t:slim X2

Insulin Pump

with **Control-IQ+** Technology

Quick Start Guide

TANDEM™ Diabetes Care

MG/DL

T:SLIM X2 INSULIN PUMP WITH CONTROL-IQ+ TECHNOLOGY QUICK START GUIDE

Software Version: Control-IQ+ 7.10

This quick start guide is designed to assist you or your trusted caregiver with getting started on your t:slim X2 insulin pump with Control-IQ+™ technology. Inside, you will find steps to set up your pump, mobile app, connect to your continuous glucose monitoring (CGM), and information on initiating pump therapy.This Quick Start Guide also contains important safety information and an explanation of some of the alerts and alarms you may see on your pump.Training is also required to start pump therapy.

The system consists of the t:slim X2 insulin pump, the embedded Control-IQ+ algorithm, and the t:slim X2 3mL cartridge. It must be used with a compatible infusion set. The pump may be used with compatible CGM.

To access the complete t:slim X2 user guide for your software version, do either of the following:

- Access and download a digital copy from https://www.tandemdiabetes.com/support/resources/documents or scan this QR code:

- To request a free, printed copy, call Customer Technical Support at 1 (877) 801-6901

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CHAPTER 1

Overview

1.1 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 2 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.

1.2 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

1.3 Compatible iCGMs

Compatible CGMs include the following iCGMs:

- Dexcom G6 CGM
- Dexcom G7 CGM
- Abbott FreeStyle Libre 3 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.

1.4 Important User Information

Review all instructions in this quick start guide before using the pump.

If you are not able to use the pump according to the instructions in this 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 quick start guide.

Pay special attention to Warnings and Precautions, listed in Chapter 12 Important Safety Information. Warnings and Precautions are identified with a ⚠ or ⚠ symbol.

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

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.

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

1.5 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.

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.

1.6 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 of 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.

1.7 Training Resources

- Printed user guides, online user guides, quick start guide, quick reference sheets
- In-app guide, accessible through the Tandem t:slim app, or online: tandemdiabetes.com/mobilesupport
- Tandem Diabetes Care pump training learning center: tandemdiabetes.com/support/insulin-pump-training

1.8 Pump Accessories

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

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, or screen protectors, contact Customer Technical Support or your usual supplier of diabetes products.

1.9 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.

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

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.

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

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.

1.10 Turning the Pump On and Off

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.

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.

1.11 Caring for Your Pump

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

- Do not use your pump if you believe it has been damaged for any reason.
- If you drop your pump, 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

- 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 about proper pump disposal. Follow local regulations for disposal of potentially biohazardous materials such as used cartridges, needles, syringes, infusion sets, and sensors.

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CHAPTER 2

Getting Started

2.1 Using the Touchscreen

- To turn on your pump screen, first press the **Screen On/Quick Bolus** button, then tap the screen with your finger pad.
- The screen must be unlocked by tapping **1–2–3** in sequence.
- There is an optional Security PIN feature that can be set up to prevent unintentional access. See Section 2.12 Turn Security PIN On or Off.
- To turn the pump screen off, press the **Screen On/Quick Bolus** button. This turns off the screen, but not the pump.
- The touchscreen will turn off after 3 unintentional taps. The pump remains on.

2.2 Explanation of t:slim X2 Insulin Pump Icons

The following icons may appear on your pump Home Screen:

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 units/hour is active.
	A temporary basal rate of 0 units/hour 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.

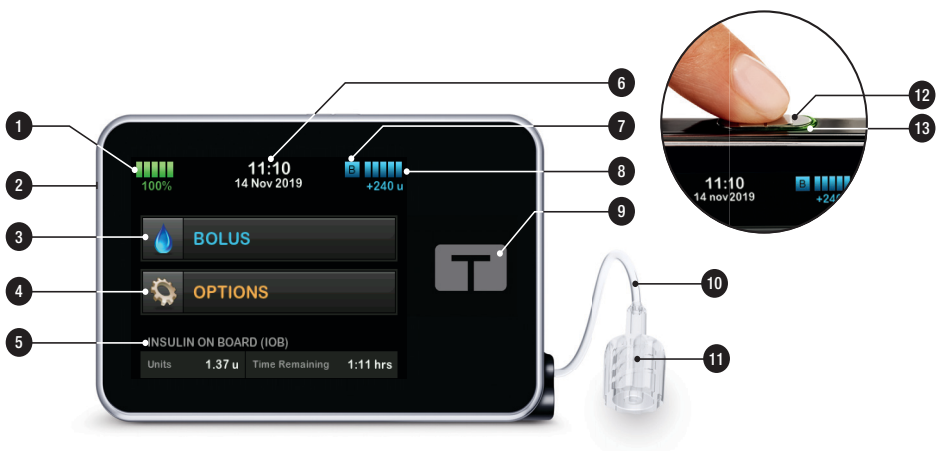
Pump Icon Definitions (Continued)

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 2.12 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.

2.3 Home Screen

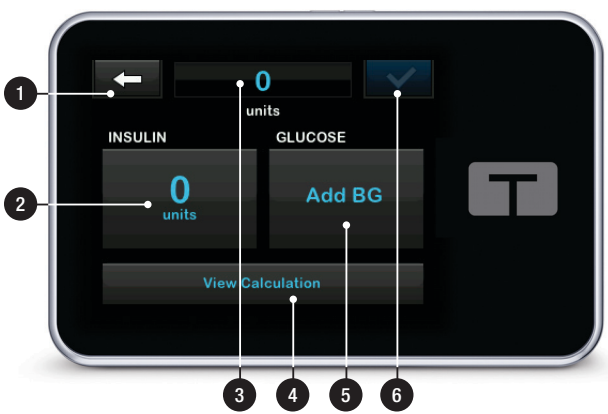
1. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
2. **USB Port:** Port to charge your pump battery. Close the cover when not in use.
3. **Bolus:** Program and deliver a bolus.
4. **Options:** Stop/Resume 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.



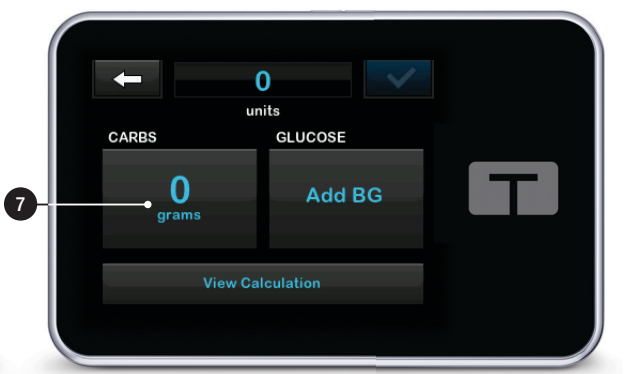
2.4 Bolus Screen

1. : Returns to the *Home* screen.
2. **Insulin:** Enter units of insulin. Can be changed to units of carbs.
3. **Units:** Displays total units calculated. Tap to enter a bolus request or change a bolus.
4. **View Calculation:** Displays how the insulin dose was calculated using the current settings.
5. **Glucose:** Enter BG or sensor glucose level. See Section 8.2 Correction Bolus Calculation for guidance on values.
6. : Moves to next step.
7. **Carbs:** Enter grams of carbohydrate. Can be changed to units of insulin.

Using Units

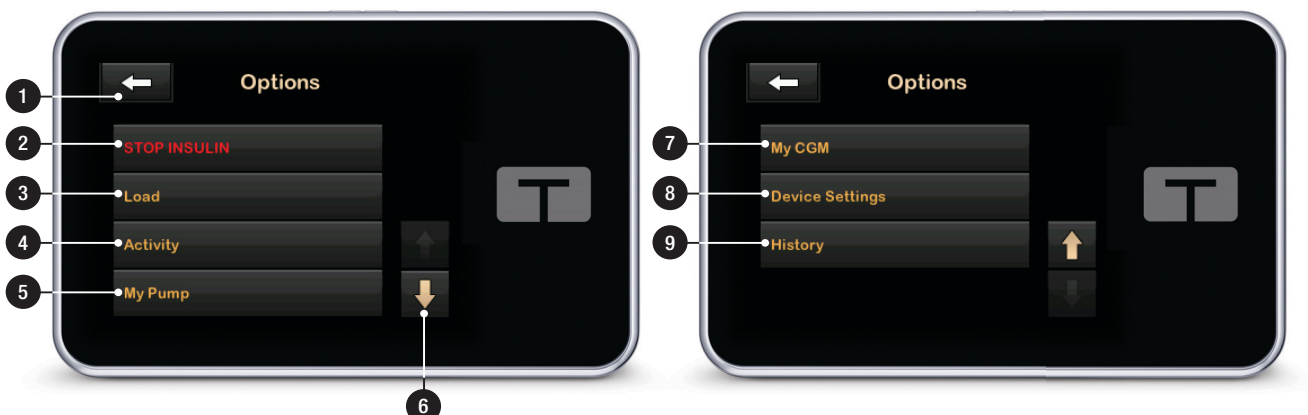


Using Grams



2.5 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:** See *My Pump* screen.
6. **Up/Down Arrow:** Indicates there is more information
7. **My CGM:** Displays options to configure and use a compatible CGM.
8. **Device Settings:** See *Device Settings* screen.
9. **History:** Displays historical log of pump and CGM events.

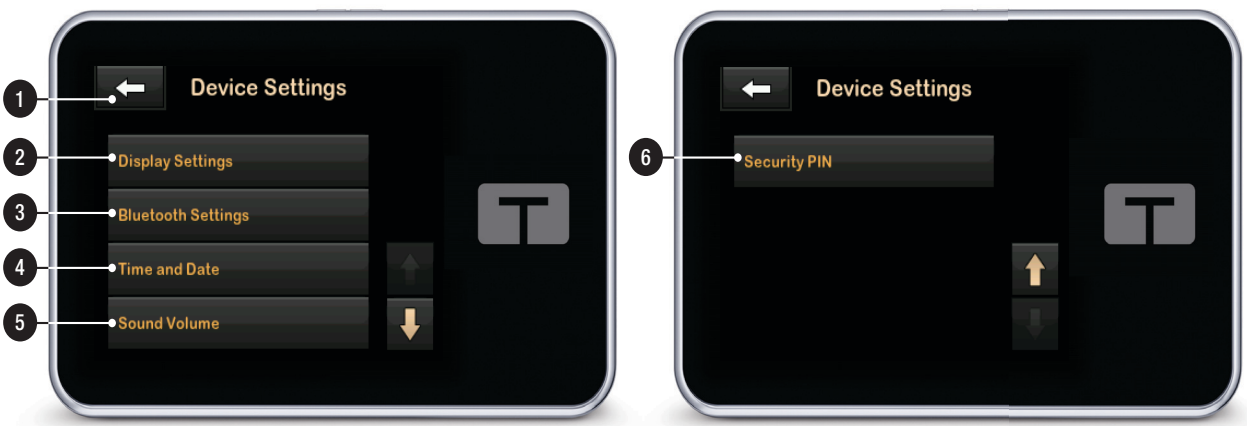


2.6 My Pump Screen

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.

2.7 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 various pump events.
6. **Security PIN:** Turn on/off the Security PIN.

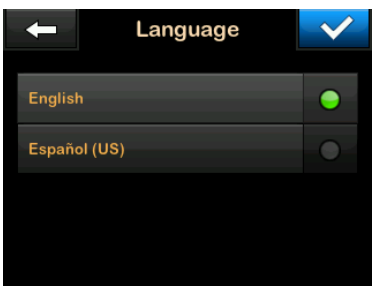


2.8 Selecting Your Language

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.

