3. Tap **Weight**.
4. Tap **Pounds** or **Kilograms** to set the unit of weight.
5. Tap ✓.
6. Use the on-screen keypad to enter the weight value. Weight can be set from a minimum of 1 pound or kilogram to a maximum of 999 pounds or kilograms.
7. Tap ✓.
8. Tap **Total Daily Insulin**.
9. Use the numeric keypad to enter the total units of insulin typically required in a 24-hour period. Total Daily Insulin can be set from a minimum of 1 unit to a maximum of 999 units. This amount needs to include both long acting and rapid insulin.

NOTE

The values entered in the profile settings screen for weight and TDI are separate from the values entered for weight and TDI for Control-IQ+ technology. See Chapter 31 Configuring and Using Control-IQ+ Technology for instructions on activating Control-IQ+ technology.

NOTE

If the values entered for weight or TDI result in a Basal Rate, Correction Factor, or Carb Ratio that fall outside the pump's allowable ranges, no profile will be created, and a message will direct you to contact your Tandem trainer or doctor for further guidance. See Section 6.1 Personal Profiles Overview for allowable Basal Rate, Correction Factor, and Carb Ratio ranges.

10. Tap ✓.
11. Tap ✓ to save weight and TDI settings.

✓ The *CREATING PROFILE SETTINGS* screen is temporarily displayed.

⚠ PRECAUTION

The Profile Settings feature is meant to work with TDI based on injection therapy. Do not use the Profile Settings feature if you are coming from pump therapy. Using the Profile Settings feature with a TDI from existing pump therapy can result in under-delivery of insulin and could lead to hyperglycemia (high BG). Always test your BG as needed.

Enter All Settings

To enter pump settings provided by your health care provider to create your first profile:

1. Tap **Enter My Own Settings**.
2. Using the on-screen keypad, enter a profile name (up to 16 characters) and tap ✓.
3. Tap **Press to Set Up**.
4. Program your pump settings as shown in Section 6.4 Programming a New Personal Profile.

6.3 Creating a New Profile

Creating Personal Profiles

You can create up to six Personal Profiles; however, only one can be

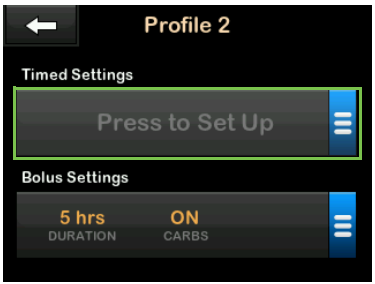
active at a time. In the *Personal Profiles* screen, the active profile is positioned at the top of the list and is marked as ON.

Consult your healthcare provider to accurately set Personal Profile settings.

To create a new personal profile:

1. From the *Home* screen, tap OPTIONS.
2. Tap My Pump.
3. Tap Personal Profiles.
4. Tap + to create a new profile.
5. Using the on-screen keypad, enter a profile name (up to 16 characters) and tap ✓.

   To use the letter keypad, tap once for first letter displayed, two quick taps for middle letter; and three quick taps for the third letter.
6. Tap Press to Set Up to begin setting insulin delivery settings.



6.4 Programming a New Personal Profile

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

- You must program a Basal Rate in order to have a Personal Profile that you can activate.
- You must have Carbs turned on, and you must set a Basal Rate, Correction Factor, Carb Ratio, and Target BG in order to turn Control-IQ+ technology on.
- Be sure to tap ✓ after entering or changing a value.

⚠ PRECAUTION

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

Timed Settings

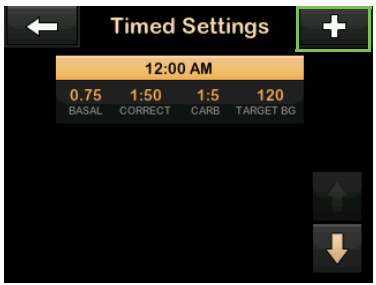
1. Once the new profile has been created, tap **Basal**.
2. Using the on-screen keypad, enter your Basal Rate and tap ✓.

   NOTE

   If you have previously set a Basal Limit in the Pump Settings, then the Basal Rate entered here must be lower than the Basal Limit entered in the Pump Settings.
3. Tap **Correction Factor**.
4. Using the on-screen keypad, enter your Correction Factor and tap ✓.
5. Tap **Carb Ratio**.
6. Using the on-screen keypad, enter your Carb Ratio and tap ✓.
7. Tap **Target BG**.
8. Using the on-screen keypad, enter your Target BG and tap ✓.

   NOTE

   Once Control-IQ+ technology is turned on, the default Target BG is set to 110 mg/dL. For details about target ranges and how Control-IQ+ technology works, see Chapter 30 Introduction to Control-IQ+ Technology.
9. Review entered values and tap ✓.
10. Confirm Settings.
    - Tap ✓ if entered data is correct.
    - Tap ✗ to make changes.
11. Tap ← to set the Bolus Settings, or tap + to create additional time segments.



Adding More Time Segments

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

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

3. On the *Add Segment* screen, tap **Time of Day** to select AM or PM, if applicable.

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

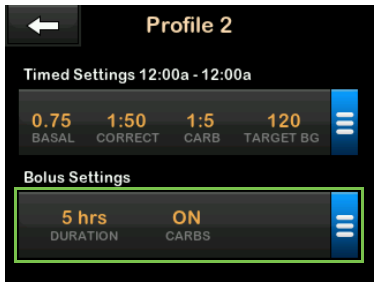
4. Tap ✔.

5. Repeat steps 1 to 11 from Timed Settings for each segment you want to create (up to 16).

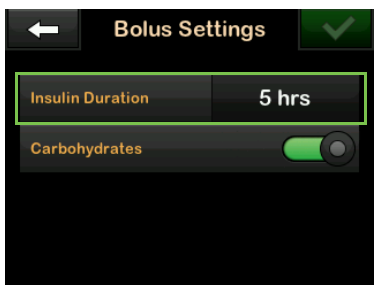
   To find time segments in the list that are not displayed on the first screen, tap the **Down Arrow**.

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 hours) and tap ✔.

4. Review entered values and tap ✔.

5. Confirm Settings.

   - Tap ✔ if entered data is correct.
   - Tap ✖ to make changes.

Adding More Personal Profiles

If you want to add a profile that shares settings with an existing profile, see Section 6.6 Duplicating an Existing Profile.

6.5 Editing or Reviewing an Existing Profile

1. From the *Home* screen, tap **OPTIONS** then tap **My Pump**, then tap **Personal Profiles**, and then tap the name of the Personal Profile to edit or review.

2. Tap **Edit**.

NOTE

To review settings without editing, 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.

3. Tap **Timed Settings** panel.
4. Tap the desired time segment to edit.
5. Tap **Basal**, **Correction Factor**, **Carb Ratio** or **Target BG** to make changes as needed and use the on-screen keypad to enter changes. Tap  .
6. View recent changes and tap  .
7. Confirm Settings.
   - Tap  if entered data is correct.
   - Tap  to make changes.
8. Edit other time segments within the Timed Settings by tapping on them and repeating steps 4 – 7.
9. Tap  after editing all of the time segments.
10. Tap the **Bolus Settings** panel to change Insulin Duration Carbohydrates as needed. Use the on-screen keypad to enter desired changes. Tap  .
11. Confirm Settings.
    - Tap  if entered data is correct.
    - Tap  and make changes.

NOTE

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

NOTE

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

6.6 Duplicating an Existing Profile

1. From the *Home* screen, tap **OPTIONS**, then tap **My Pump,** then tap **Personal Profiles,** and then tap the name of the Personal Profile to duplicate.
2. Tap **Duplicate**.
3. Confirm profile to duplicate by tapping  .
4. 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 duplicated profile.

5. Tap the **Timed Settings** or **Bolus Settings** panel to make changes to the new profile.

6.7 Activating an Existing Profile

1. From the *Home* screen, tap **OPTIONS**, then tap **My Pump,** then tap **Personal Profiles,** and then tap the name of the Personal Profile to be activated.
   - The Activate and Delete options are disabled for the active profile

because the profile is already activated. You cannot delete a profile until you have activated another profile.

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

2. Tap **Activate**.

✓ A screen to confirm the activation request is displayed.

3. Tap  .

✓ *PROFILE ACTIVATED* screen is displayed.

6.8 Renaming an Existing Profile

1. From the *Home* screen, tap **OPTIONS**, then tap **My Pump**, then tap **Personal Profiles**, and then tap the name of the Personal Profile to be renamed.

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

3. Using the on-screen keypad, rename the profile name (up to 16 characters) and tap  .

6.9 Deleting an Existing Profile

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

NOTE

The active Personal Profile cannot be deleted.

2. Tap **Delete**.

3. Tap  .

✓ *PROFILE DELETED* screen is displayed.

6.10 Starting a Temporary Basal Rate

A Temp Rate is used to change, by percentage, the current Basal Rate by percentage for a period of time. This feature can be helpful for situations such as exercise or illness.

The default values for the Temp Rate are 100% (current Basal Rate) and a Duration of 15 minutes. 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/hour, 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/hour, or more than your Basal Limit set up in the Pump Settings, you will be notified that the selected rate is too high and that it will be reduced so that it does not exceed the maximum allowable rate for delivery.

1. From the *Home* screen, tap **OPTIONS**, then tap **Activity**, then tap **Temp Rate**, then tap **Temp Rate** again.

2. 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%.

3. Tap  .

4. 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.

5. Verify settings and tap  .

✓ The *TEMP RATE STARTED* screen is temporarily displayed.

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

- An T in an orange box means a Temp Rate is active.
- A T in a red box means a Temp Rate of 0 u/hr is active.

NOTE

If a Temp Rate is active when you stop insulin, including when you change a cartridge or infusion set, the Temp Rate timer will remain active. The Temp Rate will be resumed when insulin delivery is resumed as long as there is time remaining on the Temp Rate timer.

6.11 Stopping a Temp Rate

To stop an active Temp Rate:

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

2. Tap **Activity**.

3. On the *Activity* screen, tap  on the right side of Temp Rate.

4. On the confirmation screen, tap  .

✓ The *TEMP RATE STOPPED* screen appears before returning to the *Activity* screen.

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CHAPTER 7

Infusion Site Care and Loading Cartridge

7.1 Infusion Site Selection and Care

⚠ 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
ONLY use infusion sets that are 23, 32, or 43 inches in length and approved for use with the t:slim X2 pump. **NEVER** use the 5-inch AutoSoft XC infusion set with the t:slim X2.

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

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

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

⚠ PRECAUTION
CHECK your infusion site daily for proper placement and leaks. **REPLACE** your infusion set if you notice leaks around the site, or if you suspect your infusion set cannula may have become dislodged. Improperly placed sites or leaks around the infusion site can result in under delivery of insulin.

General Guidelines

Site Selection

- Your infusion set can be worn anywhere on your body that you would normally inject insulin. Absorption varies from site to site. Discuss options with your healthcare provider.
- The most commonly used sites are the abdomen, upper buttocks, hips, upper arms, and upper legs.
- The abdomen is the most popular site because of access to fatty tissue. If using the abdominal area, **AVOID**:
  - Areas that would constrict the site such as the belt line, waistline, or where you would normally bend.
  - Areas 2 inches (5 cm) around your belly button.
- **AVOID** sites with any scars, moles, stretch marks, or tattoos.
- **AVOID** site areas within 3 inches (7.6 cm) of your CGM sensor site.

Site Rotation

⚠ PRECAUTION
CHANGE your infusion set every 48 hours if using Humalog insulin; every 72 hours if using NovoLog insulin. Wash your hands with anti-bacterial soap before handling the infusion

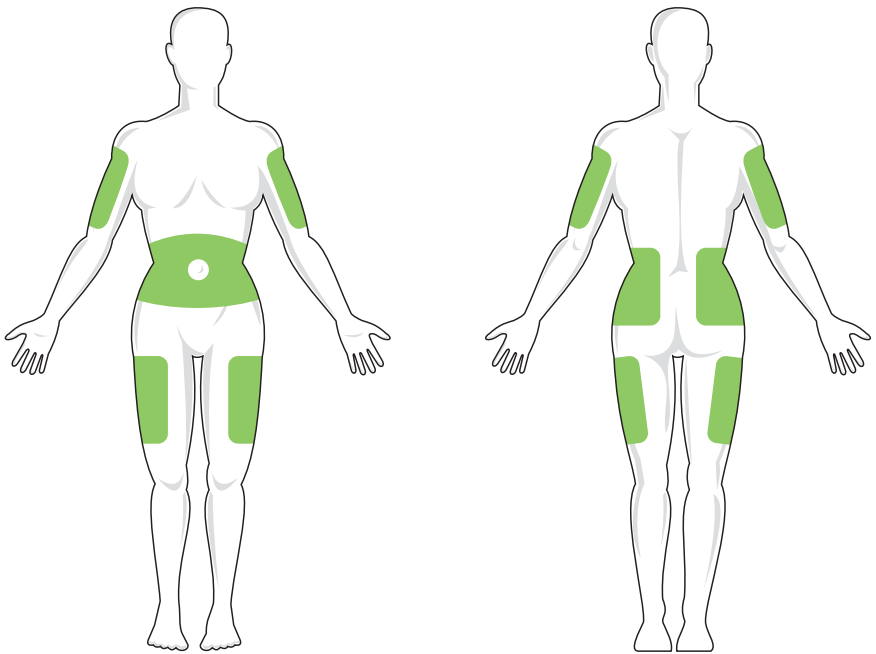
set and thoroughly clean the insertion site on your body to avoid infection. Contact your healthcare provider if you have symptoms of infection at your insulin infusion site.

- The infusion set must be replaced and rotated every 48 hours if using Humalog insulin; every 72 hours if using NovoLog insulin, or more often if needed.
- With experience, you will find areas that not only provide better absorption, but are more comfortable. Keep in mind, using the same areas may cause scarring or lumps which can affect insulin absorption.
- Consult your healthcare provider to establish a rotation schedule that best fits your needs.

Keep it Clean

- When changing your infusion set, use clean techniques to avoid an infection.
- Wash your hands, use antiseptic wipes or infusion site preparation products, and keep the area clean.

Areas of Body for Infusion Set Insertion



- Site preparation products that have both an antiseptic and an adhesive are encouraged.

7.2 Cartridge Instructions for Use

For complete cartridge labeling, consult the cartridge instructions for use included in the t:slim™ cartridge box.

7.3 Filling and Loading a t:slim X2 Cartridge

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

⚠ WARNING

ONLY use U-100 insulin analogs that have been tested and found to be compatible for use in the pump, listed in Section 1.6 Compatible Insulins. Use of insulin with greater or lesser concentration can result in an over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

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

⚠ WARNING

DO NOT reuse cartridges. Reuse of cartridges may result in over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ 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 changing the cartridge or filling the tubing. Failure to disconnect your infusion set from your body before changing the cartridge or filling the tubing can result in over delivery of insulin. This can cause hypoglycemia (low BG) events.

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

- 1 unopened cartridge
- 3.0 mL syringe and fill needle
- one vial of compatible insulin, listed in Section 1.6 Compatible Insulins
- alcohol prep swab
- 1 new infusion set
- infusion set instructions for use

⚑ NOTE

The pump will beep or vibrate, depending on your pump settings, while the tubing is filling with insulin. To change the Fill Tubing sound setting, see Section 5.13 Sound Volume.

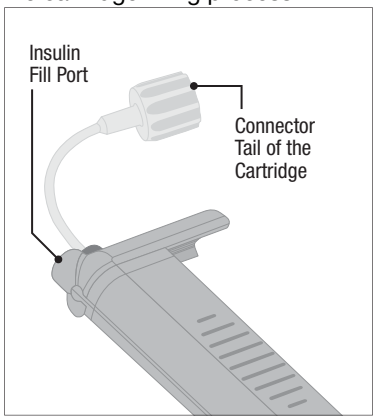
⚑ NOTE

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

⚑ NOTE

Control-IQ+™ technology will continue to make calculations based on CGM values while the cartridge is being filled. Since there is no insulin delivered during the cartridge fill process, there will be no actual Basal Rate adjustments until the cartridge is filled and loaded back onto the pump. Control-IQ+ technology will then immediately begin to operate normally.

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



⚠ PRECAUTION

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

Drawing Insulin from Vial into Syringe

⚠ PRECAUTION

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

The pump requires a minimum of 50 units of insulin in the cartridge after the load process is complete. To account for the insulin used while filling your infusion set tubing, add at least 45 units to the amount of insulin you want available for delivery. When drawing insulin into the syringe, we recommend including at least 120 units of insulin.

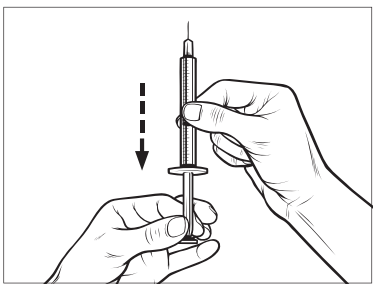
1. Inspect the needle and syringe package for any signs of damage. Discard any damaged product.

2. Wash your hands thoroughly.

3. Wipe the rubber septum of the insulin vial with an alcohol swab.

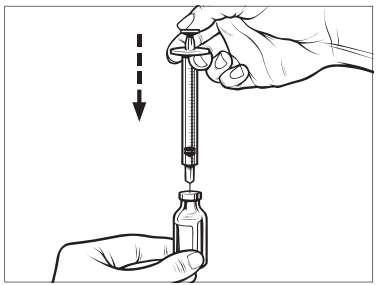
4. Remove the needle and syringe from their packaging. Securely twist needle onto syringe. Safely remove protective cap from needle by pulling outward.

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



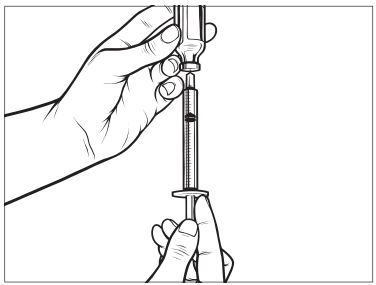
6. With insulin vial upright, insert needle into vial. Inject air from

syringe into vial. Maintain pressure on syringe plunger.

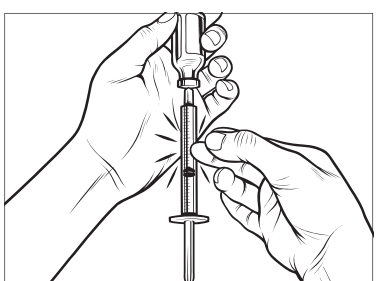


7. With needle still inserted into vial, turn vial and syringe upside down. Release syringe plunger. Insulin will begin to flow from the vial into the syringe.

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:

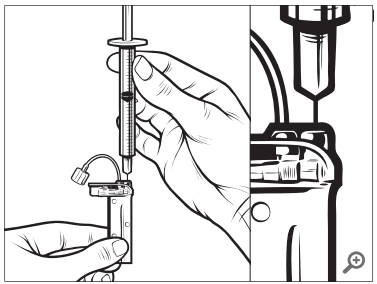
    - If there are air bubbles present, repeat step 9.
    - If no air bubbles are present, remove the filling needle from the vial.

Filling the Cartridge

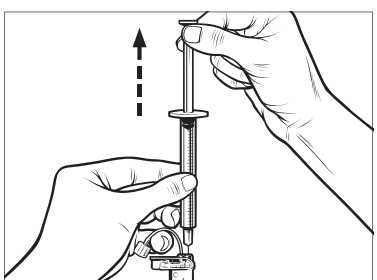
1. Inspect the cartridge package for any signs of damage. Discard any damaged product.

2. Open the package and remove the cartridge.

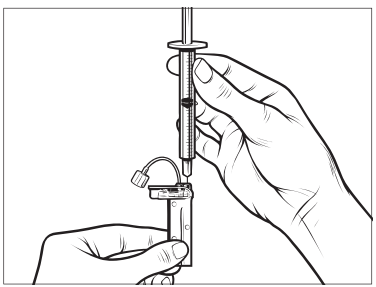
3. Hold the cartridge upright and gently insert the needle into the white insulin fill port on the cartridge. The needle is not intended to go all the way in, so do not force it.



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.

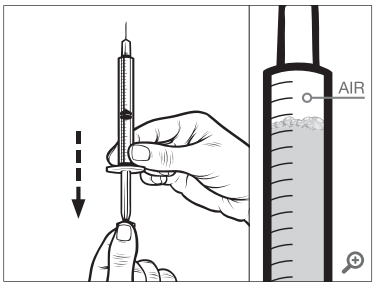


5. Make sure the needle is still in the fill port and release the plunger. Pressure will pull the plunger to its neutral position but it will NOT push any air back inside the cartridge.

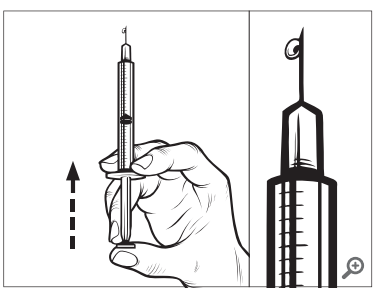


6. Withdraw the needle from the fill port.

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.

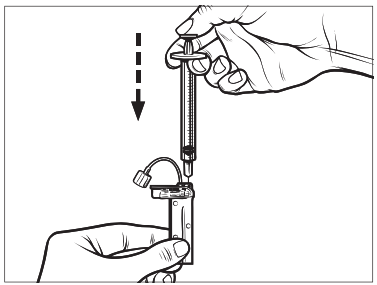


8. Gently press on the plunger to remove air bubbles until insulin fills the needle hub and you see a drop of insulin at the tip of the needle.



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 local regulations.

7.4 Loading a Cartridge

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

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

2. Tap **Load**.

   During the load sequence, the **Tandem logo** is disabled. Tapping it will not return to the *Home* screen.

3. Tap **Change Cartridge**.

4. A screen will display to notify you that all insulin deliveries will be stopped. Tap ✔ to continue.

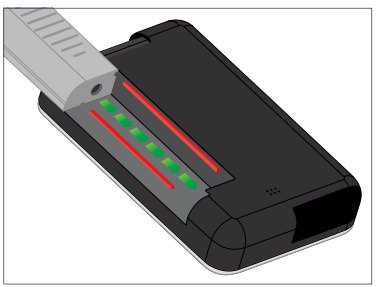
   NOTE
   This screen will not be displayed if this is the first time loading a new cartridge and you have not started actively pumping.

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

✓ *PREPARING FOR CARTRIDGE* screen is displayed.

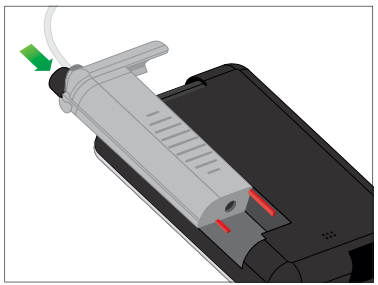
6. Remove the used cartridge. If needed, place the cartridge removal tool or the edge of a coin in the slot at the bottom of the cartridge and twist to aid in the removal of the cartridge.

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



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

cartridge onto the pump. Tap the UNLOCK icon when completed.



9. Tap ✓ to continue.

✓ *DETECTING CARTRIDGE* screen is displayed.

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

10. Tap OK to fill the tubing. See Section 7.5 Filling Tubing.

⚠ WARNING

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

7.5 Filling Tubing

⚠ WARNING

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

⚠ WARNING

ONLY use infusion sets that are 23, 32, or 43 inches in length and approved for use with the t:slim X2 pump. **NEVER** use the 5-inch AutoSoft XC infusion set with the t:slim X2.

⚑ NOTE

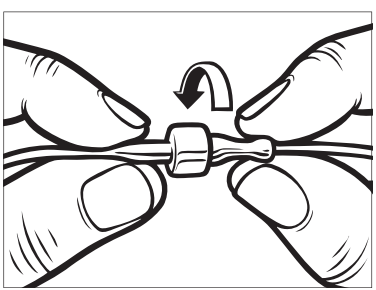
The pump will beep or vibrate, depending on your pump settings, while the tubing is filling with insulin. To change the Fill Tubing sound setting, see Section 5.13 Sound Volume.

To fill the tubing:

1. Confirm the infusion set is not connected to your body.

2. Ensure that the new infusion set package is not damaged, and remove the sterile tubing from the package. If the package is damaged or opened, discard properly and use another tubing set. Be careful to keep the tubing connector away from unclean areas.

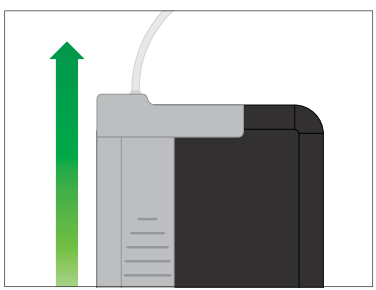
3. Attach the infusion set tubing to the tubing connector on the cartridge tubing. Twist clockwise until finger tight.



⚠ WARNING

ALWAYS ensure there is a tight connection between the cartridge tubing and the infusion set tubing. A loose connection can cause insulin to leak, resulting in under delivery of insulin. This can cause hyperglycemia (high BG) events.

4. Hold the pump vertically to ensure any air in the cartridge will be dispelled first. Tap **START**. The pump will beep and vibrate regularly while the tubing is being filled, depending on your Sound Volume settings.



✓ *STARTING FILL* screen is displayed.

⚑ NOTE

The tubing must be filled with a minimum of 10 units of insulin during each fill cycle.

5. Tap **STOP** after 3 drops of insulin are seen at the end of the infusion set tubing.

✓ *STOPPING FILL* screen is displayed.

✓ *DETECTING INSULIN* screen is displayed.

6. Verify that drops are seen and tap **DONE**. If you want to insert your infusion set, see Section 7.7 Filling Cannula.

- If you do not see drops, tap **FILL**. The *Fill Tubing* screen appears. Repeat steps 4 and 5 until you see 3 drops of insulin at the end of the tubing.

⚑ NOTE

If you do not tap **STOP**, a notification screen will appear letting you know that the maximum amount of 30 units has been filled. Do one of the following:

» If you are finished filling the tubing, tap **DONE**. The *Fill Tubing is complete* screen is temporarily displayed.

» If you want to fill the tubing with more than 30 units, confirm the tubing is not connected to your body, then tap **FILL** to go back to the *Fill Tubing* screen and repeat step 4.

✓ A screen will display to instruct you to insert a new infusion set and connect to the filled tubing.

7.6 Filling Tubing without Changing the Cartridge

To fill the tubing without changing the cartridge:

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Load**.
3. Tap **Fill Tubing**.
4. A screen will display to notify you that all insulin deliveries will be stopped. Tap ✔.

5. Confirm that the tubing is disconnected from your body and tap ✓ to continue.

6. Tap **FILL** if you did not install a new cartridge and want to fill the tubing.

7. Proceed to Section 7.5 Filling Tubing.

⚠ PRECAUTION

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

7.7 Filling Cannula

⚑ NOTE

If you are inserting a steel needle infusion set, carefully follow the instructions for use accompanying your infusion set and skip this section. Steel needle infusion sets do not have a cannula.

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.

To Fill the Cannula:

1. Insert a new infusion set according to the instructions for use accompanying your infusion set.

2. Connect the filled tubing to your infusion site.

3. Tap **Fill Cannula**.

4. Tap ✓.

5. Tap **Edit Fill Amount**.

✓ The cannula fill amount displayed is based on your last cannula fill amount. Filling stops at this amount.

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

7. Tap **START**.

✓ The *STARTING FILL* screen is displayed.

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

⚑ NOTE

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

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

8. If the Site Reminder is turned off, the Load screen is displayed. Tap ✓ to resume insulin if finished, or tap **Site Reminder** to set reminder (see Section 7.8 Setting Site Reminder). Otherwise, skip to step 9.

9. If Site Reminder is turned on, the pump will automatically display the

Site Reminder screen (see the next section).

NOTE

After tubing fill is complete, when the pump returns to the *Home* screen, the insulin level displays an estimate of insulin in the cartridge (e.g., **+60 u** means that more than 60 units were detected in the cartridge).

After 10 units are delivered, the insulin level displays the actual number of units in the cartridge and the plus sign disappears.

The insulin level displayed will decrease 5 units at a time until 40 units remain. When less than 40 units remain, it will begin decreasing 1 unit at a time until there is 1 unit remaining.

7.8 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 settings are correct and skip to step 6. Tap **Edit Reminder** to change settings.
2. Tap **Remind Me In** and select the number of days (1–3).

✓ The default for the Site Reminder is set for 3 days

3. Tap **Remind Me At**. Use the on-screen keypad to enter time and tap ✓.
4. Tap **Time of Day** to change AM or PM, if applicable. Tap ✓.
5. Verify Site Reminder is set correctly and tap ✓.

✓ *SETTING SAVED* screen is displayed.

✓ *Load* screen is displayed.

6. Tap ✓.

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

7. Tap ✓.

NOTE

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

✓ *RESUMING INSULIN* screen is temporarily displayed.

NOTE

Control-IQ+ technology will continue to operate while changing a cartridge. If you complete a cartridge change and resume insulin while Control-IQ+ technology is adjusting insulin, insulin will resume until the next five minute CGM reading. At this time the pump will resume normal operation.

CHAPTER 8

Manual Bolus

8.1 Manual Bolus Overview

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

⚠ WARNING
Delivering large boluses, or delivering multiple boluses back to back may cause hypoglycemia (low BG) events. Pay attention to IOB and the bolus calculator recommended dose before delivering large or multiple boluses.

⚠ WARNING
If you have initiated a bolus and do not see a reduction in BG after an hour or more, it is recommended that you check your infusion set for an occlusion, air bubbles, or for leaks or cannula dislodgement. If the condition persists, call Customer Technical Support or seek medical attention as required.

⚑ NOTE
The information in this chapter does NOT apply to boluses delivered automatically by Control-IQ+™ technology. For information about Automatic Bolus Delivery, see Automatic Correction Bolus Delivery in Section 30.2 How Control-IQ+ Technology Works.

A bolus is a quick dose of insulin that is usually delivered to cover food eaten or to correct high glucose. A bolus can be requested from either the t:slim X2™ insulin pump or the Tandem t:slim™ mobile app.

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

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

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

If Carbs is turned on in your active Personal Profile, you will enter grams of carbohydrate and the bolus will be calculated using your Carb Ratio.

If you are not using Control-IQ+ technology and Carbs is turned off in your active Personal Profile, you will enter units of insulin to request the bolus.

⚑ NOTE
If you deliver a manual bolus, Control-IQ+ technology will not be able to deliver an automatic correction bolus until 60 minutes after the manual bolus has completed.

Before you use the Tandem t:slim mobile app to deliver a bolus, ensure your smartphone's security feature (e.g., screen lock, passcode, face recognition) is turned on. Never share your security PIN/password or authorize any other person to access your smartphone via their biometric

information to avoid unintentional changes in your delivery of insulin.

NOTE

If your smartphone is not connected to the pump, you can only request a bolus from the pump. For more information on establishing a connection between your smartphone and the pump, see Section 4.3 Connecting to a Smartphone.

⚠ PRECAUTION

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

8.2 Initiating a Bolus

To request a bolus, tap **BOLUS** on your pump's *Home* screen or tap **Bolus** from the *Navigation* bar in the Tandem t:slim mobile app.

⚠ WARNING

You have 10 seconds to cancel a bolus after requesting it to completely avoid insulin delivery; both the pump and the Tandem t:slim mobile app will say "requesting bolus" during this time. See Section 8.10 Canceling or Stopping a Bolus Using the Pump or Section 8.15 Canceling or Stopping a Bolus Using the Tandem t:slim Mobile App for instructions to cancel a bolus.

You can request a bolus using the Tandem t:slim mobile app when each of the following conditions are true:

- You have a compatible smartphone (see tandemdiabetes.com/mobilesupport)
- Your smartphone is connected to your pump
- You have a native security feature of your smartphone turned on

See Section 8.11 Bolus Delivery Using the Tandem t:slim Mobile App for further instructions to use the Tandem t:slim mobile app to request a bolus.

8.3 Correction Bolus Calculation

Once the pump knows your glucose value, it will determine whether to recommend that a correction bolus to be added to any other bolus requested on the *Bolus* screen. The pump can receive your glucose value from manual entry into the pump or the CGM.

When your glucose value is:

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

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

Glucose Value Auto-Population with CGM

⚠ PRECAUTION

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

When using a compatible CGM, there is no need to take a fingerstick to make a treatment decision, as long as your symptoms match the CGM readings. The t:slim X2 insulin pump and the Tandem t:slim mobile app can automatically use CGM readings in their respective bolus calculators when Control-IQ+ technology is enabled and there is a valid reading and trend arrow available from the CGM. If your CGM readings don't match your symptoms, it is recommended that you wash your hands thoroughly and use your BG meter to replace the CGM reading in the bolus calculator if the BG meter value matches your symptoms. If you want to align your Dexcom CGM with your BG meter, you should follow the instructions to calibrate your Dexcom CGM. Do not take insulin doses too close together, often referred to as stacking insulin. If you have recently given a bolus, you might wait 60 minutes to see if your readings respond to the bolus.

⚑ NOTE

Retrospective analysis of the pivotal study results indicated that there was an increased incidence of CGM values <70 mg/dL five hours after a bolus was delivered when glucose values were auto-populated. See Chapter 33 Overview of Control-IQ and Control-IQ+ Technology Clinical Studies for more information.

Your glucose value is automatically entered into the GLUCOSE field on the *Bolus* screen when each of the following conditions are true:

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

  ⚑ NOTE

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

- A CGM value is present

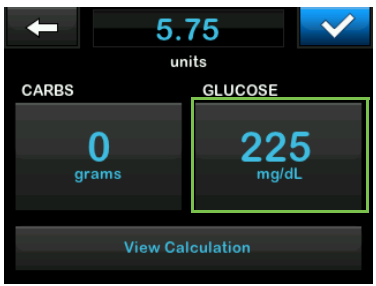
  ⚠ PRECAUTION

  Your sensor value is **NOT** automatically populated into the *Bolus* screen during the first 12 hours of wearing an Abbott FreeStyle Libre 2 Plus Sensor CGM. Check your BG to confirm your sensor values before making any treatment decisions.

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

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

To change the glucose value auto-populated from your CGM you can tap on the GLUCOSE value on the *Bolus* screen. The following example shows the *Bolus* screen on the pump.



NOTE

If the glucose value auto-populated from your CGM was above or below your Target BG, your pump will present you with the *Above Target* or *Below Target Correction Bolus* confirmation screen.

Correction Bolus Confirmation Screens

To access the *Correction Bolus* confirmation screen on the pump, tap **BOLUS** from the *CGM Home* screen.

- If your CGM value or trend arrow are not available on the *Home* screen, the *Bolus* screen appears.
- If you have a CGM value and trend arrow, the *Correction Bolus* confirmation screen appears (if appropriate).

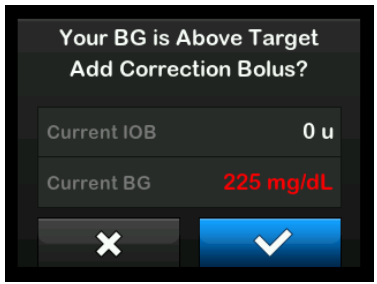
You cannot tap the **Current BG** value on these *Correction Bolus* confirmation screens to change the glucose value auto-populated from your CGM.

Tap either ✓ or ✗ and proceed to the *Bolus* screen to change the glucose value as described above. Once the value is changed, if the manually inputted value is above or below your Target BG, your pump will again present you with the *Above Target* or *Below Target* confirmation screen where you can choose to accept the correction bolus or decline it.

Above Target

If your glucose value is above your Target BG, you can calculate and add a correction bolus to any other bolus you request.

Calculate and add a correction bolus from the pump as follows:

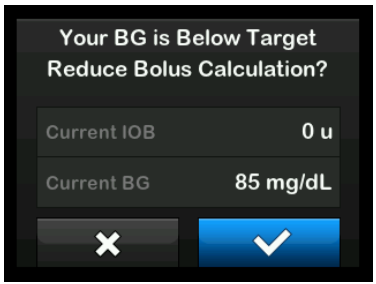


- To accept the correction bolus tap ✓. A correction bolus is calculated and will be added to any food bolus you request on the *Bolus* screen.
- To decline the correction bolus, tap ✗. No correction bolus will be added to any food bolus you request on the *Bolus* screen.

Below Target

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

correction bolus from any other bolus you request.



Calculate and apply a correction bolus from the pump as follows:

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

Within Target

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

BG Value Manual Entry

If your glucose value was not auto-populated on the *Bolus* screen based on the conditions needed for that feature, you will need to manually enter your BG value into the pump before confirming bolus delivery. The conditions needed for the auto-populate feature are:

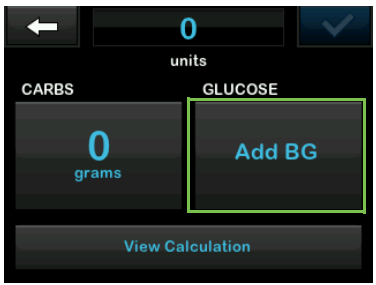
- Control-IQ+ technology is turned on and available
- A CGM session is active
- A CGM value is present
- A CGM trend arrow is available

NOTE

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

The *Correction Bolus* confirmation screens are displayed, if appropriate, after you manually enter your BG value on the *Bolus* screen. Manually enter your BG value into the pump as follows:

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



3. Using the on-screen keypad, enter your BG value.
4. Tap ✓ to save the BG value in your pump history.

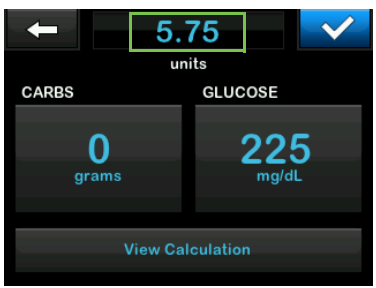
NOTE

This saves the BG value in your pump history whether or not a bolus is delivered.

5. Follow the steps in the appropriate Target section above depending on the results of your BG value.

8.4 Bolus Override

You can override the calculated bolus by tapping on the calculated units value and entering the units of insulin you want delivered. The bolus override is always an available option; the following example shows the bolus override on the pump screen.



8.5 Food Bolus Using Units

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

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

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

✓ The *BOLUS INITIATED* screen is temporarily displayed.

8.6 Food Bolus Using Grams

To deliver a food bolus using the pump:

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

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

6. Confirm Request.

   - Tap ✓ if entered data is correct.
   - Tap ✗ to go back to make changes or view calculations.

7. Tap ✓.

✓ The *BOLUS INITIATED* screen is temporarily displayed.

✓ After the bolus delivery is complete, an icon displays below the CGM graph.

NOTE

Each bolus icon represents one bolus delivery. Hash marks on the bolus bar denote time increments based on your graph settings; these hash marks may temporarily obstruct a bolus icon as the graph changes over time.

8.7 Extended Bolus

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

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

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

2. Tap **0 grams** (or **0 units**).

3. Use the on-screen keypad to enter grams of carb (or units of insulin). Tap ✓.

4. If desired, tap **Add BG**, use the on-screen keypad to enter a glucose value, and tap ✓.

5. Tap ✓ to confirm the units of insulin to be delivered.

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

6. Confirm Request.

   - Tap ✓ if entered data is correct.
   - Tap ✗ to go back to make changes or view calculations.

7. Tap **EXTENDED** to turn on the extended feature, then tap ✓.

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

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

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

   For the DELIVER NOW portion, the minimum amount the pump can deliver is 0.05 units. You may set this amount to 0 units if you would like the entire bolus to be delivered in the DELIVER LATER portion. Any amount entered between 0.00-0.05 units will automatically be rounded up to 0.05 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. You can choose between 15 minutes and 8 hours in one minute increments. Tap ✓.

12. Tap ✓.

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

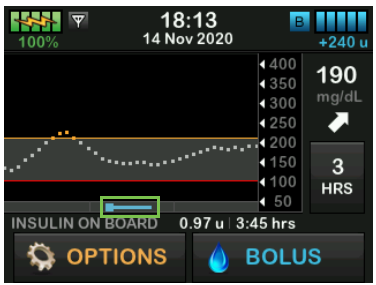
13. Confirm Request.

    - Tap ✓ if entered data is correct.
    - Tap ✗ to go back to make changes or view calculations.

14. Tap ✓.

✓ The *BOLUS INITIATED* screen is temporarily displayed.

✓ After the bolus delivery is complete, an icon displays below the CGM graph.



