Tandem Mobi™ System

User Guide

TANDEM™ Diabetes Care

MG/DL

TANDEM MOBI SYSTEM USER GUIDE
Pump Model: 1004000, Software Version: Control-IQ+ (7.9)

This user guide is designed to assist you or your trusted caregiver with the features and functions of the Tandem Mobi™ system. 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 user 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.

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

To access the technical user guide for your software version, or to replace or update this user guide, do one of the following:

- Access and download digital copies from https://www.tandemdiabetes.com/support-center or scan this QR code:

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

Tandem Diabetes Care, Inc.
12400 High Bluff Drive
San Diego, CA 92130 USA
tandemdiabetes.com

SIX-DIGIT PAIRING PIN:

NOTE
Do not share this PIN and always store your user guide in a secure location.

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CHAPTER 1

Overview

1.1 Indications for Use

The Tandem Mobi 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 individuals 2 years of age and greater.

Control-IQ+ technology is intended for use with compatible interoperable continuous glucose monitors (iCGM), 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 not a substitute for your own active diabetes management.

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 Tandem Mobi system is designed for use with rapid acting insulin analogs that have been tested and found to be safe for use in the pump:

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

NovoLog and Humalog are compatible with the system for use up to 72 hours (3 days). If you have questions about using other insulins, contact your healthcare provider. Always consult your healthcare provider and refer to the insulin labeling prior to use.

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

1.3 Compatible CGMs

Compatible CGMs include the following CGMs:

- Dexcom G6 CGM
- Dexcom G7 CGM

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

Dexcom CGMs are sold and shipped separately by Dexcom.

1.4 Compatible Apps

The pump is compatible only with the Tandem Mobi mobile app. Only one app may be paired with the pump at a time.

If you are unable to access the Tandem Mobi mobile app for any reason, the pump will continue to deliver insulin if previously programmed. See Chapter 6 Disconnected States for more details.

1.5 Important User Information

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

If you are not able to use the system according to the instructions in this user guide 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 Dexcom CGM, it is still very important that you review all instructions in this user guide.

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

Younger children may inadvertently press the **Pump** button or the Tandem Mobi mobile app, leading to unintentional delivery of insulin or stopping insulin delivery.

We recommend reviewing the Quick Bolus capability of the pump and determining how they best fit with your care plan. See Section 9.8 Quick Bolus for more information.

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

⚠ WARNING

It is the responsibility of the healthcare provider and caregiver to determine the extent to which the user is capable of independently operating this device and the Tandem Mobi mobile app.

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

Report any serious incident that occurs in relation to the Tandem Diabetes Care products to Tandem Diabetes Care.

1.6 Verification of Proper System Functionality

A power supply (AC adapter with charging pad) is provided with your pump. Before using your pump, ensure that the following occur when you place the pump on a powered charging pad:

- You see the pump status lights turn on above the **Pump** button or around the charging pad
- You notice a vibratory alert
- You see a charge symbol (lightning bolt) on the pump battery level indicator on the Tandem Mobi mobile app

⚠ PRECAUTION

CONFIRM that you can hear audible beeps, feel the pump vibrate, and see the pump status lights illuminate when you place the pump on charging pad. These features are used to notify you about alerts, alarms, and other conditions that require your attention. If these features are

not working, discontinue use of your pump and contact Customer Technical Support.

⚠ PRECAUTION

ALWAYS consult your healthcare provider if you suspect that your insulin delivery setting may have changed unexpectedly. ALWAYS pay attention to pump notifications, alerts, and alarms as they may indicate that someone else is trying to interference with your pump. If you ever suspect that someone else is trying to connect or interfere with your pump, stop using it and contact Customer Technical Support immediately.

1.7 System Terminology

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 sensor glucose value goal, an exact number, not a range. When a BG or sensor glucose value is sent to 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 BG. 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 BG that is lowered by 1 unit of insulin. Also known as the Insulin Sensitivity Factor (ISF).

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

Grams
Grams are the measurement for a carbohydrate.

Insulin Duration
Insulin duration is the amount of time that insulin is active and available in the body after a bolus has been delivered.

This also relates to the calculation for Insulin on Board.

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 PIN
A unique six-digit identification number that will secure communication between the pump and smartphone. Your paring PIN is found below the serial number, near the QR code of your pump. This barcode is visible when the insulin cartridge has not been loaded.

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 **Pump** button) is a way to deliver a bolus by following beep/vibration commands without using the Tandem Mobi mobile app.

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 charging pad's USB-C port.

CGM Terminology

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

Applicator
The applicator is a disposable part which contains the sensor with an insertion needle inside. The entire applicator is disposed of once the sensor is inserted.

Calibration
Calibration is when you enter BG values from a BG meter into the Tandem Mobi mobile app. Calibrations may be needed for your pump to show continuous glucose readings and trend information.

CGM
Continuous glucose monitoring.

CGM Reading
A CGM sensor glucose reading shown on your Tandem Mobi mobile app. This reading is in mg/dL units and is updated every 5 minutes.

HypoRepeat
HypoRepeat is an optional CGM auditory and vibration alert setting that keeps repeating the fixed low alert every 5 seconds until your sensor

glucose value rises above 55 mg/dL or you confirm it. This alert can be helpful if you want extra awareness for severe lows. This alert setting is enabled when the pump is disconnected from your smartphone.

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

Pairing Code – Dexcom G7 Only
A unique code provided with each individual CGM sensor, used to pair the Tandem Mobi pump with that sensor. This code is not related to the pairing PIN used to pair the pump to a smartphone.