2.9 Edit Time and Date

To Edit Time:

1. From the *Home* screen, tap OPTIONS, then tap the Down Arrow, then tap Device Settings, then tap Time and Date, and then tap Edit Time.
2. Tap Time.
3. Using the on-screen keypad, enter the hour and minutes. Verify and tap ✓.
4. Tap Time of Day to set AM or PM, or tap the 24-hour Time toggle setting to on.
5. Verify the correct time is set and tap ✓.

To 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 ✓.

2.10 Display Settings

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

You can set this time to 15, 30, 60, or 120 seconds. The default time is 30 seconds.

1. From the *Home* screen, tap OPTIONS, then tap the Down Arrow, then tap Device Settings.

then tap **Display Settings**, and then tap **Screen Timeout**.

2. Select preferred time and tap ✓.

2.11 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.

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

2.12 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**, then tap the **Down Arrow**, then tap **Device Settings**, then tap the **Down Arrow**, and then tap **Security PIN**.
2. Tap **Security PIN** to toggle the feature on.
3. Tap ✓ to create your Security PIN.
4. Using the keypad, enter a number between four and six digits. A PIN may not begin with the number zero.
5. Tap ✓.
6. Tap OK to verify your Security PIN.
7. Use the keypad to repeat and verify the new Security PIN.
8. Tap ✓.

✓ A *PIN CREATED* screen is displayed.

9. Tap ✓ to turn the Security PIN on.
10. 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**, then tap the **Down Arrow**, then tap **Device Settings**, then tap the **Down Arrow**, and then tap **Security PIN**.
2. Tap **Change Security PIN**.
3. Tap OK.
4. Using the keypad, enter the current Security PIN. If you forget your Security PIN, use the override code **314159**.

5. Tap  .

6. Tap  to enter a new Security PIN.

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

8. Tap  .

9. Tap  to verify your new Security PIN.

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

11. Tap  .

✓ A *PIN UPDATED* screen is displayed.

12. Tap  .

CHAPTER 3

Tandem t:slim Mobile App and Source

3.1 Tandem t:slim Mobile App Overview

- The Tandem t:slim™ mobile app is a companion app for the t:slim X2™ insulin pump and can only be used with a compatible smartphone.
- You must 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. To download the Tandem t:slim mobile app, go to Google Play™ or the App Store®. For installation instructions, visit support.tandemdiabetes.com.
- Pump alerts and alarms must be cleared on your pump, however, you can use the Tandem t:slim mobile app to enable them as push notifications on your smartphone.

3.2 Tandem Source Platform Overview

- The Tandem Source™ platform is a web-based system that supports diabetes management by displaying and analyzing information uploaded from your pump.
- You can upload data directly from your pump to the Source Platform, or your Tandem t:slim mobile app can wirelessly upload your pump data as long as it is paired with your pump.
- Your Tandem Source login information is the same as your Tandem t:slim mobile app login information.
- To create your Tandem Source account, visit source.tandemdiabetes.com
- For Tandem Source user guides and further information and instruction, visit tandemdiabetes.com/products/software-apps/tandem-source

3.3 Install the Tandem t:slim Mobile App

- Enable smartphone security before using the Tandem t:slim mobile app to administer a bolus.
- Allow all permission requests from the Tandem t:slim mobile app to ensure you receive all notifications from your pump. 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.
- The Tandem t:slim mobile app will guide you through setup. Carefully follow each step and ensure you are entering all information correctly.
- Please see the t:slim X2 User Guide, the Tandem t:slim app webpage, or the in-app guide for full instructions and information on the mobile app.

3.4 Connecting to a Smartphone

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.

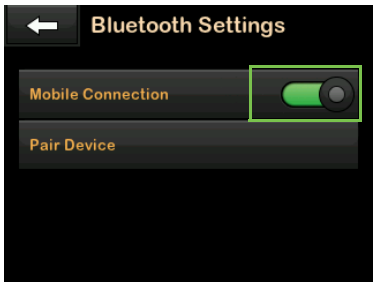
   If you are a new user, create an account as shown in Section 3.3 Install the Tandem t:slim Mobile App.

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

2. From your pump's *Home* screen:

   a. Tap **OPTIONS**, then tap the **Down Arrow**, then tap **Device Settings**, and then tap **Bluetooth Settings**.

   b. 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**.

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. This code is only valid for 5 minutes. Do not tap ✕ on your pump. It will return you to Bluetooth settings to repeat step 4. 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.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.

6. 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.

3.5 Unpair from a Smartphone

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 Section 3.4 Connecting to a Smartphone.

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3.6 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.

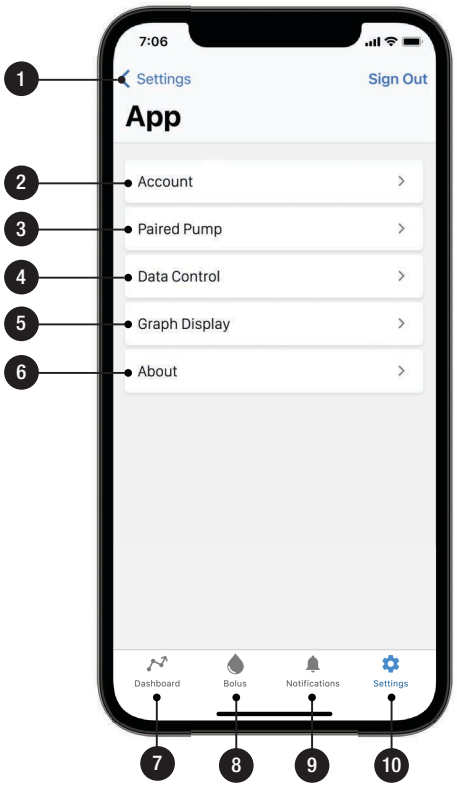
6. About: Access additional information, including various product identifiers, links to important safety information, consent statements, and instructions for use.

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.

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
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CHAPTER 4

My CGM

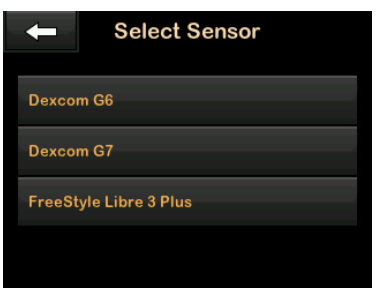
4.1 Choosing Your Sensor Type

You will be prompted to choose your sensor type the first time using your pump.

Ensure your CGM is connected to the t:slim X2 pump before pairing the CGM with any other devices or mobile apps.

If you need to switch CGM types, you can do so from the **OPTIONS** menu on your pump as follows:

1. Tap **OPTIONS**, then tap the **Down Arrow**, then tap **My CGM**, then tap **Change Sensor Type**.
2. Select your sensor type.



3. Begin the appropriate sensor pairing process as described in Section 4.2 Enter Your Dexcom G6 Transmitter ID, Section 4.6 Start the Dexcom G7 Sensor, or Chapter 4 Start the Abbott FreeStyle Libre 3 Plus Sensor.

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.
- You cannot change your transmitter ID or pairing code during a sensor session. Make sure you have removed your sensor and stopped your sensor session before changing your transmitter ID or pairing code.

4.2 Enter Your Dexcom G6 Transmitter ID

1. Remove the transmitter from its packaging.
2. From the *Home* screen, tap **OPTIONS**, then tap the **Down Arrow**, then tap **My CGM**, and then tap **Transmitter ID**.
3. 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.
4. Tap  .
5. To make sure that the correct transmitter ID is entered, you will be prompted to enter it a second time.
6. Repeat step 6 above, then tap  .

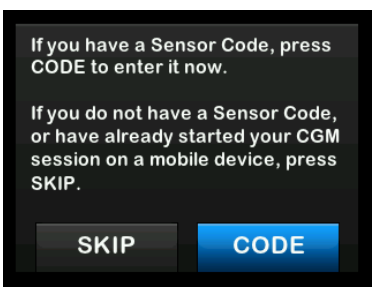
4.3 Start the Dexcom G6 Sensor

To start a Dexcom G6 CGM sensor session, follow the steps below.

1. From the *Home* screen, tap **OPTIONS**, then tap the **Down Arrow**, then tap **My CGM**, and then 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.

2. 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:

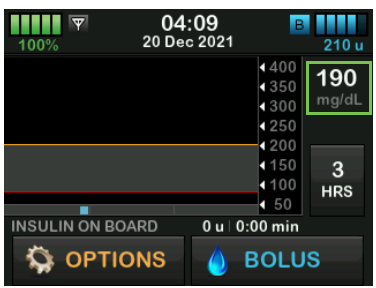
- Make sure your pump and CGM are within 20 feet (6 meters) of each other without obstruction. Re-check in 10 minutes to see if the out of range symbol is still active.
- If the pump and CGM are still not communicating, check the *My CGM* screen to make sure the correct transmitter ID is entered.
- If the correct transmitter ID is entered and the pump and CGM are still not communicating, contact Customer Technical Support.

4.4 Dexcom G6 Sensor Startup Period

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.

At the end of the 2-hour startup period, the countdown symbol will be replaced with the current CGM reading.



4.5 Ending a Dexcom G6 Sensor Session Before Automatic Shutoff

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**, then tap the **Down Arrow**, then tap **My CGM**, and then tap **STOP G6 SENSOR**.

2. 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.

4.6 Start the Dexcom G7 Sensor

To start a Dexcom G7 CGM sensor session, follow the steps below.

1. From the *CGM Home* screen, tap **OPTIONS**, then tap the **Down Arrow**, then tap **My CGM**, and then tap **START G7 SENSOR**.

✓ Once you start a sensor session, the **START G7 SENSOR** option is replaced with **STOP G7 SENSOR**.

2. Enter your pairing code. Tap ✔ to confirm.

3. Re-enter your pairing code and tap ✔ to confirm.

4. 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.

4.7 Dexcom G7 Sensor Startup Period

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.

At the end of the 30-minute startup period, the countdown symbol will be replaced with the current CGM reading.

You can insert a new Dexcom G7 sensor and begin its 30-minute startup period during an active sensor session. If you do, the new sensor startup period occurs while you still receive readings from the active sensor.

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 4.6 Start the Dexcom G7 Sensor to start your new sensor.

4.8 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**, then tap the **Down Arrow**, then tap **My CGM**, and then tap **STOP G7 SENSOR**.
2. 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.

4.9 Start the Abbott FreeStyle Libre 3 Plus Sensor

You will need to start an Abbott FreeStyle Libre 3 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 sensor session.

Your Abbott FreeStyle Libre 3 Plus cannot be paired to both the Abbott FreeStyle Libre 3 app and your pump at the same time. Ensure your CGM is not paired with any other device before pairing to your pump.

To start an Abbott FreeStyle Libre 3 CGM sensor session, follow the steps below.

1. From your pump, return to the *Home* screen.

2. From the Tandem t:slim mobile app, tap **Settings** on the *Navigation* bar, then tap **CGM**, and then tap **FreeStyle Libre 3 Plus**.

✓ The *Start Sensor* screen appears. For iOS smartphones, see step 3; for Android smartphones, see step 4.

3. 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 5.

4. 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.

5. When the *Sensor Session Started* screen appears, tap **OK**.

✓ If the *Treatment Decisions* screen appears, tap **I Understand**.

✓ Your Tandem t:slim mobile app will return to the *Dashboard* 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 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 sensor are still not communicating, contact Customer Technical Support.