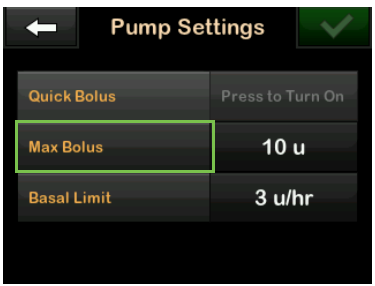
Only one extended bolus can be active at any given time. However, if the DELIVER LATER portion of an extended bolus is active, you can request another standard bolus.

8.8 Max Bolus

The Max Bolus setting allows you to set a limit to the maximum insulin delivery amount for a single bolus.

The default setting for Max Bolus is 10 units, but can be set to any value between 1 to 25 units. To adjust the Max Bolus setting, follow these steps.

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



6. Using the on-screen keypad, enter the desired amount for maximum bolus (1–25 units) and tap ✓.

NOTE

If you set the max bolus to 25 units and a bolus larger than 25 units is calculated using your Carb Ratio or Correction Factor, after the bolus is delivered a reminder screen will appear. The option of delivering the remaining amount of the bolus up to an additional 25 units will be given (see Section 13.9 Max Bolus Alerts). You must confirm delivery of this additional amount from your pump.

8.9 Quick Bolus

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

Quick Bolus can be set to correspond to either units of insulin or grams of carbohydrate. When Control-IQ+ technology is enabled, it will use the Quick Bolus as a correction bolus if configured as units of insulin, or as a food bolus if configured as grams of carbohydrate. Control-IQ+ technology uses the information about carbohydrate intake to optimize insulin delivery after eating.

Configure Quick Bolus

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

NOTE

It is recommended to use grams of carbohydrate in a bolus delivery whenever using Control-IQ+ technology.

1. From the *Home* screen, tap OPTIONS.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap **Pump Settings**.
5. Tap **Quick Bolus**.
6. Tap **Increment Type**.
7. Tap **units of insulin** or **grams of carbohydrate** to select. Tap ✓.
8. Tap **Increment Amount**.

9. Select the preferred increment amount.

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

10. Review entered values and tap  .

11. Confirm Settings.

    - Tap  if entered data is correct.
    - Tap  to go back to make changes.

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

Deliver a Quick Bolus

If the Quick Bolus function is turned on, you can deliver a bolus by pressing the **Screen On/Quick Bolus** button to deliver your bolus. Quick boluses are delivered as standard boluses (there is no glucose value entry or extended bolus).

⚠ PRECAUTION
ALWAYS check the pump screen to confirm correct programming of the bolus amount when you first use the Quick Bolus feature. Checking the screen will ensure that you are correctly using the beep/vibration commands to program the intended bolus amount.

1. Press and hold the **Screen On/Quick Bolus** button. The *Quick Bolus* screen will appear. Listen for two beeps (if sound volume is set to beep) or feel for vibrations (if sound volume is set to vibrate).

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

3. Wait for the pump to beep/vibrate once for each increment pressed to confirm desired amount.

4. After the pump beeps/vibrates, press and hold the **Screen On/Quick Bolus** button for several seconds to deliver the bolus.

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

If more than 10 seconds have passed with no input, the bolus is canceled and never delivered. In this case, the Incomplete Bolus Alert will be displayed on your pump and (if applicable) on your smartphone via the Tandem t:slim mobile app.

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

You cannot exceed 20 consecutive 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, check the screen to confirm the bolus amount. If the *Quick Bolus* screen does not display the correct bolus amount, use the touchscreen to enter bolus information.

✓ The *BOLUS INITIATED* screen is temporarily displayed.

NOTE

If Control-IQ+ technology is on and has adjusted insulin delivery during a Quick Bolus, the remaining Quick Bolus insulin will be delivered.

8.10 Canceling or Stopping a Bolus Using the Pump

You have 10 seconds to cancel a bolus after requesting it to completely avoid insulin delivery; the pump will say "requesting bolus" during this time.

To cancel a bolus request from the pump:

1. Tap **1–2–3** to access the *Home* screen.
2. Tap  to cancel the bolus.

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

NOTE

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

To stop a bolus after delivery has started:

1. Tap **1–2–3** to access the *Home* screen.
2. Tap  to stop delivery.
3. Tap  .

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

✓ Units requested and delivered are shown.

4. Tap  .

8.11 Bolus Delivery Using the Tandem t:slim Mobile App

Before you use the Tandem t:slim mobile app to deliver a bolus, enable your smartphone security feature (e.g., screen lock, passcode, face recognition). Never share your security PIN/password or authorize any other person to access your smartphone via their biometric information to avoid unintentional delivery of insulin.

NOTE

If your smartphone is not compatible with the Bolus Delivery feature set of the Tandem t:slim mobile app, you cannot use the Tandem t:slim mobile app to request, cancel, or stop a bolus. For an up-to-date list of supported smartphones, please visit tandemdiabetes.com/mobilesupport, or tap **Help** on the Tandem t:slim mobile app *Settings* screen.

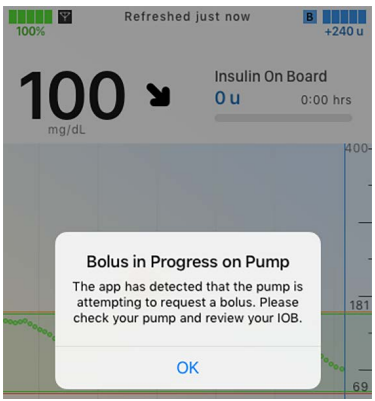
You can use the Tandem t:slim mobile app to deliver the following boluses:

- Correction bolus (see Section 8.12 Correction Bolus Using the Tandem t:slim Mobile App)
- Override bolus (see Section 8.13 Bolus Override Using the Tandem t:slim Mobile App)
- Food bolus using either units of insulin or grams of carbohydrate (see Section 8.14 Food Bolus Using the Tandem t:slim Mobile App)

You must use your pump for the following features:

- Extended Bolus (see Section 8.7 Extended Bolus)
- Max Bolus setting (see Section 8.8 Max Bolus)
- Quick Bolus (see Section 8.9 Quick Bolus)

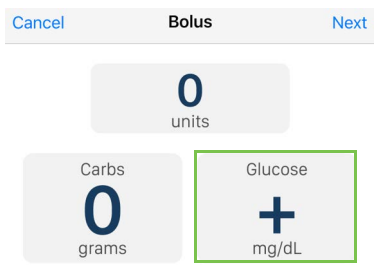
If you request any bolus from the pump, you must complete it on the pump. If you attempt to request a bolus from the Tandem t:slim mobile app while a bolus request is active on the pump, the Tandem t:slim mobile app will generate the *Bolus in Progress on Pump* notification and prevent you from starting a bolus.



8.12 Correction Bolus Using the Tandem t:slim Mobile App

Once the Tandem t:slim mobile app knows your glucose value, it will determine whether to recommend that a correction bolus to be added to any other bolus requested on the *Bolus* screen. The Tandem t:slim mobile app can receive your glucose value from manual entry into the Tandem t:slim mobile app or auto-populate from the CGM. See Glucose Value Auto-Population with CGM for more information about automatically populated glucose values.

To change the glucose value auto-populated from your CGM you can tap on the GLUCOSE value on the *Bolus* screen. The following example shows the *Bolus* screen in the Tandem t:slim mobile app.



Correction Bolus Confirmation Screens

To access the Correction Bolus confirmation screen on the Tandem t:slim mobile app and enable the Correction Bolus toggle, tap Bolus on the Navigation bar.

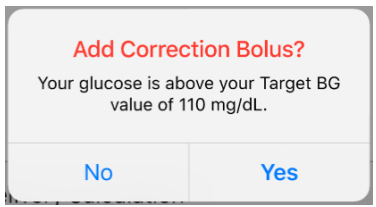
- If your CGM value or trend arrow are not available on the Home screen, the Correction Bolus confirmation screen appears after you enter your glucose value into the Tandem t:slim mobile app as described above.
- If you have a CGM value and trend arrow, the Correction Bolus confirmation screen appears when you tap Bolus (if appropriate).

Above Target

If your BG or sensor glucose value is above your Target BG, you can calculate and add a correction bolus to any other bolus you request.

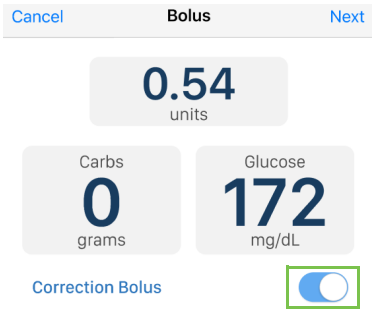
Calculate and add a correction bolus from the Tandem t:slim mobile app as follows:

- To accept the correction bolus, tap **Yes** on the *Correction Bolus* confirmation screen.



- To decline the correction bolus, tap **No** on the *Correction Bolus* confirmation screen.

If you tap **Yes**, the Correction Bolus toggle will be turned on. You can later decline the correction bolus by tapping the Correction Bolus toggle to the OFF position.

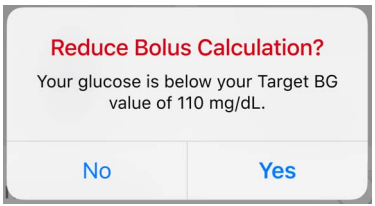


Below Target

If your BG or sensor glucose value is below your Target BG, the Tandem t:slim mobile app presents you with the option to subtract a correction bolus from any other bolus you request; any values the Tandem t:slim mobile app delivery calculation shows in red are subtracted from the calculated bolus amount.

Calculate and add a correction bolus from the Tandem t:slim mobile app as follows:

- To accept the correction bolus, tap **Yes** on the *Correction Bolus* confirmation screen.

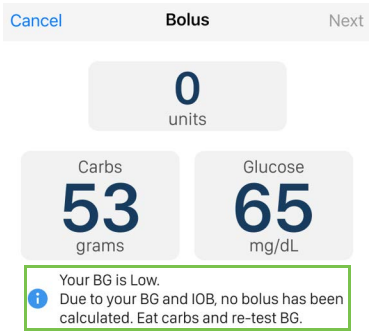


- To decline the correction bolus, tap **No** on the *Correction Bolus* confirmation screen.

If you tap **Yes**, the Correction Bolus toggle will be turned on. You can later decline the correction bolus by tapping the Correction Bolus toggle to the OFF position

NOTE

If your blood glucose is below 70 mg/dL, the food bolus will be reduced to automatically correct for the low glucose value. In this case, the Correction toggle will be unavailable, and the Tandem t:slim mobile app will display the Low BG Alert in its place.



Within Target

If your BG or sensor glucose value is the same value as your Target BG, no correction bolus will be included in the bolus calculation.

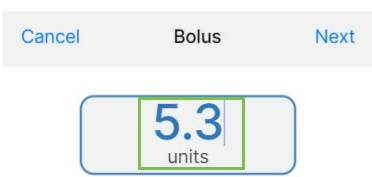
BG Value Manual Entry Using the Tandem t:slim Mobile App

Manually enter your BG value into the Tandem t:slim mobile app as follows:

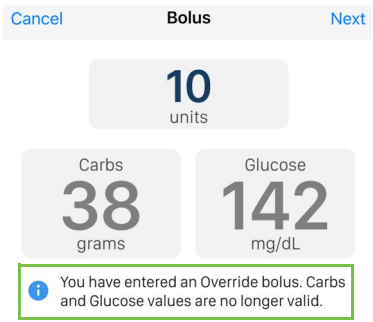
1. From the navigation bar, tap **Bolus**.
2. Tap **Glucose**.
3. Use the on-screen number keypad to enter your BG value.
4. Tap **Done** (iOS) or ✔ (Android) on the number keypad to save your BG value in your pump history and close the number keypad.
5. Follow the steps in the appropriate Target section above depending on the results of your BG value.

8.13 Bolus Override Using the Tandem t:slim Mobile App

You can override the calculated bolus by tapping on the calculated units value and entering the units of insulin you want delivered. The bolus override is always an available option; the following example shows the bolus override in the Tandem t:slim mobile app.



If you use the Tandem t:slim mobile app to set the override bolus value, the Bolus Override Alert will appear as an informational message on the *Bolus* screen.



8.14 Food Bolus Using the Tandem t:slim Mobile App

To deliver a food bolus using the Tandem t:slim mobile app:

1. Tap the **Bolus** icon on the *Navigation* bar.
2. Tap **0 grams** or **0 units** on the left side of the screen, depending on the settings in your active Personal Profile.
3. Use the number keypad to enter units of insulin or grams of carb to be delivered.
4. Tap **Done** (iOS) or ✔ (Android) on the number keypad to close the keypad.

✓ The total bolus amount at the top of the screen updates (if applicable).

5. Tap **Next** (iOS) or → (Android) to confirm the units of insulin to be delivered.

✓ The *Confirm Bolus* screen is temporarily displayed.

6. Confirm request:
   - Tap **Next** (iOS) or ✔ (Android) if entered data is correct.
   - Tap **Back** (iOS) or **X** (Android) to go back to make changes or view calculations.
7. Tap the **Deliver Bolus** icon.
8. The Tandem t:slim mobile app will generate a confirmation prompt; use your smartphone's security feature to confirm the bolus request or tap **Cancel** to return to the *Bolus* screen.

✓ The Tandem t:slim mobile app returns you to the dashboard.

9. A bolus bar appears above the navigation bar until the entire bolus has been delivered, including a cancel/stop button as well as the bolus type and amount requested.

8.15 Canceling or Stopping a Bolus Using the Tandem t:slim Mobile App

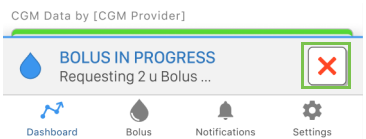
⚠ WARNING

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

You may cancel or stop any bolus via the Tandem t:slim mobile app as long as the Tandem t:slim mobile app has a Bluetooth connection to the pump, regardless of whether you initiated the bolus from the pump or the Tandem t:slim mobile app.

To cancel a bolus request from the Tandem t:slim mobile app:

1. Tap ☒ to cancel delivery.



NOTE

The ☒ is always available in the Tandem t:slim mobile app as part of the bolus bar during bolus delivery; you don't need to visit the *Bolus* screen to cancel a bolus.

2. Tap **Yes** in the confirmation prompt to cancel the bolus.

✓ The Bolus Stopped Alert appears and lists the units delivered as 0.

To stop a bolus after delivery has started:

1. Tap ☒ on the Tandem t:slim mobile app bolus bar to stop delivery.
2. Tap **Yes** on the Tandem t:slim mobile app confirmation prompt.

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

✓ Units requested and delivered are shown.

3. Tap **OK** on the Tandem t:slim mobile app informational message.

8.16 Pump Connection Lost

Connection Lost During Bolus Request

If your smartphone becomes disconnected from the pump while you are requesting a bolus before you confirm bolus delivery, the Tandem t:slim mobile app generates a Pump Connection Lost Alert. When you receive this notification, tap **OK** to return to the dashboard.

- No bolus will be delivered. Use the pump to deliver this bolus.
- Check your smartphone's Bluetooth connection and Bluetooth settings.
- You cannot use the Tandem t:slim mobile app to request a bolus until you have restored your smartphone's connection to the pump.

Connection Lost During Bolus Delivery

If your smartphone becomes disconnected from the pump while the

pump is delivering a bolus, the Tandem t:slim mobile app generates a Pump Connection Lost Alert. When you receive this notification, the Tandem t:slim mobile app will return you to the dashboard.

- Your pump will still deliver the remainder of the bolus unless you use the pump to stop the bolus.
- You must re-establish the connection between your smartphone and the pump before you use the Tandem t:slim mobile app to deliver another bolus. Despite disconnection, your pump IOB will be updated to reflect the delivered bolus. See Section 4.3 Connecting to a Smartphone.

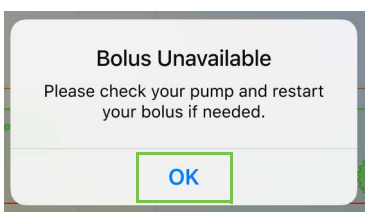
⚠ PRECAUTION

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

⚑ NOTE

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

Even if the Tandem t:slim mobile app has established a connection with the pump, you cannot use the Tandem t:slim mobile app to request a bolus until it has received your bolus settings from the pump. If you tap **Bolus** during this time to request a bolus, the Tandem t:slim mobile app will generate a Bolus Unavailable Alert as shown in the following example; tap **OK** to return to the dashboard.



CHAPTER 9

Starting, Stopping, or Resuming Insulin

9.1 Starting Insulin Delivery

Insulin delivery starts once you have a Personal Profile configured and activated. See Chapter 6 Insulin Delivery Settings for instructions on creating, configuring, and activating a Personal Profile.

9.2 Stopping Insulin Delivery

You can stop all insulin delivery at any time. When you stop all insulin delivery, any active bolus and any active temp rate are immediately stopped. No insulin delivery can take place while your pump is stopped. The pump will present a Resume Pump Alarm to remind you to manually resume insulin after a certain period of time. The default setting for this alarm is 15 minutes.

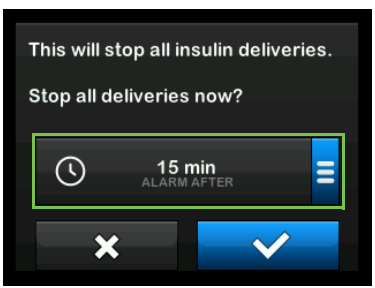
1. From the *Home* screen, tap OPTIONS.
2. Tap STOP INSULIN.

✓ A confirmation screen displays.

3. To change the Resume Pump Alarm setting, skip to Step 4. Otherwise, tap ✓ to accept the default setting.

✓ The *All Deliveries Stopped* screen appears before returning to the *Home* screen showing the status ALL DELIVERIES STOPPED. A red exclamation mark icon also appears to the right of the time and date.

4. To change the Resume Pump Alarm setting, tap the panel in the middle of the screen.



5. Select the radio button that corresponds with the time you would like the Resume Pump Alarm to display.

✓ The pump returns to the confirmation screen.

✓ The pump will save the new alarm time, and will use this setting the next time insulin is manually suspended, unless the pump has been reset, in which case the default setting will be used.

6. Tap ✓.

✓ The *All Deliveries Stopped* screen appears before returning to the *Home* screen showing the status ALL DELIVERIES STOPPED. A red exclamation mark icon also appears to the right of the time and date.

NOTE

If you manually stop insulin delivery, you must manually resume insulin delivery. Control-IQ+™ technology does not automatically resume insulin if you stop it manually.

9.3 Resuming Insulin Delivery

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

1. Tap **1–2–3**.
2. Tap ✔.

✓ The *RESUMING INSULIN* screen is temporarily displayed.

– OR –

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

The *RESUMING INSULIN* screen is temporarily displayed.

9.4 Disconnecting When Using Control-IQ+ Technology

When you need to disconnect your pump from your body, stop insulin delivery. Stopping insulin delivery tells the pump that you are not actively delivering insulin, which also stops Control-IQ+ technology so that it does not continue to calculate insulin delivery adjustments.

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CHAPTER 10

t:slim X2 Insulin Pump Information and History

10.1 t:slim X2 Pump Info

Your t:slim X2™ pump allows access to information about your pump. In the *Pump Info* screen you have access to items such as your pump Serial Number, Customer Technical Support contact information, website, and software/hardware versions.

1. From the *Home* screen, tap OPTIONS.
2. Tap My Pump.
3. Tap Pump Info.
4. Scroll through the Pump Info using the Up/Down Arrows.

10.2 t:slim X2 Pump History

Pump History displays a historical log of pump events. At least 30 days of data can be viewed in History. When the maximum number of events is reached, the oldest events are removed from the history log and replaced with the most recent events. The following can be viewed in Pump History:

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

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

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

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

The Complete section includes all information from each section as well as any changes to settings.

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

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

- The letters “PB” indicate a bolus requested, canceled, or stopped via the pump.
- The letters “RB” indicate a bolus requested, canceled, or stopped via the Tandem t:slim mobile app.

The Control-IQ+™ technology history shows the historical log of the Control-IQ+ technology status, including when the feature is enabled or disabled, when Basal Rate changes were made, and when Control-IQ+ technology boluses were delivered. The rate of insulin delivery may change as frequently as every five minutes.

1. From the *Home* screen, tap OPTIONS.
2. Tap the Down Arrow.
3. Tap History.
4. Tap Pump History.
5. Tap desired option.

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

NOTE

You must access these logs on the pump; the Tandem t:slim™ mobile app does not display the pump history logs.

10.3 Tandem t:slim Mobile App Info

The Tandem t:slim mobile app allows access to information about the Tandem t:slim mobile app.

- The *Help* screen gives you access to items such as an in-app guide to Tandem t:slim mobile app configuration and use, a list of frequently asked questions, and Customer Technical Support contact information.
- The *About* screen gives you access to items such as the Tandem t:slim mobile app instructions for use, legal information, and Tandem t:slim mobile app software version.

To find the *Help* and *About* screens, from your Tandem t:slim mobile app, tap **Settings**.

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CHAPTER 11

t:slim X2 Insulin Pump Reminders

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

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

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

Reminders notify you with a single sequence of two notes or a single vibration depending on the volume/vibrate setting in Sound Volume. They repeat every 10 minutes until acknowledged. Reminders do not escalate.

11.1 Low BG Reminder

The Low BG Reminder prompts you to re-test your BG after a low glucose value is read. When turning this reminder on, you need to set a low glucose value that triggers the reminder, as well as how much time should pass before the reminder occurs.

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

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **Low BG**.
6. Low BG is set to on; to turn off, tap **Low BG**.
   a. Tap **Remind Me Below** and using the on-screen keypad, enter a Low BG value (from 70 to 120 mg/dL) that you want to trigger the reminder, then tap  .
   b. Tap **Remind Me After** and using the on-screen keypad, enter the time (from 10 to 20 min), then tap  .
   c. Tap  when all changes are complete.

To Respond to the Low BG Reminder

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

11.2 High BG Reminder

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

reminder, as well as how much time should pass before the reminder occurs.

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

1. From the *Home* screen, tap OPTIONS.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **High BG**.
6. High BG is set to on; to turn off, tap **High BG**.
    a. Tap **Remind Me Above** and using the on-screen keypad, enter a High BG value (from 150 to 300 mg/dL) that you want to trigger the reminder, then tap  .
    b. Tap **Remind Me After** and using the on-screen keypad, enter the time (from 1 to 3 hours), then tap  .
    c. Tap  when all changes are complete.

To Respond to the High BG Reminder

To clear the reminder tap  and then check your glucose.

11.3 After Bolus BG Reminder

The After Bolus BG Reminder prompts you to test your BG at a selected time after bolus delivery. When turning this reminder on, you need to set how much time should pass before the reminder occurs. The default is 1 hour and 30 minutes. It can be set from 1 to 3 hours.

1. From the *Home* screen, tap OPTIONS.
2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Reminders**.
5. Tap **After Bolus BG**.
6. After Bolus BG is set to on; to turn off, tap **After Bolus BG**.
7. Tap **Remind Me After** and using the on-screen keypad, enter the time (from 1 to 3 hours) that you want to trigger the reminder, then tap  .
8. Tap  when all changes are complete.

To Respond to the After Bolus BG Reminder

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

11.4 Missed Meal Bolus Reminder

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

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

To Respond to the Missed Meal Bolus Reminder

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

11.5 Site Reminder

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

For detailed information on the Site Reminder feature, see Section 7.8 Setting Site Reminder.

To Respond to the Site Reminder

To clear the reminder tap  and change your infusion set.

CHAPTER 12

User Settable Alerts and Alarms

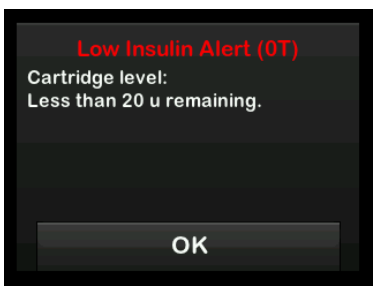
12.1 Low Insulin Alert

Your t:slim X2™ pump keeps track of how much insulin remains in the cartridge and alerts you when it is low. The default for this alert is preset to 20 units. You can set this alert setting anywhere between 10 and 40 units. When the insulin amount goes below 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 OK. Change your insulin cartridge following the instructions in Section 7.3 Filling and Loading a t:slim X2 Cartridge.



12.2 Auto-Off Alarm

Your pump can stop insulin delivery and alert you (or whoever is with you) if there has been no interaction with the pump within a specified period of time, particularly if you do not wear a CGM or use Control-IQ™ technology.

The default for this alarm is preset to off. If you turn this feature on, the default time is 12 hours. You can set it anywhere between 5 and 24 hours. 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.

The Auto-Off Alarm beeps and appears on the screen, and insulin delivery stops, when you exceed the set number of hours without any of the following actions:

- Deliver a Quick Bolus.
- Press the **Screen On/Quick Bolus** button and then tap **1-2-3** to unlock the pump.
- Performed certain actions within the Tandem t:slim mobile app.

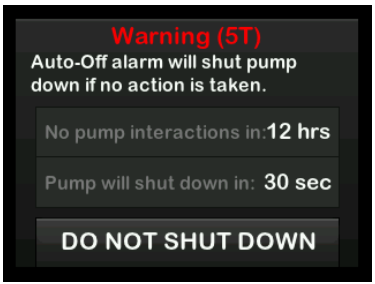
Enable and configure the Auto-Off Alarm as follows:

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

2. Tap **My Pump**.
3. Tap **Alerts & Reminders**.
4. Tap **Pump Alerts**.
5. Tap **Auto-Off**. A confirmation screen will appear.
   - Tap ✓ to continue.
   - Tap ✗ to go back.
6. Verify Auto-Off is set to on, then tap **Time**.
7. Using the on-screen keypad, enter the number of hours (from 5 to 24 hours) that you want the Auto-Off Alarm to be triggered, and tap ✓.
8. Tap ✓, then tap ✓ when all changes are complete.
9. Tap the **Tandem logo** to return to the *Home* screen.

To Respond to Auto-Off Warning

Tap **DO NOT SHUT DOWN**.

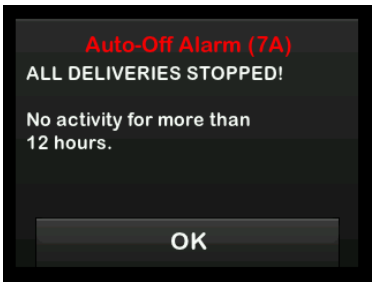


✓ The warning clears and the pump returns to normal operation.

If you do not clear the warning within the 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 OK.



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

You must resume delivery to continue therapy, see Section 9.3 Resuming Insulin Delivery.

12.3 Max Basal Alert

Your pump allows you to set a limit to the Basal Rate that the pump will not allow you to exceed during a Temp Rate.

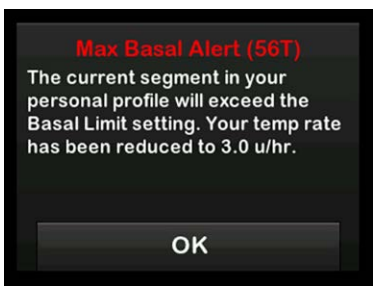
Once the Basal Limit in the Pump Settings has been set up (see Section 5.11 Basal Limit), you will receive an alert if the following scenarios occur.

1. A Temp Rate was requested that exceeds the Basal Limit.

2. A Temp Rate is in progress, and a new Personal Profile time segment has begun, causing the Temp Rate to exceed the Basal Limit.

To Respond to Max Basal Alert

Tap OK to accept the reduced Temp Rate. The reduced Temp Rate value is the same Basal Limit value that was set up in Personal Profiles.



CHAPTER 13

t:slim X2 Insulin Pump Alerts

Your pump lets you know important information about the pump 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 1 or 2 sequences of 3 notes or 1 or 2 vibrations depending on the alert type and the volume/vibrate setting selected in Sound Volume. They repeat regularly until acknowledged. Alerts do not escalate.

The Tandem t:slim™ mobile app also can provide messages, alerts, and alarms from your t:slim X2™ pump as push notifications on your smartphone. These push notifications will be identical to your pump's display unless otherwise noted in this chapter.

⚠ PRECAUTION

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

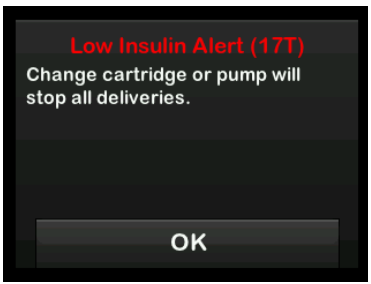
⚑ NOTE

There is an additional list of alerts and errors related to CGM use in Chapter 26 CGM Alerts and Errors.

⚑ NOTE

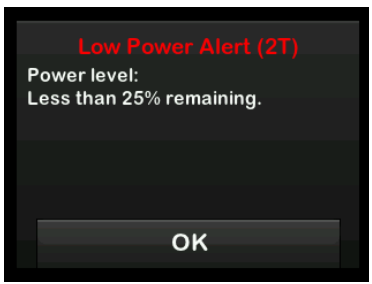
There is an additional list of alerts related to Control-IQ+™ technology use in Chapter 32 Control-IQ+ Technology Alerts.

13.1 Low Insulin Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	5 units or less of insulin remain in the cartridge.
	How will the pump notify me?	1 sequence of 3 notes or 1 vibration depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump 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.

13.2 Low Power Alerts

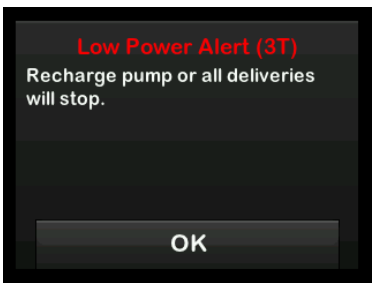
Low Power Alert 1

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Less than 25% of battery power remains.
	How will the pump notify me?	1 sequence of 3 notes or 1 vibration depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap OK. Charge your pump as soon as possible to avoid the second Low Power Alert.

NOTE

Once the Low Power Alert occurs, the low-power indicator (a single red bar on the battery level display on the *Home* and *Lock* screens) appears.

Low Power Alert 2

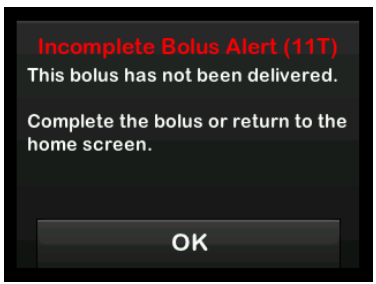
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Less than 5% of battery power remains. Insulin delivery will continue for 30 minutes and then the pump will power off and insulin delivery will stop.
	How will the pump notify me?	1 sequence of 3 notes or 1 vibration depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap OK. Charge your pump immediately to avoid the Low Power Alarm and pump power off.

NOTE

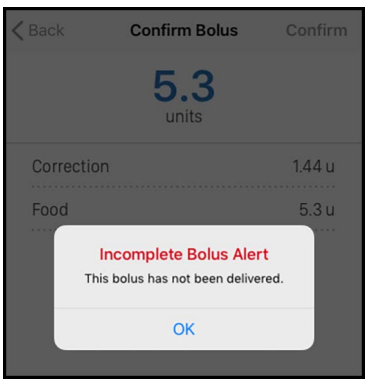
Once the Low Power Alert occurs, the low-power indicator (a single red bar on the battery level display on the *Home* and *Lock* screens) appears.

13.3 Incomplete Bolus Alert

Incomplete Bolus Alert – Pump Screen

Screen	Explanation	
What will I see on the screen? 	What does it mean?	You started a bolus request but did not complete the request within 90 seconds.
	How will the pump notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap OK. The *Bolus* screen will appear. Continue with your bolus request.

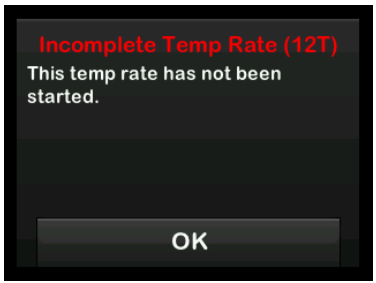
Incomplete Bolus Alert – Tandem t:slim Mobile App

Screen	Explanation	
What will I see in the Tandem t:slim mobile app*? 	What does it mean?	You started a bolus request but did not complete the request within 90 seconds.
	How will the Tandem t:slim mobile app notify me?	• If the Tandem t:slim mobile app is open and on the *Bolus* screen, an informational message appears. • If you receive the Incomplete Bolus Alert due to interaction with other smartphone features (e.g., answering a call, using another app) or other screens in the Tandem t:slim mobile app, you will receive the alert as a notification banner.
	Will the Tandem t:slim mobile app re-notify me?	No, the alert remains on the Tandem t:slim mobile app screen until you tap **OK**.
	How should I respond?	Tap **OK** on the informational message in the Tandem t:slim mobile app. The *Bolus* screen will appear. Continue with your bolus request.

NOTE

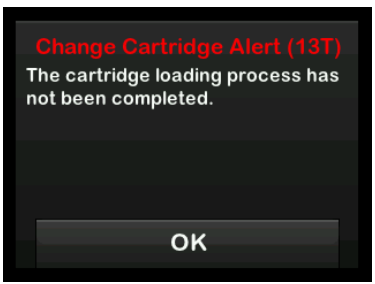
The Incomplete Bolus Alert is the only alert in this chapter that appears differently on the pump. All other pump alerts are identical in the Tandem t:slim mobile app.

13.4 Incomplete Temp Rate Alert

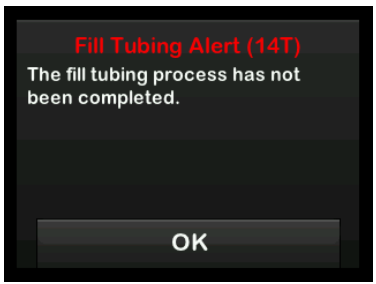
Screen	Explanation	
What will I see on the screen?  	What does it mean?	You started to set up a temp rate but did not complete the request within 90 seconds.
	How will the pump notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	1. Tap OK. 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.

13.5 Incomplete Load Sequence Alerts

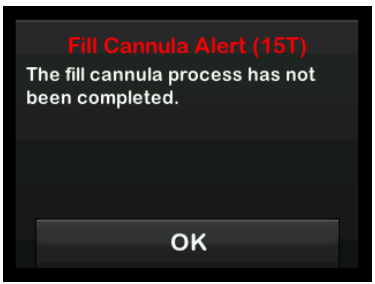
Incomplete Cartridge Change Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	You selected **Change Cartridge** from the *Load* menu but did not complete the process within 3 minutes.
	How will the pump notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap OK. Complete the cartridge change process.

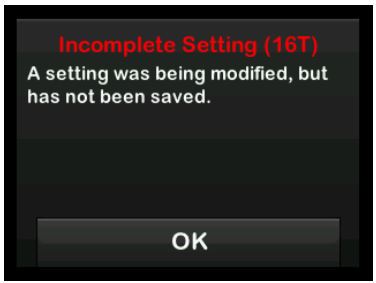
Incomplete Fill Tubing Alert

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

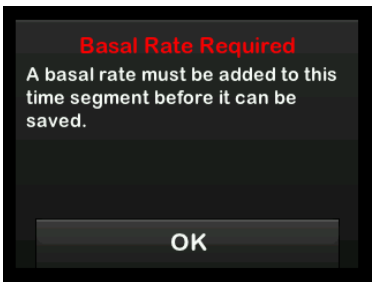
Incomplete Fill Cannula Alert

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

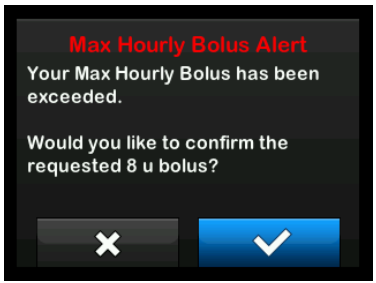
13.6 Incomplete Setting Alert

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

13.7 Basal Rate Required Alert

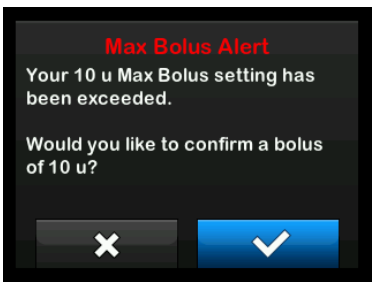
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You did not enter a Basal Rate in a time segment in Personal Profiles. A Basal Rate must be entered in each time segment (rate can be 0 u/hr).
	How will the pump notify me?	Display only, the pump will not beep or vibrate.
	Will the pump 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.

13.8 Max Hourly Bolus Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	In the previous 60 minutes, you requested total bolus delivery that is more than 1.5 times your Max Bolus setting.
	How will the pump notify me?	Display only, the pump will not beep or vibrate.
	Will the pump 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.

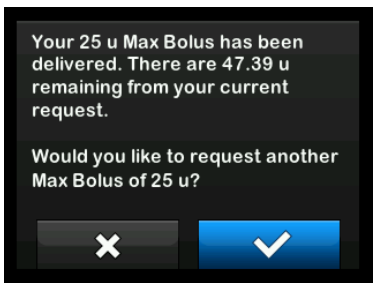
13.9 Max Bolus Alerts

Max Bolus Alert 1

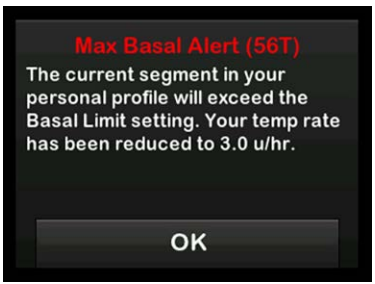
Screen	Explanation	
What will I see on the screen? 	What does it mean?	You requested a bolus larger than the Max Bolus setting in your active Personal Profile.
	How will the pump notify me?	Display only, the pump will not beep or vibrate.
	Will the pump re-notify me?	No, you must tap ✕ or ✓ to deliver 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.

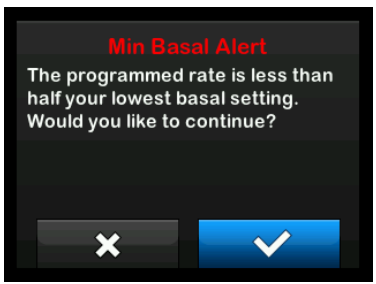
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your Max Bolus is set to 25 units and you requested a bolus larger than 25 units.
	How will the pump notify me?	Display only, the pump will not beep or vibrate.
	Will the pump re-notify me?	No, you must tap ✕ or ✓ to deliver the remaining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

13.10 Max Basal Alert

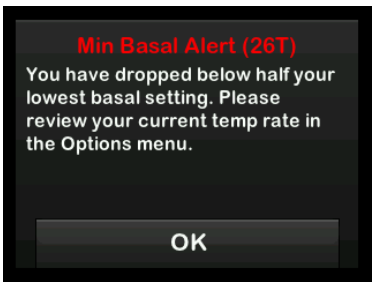
Screen	Explanation	
What will I see on the screen?  	What does it mean?	An active Temp Rate exceeds your Basal Limit setting due to a new timed segment activation within Personal Profiles. This alert will only display once your timed segment changes.
	How will the pump notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibration setting selected in Sound Volume.
	Will the pump re-notify me?	No, you must tap OK to move forward.
	How should I respond?	Tap OK to accept the reduced Temp Rate. The reduced Temp Rate value is the same Basal Limit value that was set up in Personal Profiles.

13.11 Min Basal Alerts

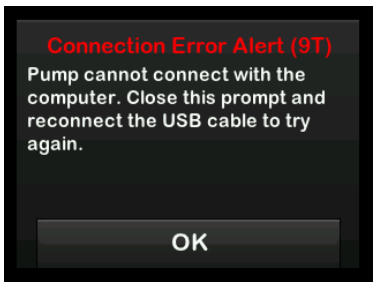
Min Basal Alert 1

Screen	Explanation	
What will I see on the screen? 	What does it mean?	When entering a Basal Rate or requesting a temp rate, you requested a Basal Rate less than half of the lowest basal rate defined in your Personal Profile.
	How will the pump notify me?	Display only, the pump will not beep or vibrate.
	Will the pump re-notify me?	No, you must tap ✕ or ✓ to move forward.
	How should I respond?	• Tap ✕ to return to the previous screen to adjust the amount. • Tap ✓ to dismiss the alert and continue with the request.