Receiver
When the Dexcom CGM is used with the system to display CGM readings, the Tandem Mobi mobile app replaces the receiver for the therapeutic CGM. A smartphone with the Dexcom app may be used in addition to the Tandem Mobi mobile app to receive sensor readings.

Rise and Fall (Rate of Change) Alerts
Rise and fall alerts occur based on how much and how fast your sensor glucose levels rise or fall.

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

Sensor
The sensor is the part that of the CGM that is inserted under your skin, which allows it to measure your glucose levels.

Sensor Code – Dexcom G6 Only
A code provided with each individual CGM sensor. If used, the sensor code allows the Dexcom G6 to be used without the need for fingersticks or calibrations.

Sensor Glucose Data Gaps
Glucose data gaps occur when your pump is unable to provide a sensor glucose reading.

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

Sensor Pod – Dexcom G6 Only
The sensor pod is the small plastic base of the sensor attached to your skin that holds the transmitter in place.

Startup Period
Once a new sensor session is started on the pump, the startup period is an interval during which the new sensor is establishing connection with the pump. Sensor glucose readings are not provided during this time.

Transmitter
The Dexcom G6 transmitter is the part of the CGM that snaps into the sensor pod and wirelessly sends sensor glucose information to your pump.

The Dexcom G7 has a streamlined all-in-one sensor with a built-in disposable transmitter.

Transmitter ID – Dexcom G6 Only
The transmitter ID is a series of numbers and/or letters that you enter into your Tandem Mobi mobile app to

let it connect and communicate with the transmitter.

Trend (Rate of Change) Arrows
Trend arrows show how fast your sensor glucose levels are changing. There are seven different arrows that show when your sensor glucose direction and speed change.

1.8 Training Resources

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

1.9 Pump Accessories

Your package should include the following items:

- Tandem Mobi™ insulin pump
- Tandem Mobi charging pad
- USB-C charging pad cable
- Tandem Mobi Quick Reference Guide
- Tandem Mobi System User Guide
- Tandem Mobi pump case
- Tandem Mobi adhesive sleeve
- Tandem Mobi adhesive sleeve instructions for use
- AC adapter

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

Your pump comes with a protective cover in the place where the cartridge is normally inserted. Remove this cover and load a cartridge prior to initiating insulin delivery.

The Tandem Mobi pump 2mL cartridge with t:lock™ connector consists of the reservoir chamber and a plunger 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 securely connects the cartridge to the infusion set. Use only Tandem Mobi 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:

- USB cables
- charging pad
- case(s)/clip(s)

Supply Reordering
To order cartridges, infusion sets, supplies, or accessories, please contact Customer Supplies Support or your usual supplier of diabetes products.

1.10 System Description

The Tandem Mobi system consists of:

- The Tandem Mobi insulin pump

- The embedded Control-IQ+ algorithm
- The Tandem Mobi 2 mL cartridge
- Compatible infusion set
- The Tandem Mobi mobile app

The system may be used in combination with compatible glucose monitoring (CGM).

1.11 Emergency Kit

You should always have an appropriate emergency kit with you. At the very least, this kit should include an insulin syringe and vial of insulin or a prefilled insulin pen with you 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
- Ketone strips
- Fast-acting carbohydrate to treat low BG
- Extra snack for longer coverage than fast-acting carbohydrate
- Glucagon emergency kit
- Rapid-acting insulin and syringes or a prefilled insulin pen and pen needles
- Infusion sets (minimum of 2)
- Insulin pump cartridges (minimum of 2)
- Pump charging pad, USB cable, and wall adapter
- Infusion site preparation products (antiseptic wipes, skin adhesive)
- Diabetes identification card or jewelry
- Smartphone charger

CHAPTER 2

Getting to Know Your Tandem Mobi System

2.1 Pump Components/Diagram

1. **Pump status lights:** Illuminates to indicate pumping status and when charging. To check pump status, press and release **Pump** button once.

2. **Pump button:** Turns the pump on/off, programs a Quick Bolus (if enabled), snoozes alerts and alarms (if enabled), activates the pump status lights.

   ⚠ PRECAUTION
   If the **Pump** button is not responding properly, disconnect the infusion site from your body and call Customer Technical Support.

3. **t:lock Connector:** Connects the cartridge tubing to the infusion set tubing.

4. **Cartridge Tubing:** Tubing that is attached to the cartridge.

2.2 Pump Status Light Colors

The follow table describes what the pump status light colors represent.

Color Definitions

Color	Definition
	Green Represents: **Either** basal delivery (standard or Temp Rate) **or** confirmation of an action from the Tandem Mobi mobile app.
	Blue Represents: **Either** a bolus delivery **or** the tubing is being filled during cartridge load.
	White Represents: **Either** the pump is charging **or** the insulin delivery has been stopped manually.
	Yellow Represents: **Either** an alert **or** reminder.
	Red Represents: **Either** an alarm **or** malfunction **and** all insulin delivery has stopped.

2.3 Pump Status Light Patterns

The patterns in the table below appear automatically when an alert, alarm, or malfunction is present or when insulin delivery has been stopped manually. These patterns may also appear when you check the pump status by pressing and releasing the **Pump** button.

Blinking Pattern Definitions

Pattern	Definition
Both lights blink white three times 	All insulin deliveries were stopped manually.
Both lights blink yellow once 	A pump reminder is displayed on the Tandem Mobi mobile app.
Both lights blink yellow two times 	A pump or CGM alert is displayed on the Tandem Mobi mobile app. Check the Tandem Mobi mobile app.
Both lights blink red three times 	Insulin delivery has stopped. Pump malfunction or alarm Check the Tandem Mobi mobile app.

The patterns in the table below appear when you initiate an insulin delivery, or when you check the pump status by pressing and releasing the **Pump** button.