4.10 Abbott FreeStyle Libre 3 Plus Sensor Startup Period

The Abbott FreeStyle Libre 3 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. During the startup period, a 1-hour countdown symbol appears on both the *CGM Home* screen and the Tandem t:slim mobile

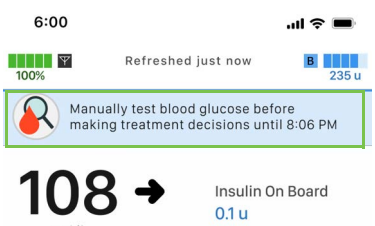
app *Dashboard* screen, which fills in over time. The Tandem t:slim mobile app also displays the remaining time.

At the end of the 1-hour startup period, the countdown symbol will be replaced with the current CGM reading.

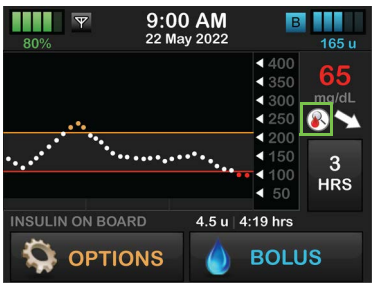
Check BG Icon

After the 1-hour startup period, the Tandem t:slim mobile app *Dashboard* screen and the pump *CGM Home* screen may display the Check BG icon for an additional 11 hours. If 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.



4.11 Ending an Abbott FreeStyle Libre 3 Plus Sensor Session Before Automatic Shutoff

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**, then tap the **Down Arrow**, then tap **My CGM**, and then tap **STOP SENSOR**.
2. Tap ✔.
3. 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.

4.12 Setting Your High Glucose Alert and Repeat Feature

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

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

4. 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.

5. Tap  .

   You can use the repeat feature to set a time for the High Alert to sound again. The default is never. It can be set to sound again every 15 minutes, 30 minutes, 1 hour, 2 hours, 3 hours, 4 hours, or 5 hours.

To Set Up the Repeat Feature:

1. Tap **Repeat**.

2. 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.

3. Tap  .

4.13 Setting Your Low Glucose Alert and Repeat Feature

1. From the *Home* screen, tap **OPTIONS**, then tap the **Down Arrow**, then tap **My CGM**, then tap **CGM Alerts**, and then tap **High and Low**.

2. To Set the Low Alert, tap **Low Alert**.

3. Tap **Alert Me Below**.

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

4. 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.

5. Tap  .

   You can use the repeat feature to set a time for the Low Alert to sound again. The default is never. It can be set to sound again every 15 minutes, 30 minutes, 1 hour, 2 hours, 3 hours, 4 hours, or 5 hours.

To Set Up the Repeat Feature:

1. Tap **Repeat**.

2. 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.

3. Tap  .

4.14 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.

4.15 Setting Your Rise Alert

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

   To change your selection, tap **Rate**.
4. Tap **2 mg/dL/min** to select.

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

5. Tap ✓.

4.16 Setting Your Fall Alert

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

   To change your selection, tap **Rate**.
4. Tap **2 mg/dL/min** to select.

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

5. Tap ✓.

4.17 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. We recommend leaving this alert on.

Control-IQ+™ technology will operate for the first 15 minutes that the pump and CGM are out of range. After 20 minutes, Control-IQ+ technology operation will stop until the devices are back in range.

To Set Your Out of Range Alert:

1. From the *Home* screen, tap **OPTIONS**, then tap the **Down Arrow**, then tap **My CGM**, then tap **CGM Alerts**, and then tap **Out of Range**.

   The default is set to on and the time is set to 20 minutes.

2. To change the time, tap **Alert After**.

3. 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  .

4. Tap  .

4.18 CGM Trend Graphs

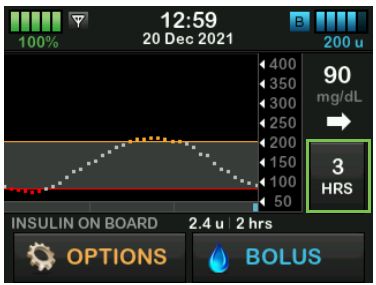
You can view your past sensor glucose trend information on your *CGM Home* screen.

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.

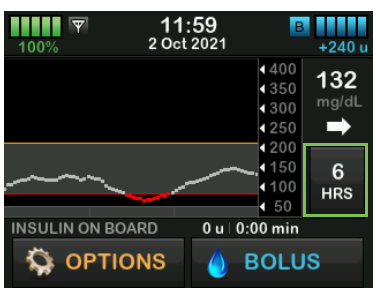
Your trend graph shows a flat line or dots at 50 or 400 mg/dL when your glucose is outside this range.

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

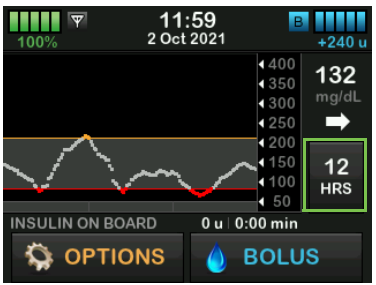
3 Hour Trend Graph (default view) shows you your current sensor glucose reading along with the last 3 hours of sensor glucose readings.



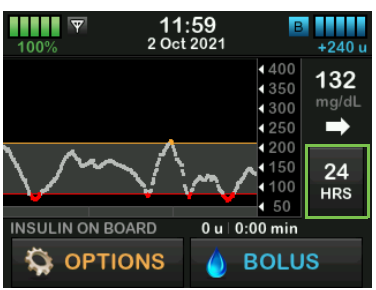
6 Hour Trend Graph shows you your current sensor glucose reading along with the last 6 hours of sensor glucose readings.



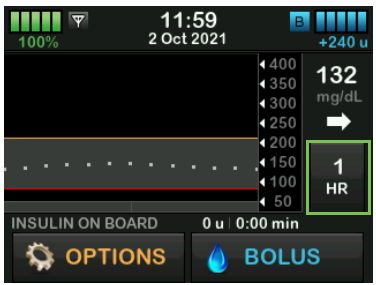
12 Hour Trend Graph shows you your current sensor glucose reading along with the last 12 hours of sensor glucose readings.



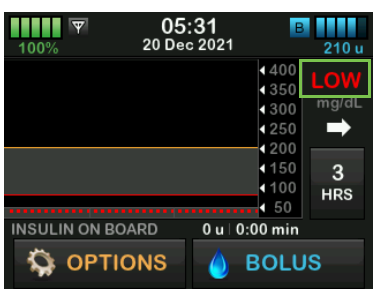
24 Hour Trend Graph shows you your current sensor glucose reading along with the last 24 hours of sensor glucose readings.



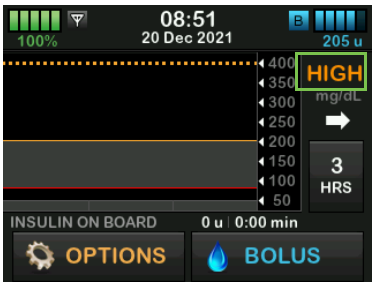
1 Hour Trend Graph shows you your current sensor glucose reading along with the last 1 hour of sensor glucose readings.



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



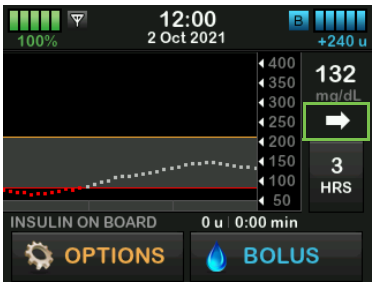
HIGH shows when your most recent sensor glucose reading is greater than 400 mg/dL.



4.19 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 your CGM sensor session:

CGM Sensor Trend Arrow Definitions

Symbol	Dexcom Definition	Abbott Definition
	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.	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.
	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 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: 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.	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.
	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.	This trend arrow will not appear on your pump during an Abbott CGM sensor session.
	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 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: 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.	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.
	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/dLin 15 minutes.	This trend arrow will not appear on your pump during an Abbott CGM sensor session.

CGM Sensor Trend Arrow Definitions (Continued)

No Arrow	No rate of change information: The CGM cannot calculate how fast your sensor glucose is rising or falling at this time.	Your pump will always show a trend arrow during an Abbott FreeStyle Libre 3 Plus sensor session.

4.20 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 when connectivity is restored and readings begin to appear.

- During Dexcom G6 or G7 sensor sessions, the pump backfills missing data points up to 6 hours in the past.
- During Abbott FreeStyle Libre 3 Plus sensor sessions, the pump backfills missing data points up to 15 days in the past.

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 9 Getting to Know Control-IQ+ Technology.

4.21 Calibration Overview (Dexcom Only)

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.

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.

4.22 Startup Calibration (Dexcom Only)

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**, then tap the **Down Arrow**, and then tap **My CGM**.

5. Tap **Calibrate CGM**.

6. 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.

7. Tap ✓.

8. 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.

9. Tap **Calibrate CGM** to enter your second BG value.

✓ The on-screen keypad will appear.

10. 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).

11. Take a BG measurement using your BG meter. Carefully apply the blood sample to the test strip following your BG meter manufacturer's instructions.

12. Follow steps 6 –8 to enter your second BG value.

4.23 Calibration BG Value and Correction Bolus (Dexcom Only)

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 8.2 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.

4.24 Reasons You May Need to Calibrate (Dexcom Only)

You may need to calibrate your Dexcom CGM sensor 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.

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CHAPTER 5

Insulin Delivery Settings

5.1 Overview

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), range: 0 and 0.1 to 15 units/hour
- Correction Factor (amount 1 unit of insulin lowers BG), range: 1 unit:1 mg/dL to 1 unit:600 mg/dL
- Carb Ratio (grams of carbohydrate covered by 1 unit of insulin), 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
- Target BG (your ideal BG level, measured in mg/dL), 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)

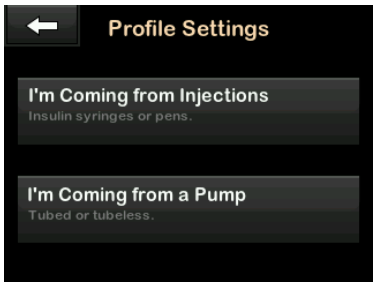
The default settings and ranges for Bolus Settings are as follows:

- Insulin Duration (default: 5 hours; range: 2 to 8 hours)
- Carbs (default: dependent on pump history)

5.2 Creating Your First Profile

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

✓ The *Profile Settings* screen appears.

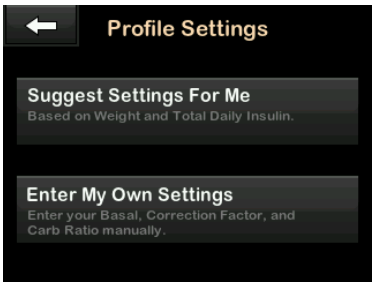


- If you tap **I'm Coming from Injections**, you can either create your own profile by tapping **Enter My Own Settings** or use the pump's default settings by tapping **Suggest Settings for Me**.
- If you tap **I'm Coming from a Pump**, you will create and enter your first profile as described in Section 5.3 Creating a New Profile.

Default Settings

To use the default pump settings 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.
10. Tap ✓.
11. Tap ✓ to save weight and TDI settings.

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

Enter All Settings

To enter pump settings provided by your healthcare 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 5.4 Programming a New Personal Profile.

5.3 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.

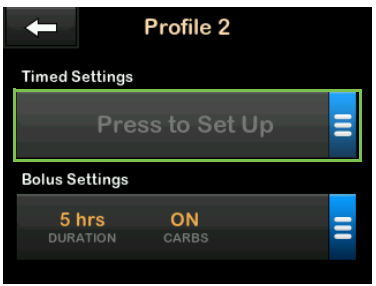
Consult your healthcare provider to accurately set Personal Profile settings.