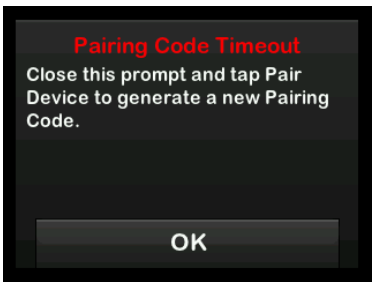
Min Basal Alert 2

Screen	Explanation	
What will I see on the screen?  	What does it mean?	An active temp rate dropped below half of your lowest basal setting defined in your Personal Profile.
	How will the pump notify me?	1 sequence of 3 notes or 1 vibration depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap OK and review your current temp rate in the *Activity* menu.

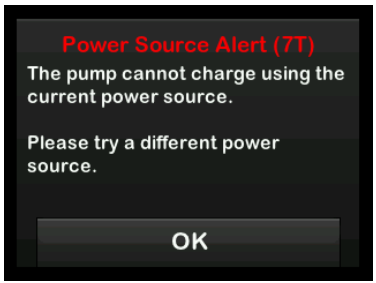
13.12 Connection Error Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	You connected your pump to a computer with the USB cable to charge it, upload data to the Tandem t:slim web application, or upload data to the Tandem Source platform, and a connection could not be made.
	How will the pump notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap OK. Disconnect and reconnect the USB cable to try again.

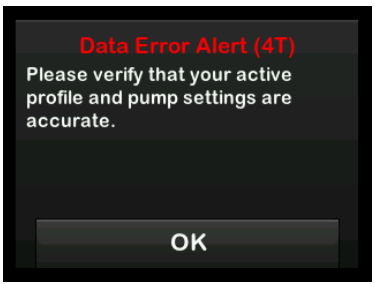
13.13 Pairing Code Timeout

Screen	Explanation	
What will I see on the screen?  	What does it mean?	You attempted to connect a smartphone to the pump, but the pairing process took too long (more than 5 minutes) and was unsuccessful.
	How will the pump notify me?	Display only, the pump will not beep or vibrate.
	Will the pump re-notify me?	No.
	How should I respond?	Tap OK. Try to pair the smartphone again.

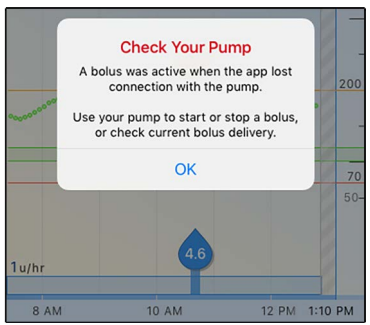
13.14 Power Source Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	You connected your pump to a power source that does not have enough power to charge the pump.
	How will the pump notify me?	1 sequence of 3 notes or 1 vibration depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap OK. Connect the pump to a different power source to charge.

13.15 Data Error Alert

Screen	Explanation	
What will I see on the screen?  	What does it mean?	Your pump encountered a condition that could potentially result in a loss of data.
	How will the pump notify me?	2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap OK. Check your Personal Profiles and pump settings to verify that they are accurate. See Section 6.5 Editing or Reviewing an Existing Profile.

13.16 Pump Connection Lost Alert – Tandem t:slim Mobile App

Screen	Explanation	
What will I see in the Tandem t:slim mobile app? 	What does it mean?	You started a bolus request in the Tandem t:slim mobile app, but your smartphone became disconnected from your pump before or during bolus delivery.
	How will the Tandem t:slim mobile app notify me?	• If the Tandem t:slim mobile app is open and on the *Bolus* screen, an informational message appears. • If bolus delivery is in progress, you will receive the alert as a notification banner.
	Will the Tandem t:slim mobile app re-notify me?	No, the alert remains on the Tandem t:slim mobile app screen until you tap **OK**.
	How should I respond?	Tap **OK** to return to the Dashboard. • If bolus delivery is in progress, your pump will still deliver the remainder of the bolus unless you use your pump to stop the bolus. • You cannot use the Tandem t:slim mobile app to request another bolus until you have restored your smartphone's connection to the pump.

NOTE

The Pump Connection Lost Alert is the only alert in this chapter that appears in the Tandem t:slim mobile app but not on the pump.

CHAPTER 14

t:slim X2 Insulin Pump Alarms

⚠ PRECAUTION

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

Your t:slim X2™ pump lets you know important information about the pump 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 vibe. Alarms repeat regularly until the condition that caused the alarm is corrected.

The Tandem t:slim™ mobile app also can provide messages, alerts, and alarms from your t:slim X2 pump as push notifications on your smartphone. These push notifications will be identical to your pump's display unless otherwise noted in this chapter.

⚠ PRECAUTION

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

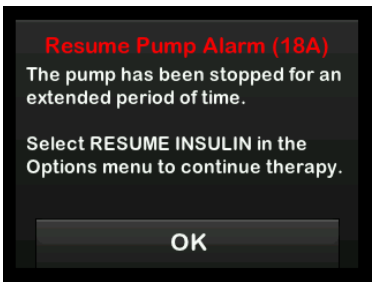
⚑ NOTE

There is a list of alerts and errors related to CGM use in Chapter 26 CGM Alerts and Errors.

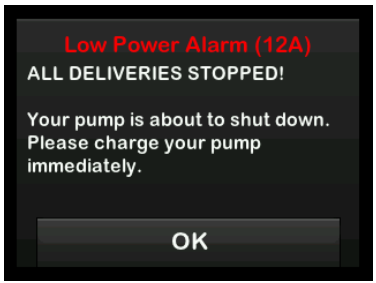
⚑ NOTE

There is a list of alerts related to Control-IQ+™ technology use in Chapter 32 Control-IQ+ Technology Alerts.

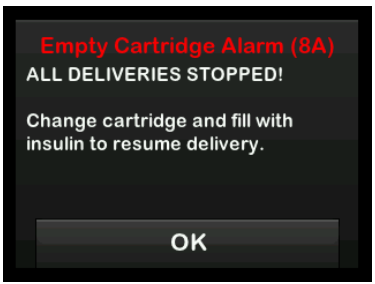
14.1 Resume Pump Alarm

Screen	Explanation	
What will I see on the screen?  	What does it mean?	You selected **STOP INSULIN** in the *Options* menu and insulin delivery has been stopped for more than 15 minutes.
	How will the pump notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump re-notify me?	Yes. • If not acknowledged by tapping OK, the pump will re-notify you every 3 minutes at highest volume and vibrate. • If acknowledged by tapping OK, the pump will re-notify you in 15 minutes.
	How should I respond?	To resume insulin, from the *Options* menu, tap **RESUME INSULIN** and tap ✓ to confirm.

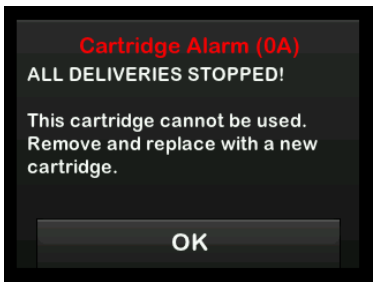
14.2 Low Power Alarm

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected a power level of 1% or less remaining and all deliveries have stopped.
	How will the pump notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump 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.

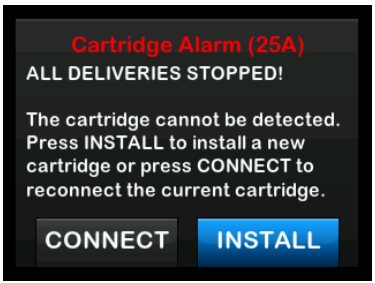
14.3 Empty Cartridge Alarm

Screen	Explanation	
What will I see on the screen?  	What does it mean?	Your pump detected that the cartridge is empty and all deliveries have stopped.
	How will the pump notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump re-notify me?	Yes, every 3 minutes until you change the cartridge.
	How should I respond?	Tap OK. Change your cartridge immediately by tapping **OPTIONS** from the *Home* screen, then **Load** and follow the instructions in Section 7.3 Filling and Loading a t:slim X2 Cartridge.

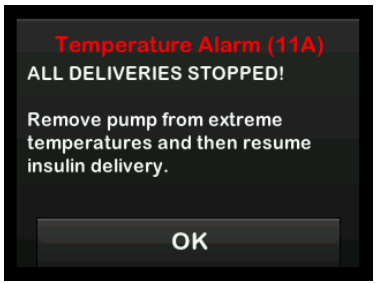
14.4 Cartridge Error Alarm

Screen	Explanation	
What will I see on the screen?  	What does it mean?	Your pump detected that the cartridge could not be used and all deliveries have stopped. This can be caused by cartridge defect, not following the proper procedure to load the cartridge, or over filling the cartridge (with more than 300 units of insulin).
	How will the pump notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump re-notify me?	Yes, every 3 minutes until you change the cartridge.
	How should I respond?	Tap OK. Change your cartridge immediately by tapping **OPTIONS** from the *Home* screen, then **Load** and follow the instructions in Section 7.3 Filling and Loading a t:slim X2 Cartridge.

14.5 Cartridge Removal Alarm

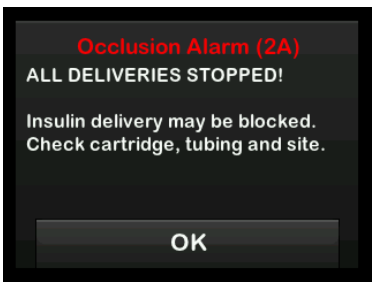
Screen	Explanation	
What will I see on the screen?  	What does it mean?	Your pump detected that the cartridge has been removed and all deliveries have stopped.
	How will the pump notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will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

14.6 Temperature Alarm

Screen	Explanation	
What will I see on the screen?  	What does it mean?	Your pump detected an internal temperature below 35ºF (2ºC) or above 113ºF (45ºC) or a battery temperature below 35ºF (2ºC) or above 125ºF (52ºC) and all deliveries have stopped.
	How will the pump notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump re-notify me?	Yes, every 3 minutes until a temperature in the operating range is detected.
	How should I respond?	Tap OK. Remove the pump from the extreme temperature and then resume insulin delivery.

14.7 Occlusion Alarms

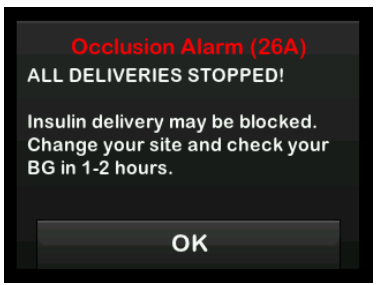
Occlusion Alarm 1

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected that insulin delivery is blocked and all deliveries have stopped. See Section 34.4 t:slim X2 Pump Performance Characteristics for more information on how long it can take the pump to detect an occlusion.
	How will the pump notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump re-notify me?	Yes, every 3 minutes until you resume insulin delivery.
	How should I respond?	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 *Options* menu, tap **RESUME INSULIN** and tap ✓ to confirm.

NOTE

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.

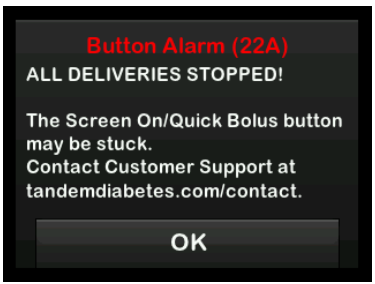
Occlusion Alarm 2

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected a second occlusion alarm shortly after the first occlusion alarm and all deliveries have stopped.
	How will the pump notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump re-notify me?	Yes, every 3 minutes until you resume insulin delivery.
	How should I respond?	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.

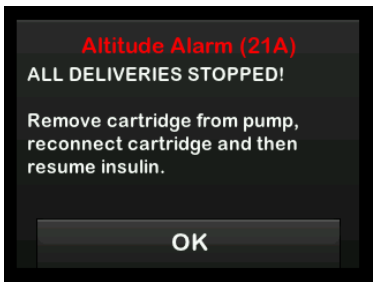
NOTE

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.

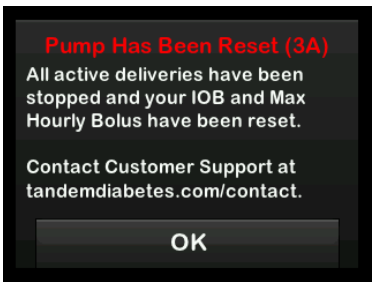
14.8 Screen On/Quick Bolus Button Alarm

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

14.9 Altitude Alarm

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump detected a pressure difference between inside the cartridge and the surrounding air within the validated operating range of -1,300 feet to 10,000 feet (-396 meters to 3,048 meters) and all deliveries have stopped.
	How will the pump notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump re-notify me?	Yes, every 3 minutes until the condition is corrected.
	How should I respond?	Tap OK. Remove the cartridge from the pump (this will allow the cartridge to fully vent) and then reconnect the cartridge.

14.10 Reset Alarm

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your pump experienced a reset and all deliveries have been stopped.
	How will the pump notify me?	3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Sound Volume.
	Will the pump 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 15

t:slim X2 Insulin Pump Malfunction

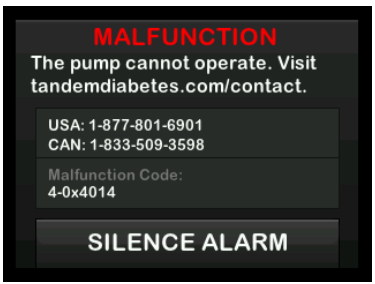
15.1 Malfunction

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

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

⚠ PRECAUTION

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

Screen	Explanation	
What will I see on the screen?  	What does it mean?	Your pump detected a critical error and all deliveries have been stopped. Use your backup insulin method, or contact your healthcare provider for an alternate insulin delivery plan.
	How will the pump notify me?	3 sequences of 3 notes at highest volume and 3 vibrations.
	Will the pump re-notify me?	Yes, every 3 minutes until you acknowledge the malfunction by tapping **SILENCE ALARM**.
	How should I respond?	• Write down the Malfunction Code number that appears on the screen. • Tap **SILENCE ALARM**. The *MALFUNCTION* 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 16

Taking Care of Your Pump

16.1 Overview

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

Cleaning Your Pump

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

Maintaining Your Pump

The pump requires no preventative maintenance.

Inspecting Your Pump for Damage

⚠ PRECAUTION

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

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

Storing Your Pump

If you need to stop using your pump for a long period of time, you can place the pump in storage mode. To place the pump in storage mode, connect the pump to a power source and then press and hold down the Screen On/Quick Bolus button for 30 seconds. The pump will beep 3 times before going into storage mode. Disconnect the pump from the power source.

Keep the pump protected when not in use. Store at temperatures between -4°F (-20°C) and 140°F (60°C) and at relative humidity levels between 20% and 90%.

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

Disposing of System Components

Consult Customer Technical Support for instructions for disposal of devices containing electronic waste such as your pump. Follow local regulations for disposal of potentially biohazardous materials such as used cartridges, needles, syringes, infusion sets, and sensors.

CHAPTER 17

Lifestyle Issues and Travel

17.1 Overview

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

⚠ PRECAUTION

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

Physical Activity

The pump can be worn during most forms of exercise, such as running, cycling, hiking, and resistance training. During exercise, the pump can be worn in the provided case, your pocket, or other third-party "sport cases." When choosing third-party pump cases or stickers, do not cover the six vent holes on the back of the pump.

⚠ PRECAUTION

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

For activities where contact is a concern, such as baseball, hockey, martial arts, or basketball, you can disconnect from your pump for short periods of time. If planning to disconnect from your pump, discuss a plan with your healthcare provider to compensate for any basal insulin delivery you miss while disconnected, and be sure to continue to check your BG levels. Even if you disconnect your tubing from your infusion site, the pump should continue to receive data from the CGM as long as it is within the 20-foot (6-meter) range without obstruction.

Aquatic Activities

⚠ PRECAUTION

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

Your pump is watertight to a depth of 3 feet (0.91 meters) for up to 30 minutes (IP27 rating), but it is not waterproof. Your pump should not be worn while swimming, scuba diving, surfing, or during any other activities that could submerge the pump for an extended period of time. Your pump should not be worn in hot tubs, whirlpools, or saunas.

Extreme Altitudes

Some activities, such as hiking, skiing or snowboarding, could expose your pump to extreme altitudes. The pump has been tested at altitudes up to 10,000 feet (3,048 meters) at standard operating temperatures.

Extreme Temperatures

You should avoid activities which could expose your pump to temperatures below 41ºF (5ºC) or above 99ºF (37ºC), as insulin can freeze at low temperatures or degrade at high temperatures.

Other Activities Which Require Removing Your Pump

⚠ PRECAUTION

If you remove your pump for 30 minutes or longer, it is recommended that you suspend insulin delivery. If insulin is not suspended, Control-IQ+™ technology will continue to operate while the pump is removed, and will continue to dose insulin.

There are other activities, such as bathing and intimacy, when it may be more convenient for you to remove your pump. It is safe to do so for short periods of time. If planning to disconnect from your pump, discuss a plan with your healthcare provider for compensating for any basal delivery you miss while disconnected, and be sure to check your BG levels frequently. Missing basal delivery could cause your BG to rise.

Travel

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

- The items listed in the Emergency Kit described in Section 1.10 Emergency Kit.
- A prescription for both rapid-acting and long-acting insulin of the type recommended by your healthcare provider in case you need to take insulin by injection.
- A letter from your healthcare provider explaining the medical need for your insulin pump and other supplies.

Traveling by Air

⚠ PRECAUTION

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

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

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

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

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

If you enable Airplane mode on your smartphone, you must maintain an active Bluetooth connection between your smartphone and your pump to use

the Tandem t:slim™ mobile app. You can always use your pump to deliver a bolus if you cannot connect your smartphone and pump. Please check with your airline carrier and smartphone manufacturer instructions prior to traveling to determine conditions for using Bluetooth.

⚠ WARNING

ALWAYS use your t:slim X2™ insulin pump for therapy decisions if your Bluetooth connection between your smartphone and pump is disabled.

⚑ NOTE

The Tandem t:slim mobile app requires an active Bluetooth connection to connect with your pump. If you turn on Airplane mode, make sure you keep Bluetooth enabled to connect to your pump.

3 CGM Features

CHAPTER 18

Important Safety Information When Using the t:slim X2 Insulin Pump with a Compatible CGM

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

18.1 CGM Warnings

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

⚠ WARNING
DO NOT expect CGM alerts until after the CGM startup period has ended. You will NOT get any sensor glucose readings or alerts until after the startup period ends. During this time you might miss severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING
If a sensor session is ended, either automatically or manually, you will not receive any CGM alerts. In order to receive CGM alerts on your pump and/or your Tandem t:slim mobile app, a sensor session must be started and transmitting sensor values to the pump.

18.2 CGM Precautions

⚠ PRECAUTION
ALWAYS carefully follow the instructions for use accompanying your CGM sensor for proper site selection and insertion. The insulin might affect sensor accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION
Continue to use a BG meter and test strips in order to make treatment decisions during the CGM sensor startup period.

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

⚠ PRECAUTION
AVOID separating the CGM and pump by more than 20 feet (6 meters). The transmission range from the CGM 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 CGM 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.

Using a Dexcom CGM with Your t:slim X2™ Insulin Pump

⚠ PRECAUTION
To calibrate the CGM, **DO** enter the exact BG value that your BG meter displays within 5 minutes of a carefully performed BG measurement. Do not enter sensor glucose values for calibration. Entering incorrect BG values, BG values obtained more than 5 minutes before entry, or sensor glucose readings might

affect sensor accuracy and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ PRECAUTION

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

Using an Abbott FreeStyle Libre 2 Plus Sensor with Your t:slim X2 Insulin Pump

⚠ PRECAUTION

ALWAYS use a BG meter to confirm sensor values when making treatment decisions while the Check BG icon is displayed, or when CGM readings are inconsistent with your signs and symptoms.

⚠ PRECAUTION

Your sensor value is **NOT** automatically populated into the *Bolus* screen during the first 12 hours of wearing an Abbott FreeStyle Libre 2 Plus Sensor CGM. Check your BG to confirm your sensor values before making any treatment decisions.

18.3 Potential Benefits From Using the t:slim X2 Insulin Pump with CGM

When paired with a Dexcom CGM sensor, your pump can receive CGM readings every 5 minutes. When paired with an Abbott FreeStyle Libre 2 Plus CGM sensor, your pump can receive CGM readings every minute. CGM readings are displayed every 5 minutes as a trend graph on the *CGM Home* screen. You can also program your pump to alert you when your CGM readings are above or below a given level, or are rising or falling quickly. Unlike the readings from a standard BG meter, CGM readings allow you to view trends in real time, as well as capture information when you would otherwise be unable to check your blood sugar, such as while you are asleep. This information can be useful for you and your healthcare provider when considering changes to your therapy. In addition, the programmable alerts can help you to spot potential low or high BG sooner than you would using a only a BG meter.

18.4 Possible Risks From Using the t:slim X2 Insulin Pump with CGM

During a Dexcom CGM session, 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 CGM 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 CGMs take readings from fluid below the skin (interstitial fluid) instead of blood. There are differences in how glucose is measured in the blood compared to how it is measured in interstitial fluid, and glucose is absorbed into the interstitial fluid slower than it is absorbed into the blood, which can cause CGM readings to lag behind readings from a BG meter.

3 CGM Features

CHAPTER 19

Getting to Know Your CGM System

19.1 CGM Terminology

Alternate Site BG Testing
Alternate site BG testing is when you take a BG value on your BG meter using a blood sample from an area on your body other than your fingertip. When wearing a Dexcom CGM, do not use alternate site testing to calibrate your sensor.

Applicator
The applicator is a disposable part which contains the sensor with an insertion needle inside. The entire applicator is disposed of once the sensor is inserted.

Calibration – Dexcom CGM Only
Calibration is when you enter BG values from a BG meter into the pump. Calibrations may be needed for your pump to show continuous glucose readings and trend information.

CGM
Continuous glucose monitoring.

CGM Reading
A CGM reading is a sensor glucose reading shown on your pump. This reading is in mg/dL units.

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

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

Pairing Code – Dexcom G7 Only
A unique code provided with each individual CGM sensor, used to pair the t:slim X2™ pump with that sensor. This code is not related to the pairing code used to pair the pump to a smartphone.

Receiver – Dexcom CGM Only
When a Dexcom CGM is used with the pump to display CGM readings, the insulin pump replaces the receiver for the therapeutic CGM. A smartphone with the Dexcom app may be used in addition to the pump to receive sensor readings.

Rise and Fall (Rate of Change) Alerts
Rise and fall alerts occur based on how much and how fast your glucose levels rise or fall.

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

Sensor
The sensor is the part of the CGM that is inserted under your skin, which allows it to measure your glucose levels.

Sensor Code – Dexcom G6 Only
A code provided with each individual Dexcom G6 sensor. If used, the sensor code allows the Dexcom G6 to be used without the need for fingersticks or calibrations.

Sensor Glucose Data Gaps
Glucose data gaps occur when your pump is unable to provide a sensor glucose reading.

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

Startup Period
Once a new sensor session is started on the pump, the startup period is an interval during which the new sensor is establishing a connection with the pump. Sensor glucose readings are not available during this time.

Transmitter
The Dexcom G6 transmitter is the part of the CGM that snaps into the sensor pod and wirelessly sends glucose information to your pump.

The Dexcom G7 and the Abbott FreeStyle Libre 2 Plus Sensor each have a streamlined all-in-one sensor with a built-in disposable transmitter.

Transmitter ID – Dexcom G6 Only
The transmitter ID is a series of numbers and/or letters that you enter into your pump to let it connect and communicate with the transmitter.

Trend (Rate of Change) Arrows
Trend arrows show how fast your glucose levels are changing. Different arrows show when your glucose direction and speed change.

19.2 Explanation of Dexcom CGM Pump Icons

When wearing a Dexcom CGM, the following CGM icons may appear on your pump screen:

CGM Icon Definitions — Dexcom

Symbol	Meaning
	Unknown sensor reading.
	CGM sensor session is active, but the transmitter and pump are out of range.
	The CGM sensor has failed.
	The CGM sensor session has ended.
	Wait 15 minutes calibration error.
	Startup calibration is required (2 BG values; Dexcom G6 only).
	Additional startup calibration is required (Dexcom G6 only).
	CGM calibration is required.

Symbol	Meaning
	Transmitter error (Dexcom G6 only).
	CGM sensor session is active, and the transmitter is communicating with the pump.
	CGM sensor session is active, but the transmitter is not communicating with the pump.
	Sensor startup first segment.
	Sensor startup second segment.
	Sensor startup third segment.
	Sensor startup final segment.

19.3 Explanation of Abbott FreeStyle Libre 2 Plus Sensor CGM Pump Icons

When wearing the Abbott FreeStyle Libre 2 Plus Sensor CGM, the following CGM icons may appear on your pump screen:

CGM Icon Definitions — Abbott FreeStyle Libre 2 Plus Sensor

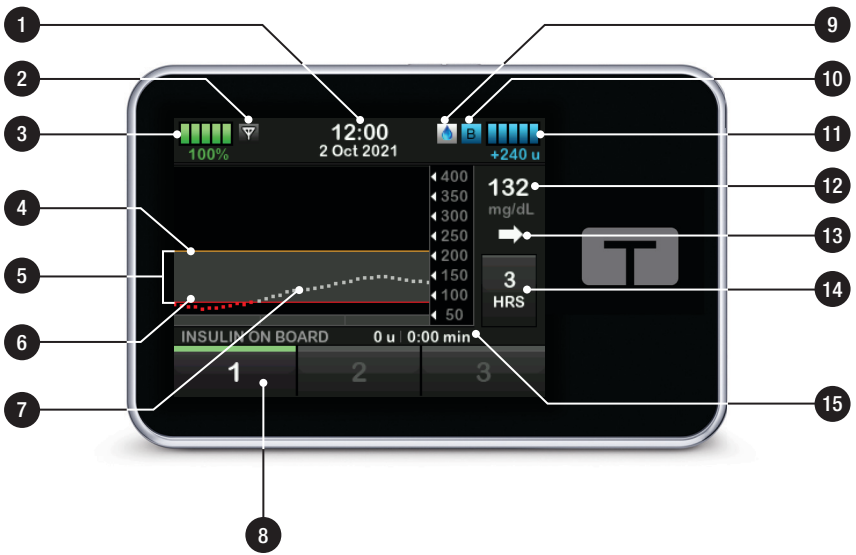
Symbol	Meaning
	Unknown sensor reading.
	CGM sensor session is active, but the CGM sensor and pump are out of range.
	The CGM sensor has failed.
	The CGM sensor session has ended.
	Sensor Startup first segment.
	Sensor startup third segment.
	Sensor startup fifth segment.

Symbol	Meaning
	A CGM reminder, alert, error, or alarm is active; this symbol will only appear on the *CGM Lock* screen.
	CGM sensor session is active, and the CGM sensor is communicating with the pump.
	CGM sensor session is active, but the CGM sensor is not communicating with the pump.
	Check BG Icon. The CGM sensor session started less than 12 hours ago; confirm sensor glucose readings with a BG test before making treatment decisions.
	Sensor startup second segment.
	Sensor startup fourth segment.
	Sensor startup final segment.

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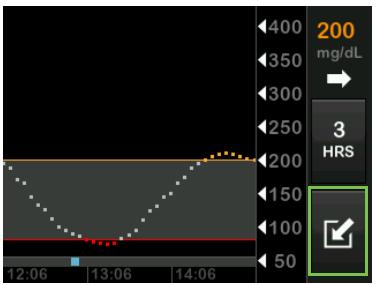
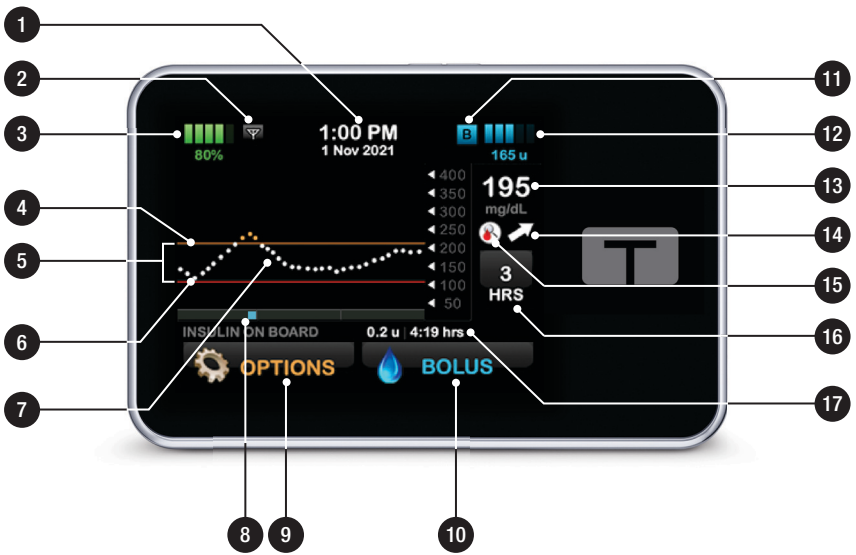
19.5 CGM Home Screen

1. Time and Date Display: Displays the current time and date.
2. Antenna: Indicates communication status between pump and CGM.
3. Battery Level: Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
4. High Glucose Alert Setting.
5. Sensor Glucose Target Range.
6. Low Glucose Alert Setting.
7. Graph of Most Recent Sensor Glucose Readings.
8. Bolus icon: Denotes a bolus delivery.
9. Options: Stop/Resume insulin delivery, manage pump and CGM settings, start/stop activities, load a cartridge, and view history.
10. Bolus: Program and deliver a bolus.
11. Status: Displays current pump settings and insulin delivery status.
12. Insulin Level: Displays the current amount of insulin in the cartridge.
13. Most Recent Sensor Glucose Reading.
14. Trend Arrow: Indicates direction and rate of change.
15. Check BG Icon (Abbott FreeStyle Libre 2 Plus Sensor CGM only): Appears during the first 12 hours of sensor wear. See Section 23.14 Abbott FreeStyle Libre 2 Plus Sensor Startup Period.
16. Trend Graph Time (HRS): 1, 3, 6, 12 and 24 hour views available.
17. Insulin On Board (IOB): Amount and time remaining of any active insulin on board.

To view CGM information on the full screen:
From the *CGM Home* screen tap anywhere on the CGM trend graph.Tap the “minimize” icon to return to the *CGM Home* screen.

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OPTIONS
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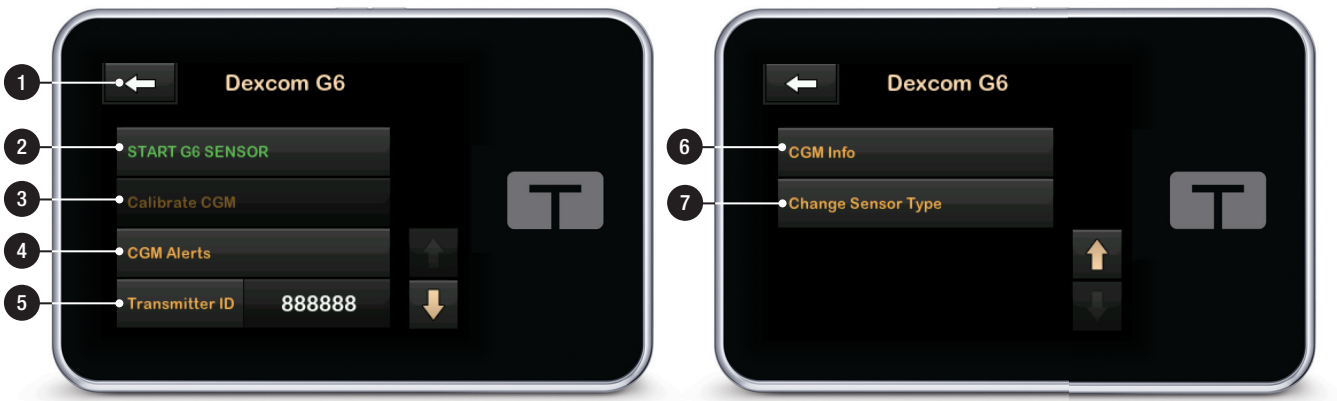
19.6 Dexcom G6 Screen

The *Dexcom G6* screen can be accessed from the *My CGM* screen by tapping **Change Sensor Type**. See Section 23.1 Choosing Your Sensor Type.

1.  : Returns to the *Options* screen.
2. **Start G6 Sensor:** Starts a CGM session. If sensor is active, STOP G6 SENSOR will be displayed.
3. **Calibrate CGM:** Enter a calibration BG value. Only active when sensor session is active. Calibration is optional.
4. **CGM Alerts:** Customize CGM Alerts.
5. **Transmitter ID:** Enter the transmitter ID.
6. **CGM Info:** View the CGM information.
7. **Change Sensor Type:** Return to the *Select Sensor* screen to start a new sensor session with a different sensor type.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Dexcom G6
START G6 SENSOR
Calibrate CGM
CGM Alerts
Transmitter ID
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Dexcom G6
CGM Info
Change Sensor Type

19.7 Dexcom G7 Screen

The *Dexcom G7* screen can be accessed from the *My CGM* screen tapping **Change Sensor Type**. See Section 23.1 Choosing Your Sensor Type.

1.  : Returns to the *Options* screen.

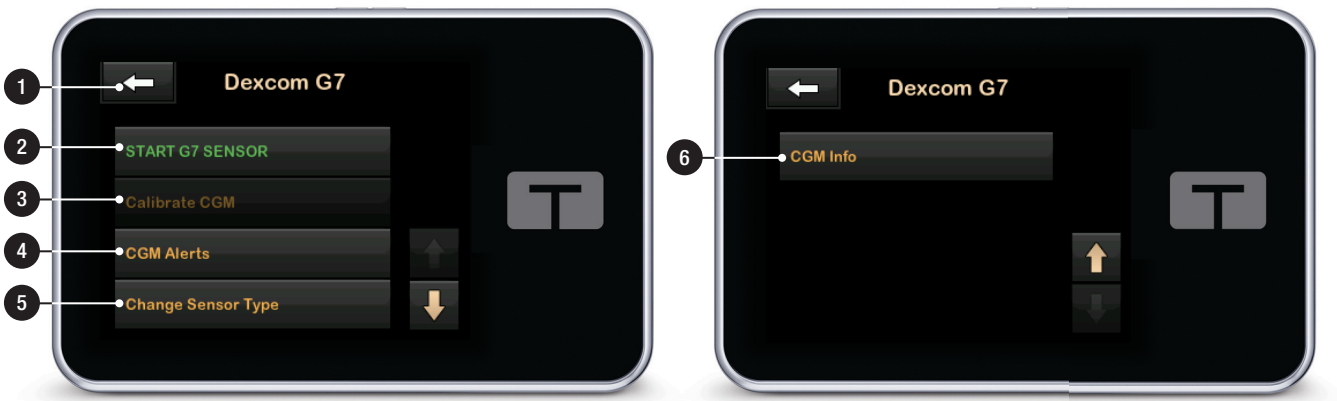
2. **Start G7 Sensor:** Starts a CGM session. If sensor is active, **STOP G7 SENSOR** will be displayed.

3. **Calibrate CGM:** Enter a calibration BG value. Only active when sensor session is active. Calibration is optional.

4. **CGM Alerts:** Customize CGM Alerts.

5. **Change Sensor Type:** Return to the *Select Sensor* screen to start a new sensor session with a different sensor type.

6. **CGM Info:** View the CGM information.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Dexcom G7
START G7 SENSOR
Calibrate CGM
CGM Alerts
Change Sensor Type
Dexcom G7
CGM Info

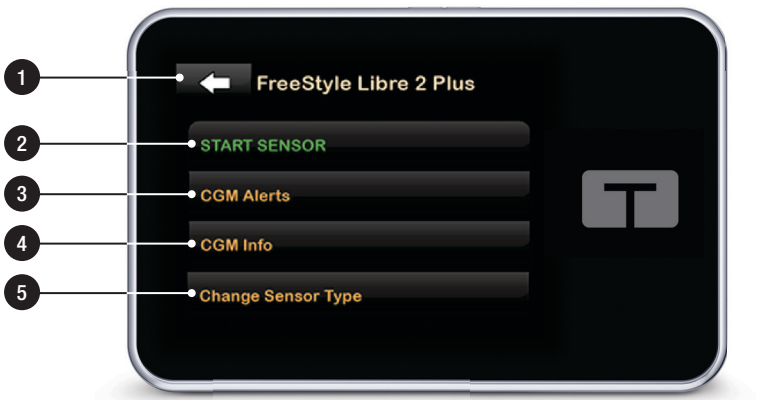
19.8 Abbott FreeStyle Libre 2 Plus Sensor CGM Screen

The *FreeStyle Libre 2 Plus* screen can be accessed from the *My CGM* screen by tapping **Change Sensor Type**. See Section 23.1 Choosing Your Sensor Type.

1. : Returns to the *Options* screen.
2. **Start Sensor:** Starts a CGM session. The pump prompts you to start the CGM session from the Tandem t:slim mobile app; tap OK to return to the *FreeStyle Libre 2 Plus* screen.
3. **CGM Alerts:** Customize CGM Alerts.
4. **CGM Info:** View the CGM information.
5. **Change Sensor Type:** Return to the *Select Sensor* screen to start a new sensor session with a different CGM sensor.

NOTE

You must start an Abbott FreeStyle Libre 2 Plus Sensor session from your Tandem t:slim mobile app. If you tap **FreeStyle Libre 2 Plus** on the *Select Sensor* screen, a prompt screen will direct you to use your Tandem t:slim mobile app instead.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FreeStyle Libre 2 Plus
START SENSOR
CGM Alerts
CGM Info
Change Sensor Type

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3 CGM Features

CHAPTER 20

CGM Overview

20.1 CGM System Overview

This section of the user guide covers instructions for using a CGM with your t:slim X2™ pump. Use of a CGM is optional, but in order to use Control-IQ+™ technology, CGM is required. When used, a CGM allows readings from your sensor to be displayed on your pump screen. To make treatment decisions during a new sensor startup period, you will also need a commercially available BG meter to use with your pump.

Compatible CGMs are the Dexcom G6 CGM, the Dexcom G7 CGM and the Abbott FreeStyle Libre 2 Plus Sensor CGM.

- The Dexcom G7 CGM and the Abbott FreeStyle Libre 2 Plus Sensor CGM each consist of a sensor with a built-in transmitter.
- The Dexcom G6 CGM consists of a sensor and transmitter.

All three CGM systems are devices that are inserted under the skin to continuously monitor glucose levels from interstitial fluid (the fluid under your skin). The CGM uses Bluetooth wireless technology communication.

- Dexcom CGM readings are updated every 5 minutes.
- Abbott FreeStyle Libre 2 Plus Sensor CGM numeric readings are updated every minute and trend graph readings are updated 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 CGM sensor, connecting and pairing to a CGM, and CGM product specifications, visit the manufacturer's website for applicable product instructions and training information.

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

⚠ PRECAUTION

AVOID separating the CGM and pump by more than 20 feet (6 meters). The transmission range from the CGM 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 CGM 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.

20.2 Device Connection Overview

Dexcom CGM Connection Overview

Dexcom CGMs only allow pairing with one medical device at a time (either the t:slim X2 pump or the Dexcom receiver), but you can still use the Dexcom G6 CGM app or the Dexcom

G7 CGM app and your pump simultaneously.

Neither the Dexcom G6 CGM app nor the Dexcom G7 CGM app connect directly to the Tandem t:slim™ mobile app. CGM readings in the Tandem t:slim mobile app are provided through the t:slim X2 insulin pump connection.

You can also use both the Dexcom G6 and Dexcom G7 mobile apps and the Tandem t:slim mobile app at the same time. The Dexcom G6 and Dexcom G7 mobile apps can be used to start and stop sensor sessions as well as connect with the other Dexcom compatible services.

Abbott FreeStyle Libre 2 Plus Sensor CGM Connection Overview

The Abbott FreeStyle Libre 2 Plus Sensor CGM only allows pairing with exactly one device at a time. Ensure your Abbott FreeStyle Libre 2 Plus Sensor CGM is not connected to the Abbott FreeStyle Libre 2 System App or Reader before pairing the CGM with your pump. CGM readings in the Tandem t:slim mobile app are provided through the t:slim X2 insulin pump connection.

20.3 Receiver (t:slim X2 Insulin Pump) Overview

To review the icons and controls displayed on the *Home* screen with CGM enabled, see Section 19.5 CGM Home Screen.