Solid and Pulsating Pattern Definitions

Pattern	Definition
Lights are alternating and pulsating green 	Basal rate delivery
One light is solid green and the other light is pulsating green 	Temp rate delivery

Pattern	Definition
Lights are alternating and pulsating blue 	Bolus delivery
One light is solid blue and the other light is pulsating blue 	Extended bolus delivery

2.4 Charging the Pump

The pump is powered by an internal lithium polymer rechargeable battery. A full charge will typically last between 3 and 5 days, depending on your use. Please be aware that the battery life on a single charge can vary considerably depending on individual usage, including insulin delivered, Tandem Mobi mobile app use, and frequency of reminders, alerts, and alarms.

When you first receive your pump, you will need to charge it before it can be used. To charge the battery, place the pump on top of the charging pad within the pump outline. Ensure the pump is seated in the outlined charge nest. The t:lock™ connector on the pump should align to the t:lock connector outline on the top of the charging pad. If the pump is not seated correctly, it will not charge.

When the pump is initially placed, the charging pad will light up for approximately 30 seconds to indicate charging and then dim.

Charge the pump until the pump status lights above the Pump button is displaying two solid, white lights. The initial charge can take up to 2 hours.

The pump status lights will also indicate charge amount. When charging, the pump status lights will display one pulsating light if the charge amount is less than 50%.

When the charge amount is above 50%, the pump status lights will display one solid white light and another pulsating white until fully charged. These lights will remain lit until fully charged.

If the charge amount is very low, the pump status lights will display one pulsating in red light first or may not turn on.

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.

⚠ WARNING

DO NOT place metal objects on the charging pad.

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 USB-C port on the charging pad.
4. Remove any accessories from the pump prior to placing the pump on the charging pad, as they may interfere with charging.
5. Place the pump on charging pad.

6. Check to make sure the pump status lights display and that the charging pad illuminates.

Charging Tips

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

2.5 Turning the Pump On and Off

Place your pump on the charging pad, and press and hold the **Pump** button for 5 seconds. The pump will beep four times when it has turned on and is ready for use.

To turn the pump off completely, place the pump on the charging pad and hold the **Pump** button down for 20 seconds. The pump will beep three times before it turns off.

2.6 Updating the Pump Software

For warnings and precautions associated with updating your pump software, see Section 12.5 Mobile Tandem Device Updater Warnings and Section 12.7 Tandem Mobi Mobile App Precautions.

Eligible pumps with an available update may do so remotely using the mobile Tandem Device Updater, giving you access to new software features. When an update is available, you will be notified by an email from Tandem, as well as through a push notification on the Tandem Mobi mobile app.

For instructions on updating your pump software, follow the steps in the Tandem Mobi mobile app, or visit tandemdiabetes.com/support/software-updates/how-to.

2.7 Explanation of Icons

The following icons may appear on the Tandem Mobi™ mobile app:

Tandem Mobi Mobile App Icon Definitions

Symbol	Definition
	The amount of charge left in the pump battery.
	A system reminder, alert, error, or alarm is active.
	All insulin deliveries are stopped.
	A bolus is being delivered; displays the date and time the most recent bolus was delivered.
	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.
	Displays the current Personal Profile information.

Symbol	Definition
	The amount of insulin remaining in the cartridge.
	A temporary basal rate is active.
	A temporary basal rate of 0 units/hour is active.
	Control-IQ+ technology is delivering an automatic correction bolus (or an automatic bolus).
	Control-IQ+ technology is on 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.
	Displays the date and time of the most recent calibration.

Tandem Mobi Mobile App Icon Definitions (Continued)

Symbol	Definition
	Displays the date and time the current CGM sensor session was started.
	CGM sensor session is active, and the CGM is communicating with the pump; displays the CGM battery status.
	CGM sensor session is active, but the CGM and pump are out of range.
	The CGM sensor has failed.
	Calibration is required.
	Additional startup calibration is required.
	Bluetooth connection has been lost between the pump and smartphone.
	Sleep is on.
	The associated setting is turned off.
	Stop insulin delivery, sensor session, or activity.

Symbol	Definition
	Unknown sensor reading.
	CGM sensor session is active, but the CGM is not communicating with the pump.
	Transmitter error.
	The CGM sensor session has ended.
	Startup calibration is required (2 BG values).
	Wait 15 minutes calibration error.
	Control-IQ+ technology off or inactive due to disconnection between the pump and smartphone.
	Exercise is on.
	The associated setting is turned on.
	Start insulin delivery, sensor session, or activity.

Tandem Mobi Mobile App Icon Definitions (Continued)

Symbol	Definition
	Time was changed forward.
✔	Save (Android devices only). Tap to save settings on the screen.
→	Accept (Android devices only). Tap to continue to the next screen or to answer yes to a message on the screen.

Symbol	Definition
	Time was changed backward.
X	Cancel (Android devices only). Tap to cancel the current operation.

2.8 Navigation Bar

The *Navigation* bar appears at the bottom of the Tandem Mobi mobile app. The following provides a summary of what each menu item displays.

1. **Dashboard:** Pump status bar, current glucose reading, IOB status, CGM graph, time in range information, and current status.