To create a new personal profile:

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

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

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



5.4 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.

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:

- 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.Timed Settings

Timed Settings

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

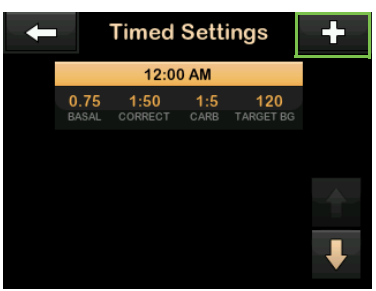
8. Using the on-screen keypad, enter your Target BG and tap ✓.

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.

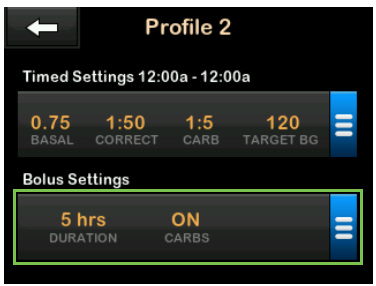
4. Tap ✓.

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

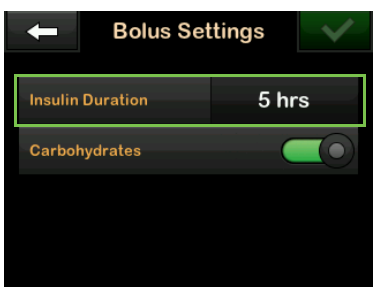
To find time segments in the list that are not displayed on the first screen, tap the **Down Arrow**.

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.

5.5 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.

- To add a time segment, tap .
- To delete a time segment, tap the X to the left of the time segment, then tap .
- For more profile setting instructions, such as duplicating a profile or renaming a profile, see Chapter 6 Insulin Delivery Settings in the Tandem t:slim X2 User Guide.

5.6 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.

5.7 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.

5.8 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  .

5.9 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.

5.10 Basal Limit

- The Basal Limit allows you to set an upper limit for your basal rate which you will set up later in your Personal Profiles.

- Your healthcare provider should help you set a proper basal limit, between 0.2 to 15 units/hour.

1. From the *Home* screen, tap **OPTIONS**, then tap **My Pump**, then tap **Personal Profiles**, and then tap **Pump Settings**.

2. Tap **Basal Limit**.

3. Using the on-screen keypad, enter a Basal Limit amount that is between 0.2–15 units.

4. Tap ✓.

5. Review the Basal Limit value and tap ✓.

6. Confirm settings and tap ✓.

- The default Basal Limit is 3 units per hour.

- Setting a Basal Limit does not affect the functionality of Control-IQ+ technology. Basal Limit may be exceeded if Control-IQ+ technology will predict you need more insulin to stay in range.

5.11 Starting a Temporary Basal Rate

A Temp Rate is used to change the current Basal Rate by percentage for a period of time.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.

Your pump will notify you if you program a Temp rate that is too low or too high.

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.

- A T in an orange box means a Temp Rate is active.
- A T in a red box means a Temp Rate of 0 units/hour is active.

5.12 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.

5.13 Stopping or Resuming Insulin Delivery

To Stop all Insulin Deliveries:

You can stop all insulin delivery at any time. This stops all active boluses and temp rates.

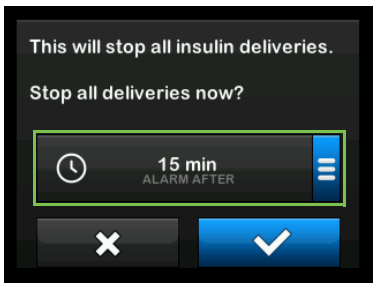
1. From the *Home* screen, tap OPTIONS.
2. Tap STOP INSULIN.

✓ 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.

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.

To Resume 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.

CHAPTER 6

Loading Cartridge

6.1 Cartridge Instructions for Use

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

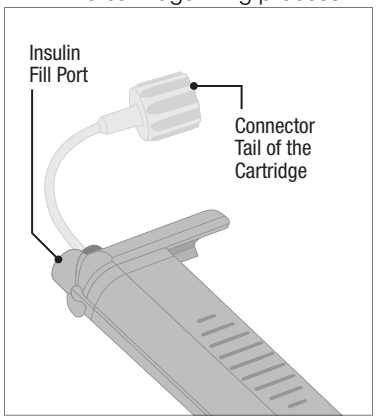
6.2 Filling and Loading a t:slim X2 Cartridge

To prepare, 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 1.2 Compatible Insulins
- alcohol prep swab
- 1 new infusion set
- infusion set instructions for use

Before you begin:

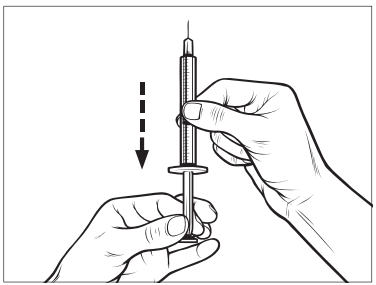
- Wash your hands with soap and water.
- Clean the top of the insulin vial with an alcohol prep swab.
- Inspect all packaging and materials for signs of damage before using. Discard any damaged materials. The illustration below identifies the connector and insulin fill port used in the cartridge filling process.



Drawing Insulin from Vial into Syringe

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

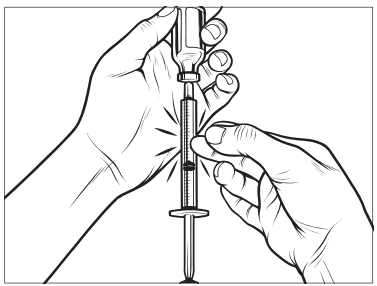
2. Draw air into syringe up to the amount of insulin desired. You must add at least an additional 45 units of insulin to your desired insulin amount to account for the insulin used while filling your infusion set tubing. We recommend using at least 120 units of insulin total.



3. With insulin vial upright, insert needle into vial. Inject air from syringe into vial. Maintain pressure on syringe plunger. 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. Slowly pull back the plunger to the desired amount of insulin.

4. 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.

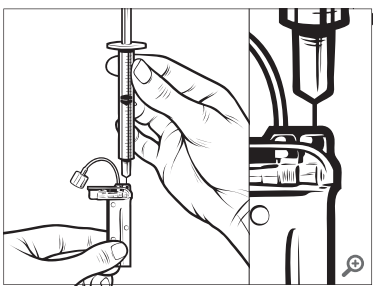


5. Check the syringe for air bubbles and do one of the following:

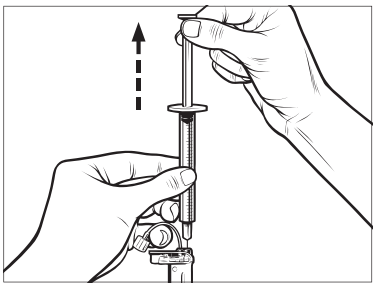
   - If there are air bubbles present, repeat step 4.
   - If no air bubbles are present, remove the filling needle from the vial.

Filling the Cartridge

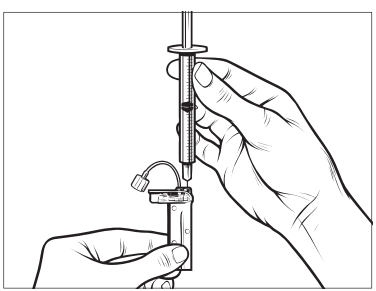
1. Remove the cartridge and hold upright. Gently insert the needle into the white insulin fill port on the cartridge. The needle is not intended to go all the way in, so do not force it.



2. 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.

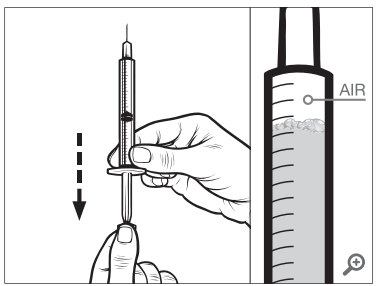


3. Make sure the needle is still in the fill port and release the plunger. Pressure will pull the plunger to its neutral position but it will NOT push any air back inside the cartridge.

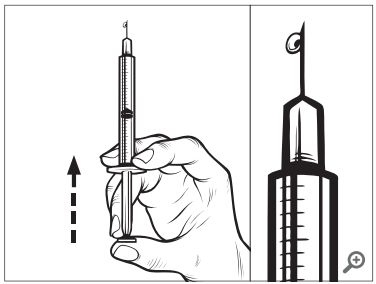


4. Withdraw the needle from the fill port.

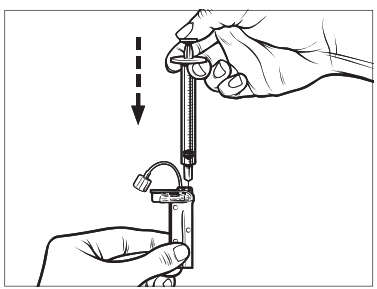
5. Turn the syringe upright and pull down on the plunger. Flick the barrel to make sure that any air bubbles rise to the top.



6. 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.



7. 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.



8. 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.

9. Always dispose of used needles, syringes, cartridges, and infusion sets following local regulations.

6.3 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.

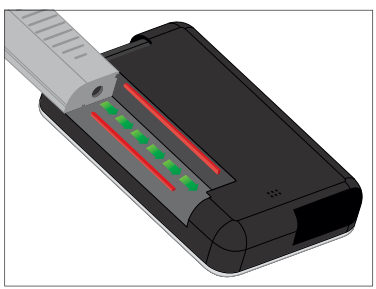
3. Tap **Change Cartridge**.

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

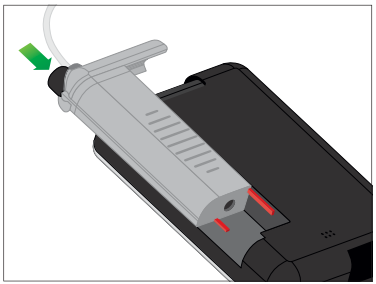
✓ *PREPARING FOR CARTRIDGE* screen is displayed.

5. 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.

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



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



8. Tap ✓ to continue.

✓ *DETECTING CARTRIDGE* screen is displayed.

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

9. Tap OK to fill the tubing.

6.4 Filling Tubing

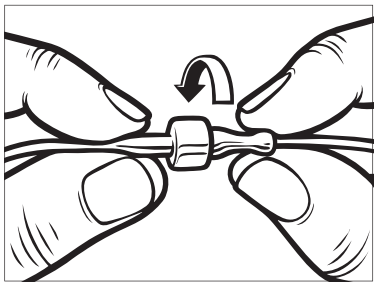
To fill the tubing:

1. Confirm the infusion set is not connected to your body. **Never** fill tubing while the infusion set is connected to your body.

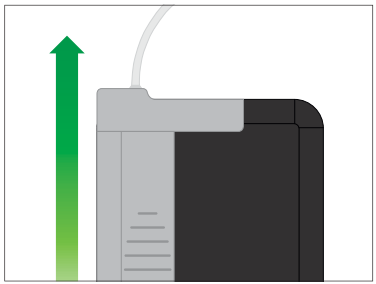
2. Ensure that the new infusion set package is not damaged, and remove the sterile tubing from the package. If the package is damaged or opened, discard properly and use another tubing set. Be careful to keep the tubing connector away from unclean areas.

3. Attach the infusion set tubing to the tubing connector on the cartridge

tubing. Twist clockwise until finger tight.



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 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.

6.5 Filling Cannula

To Fill the Cannula:

1. Connect the filled tubing to your infusion site and tap **Fill Cannula**.
2. Tap ✓.
3. Tap **Edit Fill Amount**.

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

4. Select amount needed for cannula fill 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.
5. Tap **START**.

✓ The *STARTING FILL* screen is displayed.