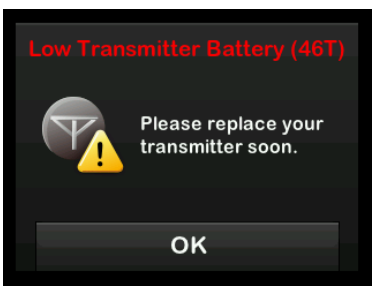
20.4 Dexcom G6 Transmitter Overview

This section provides information about CGM devices that have a separate transmitter. The information contained in this section is specific to the Dexcom G6 CGM and is provided as an example. For information about the Dexcom G6 transmitter, visit the manufacturer's website for applicable product instructions.

⚠ PRECAUTION

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

The transmitter battery will last approximately three months. 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.



20.5 Sensor Overview

For information about your CGM sensor, visit the manufacturer's website for applicable product instructions.

3 CGM Features

CHAPTER 21

CGM Settings

21.1 About Bluetooth Technology

Bluetooth Low Energy technology is a type of wireless communication used in cell phones and many other devices. Your pump uses Bluetooth wireless technology communication to wirelessly pair together with other devices, such as a CGM or smartphone running the Tandem t:slim™ mobile app. This allows the pump to wirelessly communicate with paired devices securely and only with each other.

21.2 Disconnecting from the Dexcom Receiver

Dexcom CGMs only allow pairing with one medical device at a time. Ensure your CGM is not connected to the receiver before pairing with the pump by doing the following:

Before pairing your CGM to the pump, turn off the Dexcom receiver and wait 15 minutes. This allows the Dexcom CGM to forget the connection currently in place with the Dexcom receiver.

NOTE

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

You may still use a smartphone with the Dexcom G6 or Dexcom G7 CGM app simultaneously with your pump.

21.3 Setting CGM Volume

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

To set your sound volume, see Section 5.13 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 pump vibrates and beeps.
- If the alert is not confirmed in 5 more minutes, the pump 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 pump repeats the alert sequence in 30 minutes (HypoRepeat option only).

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  .

Sound Option Descriptions (Dexcom only)

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

Sound Option Descriptions (Abbott only)

CGM Volume	Vibrate	Soft	Normal	HypoRepeat
High Alert	2 short vibrates	2 short vibrates + 2 low beeps	2 short vibrates + 2 medium beeps	2 short 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 short vibrates	2 short vibrates + 2 low rising beeps	2 short vibrates + 2 medium rising beeps	2 short vibrates + 2 medium rising beeps
Fall Alert	2 short vibrates	2 short vibrates + 2 low falling beeps	2 short vibrates + 2 medium falling beeps	2 short vibrates + 2 medium falling beeps
Rapid Fall Alert	3 short vibrates	3 short vibrates + 3 low falling beeps	3 short vibrates + 3 medium falling beeps	3 short vibrate + 3 medium falling beeps
Out of Range Alert	1 long vibrate	1 long vibrate + 2 low beeps	1 long vibrate + 2 medium beeps	1 long vibrate + 2 medium beeps
Fixed Low Alert	3 short vibrates	3 short vibrates + 3 medium tones	3 short vibrates + 3 medium tones	3 short vibrates + 3 medium beeps
All Other Alerts	1 long vibrate	1 long vibrate + 2 low beeps	1 long vibrate + 2 medium beeps	1 long vibrate + 2 medium beeps

21.4 CGM Info

CGM Info contains important information about your device.

If you use a Dexcom CGM, the following can be found in CGM Info:

- Firmware Revision
- Hardware Revision
- BLE Hardware ID
- Software Number

If you use an Abbott FreeStyle Libre 2 Plus Sensor CGM, the following can be found in CGM Info:

- Manufacturer
- Model
- Sensor ID
- Status
- Sensor Start Date
- Sensor End Date

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.

3 CGM Features

CHAPTER 22

Setting CGM Alerts

Setting Your CGM Alerts

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

NOTE

The following applies to setting CGM alerts on the pump. If you are using a Dexcom CGM app, any alerts that have been set up in the app are not automatically transferred to the pump and must be set up separately.

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

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

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

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

High and Low Glucose Alerts

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

22.1 Setting Your High Glucose Alert and Repeat Feature

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

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

   NOTE

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

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

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

hour, 2 hours, 3 hours, 4 hours, or 5 hours when your sensor glucose reading remains above the High Alert value.

To Set Up the Repeat Feature:

10. Tap **Repeat**.

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

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

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

12. Tap  .

22.2 Setting Your Low Glucose Alert and Repeat Feature

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

2. Tap the **Down Arrow**.

3. Tap **My CGM**.

4. Tap **CGM Alerts**.

5. Tap **High and Low**.

6. To Set the Low Alert, tap **Low Alert**.

7. Tap **Alert Me Below**.

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

   NOTE

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

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

9. Tap  .

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

To Set Up the Repeat Feature:

10. Tap **Repeat**.

11. To select the repeat time, tap the time you want the alert to sound again. For instance, if you select **1 hr**, the alert will sound every hour as long as your sensor glucose reading remains below the Low Alert Value.

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

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

12. Tap  .

22.3 Rate Alerts

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

Examples

If you set your Fall Alert to 2 mg/dL per minute and your sensor glucose readings fall at this rate or faster, the CGM Fall Alert shows one arrow pointing down. 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 pump vibrates or beeps according to your CGM volume selection. During a Dexcom sensor session, the CGM Rise Alert shows two arrows pointing up; during an Abbott FreeStyle Libre 2 Plus sensor session, the CGM Rise Alert shows one arrow pointing up.

22.4 Setting Your Rise Alert

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

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

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

8. Tap **2 mg/dL/min** to select.

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

9. Tap ✔.

22.5 Setting Your Fall Alert

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

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

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

8. Tap **2 mg/dL/min** to select.

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

9. Tap ✔.

22.6 Setting Your Out of Range Alert

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

The Out of Range Alert lets you know when your CGM and pump are not communicating with each other. This alert is on by default.

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

Your CGM is providing the data that Control-IQ+™ technology requires to make predictions to automate insulin dosing.

Keep the CGM 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 CGM and pump are not communicating, you will not get sensor glucose readings or alerts. The default value is on and will alert after 20 minutes.

The Out Of Range symbol appears on the pump *CGM Home* screen and on the *Out of Range Alert* screen (if turned on) when the CGM 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 CGM and pump are back in range.

NOTE
Control-IQ+ technology will continue to operate for the first 15 minutes that the CGM and pump are out of range. Once the Out of Range condition is present for 20 minutes, Control-IQ+

technology will stop operation until the two devices are within range.

To Set Your Out of Range Alert:

1. From the *Home* screen, tap OPTIONS.
2. Tap the Down Arrow.
3. Tap My CGM.
4. Tap CGM Alerts.
5. Tap Out of Range.

   The default is set to on and the time is set to 20 minutes.
6. To change the time, tap Alert After.
7. Using the on-screen keypad, enter the time after which you want to be alerted (between 20 minutes and 3 hours and 20 minutes) then tap  .
8. Tap  .

CHAPTER 23

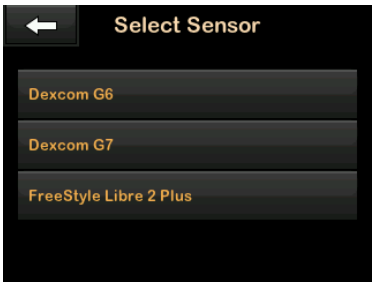
Starting or Stopping a CGM Sensor Session

23.1 Choosing Your Sensor Type

If this is the first time you have used your pump, or if you have updated your pump software since you began your last sensor session, you will be prompted to choose your CGM type. After your initial selection, the pump will default to that selection.

If you need to switch CGM types, you can do so from the OPTIONS menu on your pump as follows:

1. Tap OPTIONS.
2. Tap the Down Arrow.
3. Tap My CGM.
4. Tap Change Sensor Type.
5. Select your sensor type.



6. Begin the appropriate sensor pairing process as described in Section 23.2 Enter Your Dexcom G6 Transmitter ID or Section 23.8 Start the Dexcom G7 Sensor.

23.2 Enter Your Dexcom G6 Transmitter ID

To activate the Bluetooth wireless technology communication between your pump and a Dexcom G6 CGM, you need to enter the unique transmitter ID into your pump. Once the transmitter ID has been entered into your pump, the two devices can be paired, allowing your sensor glucose readings to be displayed on your pump.

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

1. Remove the transmitter from its packaging.

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

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

The transmitter ID can be found on the back of your transmitter or on the transmitter box.

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

7. Tap  .

8. To make sure that the correct transmitter ID is entered, you will be prompted to enter it a second time.

9. Repeat step 6 above, then tap  .

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

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

23.3 Start the Dexcom G6 Sensor

To start a CGM session, follow the steps below.

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

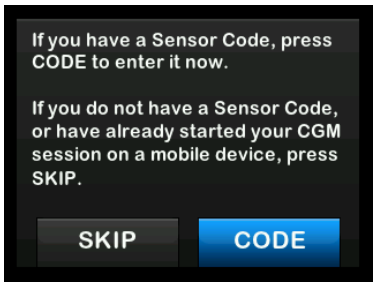
2. Tap the Down Arrow.

3. Tap My CGM.

4. Tap START G6 SENSOR.

✓ Once you start a sensor session, the START G6 SENSOR option is replaced with STOP G6 SENSOR.

The following screen displays prompting you to either enter the sensor code, or to skip this step. If you choose to enter the sensor code, you will not be prompted to calibrate for the duration of the sensor session. For information about Dexcom G6 CGM sensor codes, visit the manufacturer's website for applicable user guides.



Tap CODE to enter the 4-digit sensor code. If you don't have a code, or if you have already started a sensor session with the Dexcom G6 CGM app, you can tap SKIP.

If you don't enter a code into the t:slim X2™ pump, you will need to calibrate your sensor every 24 hours. A prompt to calibrate will be displayed on the pump.

5. Tap  to confirm.

✓ The *SENSOR STARTED* screen will appear to let you know your sensor startup has begun.

✓ Your pump will return to the *CGM Home* screen with the 3 hour trend graph and the sensor startup countdown symbol displayed.

Check your pump *CGM Home* screen 10 minutes after starting your sensor session to make sure your pump and CGM are communicating. The antenna symbol should be to the right of the battery indicator and should be white.

If you see the out of range symbol below the insulin level indicator, and the antenna symbol is grayed out, follow these troubleshooting tips:

- Make sure your pump and CGM 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.
- If the pump and CGM are still not communicating, check the *My CGM* screen to make sure the correct transmitter ID is entered.
- If the correct transmitter ID is entered and the pump and CGM are still not communicating, contact Customer Technical Support.

23.4 Dexcom G6 Sensor Startup Period

The Dexcom G6 sensor needs a 2-hour startup period to adjust to being under your skin. You will not get sensor glucose readings or alerts until the 2-hour startup period ends. For information about Dexcom G6 CGM sensor startup periods, visit the manufacturer's website for applicable product instructions.

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

Sensor Startup Period Timeline

⚠ PRECAUTION

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

⚑ NOTE

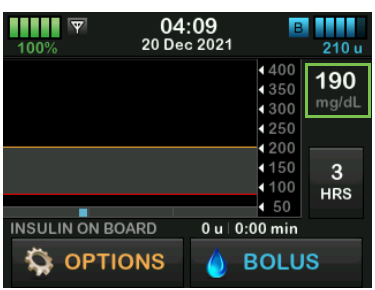
During the sensor startup period, Control-IQ+™ technology will not adjust profile Basal Rates or deliver automatic correction boluses. The sensor must be actively providing readings for Control-IQ+ technology to operate.

Example Start-up Screens

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

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

At the end of the 2-hour startup period, the countdown symbol will be replaced with the current CGM reading.



Follow the instructions in the next chapter to calibrate your sensor. Skip the calibration instructions if you entered a sensor code. You may enter a calibration into the pump at any time, even if you have already entered sensor code. Pay attention to your symptoms, and if they do not match the current CGM readings, you may choose to enter a calibration.

Ending a Dexcom G6 Sensor Session

When the sensor session ends, you will need to replace the sensor and start a new sensor session. In some cases your sensor session may end early. You may also choose to end the sensor session early. However, if you end a sensor session early, you cannot re-start the session with that same sensor. A new sensor must be used.

⚑ NOTE

DO NOT throw away the transmitter at the end of a sensor session. Continue use of the transmitter until the pump notifies you that the transmitter battery is about to expire. Wipe the outside of the transmitter with isopropyl alcohol between sensor sessions.

Sensor glucose alerts and alarms do not work after the sensor session ends. Once the sensor session has ended, CGM readings are not available. If you are using Control-IQ+ technology, it becomes inactive when a CGM sensor session is ended.

23.5 Dexcom G6 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 24 hours remaining, 2 hours remaining, and 30 minutes remaining before your session ends. You will continue to receive sensor glucose readings after each reminder.

When you see the *Sensor Expiring Soon* screen:

1. Tap OK to return to the previous screen.

✓ The *Sensor Expiring Soon* screen will show again when there are 2 hours remaining, and when there are 30 minutes remaining.

✓ After the final 30 minutes, the *Replace Sensor* screen is displayed.

2. Tap OK.

✓ The *CGM Home* screen will appear with the Replace Sensor icon in the place where sensor glucose readings normally show.

New sensor glucose readings do not show on your pump or Tandem t:slim mobile app after your sensor session ends. You must remove your sensor, insert a new sensor, and start a new sensor session.

23.6 Ending a Dexcom G6 Sensor Session Before Automatic Shut-Off

You can end your sensor session at any time before the automatic sensor shutoff. To end your sensor session early:

1. From the *Home* screen, tap OPTIONS.
2. Tap the Down Arrow.
3. Tap My CGM.
4. Tap STOP G6 SENSOR.
5. Tap ✓ to confirm.

✓ The *SENSOR STOPPED* screen is temporarily displayed.

✓ The *CGM Home* screen will appear with the Replace Sensor icon in the place where sensor glucose readings normally show.

New sensor glucose readings do not show on your pump or Tandem t:slim mobile app after your sensor session ends. You must remove your sensor, insert a new sensor, and start a new sensor session.

23.7 Removing the Dexcom G6 Sensor and Transmitter

⚠ WARNING

DO NOT ignore broken or detached sensor wires. A sensor wire could remain under your skin. If a sensor wire breaks off under your skin and you can't see it, don't try to remove it. Contact your healthcare provider. Also seek

professional medical help if you have symptoms of infection or inflammation (redness, swelling, or pain) at the insertion site. If you experience a broken sensor, please report this to Customer Technical Support.

For information about removing the Dexcom G6 sensor and Dexcom G6 transmitter, visit the manufacturer's website for applicable product instructions.

23.8 Start the Dexcom G7 Sensor

To start a Dexcom G7 CGM session, follow the steps below.

1. From the *CGM Home* screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **My CGM**.
4. Tap **START G7 SENSOR**.

✓ Once you start a sensor session, the **START G7 SENSOR** option is replaced with **STOP G7 SENSOR**.

5. Enter your pairing code. Tap  to confirm.
6. Re-enter your pairing code and tap  to confirm.
7. Start your sensor. Tap  to confirm.

✓ The *SENSOR STARTED* screen will appear to let you know your sensor startup has begun.

✓ Your pump will return to the *CGM Home* screen with the 3 hour trend graph and the sensor startup countdown symbol displayed.

Check your pump *CGM Home* screen 10 minutes after starting your sensor session to make sure your pump and CGM are communicating. The antenna symbol should be to the right of the battery indicator and should be white.

If you see the out of range symbol below the insulin level indicator, and the antenna symbol is grayed out, follow these troubleshooting tips:

- Make sure your pump and CGM 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.
- If the pump and CGM are still not communicating, contact Customer Technical Support.

23.9 Dexcom G7 Sensor Startup Period

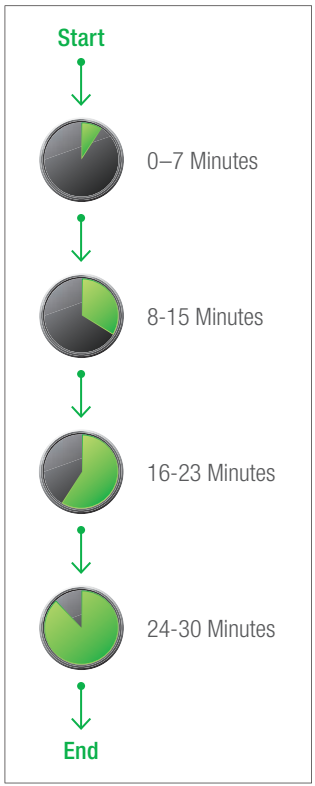
The Dexcom G7 sensor needs a 30-minute startup period to adjust to being under your skin. This startup period begins automatically when the sensor is inserted.

You will not get sensor glucose readings or alerts until the 30-minute startup period ends. For information about Dexcom G7 CGM sensor startup periods, visit the manufacturer's website for applicable product instructions.

During the startup period, the *CGM Home* screen on your pump shows a 30-minute countdown symbol in the upper right portion of the screen. The

countdown symbol fills in over time to show that you are getting closer to the active sensor session.

Sensor Startup Period Timeline



⚠ PRECAUTION

Continue to use a BG meter and test strips in order to make treatment decisions during the 30-minute startup period.

⚑ NOTE

During the sensor startup period, Control-IQ+ technology will not adjust profile Basal Rates or deliver automatic correction boluses. The sensor must be actively providing readings for Control-IQ+ technology to operate.

At the end of the 30-minute startup period, the countdown symbol will be replaced with the current CGM reading.

⚑ NOTE

ALWAYS keep the pairing code for your new sensor in order to pair the new sensor with your pump after your active sensor session has expired. See Section 23.8 Start the Dexcom G7 Sensor to start your new sensor.

23.10 Dexcom G7 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 24

hours remaining and 2 hours remaining. After the sensor has expired, a 12-hour grace period begins. You will continue to receive sensor glucose readings during the grace period. During the grace period, the pump tells you when there are 2 hours remaining, and again when there are 30 minutes remaining.

When you see the *Sensor Expiring Soon* screen:

1. Tap OK to return to the previous screen.

✓ If you choose not to stop your sensor when you see the *Sensor Expiring Soon* screen, the *Sensor Expiring Soon* screen will show again when there are 12 hours remaining and again when there are 2 hours remaining.

✓ The sensor will then be in the 12 hour grace period, and the *Sensor Expiring Soon* screen will show when there are 2 hours remaining and again when there are 30 minutes remaining.

✓ After the final 30 minutes, the *Replace Sensor* screen is displayed.

2. Tap OK.

✓ The *CGM Home* screen will appear with the Replace Sensor icon in the place where sensor glucose readings normally show.

New sensor glucose readings do not show on your pump or Tandem t:slim mobile app after your sensor session ends. You must remove your sensor, insert a new sensor, and start a new sensor session.

23.11 Ending a Dexcom G7 Sensor Session Before Automatic Shut-Off

You can end your sensor session at any time before the automatic sensor shutoff. To end your sensor session early:

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

2. Tap the Down Arrow.

3. Tap My CGM.

4. Tap STOP G7 SENSOR.

5. Tap ✓ to confirm.

✓ The *SENSOR STOPPED* screen is temporarily displayed.

✓ The *CGM Home* screen will appear with the Replace Sensor icon in the place where sensor glucose readings normally show.

New sensor glucose readings do not show on your pump or Tandem t:slim mobile app after your sensor session ends. You must remove your sensor, insert a new sensor, and start a new sensor session.

23.12 Removing the Dexcom G7 Sensor

⚠ 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 G7 CGM, visit the manufacturer's website for applicable product instructions.

23.13 Start the Abbott FreeStyle Libre 2 Plus Sensor

You will need to start an Abbott FreeStyle Libre 2 Plus Sensor CGM session using the Tandem t:slim mobile app and keep your smartphone within 5 feet of your pump during sensor startup. Connect your pump to the Tandem t:slim mobile app prior to starting a CGM session as shown in Section 4.3 Connecting to a Smartphone.

NOTE

Ensure your Abbott FreeStyle Libre 2 Plus Sensor CGM is not connected to the Abbott FreeStyle Libre 2 System App or Reader before pairing the CGM with your pump. The Abbott FreeStyle Libre 2 Plus CGM only allows pairing with exactly one device at a time.

To start a CGM session, follow the steps below.

1. From the Tandem t:slim mobile app, tap **Settings** on the *Navigation* bar.
2. Tap **CGM**.
3. Tap **FreeStyle Libre 2 Plus**.

✓ The *Start Sensor* screen appears. For iOS smartphones, see step 4; for Android smartphones, see step 5.

4. From your iOS smartphone, tap **Start Scanning**.

✓ When prompted by the Tandem t:slim mobile app, hold the top of your smartphone near your sensor until the *Scan Complete* screen appears and your phone vibrates or you hear a sound. Skip to step 6.

5. From your Android smartphone, in your smartphone settings menu, ensure Near Field Communication (NFC) is enabled.

✓ When prompted by the Tandem t:slim mobile app, hold the back of your smartphone near your sensor until your phone vibrates twice or you hear two sounds.

6. When the *Sensor Session Started* screen appears, tap **OK**.

✓ The *Treatment Decisions* screen appears.

7. Tap **Next**.

✓ Your Tandem t:slim mobile app will return to the *CGM* screen.

Check your pump *CGM Home* screen 10 minutes after starting your sensor session to make sure your pump and CGM sensor are communicating. The antenna symbol should be to the right of the battery indicator and should be white.

If you see the out of range symbol below the insulin level indicator, and the

antenna symbol is grayed out, follow these troubleshooting tips:

- Make sure your pump and CGM sensor 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.
- If the pump and transmitter are still not communicating, contact Customer Technical Support.

23.14 Abbott FreeStyle Libre 2 Plus Sensor Startup Period

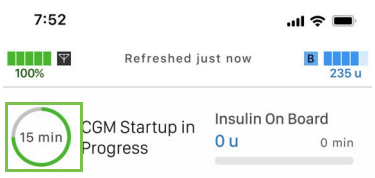
The Abbott FreeStyle Libre 2 Plus sensor needs a 1-hour startup period to adjust to being under your skin. You will not get sensor glucose readings or alerts until the 1-hour startup period ends. For information about the Abbott FreeStyle Libre 2 Plus CGM sensor startup period, visit the manufacturer's website for applicable product instructions.

During the startup period, a 1-hour countdown symbol appears on both the *CGM Home* screen and the Tandem t:slim mobile app *Dashboard* screen. The countdown symbol fills in over time to show that you are getting closer to the active sensor session. The Tandem t:slim mobile app will also display the time remaining in the startup period.

⚠ PRECAUTION
Continue to use a BG meter and test strips in order to make treatment decisions during the 1-hour startup period.

Example Start-up Screens

The following is an example of the countdown symbol on the Tandem t:slim mobile app *Dashboard* screen.



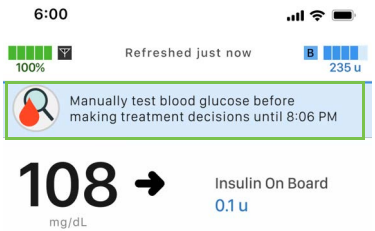
The following is an example of the countdown symbol on the *CGM Home* screen.

At the end of the 1-hour startup period, the countdown symbol will be replaced with the current CGM reading and the Check BG icon.

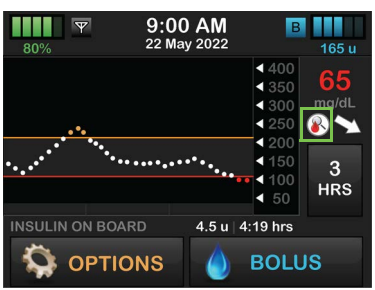
Check BG Icon

After the 1-hour startup period, the Tandem t:slim mobile app *Dashboard* screen and the pump *CGM Home* screen will display the Check BG icon for an additional 11 hours. When the Check BG icon is displayed, check your BG to confirm your sensor values before making any treatment decisions.

The following is an example of the Check BG icon on the Tandem t:slim mobile app *Dashboard* screen.



The following is an example of the Check BG icon on the *CGM Home* screen.



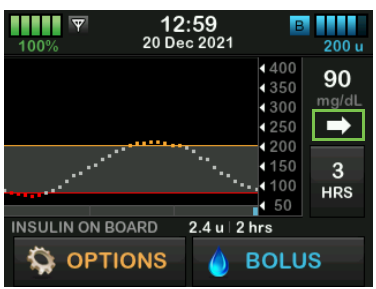
⚠ PRECAUTION

ALWAYS use a BG meter to confirm sensor values when making treatment decisions while the Check BG icon is displayed, or when CGM readings are inconsistent with your signs and symptoms.

⚠ PRECAUTION

Your sensor value is **NOT** automatically populated into the *Bolus* screen during the first 12 hours of wearing an Abbott FreeStyle Libre 2 Plus Sensor CGM. Check your BG to confirm your sensor values before making any treatment decisions.

The Check BG icon will disappear 12 hours after your pump and CGM sensor begin communicating.



23.15 Abbott FreeStyle Libre 2 Plus 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 24 hours remaining, 2 hours remaining, and 30 minutes remaining before your session ends. You will continue to receive sensor glucose readings after each reminder.

When you see the *Sensor Expiring Soon* screen:

1. Tap OK to return to the previous screen.

✓ The *Sensor Expiring Soon* screen will show again when there are 2 hours remaining, and when there are 30 minutes remaining.

✓ After the final 30 minutes, the *Replace Sensor* screen is displayed.

2. Tap OK.

✓ The *CGM Home* screen will appear with the Replace Sensor icon in the place where sensor glucose readings normally show.

New sensor glucose readings do not show on your pump or Tandem t:slim mobile app after your sensor session ends. You must remove your sensor, insert a new sensor, and start a new sensor session.

23.16 Ending an Abbott FreeStyle Libre 2 Plus Sensor Session Before Automatic Shut-Off

You can end your sensor session at any time before the automatic sensor shutoff. To end your sensor session early:

1. From the *Home* screen, tap OPTIONS.
2. Tap the Down Arrow.
3. Tap My CGM.
4. Tap STOP SENSOR.
5. Tap  .
6. Tap  to confirm.

✓ The *SENSOR STOPPED* screen is temporarily displayed.

✓ The *CGM Home* screen will appear with the Replace Sensor icon in the place where sensor glucose readings normally show.

New sensor glucose readings do not show on your pump or Tandem t:slim mobile app after your sensor session ends. You must remove your sensor, insert a new sensor, and start a new sensor session.

23.17 Removing the Abbott FreeStyle Libre 2 Plus Sensor

For information about removing the Abbott FreeStyle Libre 2 Plus sensor, visit the manufacturer's website for applicable product instructions.

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3 CGM Features

CHAPTER 24

Calibrating Your Dexcom CGM System

Calibration is required for the Dexcom G6 CGM if you did not enter a sensor code when starting the sensor session. It is optional at all other times.

Calibration is optional for the Dexcom G7 CGM and can be performed if you have symptoms that do not align with your posted CGM values.

24.1 Calibration Overview

If you are using the Dexcom G6 and did not enter a CGM sensor code when starting a sensor session, you will be prompted to calibrate at the following intervals:

- 2-hour startup: 2 calibrations 2 hours after you start your sensor session
- 12-hour update: 12 hours after the 2 hour start up calibration
- 24-hour update: 24 hours after the 2 hour start up calibration
- Every 24 hours: every 24 hours after the 24-hour update
- When notified

On the first day of your sensor session, you must enter four BG values into your pump to calibrate. You must enter one BG value to calibrate every 24 hours after your first startup calibration. The pump will remind you when these calibrations are required. In addition, you may be prompted to enter additional BG values to calibrate as needed.

When calibrating, you must enter your BG values into the pump by hand. You can use any commercially available BG meter. You must calibrate with accurate BG meter values to get accurate sensor glucose readings.

Follow these important instructions to obtain BG values when calibration is needed:

- BG values used for calibration must be between 20 to 600 mg/dL and must have been taken within the past 5 minutes.
- Your sensor cannot be calibrated if the glucose value from your BG meter is less than 20 mg/dL or greater than 600 mg/dL. For safety reasons, it is recommended that you treat your BG value before calibrating.
- Make sure a sensor glucose reading shows in the upper right portion of the *CGM Home* screen before calibrating.
- Make sure the antenna symbol is visible to the right of the battery indicator on the *CGM Home* screen and is active (white, not grayed out) before calibrating.
- Always use the same BG meter to calibrate that you routinely use to measure your BG. Do not switch your BG meter in the middle of a sensor session. BG meter and strip accuracy vary between BG meter brands.
- The accuracy of the BG meter used for calibration may affect the accuracy of sensor glucose readings. Follow your BG meter manufacturer's instructions for BG testing.

24.2 Startup Calibration

If you did not enter a sensor code when starting the Dexcom G6 CGM, the pump will prompt you to calibrate to provide accurate information. If you are choosing to calibrate either the Dexcom G6 CGM or the Dexcom G7 CGM, begin at Step 1 below.

NOTE

The instructions in this section do not apply if you entered the sensor code when you started the sensor session, unless you are doing an optional calibration.

After the CGM startup period is complete, the *Calibrate CGM Alert* screen will appear, letting you know that two separate BG values from your BG meter must be entered. You will not see sensor glucose readings until the pump accepts the BG values.

1. From the *Calibrate CGM Alert* screen, tap OK.

✓ The *CGM Home* screen will appear with two blood drops in the upper right portion of the screen. The two blood drops will stay on the screen until you enter two separate BG values to calibrate.

2. Wash and dry your hands, make sure your BG test strips have been stored properly and are not expired, and make sure your BG meter is properly coded (if required).

3. Take a BG measurement using your BG meter. Carefully apply the blood sample to the test strip following your BG meter manufacturer's instructions.

⚠ PRECAUTION

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

4. Tap **OPTIONS**.

5. Tap the **Down Arrow**.

6. Tap **My CGM**.

7. Tap **Calibrate CGM**.

8. Using the on-screen keypad, enter the BG value from your BG meter.

⚠ PRECAUTION

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

9. Tap ✓.

10. Tap ✓ to confirm the calibration.

    Tap ✗ if the BG value does not exactly match the reading from your BG meter. The on-screen keypad will reappear. Enter the exact reading from your BG meter.

✓ The *CALIBRATION ACCEPTED* screen will appear.

✓ The *My CGM* screen will appear.

11. Tap **Calibrate CGM** to enter your second BG value.

✓ The on-screen keypad will appear.

12. Wash and dry your hands, make sure your BG test strips have been stored properly and are not expired, and make sure your BG meter is properly coded (if required).

13. Take a BG measurement using your BG meter. Carefully apply the blood sample to the test strip following your BG meter manufacturer's instructions.

14. Follow steps 8 –10 to enter your second BG value.

24.3 Calibration BG Value and Correction Bolus

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

- If you enter a calibration value that is above your Target BG in Personal Profiles:
  - » If Control-IQ+™ technology is disabled, the *Above Target Correction Bolus* confirmation screen will appear. To add a correction bolus, tap  , then follow the instructions in Section 8.3 Correction Bolus Calculation.
  - » If Control-IQ+ technology is enabled, the pump will return to the *My CGM* screen.
- If you enter a calibration value that is below your Target BG in Personal Profiles, a message screen will indicate "Your BG is Below Target", and other important information will appear on the screen.
- If you enter your Target BG as a calibration value, the pump will return to the *CGM Home* screen.

24.4 Reasons You May Need to Calibrate

You may need to calibrate if your symptoms do not match the glucose values provided by your CGM.

If you see the *CALIBRATION ERROR* screen, you will be prompted to enter a BG value to calibrate in either 15 minutes or 1 hour, depending on the error.

NOTE

Although it is not required, and you will not be prompted to calibrate, you may enter a calibration into the pump at any time, even if you have already entered a sensor code. Pay attention to your symptoms, and if they do not match the current CGM readings, you may choose to enter a calibration.

3 CGM Features

CHAPTER 25

Viewing CGM Data on Your t:slim X2 Insulin Pump

25.1 Overview

⚠ WARNING

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

The pump screens in this section illustrate the screen when Control-IQ+™ technology is off. For information about CGM screens when Control-IQ+ technology is on, see Section 31.9 Control-IQ+ Technology Information on Your Screen.

This section teaches you how to view your sensor glucose readings and trend information.

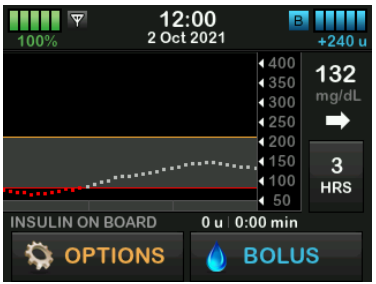
- During a Dexcom CGM sensor session, your readings are updated every 5 minutes.
- During an Abbott FreeStyle Libre 2 Plus CGM sensor session, your readings are updated every minute.
- During an active CGM sensor session, the trend graph is updated every 5 minutes regardless of which CGM sensor you are wearing.

The trend graph provides additional information that your BG meter does not. It shows the direction your sensor glucose is changing and how fast it is changing. The trend graph can also show you where your sensor glucose has been over time.

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

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

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



- The current time and date are shown at the top of the screen in the middle.
- Each “dot” on the trend graph is a sensor glucose reading reported every 5 minutes.
- Your High Alert setting shows as an orange line across the trend graph.
- Your Low Alert setting shows as a red line across the trend graph.
- The gray zone highlights your target sensor glucose range, between your High and Low Alert settings.

- Sensor glucose readings are shown in milligrams per deciliter (mg/dL).
- If your sensor glucose reading is between your High and Low Alert settings, it is shown in white.
- If your sensor glucose reading is above your High Alert setting, it is shown in orange.
- If your sensor glucose reading is below your Low Alert setting, it is shown in red.
- If your sensor glucose reading is 55 mg/dL or lower, it is shown in red, regardless of the Low Alert setting.

25.2 CGM Trend Graphs

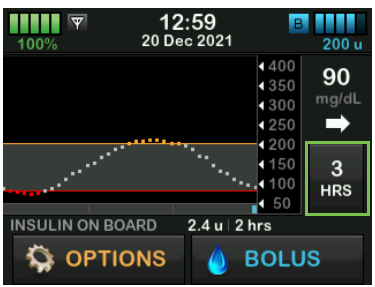
You can view your past sensor glucose trend information on your *CGM Home* screen.

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

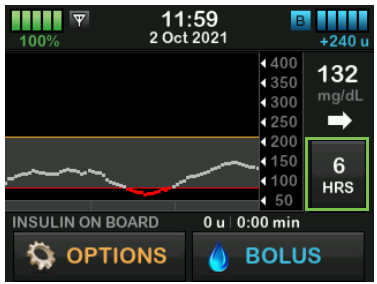
Your trend graph shows a flat line or dots at 50 or 400 mg/dL when your glucose is outside this range.

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

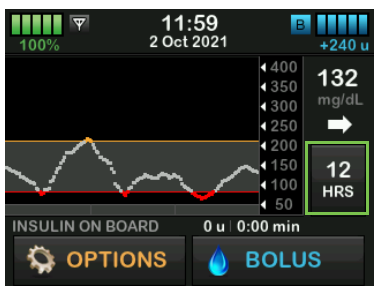
3 Hour Trend Graph (default view) shows you your current sensor glucose reading along with the last 3 hours of sensor glucose readings.



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

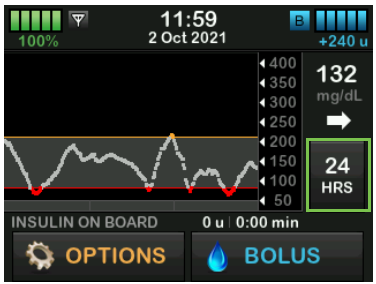


12 Hour Trend Graph shows you your current sensor glucose reading along with the last 12 hours of sensor glucose readings.

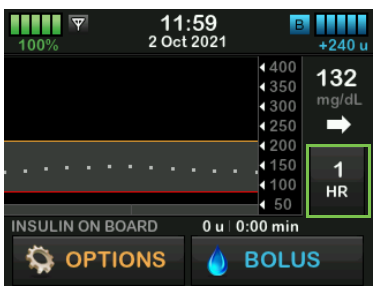


24 Hour Trend Graph shows you your current sensor glucose reading along

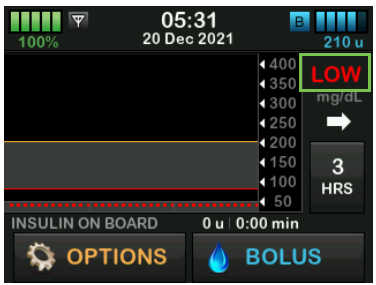
with the last 24 hours of sensor glucose readings.



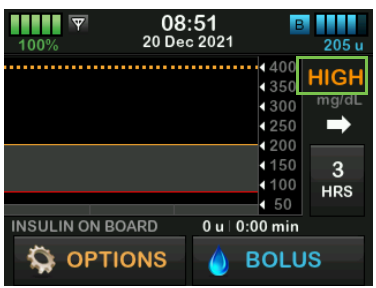
1 Hour Trend Graph shows you your current sensor glucose reading along with the last 1 hour of sensor glucose readings.



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



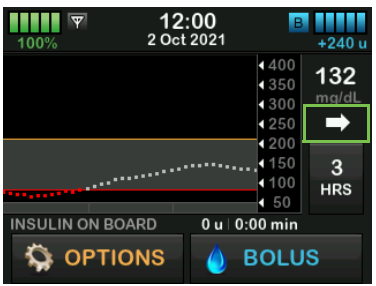
HIGH shows when your most recent sensor glucose reading is greater than 400 mg/dL.



25.3 Rate of Change Arrows

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

The trend arrows show below your current sensor glucose reading.



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

If there are missed communications between the CGM and your pump during the last 15–20 minutes due to being out of range or due to an error

condition, an arrow may not display. If the trend arrow is missing, and you are concerned that your BG level may be rising or falling, take a BG measurement using your BG meter.

The table below shows the different trend arrows you may see during a Dexcom CGM sensor session:

Dexcom CGM Trend Arrow Definitions

	Constant: Your sensor glucose is steady (not increasing/decreasing more than 1 mg/dL each minute). Your sensor glucose could increase or decrease by up to 15 mg/dL in 15 minutes.
	Slowly rising: Your sensor glucose is rising 1–2 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase up to 30 mg/dL in 15 minutes.
	Rising: Your sensor glucose is rising 2–3 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase up to 45 mg/dL in 15 minutes.
	Rapidly rising: Your sensor glucose is rising more than 3 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase more than 45 mg/dL in 15 minutes.

	Slowly falling: Your sensor glucose is falling 1–2 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease up to 30 mg/dL in 15 minutes.
	Falling: Your sensor glucose is falling 2–3 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease up to 45 mg/dL in 15 minutes.
	Rapidly falling: Your sensor glucose is falling more than 3 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease more than 45 mg/dL in 15 minutes.
No Arrow	No rate of change information: The CGM cannot calculate how fast your sensor glucose is rising or falling at this time.

The table below shows the different trend arrows you may see during an Abbott FreeStyle Libre 2 Plus CGM sensor session:

Abbott FreeStyle Libre 2 Plus CGM Trend Arrow Definitions

	Changing Slowly: Your sensor glucose is steady (increasing/decreasing 1 mg/dL or less each minute). Your sensor glucose could increase or decrease by up to 30 mg/dL in 30 minutes.
	Rising: Your sensor glucose is rising between 1 and 2 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase up to 60 mg/dL in 30 minutes.
	Rising Quickly: Your sensor glucose is rising more than 2 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase more than 60 mg/dL in 30 minutes.

	Falling: Your sensor glucose is falling between 1 and 2 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease up to 60 mg/dL in 30 minutes.
	Falling Quickly: Your sensor glucose is falling more than 2 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease more than 60 mg/dL in 30 minutes.

25.4 CGM History

CGM History displays the historical log of CGM events. At least 30 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 any Dexcom 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 the section you want to view. Each section is organized by date. Tap the date to view events from that day. Use the **Down Arrow** to scroll to more dates.

25.5 Missed Readings

If your pump misses CGM readings for a period of time, you will see three dashes where the CGM reading typically displays on the *CGM Home* screen and on the *CGM Lock* screen. The pump will automatically attempt to backfill missing data points up to 6 hours in the past when connectivity is restored and readings begin to appear. If the sensor glucose number or trend arrow is missing, and you are concerned that your BG level may be rising or falling, take a BG measurement using your BG meter.