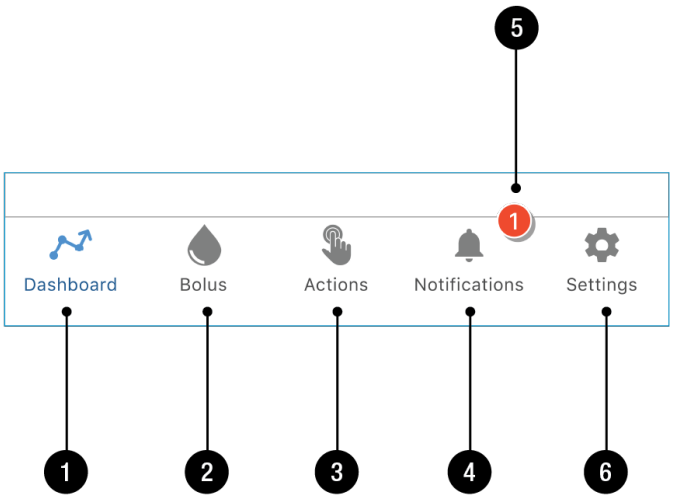
2. **Bolus:** Program and deliver a bolus.

3. **Actions:** Stop and resume insulin delivery, start and stop activities, load and change a cartridge.

4. **Notifications:** Lists all recent notifications from the system.

5. **Notification Badge**: Displays number of active, unread notifications on the *Navigation* bar.

6. **Settings:** Adjust settings for the pump, the CGM, alerts and alarms, and the Tandem Mobi mobile app.



2.9 Dashboard Screen

The *Dashboard* screen can be accessed from the *Navigation* bar.

1. **Pump Status Bar:** Displays icons that represent the status of the battery amount, the insulin amount, insulin delivery, data refresh timing, CGM connection, alerts, alarms, and reminders.

2. **Glucose & IOB Bar:** Displays the most recent 5-minute sensor glucose, CGM trend arrow, and IOB information.

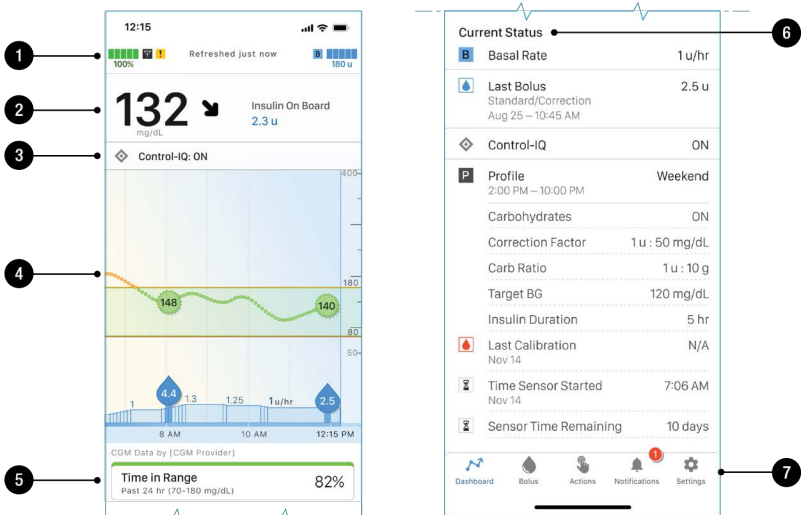
3. **Activity Bar:** Displays Control-IQ+ Sleep or Exercise icons, Control-IQ+ technology status, and indicates when insulin delivery has been stopped.

4. **Graph:** Displays CGM readings, estimated glucose value, BG thresholds, BG events, bolus events, and basal events.

5. **Time in Range Tile:** Displays the current duration and percentage of time within recommended CGM thresholds.

6. **Current Status:** Displays the time in range information, current basal rate, bolus information, Control-IQ+ technology status, active Personal Profile settings, and CGM settings.

7. **Navigation Bar:** Provides access to other screens within the Tandem Mobi mobile app.



2.10 Bolus Screen

1. **Cancel:** Returns to the *Dashboard* screen.

2. **Next:** Moves to next step.

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

4. **Carbs:** Enter grams of carbohydrate. This may display units of insulin based on your Personal Profile settings. See Section 3.3 Creating a New Personal Profile for more information.

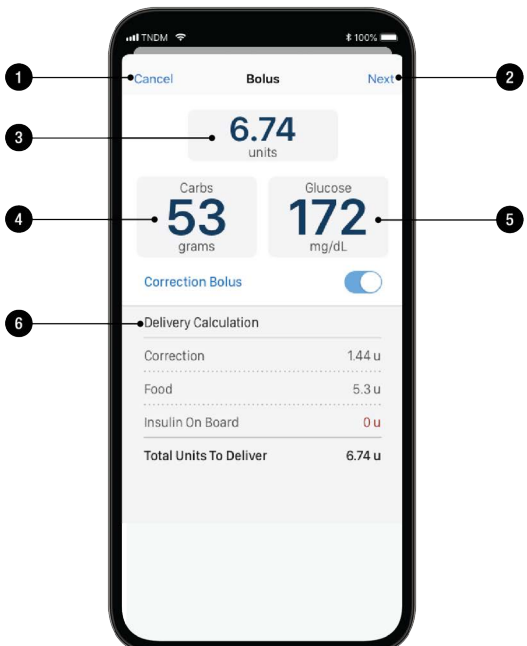
5. **Add Glucose:** Enter BG or sensor glucose level. See Section 9.2 Correction Bolus Calculation for details.

   For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's user guide.

   You can also see Section 4.17 Rate of Change Arrows.