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

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.

6.6 Setting Site Reminder

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 is 3 days.
3. Tap **Remind Me At** and use 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 ✓.

✓ *RESUMING INSULIN* screen is temporarily displayed.

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CHAPTER 7

Infusion Site Care

7.1 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

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

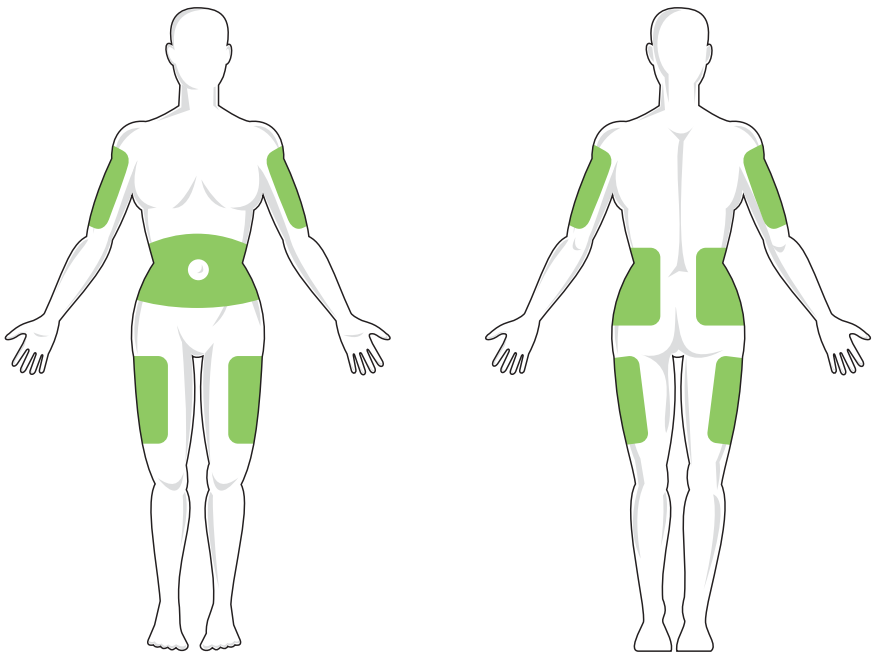
Keep it Clean

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

7.2 Infusion Site Follow-Up

- Two hours after a site change, check your glucose.
- Do not change sites before bedtime.
- Always disconnect from infusion site, not tubing connector.
- If you have any concerns about your infusion site, change it out.

Areas of Body for Infusion Set Insertion



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CHAPTER 8

Delivering Boluses

8.1 Manual Bolus Overview

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

It can be requested from your pump or Tandem t:slim mobile app. For more information about the mobile bolus feature set, please see your t:slim X2 User Guide.

A bolus can be a minimum of 0.05 units to a maximum of 25 units.

If Carbs are turned on in your active personal profile, you will enter grams of carbohydrate. The bolus will be calculated using your carb ratio.

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

8.2 Correction Bolus Calculation

Once the pump knows your glucose value, it will determine whether to recommend that a correction bolus 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:

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.

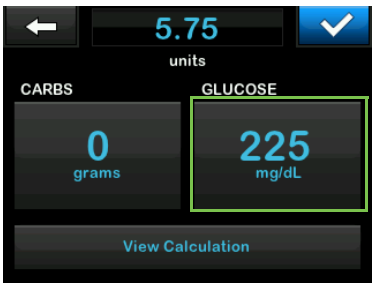
Your glucose value is automatically entered into the GLUCOSE field on the *Bolus* screen when each of the following conditions are true:

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

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

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

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



Correction Bolus Confirmation Screens

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

- If either your CGM value or trend arrow is 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.

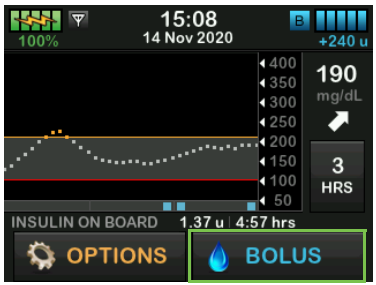
8.3 Delivering a Bolus

Your pump can deliver a food bolus to cover carbohydrate intake or a correction bolus to bring you BG back to target.

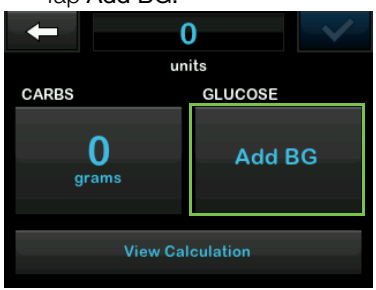
For a correction bolus:

- 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:



- Tap Add BG:

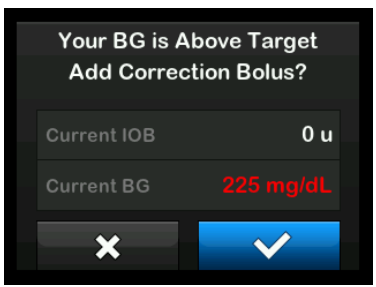


- Enter your BG value, and tap ✓ to save the value to your pump. Depending on whether your BG value is above or below target, follow either of the steps below:

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.

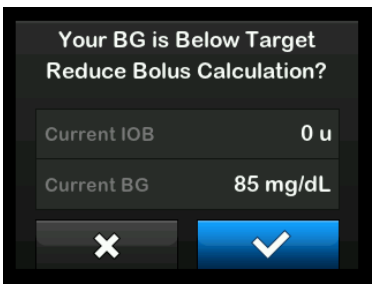
Calculate and add a correction bolus from the pump as follows:



- 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.

8.4 Food Bolus

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

✓ The *BOLUS INITIATED* screen is temporarily displayed.

Food Bolus Using Grams:

1. From the *Home* screen, tap **BOLUS**.
2. Tap **0 grams**.
3. Using the on-screen keypad enter grams of carb and tap ✓.
   - To add multiple carb values, enter the first value, then tap +, enter the second value, then 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.

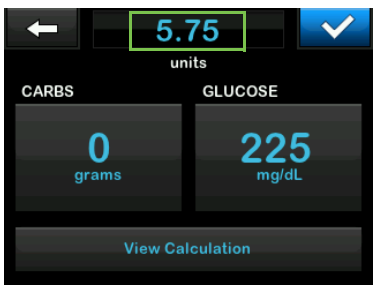
   You can always tap **View Calculation** to display the *Delivery Calculation* screen.
6. Confirm Request.
   - Tap ✓ if entered data is correct.
   - Tap ✗ to go back to make changes or view calculations.
7. Tap ✓.

✓ The *BOLUS INITIATED* screen is temporarily displayed.

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

8.5 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.



8.6 Extended Bolus

The Extended Bolus feature allows you to deliver part of the bolus now and part of the bolus slowly over a period of up to 8 hours, or to deliver the whole bolus over an extended period of time.

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.
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.

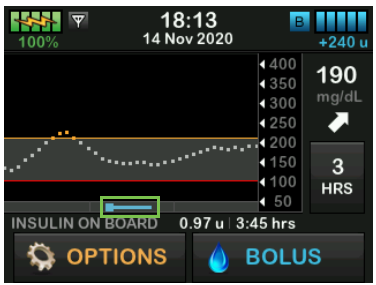
13. Confirm Request.

    - 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.

8.7 Max Bolus

To limit the number of units you can deliver in a single bolus:

1. From the *Home* screen, tap **OPTIONS**, then tap **My Pump**, then tap **Personal Profiles**, and then tap **Pump Settings**.
2. Tap **Max Bolus**.

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

8.8 Quick Bolus

- Quick Bolus can be set to correspond to either units of insulin or grams of carbohydrate.
- 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.

- When Quick Bolus is turned on, you deliver a bolus by pressing the **Screen On/Quick Bolus** button to deliver your bolus. There is no glucose entry or extended option for Quick Bolus.

1. From the *Home* screen, tap **OPTIONS**, then tap **My Pump**, then tap **Personal Profiles**, then tap **Pump Settings**, then tap **Quick Bolus**, and then tap **Increment Type**.
2. Tap **units of insulin** or **grams of carbohydrate** to select. Tap  .
3. Tap **Increment Amount**.
4. Select the preferred increment amount.
5. Review entered values and tap  .
6. Confirm Settings.
   - Tap  if entered data is correct.
   - Tap  to go back to make changes.

Deliver a Quick Bolus

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.

Tap  on the *Quick Bolus* screen to cancel the bolus.

When Using Quick Bolus Feature:

- If 10 seconds pass with no input, the bolus is canceled.
- You cannot exceed the Max Bolus setting defined in your Pump Settings.
- You cannot exceed 20 consecutive button presses.
- If you hear a different tone, or your pump stops vibrating during programming, check the screen to confirm bolus amount.

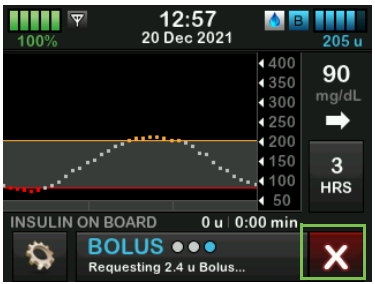
8.9 Canceling or Stopping a Bolus Using the Pump

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.

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 OK.

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CHAPTER 9

Getting to Know Control-IQ+ Technology

9.1 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.

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 5 Insulin Delivery Settings for more information about Personal Profiles.

9.2 Explanation of Control-IQ+ Technology Icons

If you have a CGM sensor 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 units/hour is active.
	Control-IQ+ technology is delivering an automatic correction bolus.
	The Exercise Activity is enabled.

9.3 Required Settings

Required Personal Profile Settings

- Basal rate
- Correction Factor
- Carb Ratio
- Target BG
- Carbohydrates turned on in Bolus Settings

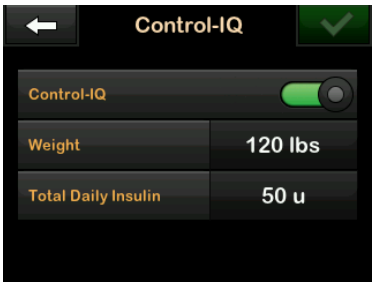
Required Control-IQ+ Technology Pump Settings

- Weight
- Total Daily Insulin

9.4 Set Weight

1. From the *Home* screen, tap **OPTIONS**, then tap **My Pump**, and then tap **Control-IQ**.

✓ The *Control-IQ* screen is displayed:



2. Tap **Weight**.
3. Tap **Pounds** or **Kilograms** to set the unit of weight.
4. Tap ✓.
5. 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).
6. Tap ✓.
7. If you are done with the Control-IQ+ technology settings, tap ✓.

✓ The *SETTING SAVED* screen is temporarily displayed.

9.5 Set Total Daily Insulin

Include both basal and bolus insulin delivered in a 24-hour period. Your healthcare provider can assist you with estimating this value, if needed.

The Total Daily Insulin value may be updated when you visit your healthcare provider.

Enter your Total Daily Insulin Value

1. From the *Home* screen, tap **OPTIONS**, then tap **My Pump**, and then tap **Control-IQ**.
2. Tap **Total Daily Insulin**.
3. 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.
4. Tap ✓.
5. If you are done with the Control-IQ+ technology settings, tap ✓.

✓ The *SETTING SAVED* screen is temporarily displayed.

6. When you are done setting up Control-IQ+ technology, tap the **Tandem logo** to return to the *CGM Home* screen.

9.6 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.