NOTE

Control-IQ+ technology will continue to operate for the first 15 minutes after CGM readings become unavailable. If connectivity is not restored after 20 minutes, Control-IQ+ technology will stop operation until CGM readings are available. While Control-IQ+ technology is not operating, your pump will continue to deliver insulin according to your Personal Profile settings. Once CGM readings are available, Control-IQ+ technology will automatically resume. For more information, see Chapter 30 Introduction to Control-IQ+ Technology.

NOTE

During an Abbott FreeStyle Libre 2 Plus sensor session, the pump cannot backfill missing data points. However, your pump will continue to

deliver insulin according to your Personal Profile setting until connectivity is restored.

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CHAPTER 26

CGM Alerts and Errors

Information in this section will help you learn how to respond to CGM alerts and errors. It applies only to the CGM portion of your pump. CGM alerts and errors do not follow the same pattern of vibration and beeps as insulin delivery reminders, alerts, and alarms.

The Tandem t:slim™ mobile app also can provide messages, alerts, and alarms from your t:slim X2™ pump as push notifications on your smartphone. These push notifications will be identical to your pump's display unless otherwise noted in this chapter.

⚠ PRECAUTION

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

⚑ NOTE

Not all alerts are applicable to all CGM types. An alert screen may vary slightly depending on the type of CGM you are using.

- Sections 26.1 through 26.10 contain common CGM errors and errors.
- For Dexcom-specific alerts, see Sections 26.11 – 26.24.
- For Abbott-specific alerts, see Sections 26.25 – 26.28.

For information on insulin delivery reminders, alerts, and alarms, see Chapter 13 t:slim X2 Insulin Pump Alerts, Chapter 14 t:slim X2 Insulin Pump Alarms, and Chapter 15 t:slim X2 Insulin Pump Malfunction.

For information on Control-IQ+™ technology alerts, see Chapter 32 Control-IQ+ Technology Alerts.

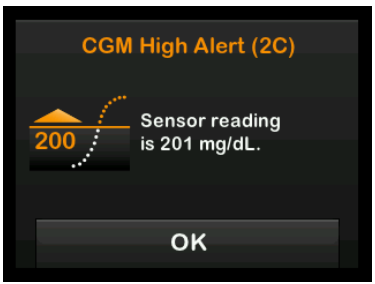
⚠ WARNING

If a sensor session is ended, either automatically or manually, Control-IQ+ technology is unavailable and will not adjust insulin. In order for Control-IQ+ technology to be enabled, a sensor session must be started and transmitting sensor values to the pump based on a sensor code, pairing code, or sensor calibration.

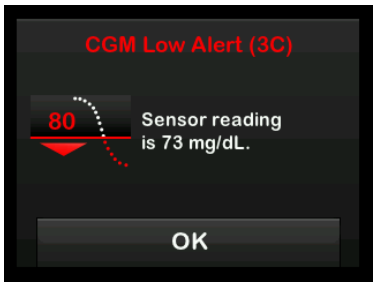
⚠ PRECAUTION

You must customize the CGM alert settings on your t:slim X2 pump and the Dexcom CGM app separately. The alert settings apply to the smartphone and pump separately.

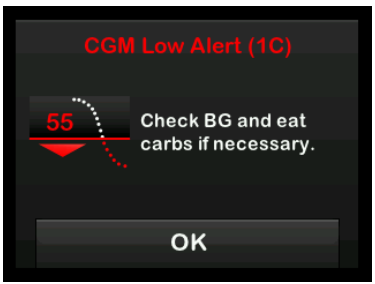
26.1 CGM High Alert

Screen	Explanation	
What will I see on the screen?  	What does it mean?	Your most recent sensor glucose reading is at or above the High Alert setting.
	How will the pump notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes until confirmed or your sensor glucose value drops below the Alert level.
	Will the pump re-notify me?	Only if you have turned on the Repeat feature.
	How should I respond?	Tap OK to confirm.

26.2 CGM Low Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your most recent sensor glucose reading is at or below the Low Alert setting.
	How will the pump notify me?	3 vibrations, then 3 vibrations/beeps every 5 minutes until confirmed or your sensor glucose value goes above the Alert level.
	Will the pump re-notify me?	Only if you have turned on the Repeat feature.
	How should I respond?	Tap OK to confirm.

26.3 CGM Fixed Low Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your most recent sensor glucose reading is at or below 55 mg/dL.
	How will the pump notify me?	4 Vibrations, then 4 vibrations/beeps every 5 minutes until confirmed or your sensor glucose value goes above 55 mg/dL.
	Will the pump re-notify me?	Yes, 30 minutes after each confirmation until your sensor glucose value goes above 55 mg/dL.
	How should I respond?	Tap OK to confirm.

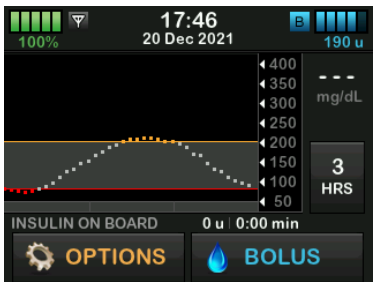
26.4 CGM Rise Alert

Screen	Explanation	
What will I see on the screen?  	What does it mean?	Your sensor glucose levels are rising at 2 mg/dL per minute or faster (at least 30 mg/dL in 15 minutes).
	How will the pump notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes or until confirmed.
	Will the pump re-notify me?	No.
	How should I respond?	Tap OK to confirm.

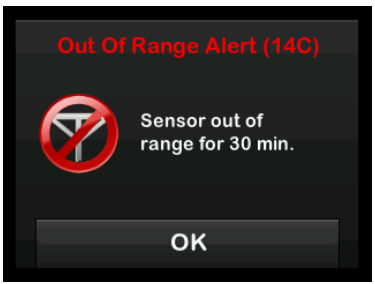
26.5 CGM Fall Alert

Screen	Explanation	
What will I see on the screen?  	What does it mean?	Your sensor glucose levels are falling at 2 mg/dL per minute or faster (at least 30 mg/dL in 15 minutes).
	How will the pump notify me?	3 vibrations, then 3 vibrations/beeps every 5 minutes or until confirmed.
	Will the pump re-notify me?	No.
	How should I respond?	Tap OK to confirm.

26.6 Unknown Sensor Glucose Reading

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The sensor is sending sensor glucose readings that the pump does not understand. You will not receive sensor glucose readings.
	How will the pump notify me?	On screen only with no vibration or beep.
	Will the pump re-notify me?	The 3 dashes will remain on the screen until a new sensor glucose reading is received and displayed in their place. If no sensor glucose readings are received after 20 minutes, the CGM Unavailable Alert will trigger. See Section 26.9 CGM Unavailable.
	How should I respond?	Wait 30 minutes for more information from the pump. If you are using a Dexcom CGM, do not enter BG values for calibration. The pump will not use BG values for calibration when "- - -" appears on the screen.

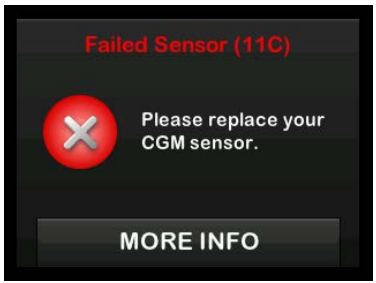
26.7 Out of Range Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The CGM and pump are not communicating. You may see slightly different error screens depending on which CGM you are using. The pump will not receive sensor glucose readings, and Control-IQ+ technology is not able to predict sensor glucose levels or adjust insulin delivery.
	How will the pump notify me?	1 vibrate, then vibration/beep every 5 minutes until the CGM and pump are back in range.
	Will the pump re-notify me?	Yes, if the CGM and pump remain out of range.
	How should I respond?	Tap OK to confirm and move the CGM and pump closer together, or remove the obstruction between them.

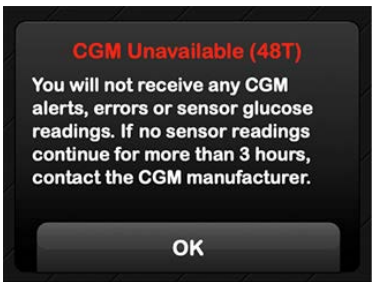
⚠ WARNING

Control-IQ+ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate settings in your active Personal Profile.

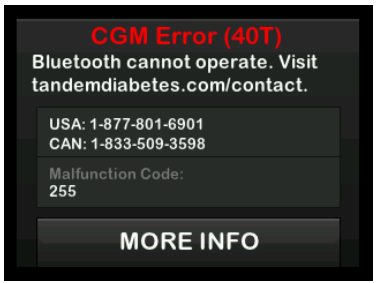
26.8 Failed Sensor Error

Screen	Explanation	
What will I see on the screen?  	What does it mean?	The sensor is not working properly and the CGM session has stopped.
	How will the pump notify me?	1 vibration, then vibration/beep every 5 minutes.
	Will the pump re-notify me?	No.
	How should I respond?	Tap **MORE INFO**. A screen notifies you that your CGM session has stopped and that insulin delivery will continue as normal. Replace the sensor and begin a new CGM session.

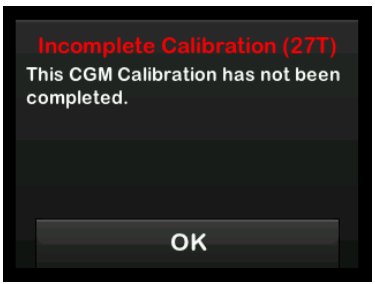
26.9 CGM Unavailable

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your CGM session has been stopped for more than 20 minutes and the CGM can no longer be used.
	How will the pump notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes or until confirmed.
	Will the pump re-notify me?	No. If the condition persists for 3 hours, the *Failed Sensor* alert will be displayed. See Section 26.8 Failed Sensor Error.
	How should I respond?	Tap OK and contact the CGM manufacturer.

26.10 CGM System Error

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your CGM System is not working properly; the CGM session has stopped and the CGM can no longer be used.
	How will the pump notify me?	1 vibration, then vibration/beep every 5 minutes.
	Will the pump re-notify me?	No.
	How should I respond?	• Write down the Malfunction Code number that appears on the screen. • Tap **MORE INFO**. A screen notifies you that your CGM session has stopped and that insulin delivery will continue as normal. • Call Customer Technical Support.

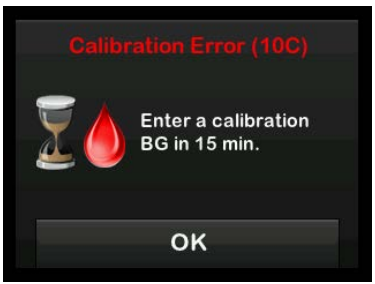
26.11 Incomplete Calibration (Dexcom Only)

Screen	Explanation	
What will I see on the screen?  	What does it mean?	If you start to enter a calibration value using the keypad and do not complete the entry within 90 seconds, this screen appears.
	How will the pump notify me?	2 beeps or vibrations depending on Sound Volume selected.
	Will the pump 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.

26.12 Calibration Timeout (Dexcom Only)

Screen	Explanation	
What will I see on the screen?  	What does it mean?	If you start to enter a calibration value using the keypad and do not complete the entry within 5 minutes, this screen appears.
	How will the pump notify me?	2 beeps or vibrations depending on Sound Volume selected.
	Will the pump re-notify me?	Yes, every 5 minutes until confirmed.
	How should I respond?	Tap OK and obtain a new BG value using your BG meter. Enter the value using the on-screen keypad to calibrate the CGM.

26.13 Calibration Error Alert (Dexcom Only)

Screen	Explanation	
What will I see on the screen?  	What does it mean?	The CGM cannot calibrate using the last BG meter value you entered.
	How will the pump notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the pump re-notify me?	No.
	How should I respond?	Tap OK to confirm. Give the CGM and your glucose time to adjust by waiting at least 15 minutes. If calibration is still desired or readings do not appear, try again, If sensor glucose readings do not appear after your last calibration, visit the CGM manufacturer's website for applicable product instructions.

26.14 CGM Rapid Rise Alert (Dexcom Only)

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your sensor glucose levels are rising at 3 mg/dL per minute or faster (at least 45 mg/dL in 15 minutes).
	How will the pump notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes or until confirmed.
	Will the pump re-notify me?	No.
	How should I respond?	Tap OK to confirm.

26.15 CGM Rapid Fall Alert (Dexcom Only)

Screen	Explanation	
What will I see on the screen?  	What does it mean?	Your sensor glucose levels are falling at 3 mg/dL per minute or faster (at least 45 mg/dL in 15 minutes).
	How will the pump notify me?	3 vibrations, then 3 vibrations/beeps every 5 minutes or until confirmed.
	Will the pump re-notify me?	No.
	How should I respond?	Tap OK to confirm.

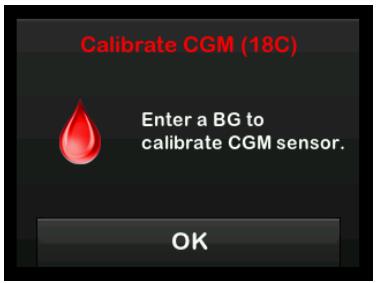
26.16 Startup Calibration Alert (Dexcom G6 Only)

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The startup period is complete. This will only appear if you did not enter a sensor code.
	How will the pump notify me?	1 vibration, then vibration/beep every 5 minutes until acknowledged.
	Will the pump re-notify me?	Yes, every 15 minutes until you calibrate.
	How should I respond?	Tap OK and enter 2 separate BG values to calibrate the CGM and start your CGM session.

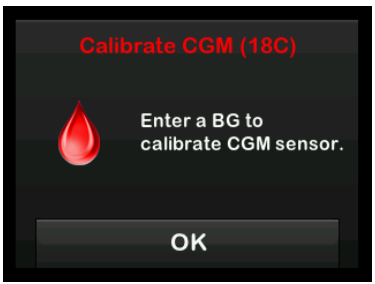
26.17 Second Startup Calibration Alert (Dexcom G6 Only)

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The CGM needs an additional BG value to complete startup calibration. This will only appear if you did not enter a sensor code.
	How will the pump notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the pump 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 CGM and start your CGM session.

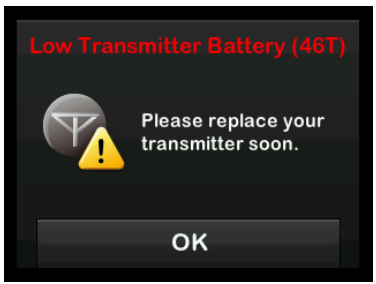
26.18 12 Hour Calibration Alert (Dexcom G6 Only)

<table>
<tr><th>Screen</th><th colspan="2">Explanation</th></tr>
<tr><td rowspan="4">What will I see on the screen?
 
</td><td>What does it mean?</td><td>The CGM needs a BG value to calibrate. This will only appear if you did not enter a sensor code.</td></tr>
<tr><td>How will the pump notify me?</td><td>On screen only with no vibration or beep.</td></tr>
<tr><td>Will the pump re-notify me?</td><td>Yes, every 15 minutes.</td></tr>
<tr><td>How should I respond?</td><td>Tap OK and enter a BG value to calibrate the CGM.</td></tr>
</table>

26.19 Calibration Required Alert (Dexcom G6 Only)

Screen	Explanation	
What will I see on the screen?  	What does it mean?	The CGM needs a BG value to calibrate. Sensor glucose readings will not be displayed at this time.
	How will the pump notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the pump re-notify me?	Yes, every 15 minutes.
	How should I respond?	Tap OK and enter a BG value to calibrate the CGM.

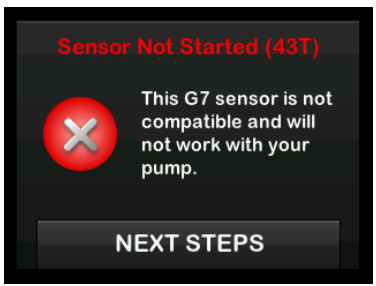
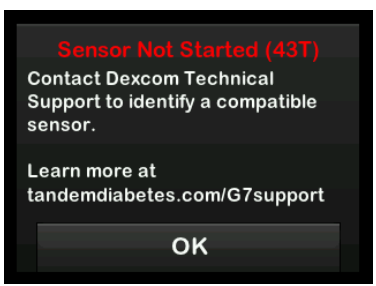
26.20 Low Transmitter Battery Alert (Dexcom G6 Only)

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Dexcom G6 transmitter battery is low.
	How will the pump notify me?	1 vibration, then vibration/beep every 5 minutes until confirmed.
	Will the pump re-notify me?	Yes, the alarm will notify you when there are 21, 14, and 7 days of transmitter battery life remaining.
	How should I respond?	Tap OK to confirm. Replace the transmitter as soon as possible.

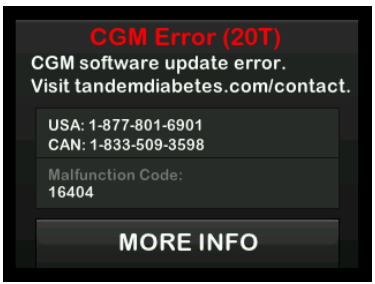
26.21 Transmitter Error (Dexcom G6 Only)

Screen	Explanation	
What will I see on the screen?  	What does it mean?	The Dexcom G6 transmitter has failed and the CGM session has stopped.
	How will the pump notify me?	1 vibration, then vibration/beep every 5 minutes.
	Will the pump re-notify me?	No.
	How should I respond?	Tap **MORE INFO**. A screen notifies you that your CGM session has stopped and that insulin delivery will continue as normal. Replace the transmitter immediately.

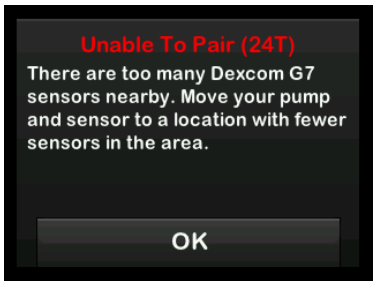
26.22 Incompatible Sensor Alert (Dexcom G7 Only)

Screen	Explanation	
What will I see on the screen?   	What does it mean?	The Dexcom G7 CGM you are attempting to pair is not compatible with your pump.
	How will the pump notify me?	1 beep/vibration, then beep/vibration every 5 minutes until confirmed.
	Will the pump re-notify me?	No.
	How should I respond?	Tap **NEXT STEPS**. A screen notifies you to contact Dexcom technical support. Tap OK to close the alert.

26.23 CGM Error (Dexcom G7 Only)

Screen	Explanation	
What will I see on the screen?  	What does it mean?	Your Dexcom G7 CGM sensor is not working properly; the CGM session has stopped and the CGM can no longer be used.
	How will the pump notify me?	1 vibration, then vibration/beep every 5 minutes.
	Will the pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Contact technical support first. To acknowledge the alert, tap **MORE INFO** and then OK.

26.24 Unable to Pair (Dexcom G7 Only)

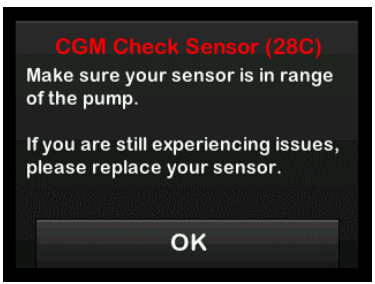
Screen	Explanation	
What will I see on the screen? 	What does it mean?	Your Dexcom G7 CGM has attempted to pair too many times while in an area with too many Dexcom G7 sensors.
	How will the pump notify me?	1 vibration, then vibration/beep every 5 minutes.
	Will the pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap OK, and relocate to an area with fewer sensors to attempt pairing again.

NOTE

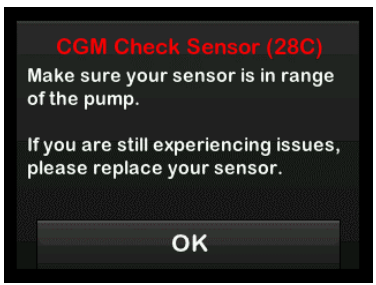
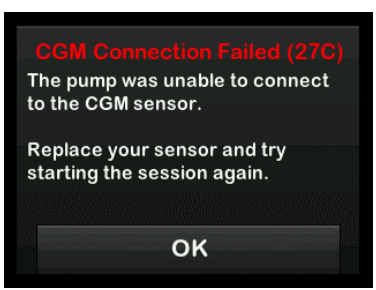
If the alert is displayed and the pump joins a CGM session, the alert will clear.

26.25 CGM Check Sensor Alert (Abbott FreeStyle Libre 2 Plus Sensor Only)

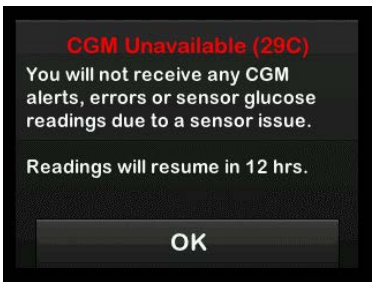
Insertion Error

Screen	Explanation	
What will I see on the screen?  	What does it mean?	The CGM sensor is unable to connect to the pump upon initial sensor insertion.
	How will the pump notify me?	1 vibrate, then vibration/beep every 5 minutes until the CGM and pump are back in range or you begin a new CGM sensor session.
	Will the pump re-notify me?	Yes, every 20 minutes until the CGM and pump are back in range. If the condition persists for 60 minutes, the *Failed Sensor* alert will be displayed. See Section 26.8 Failed Sensor Error.
	How should I respond?	Tap OK to confirm, and move the CGM and pump closer together, or remove the obstruction between them.

Pairing Error

Screen	Explanation	
What will I see on the screen?   	What does it mean?	The CGM sensor is unable to connect to the pump and establish a Bluetooth connection.
	How will the pump notify me?	1 vibrate, then vibration/beep every 5 minutes until the CGM and pump are back in range or you begin a new CGM sensor session.
	Will the pump re-notify me?	Yes, every 20 minutes until the CGM and pump are back in range. If the condition persists for 3 hours, the *CGM Connection Failed* alert will be displayed.
	How should I respond?	• If you see the *CGM Check Sensor* screen, tap OK to confirm and move the CGM and pump closer together, or remove the obstruction between them. • If you see the *CGM Connection Failed* screen, tap OK. Replace the sensor and begin a new CGM session.

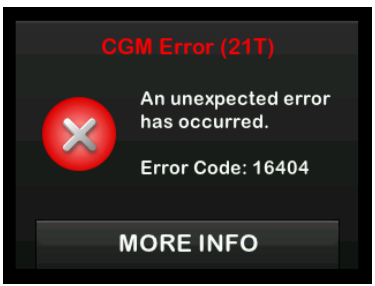
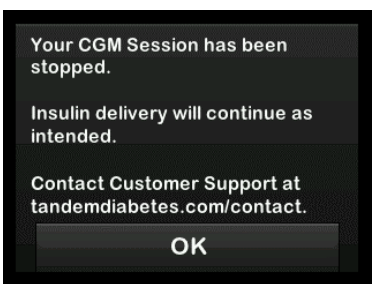
26.26 CGM Unavailable Alert (Abbott FreeStyle Libre 2 Plus Sensor Only)

Screen	Explanation	
What will I see on the screen?  	What does it means?	The sensor is sending sensor glucose readings that the pump does not understand. You will not receive sensor glucose readings until after the first 12 hours of sensor wear.
	How will the pump notify me?	1 vibrate, then vibration/beep every 5 minutes until acknowledged.
	Will the pump re-notify me?	Yes, every 60 minutes until the end of the first 12 hours of sensor wear.
	How should I respond?	Tap OK to confirm. The alert will indicate when your sensor glucose readings will resume.

26.27 Sensor Temperature Alert (Abbott FreeStyle Libre 2 Plus Sensor Only)

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The CGM sensor is outside of its operating temperature range.
	How will the pump notify me?	On-screen only with no vibration or beep.
	Will the pump re-notify me?	Yes, if the CGM sensor remains outside of its operating temperature range.
	How should I respond?	Move the CGM sensor to a temperature above 50°F (10°C) and below 113°F (45°C). Tap OK to confirm.

26.28 CGM System Error (Abbott FreeStyle Libre 2 Plus Sensor Only)

Screen	Explanation	
What will I see on the screen?  	What does it mean?	Your CGM System is not working properly; the CGM session has stopped and the CGM can no longer be used.
	How will the pump notify me?	1 vibration, then vibration/beep every 5 minutes.
	Will the pump re-notify me?	No.
	How should I respond?	• Write down the Error Code number that appears on the screen. • Tap **MORE INFO**. A screen notifies you that your CGM session has stopped and that insulin delivery will continue as normal. • Tap OK. Contact Customer Technical Support and provide the Error Code number that you wrote down.

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CHAPTER 27

CGM Troubleshooting

This chapter provides helpful tips and instructions to help you fix issues you may have while using the CGM portion of your pump.

If the troubleshooting steps in this chapter do not fix your issue, contact Customer Technical Support.

The following tips are specific to troubleshooting the CGM connected to your pump. For more information about CGM troubleshooting, visit the manufacturer's website for applicable product instructions.

27.1 CGM Pairing Troubleshooting

Possible issue:

Difficulty pairing your CGM with your t:slim X2™ insulin pump.

Dexcom Troubleshooting tip:

The Dexcom CGM only allows pairing with one medical device at a time. Ensure your CGM is not connected to the Dexcom receiver before pairing with the pump. You may still use a smartphone with the Dexcom G6 or Dexcom G7 apps simultaneously with your pump. See Section 21.2 Disconnecting from the Dexcom Receiver.

Abbott FreeStyle Libre 2 Plus Troubleshooting tip:

The Abbott FreeStyle Libre 2 Plus CGM only allows pairing with one device at a time. Ensure your CGM is not connected to the Abbott FreeStyle Systems App or Reader before pairing with the pump.

27.2 Calibration Troubleshooting – Dexcom only

To ensure proper calibration of your Dexcom CGM, follow these important tips.

Before you take a BG value for calibration, wash your hands, make sure your BG test strips have been stored properly and are not expired, and make sure that your BG meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions that came with your BG meter or test strips.

Do not calibrate if you see the Out of Range symbol in the place where your sensor glucose readings are normally shown on the screen.

Do not calibrate if you see "- - -" in the place where your sensor glucose readings are normally shown on the screen.

Do not calibrate if your BG value is below 20 mg/dL or above 600 mg/dL.

27.3 Unknown Sensor Reading Troubleshooting

When your CGM cannot provide a sensor glucose reading, "- - -" shows in the place where your sensor glucose is normally shown on the screen. This means that the pump does not understand the sensor signal temporarily.

Often the pump 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 the CGM manufacturer.

If you are using a Dexcom CGM, do not enter any BG values for calibration when you see "- - -" on your screen. The pump 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 is not dislodged or peeling up.
- Dexcom G6 only: Make sure your transmitter is snapped in completely.
- Make sure nothing is rubbing the sensor (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.
- Dexcom G6 only: Wipe the bottom of the transmitter with an isopropyl alcohol wipe. Place the transmitter on a clean, dry cloth and air dry for 2–3 minutes.

27.4 Out of Range/No Antenna Troubleshooting

⚠ WARNING

Control-IQ+™ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate settings in your active Personal Profile.

⚠ PRECAUTION

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

If you see the Out of Range icon on your screen in the place where your sensor glucose reading normally shows, then your t:slim X2 pump is not communicating with your CGM 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 CGM. 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 closer together and remove any obstructions. Wait 10 minutes and communication should be restored.

If you are using a Dexcom CGM:

- You must enter your transmitter ID or pairing code correctly into your pump to receive sensor glucose readings (see Section 23.1 Choosing Your Sensor Type).

- Make sure you have removed your sensor and stopped your sensor session before changing your transmitter ID or pairing code. You cannot change your transmitter ID or pairing code during a sensor session.

If you are still having trouble getting sensor glucose readings, contact Customer Technical Support.

27.5 Failed Sensor Troubleshooting

The pump 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.
- If using a Dexcom G6 sensor, make sure your transmitter is snapped in completely.
- Make sure nothing is rubbing the sensor pod (e.g., clothing, seat belts, etc.).
- Make sure you have selected a good insertion site.

27.6 Sensor Inaccuracies – Dexcom only

Inaccuracies are usually related to your sensor only and not to your CGM or pump. Your sensor glucose readings are meant to be used for trending purposes only. The sensor measures glucose in the fluid under the skin—not in blood, and sensor glucose readings are not identical to readings from your BG meter.

⚠ PRECAUTION

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

If the difference between your sensor glucose reading and BG value is greater than 20% of the BG value for sensor readings >80 mg/dL or greater than 20 mg/dL for sensor readings <80 mg/dL, wash your hands and take another BG measurement. If the difference between this second BG measurement and the sensor is still greater than 20% for sensor readings >80 mg/dL or greater than 20 mg/dL for sensor readings <80 mg/dL, recalibrate your sensor using the second BG value. The sensor glucose reading will correct over the next 15 minutes. If you see differences between your sensor glucose readings and BG values outside of this acceptable range, follow the troubleshooting tips below before inserting another sensor:

- Make sure your sensor is not expired.

- Make sure you do not calibrate when "- - -" or the Out of Range icon are on the screen.
- Do not use alternative BG site testing (blood from your palm or forearm, etc.) for calibration as alternative site readings may be different than those from a BG value. Use a BG value only from your fingers for calibration.
- Use only BG values between 20–600 mg/dL for calibration. If one or more of your values is outside of this range, the receiver will not calibrate.
- Use the same BG meter you routinely use to measure your BG to calibrate. Do not switch your BG meter in the middle of a sensor session. BG meter and strip accuracy vary between BG meter brands.
- Before taking a BG measurement for calibration, wash your hands, make sure your BG test strips have been stored properly and are not expired, and make sure that your BG meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions provided with your BG meter or test strips.
- Make sure you are using your BG meter following the manufacturer's instructions to get accurate BG values for calibration.

27.7 Sensor Inaccuracies – Abbott FreeStyle Libre 2 Plus only

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

The FreeStyle Libre 2 Plus sensor does not require manual BG calibration. If you believe your sensor glucose readings are not correct or are inconsistent with how you feel, perform a BG test to confirm your sensor glucose readings and treat based on that result. If the problem continues, consider replacing your sensor. Please contact Abbott customer service for assistance.

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CHAPTER 28

Control-IQ+ Technology Important Safety Information

The following includes important safety information related to Control-IQ+™ technology. The information presented in this chapter does not represent all warnings and precautions related to the pump. Pay attention to other warnings and precautions listed throughout this user guide as they relate to special circumstances, features, or users.

28.1 Control-IQ+ Technology Warnings

⚠ WARNING
Control-IQ+ technology has not been evaluated in pregnant women or persons on dialysis. Sensor glucose readings may be inaccurate in these populations and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING
Control-IQ+ technology has not been evaluated in critically ill patients. It is not known how different conditions or medications common to the critically ill population may affect the performance of the Control-IQ+ technology. Sensor glucose readings may be inaccurate in critically ill patients, and solely relying on the sensor glucose alerts and readings for treatment decisions could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

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

⚠ WARNING
Control-IQ+ technology is not a substitute for understanding and being ready at any time to take over manual control of your current or future diabetes therapy.

⚠ WARNING
Control-IQ+ technology is not designed to prevent all hypoglycemia (low BG) or hyperglycemia (high BG).

⚠ WARNING
Control-IQ+ technology adjusts the delivery of insulin, but does not treat low BG. Always pay attention to your symptoms, manage your BG level, and treat according to the recommendations of your healthcare provider.

⚠ WARNING
Do not use Control-IQ+ technology unless recommended by your healthcare provider.

⚠ WARNING
Do not use Control-IQ+ technology until you have received training.

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

⚠ WARNING
Control-IQ+ technology reverts to your programmed Basal Rate when the pump has not received a CGM reading for 20 minutes. For example, when the pump and CGM are out of range, during the sensor startup period, when a sensor session ends, or when there is a transmitter or sensor error.

⚠ WARNING
If a sensor session is ended, either automatically or manually, Control-IQ+ technology is unavailable and will not adjust insulin. In order for Control-IQ+ technology to be enabled, a sensor session must be started and transmitting sensor values to the pump.

⚠ WARNING

DO NOT use manual injections or inhaled insulins while using Control-IQ+ technology. Using insulin not provided by the pump while using closed loop therapy can cause the pump to over deliver insulin, which can lead to severe hypoglycemia (low BG) events.

Using Control-IQ+ Technology with Dexcom CGM

⚠ WARNING

DO NOT use Control-IQ+ technology if you are taking hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anemia. The use of hydroxyurea will result in sensor glucose readings that are higher than actual glucose levels. The level of inaccuracy in sensor glucose readings is based on the amount of hydroxyurea in the body. Control-IQ+ technology relies on sensor glucose readings to adjust insulin, provide automatic correction boluses, and provide high and low glucose alerts. If Control-IQ+ technology receives sensor readings that are higher than actual glucose levels, it could result in missed hypoglycemia alerts and errors in diabetes management, such as delivery of excess basal insulin and correction boluses, including automatic correction boluses. Hydroxyurea can also result in errors when reviewing, analyzing and interpreting historical patterns for assessing glucose control. Use your BG meter and consult with your healthcare provider about alternative glucose monitoring approaches.

28.2 Control-IQ+ Technology Precautions

⚠ PRECAUTION

You must continue to take boluses to cover food eaten or to correct a high sensor glucose value. Read all Control-IQ+ technology instructions before activating Control-IQ+ technology.

⚠ PRECAUTION

If you remove your pump for 30 minutes or longer, it is recommended that you suspend insulin delivery. If insulin is not suspended, Control-IQ+ technology will continue to operate while the pump is removed, and will continue to dose insulin.

⚠ PRECAUTION

We recommend that you keep the CGM Out of Range Alert turned on to notify you if your CGM is disconnected from your pump whenever you are not actively monitoring your pump status. Your CGM is providing the data that Control-IQ+ technology requires to make predictions to automate insulin dosing.

⚠ PRECAUTION

We recommend that you enable the High Glucose Alert and the Low Glucose Alert when using Control-IQ+ technology so that you will be notified if sensor glucose readings are outside of your target range, and you can treat high or low BG according to your healthcare provider's recommendations.

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CHAPTER 29

Getting to Know Control-IQ+ Technology

29.1 Responsible Use of Control-IQ+ Technology

Systems like the t:slim X2™ insulin pump with Control-IQ+™ technology are not substitutes for the active management of diabetes, including manually bolusing for meals. There are common scenarios in which automated systems cannot prevent a hypoglycemic event. Control-IQ+ technology relies on current CGM sensor readings to function and will not be able to predict sensor glucose values and suspend insulin delivery if a patient's CGM is not functioning properly or their pump is unable to receive the CGM signal. Patients should be instructed to always use the components of the pump system (pump, cartridges, CGM, and infusion sets) according to the applicable instructions for use and check them regularly to make sure they are functioning as expected. Patients should always pay attention to their sensor glucose values, actively monitor and manage BG, and treat accordingly.

29.2 Explanation of Control-IQ+ Technology Icons

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

Control-IQ+ Technology Icon Definitions

Symbol	Meaning
	Control-IQ+ technology is enabled but not actively increasing or decreasing basal insulin delivery.
	Control-IQ+ technology is increasing basal insulin delivery.
	Control-IQ+ technology is decreasing basal insulin delivery.
	Control-IQ+ technology has stopped basal insulin delivery.
	Control-IQ+ technology is delivering an automatic correction bolus.
	The Sleep Activity is enabled.
	Control-IQ+ technology delivered an automatic correction bolus.

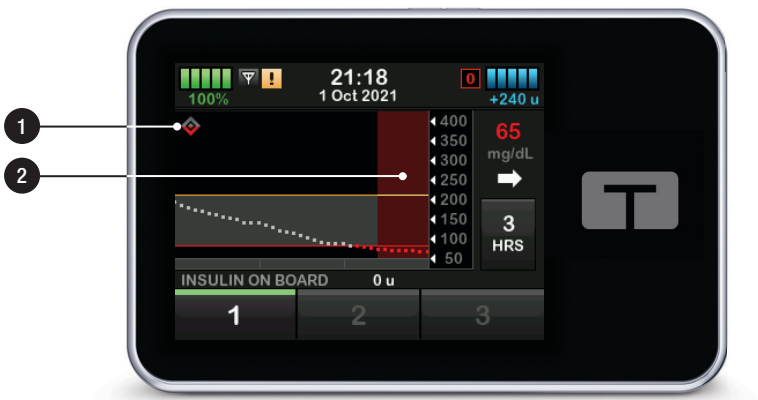
Symbol	Meaning
	Basal insulin is programmed and being delivered.
	Control-IQ+ technology is increasing basal insulin delivery.
	Control-IQ+ technology is decreasing basal insulin delivery.
	Basal insulin delivery is stopped and a Basal Rate of 0 u/hr is active.
	Control-IQ+ technology is delivering an automatic correction bolus.
	The Exercise Activity is enabled.

29.3 Control-IQ+ Technology Lock Screen

The *Control-IQ+ Lock* screen appears any time you turn on the screen and you are using your pump with a CGM and Control-IQ+ technology enabled. The *Control-IQ+ Lock* screen is the same as the *CGM Lock* screen, with the following additions. See Section 19.4 CGM Lock Screen.

1. Control-IQ+ Technology Status: Indicates the status of Control-IQ+ technology.

2. CGM Graph Shading: Red shading indicates Control-IQ+ technology is, or was, delivering 0 units of insulin for the period indicated.


1
2
100%
21:18
1 Oct 2021
0
+240 u
400
350
300
250
200
150
100
50
65
mg/dL
3
HRS
INSULIN ON BOARD
0 u
1
2
3

29.4 Control-IQ+ Technology Home Screen

The *Home* screen with Control-IQ+ technology enabled is identical to the *CGM Home* screen, with the following additions. See Section 19.5 CGM Home Screen.

1. Control-IQ+ Technology Status: Indicates the status of Control-IQ+ technology.

2. Control-IQ+ Activity Status: Indicates an Activity is enabled.

3. CGM Graph Shading: Red shading indicates Control-IQ+ technology is, or was, delivering 0 units of insulin for the period indicated.


1
2
3
100%
14:58
1 Oct 2021
+240 u
400
350
300
250
200
150
100
50
115
mg/dL
3
HRS
INSULIN ON BOARD
0 u
OPTIONS
BOLUS

29.5 Control-IQ+ Technology Screen

1. Control-IQ on/off: Turns on, or off, Control-IQ+ technology.

2. Weight: Displays your current weight. This value is manually entered in on the numerical keypad.

   NOTE

   Your weight should be representative of what you weigh when you start Control-IQ+ technology. Weight can be updated when you visit your healthcare provider. The minimum value for weight is 20 pounds (9 kilograms). The maximum value for weight is 440 pounds (200 kilograms).

3. Total Daily Insulin: Displays your current total daily insulin value in units. This value is manually entered in on the numerical keypad.

   NOTE

   If you don't know your Total Daily Insulin (TDI), speak with your healthcare provider to get this value. The minimum value for TDI is 5 units. The maximum value for TDI is 200 units.


Control-IQ
1
Control-IQ
2
Weight
120 lbs
3
Total Daily Insulin
50 u

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CHAPTER 30

Introduction to Control-IQ+ Technology

30.1 Control-IQ+ Technology Overview

Control-IQ+™ technology is a feature of the t:slim X2™ pump that automatically adjusts insulin dosing in response to readings from a CGM. The pump can be used with or without Control-IQ+ technology enabled. The following sections describe how Control-IQ+ technology works and how it responds to CGM values while you are awake, sleeping, and exercising.

⚠ PRECAUTION
You must continue to take boluses to cover food eaten or to correct a high sensor glucose value. Read all Control-IQ+ technology instructions before activating Control-IQ+ technology.

⚑ NOTE
The target CGM ranges used by Control-IQ+ technology are not customizable.

⚑ NOTE
The Insulin On Board (IOB) Time Remaining, which indicates how long the total units of insulin from food and correction boluses will be active in the body, is not displayed when Control-IQ+ technology is enabled due to the variability of insulin delivery when automatically responding to CGM values. The IOB units will always be displayed on the *Home* and *Lock* screens.

30.2 How Control-IQ+ Technology Works

⚠ WARNING
Control-IQ+ technology is not a substitute for understanding and being ready at any time to take over manual control of your current or future diabetes therapy.

⚠ WARNING
Control-IQ+ technology is not designed to prevent all hypoglycemia (low BG) or hyperglycemia (high BG).

⚠ WARNING
Control-IQ+ technology adjusts the delivery of insulin, but does not treat low BG. Always pay attention to your symptoms, manage your BG level, and treat according to the recommendations of your healthcare provider.

⚠ WARNING
Do not use Control-IQ+ technology unless recommended by your healthcare provider.