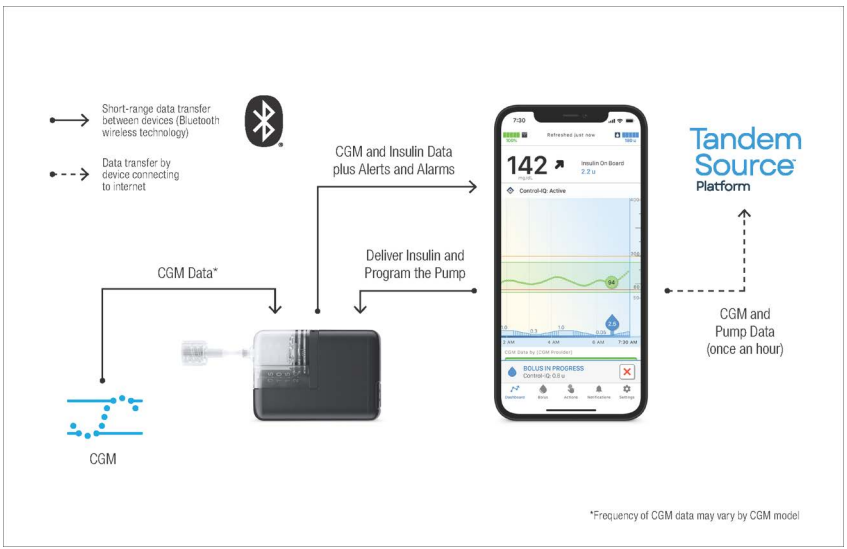
   You can choose to use this value or enter another value from an alternate testing method.

6. **Delivery Calculation:** Displays how the insulin dose was calculated using the current settings.



2.11 Connection Between the Tandem Mobi Mobile App and the Tandem Mobi Insulin Pump

The Tandem Mobi mobile app allows you to program settings on your Tandem Mobi insulin pump, once your pump and smartphone have been paired. For more information on the pairing process, see Section 2.13 Pairing the Tandem Mobi Mobile App with Your Pump. Below is a diagram explaining the relationship between the Tandem Mobi mobile app and your pump.



NOTE

The pump only accepts communications from a known linked device such as a CGM or personal smartphone. You must pair each device with your pump. The pump wireless communications are protected with encryption and authentication.

2.12 Download and Log in to the Tandem Mobi Mobile App

Before you begin:

- Ensure your smartphone and the Tandem Mobi™ mobile app are compatible. See https://www/tandemdiabetes.com/compatibility.
- Turn off smartphone automatic OS updates.
- Ensure your smartphone security feature is set-up (e.g. PIN, facial recognition, fingerprint, pattern recognition).
- Disable battery optimization on your smartphone. This is the same as disabling Low Power Mode. This ensures your app can run in the background and receive alerts and alarms.
- Download the Tandem Mobi mobile app from Google Play™ or the App Store®.
- For more help, visit tandemdiabetes.com/mobilesupport
- You can also access help from the app *Settings* screen. Tap **Help**, then **App Guide**, and then choose **Smartphone Setup** from the index.

If you have an existing Tandem Source account, log in using your credentials.

You should allow all permission requests from the Tandem Mobi mobile app so that you receive all notifications from your pump. For Android users, to use Bluetooth technology, the Tandem Mobi mobile app may ask for access to your device location; tap **Allow**.

If you are a new user, tap **Create Account**. Follow the prompts in your app to create your account.

Updating the Tandem Mobi Mobile App

When updates to the Tandem Mobi mobile app are available from Google Play™ or the App Store, download and install updates. Do not uninstall the app.

Updating Your Smartphone

It is recommended that you disable automatic OS updates on your smartphone. Before you manually update your phone OS, confirm that the Tandem Mobi mobile app is compatible with the new OS. For more information about managing automatic updates access the *Settings* screen from the Tandem Mobi mobile app. Tap **Help**, then **App Guide**, and then choose **Smartphone Setup** from the index.

2.13 Pairing the Tandem Mobi Mobile App with Your Pump

- Always pair to your phone using the Tandem Mobi mobile app. Do not pair through your phone's Bluetooth menu.

- Your pump can only be paired with one app at a time.
- This pairing process is separate from your CGM pairing process.
- Pair your devices in a controlled environment, such as your home hour healthcare provider's office. Pairing medical devices is a sensitive operation.
- Your pump must be connected to your smartphone to program your pump.
- Always keep the Tandem Mobi mobile app running in the background. This allows pump alerts, alarms, and notifications to be displayed on your smartphone.
- Do not force quit the app while data is syncing. Allow app time to sync.

To begin the pairing process, open the Tandem Mobi mobile app and follow the step-by-step instructions provided in-app.

Your Tandem Mobi mobile app will remain synchronized with your pump as long as a Bluetooth connection is maintained. The Tandem Mobi mobile app frequently uploads your pump's data into the Tandem Source platform whenever it is in Wi-Fi or cellular range, depending on your data use settings. This allows you and your healthcare provider easy access to your data via the Tandem Source platform.

2.14 Unpairing the Tandem Mobi Mobile App from Your Pump

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

If you replace your smartphone, turn off Bluetooth on the old phone to pair your pump to the new phone.

Unpair a smartphone from a working pump using your Tandem Mobi mobile app:

1. From the *Navigation* bar, tap **Settings**.
2. Tap **App**.
3. Tap **Paired Pump**.
4. Tap **Unpair**. A confirmation prompt will appear.
5. Tap **Unpair**. The Tandem Mobi mobile app displays a *Your pump has been unpaired* banner confirming that your pump has been unpaired and returns you to the pairing screen.

2.15 Set Mobile Notifications

The Tandem Mobi mobile app displays notifications generated by your pump or sent from the Tandem cloud, including pump alerts, alarms, and reminders.

To turn on push notifications:

1. From the *Navigation* bar, tap **Settings**.
2. Tap **Alerts & Sounds**.

Tap **App Notification Settings** to toggle push notifications as desired.