9.7 Control-IQ+ Technology and Activity

When Control-IQ+ technology is turned on, you can choose to activate Sleep or Exercise Activity to help with automated insulin dosing. Sleep and Exercise Activities cannot be activated at the same time. The table below illustrates the target glucose values used by Control-IQ+ technology, Sleep Activity, and Exercise Activity:

				zzz
Delivers	AutoBolus	180	180	×
Increases	Basal Insulin	160	160	120
Maintains	Profile Settings	112.5	140	112.5
Decreases	Basal Insulin	70	80	70
Stops	Basal Insulin			

9.8 Schedule Sleep

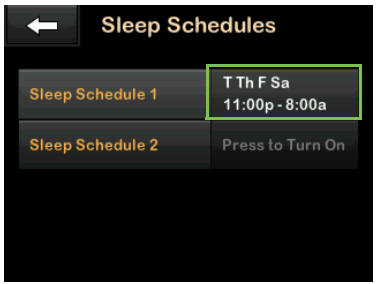
Sleep can be scheduled to turn on and off automatically or manually.

You are able to configure two different sleep schedules to account for changes in lifestyle, such as during the week and during the weekend.

1. From the *Home* screen, tap **OPTIONS**, tap **Activity**, then tap **Sleep**, and then tap **Sleep Schedules**.

2. Select which Sleep Schedule to configure.

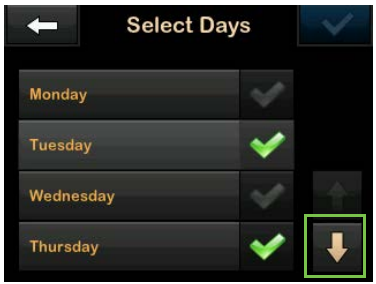
   - If no Sleep Schedules are configured, tap **Sleep Schedule 1**.
   - If you are editing an existing schedule, tap the schedule summary that displays to the right of the sleep schedule you want to edit.



3. 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.

4. 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. A green check means that day is active. A grey check means that day is inactive.

   Tap the **Down Arrow** to see more days of the week.



5. When you are finished selecting the days, tap ✓. If no days are selected when you tap ✓, the schedule is incomplete and the remaining instructions do not apply.

6. Tap **Start Time**.

7. Tap **Time**. The numbered keypad is displayed.

8. 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.

9. Tap . This returns you to the *Start Time* screen.

10. Tap **AM** or **PM** to set the Time of Day, if applicable.

11. Tap . This returns you to the *Sleep Schedule 1* screen.

12. Tap **End Time**.

13. Tap **Time**. The numbered keypad is displayed.

14. Enter the time you would like the Sleep Schedule to end and tap . This returns you to the *End Time* screen.

15. Tap **AM** or **PM** to set the Time of Day, if applicable.

16. Tap . The *Sleep Schedule 1* screen is displayed.

17. Tap to save the schedule.

✓ The *SETTING SAVED* screen is temporarily displayed, followed by the *Sleep Schedules* screen.

18. When you are done configuring sleep, tap to return to the *Activity* screen or tap the **Tandem logo** to return to the *Home* screen.

Enable a Sleep Schedule

1. From the *Home* screen, tap **OPTIONS**, then tap **Activity**, then tap **Sleep**, and then tap **Sleep Schedules**.

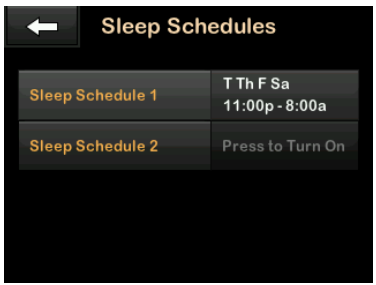
2. Tap the schedule summary next to the name of the Sleep Schedule you want to enable. (If no sleep schedules are configured, see Section 9.8 Schedule Sleep.)

3. Tap .

Disable a Sleep Schedule

1. From the *Home* screen, tap **OPTIONS**, then tap **Activity**, then tap **Sleep**, and then tap **Sleep Schedules**.

   Tap the schedule summary next to the Sleep Schedule you want to disable.



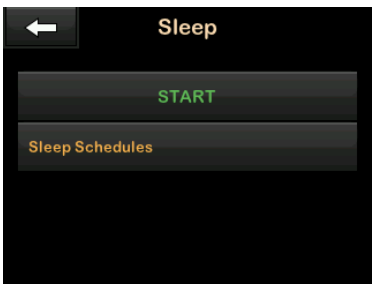
2. Tap the toggle next to the schedule name.

3. Tap .

9.9 Manually Start or Stop Sleep

Manually Start Sleep

1. From the *Home* screen, tap **OPTIONS**, then tap **Activity**, then tap **Sleep**, and then tap **START**.

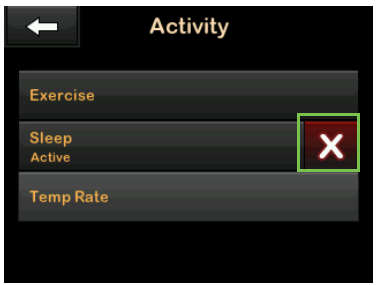


✓ A *SLEEP STARTED* screen is temporarily displayed. The Sleep icon is displayed on the *Home* screen.

Sleep will automatically be disabled if Exercise is enabled.

Manually Stop Sleep

1. From the *Home* screen, tap **OPTIONS**.
2. Tap **Activity**.
3. Tap ✕.



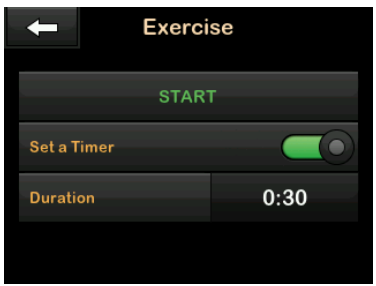
✓ A *SLEEP STOPPED* message is temporarily displayed. The Sleep icon is removed from the *Home* screen.

9.10 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.

Enable Exercise with a Timer

1. From the *Home* screen, tap **OPTIONS**, then tap **Activity**, then tap **Exercise**, and then tap **Set a Timer**.
2. 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 3.



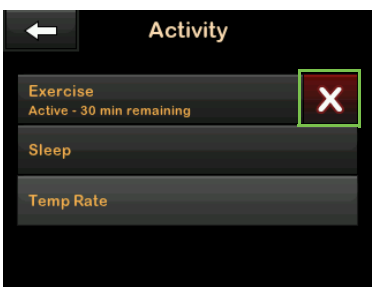
3. Tap **Duration**. The number keypad is displayed. You may enter an Exercise duration between 30 minutes and 8 hours. The pump will save this new duration for the next time you enable Exercise.
4. Tap ✓.
5. Tap **START**.

✓ 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

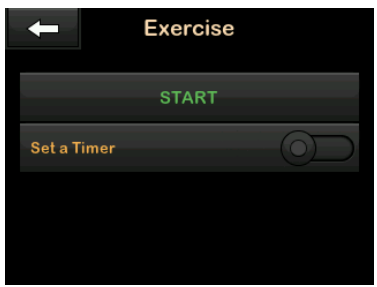
1. From the *Home* screen, tap **OPTIONS** and then tap **Activity**.
2. Tap  .



✓ 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**, then tap **Activity**, and then tap **Exercise**.
2. Tap **Start**.

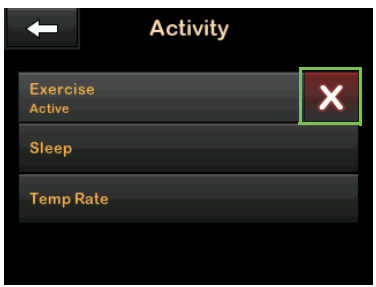


✓ An *EXERCISE STARTED* message is temporarily displayed. The Exercise icon is displayed on the *Home* screen.

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** and then tap **Activity**.
2. Tap  .



An *EXERCISE STOPPED* message is temporarily displayed. The Exercise icon is removed from the *Home* screen.

CHAPTER 10

Reminders, Alerts, and Alarms

10.1 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**, then tap **My Pump**, then tap **Alerts & Reminders**, and then tap **Pump Reminders**.
2. Tap **Missed Meal Bolus**.
3. 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.

10.2 Low Insulin Alert

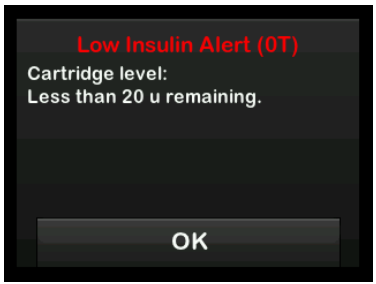
Your pump tracks how much insulin remains in your cartridge and alerts you when it is low. The default for this alert is preset to 20 units. You can set this alert anywhere between 10 and 40 units.

1. From the *Home* screen, tap **OPTIONS**, then tap **My Pump**, then tap **Alerts & Reminders**, and then tap **Pump Alerts**.
2. Tap **Low Insulin**.
3. Using the on-screen keypad, enter the number of units that you want the Low Insulin Alert value to be set to, and tap  .
4. Tap  when all changes are complete.

To Respond to the Low Insulin Alert

To clear the alert, tap  . Change your insulin cartridge following the

instructions in Section 6.2 Filling and Loading a t:slim X2 Cartridge.



10.3 Auto-Off Alarm

Your pump can stop insulin delivery and alert 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 performing any of the following actions:

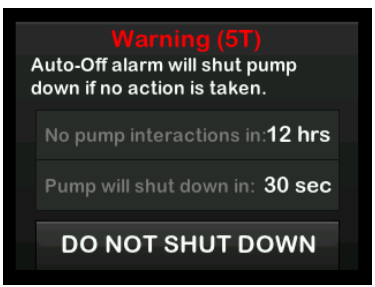
- Delivering a Quick Bolus.
- Pressing the **Screen On/Quick Bolus** button and then tapping **1-2-3** to unlock the pump.
- Performing certain actions within the Tandem t:slim mobile app.

Enable and configure the Auto-Off Alarm as follows:

1. From the *Home* screen, tap **OPTIONS**, then tap **My Pump**, then tap **Alerts & Reminders**, and then tap **Pump Alerts**.
2. Tap **Auto-Off**. A confirmation screen will appear.
   - Tap ✓ to continue.
   - Tap ✕ to go back.
3. Verify Auto-Off is set to on, then tap **Time**.
4. 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 ✓.
5. Tap ✓, then tap ✓ when all changes are complete.
6. Tap the **Tandem logo** to return to the *Home* screen.

To Respond to Auto-Off Warning

Tap **DO NOT SHUT DOWN**.

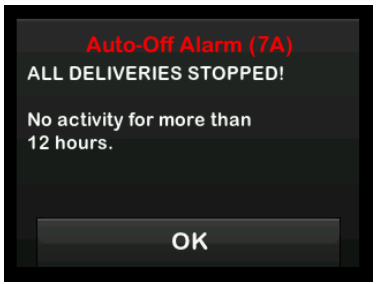


If you do not clear the warning within the 30-second countdown period, the Auto-Off Alarm occurs, accompanied by an audible alarm. This alarm notifies

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 5.13 Stopping or Resuming Insulin Delivery.

10.4 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.

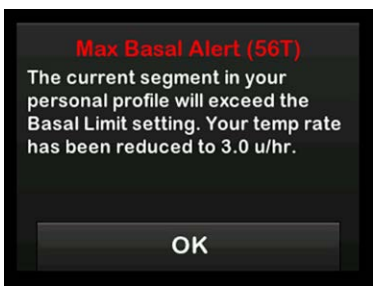
Once the Basal Limit in the Pump Settings has been set up (see Section 5.10 Basal Limit), you will receive an alert if the following scenarios occur.