⚠ WARNING
Do not use Control-IQ+ technology until you have received training.

⚠ WARNING
Control-IQ+ technology relies on current CGM sensor readings and will not be able to accurately predict BG levels and adjust insulin delivery if for any reason your CGM is not functioning properly, or the pump has not received any CGM sensor values in 21 minutes.

⚠ PRECAUTION
We recommend that you enable the High Glucose Alert and the Low Glucose Alert when using Control-IQ+ technology so that you will be notified if sensor glucose readings are outside of your target range, and you can treat high or low BG according to your healthcare provider's recommendations.

Control-IQ+ technology responds to the actual CGM readings as well as predicts CGM values 30 minutes in the future. Insulin delivery is automatically adjusted based on the predicted CGM value, your active Personal Profile, and whether or not a Control-IQ+ technology Activity is enabled.

NOTE

Control-IQ+ technology activity types are not automatically enabled, and must be set up as a scheduled occurrence or turned on as needed. For more information, see sections 31.5 Schedule Sleep, 31.7 Manually Start or Stop Sleep, and 31.8 Enable or Disable Exercise.

Control-IQ+ technology adjusts insulin delivery in several ways to help keep your actual glucose value within the target range. It will decrease or suspend insulin delivery when predicted sensor glucose values are below a preset treatment value, increase insulin delivery when predicted sensor glucose values are above a preset treatment value, and automatically deliver a correction bolus once per hour, as needed. The automatic correction bolus is based on a predicted sensor glucose value. There are maximum insulin delivery limits based on your Personal Profile settings. These different insulin delivery actions are described below. Each of the insulin delivery adjustments occurs in different ways depending on whether you are using the Sleep Activity, using the Exercise Activity, or neither. For more detail on how insulin adjustments are made for different activities see Sections Control-IQ+ Technology With No Activity Enabled, Control-IQ+ Technology During Sleep, and Control-IQ+ Technology During Exercise Activity in this chapter.

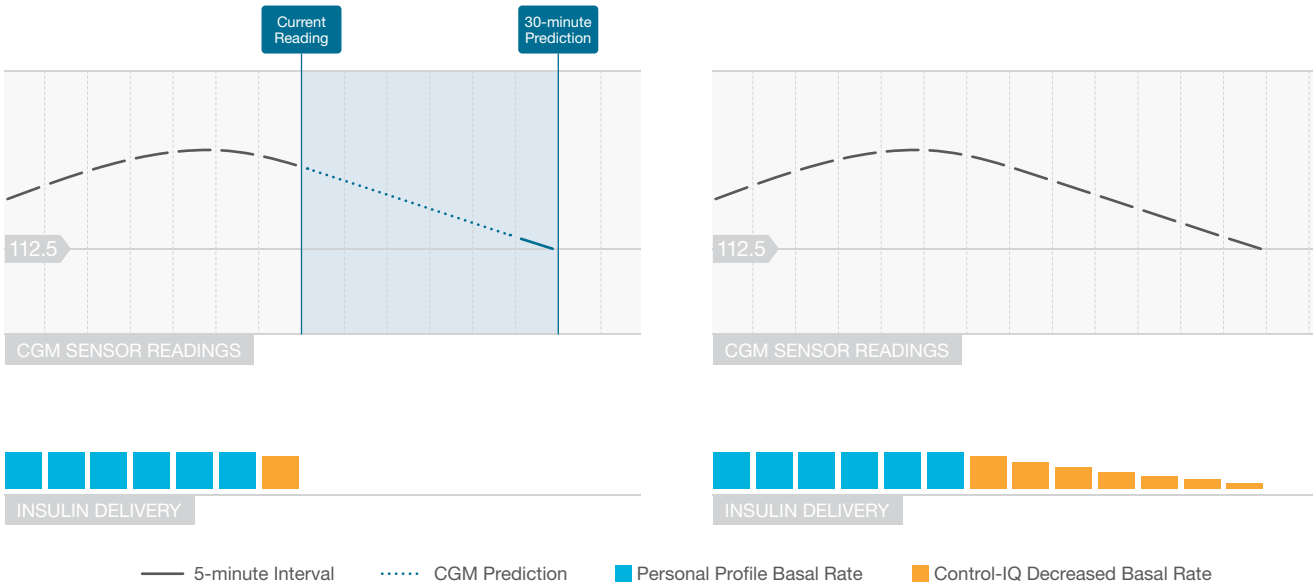
Personal Profile Basal Rate Delivery

When the predicted CGM value is within the treatment value range (112.5 mg/dL–160 mg/dL), the pump will deliver insulin at the rate determined by the active Personal Profile settings.

All Personal Profile settings must be completed in order to use Control-IQ+ technology. See Chapter 6 Insulin Delivery Settings for more information about Personal Profiles.

Decreased Insulin Delivery

When Control-IQ+ technology predicts that your sensor glucose value will be at or below a preset treatment value (112.5 mg/dL) 30 minutes in the future, the rate of insulin delivery will start decreasing to attempt to keep the actual sensor glucose values within the target range. The following diagrams depict how the pump uses 30 minute predictions to gradually decrease insulin delivery compared to the personal profile Basal Rate. The diagram on the left depicts the prediction, the diagram on the right depicts how the insulin and CGM readings might look if the CGM graph continued on the trend.



NOTE

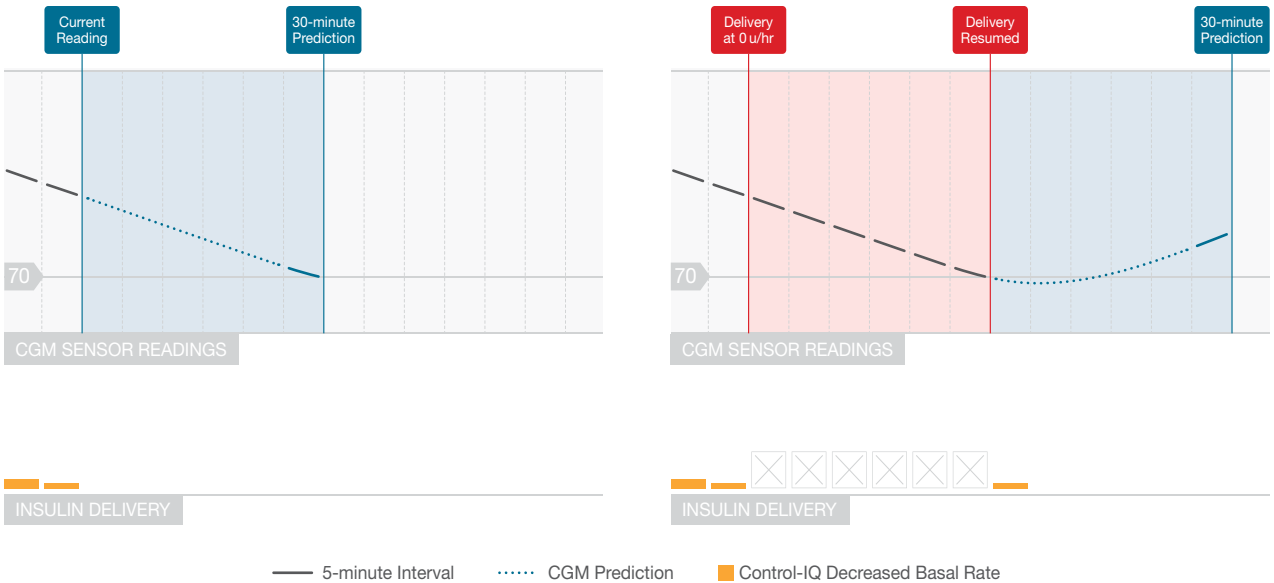
Diagrams are for illustrative purposes only and are not intended to reflect actual results.

Insulin Decreased or Delivering 0 Units per Hour

Control-IQ+ technology can reduce the basal delivery to a percent of the Basal Rate in addition to completely suspending. When Control-IQ+ technology predicts that your sensor glucose value will be lower than a preset treatment value (70 mg/dL) 30 minutes in the future, insulin delivery will decrease and may set the Basal Rate at 0 units per hour if necessary to attempt to keep the actual sensor glucose values within the target range. Manual boluses can still be delivered when Control-IQ+ technology is decreasing or suspending insulin. The following diagrams depict an illustration of when Control-IQ+ technology might set the insulin delivery rate to 0 units per hour, and when it will resume at a decreased rate after the 30 minute prediction is above the target sensor glucose value.

NOTE

When Control-IQ+ technology sets the basal rate to 0 units per hour, bolus deliveries will continue. This includes starting a new bolus and any remaining bolus from an extended bolus delivery.



NOTE

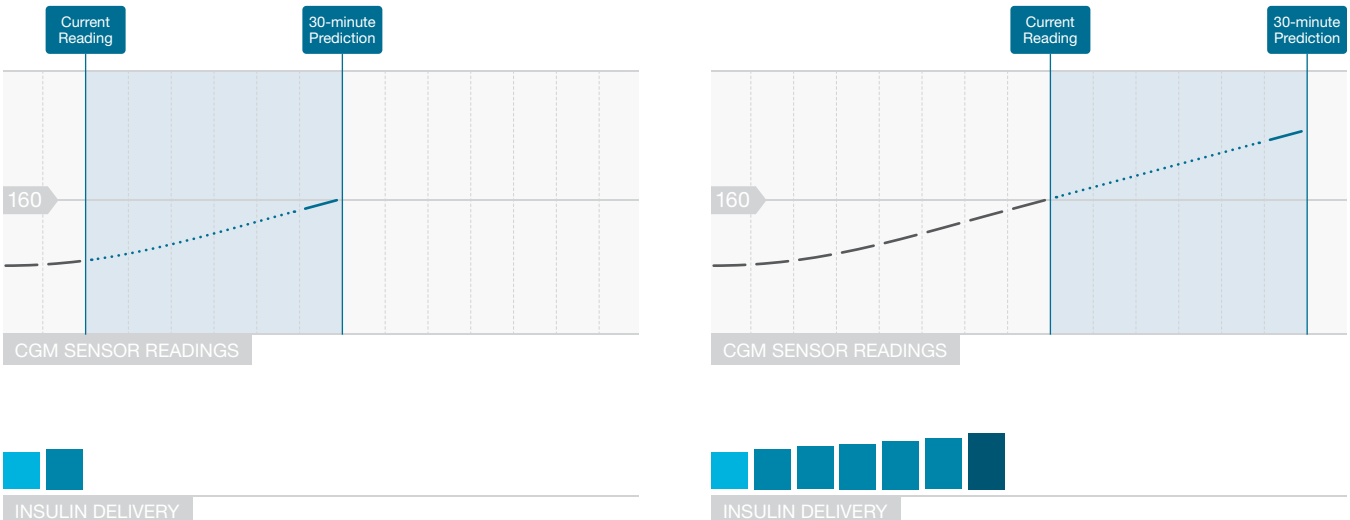
Diagrams are for illustrative purposes only and are not intended to reflect actual results.

Increasing Insulin Delivery

When Control-IQ+ technology predicts that your sensor glucose value will be at or above a preset treatment value (160 mg/dL) 30 minutes in the future, the rate of insulin delivery will start increasing to attempt to keep the actual CGM values within the target CGM range. The following diagrams depict when Control-IQ+ technology might be increasing and delivering at the maximum increased Basal Rate.

Maximum Insulin Delivery

When Control-IQ+ technology predicts that your sensor glucose value will be above a preset treatment value (160 mg/dL) 30 minutes in the future, but the maximum rate of insulin delivery has been reached, Control-IQ+ technology stops increasing the insulin delivery rate. The maximum insulin delivery rate is a calculated value that is dependent on an individual's Correction Factor setting (found in the active Personal Profile), the Total Daily Insulin estimated by Control-IQ+ technology based on actual total daily insulin values, and the current insulin on board (IOB).



NOTE

Diagrams are for illustrative purposes only and are not intended to reflect actual results.

Automatic Correction Bolus Delivery

When Control-IQ+ technology predicts that your CGM value will be at or above a preset treatment value (180 mg/dL) 30 minutes in the future, and when Control-IQ+ technology is either Increasing Insulin Delivery or delivering Maximum Insulin Delivery, the pump will automatically deliver correction boluses to attempt to achieve the target range.

The automatic correction bolus will deliver a total correction bolus calculated based on the Personal Profile Correction Factor and predicted CGM reading. The target sensor glucose for the automatic correction bolus is 110 mg/dL. Automatic correction bolus delivery occurs at most once every 60 minutes, and will not be delivered within 60 minutes of the start, cancellation, or completion of an automatic bolus or manual bolus. For an extended bolus, this 60 minutes does not start until after the DELIVER NOW duration has completed. The percentage and duration between boluses is designed to avoid insulin stacking that may cause unsafe reductions in sensor glucose values.

NOTE

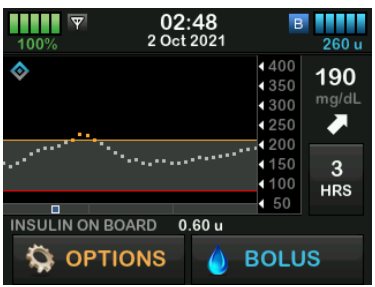
Each automatic correction bolus delivery can be manually canceled or stopped during the delivery in the same way that a Manual Bolus can be stopped. See Section 8.10 Canceling or Stopping a Bolus Using the Pump and Section 8.15 Canceling or Stopping a Bolus Using the Tandem t:slim Mobile App.

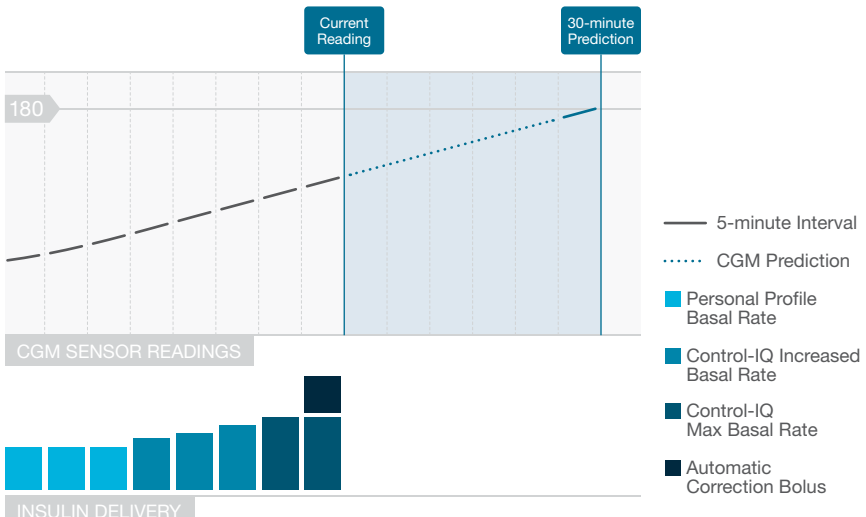
NOTE

The maximum amount of insulin that an automatic correction bolus will deliver is 6 units. This value cannot be increased, but you may choose to deliver a manual bolus after the automatic correction bolus delivery is complete.

⚠ PRECAUTION

The pump does not activate sound or vibration to indicate when an automatic correction bolus delivery has started. The following pump screens indicate that an automatic correction bolus is being delivered and that an automatic correction bolus was delivered, respectively.





NOTE

Diagrams are for illustrative purposes only and are not intended to reflect actual results.

30.3 Control-IQ+ Technology and Activity

When Control-IQ+ technology is turned on you can choose to activate Sleep or Exercise to help the pump adjust the automated insulin dosing settings as described in previous sections.

If you have not started either Sleep or Exercise, the pump will use the settings described in the following section.

Control-IQ+ Technology With No Activity Enabled

The CGM range targeted by Control-IQ+ technology with no Activity enabled is 112.5–160 mg/dL. This range is wider than the Sleep and Exercise ranges to account for the variability of factors that affect CGM values while people are awake and not exercising.

Decreasing Insulin With No Activity Enabled

Insulin is decreased when Control-IQ+ technology predicts a CGM reading of ≤112.5 mg/dL 30 minutes in the future.

Suspended Insulin With No Activity Enabled

Insulin is set to 0 units/hour when Control-IQ+ technology predicts a CGM reading ≤70 mg/dL 30 minutes in the future.

Increasing Insulin With No Activity Enabled

Insulin is increased when Control-IQ+ technology predicts a CGM reading of ≥160 mg/dL 30 minutes in the future.

Automatic Correction Bolus With No Activity

When no Activity is enabled, Control-IQ+ technology will deliver automatic correction boluses as described in the Automatic Correction Bolus Delivery section of this chapter.

Control-IQ+ Technology During Sleep

The Control-IQ+ technology Sleep Activity range is targeted during scheduled sleep times and when the Sleep Activity is manually started (until it is stopped). See Chapter 31 Configuring and Using Control-IQ+ Technology and see Section 31.6 Enable or Disable a Sleep Schedule for instructions on setting the hours you plan to sleep and Section 31.7 Manually Start or Stop Sleep for starting the Sleep Activity manually in that chapter.

The CGM range targeted by Control-IQ+ technology during the Sleep Activity is 112.5 mg/dL–120 mg/dL. This range is smaller than the target range with no Activity enabled since there are fewer variables that affect CGM values while you are sleeping. During the Sleep Activity, Control-IQ+ technology will not deliver automatic correction boluses.

Decreasing Insulin During Sleep Activity

Insulin is decreased when Control-IQ+ technology predicts a CGM reading of ≤112.5 mg/dL 30 minutes in the future.

Suspended Insulin During Sleep Activity

Insulin is set to 0 units/hour when Control-IQ+ technology predicts a CGM reading ≤70 mg/dL 30 minutes in the future.

Increasing Insulin During Sleep Activity

Insulin is increased when Control-IQ+ technology predicts a CGM reading of ≥120 mg/dL 30 minutes in the future.

Automatic Correction Bolus During Sleep Activity

Automatic correction boluses will not be delivered while Sleep is enabled.

When Control-IQ+ technology switches back to the settings with no Activity enabled, whether according to scheduled wake time or due to manually stopping Sleep, the transition from the targeted sleep CGM range to targeted settings with no Activity enabled CGM range occurs slowly and can take 30-60 minutes. This helps ensure that actual CGM values transition gradually.

Control-IQ+ Technology During Exercise Activity

During the Exercise Activity, Control-IQ+ technology uses the target CGM range 140 mg/dL–160 mg/dL. This target range is smaller and higher than the target range with no Activity enabled to accommodate the likely natural drop in glucose following exercise.

If the Exercise Activity is on when a Sleep Schedule is due to begin, the Sleep Schedule does not start until the Exercise timer ends, or if you stop the Exercise Activity manually.

Decreasing Insulin During Exercise Activity

Insulin is decreased when Control-IQ+ technology predicts a CGM reading of <140 mg/dL 30 minutes in the future.

Suspended Insulin During Exercise Activity

Insulin is set to 0 units/hour when Control-IQ+ technology predicts a CGM reading <80 mg/dL 30 minutes in the future.

Increasing Insulin During Exercise Activity

Insulin is increased when Control-IQ+ technology predicts a CGM reading of >160 mg/dL 30 minutes in the future.

Automatic Correction Bolus During Exercise Activity

When the Exercise Activity is enabled, Control-IQ+ technology will deliver automatic correction boluses as described in the Automatic Correction Bolus Delivery section of this chapter.

See Chapter 31 Configuring and Using Control-IQ+ Technology for instructions on starting or stopping Exercise.

For a summary of all treatment values and how they are different for each Activity, see the diagram on the next page.

		Control-IQ	Sleep Activity	Exercise Activity
Delivers	Delivers an automatic correction bolus if sensor glucose is predicted to be above ___ mg/dL	180	––	180
Increases	Increases basal insulin delivery if sensor glucose is predicted to be above ___ mg/dL	160	120	160
Maintains	Maintains active Personal Profile settings when sensor glucose is between ___ - ___ mg/dL	112.5 - 160	112.5 - 120	140 - 160
Decreases	Decreases basal insulin delivery if sensor glucose is predicted to be below ___ mg/dL	112.5	112.5	140
Stops	Stops basal insulin delivery if sensor glucose is predicted to be below ___ mg/dL	70	70	80

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CHAPTER 31

Configuring and Using Control-IQ+ Technology

31.1 Required Settings

Required Personal Profile Settings

In order to use Control-IQ+™ technology, the following Personal Profile settings must be configured. See Chapter 6 Insulin Delivery Settings for instructions about setting these values.

- Basal rate
- Correction Factor
- Carb Ratio
- Target BG
- Carbohydrates turned on in Bolus Settings

Required Control-IQ+ Technology Pump Settings

In addition to the required Personal Profile settings, there are two values specific to Control-IQ+ technology that must be set. These are:

- Weight
- Total Daily Insulin

Recommended Control-IQ+ Technology Pump Settings

Although Sleep can be started and stopped manually, it is recommended that you schedule sleep. This chapter explains how to do both. The following settings are required to schedule sleep:

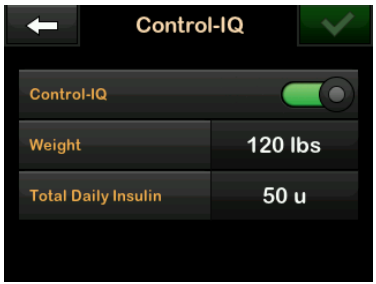
- Selected Days
- Start Time
- End Time

31.2 Set Weight

Control-IQ+ technology cannot be turned on unless Weight is entered. The Weight value may be updated when you visit your healthcare provider.

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Control-IQ**.

✓ The *Control-IQ* screen is displayed.



4. Tap **Weight**.
5. Tap **Pounds** or **Kilograms** to set the unit of weight.
6. Tap ✓.
7. Enter the weight value on the numeric keypad. Weight can be set from a minimum of 20 pounds (9 kilograms) to a maximum of 440 pounds (200 kilograms).
8. Tap ✓.
9. If you are done with the Control-IQ+ technology settings, tap ✓.

✓ The *SETTING SAVED* screen is temporarily displayed.

31.3 Set Total Daily Insulin

Control-IQ+ technology cannot be turned on unless Total Daily Insulin is entered. The Total Daily Insulin value is used by Control-IQ+ technology to calculate the maximum insulin delivery rate and to maintain a safe and effective increase in insulin dose.

The Total Daily Insulin value may be updated when you visit your healthcare provider.

NOTE

Once you have used Control-IQ+ technology, it will maintain and use the actual total insulin delivered, including the adjustments made to basal and all types of boluses while using the pump. It is important to update the Total Daily Insulin setting in the *Control-IQ* screen when you visit your healthcare provider. This value is used for the 2-hour maximum insulin alert.

An estimate of Total Daily Insulin should be entered. Include all types of insulin (basal and bolus) delivered in a 24-hour period. Consult your healthcare provider if you need assistance estimating your insulin requirements.

Enter your Total Daily Insulin Value

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Control-IQ**.
4. Tap **Total Daily Insulin**.
5. Use the numeric keypad to enter the total units of insulin typically required in a 24-hour period. Total Daily Insulin can be set from a minimum of 5 units to a maximum of 200 units.
6. Tap  .
7. If you are done with the Control-IQ+ technology settings, tap  .

✓ The *SETTING SAVED* screen is temporarily displayed.

8. When you are done setting up Control-IQ+ technology, tap the **Tandem logo** to return to the *CGM Home* screen.

31.4 Turn Control-IQ+ Technology On or Off

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Control-IQ**.
4. To turn Control-IQ+ technology on, tap the toggle next to **Control-IQ**.
5. To turn Control-IQ+ technology off, tap the toggle next to **Control-IQ**.
   - Tap  to confirm and turn Control-IQ+ technology off.
   - Tap  to leave Control-IQ+ technology on.

31.5 Schedule Sleep

Control-IQ+ technology operates differently during Sleep than with no Activity enabled. Sleep can be scheduled to turn on and off automatically, or it can be turned on and off manually. This section covers

how to set Sleep to turn on and off automatically. For detailed information about how to use Control-IQ+ technology, see Chapter 30 Introduction to Control-IQ+ Technology.

You can configure two different Sleep Schedules to account for changes in lifestyle, such as a weekday sleep schedule and a weekend sleep schedule.

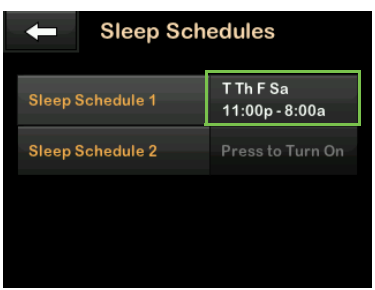
NOTE

If you manually start Sleep before a Sleep Schedule begins, it does not impact the scheduled wake time. For example, if your Sleep Schedule is set from 10pm to 6am (22:00 to 6:00), and you start Sleep manually at 9pm (21:00), Sleep will end at 6am (6:00) as scheduled; unless manually stopped.

NOTE

Exercise and Sleep may not be enabled at the same time. If Exercise is active at the time a Sleep Schedule is set to begin, the Sleep Schedule does not start until the Exercise timer ends, or if you stop Exercise manually.

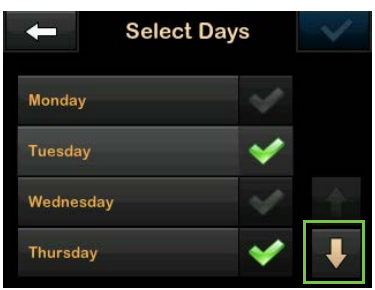
1. From the *Home* screen, tap OPTIONS.
2. Tap **Activity**.
3. Tap **Sleep**.
4. Tap **Sleep Schedules**.
5. Select which Sleep Schedule to configure.
   - If no Sleep Schedules are configured, tap **Sleep Schedule 1**.
   - If you are editing an existing schedule, tap the schedule summary that displays to the right of the sleep schedule you want to edit.



6. On the Sleep Schedule screen, tap **Selected Days**. The default is the current day of the week only, according to the day of the week set on the pump.
7. On the Select Days screen, tap the **checkmark** to the right of each day of the week that you want included in the Sleep Schedule.

   When a checkmark is green, the corresponding day of the week is active. To deactivate a day, tap the associated checkmark again so that it turns gray.

   Tap the **Down Arrow** to see more days of the week.



8. When you are finished selecting the days, tap  .

   NOTE

   If no days are selected when you tap  , the schedule is set to off and the remaining sleep schedule settings are not displayed. The remaining instructions do not apply to an incomplete schedule.

9. Tap **Start Time**.

10. Tap **Time**. The numbered keypad is displayed.

11. Enter the time you would like the Sleep Schedule to start by entering the number(s) for the hour followed by the minutes. For example, tap **9 3 0** to set the time to 9:30 or **2 1 0 0** to set the time to 21:00.

12. Tap  . You are returned to the *Start Time* screen.

13. Tap **AM** or **PM** to set the Time of Day, if applicable.

14. Tap  . You are returned to the *Sleep Schedule 1* screen.

15. Tap **End Time**.

16. Tap **Time**. The numbered keypad is displayed.

17. Enter the time you would like the Sleep Schedule to end and tap  . You are returned to the *End Time* screen.

18. Tap **AM** or **PM** to set the Time of Day, if applicable.

19. Tap  . The *Sleep Schedule 1* screen is displayed.

20. Tap  to save the schedule.

✓ The *SETTING SAVED* screen is temporarily displayed, followed by the *Sleep Schedules* screen.

21. When you are done configuring sleep, tap  to return to the *Activity* screen or tap the **Tandem logo** to return to the *Home* screen.

31.6 Enable or Disable a Sleep Schedule

Once a Sleep Schedule is configured, it is enabled by default when it is saved. If you have multiple Sleep Schedules configured, you can change the enabled Sleep Schedule or turn them off completely.

Enable a Sleep Schedule

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

2. Tap **Activity**.

3. Tap **Sleep**.

4. Tap **Sleep Schedules**.

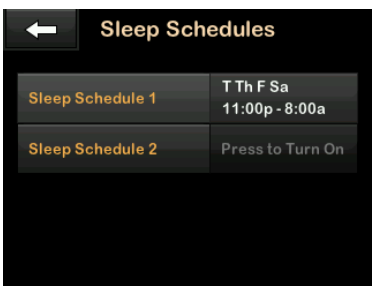
5. Tap the schedule summary next to the name of the Sleep Schedule you want to enable. (If no sleep schedules are configured, see Section 31.5 Schedule Sleep.)

6. Tap  .

Disable a Sleep Schedule

1. From the *Home* screen, tap OPTIONS.
2. Tap **Activity**.
3. Tap **Sleep**.
4. Tap **Sleep Schedules**.

   Tap the schedule summary next to the Sleep Schedule you want to disable.



5. Tap the toggle next to the schedule name.
6. Tap  .

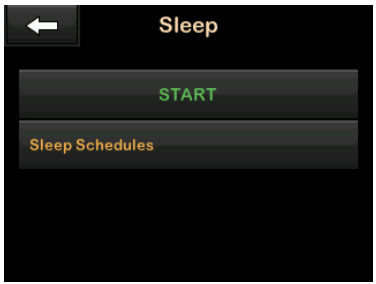
31.7 Manually Start or Stop Sleep

In addition to scheduling sleep, Sleep can be manually started and/or stopped.

Sleep time determines when Control-IQ+ technology, if enabled, switches to Sleep activity. Control-IQ+ technology must be on and a CGM session must be active to start Sleep.

Manually Start Sleep

1. From the *Home* screen, tap OPTIONS.
2. Tap **Activity**.
3. Tap **Sleep**.
4. Tap **START**.



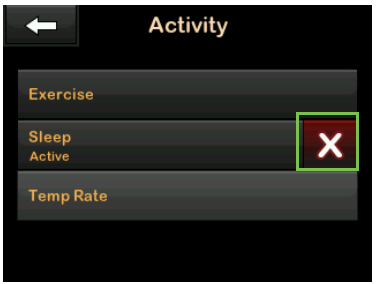
✓ A *SLEEP STARTED* screen is temporarily displayed. The Sleep icon is displayed on the *Home* screen.

Sleep will automatically be disabled if Exercise is enabled.

Manually Stop Sleep

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

3. Tap .



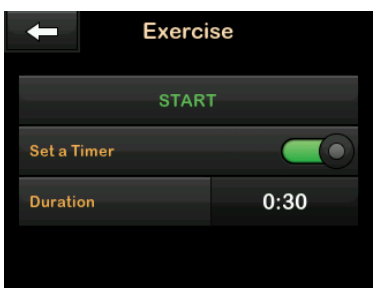
✓ A *SLEEP STOPPED* message is temporarily displayed. The Sleep icon is removed from the *Home* screen.

31.8 Enable or Disable Exercise

You can choose between two types of Exercise. Exercise can be turned on and off manually or be set to a custom duration. For detailed information about how to use Control-IQ+ technology, see Chapter 30 Introduction to Control-IQ+ Technology.

Enable Exercise with a Timer

1. From the *Home* screen, tap OPTIONS.
2. Tap **Activity**.
3. Tap **Exercise**.
4. Tap **Set a Timer**.
5. The default duration is 30 minutes. Tap **START** to start the exercise activity for 30 minutes. If you would like to edit the duration, proceed to step 6.



6. Tap **Duration**. The number keypad is displayed. You may enter an Exercise duration between 30 minutes and 8 hours. The pump will save this new duration for the next time you enable Exercise.
7. Tap .
8. Tap **START**.

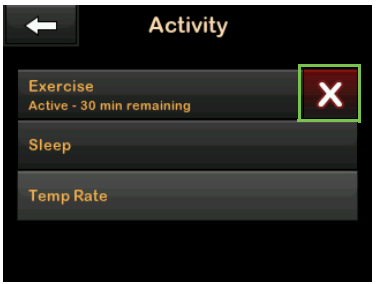
✓ An *EXERCISE STARTED* message is temporarily displayed. The Exercise icon is displayed on the *Home* screen.

Exercise will automatically be disabled once the set duration ends, or if Sleep is enabled manually. If enabled, a Sleep Schedule will not start until the Exercise timer ends.

Manually Disable Exercise before the Timer Ends

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

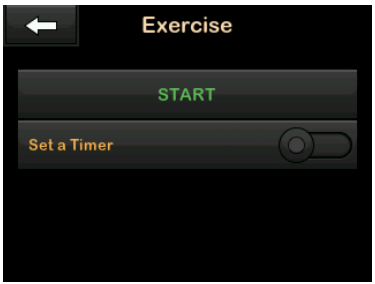
3. Tap ✕.



✓ An *EXERCISE STOPPED* message is temporarily displayed. The Exercise icon is removed from the *Home* screen.

Enable Exercise Without a Set Timer

1. From the *Home* screen, tap OPTIONS.
2. Tap **Activity**.
3. Tap **Exercise**.
4. Tap **Start**.

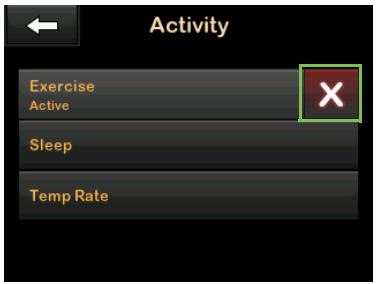


✓ An *EXERCISE STARTED* message is temporarily displayed. The Exercise icon is displayed on the *Home* screen.

Exercise is now enabled and will remain on until it is disabled manually, or if Sleep is enabled manually. If enabled, a Sleep Schedule will not start until the Exercise is disabled manually.

Disable Continual Exercise Without a Set Timer

1. From the *Home* screen, tap OPTIONS.
2. Tap **Activity**.
3. Tap ✕.



✓ An *EXERCISE STOPPED* message is temporarily displayed. The Exercise icon is removed from the *Home* screen.

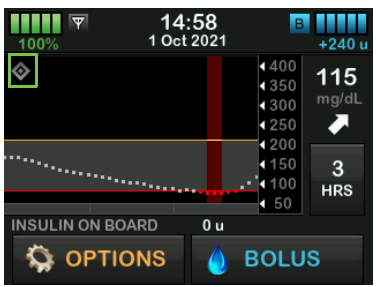
31.9 Control-IQ+ Technology Information on Your Screen

Control-IQ+ Technology Status Icon

When Control-IQ+ technology is on, the CGM Trend Graph displays a diamond icon in the top left corner. This icon uses different colors to communicate information about how Control-IQ+ technology is operating. Each different color and its meaning can be found in

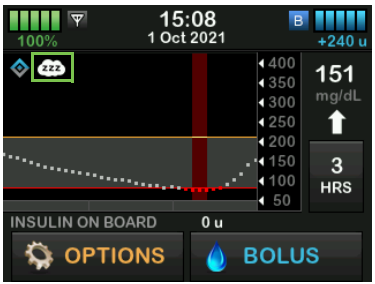
Section 29.2 Explanation of Control-IQ+ Technology Icons.

When Control-IQ+ technology is on but not active (i.e. insulin is being delivered normally), the diamond icon is gray as depicted below. Regardless of the color, the icon always appears in the same place.



Exercise and Sleep Icons

When Exercise or Sleep is turned on, the respective icon displays in the same place on the screen, since they can never be active at the same time. The following image shows the sleep icon active on the CGM Trend Graph screen.

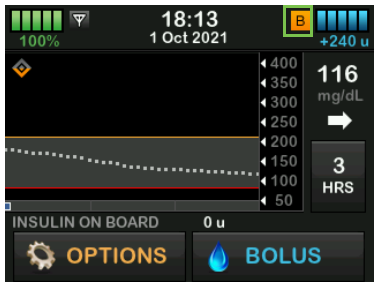


When Exercise is on, the Exercise icon is displayed in the same location.

Basal Status Icons

There are several basal status icons that display in different colors, each of which communicates information about how Control-IQ+ technology is operating. Each different color and its meaning can be found in Section 29.2 Explanation of Control-IQ+ Technology Icons.

The following image highlights where the basal status icons display.



Automatic Correction Bolus Status Icon

When Control-IQ+ technology is on and delivering an automatic correction bolus, an icon displays to the left of the basal status icon. (The manual bolus icon displays in the same place on the screen; see the Section 3.3 Explanation of t:slim X2 Insulin Pump Icons for the manual bolus icon image.) The following image shows the location of the bolus icon.

NOTE

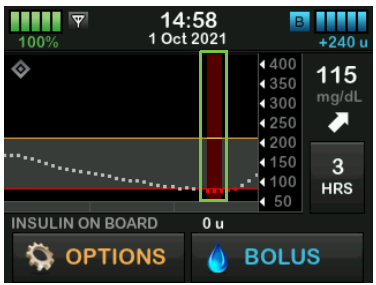
The text **BOLUS** followed by 3 ellipses displays below the CGM graph. The **Control-IQ+**

technology text appearing below **BOLUS** indicates that there is an automatic correction bolus delivered by Control-IQ+ technology. The amount of the bolus is also displayed.

CGM Trend Graph Insulin Delivery Suspended

Portions of the CGM Trend Graph that display a red band in the background indicate the times when Control-IQ+ technology was delivering 0 units/hour.

Each dot on the CGM graph represents a five-minute increment.



CHAPTER 32

Control-IQ+ Technology Alerts

Information in this section will help you learn how to respond to Control-IQ+™ technology alerts and errors. It applies only to the Control-IQ+ technology within your pump. The Control-IQ+ technology alerts follow the same pattern as other pump alerts according to your Sound Volume selection.

The Tandem t:slim™ mobile app also can provide messages, alerts, and alarms from your t:slim X2™ pump as push notifications on your smartphone. These push notifications will be identical to your pump's display unless otherwise noted in this chapter.

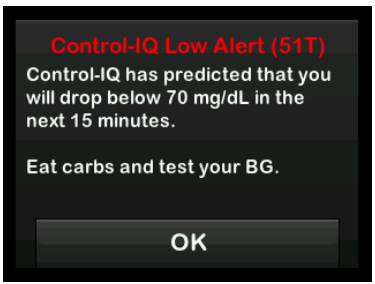
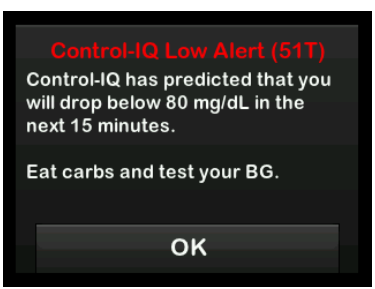
⚠ PRECAUTION

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

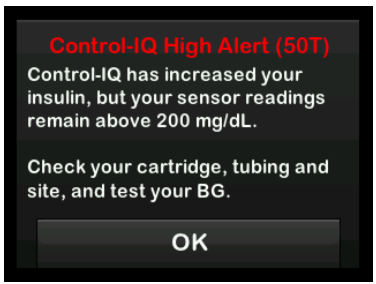
For information on insulin delivery reminders, alerts, and alarms see Chapters 13 t:slim X2 Insulin Pump Alerts, 14 t:slim X2 Insulin Pump Alarms, and 15 t:slim X2 Insulin Pump Malfunction.

For information on CGM Alerts and Errors, see Chapter 26 CGM Alerts and Errors.

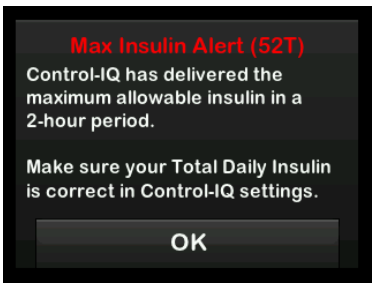
32.1 Control-IQ Low Alert

Screen	Explanation	
What will I see on the screen?   	What does it mean?	Control-IQ+ technology Low Alert has predicted that your sensor glucose reading will drop below 70 mg/dL, or below 80 mg/dL if Exercise is enabled, in the next 15 minutes.
	How will the pump notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes until acknowledged.
	Will the pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Eat carbs and test your BG. Tap OK to close the alert screen.

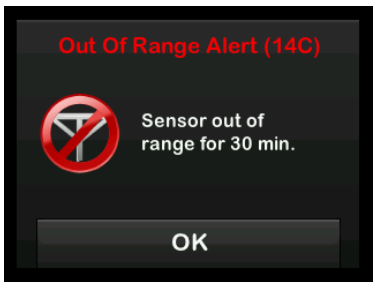
32.2 Control-IQ High Alert

Screen	Explanation	
What will I see on the screen? 	What does it mean?	Control-IQ+ technology has three hours of CGM data available and has increased insulin delivery, but detects a sensor glucose reading above 200 mg/dL and does not predict that the sensor glucose reading will decrease in the next 30 minutes.
	How will the pump notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes until acknowledged.
	Will the pump re-notify me?	Yes, every 5 minutes until acknowledged, and then every 2 hours if the issue still persists.
	How should I respond?	Check your cartridge, tubing, and site, and test your BG. Treat your high sensor glucose as necessary. Tap OK to close the alert screen.