To ensure you receive notifications on the Tandem Mobi mobile app, confirm the smartphone sound mode is not set

to mute, and enable the following settings:

- Tandem Mobi mobile app notifications
- Bluetooth technology

If you enable a privacy mode that restricts push notifications, such as Focus Mode or Do Not Disturb, always adjust your smartphone settings to still allow notifications from the Tandem Mobi mobile app. For more information, in the Tandem Mobi mobile app Settings screen, tap **Help**, then **App Guide**, and then choose **Smartphone Setup** from the index.

CHAPTER 3

Pump Settings

3.1 Overview

This section describes how to program pump settings that affect insulin delivery, how to input Control-IQ+ settings, how to set-up quick bolus, how to set bolus and basal delivery limits, and how to program pump time and date.

3.2 Personal Profiles Overview

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

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

When you create a Personal Profile, you can set any or all of the following in a Time Segment:

- 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. For example a carb ratio of 1:8.2 can be programmed.

- 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)
- Carbohydrates (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: on)

Insulin Duration and Insulin on Board (IOB)

3.3 Creating a New Personal Profile

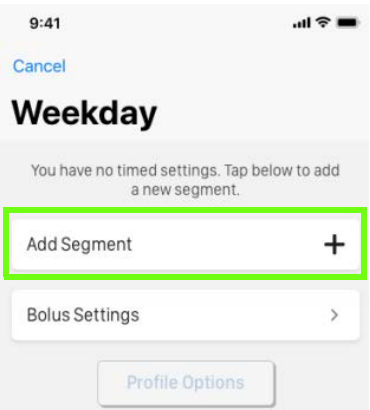
You can create up to six Personal Profiles; however, only one can be active at a time. In the Personal Profiles screen, the active profile is marked as Active.

To create a new Personal Profile:

1. From the *Navigation* bar, tap **Settings**.
2. Tap **Pump**.
3. Tap **Personal Profiles**.
4. Tap **Add New Profile**.

5. Tap the *Profile Name* field, and using the on-screen keyboard, enter a profile name (up to 16 characters) and tap **Next**.

6. Tap **Add Segment** to begin setting insulin delivery settings.



3.4 Programming a New Personal Profile

Once the Personal Profile has been created, the settings must be programmed. Consult your healthcare provider to accurately set Personal Profile settings. The first time segment always starts at midnight and cannot be edited.

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 Carbohydrates turned on, and you must set a Basal Rate, Correction Factor, Carb Ratio, and Target BG in order to turn Control-IQ+ technology on.

Time Segments

1. On the *Time Segment* screen, Tap **Basal Rate**.

2. Using the on-screen keyboard, enter your Basal Rate and tap Tap **Correction Factor**.

3. Using the on-screen keyboard, enter your Correction Factor and tap **Done**.

4. Tap **Carb Ratio**.

5. Using the on-screen keyboard, enter your Carb Ratio and tap **Done**.

6. Tap **Target BG**.

7. Using the on-screen keyboard, enter your Target BG and tap **Done**

8. Review entered values and tap **Save**.

✓ A *Time Segment has been saved* banner is displayed at the top of the Tandem Mobi mobile app.

Adding More Time Segments

You may add up to 16 Time Segments to any Personal Profile. To set up additional Time Segments:

1. When you are in an already named Personal Profile, tap **Add Segment**.

2. Tap **Start Time**.

3. Using the on-screen time picker, select the time (hour, minutes, and time of day) that you want the Time Segment to begin, and tap **Done**.

4. Repeat Steps 1 – 8 from Time Segments for each Time Segment you want to create.

Deleting Time Segments

To delete an existing Time Segment:

1. When you are in an already named Personal Profile, tap the start time of the Time Segment you wish to delete.

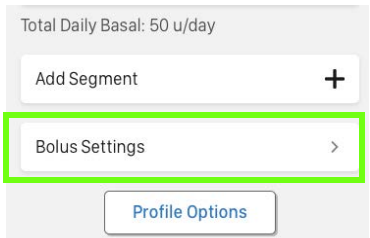
2. Tap **Delete Segment**.

3. Tap **Yes**.

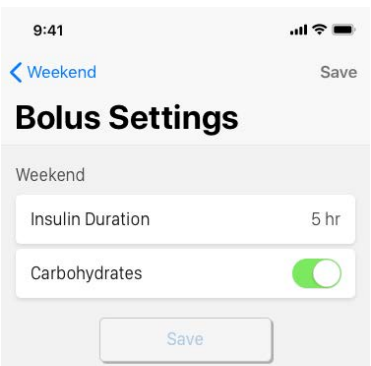
✓ A *Time Segment deleted* banner is displayed at the top of the Tandem Mobi mobile app.

Bolus Settings

1. From the named Personal Profile, tap **Bolus Settings**.



2. Tap **Insulin Duration**.



3. Using the on-screen time picker, enter the time in hours and minutes for the duration of insulin action. The minimum duration is two hours and the maximum duration is eight hours.

4. Tap **Done**.

5. By default, the Carbohydrates toggle is set to on. Tap the toggle next to **Carbohydrates** to turn this feature off in order to use units of insulin for bolus calculation.

6. Tap **Save**.

✓ A *Bolus Settings have been saved* banner is displayed at the top of the Tandem Mobi mobile app.

7. Tap **Personal Profiles** in the upper left corner to return to the previous screen.

Adding More Personal Profiles

1. From the *Navigation* bar, tap **Settings** then tap **Pump**, and then tap **Personal Profiles**.

2. Tap **Add New Profile**.
3. Name the new Personal Profile.
4. Repeat steps for Time Segments and Bolus Settings.

You are able to edit, review, duplicate, activate, rename, and delete existing profiles. For full instructions on how to do so, please see the Tandem Mobi Technical User Guide.