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 Profile:



10.5 Alerts and Alarms Overview

Your pump will notify you about alerts, alarms, and errors related to the pump, your CGM, and Control-IQ+ technology.

For further information on these alerts, including screen images, see the following chapters in the full User Guide:

- Chapter 13 Pump Alerts
- Chapter 14 Pump Alarms
- Chapter 15 Pump Malfunction
- Chapter 26 CGM Alerts and Errors
- Chapter 32 Control-IQ+ Technology Alerts.

- Your pump lets you know important information about the pump with Reminders, Alerts, and Alarms.
- Reminders are displayed to notify you about an option you've set.

- Alerts display automatically to notify you about safety conditions that you need to know.
- Alarms display automatically to let you know of an actual or potential stopping of insulin delivery. Pay special attention to Alarms.
- Alerts notify you with 1 or 2 sequences of 3 notes or 1 or 2 vibrations. They repeat until acknowledged.
- Alarms notify you with 3 sequences of 3 notes or 3 vibrations. If not acknowledged, alarms escalate to highest volume and vibration. Alarms repeat regularly until the condition that caused the alarm is corrected.
- All alarms and alerts will either beep or vibrate, based on settings you select in Sound.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.

Alerts Related to the Pump

Alert	Explanation
Low Insulin Alert	5 units or less of insulin remain in the cartridge. Pump will notify with 1 sequence of 3 notes or 1 vibration and continue to notify every 5 minutes until acknowledged. To respond, tap OK. Change your cartridge as soon as possible to avoid the Empty Cartridge Alarm and running out of insulin.
Low Power Alert 1	Less than 25% of battery power remains. Pump will notify with 1 sequence of 3 notes or 1 vibration and continue to notify every 5 minutes until acknowledged. To respond, tap OK. Charge your pump as soon as possible to avoid the second Low Power Alert.
Low Power Alert 2	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. Pump will notify with 1 sequence of 3 notes or 1 vibration and continue to notify every 5 minutes until acknowledged. To respond, tap OK. Charge your pump immediately to avoid the Low Power Alarm and pump power off.
Incomplete Bolus Alert	You started a bolus request but did not complete the request within 90 seconds. Pump will notify with 2 sequences of 3 notes or 2 vibrations and continue to notify every 5 minutes until acknowledged. To respond, tap OK. The *Bolus* screen will appear. Continue with your bolus request.
Incomplete Temp Rate Alert	You started to set up a temp rate but did not complete the request within 90 seconds. Pump will notify with 2 sequences of 3 notes or 2 vibrations and continue to notify every 5 minutes until acknowledged. To respond, tap OK to continue setting up Temp Rate, or tap ← to stop setting up Temp Rate.
Incomplete Load Sequence Alerts (for Cartridge Change, Fill Tubing, and Fill Cannula)	You selected **Change Cartridge**, **Fill Tubing**, or **Fill Cannula** from the *Load* menu but did not complete the process within 3 minutes. Pump will notify with 2 sequences of 3 notes or 2 vibrations and continue to notify every 5 minutes until acknowledged. To respond, tap OK and complete the load sequence.
Incomplete Setting Alert	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. Pump will notify with 2 sequences of 3 notes or 2 vibrations and continue to notify every 5 minutes until acknowledged. To respond, tap OK and complete programming.

Alert	Explanation
Basal Rate Required Alert	You did not enter a Basal Rate in a time segment in Personal Profiles. A Basal Rate must be entered in each time segment. Pump will notify with display only. To respond, tap OK and enter a Basal Rate in the time segment.
Max Hourly Bolus Alert	In the previous 60 minutes, you requested total bolus delivery that is more than 1.5 times your Max Bolus setting. Pump will notify with display only. To respond, tap ✕ to return to the *Bolus* screen and adjust the bolus delivery amount and then tap ✓ to confirm the bolus.
Max Bolus Alerts 1 & 2	You requested a bolus larger than the Max Bolus setting in your active Personal Profile. Pump will notify with display only. To respond, tap ✕ to cancel or adjust the bolus, or tap ✓ to deliver the bolus.
Max Basal Alert	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. Pump will notify with 2 sequences of 3 notes or 2 vibrations. To 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.
Min Basal Alert 1	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. Pump will notify with display only. To respond, tap ✕ to return to the previous screen to adjust the amount and then tap ✓ to dismiss the alert and continue with the request.
Min Basal Alert 2	An active temp rate dropped below half of your lowest basal setting defined in your Personal Profile. Pump will notify with 1 sequence of 3 notes or 1 vibration and continue to notify every 5 minutes until acknowledged. To respond, tap OK and review your current temp rate in the *Activity* menu.
Connection Error Alert	You connected your pump to a computer with the USB cable to charge it, upload data to the Tandem Source platform, and a connection could not be made. Pump will notify with 2 sequences of 3 notes or 2 vibrations and continue to notify every 5 minutes until acknowledged. To respond, tap OK. Disconnect and reconnect the USB cable to try again.
Pairing Code Timeout Alert	You attempted to connect a smartphone to the pump, but the pairing process took too long (more than 5 minutes) and was unsuccessful. Pump will notify with display only. To respond, tap OK and try to pair the smartphone again.

Alert	Explanation
Power Source Alert	You connected your pump to a power source that does not have enough power to charge the pump. Pump will notify with 1 sequence of 3 notes or 1 vibration and continue to notify every 5 minutes until acknowledged. To respond, tap OK. Connect the pump to a different power source to charge.
Data Error Alert	Your pump encountered a condition that could potentially result in a loss of data. Pump will notify with 2 sequences of 3 notes or 2 vibrations and continue to notify every 5 minutes until acknowledged. To respond, tap OK and check your Personal Profiles and pump settings to verify that they are accurate.

Alarms Related to the Pump

Alarm	Explanation
Resume Pump Alarm	You selected **STOP INSULIN** in the *Options* menu and insulin delivery has been stopped for more than 15 minutes. Pump will notify with 3 sequences of 3 notes or 3 vibrations and will continue to notify as follows: 1. If not acknowledged by tapping OK, the pump will re-notify you every 3 minutes at highest volume and vibrate, or 2. If acknowledged by tapping OK, the pump will re-notify you in 15 minutes. To resume insulin, from the *Options* menu, tap **RESUME INSULIN** and tap ✓ to confirm.
Low Power Alarm	Your pump detected a power level of 1% or less remaining and all deliveries have stopped. Pump will notify with 3 sequences of 3 notes or 3 vibrations and will continue to notify every 3 minutes until no power remains and the pump shuts down. To respond, tap OK and charge your pump immediately.
Empty Cartridge Alarm	Your pump detected that the cartridge is empty and all deliveries have stopped. Pump will notify with 3 sequences of 3 notes or 3 vibrations and will continue to notify every 3 minutes until you change the cartridge. To respond, tap OK. Change your cartridge immediately by tapping **OPTIONS** from the *Home* screen and then follow the load sequence.
Cartridge Error Alarm	Your pump detected that the cartridge could not be used and all deliveries have stopped. Pump will notify with 3 sequences of 3 notes or 3 vibrations and will continue to notify every 3 minutes until you change the cartridge. To respond, tap OK. Change your cartridge immediately by tapping **OPTIONS** from the *Home* screen and then follow the load sequence.
Cartridge Removal Alarm	Your pump detected that the cartridge has been removed and all deliveries have stopped. Pump will notify with 3 sequences of 3 notes or 3 vibrations and will continue to notify every 3 minutes until you reconnect the current cartridge or change the cartridge. To respond, tap **CONNECT** to reattach the current cartridge. Tap **INSTALL** to load a new cartridge.
Temperature Alarm	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. Pump will notify with 3 sequences of 3 notes or 3 vibrations and will continue to notify every 3 minutes until a temperature in the operating range is detected. To respond, tap OK. Remove the pump from the extreme temperature and then resume insulin delivery.

Alarm	Explanation
Occlusion Alarm 1	Your pump detected that insulin delivery is blocked and all deliveries have stopped. Pump will notify with 3 sequences of 3 notes or 3 vibrations and will continue to notify every 3 minutes until you resume insulin delivery. To 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.
Occlusion Alarm 2	Your pump detected a second occlusion alarm shortly after the first occlusion alarm and all deliveries have stopped. Pump will notify with 3 sequences of 3 notes or 3 vibrations and will continue to notify every 3 minutes until you resume insulin delivery. To 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.
Screen On/Quick Bolus Button Alarm	The **Screen On/Quick Bolus** button (on the top of your pump) is stuck or not functioning properly and all deliveries have stopped. Pump will notify with 3 sequences of 3 notes or 3 vibrations and will continue to notify every 3 minutes until the condition is corrected. To respond, tap OK and contact Customer Technical Support.
Altitude Alarm	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. Pump will notify with 3 sequences of 3 notes or 3 vibrations and continue to notify every 3 minutes until the condition is corrected. To respond, tap OK. Remove the cartridge from the pump (this will allow the cartridge to fully vent) and then reconnect the cartridge.
Reset Alarm	Your pump experienced a reset and all deliveries have been stopped. Pump will notify with 3 sequences of 3 notes or 3 vibrations and continue to notify every 3 minutes until you tap OK. To respond, tap OK. Contact Customer Technical Support.

Pump Malfunction

Alert	Explanation
Malfunction	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. Pump will notify with 3 sequences of 3 notes at highest volume and 3 vibrations, and will continue to notify every 3 minutes until you acknowledge the malfunction by tapping **SILENCE ALARM**. To respond, first write down the Malfunction Code number that appears on the screen, and then tap **SILENCE ALARM**. The *MALFUNCTION* screen will remain on the pump even though the alarm is silenced. Last, contact Customer Technical Support and provide the Malfunction Code number that you wrote down.

Alerts Related to Your CGM

Alert	Explanation
CGM High Alert	Your most recent sensor glucose reading is at or above the High Alert Setting. Pump will notify with 2 vibrations followed by 2 vibrations or beeps every 5 minutes until you press OK or your glucose value drops below the Alert level.
CGM Low Alert	Your most recent sensor glucose reading is at or below the Low Alert setting. Pump will notify with 3 vibrations then 3 vibrations or 3 beeps every 5 minutes until you press OK or your sensor glucose value goes above the Alert Level.
CGM Fixed Low Alert	Your most recent sensor glucose reading is at or below 55 mg/dL. Pump will notify with 4 vibrations then 4 vibrations or 4 beeps every 5 minutes until you press OK or your glucose goes above 55 mg/dL. Pump will continue to notify every 30 minutes until your glucose goes above 55 mg/dL.
CGM Rise Alert	Your sensor glucose levels are rising at 2 mg/dL per minute or faster (at least 30 mg/dL in 15 minutes). Pump will notify with 2 vibrations every 5 minutes until you press OK.
CGM Fall Alert	Your sensor glucose levels are falling at 2 mg/dL per minute or faster (at least 30 mg/dL in 15 minutes). Pump will notify with 3 vibrations then 3 beeps or 3 vibrations every 5 minutes until you press OK.
Unknown Sensor Glucose Reading	The sensor is sending sensor glucose readings that the pump does not understand. You will not receive sensor glucose readings. Pump will notify on screen only with 3 dashes in place of CGM reading. 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.
Out of Range Alert	The CGM and pump are not communicating. The pump will not receive sensor glucose readings, and Control-IQ+ technology is not able to predict sensor glucose levels or adjust insulin delivery. Pump will notify with 1 vibration then 1 beep or 1 vibration every 5 minutes until the pump and CGM are back in range. To respond, tap OK and remove distance or obstruction between pump and CGM.
Failed Sensor Alert	The sensor is not working properly and the CGM sensor session has stopped. Pump will notify with 1 vibration then 1 beep or 1 vibration every 5 minutes. Tap **MORE INFO** and replace your CGM.