32.3 Max Insulin Alert

Screen	Explanation	
What will I see on the screen?  	What does it mean?	The pump has delivered the maximum allowable 2 hour insulin amount based on your Total Daily Insulin setting. You see this alert when Control-IQ+ technology has delivered 50% of your Total Daily Insulin (through basal and/or bolus deliveries) over the previous rolling 2 hour window, and detects this condition for 20 minutes in a row. Control-IQ+ technology will suspend insulin delivery for a minimum of 5 minutes, and then resume insulin delivery once the condition is no longer detected.
	How will the pump notify me?	2 vibrations, then 2 vibrations/beeps every 5 minutes until acknowledged.
	Will the pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	Tap OK.

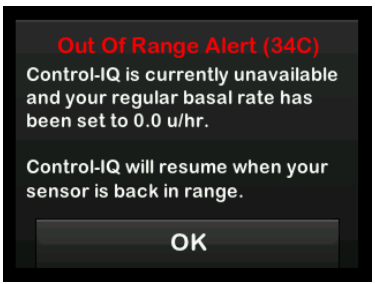
32.4 Out of Range Alert – Control-IQ+ Technology Disabled

Screen	Explanation	
What will I see on the screen? 	What does it mean?	The CGM and pump are not communicating. You may see slightly different error screens depending on which CGM you are using. The pump will not receive sensor glucose readings, and Control-IQ+ technology is not able to predict sensor glucose levels or adjust insulin delivery.
	How will the pump notify me?	1 vibrate, then vibration/beep every 5 minutes until the CGM and pump are back in range.
	Will the pump re-notify me?	Yes, if the CGM and pump remain out of range.
	How should I respond?	Tap OK to confirm and move the CGM and pump closer together, or remove the obstruction between them.

⚠ WARNING

Control-IQ+ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate settings in your active Personal Profile.

32.5 Out of Range Alert – Control-IQ+ Technology Enabled

Screen	Explanation	
What will I see on the screen?  	What does it mean?	Control-IQ+ technology is turned on, but the CGM and pump are not communicating. You may see slightly different error codes depending on which CGM you are using. The pump will not receive sensor glucose readings. Control-IQ+ technology will continue to adjust basal rates and deliver automatic correction boluses for the first 20 minutes that the CGM and pump are out of range. Control-IQ+ technology will resume automated insulin dosing once the CGM and pump are back within range.
	How will the pump notify me?	1 vibrate, then vibration/beep every 5 minutes until the CGM and pump are back in range.
	Will the pump re-notify me?	Yes, if the CGM and pump remain out of range.
	How should I respond?	Tap OK to confirm and move the CGM and pump closer together, or remove the obstruction between them.

⚠ WARNING

Control-IQ+ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate settings in your active Personal Profile.

⚑ NOTE

It is recommended that you keep the Out of Range Alert turned on and set to 20 minutes. If your pump and CGM are not connected for 20 minutes, Control-IQ+ technology will not work. Control-IQ+ technology will begin working immediately when the CGM and pump are back within range.

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CHAPTER 33

Overview of Control-IQ and Control-IQ+ Technology Clinical Studies

33.1 Introduction

The following data represents the clinical performance of the t:slim X2™ insulin pump with Control-IQ™ technology in multiple studies.

The first pivotal study (DCLP3) included participants ≥14 years old. A second pivotal study (DCLP5) included participants 6 years to 13 years old. A third pivotal study (PEDAP) included participants 2 years to <6 years old. These three studies used the original version of Control-IQ technology, Control-IQ technology (v1.0), and were all randomized control trials (RCTs).

Three more pivotal trials were subsequently performed. The PEDAP trial was extended for a 3-month extension phase where all participants used the study device. High insulin use was evaluated in the Higher-IQ trial, a single arm study. Control-IQ technology was evaluated in an RCT in adults with Type 2 diabetes in the 2IQP study. These three studies used an updated version of Control-IQ technology, Control-IQ+ technology (v1.5).

All participants in these studies used the Dexcom G6 CGM.

Control-IQ technology has not been evaluated in children under 2 years of age. The safety and/or effectiveness of Control-IQ technology in children under 2 years of age is unknown.

33.2 Software Version History

Control-IQ+ technology (v1.5) introduced changes to allow for a wider range of weight and TDI input. Other changes were implemented and are outlined in the table below.

Parameter	Control-IQ 1.0	Control-IQ+ (v1.5)
Minimum Total Daily Insulin Entry	10 units	5 units
Maximum Total Daily Insulin Entry	100 units	200 units
Minimum Weight Entry	55 pounds	20 pounds
Maximum Weight Entry	308 pounds	440 pounds
Correction Factor Range Accepted by Algorithm	1:10 to 1:200	1:10 to 1:600
Maximum Extended Bolus Duration	2 hours	8 hours
Temporary Basal Rates with Closed-Loop Active	No	Yes
Basal Rate Clipping*	Yes	No
**Limited to 3 units/hour when delivering programmed basal rate*		

33.3 The DCLP 3 Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 6 months under normal conditions in adults and adolescents 14 years of age or older. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to the use of sensor augmented pump (SAP) therapy alone (the control arm), labeled as Control-IQ technology and SAP in the tables in this section.

168 participants were randomly assigned to use Control-IQ technology or SAP for the study in a 2:1 ratio. The Control-IQ technology arm included 112 participants and the SAP arm included 56 participants. All 168 participants completed the trial.

Baseline characteristics of study participants are provided in this section. The study population consisted of patients with a clinical diagnosis of type 1 diabetes, 14 to 71 years of age, treated with insulin via an insulin pump or injections for at least one year. Females known to be pregnant were not included.

The summary statistics presented for the DCLP3 describe the primary outcome measure of the sensor glucose time in range between 70–180 mg/dL reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study is not designed to determine difference in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm used the original Control-IQ algorithm (Control-IQ technology v1.0).

The primary outcome sensor time in range 70–180 mg/dL showed a mean adjusted difference 11% improvement with Control-IQ technology use compared to the control arm.

There was one episode of Diabetic Ketoacidosis (DKA), caused by infusion site failure in the Control-IQ technology arm. There were no severe hypoglycemic events in the DCLP3 with Control-IQ technology use. No other serious adverse events related to the device were reported.

Baseline Characteristics

DCLP3: Baseline Characteristics including Demographics at Enrollment (N=168)

Characteristic		Control-IQ (n=112)	SAP (n=56)
Age (years)			
	Mean ± SD	33 ± 16	33 ± 17
	Range	14 to 71	14 to 63
	<18 years	31 (28%)	17 (30%)
	≥18 years	81 (72%)	39 (70%)
Sex – Female n (%)		54 (48%)	30 (54%)
Race / Ethnicity*			
	White non-Hispanic	94 (86%)	53 (95%)
	Black / African American	4 (4%)	0 (0%)
	Asian	3 (3%)	2 (4%)
	Native Hawaiian / Other Pacific Islander	1 (<1%)	0 (0%)
	More than one race	7 (6%)	1 (2%)
Income†			

DCLP3: Baseline Characteristics including Demographics at Enrollment (N=168) (Continued)

	<$50,000	10 (11%)	2 (4%)
	$50,000 – <$100,000	24 (27%)	18 (36%)
	≥$100,000	55 (62%)	30 (60%)
Education‡			
	≤High School Diploma	3 (3%)	6 (11%)
	Associates Degree or Some College	13 (12%)	7 (13%)
	Bachelor's Degree	51 (46%)	21 (38%)
	Master's Degree	32 (28%)	17 (30%)
	Doctoral or Professional Degree	13 (12%)	5 (9%)
Health Insurance§			
	Private	102 (94%)	50 (91%)
	CHP or another government / Medicaid	5 (5%)	5 (9%)
	None	2 (2%)	0 (0%)

**Three subjects in the Control-IQ technology arm did not provide race information.*

†Twenty-three subjects in the Control-IQ technology arm and 6 in SAP arm did not provide income information.

‡Highest level completed by the subject, or the primary caregiver if the participant was <18 years old. One subject in the Control-IQ technology arm did not provide education information.

§Three subjects in the Control-IQ technology arm and one in the SAP arm did not provide insurance information.

Adverse Effects

The following tables provide a full list of adverse events that occurred during the main part of the DCLP3 study:

DCLP3: Types of Adverse Events by Treatment Arm (N=168)

		Number of Events	
		Control-IQ (n=112)	SAP (n=56)
Total Number of Adverse Events		13	3
Adverse Events Related to Study Device			
	Ketosis (Infusion Site Failure)	3	0
	Hyperglycemia (Infusion Site Failure)	4	2
	Hyperglycemia (Defected Cartridge)	1	0
	Diabetic Ketoacidosis (Infusion Set Failure)	1	0
Adverse Effects Not Related to a Study Device			
	Hyperglycemia (User Error)	3	0
	Hyperglycemia (Respiratory Infection)	0	1
	Coronary Bypass Surgery	1	0
	Otitis Externa	1	0
	Concussion	1	0

Adverse Effects

The following table provides a list of only hyperglycemia or ketosis events during the DCLP3 study:

DCLP3: Hyperglycemia/Ketosis Events by Treatment Arm (N=168)

	Number of Events	
	Control-IQ (n=112)	SAP (n=56)
Ketosis (Infusion Site Failure)	3	0
Hyperglycemia (Infusion Site Failure)	4	2
Hyperglycemia (Defected Cartridge)	1	0
Diabetic Ketoacidosis (Infusion Set Failure)	1	0
Hyperglycemia (User Error)*	3	0
Hyperglycemia (Respiratory Infection)	0	1

**Discontinued pump, forgot to replace*

Intervention Compliance

The following table provides an overview of how often the t:slimX2 insulin pump with Control-IQ technology was used in the Control-IQ technology arm:

DCLP3: Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over the 6-Month Period (n=112)

	Average Pump Use*	Average Time Control-IQ Available**
Weeks 1–4	100%	91%
Weeks 5–8	99%	91%
Weeks 9–12	100%	91%
Weeks 12–16	99%	91%
Weeks 17–20	99%	91%
Weeks 21–End	99%	82%
Overall	99%	89%

**The denominator is the total possible time within the 6-month study period.*
***Control-IQ Available is calculated as the percent of time when Control-IQ technology was available and operating normally during the 6-month study period.*

Primary Analysis

The primary outcome of the DCLP3 was to compare the CGM sensor values in range between 70–180 mg/dL between the Control-IQ technology and the SAP arms. The data represent the overall system performance 24-hours per day.

DCLP3: Comparison of CGM Values Between Control-IQ and SAP Users (N=168)

Characteristic	Control-IQ	SAP	Difference Between Study Arm and Control Arm
Average Sensor Glucose (std dev)	156 mg/dL (19 mg/dL)	170 mg/dL (25 mg/dL)	-14 mg/dL
Average% 70–180 mg/dL (std dev)	71.4% (11.7%)	59.2% (14.6%)	+11%
Average % >180 mg/dL (std dev)	27% (12%)	38.5% (15.2%)	-10%
Average % <70 mg/dL (std dev)	1.59% (1.15%)	2.25% (1.46%)	-0.88%
Average % <54 mg/dL (std dev)	0.29% (0.29%)	0.35% (0.32%)	-0.10%

The following table describes the average time participants in both the Control-IQ technology arm and the SAP arm spent with sensor glucose levels between 70–180 mg/dL by month at baseline and during the study period:

DCLP3: Percentage of Time in Range per Study Arm by Month (N=168)

Month	Control-IQ	SAP
Baseline	61%	59%
Month 1	73%	62%
Month 2	72%	60%
Month 3	71%	60%
Month 4	72%	58%
Month 5	71%	58%
Month 6	70%	58%

Secondary Analysis

The following table shows secondary analysis comparing the percent of time that participants spent at the indicated sensor glucose levels during the daytime and nighttime for the DCLP3:

DCLP3: Secondary Analysis by Time of Day (N=168)

Characteristic	Unit of Measure	Daytime		Nighttime	
		Control-IQ	SAP	Control-IQ	SAP
Overall Sensor Glucose Control	Average Sensor Glucose (std dev)	158 mg/dL (20 mg/dL)	170 mg/dL (26 mg/dL)	150 mg/dL (18 mg/dL)	170 mg/dL (27 mg/dL)
	Average % Sensor Glucose 70–180 mg/dL (std dev)	69.8% (12.4%)	59.4% (14.6%)	76.1% (12.4%)	58.5% (16.2%)

The following table compares the percent of time spent between 70–180 mg/dL across the different baseline HbA1c values observed in the DCLP3 study in both treatment arms:

Percentage of Time in Range per Study Arm by Baseline HbA1c (N=168)

Baseline HbA1c	Time in Range	
	Control-IQ	SAP
≤6.5%	85%	78%
6.6%–7.0%	76%	69%
7.1%–7.5%	71%	49%
7.6%–8.0%	69%	56%
≥8.1%	60%	47%

The following table compares the average HbA1c values for all DCLP3 participants at baseline, after 13 weeks, and after 26 weeks. There was a relative difference of -0.33% between the Control-IQ technology arm and the SAP arm:

Comparison of HbA1c Values (N=168)

Time Period	Control-IQ	SAP
Baseline	7.40%	7.40%
After 13 Weeks	7.02%	7.36%
After 26 Weeks	7.06%	7.39%

The following table compares the change in HbA1c values for participants over the course of the DCLP3:

DCLP3: Change in HbA1c Values from Randomization to 26 Weeks (N=168)

			Number of Subjects (% of Subjects) with Change in HbA1c									
			Decrease >1%		Decrease 0 to 1%		No Change		Increase 0 to 1%		Increase >1%	
			n	%	n	%	n	%	n	%	n	%
Baseline Central Lab HbA1c		n										
5% ≤ HbA1c < 6%	Treatment	8	0	0%	1	13%	0	0%	7	88%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%
6% ≤ HbA1c < 7%	Treatment	30	0	0%	18	60%	3	10%	9	30%	0	0%
	Control	19	0	0%	10	53%	0	0%	9	47%	0	0%
7% ≤ HbA1c < 8%	Treatment	45	4	9%	33	73%	2	4%	5	11%	1	2%
	Control	22	0	0%	11	50%	1	5%	8	36%	2	9%
8% ≤ HbA1c < 9%	Treatment	22	5	23%	15	68%	1	5%	1	5%	0	0%
	Control	13	0	0%	8	62%	0	0%	4	31%	1	8%
9% ≤ HbA1c < 10%	Treatment	4	1	25%	2	50%	0	0%	1	25%	0	0%
	Control	1	0	0%	0	0%	0	0%	1	100%	0	0%
HbA1c ≥ 10%	Treatment	2	2	100%	0	0%	0	0%	0	0%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%

DCLP3: Change in HbA1c Values from Randomization to 26 Weeks (N=168) (Continued)

			Number of Subjects (% of Subjects) with Change in HbA1c									
Overall	Treatment	111	12	11%	69	62%	6	5%	23	21%	1	<1%
	Control	55	0	0%	29	53%	1	2%	22	40%	3	5%

33.4 The DCLP5 Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in children age 6 to 13 years of age. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to the use of SAP therapy alone (the control group).

The study design was very similar to DCLP3. In DCLP5, participants (N=101) were randomly assigned to Control-IQ technology or SAP in a 3:1 ratio. In this study, the Control-IQ technology arm included 78 participants. Like the DCLP3, this study population had a clinical diagnosis of type 1 diabetes. Unlike the DCLP3, the DCLP5 had participants 6 to 13 years of age. They were treated with insulin via an insulin pump or injections for at least one year. They weighed ≥55 pounds (25 kilograms) and ≤308 pounds (140 kilograms) and took at least 10 units of insulin a day. Females known to be pregnant were not included. Participants were required to be living with at least one parent or guardian knowledgeable about diabetes and managing diabetes-related emergencies and willing to participate in all training sessions.

No participants were enrolled in the DCLP5 study who had inpatient psychiatric treatment in the past 6 months, the presence of a known adrenal disorder, untreated thyroid disease, cystic fibrosis, severe infectious process not anticipated to resolve prior to study procedures (e.g. meningitis, pneumonia, osteomyelitis), any skin condition in the area of insertion that prevents safe sensor or pump placement (e.g. bad sunburn, pre-existing dermatitis, intertrigo, psoriasis, extensive scarring, cellulitis), abnormal liver function tests (transaminase >3 times the upper limit of normal), or abnormal renal function test results (estimated glomular filtration rate [GFR] <60 mL/minute/1.7m^2). Participants were also excluded for use of any medication, any carcinogenic disease, or other significant medical disorder if that injury, medication, or disease in the judgment of the investigator would affect the completion of the protocol.

The summary statistics presented for the DCLP5 describe the primary outcome measure of the sensor glucose time in range between 70–180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study is not designed to determine difference in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm use the original Control-IQ algorithm (Control-IQ technology v1.0). There were no episodes of DKA in the DCLP5. There were no severe hypoglycemic events in the DCLP5 with Control-IQ technology use. No other serious adverse events related to the device were reported.

Baseline Characteristics

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
Age (years)			
	6 – 9	21 (27%)	8 (35%)
	10 – 13	57 (73%)	15 (65%)
	Median (IQR)	11 (9, 12)	10 (8, 13)
	Range	6 to 13	6 to 13
Sex – Female n (%)		38 (49%)	12 (52%)
Race / Ethnicity*			
	White non-Hispanic	64 (82%)	18 (78%)
	Hispanic or Latino	6 (8%)	2 (9%)
	Black / African American	0 (0%)	0 (0%)
	Asian	1 (1%)	1 (4%)
	More than one race	7 (9%)	2 (9%)
Annual Household Income			
	<$25,000	0 (0%)	0 (0%)
	$25,000 – <$35,000	2 (3%)	0 (0%)
	$35,000 – <$50,000	1 (1%)	2 (10%)

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101) (Continued)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
	$50,000 – <$75,000	5 (7%)	0 (0%)
	$75,000 – <$100,000	13 (18%)	4 (19%)
	$100,000 – <$200,000	27 (36%)	8 (38%)
	≥$200,000	26 (35%)	7 (33%)
Parent Education			
	≤High School Diploma	2 (3%)	0 (0%)
	Associates Degree or Some College	5 (6%)	1 (4%)
	Bachelor's Degree	32 (41%)	9 (39%)
	Master's Degree	34 (44%)	11 (48%)
	Doctoral or Professional Degree	5 (6%)	2 (9%)
Health Insurance			
	Private	102 (94%)	50 (91%)
	CHP or another government / Medicaid	5 (5%)	5 (9%)
	Military	2 (3%)	1 (4%)
	Other	0 (0%)	0 (0%)
	None	0 (0%)	0 (0%)

**Missing data (CLC/SAP): annual household income 4 (5%)/2 (9%), total daily insulin 1 (1%)/0 (0%). All other variables have no missing data.*

Adverse Effects

The following tables provide a full list of adverse events that occurred during the main part of the DCLP5 study:

DCLP5: Types of Adverse Events by Treatment Arm (N=101)

		Number of Events	
		Control-IQ (n=78)	SAP (n=23)
Total Number of Adverse Events		16	3
Adverse Events Related to Study Device			
	Ketosis (Infusion Site Failure)	8	0
	Abscess at Sensor Site (CGM Sensor)	0	2
	Hyperglycemia (Defected Cartridge)	1	0
Adverse Effects Not Related to a Study Device			
	Hypoglycemia (User Error)	1	0
	Ketosis (User Error)	2	1
	Ketosis (Gastroenteritis)	1	0
	Hyperglycemia (User Error)	2	0
	Accidental Over-Delivery of Insulin (User Error)*	1	0
One subject primed tubing while connected to body. This was a serious adverse event, requiring treatment in the emergency room for hypoglycemia prevention.			

The following table provides a list of only hyperglycemia or ketosis events during the DCLP5 study:

DCLP5: Hyperglycemia/Ketosis Events by Treatment Arm (N=101)

	Number of Events	
	Control-IQ (n=78)	SAP (n=23)
Ketosis (Infusion Site Failure)	8	0
Hyperglycemia (Defected Cartridge)	1	0
Ketosis (User Error)*	2	1
Ketosis (Gastroenteritis)	1	0
Hyperglycemia (User Error)†	2	0

**Improper cartridge fill*
†Failed to recharge pump battery

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used in the Control-IQ technology arm:

DCLP5: Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over the 4-Month Period (n=78)

	Average Time Control-IQ Available*
Weeks 1–4	93.4%
Weeks 5–8	93.8%
Weeks 9–12	94.1%
Weeks 13–End	94.4%
Overall	92.8%

**Control-IQ Available is calculated as the percent of time when Control-IQ technology was available and operating normally during the 4-month study period.*

Primary Analysis

The primary outcome of the DCLP5 was to compare the CGM sensor values in range between 70–180 mg/dL between the Control-IQ technology arm and the SAP arm. The data represent the overall system performance 24 hours per day.

DCLP5: Comparison of CGM Values Between Control-IQ and SAP Users (N=101)

Characteristic	Control-IQ	SAP	Difference Between Study Arm and Control Arm
Average Sensor Glucose (std dev)	162 mg/dL (18 mg/dL)	179 mg/dL (26 mg/dL)	-17 mg/dL
Average % 70 – 180 mg/dL (std dev)	67% (10%)	55% (13%)	+11%
Average % >180 mg/dL (std dev)	31% (10%)	43% (14%)	-10%
Average % <70 mg/dL (std dev)	1.8% (1.38%)	2.1% (1.18%)	-0.40%
Average % <54 mg/dL (std dev)	0.34% (0.35%)	0.38% (0.35%)	-0.07%

The following table describes the average time participants in both the Control-IQ technology arm and the SAP arm spent with sensor glucose levels between 70–180 mg/dL by month at baseline and during the study period.

DCLP5: Percentage of Time in Range per Study Arm by Month (N=101)

Month	Control-IQ	SAP
Baseline	53%	51%
Month 1	68%	56%
Month 2	68%	54%
Month 3	67%	56%
Month 4	66%	55%

Secondary Analysis

Secondary analysis comparing the percent of time that participants spent at the indicated sensor glucose levels during the daytime and nighttime for the DCLP5 are shown below:

DCLP5: Secondary Analysis by Time of Day (N=101)

Characteristic	Unit of Measure	Daytime		Nighttime	
		Control-IQ	SAP	Control-IQ	SAP
Overall Sensor Glucose Control	Average Sensor Glucose (std dev)	167 mg/dL (21 mg/dL)	179 mg/dL (27 mg/dL)	146 mg/dL (16 mg/dL)	180 mg/dL (27 mg/dL)
	Average % Sensor Glucose 70 – 180 mg/dL (std dev)	63% (11%)	56% (14%)	80% (9%)	54% (16%)

The following table compares the change in HbA1c values for participants over the course of the DCLP5:

DCLP5: Change in HbA1c Values from Randomization to 16 Weeks (N=101)

			Number of Subjects (% of Subjects) with Change in HbA1c									
			Decrease >1%		Decrease 0 to 1%		No Change		Increase 0 to 1%		Increase >1%	
			n	%	n	%	n	%	n	%	n	%
Baseline Central Lab HbA1c		n										
5% ≤ HbA1c < 6%	Treatment	3	0	0%	0	0%	2	67%	1	33%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	%0
6% ≤ HbA1c < 7%	Treatment	18	0	0%	9	50%	1	6%	8	44%	0	0%
	Control	3	0	0%	1	33%	0	0%	2	67%	0	0%
7% ≤ HbA1c < 8%	Treatment	28	3	11%	20	71%	0	0%	5	18%	0	0%
	Control	8	0	0%	5	63%	0	0%	2	25%	1	13%
8% ≤ HbA1c < 9%	Treatment	20	11	55%	9	45%	0	0%	0	0%	0	0%
	Control	10	0	0%	7	70%	0	0%	3	30%	0	0%
9% ≤ HbA1c < 10%	Treatment	7	5	71%	1	14%	0	0%	1	14%	0	0%
	Control	1	0	0%	1	100%	0	0%	0	0%	0	0%

HbA1c ≥ 10%	Treatment	1	0	0%	1	100%	0	0%	0	0%	0	0%
	Control	1	0	0%	1	100%	0	0%	0	0%	0	0%
Overall	Treatment	77	19	25%	40	52%	3	4%	15	19%	0	0%
	Control	23	0	0%	15	65%	0	0%	7	30%	1	4%

33.5 The PEDAP Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 4 months under normal conditions in preschoolers 2 to <6 years of age. The system's performance was evaluated in an RCT comparing use of Control-IQ technology to Standard Care (SC, the control group), which included SAP therapy and multiple daily injection (MDI) therapy.

In PEDAP, participants (N=102) were randomly assigned to Control-IQ technology or SC in a 2:1 ratio.

The Control-IQ technology arm included 68 participants, and the SC arm included 34 participants. Participants had a clinical diagnosis of type 1 diabetes and were 2 to 5 years of age. They were treated with insulin via an insulin pump or injections for at least 6 months. They weighed at least 9 kilograms (20 pounds) and took at least 5 units of insulin per day.

Participants were required to be living with at least one parent or guardian knowledgeable about diabetes and managing diabetes-related emergencies and willing to participate in all training sessions. No participants had a history of adrenal insufficiency, untreated thyroid disease, used oral or injectable steroids within the last 8 weeks, history of chronic renal disease or currently on hemodialysis, hemophilia or any other bleeding disorder, history of >1 severe hypoglycemic event with seizure or loss of consciousness in the last 3 months, history of >1 DKA event in the last 6 months not related to illness, infusion set failure, or initial diagnosis, known ongoing adhesive intolerance, or condition, in the opinion of the investigator, would put the participant or study at risk. Concurrent use of any non-insulin glucose lowering agent (including GLP-1 agonists, Symlin, DPP-4 inhibitors, and sulfonylureas) was not allowed.

The summary statistics presented describe the primary outcome measure of the sensor glucose time in range 70–180 mg/dL, by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study was not designed to determine differences in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm used the original Control-IQ algorithm (Control-IQ technology v1.0), modified to allow lower weight and total daily insulin dose entry.

The primary outcome sensor time in range showed a mean adjusted difference 12.4% improvement with Control-IQ technology use compared to SC.

There was one episode of DKA caused by infusion site failure, in the Control-IQ arm. There were two cases of severe hypoglycemia in the Control-IQ technology arm and one in the SC arm. No other serious adverse events related to the device were reported.

Baseline Characteristics

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102)

Characteristic		Overall (n=102)	Control-IQ (n=68)	SC (n=34)
Age (years)				
	Mean ± SD	3.94 ± 1.24	3.84 (1.23)	4.06 (1.25)
	Range	2.00 to 5.98	2.00 to 5.98	2.02 to 5.90
	2 to <4	47 (46%)	31 (46%)	16 (47%)
	4 to <6	55 (54%)	37 (54%)	18 (53%)
Weight (kg)				
	Mean (SD)	17.7 (4.2)	17.7 (4.7)	17.7 (3.3)
	Range	11.1 to 44.7	11.1 to 44.7	11.8 to 23.9
Total Daily Insulin (units/kg/day)				
	Median (IQR)	0.66 (0.54, 0.79)	0.66 (0.55, 0.77)	0.66 (0.51, 0.80)
	Range	0.26 to 2.12	0.26 to 2.12	0.31 to 1.64
Sex – Female n (%)		52 (51%)	33 (49%)	19 (56%)
Race / Ethnicity				

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102) (Continued)

Characteristic		Overall (n=102)	Control-IQ (n=68)	SC (n=34)
	White non-Hispanic	75 (74%)	50 (74%)	25 (74%)
	Black / African American	6 (6%)	4 (6%)	2 (6%)
	Asian	2 (2%)	1 (1%)	1 (3%)
	More than one race	3 (3%)	2 (3%)	1 (3%)
Income*				
	<$50,000	14 (14%)	8 (12%)	6 (19%)
	$50,000 – <$100,000	31 (33%)	19 (30%)	12 (38%)
	≥$100,000	51 (53%)	37 (57%)	14 (44%)
Parent Education				
	≤High School Diploma	9 (9%)	6 (9%)	3 (9%)
	Technical/Vocational	3 (3%)	2 (3%)	1 (3%)
	Associate Degree	11 (11%)	6 (9%)	5 (15%)
	College Graduate (Bachelor's or higher)	35 (34%)	22 (32%)	13 (38%)
	Advanced Degree (Masters, PhD, MD, etc.)	44 (43%)	32 (47%)	12 (35%)
Health Insurance				

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102) (Continued)

Characteristic		Overall (n=102)	Control-IQ (n=68)	SC (n=34)
	Private‡	78 (77%)	52 (76%)	26 (79%)
	CHP or another government / Medicaid†	22 (24%)	15 (22%)	7 (21%)
	None	1 (<1%)	1 (1%)	0 (0%)

**Missing data (CLC/SC): Health insurance 0/1, annual household income 4/2, BMI percentile 2/0, HbA1c 4/2. All other variables have no missing data.*
†For participants with Private Insurance, 7 participants also had Medicaid, 1 participant also had Medicare, and 1 participant also had other government insurance.
‡For participants with Medicaid, 1 participant also had other government insurance.

Adverse Effects

The following table provides a full list of adverse events that occurred during the main art of the PEDAP study.

PEDAP: Types of Adverse Events by Treatment Arm (N=102)

		Number of Events	
		Control-IQ (n=68)	SC (n=34)
Total Number of Adverse Events		71	14
Severe Hypoglycemic (SH) Events*		2	1
Diabetic Ketoacidosis (DKA) Events†		1	0
Other Serious Adverse Events‡ (SAEs)		0	1
Other Adverse Events *N Events/N Participants*		68/40	12/9
	Hyperglycemia with or without Ketosis Related to Study Device	39/26	0
	Hyperglycemia with or without Ketosis Not Related to Study Device	12/9	8/7
	Hypoglycemia (not severe)	2/2	0/0
	Burn	1/1	0/0

PEDAP: Types of Adverse Events by Treatment Arm (N=102) (Continued)

		Number of Events	
		Control-IQ (n=68)	SC (n=34)
	COVID-19	3/3	0/0
	Fall	1/1	0/0
	Fractured Finger	1/1	0/0
	Gastroenteritis	2/2	2/2
	Hematuria	1/1	0/0
	Medical Device Site Bleeding	1/1	0/0
	Skin Infection	3/2	0/0
	Streptococcal Sore Throat	1/1	0/0
	Upper Respiratory Infection	1/1	0/0
	Vomiting	0/0	2/1

**A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.*
†*DKA events meeting DCCT criteria.*
‡*One participant in the SC group was hospitalized for an asthma flare.*

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the PEDAP trial in the intervention arm.

PEDAP Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over 13-week Period (n=68)

	Average Time Control-IQ In Use*
Weeks 1–4	92%
Weeks 5–8	95% (n=67)
Weeks 9–13	95% (n=67)
Overall	94%

**The denominator is the number of days between the beginning of the fourth day after randomization and the end of the day before the 13-week visit, or the end of the day before the last contact date for the participant who dropped out.*

Primary Analysis

The primary outcome of PEDAP was to compare the CGM sensor values in range between 70–180 mg/dL between the Control-IQ technology arm and the SC arm. The data represent the overall system performance 24 hours per day.

PEDAP: Percent Time in Range: Primary Endpoint Tested for Superiority (N=101)

Time and Change	Control-IQ (n=67)	SC (n=34)
Baseline	57% (18)	55% (15)
13 Weeks	69% (11) (n=68)	56% (13)
Change from Baseline mean (SD)	12.5% (11.8)	1.0% (6.6)
13 week Adjusted Group Difference (95% CI) [p-value]	12.4% (9.5, 15.3) [<0.001]	

Secondary Analysis

Change in HbA1c values by baseline HbA1c subgroups is shown as follows:

PEDAP: Change in HbA1c Values by Baseline HbA1c Subgroups (Treatment n=59, Control n=31)

		N	Baseline mean (SD)	Change from Baseline Mean (SD)
Baseline HbA1c				
<7.0%	Treatment	21	6.4 (0.5)	-0.08 (0.33)
	Control	8	6.5 (0.3)	-0.18 (0.37)
7% ≤ HbA1c < 8%	Treatment	19	7.5 (0.3)	-0.51 (0.34)
	Control	8	7.4 (0.2)	-0.01 (0.36)
HbA1c ≥ 8%	Treatment	19	8.9 (0.9)	-1.22 (0.81)
	Control	15	8.5 (0.4)	-0.31 (0.40)
Overall	Treatment	59	8.9 (0.9)	-1.22 (0.81)
	Control	15	8.5 (0.4)	-0.31 (0.40)

33.6 The PEDAP Extension Phase

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in preschoolers 2 to <6 years of age. The PEDAP extension phase allowed participants in the preceding PEDAP RCT to continue in the trial for an additional 13 weeks during an Extension Phase (N=96), with all participants using Control-IQ technology for 3 more months. A subset of participants also performed meal and exercise challenges during the study.

Participants used either Closed-Loop Control (CLC) for the RCT and the extension phase of the study (CLC-CLC), or used Standard Care (SC) for the RCT arm of the study, then switched to CLC during the extension phase (SC-CLC).

Participants in the CLC-CLC arm (N=63, those who continued with Control-IQ technology) were compared to the SC-CLC group (who were in the standard care arm for the RCT, who then switched to Control-IQ technology for the extension, N=33).

The summary statistics presented for the PEDAP Extension Phase describe key CGM outcomes, as well as analysis of secondary endpoints.

All participants in the PEDAP extension phase used the updated Control-IQ algorithm, Control-IQ+ technology (v1.5).

Key CGM outcomes showed, in the CLC-CLC group, time in range 70–180 mg/dL increased from 57% at PEDAP RCT baseline to 70% at the end of the 13-week RCT, and this was sustained during the Extension Phase at 70%, with no significant change comparing the CLC use in the RCT phase to CLC use in the Extension Phase.

In the SC-CLC group, time in range 70–180 mg/dL was 55% at the PEDAP RCT baseline, 56% during the RCT, and 68% during the Extension Phase. Comparing standard care from the RCT with use of CLC in the extension, the mean difference in time in range 70–180 mg/dL was 11.8%.

There were two cases of severe hypoglycemia in the 63 participants in the CLC-CLC group (3%) unrelated to the study device, and no cases among the 33 participants in the SC-CLC group. No cases of DKA were reported. No other serious adverse events related to the device were reported.

Baseline Characteristics

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
Age at Beginning of Extension Phase (years)				
	Mean (SD)	4.17 (1.23)	4.10 (1.23)	4.32 (1.23)
	Range	2.30 to 6.33	2.33 to 6.33	2.35 to 6.22
	2 to <4	44 (46%)	29 (46%)	15 (45%)
	4 to <6	44 (46%)	31 (49%)	13 (39%)
	6 to <7	8 (8%)	3 (5%)	5 (15%)
Sex – Female n (%)		51 (53%)	32 (51%)	19 (58%)
Weight (kg)				
	Mean (SD)	18.5 (4.4)	18.7 (4.9)	18.2 (3.3)
	Range	12.2 to 47.2	12.7 to 47.2	12.2 to 24.4
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase				
	Median (IQR)	0.69 (0.59, 0.82)	0.69 (0.59, 0.80)	0.69 (0.55, 0.94)
	Range	0.42 to 1.70	0.42 to 1.70	0.44 to 1.38
Race / Ethnicity				

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96) (Continued)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
	White non-Hispanic	81 (84%)	53 (85%)	28 (85%)
	Black / African American	5 (5%)	3 (5%)	2 (6%)
	Asian	2 (2%)	1 (2%)	1 (3%)
	More than one race	8 (8%)	6 (10%)	2 (6%)
Hispanic Ethnicity		14 (15%)	9 (14%)	5 (15%)
Income at RCT Baseline*				
	<$50,000	13 (14%)	7 (11%)	6 (19%)
	$50,000 to $100,000	31 (34%)	19 (33%)	12 (39%)
	>$100,000	46 (51%)	33 (56%)	13 (42%)
Parent Education at RCT Baseline				
	High School graduate/diploma/GED	7 (7%)	4 (6%)	3 (9%)
	Technical/Vocational	3 (3%)	2 (3%)	1 (3%)
	Associate Degree	11 (11%)	6 (10%)	5 (15%)
	College Graduate (Bachelor's or equivalent)	34 (35%)	22 (35%)	12 (36%)
	Advanced Degree (Masters, PhD, MD, etc.)	41 (43%)	29 (46%)	12 (36%)
Health Insurance at RCT Baseline*				

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96) (Continued)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
	Private‡	74 (78%)	49 (78%)	25 (78%)
	Medicare / Medicaid†	13 (14%)	9 (14%)	4 (12%)
	Other Government Insurance	8 (8%)	5 (8%)	3 (9%)

**Missing data (CLC-CLC/SC-CLC): Health insurance 0/1, annual household income 4/2. All other variables have no missing data.*
†For participants with Private Insurance, 6 participants also had Medicaid, 1 participant also had Medicare, and 1 participant also had other government insurance.
‡For participants with Medicaid, 1 participant also had other government insurance.

Adverse Effects

The following table provides a full list of adverse events that occurred during the PEDAP extension phase. There were no DKA events:

Summary of Adverse Events During PEDAP Extension Phase (N=96)

		Number of Events	
		CLC-CLC (n=63)	SC-CLC (n=33)
Total Number of Adverse Events		46	29
Severe Hypoglycemic (SH) Events* *N Events/N Participants*		2/2	0/0
Other Serious Adverse Events† (SAEs) *N Events/N Participants*		1/1	0/0
Other Adverse Events *N Events/N Participants*		43/34	29/16
	Hyperglycemia with or without Ketosis Related to Study Device	20/18	8/8
	Hyperglycemia with or without Ketosis Not Related to Study Device	10/8	12/4
	Hypoglycemia (not severe)	1/1	0/0
	Allergy NOS	1/1	0/0

Summary of Adverse Events During PEDAP Extension Phase (N=96) (Continued)

		Number of Events	
		CLC-CLC (n=63)	SC-CLC (n=33)
	Cellulitis	0/0	1/1
	COVID-19	3/3	0/0
	Fever	0/0	1/1
	Gastroenteritis	2/2	2/2
	Head Injury	0/0	1/1
	Influenza	1/1	0/0
	Laceration	0/0	1/1
	Pneumonia	1/1	0/0
	Skin Infection	1/1	2/2
	Upper Respiratory Infection	1/1	0/0
	Viral Syndrome	1/1	0/0
	Vomiting	1/1	1/1

**A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.*

[†] *One participant in the CLC-CLC group was hospitalized for muscle pain*

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the PEDAP extension phase. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ technology v1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ+ technology v1.5).

PEDAP Extension Phase Median Percentage of Time of Closed-Loop System Use

	CLC-CLC	SC-CLC
Weeks 1–13*	94% (n=63)	NA (n=33)
Weeks 14–17	96% (n=63)	96% (n=33)
Weeks 18–21	96% (n=62)	96% (n=32)
Weeks 22–26	96% (n=61)	96% (n=31)
Weeks 14–26**	96% (n=63)	95% (n=33)

**The denominator for Weeks 1–13 is the number of days between the beginning of the fourth day after the randomization and the end of the day before the 13-week visit.*
***Denominator for Weeks 14–26 is the number of days between the beginning of the fourth day after the Extension Training visit and the end of the day before the 26-week visit, or the end of the day before the last contact date for the participants who dropped out.*

Key CGM Outcomes

Time in range 70–180 mg/dL for all phases of the trial is shown below. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ technology v1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ+ technology v1.5).

PEDAP Extension Phase: Percent Time in Range 70–180 mg/dL: Primary Endpoint Tested for Superiority (N=96)

Time and Change	CLC-CLC (n=63)	SC-CLC (n=33)
RCT Baseline	57% (18) n=62	55% (15)
Weeks 1-13	70% (11)	56% (13)
Weeks 14-26	70% (11)	68% (9)
26 week Adjusted Group Difference (95% CI) [p-value]*	0.1% (-1.2, 1.4) [0.86]	

**The point estimate and 95% confidence interval for the difference were calculated from a direct likelihood model. This model adjusted for the RCT baseline value of the metric, age, prior CGM and pump use, and site as a random effect. P-values and confidence intervals were adjusted to control the false discovery rate.*

Secondary Analysis

The following table shows secondary analysis of HbA1c outcomes. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ technology v1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ+ technology v1.5):

PEDAP Extension Phase: HbA1c Outcomes*

		N	HbA1c (%) mean (SD)
RCT Baseline	CLC-CLC	59	7.6 (1.2)
	SC-CLC	32	7.7 (0.9)
Week 13	CLC-CLC	58	7.0 (0.7)
	SC-CLC	32	7.5 (0.9)
Week 26	CLC-CLC	55	7.1 (0.8)
	SC-CLC	28	7.2 (0.7)

**CLC-CLC group used closed-loop control for both the RCT and the extension phase. SC-CLC used standard care for the RCT and closed-loop control for the extension phase.*

33.7 The Higher-IQ Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in adults with high insulin needs.

The Higher-IQ study enrolled adults (N=34) with type 1 diabetes using at least one basal rate greater than 3 units/hour, in a single arm, prospective study of Control-IQ technology use for 13 weeks. All participants also performed meal and exercise challenges during the study.