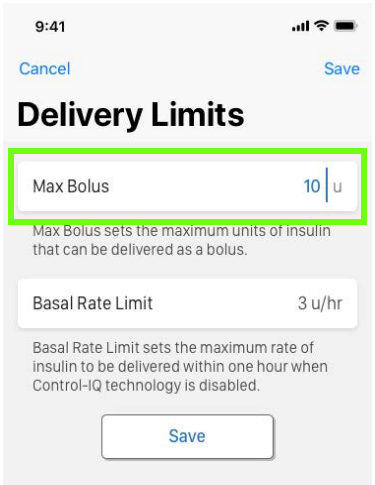
3.5 Max Bolus

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

The default setting for Max Bolus is 10 units, but can be set to a value between 1 to 25 units in one unit increments.

To adjust the Max Bolus setting:

1. From the *Navigation* bar, tap **Settings**.
2. Tap **Pump**.
3. Tap **Delivery Limits**.
4. Tap **Max Bolus**.



5. Using the on-screen keyboard, enter a Max Bolus amount.
6. Tap **Done**.
7. Review the new Max Bolus value and tap **Save**.

✓ A *Delivery Limits have been saved* banner is displayed at the top of the Tandem Mobi™ mobile app.

3.6 Basal Rate Limit

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

You are unable to set any Basal Rates or temp Basal Rates that exceed the Basal Rate Limit. You can set Basal Rate Limit from 0.2 to 15 units per hour. Work with your healthcare provider to set the proper Basal Rate Limit. The default Basal Rate Limit is 3 units per hour.

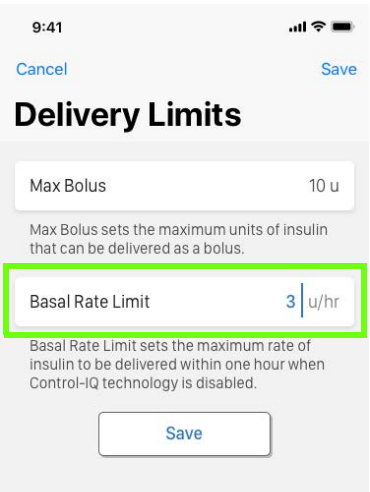
NOTE

If you are setting your Basal Rate Limit after you have set any of your Personal Profiles, you cannot set your Basal Rate Limit lower than any of your existing Basal Rates. See 3.3 Creating a New Personal Profile.

To adjust the Basal Rate Limit setting:

1. From the *Navigation* bar, tap **Settings**, then tap **Pump**, and then tap **Delivery Limits**.

2. Tap **Basal Rate Limit**.



3. Using the on-screen keyboard, enter a Basal Rate Limit amount that is between 0.2 to 15 units. The default value is 3 units.

NOTE

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

4. Tap **Done**.

5. Review the new Basal Rate Limit value and tap **Save**.

✓ A *Delivery Limits have been saved* banner is displayed at the top of the Tandem Mobi mobile app.

3.7 Enable and Set Snooze

The pump will beep or vibrate when an alert, alarm, or reminder is present. Enabling the Snooze function allows you to silence this beep or vibration for a set period of time in the event that you are unable to look at your Tandem Mobi mobile app.

To snooze an active reminder, alert, or alarm, quickly press and release the **Pump** button three times. If properly snoozed, the pump will vibrate and the pump status lights will display two green, solid lights for approximately one second.

To enable and set up Snooze, complete the following steps.

1. From the *Navigation* bar, tap **Settings**.

2. Tap **Alerts & Sounds**.

3. Tap **Pump Sounds**.

4. Tap **Snooze**.

5. Using the picker, choose a snooze time duration of **10 min**, **20 min**, or **30 min**.

6. Tap **Done** (iOS) or **OK** (Android).

7. Tap **Save**.

3.8 Set Time and Date

To manually change the time and date that your pump uses, complete the following steps.

1. From the *Navigation* bar, tap **Settings**.
2. Tap **Pump**.
3. Tap **Pump Time & Date**.
4. Tap **Set Pump Time**.
5. Using the on-screen time picker, select the time (hour, minutes, and time of day) that you want the Time Segment to begin, and tap **Done**.
6. Tap **Set Pump Date**.
7. Using the on-screen date picker, select the date (month, day, and year) that you want the Time Segment to begin, and tap **Done**.
8. Tap **Save**.

✓ A *Pump Time and Date saved* banner is displayed at the top of the Tandem Mobi mobile app.

✓ A *Pump Time & Date* informational message will appear in the *Notifications* screen reminding you that the pump time and date is different than the time and date used by your smartphone.

When the Tandem Mobi mobile app time is changed, a vertical purple line will appear on the *Dashboard* graph. Additionally, at the base of the graph, an icon displays the direction that the pump clock was changed.

3.9 Pump Info and History

To access items such as your pump serial number, Customer Technical Support contact information, website, and software/hardware versions:

1. From the *Navigation* bar, tap **Settings**, and then tap **Pump**.
2. Tap **Pump Info**.

To access pump history such as Bolus, Basal, Load, BG, Alerts and Alarms, Control-IQ, and Complete:

1. From the *Navigation* bar, tap **Settings**, then tap **App**, and then tap **History**,
2. Tap **Pump History**.

At least 14 days of data can be viewed in Pump History. To see more historical data, you may also access the reports in Tandem Source™. See the *Tandem Source Personal User Guide* for more information.

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CHAPTER 4

CGM Settings

4.1 Transferring a Sensor Session to the Tandem Mobi System

Ensure your CGM is not connected to a Dexcom receiver or a t:slim X2™ insulin pump before pairing with the Tandem Mobi pump. Do not stop your current sensor session.