Alert	Explanation
CGM Unavailable	Your CGM sensor session has been stopped for more than 20 minutes and the CGM can no longer be used. Pump will notify with 2 vibrations, then 2 beeps or 2 vibrations every 5 minutes until you tap OK.
CGM System Error	Your CGM System is not working properly; the CGM sensor session has stopped and the CGM can no longer be used. Pump will notify with 1 vibration then 1 vibration or 1 beep every 5 minutes. To respond, write down the malfunction number on the pump display, tap **MORE INFO**, and call CTS.
Incomplete Calibration (Dexcom Only)	If you start to enter a calibration value using the keypad and do not complete the entry within 90 seconds, and Incomplete Calibration screen appears. Pump will notify with 2 beeps or 2 vibrations every 5 minutes until confirmed. To respond, tap OK and complete your calibration by entering the value using the on-screen keypad.
Calibration Timeout (Dexcom Only)	If you start to enter a calibration value using the keypad and do not complete the entry within 5 minutes, a Calibration Timeout screen appears. Pump will notify with 2 beeps or 2 vibrations every 5 minutes until confirmed. To 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.
Calibration Error Alert (Dexcom Only)	The CGM cannot calibrate using the last BG meter value you entered. Pump will notify with 1 vibration, then vibrate/beep every 5 minutes until confirmed. To 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.
CGM Rapid Rise Alert (Dexcom Only)	Your sensor glucose levels are rising at 3 mg/dL per minute or faster (at least 45 mg/dL in 15 minutes). Pump will notify with 2 vibrations, then 2 vibrations or 2 beeps every 5 minutes until confirmed. To confirm, tap OK.
CGM Rapid Fall Alert (Dexcom Only)	Your sensor glucose levels are falling at 3 mg/dL per minute or faster (at least 45 mg/dL in 15 minutes). Pump will notify with 3 vibrations, then with 3 vibrations or 3 beeps every 5 minutes until confirmed. To confirm, tap OK.
Startup Calibration Alert (Dexcom G6 Only)	The startup period is complete. This will only appear if you did not enter a sensor code. Pump will notify with 1 vibrations, then 1 vibration or 1 beep every 5 minutes until acknowledged. Pump will re-notify every 15 minutes until you calibrate. To confirm, tap OK and enter 2 separate BG values to calibrate the CGM and start your CGM sensor session.

Alert	Explanation
Second Startup Calibration Alert (Dexcom G6 Only)	The CGM needs an additional BG value to complete startup calibration. This will only appear if you did not enter a sensor code. Pump will notify with 1 vibration, then 1 vibration or 2 beep every 5 minutes until confirmed. The pump will re-notify every 15 minutes until second calibration is entered. To respond, tap OK and enter a BG value to calibrate the CGM and start your CGM sensor session.
12 Hour Calibration Alert (Dexcom G6 Only)	The CGM needs a BG value to calibrate. This will only appear if you did not enter a sensor code. Pump will notify on screen only, with no beeps or vibrations. The pump will re-notify with the screen only every 15 minutes. To confirm, tap OK and enter a BG value to calibrate the CGM.
Calibration Required Alert (Dexcom G6 Only)	The CGM needs a BG value to calibrate. Sensor glucose readings will not be displayed at this time. Pump will notify with 1 vibration, then with 1 vibration or 1 beep every 5 minutes until confirmed. The pump will re-notify every 15 minutes. To confirm, tap OK and enter a BG value to calibrate the CGM.
Low Transmitter Battery Alert (Dexcom G6 Only)	The Dexcom G6 transmitter battery is low. Pump will notify with 1 vibration, then 1 vibration or 1 beep every 5 minutes until confirmed. The pump will re-notify by alarm when there are 21, 14, and 7 days of transmitter battery life remaining. To confirm, tap OK to confirm. Replace the transmitter as soon as possible.
Transmitter Error (Dexcom G6 Only)	The Dexcom G6 transmitter has failed and the CGM sensor session has stopped. Pump will notify with 1 vibration, then with 1 vibration or 1 beep every 5 minutes. To respond, tap **MORE INFO**. A screen notifies you that your CGM sensor session has stopped and that insulin delivery will continue as normal. Replace the transmitter immediately.
CGM Error (Dexcom G7 Only)	Your Dexcom G7 CGM sensor is not working properly; the CGM sensor session has stopped and the CGM can no longer be used. Pump will notify with 1 vibration, then 1 vibration or 1 beep every 5 minutes. Pump will re-notify every 5 minutes until acknowledged. To respond, Contact technical support first. To acknowledge the alert, tap **MORE INFO** and then OK.
Unable to Pair (Dexcom G7 Only)	Your Dexcom G7 CGM has attempted to pair too many times while in an area with too many Dexcom G7 sensors. Pump will notify with 1 vibration, then 1 vibration or 1 beep every 5 minutes. Pump will re-notify every 5 minutes until acknowledged. To respond, tap OK, and relocate to an area with fewer sensors to attempt pairing again.

Alert	Explanation
CGM Unavailable (Abbott FreeStyle Libre 3 Plus Sensor Only)	The sensor is sending sensor glucose readings that the pump does not understand.Pump will notify with 1 vibration, then 1 vibration or 1 beep every 5 minutes until acknowledged. Pump will re-notify every 60 minutes until the end of the first 12 hours of sensor wear. To respond, tap OK. The alert will indicate when your sensor glucose readings will resume.
Sensor Temperature (Abbott FreeStyle Libre 3 Plus Sensor Only)	The CGM sensor is outside of its operating temperature range. Pump will notify on-screen only with no vibration or beep. Pump will re-notify if the CGM sensor remains outside of its operating temperature range. To respond, move the CGM sensor to a temperature above 50°F (10°C) and below 113°F (45°C) and tap OK to confirm.

Alerts Related to Control-IQ+ Technology

Alert	Explanation
Control-IQ Low Alert	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. Pump will notify with 2 vibrations, then 2 vibrations/beeps and will continue to notify every 5 minutes until acknowledged. To respond, eat carbs and test your BG. Tap OK to close the alert screen.
Control-IQ High Alert	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. Pump will notify with 2 vibrations, then 2 vibrations/beeps and will continue to notify every 5 minutes until acknowledged, and then every 2 hours if the issue still persists. To 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.
Max Insulin Alert	The pump has delivered the maximum allowable 2 hour insulin amount based on your Total Daily Insulin setting. 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. Pump will notify with 2 vibrations, then 2 vibrations/beeps and will continue to notify every 5 minutes until acknowledged. To respond, tap OK.
Out of Range Alert - Control-IQ+ Technology Disabled	The CGM and pump are not communicating. The pump will not receive sensor glucose readings, and Control-IQ+ technology is not able to predict sensor glucose levels or adjust insulin delivery. Pump will notify with 1 vibration, then vibration/beep and will continue to notify every 5 minutes until the CGM and pump are back in range. To respond, tap OK to confirm and move the CGM and pump closer together, or remove the obstruction between them.
Out of Range Alert - Control-IQ+ Technology Enabled	Control-IQ+ technology is turned on, but the CGM and pump are not communicating. 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. Pump will notify with 1 vibration, then vibration/beep and will continue to notify every 5 minutes until the CGM and pump are back in range. To respond, tap OK to confirm and move the CGM and pump closer together, or remove the obstruction between them.

CHAPTER 11

Pump Safety and Care

11.1 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 pre-filled 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 pre-filled 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

11.2 Lifestyle and Travel

Any time you remove your pump for more than 30 minutes, it is recommended to suspend insulin delivery. This will prevent Control-IQ+™ technology from continuing to dose insulin.

Always have a plan with your healthcare provider if you plan to disconnect from your pump to compensate for missed basal insulin.

Always monitor your sensor blood glucose and manually test your BG if needed.

When choosing third-party pump cases or stickers, do not cover the six vent holes on the back of the pump.

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.”
- If necessary, you can disconnect from your pump during activity. Continue to monitor your BG and how you feel, and make a plan with your healthcare provider for while you’re disconnected, if necessary.

Aquatic Activities

- 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

- 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

- It is safe to remove your pump to bathe, shower, or for other activities where it is more convenient to do so.

Travel

For safe travel, prepare the following items:

- The items listed in the Emergency Kit described in Section 11.1 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

- Never expose your pump to X-ray.
- Always ask airport security for 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.
- While using airplane mode, you must maintain a Bluetooth connection in order to use the Tandem t:slim mobile app.

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CHAPTER 12

Important Safety Information

12.1 t:slim X2 Insulin Pump Warnings

The following includes important safety information related to your t:slim X2™ pump and its components.

⚠ WARNING
DO NOT start to use your pump or the Tandem t:slim™ mobile app before reading the quick start guide. Failure to follow the instructions in this quick start 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 1.2 Compatible Insulins. Only U-100 insulin analogs listed in Section 1.2 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 1.2 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.

12.2 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.

12.3 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.

12.4 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 quick start 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 3 Tandem t:slim Mobile App and Source 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.

12.5 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.

12.6 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**.

12.7 CGM Warnings

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.

⚠ 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.

⚠ 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.

Using a Dexcom CGM with Your t:slim X2 Insulin Pump

⚠ 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.

12.8 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.

⚠ 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.

Using a Dexcom CGM with Your t:slim X2™ Insulin Pump

⚠ PRECAUTION

To calibrate the CGM, **DO** enter the exact BG value displayed on your BG meter 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

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

⚠ 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 3 Plus Sensor with Your t:slim X2 Insulin Pump

⚠ PRECAUTION

ALWAYS use a BG meter to confirm sensor values when making treatment decisions when CGM readings are inconsistent with your signs and symptoms, or if the Check BG icon is displayed.

⚠ PRECAUTION

Your sensor value may not be automatically populated into the *Bolus* screen during the first 12 hours of wearing an Abbott FreeStyle Libre 3 Plus Sensor CGM. **ALWAYS** check your BG to confirm your sensor values before making any treatment decisions.

12.9 Control-IQ+ Technology Warnings

The following includes important safety information related to Control-IQ+™ technology.

⚠ 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 with a Dexcom CGM 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.

12.10 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.

CHAPTER 13

Technical Specifications

13.1 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.

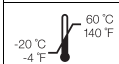
Explanation of t:slim X2 Insulin Pump Symbols

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
	Radiofrequency compliance with New Zealand regulations
	Regulatory Compliance Mark
	Humidity range
	Temperature range
	Keep Dry
	Outlet Adapter
	Pump Case

13.2 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.
- 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.
- 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 as explicitly instructed by Tandem.
- Contact Tandem's Customer Technical Support if you suspect your pump may have been compromised by any cybersecurity interference or vulnerability.

13.3 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

13.4 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.

13.5 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 3.4 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 3.4 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.

13.6 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 3 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 4.17 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.

13.7 Warranty Information

For pump warranty information for your region, visit tandemdiabetes.com/legal/warranty.

13.8 Returned Goods Policy

For information on the returned goods policy for your region, visit tandemdiabetes.com/legal/returned-goods.

13.9 t:slim X2 Pump Specifications

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

13.10 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

Wireless Technology Specifications

Specification Type	Specification Detail
Modulation	Gaussian Frequency-Shift Keying
Data Rate	2 Mbps
Data Communication Range (maximum)	20 feet (6 meters)

13.11 t:slim X2 Pump Performance Characteristics

Rate of Delivery

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

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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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