Participants were at least 18 years of age, had type 1 diabetes for at least 1 year, were users of an insulin pump for at least 3 months, had a hemoglobin AC1c 10.5% and had a weight ≤440 pounds.

Baseline characteristics of study participants are provided below. Participants with more than 1 episode of severe hypoglycemia or DKA in the last 6 months were not included. Females known to be pregnant were not included. Participants with hemophilia or any other bleeding disorder, history of adrenal insufficiency, untreated thyroid disease, chronic kidney disease which could affect CGM accuracy, history of gastroparesis, or a condition, which in the opinion of the investigator or designee, would put the participant or study at risk were not included.

Treatment with sulfonylureas, meglitinides, or Symlin was not permitted. Participants taking GLP-1 receptor agonists, DPP-4 inhibitors, and/or SGLT-2 inhibitors were allowed to continue these medications if they were on a stable dose for the last 3 months,

The summary statistics presented for Higher-IQ describe key CGM outcomes, as well as analysis of change in HbA1c.

All participants in the Higher-IQ study used the updated Control-IQ algorithm, Control-IQ+ technology (v1.5).

Key CGM outcomes showed time in range 70–180 mg/dL was 64.75% overall, with time in hypoglycemia of 1.04%.

HbA1c decreased from 7.69% at baseline to 6.87% after 13 weeks of Control-IQ technology use, a decrease of 0.82%.

There were no DKA or severe hypoglycemia events in the study. No other serious adverse events related to the device were reported.

Baseline Characteristics

Higher-IQ Baseline Characteristics Including Demographics at Enrollment (N=34)

Characteristic		All Participants Used Control-IQ (N=34)
Age (years)		
	Mean (SD)	39.9 (11.9)
	Range	20 to 66
Sex – Female n (%)		(14) 41.2%
Weight (kg)		
	Mean (SD)	114.8 (17.4)
	Range	85.1 to 169.3
Total Daily Insulin (units/kg/day)		
	Median (IQR)	1.2 (0.4)
	Range	0.5 to 2.0
Race / Ethnicity		
	White non-Hispanic	34 (100%)
	Black / African American	2 (5.9%)
	Native Hawaiian or Other Pacific Islander	1 (2.9%)
Hispanic Ethnicity		3 (8.8%)
Highest Level of Education		

Higher-IQ Baseline Characteristics Including Demographics at Enrollment (N=34) (Continued)

Characteristic		All Participants Used Control-IQ (N=34)
	Less than high school	1 (2.9%)
	High School graduate/diploma/GED	4 (11.8%)
	Some college but no degree	8 (23.5%)
	Associate Degree	3 (8.8%)
	College Graduate (Bachelor's or equivalent)	13 (38.2%)
	Advanced Degree (Masters, PhD, MD, etc.)	5 (14.7%)

Adverse Effects

The following table provides a full list of adverse events that occurred during the Higher-IQ study:

Higher-IQ – All Adverse Events (N=34)

	Number of Events
	All Participants Used Control-IQ
Total Number of Adverse Events	38
Severe Hypoglycemic (SH) Events*	0
Diabetic Ketoacidosis (DKA) Events†	0
Other Serious Adverse Events‡ (SAEs)	1
Other Adverse Events *N Events/N Participants*	37/18

Higher-IQ – All Adverse Events (N=34) (Continued)

		Number of Events
		All Participants Used Control-IQ
	Hyperglycemia with or without Ketosis Related to Study Device	1/1
	Hyperglycemia with or without Ketosis Not Related to Study Device	0/0
	Bronchitis	1/1
	Chronic Kidney Disease	1/1
	Cough	1/1
	COVID-19	2/2
	Dyslipidemia	1/1
	Hypertension	1/1
	Influenza	3/3
	Ligament Sprain	1/1
	Migraine	1/1
	Myalgia	1/1
	Nausea/Vomiting	2/2
	Oropharyngeal Pain	1/1
	Otitis Externa	1/1
	Otitis Media	2/2

Higher-IQ – All Adverse Events (N=34) (Continued)

		Number of Events
		All Participants Used Control-IQ
	Pharyngitis Streptococcal	1/1
	Skin Abrasion	1/1
	Sleep Apnea Syndrome	1/1
	Stiff Person Syndrome	1/1
	Tooth Abscess	1/1
	Tooth Fracture	1/1
	Tympanic Membrane Perforation	1/1
	Upper Respiratory Tract Infection	10/7

**A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.*
†*DKA events meeting DCCT criteria.*
‡*One participant was hospitalized for new onset atrial fibrillation.*

Intervention Compliance

The following table provides and overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the Higher-IQ trial:

Higher-IQ Intervention Adherence over the 13-week Study Period (N=34)

	Sensor Use (%)	Closed-Loop System Use (%)
Mean (SD)	97.9%	93%

Key CGM Outcomes

Key CGM outcomes are shown below, for overall, daytime, and overnight:

Higher-IQ: Percentage of Time in Glycemic Ranges (N=34)

CGM Time in Range Mean % (SD)	Overall	Daytime	Overnight
BG 70 – 180 mg/dL	64.75% (10.75)	63.47% (10.89)	68.47% (14.81)
BG >180 mg/dL	34.21% (11.05)	35.62% (11.25)	30.09% (15.01)
BG ≥250 mg/dL	10.45% (6.78)	10.74% (6.29)	9.58% (10.39)
BG 70 – 140 mg/dL	37.87% (10.75)	36.96% (10.81)	40.55% (14.43)
BG <54 mg/dL	0.20% (0.22)	0.15% (0.17)	0.35% (0.42)
BG <70 mg/dL	1.04% (0.98)	0.90% (0.90)	1.44% (1.48)

Secondary Analysis

Higher-IQ: Change in Central Lab HbA1c at 13 Weeks (N=34)

	Baseline	13 Weeks	Change from Baseline	P Value
HbA1c (%) Mean (SD)	7.69 (1.08)	6.87 (0.57)	-0.82 (0.73)	p<0.001

33.8 The 2IQP Trial

The goal of this study was to assess safety, efficacy, user satisfaction and quality of life with use of Control-IQ technology in adults with type 2 diabetes using insulin therapy with mealtime coverage for 13 weeks. The system's performance was evaluated in a RCT comparing the use of Control-IQ technology to continued use of insulin therapy by injections with a Dexcom G6 sensor (CGM arm).

319 participants were randomly assigned to use Control-IQ technology or CGM for the study in a 2:1 ratio. The Control-IQ technology arm included 215 participants, and the CGM arm included 104 participants. Participants in the Control-IQ technology arm performed meal and exercise challenges.

Baseline characteristics of study participants are provided below. The study population consisted of patients with a clinical diagnosis of type 2 diabetes, age 19 to 87 years of age, using insulin therapy with at least one injection containing rapid-acting insulin per day or an insulin pump for at least 3 months prior to enrollment. Prior use of mixed insulin with a rapid component was allowed. Females known to be pregnant were not included.

Treatment with sulfonylureas, meglitinides or Symlin was not permitted. Participants taking other noninsulin glucose-lowering medications (such as GLP-1 receptor agonists, DPP-4 inhibitors, and/or SGLT-2 inhibitors), or weight-reduction medications, were allowed to continue these medications if on a stable dose for the last 3 months.

At enrollment 9% of participants had HbA1c <7%, 30% had HbA1c from 7.0 to <8.0%, 31% had HbA1c from 8.0 to <9.0%, and 30% had HbA1c >9.0%.

The summary statistics describe the primary outcome measure of change in HbA1c compared between treatment arms. Analysis of CGM endpoints was also performed.

Results of subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of Control-IQ technology. The study was not designed to determine differences in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm used the updated Control-IQ algorithm (Control-IQ+ technology v1.5).

HbA1c improved from 8.2% at randomization to 7.3% at 13 weeks in the Control-IQ technology arm, a change of -0.9%. In the CGM arm, HbA1c improved from 8.1% at randomization to 7.7% at 13 weeks, a change of -0.3%. This represents an adjusted group difference of -0.6% favoring the Control-IQ technology arm. Sensor time in range 70-180 mg/dL showed an adjusted group difference of 14% improvement with Control-IQ technology use compared to the CGM arm at 13 weeks.

There were no DKA or hyperosmolar hyperglycemic syndrome events in the study. There was one severe hypoglycemic event in the Control-IQ technology arm, and none in the CGM arm. There was one death unrelated to the study in the CGM arm. There were no deaths in the Control-IQ technology arm. No other serious adverse events related to the device were reported.

Baseline Characteristics

2IQP: Baseline Characteristics by treatment group (N=319)

Characteristic		Control-IQ (n=215)	CGM (n=104)
Age (years)			
	Mean ± SD	59 ± 12	57 ± 12
	Range	19 to 87	23 to 80
Sex – Female n (%)		105 (49%)	49 (47%)
Weight (kg)			
	Median (IQR)	99 (84, 117)	103 (87, 117)
	Range	49 to 164	51 to 174
Total Daily Insulin (units/kg/day)			
	Median (IQR)	0.9 (0.6, 1.2)	0.9 (0.6, 1.2)
	Range	0.2 to 2.7	0.2 to 3.6
HbA1c Central Lab at Randomization*			
	Mean ± SD	8.2 (1.4)	8.1 (1.2)
	Range	5.7 to 14.1	5.2 to 12.4
Race*			

2IQP: Baseline Characteristics by treatment group (N=319) (Continued)

Characteristic		Control-IQ (n=215)	CGM (n=104)
	White	148 (69%)	74 (71%)
	Black / African American	45 (21%)	24 (23%)
	Asian	10 (5%)	3 (3%)
	Native Hawaiian / Other Pacific Islanders	2 (<1%)	0 (0%)
	American Indian / Alaskan Native	1 (<1%)	1 (<1%)
	More than one race	6 (3%)	2 (2%)
	Unknown / Not reported	3 (1%)	0 (0%)
Ethnicity			
	Hispanic or Latino	23 (11%)	11 (11%)
	Not Hispanic or Latino	190 (88%)	93 (89%)
	Unknown / Not reported	2 (<1%)	0 (0%)
Annual Household Income[†]			
	<$50,000	60 (28%)	26 (25%)
	$50,000 – <$100,000	52 (24%)	21 (20%)
	≥$100,000	53 (25%)	36 (35%)
	Unknown	11 (5%)	5 (5%)
	Does not wish to provide	39 (18%)	16 (15%)

2IQP: Baseline Characteristics by treatment group (N=319) (Continued)

Characteristic		Control-IQ (n=215)	CGM (n=104)
Education‡			
	≤High School Diploma	8 (4%)	3 (3%)
	High School graduate / diploma / GED	57 (27%)	21 (20%)
	Technical / Vocational	25 (12%)	12 (12%)
	Associate Degree	33 (15%)	16 (15%)
	College Graduate	49 (23%)	32 (31%)
	Advanced Degree (e.g. Master's, PhD, MD)	33 (15%)	16 (15%)
	Unknown	1 (<1%)	0 (0%)
	Does not wish to provide	9 (4%)	4 (4%)
Health Insurance§			
	Private	116 (54%)	65 (63%)
	Medicare	57 (27%)	15 (14%)
	Medicaid	10 (5%)	13 (13%)
	Other government insurance	23 (11%)	8 (8%)
	No coverage	2 (<1%)	2 (2%)
	Unknown / no answer	7 (3%)	1 (<1%)

**Sample not analyzable for one person in the AID group.*

Adverse Effects

The following tables provide a full list of adverse events that occurred during the main part of the 2IQP study.

2IQP: Types of Adverse Events by Treatment Arm (n=319)

		Number of Events	
		Control-IQ (n=215)	CGM (n=104)
Total Number of Adverse Events		106	26
Severe Hypoglycemic (SH) Events*		1	0
Diabetic Ketoacidosis (DKA) Events†		0	0
Hyperosmolar Hyperglycemic Syndrom (HHS) Events		0	0
Other Serious Adverse Events (SAEs)		18	7
	Back Surgery	1	0
	Breast Ductal Carcinoma	1	0
	COVID-19	2	0
	Cardiomyopathy	1	0
	Chest Pressure	1	0
	Congestive Heart Failure	1	1
	Coronary Artery Disease	0	1
	Exacerbation of Asthma	1	0
	Foot Infection	1	0

2IQP: Types of Adverse Events by Treatment Arm (n=319) (Continued)

		Number of Events	
		Control-IQ (n=215)	CGM (n=104)
	Headache	0	1
	Hip Fracture	1	0
	Hypotension	1	0
	Infection (Chronic) of Amputation Stump	1	0
	Knee Surgery NOS	1	0
	Multinodular Goiter	1	0
	Other	1	0
	Pancreatitis	1	0
	Pancreatitis (Fatal)	0	1
	Pneumonia	0	1
	Tooth Abscess	0	1
	Total Knee Replacement	1	0
	Unstable Angina	0	1
	Vitreous Hemmorrhage	1	0
Non-Serious Adverse Events			

2IQP: Types of Adverse Events by Treatment Arm (n=319) (Continued)

		Number of Events	
		Control-IQ (n=215)	CGM (n=104)
	Hyperglycemia with or without Ketosis Related to Study Device	20	0
	Hyperglycemia with or without Ketosis Not Related to Study Device	1	2
	Hypoglycemia (not severe)	10	2
	Other Reported Adverse Events	56	15

**A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.*
†DKA events meeting DCCT criteria.

Intervention Compliance

The following table provides an overview of the how often Control-IQ technology was active in the Control-IQ technology arm.

2IQP: Closed-Loop System Use Over 13-week Period

	Overall	Weeks 1-4	Weeks 5-8	Weeks 9-13
% Time Closed Loop Use *Median (Q_1, Q_3)**	93%, (87%, 95%)	93% (86%, 95%)	94% (90%, 96%)	93% (86%, 96%)
**Denominator is the number of days between the first day after initiation of pump use and the last day the pump was used in a non-suspension mode.*				

Primary Analysis

The criterion for superiority in the primary endpoint was met. In the primary analysis, mean HbA1c decreased 0.9% from 8.2±1.4% at baseline to 7.3±0.9% during follow-up in the Control-IQ technology group, and decreased 0.3% from 8.1±1.2% to 7.7±1.1% in the CGM group. The adjusted group difference [Control-IQ technology minus CGM] = -0.6%; 95% confidence interval (CI) -0.8% to 0.4%; p<0.001.

2IQP: Percent Time in Range: Primary Endpoint Tested for Superiority

Time and Change	Control-IQ	CGM
Baseline (n)	n=214*	n=104
Baseline mean (SD)	8.2% (1.4%)	8.1% (1.2%)
13 weeks (n)	n=209†	n=102‡
13 Weeks mean (SD)	7.3% (0.9%)	7.7% (1.1%)
Change from Baseline mean (SD)	-0.9% (1.1%)	-0.3% (0.9%)
13 week Adjusted Group Difference (95% CI)§ [p-value]	-0.6% (-0.8%, -0.4%) [<0.001]	

**Missing (sample not analyzable) for one participant.*

† Four participants dropped prior to 13 weeks final visit. The sample for one participant not analyzable. The sample for one participant was collected outside the pre-specified analysis window and thus not included.

‡ Two participants dropped prior to 13 weeks final visit.

§ The difference is AID – CGM. A direct likelihood model was used. This model adjusted for the baseline value of the metric and for site as a random effect.

Secondary Analysis

Change in time in range 70–180 mg/dL at 13 weeks showed a 14% adjusted group difference improvement in favor of the Control-IQ technology arm.

2IQP: Mean (SD) Change in CGM Time in Rang 70–180 mg/dL During the Study Period

Time and Change	Control-IQ	CGM
Baseline	48% (24%)	51% (21%)
13 Weeks	64% (16%)	52% (21%)
Change from Baseline	16% (19%)	1% (14%)
13 week Adjusted Group Difference (95% CI) [p-value]	14% (11%, 17%) [<0.001]	

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CHAPTER 34

Technical Specifications

34.1 Overview

This section provides tables of technical specifications, performance characteristics, options, settings, and electromagnetic compliance information for the t:slim X2™ pump. The specifications in this section meet the international standards set forth in IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, and IEC 60601-2-24.

34.2 t:slim X2 Pump Specifications

t:slim X2 Pump Specifications

Specification Type	Specification Details
Classification	External PSU: Class II, Infusion Pump. Internally-powered equipment, Type BF applied part. The risk of ignition of flammable anesthetics and explosive gases by the pump is remote. While this risk is remote, it is not recommended to operate the t:slim X2 pump in the presence of flammable anesthetics or explosive gases.
Size	3.13” x 2.0” x 0.6” (L x W x H) - (7.95 cm x 5.08 cm x 1.52 cm)
Weight (with full disposable)	3.95 ounces (112 grams)
Operating Conditions	Temperature: 41°F (5°C) to 99°F (37°C) Humidity: 20% to 90% RH non-condensing
Storage Conditions	Temperature: -4°F (-20°C) to 140°F (60°C) Humidity: 20% to 90% RH non-condensing
Atmospheric Pressure	-1,300 feet to 10,000 feet (-396 meters to 3,048 meters)
Moisture Protection	IP27: Watertight to a depth of 3 feet (0.91 meters) for up to 30 minutes
Cartridge Volume	3.0 mL or 300 units
Cannula Fill Amount	0.1 to 1.0 units of insulin

t:slim X2 Pump Specifications (Continued)

Specification Type	Specification Details
Insulin Concentration	U-100
Alarm Type	Visual, audible, and vibratory
Basal Delivery Accuracy at all Flow Rates (tested per IEC 60601-2-24)	±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 Pump Battery is Fully Discharged (including Alarm Settings and Alarm History)	Greater than 30 days
Infusion Set used for Testing	Unomedical VariSoft™ Comfort Infusion Set
Typical Operating Time when Pump is Operating at Intermediate Rate	During normal use, the intermediate rate is 2 units/hr; battery charge can be reasonably expected to last between 4 and 7 days, depending on your use of CGM and the Tandem t:slim™ mobile app features 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	The method of delivery isolates the insulin chamber from the patient and the software performs frequent monitoring of pump status. Multiple software monitors provide redundant protection against unsafe conditions. Over-infusion is mitigated by monitoring glucose, (whether via CGM, BG meter, or both), layering of redundancies and confirmations, and numerous other safeguard alarms. Users are required to review and confirm the details of all bolus deliveries, Basal Rates, and temp rates to ensure certainty before initiating a delivery. In addition, once bolus deliveries are confirmed, the user is given 5 seconds to cancel the delivery before it is started. An optional Auto-Off alarm triggers when the user has not interacted with the pump's user interface for a predefined period of time. Under-infusion is mitigated by occlusion detection and BG monitoring as BG entries are recorded. Users are prompted to treat high BG conditions with a correction bolus.
Bolus Volume at Release of Occlusion (2 units per hour Basal)	Less than 3 units with Unomedical Comfort (110cm) Infusion Set
Residual Insulin Remaining in the Cartridge (unusable)	Approximately 15 units
Minimum Audible Alarm Volume	45 dBA at 1 meter

NOTE

Accuracies stated in this table are valid for all Tandem Diabetes Care, Inc. branded infusion sets including: AutoSoft™ 90, AutoSoft™ XC, AutoSoft™ 30, VariSoft, and TruSteel™ branded infusion sets.

USB Charging/Download Cable Specifications

Specification Type	Specification Detail
Tandem P/N	004113
Length	6 feet (2 meters)
Type	USB A to USB Micro B

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

Specification Type	Specification Detail
Tandem P/N	007866
Input	100 to 240 Volts AC, 50/60 Hz
Output Voltage	5 Volts DC
Max Output Power	5 Watts
Output Connector	USB type A

Computer, USB Connector, Specifications

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

Requirements for Charging from a Computer

The t:slim X2 pump is designed to be connected to a host computer for battery charging and data transfer. The following minimum characteristics are required of the host computer:

- USB 1.1 port (or later)
- Computer compliant with 60950-1 or equivalent safety standard

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

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

⚠ WARNING

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

34.3 t:slim X2 Pump Options and Settings

t:slim X2 Pump Options and Settings

Option/Setting Type	Option/Setting Detail
Time	May be set to 12-hour or 24-hour clock (default is 12-hour clock)
Basal Rate Setting Range	0.1 – 15 units/hr
Insulin Delivery Profiles (Basal and Bolus)	6
Basal Rate Segments	16 per delivery profile
Basal Rate Increment	0.001 at 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 carb; 1:1 to 1:300 (can be set by 0.1 below 10)
BG Target Value	16 time segments. 70 to 250 mg/dL in 1 mg/dL increments
Correction Factor	16 time segments; Ratio: 1 unit of insulin reduces BG x mg/dL; 1:1 to 1:600 (1 mg/dL increments)
Duration of Insulin Action	1 time segment; 2 to 8 hours in 1-minute increments (default is 5 hrs)
Bolus Increment	0.01 at volumes greater than 0.05 units
Quick Bolus Increments	When set to units of insulin: 0.5, 1, 2, 5 units (default is 0.5 units); or when set to grams of carb: 2, 5, 10, 15 grams (default is 2 g)

t:slim X2 Pump Options and Settings (Continued)

Option/Setting Type	Option/Setting Detail
Maximum Extended Bolus Time	8 hours
Maximum Bolus Size	25 units
Maximum Automatic Bolus Size	6 units
Low Cartridge Volume Indicator	Status indicator visible on *Home* screen; Low Insulin Alert is user adjustable from 10 to 40 units (default is 20 units).
Auto-Off Alarm	On or Off (default is off); user-adjustable (5 to 24 hours; default is 12 hours, which you can change when option is set to on).
History Storage	At least 30 days of data
Language	Dependent on region of use. May be set to English, Czech, Danish, Dutch, Finnish, French, German, Italian, Norwegian, Portuguese, Spanish, or Swedish (default is English).
Security PIN	Protects from unintentional access, and blocks access to quick bolus when enabled (default is off).
Screen Lock	Protects from unintentional screen interactions.
Site Reminder	Prompts user to change infusion set. Can be set for 1 to 3 days at a time selected by user (default is off).
Missed Meal Bolus Reminder	Prompts user if a bolus has not occurred during the period of time the reminder is set for. 4 reminders available (default is off).
After Bolus Reminder	Prompts user to test BG at a selected time period after a bolus has been delivered. Can be set between 1 to 3 hours (default is off).
High BG Reminder	Prompts user to retest BG after a High BG has been entered. User selects High BG value and time for reminder (default is off).

t:slim X2 Pump Options and Settings (Continued)

Option/Setting Type	Option/Setting Detail
Low BG Reminder	Prompts user to retest BG after a Low BG has been entered. User selects Low BG value and time for reminder (default is off).

34.4 t:slim X2 Pump Performance Characteristics

The t:slim X2 insulin pump delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The following accuracy data was collected on both types of delivery in laboratory studies performed by Tandem.

Basal Delivery

To assess basal delivery accuracy, 32 t:slim X2 pumps were tested by delivering at low, medium, and high Basal Rates (0.1, 2.0, and 15 U/hr). Sixteen of the pumps were new, and 16 had been aged to simulate four years of regular use. For both aged and unaged pumps, eight pumps were tested with a new cartridge, and eight with a cartridge which underwent two years of real time aging. Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid at various time points was used to assess pumping accuracy.

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for low, medium, and high Basal Rate settings for all pumps tested. For the medium and high basal rates, accuracy is reported from the time basal delivery started with no warm-up period. For the minimum Basal Rate, accuracy is reported after a 1-hour warm-up period. For each time period, the tables show the volume of insulin requested in the first row and the volume that was delivered as measured by the scale in the second row.

Low Basal Rate Delivery Performance (0.1 U/hr)

Basal Duration (Number of Units Delivered with 0.1 units/hr Setting)	**1 hour (0.1 units)**	**6 hours (0.6 units)**	**12 hours (1.2 units)**
Amount Delivered [min, max]	0.12 units [0.09, 0.16]	0.67 units [0.56, 0.76]	1.24 units [1.04, 1.48]

Medium Basal Rate Delivery Performance (2.0 U/hr)

Basal Duration (Number of Units Delivered with 2 Units/hr Setting)	1 hour (2 units)	6 hours (12 units)	12 hours (24 units)
Amount Delivered [min, max]	2.1 units [2.1, 2.2]	12.4 units [12.0, 12.8]	24.3 units [22.0, 24.9]

High Basal Rate Delivery Performance (15 U/hr)

Basal Duration (Number of Units Delivered with 15 Units/hr Setting)	1 hour (15 units)	6 hours (90 units)	12 hours (180 units)
Amount Delivered [min, max]	15.4 units [14.7, 15.7]	90.4 units [86.6, 93.0]	181 units [175.0, 187.0]

Bolus Delivery

To assess bolus delivery accuracy, 32 t:slim X2 pumps were tested by delivering consecutive low, medium, and high bolus volumes (0.05, 2.5, and 25 units). Sixteen of the pumps were new, and 16 had been aged to simulate four years of regular use. For both aged and unaged pumps, eight pumps were tested with a new cartridge, and eight with a cartridge which underwent two years of real time aging. Water was used as a substitute for insulin for this testing. The water was pumped into a container on a scale, and the weight of the liquid at various time points was used to assess pumping accuracy.

Delivered bolus volumes were compared to the requested bolus volume delivery for minimum, intermediate, and maximum bolus volumes. The tables below show average, minimum and maximum bolus sizes observed as well as the number of boluses which were observed to be within the specified range of each target bolus volume.

Summary of Bolus Delivery Performance (n=32 pumps)

Individual Bolus Accuracy Performance	Target Bolus Size [Units]	Mean Bolus Size [Units]	Min Bolus Size [Units]	Max Bolus Size [Units]
Min Bolus Delivery Performance (n=800 boluses)	0.050	0.050	0.000	0.114
Intermediate Bolus Delivery Performance (n=800 boluses)	2.50	2.46	0.00	2.70
Max Bolus Delivery Performance (n=256 boluses)	25.00	25.03	22.43	25.91

Low Bolus Delivery Performance (0.05Units) (n=800 boluses)

	Units of Insulin Delivered After a 0.05 Unit Bolus Request									
	<0.0125 (<25%)	0.0125–0.0375 (25–75%)	0.0375–0.045 (75–90%)	0.045–0.0475 (90–95%)	0.0475–0.0525 (95–105%)	0.0525–0.055 (105–110%)	0.055–0.0625 (110–125%)	0.0625–0.0875 (125–175%)	0.0875–0.125 (175–250%)	>0.125 (>250%)
Number and Percent of Boluses Within Range	21/800 (2.6%)	79/800 (9.9%)	63/800 (7.9%)	34/800 (4.3%)	272/800 (34.0%)	180/800 (22.5%)	105/800 (13.1%)	29/800 (3.6%)	17/800 (2.1%)	0/800 (0.0%)

Intermediate Bolus Delivery Performance (2.5Units) (n=800 boluses)

	Units of Insulin Delivered After a 2.5 Unit Bolus Request									
	<0.625 (<25%)	0.625–1.875 (25–75%)	1.875–2.25 (75–90%)	2.25–2.375 (90–95%)	2.375–2.625 (95–105%)	2.625–2.75 (105–110%)	2.75–3.125 (110–125%)	3.125–4.375 (125–175%)	4.375–6.25 (175–250%)	>6.25 (>250%)
Number and Percent of Boluses Within Range	9/800 (1.1%)	14/800 (1.8%)	11/800 (1.4%)	8/800 (1.0%)	753/800 (94.1%)	5/800 (0.6%)	0/800 (0.0%)	0/800 (0.0%)	0/800 (0.0%)	0/800 (0.0%)

High Bolus Delivery Performance (25Units) (n=256 boluses)

	Units of Insulin Delivered After a 25 Unit Bolus Request									
	<6.25 (<25%)	6.25–18.75 (25–75%)	18.75–22.5 (75–90%)	22.5–23.75 (90–95%)	23.75–26.25 (95–105%)	26.25–27.5 (105–110%)	27.5–31.25 (110–125%)	31.25–43.75 (125–175%)	43.75–62.5 (175–250%)	>62.5 (>250%)
Number and Percent of Boluses Within Range	0/256 (0.0%)	0/256 (0.0%)	1/256 (0.4%)	3/256 (1.2%)	252/256 (98.4%)	0/256 (0.0%)	0/256 (0.0%)	0/256 (0.0%)	0/256 (0.0%)	0/256 (0.0%)

Rate of Delivery

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

Bolus Duration

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

Time to Occlusion Alarm*

Operating Rate	Typical	Maximum
Bolus (3 units or Greater)	1 minute 2 seconds	3 Minutes
Basal (2 units/hr)	1 Hour 4 Minutes	2 Hours
Basal (0.1 units/hr)	19 Hours 43 Minutes	36 Hours
**The time to occlusion alarm is based on insulin volume not delivered. During an occlusion event, boluses of less than 3 units may not trigger an occlusion alarm if no basal insulin is being delivered. The bolus amount will reduce the time to occlusion depending on the Basal Rate.*		

34.5 Electromagnetic Compatibility

The information contained in this section is specific to the system. This information provides reasonable assurance of normal operation, but does not guarantee such under all conditions. If the system must be used in close proximity with other electrical equipment, the system should be observed in this environment to verify normal operation. Special precautions for electromagnetic compatibility must be taken when using medical electrical equipment. The system must be placed into service with adherence to the EMC information provided here.

⚠ WARNING

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

⚠ WARNING

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

For IEC 60601-1-2 testing, Essential Performance for the Pump is defined as follows:

- The pump will not over deliver a clinically significant amount of insulin.
- The pump will not under deliver a clinically significant amount of insulin without notification to the user.
- The pump will not deliver a clinically significant amount of insulin after occlusion release.
- The pump will not discontinue reporting CGM data without notification to the user.

This section contains the following tables of information:

- Electromagnetic Emissions
- Electromagnetic Immunity
- Wireless Technology

34.6 Wireless Co-existence and Data Security

The system are designed to work safely and effectively in the presence of wireless devices typically found at home, work, retail stores, and places of leisure where daily activities occur.

⚠ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30.5 cm) to any part of the t:slim X2 pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The system is designed to send and accept Bluetooth wireless technology communication. Communication is not established until you enter the appropriate credentials into your pump.

The system and its components are designed to ensure data security and patient confidentiality using a series of cybersecurity measures, including device authentication, message encryption, and message validation.

34.7 Tandem t:slim Mobile App Security

The smartphone's biometric security or other native authentication prevents unauthorized access. Never share your security PIN/password or authorize any other person to access your smartphone via their biometric information to avoid unintentional changes in your delivery of insulin.

⚠ WARNING

DO NOT use a smartphone that has been jailbroken or rooted, or with Android developer mode on. Data may become vulnerable if you install the Tandem t:slim mobile app on a smartphone that has been jailbroken or rooted, or uses an unreleased or pre-release operating system. Only download the Tandem t:slim mobile app on Google Play™ or from the App Store®. See Section 4.3 Connecting to a Smartphone for Tandem t:slim mobile app installation.

If the app becomes corrupted or compromised, uninstall the Tandem t:slim mobile app and follow the instructions in Section 4.3 Connecting to a Smartphone to regain a known configuration of the Tandem t:slim mobile app.

Once supported, Tandem intends to support a particular smartphone and OS combination for at least one year. When the mobile app is no longer compatible with a particular smartphone or OS, no further security updates will be provided.

⚑ NOTE

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

Please report any cybersecurity incident or vulnerability to Customer Technical Support as soon as you discover it.

34.8 Electromagnetic Emissions

The system is intended for use in the electromagnetic environment specified below. Always make sure that the system is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

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

34.9 Electromagnetic Immunity

The system is intended for use in home healthcare electromagnetic environments.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

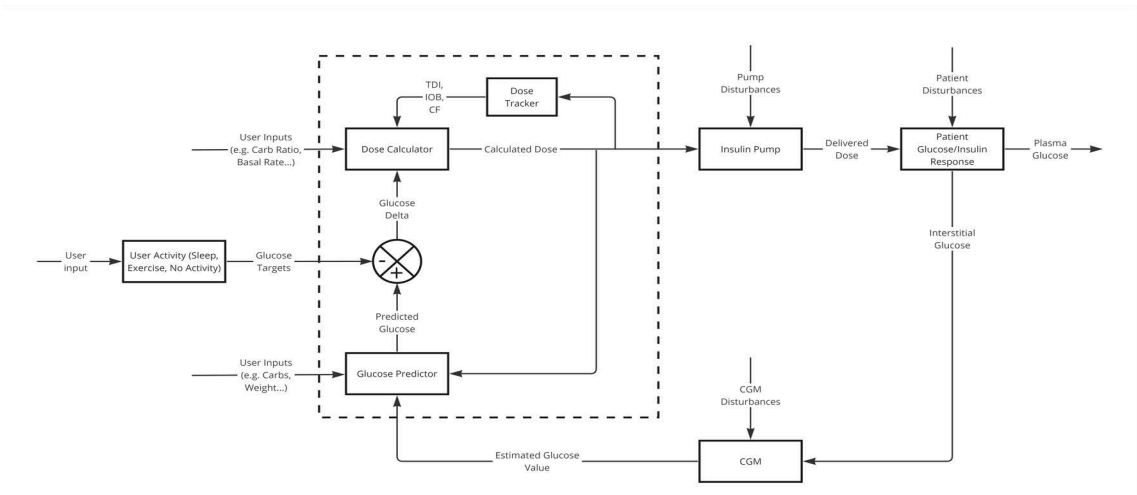
Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air
Electrical Fast Transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines (100 kHz repetition frequency)	± 2 kV for power supply lines ± 1 kV for input/output lines (100 kHz repetition frequency)
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level
Proximity Field from Wireless Transmitters	385 MHz: 27 V/m @ 18 Hz Pulse modulation 450 MHz: 28 V/m @ FM modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz Pulse modulation 810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz Pulse modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz Pulse Modulation 2450 MHz: 28 V/m @ 217 Hz Pulse modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz Pulse modulation	385 MHz: 27 V/m @ 18 Hz Pulse modulation 450 MHz: 28 V/m @ FM modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz Pulse modulation 810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz Pulse modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz Pulse Modulation 2450 MHz: 28 V/m @ 217 Hz Pulse modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz Pulse modulation
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	70% UR (30% dip in Ur) for 25 cycles 0% Ur (100% dip in Ur) for 1 cycle at 0 degrees 0% Ur (100% dip in Ur) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% Ur (100% dip in Ur) for 250 cycles	70% UR (30% dip in Ur) for 25 cycles 0% Ur (100% dip in Ur) for 1 cycle at 0 degrees 0% Ur (100% dip in Ur) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% Ur (100% dip in Ur) for 250 cycles
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	400 A/m (IEC 60601-2-24)

34.10 IEC 60601-1-10: Physiological Closed-Loop Controlled System

Control-IQ+ technology manages insulin therapy using a closed-loop control algorithm which modulates basal delivery and initiates periodic automatic correction boluses based on predicted glucose, insulin delivery history, and user input variables. The control algorithm uses continual feedback of Estimated Glucose Values (EGVs) from a Continuous Glucose Monitor (CGM), user-reported carbohydrate entries, insulin delivery history, and user weight to predict estimated blood glucose 30 minutes in the future. The control algorithm then uses this predicted glucose value, the current user mode glucose targets (e.g., exercise, sleep), and user-input pump settings to calculate the insulin delivery dose. All doses are validated by an insulin safety system to prevent over-delivery of insulin. The control algorithm is embedded in the pump application code. EGV values are received by the pump via Bluetooth wireless technology from a compatible CGM sensor. The following block diagram describes this theory of operation.



34.11 Quality of Wireless Service

The manufacturer defines the quality of service of the pump and CGM as the percent of readings successfully received by the pump. The Dexcom CGM wirelessly sends readings to the pump every 5 minutes. The Abbott FreeStyle Libre 2 Plus CGM wirelessly sends readings to the pump every minute. One of the essential performance requirements states that the pump will not discontinue reporting data and/or information from the CGM to the user without notification.

The pump notifies the user of a missed reading, or when the CGM and pump are out of range of one another in several ways. The first is when a dot is missed on the CGM Trend Graph which will occur within five minutes of the previous reading.The second indication occurs after 10 minutes when the Out of Range Icon is displayed on the *CGM Home* screen. The third is a user settable alert that will notify the user when the CGM and pump are out of range of one another. Setting this alert is defined in Section 22.6 Setting Your Out of Range Alert.

The minimum quality of wireless service of the pump and CGM assures that 90% of readings will be successfully transferred to the pump display while the CGM and pump are within 20 feet (6 meters) of each other, and no more than 12 consecutive readings (1 hour) will be missed.

For proper use of the Tandem t:slim mobile app, the pump and smartphone require successful wireless communication every 5 minutes. The quality of wireless service between the pump and smartphone hosting the Tandem t:slim mobile application is assured within 20 feet, unless there is wireless interference caused by other devices in the 2.4 GHz band. This interference may impact the smartphone's ability to maintain this quality of service. To improve the quality of service in the presence of other devices operating in the 2.4 GHz band, decrease the distance between the smartphone and the pump. If connectivity is lost, the Tandem t:slim mobile application will provide notification; use your Pump until connectivity improves.

34.12 Wireless Technology

The system utilizes wireless technology with the following characteristics:

Wireless Technology Specifications

Specification Type	Specification Detail
Wireless Technology	Bluetooth Low Energy (BLE) version 5.0
Tx/Rx Frequency Range	2.360 to 2.500 GHz
Bandwidth (per channel)	2 MHz
Radiated Output Power (maximum)	+8 dBm
Modulation	Gaussian Frequency-Shift Keying
Data Rate	2 Mbps
Data Communication Range (maximum)	20 feet (6 meters)

34.13 FCC Notice Concerning Interference

The device covered by this user guide has been certified under FCC ID: 2AA9B04.

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.

34.14 Warranty Information

For pump warranty information for your region, visit tandemdiabetes.com/legal/warranty.

34.15 Returned Goods Policy

For information on the returned goods policy for your region, visit tandemdiabetes.com/legal/warranty.

34.16 t:slim X2 Insulin Pump Event Data (Black Box)

Your t:slim X2 pump's event data is monitored and logged on the pump. The information stored on the pump may be obtained and used by Customer Technical Support and other internal Tandem personnel in accordance with our Privacy Notice for troubleshooting purposes when a pump is uploaded to a data management application that supports use of the t:slim X2 pump, or if the pump is returned. Others who may assert a legal right to know, or who obtain your consent to know such information may also have access to read and use this data. Our Privacy Notice is available on our website and through our other applications. The Privacy Notice is available at tandemdiabetes.com/privacy/privacy-policy.

34.17 Product List

For a complete product list, please contact Customer Technical Support.

Insulin Delivery

- t:slim X2 insulin pump with Control-IQ+ technology
- t:case (pump cover with clip)
- t:slim X2 user guide
- USB cable
- USB charger with power plugs
- cartridge removal tool

Consumables

- t:slim X2 cartridge (t:lock™ connector) with filling syringe and needle
- infusion set (all with t:lock connector)

Infusion sets are available in different cannula sizes, tubing lengths, insertion angles, and may come with or without an insertion device. Some infusion sets

have a soft cannula and others and have a steel needle.

Contact Customer Technical Support service for available sizes and lengths of the following infusion sets with t:lock connectors:

- AutoSoft 90 infusion set
- AutoSoft 30 infusion set
- AutoSoft XC infusion set
- VariSoft infusion set
- TruSteel infusion set

Optional Accessories/Replacement Parts

- t:case pump cover (black, blue, pink, purple, turquoise, olive)
- t:holster
- t:slim USB charging cable
- t:slim USB charger
- power plug for t:slim USB charger
- cartridge removal tool
- t:slim screen protector
- USB rubber door

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PATENTS AND TRADEMARKS

Covered by one or more patents. For a list of patents, see tandemdiabetes.com/legal/intellectual-property.

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