Make note of your transmitter ID or your Pairing Code so that you can transfer your current sensor session to the Tandem Mobi pump.

You may still use a smartphone with the Dexcom G6 or Dexcom G7 CGM apps simultaneously with your pump.

To transfer an existing sensor session from a Dexcom receiver:

1. Turn off the Dexcom receiver.
2. Wait 15 minutes. This allows the CGM to forget the connection currently in place with the Dexcom receiver.
3. Pair your CGM to the Tandem Mobi pump.

NOTE

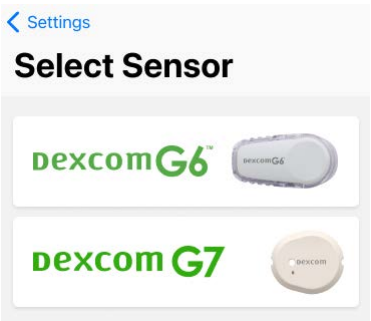
It is not enough to stop an old sensor session on your Dexcom receiver prior to pairing to the pump. The receiver power must be completely off in order to avoid connection problems.

To transfer an existing sensor session from a t:slim X2 insulin pump:

1. Put the t:slim X2 insulin pump into storage mode. Connect your pump to a power source, and then press and hold the **Screen On/Quick Bolus** button for 30 seconds.
2. Wait 15 minutes. This allows the CGM to forget the connection currently in place with the t:slim X2 insulin pump.
3. Pair your CGM to the Tandem Mobi pump.Visit the CGM manufacturer's website for applicable product instructions that also present warnings and precautions.

4.2 Choosing Your Sensor Type

If this is the first time you have used your pump, or if you have updated your pump software since you began your last sensor session, you will be prompted to choose your CGM type. From the *Settings* screen, tap **CGM** then select your preferred sensor from the *Select Sensor* screen.

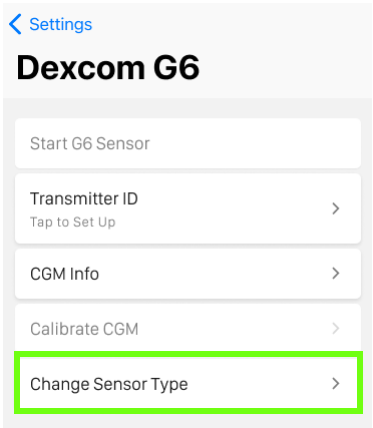


You may switch CGM types at any time. Connect your CGM to your Mobi pump before connecting it to any other app or device.

To switch from a Dexcom G6 CGM:

1. From the *Dashboard* screen, tap **Settings**, and then tap **CGM**.

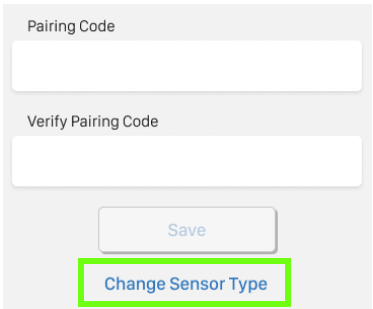
2. Tap **Change Sensor Type** at the bottom of the *Dexcom G6* screen.



3. From *Select Sensor* screen, choose the **Dexcom G7** logo.

To switch from a Dexcom G7:

1. From the *Dashboard* screen, tap **Settings**, and then tap **CGM**.
2. Tap **Change Sensor Type** at the bottom of the *Start G7 Pairing* screen.



3. From *Select Sensor* screen, choose the **Dexcom G7** logo.

4.3 Enter Your Dexcom G6 Transmitter ID

1. Remove the transmitter from its packaging.
2. From the *Dashboard* screen, tap **Settings**, then tap **CGM**, and then tap **Dexcom G6**.
3. Tap the **Transmitter ID** field.
4. Using the on-screen keyboard, enter the unique transmitter ID.

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

   The letters I, O, V, and Z are not used in transmitter IDs and should not be entered.
5. Using the on-screen keyboard, verify your transmitter ID by entering it again in the **Verify Transmitter ID** field.
6. Tap **Done** or ✔ .
7. Tap **Save**.

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

✓ Once matching values have been entered, you will be returned to the *Dexcom G6* screen.

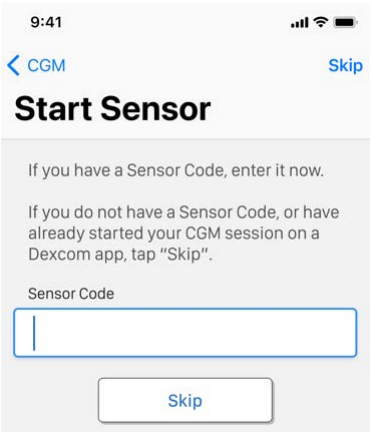
4.4 Start the Dexcom G6 Sensor

To start a sensor session, follow the steps below.

1. From the *Dashboard* screen, tap **Settings**. then tap **CGM**, then tap **Dexcom G6**, and then tap **Start G6 Sensor**.

✓ Once you start a sensor session, the Start G6 Sensor option is replaced with Stop G6 Sensor on the *Dexcom G6* screen.

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 product instructions.



2. Tap the *Sensor Code* field 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 Tandem Mobi mobile app, you will need to calibrate your sensor every 24 hours. A prompt to calibrate will be displayed on the Tandem Mobi mobile app.

3. Tap **Done**.

4. Tap **Next**.

5. On the *Start Sensor* screen, tap **Start**.

✓ The *Sensor session started* banner is displayed at the top of the Tandem Mobi mobile app to let you know your sensor startup has begun.

6. Check your *Dashboard* screen 10 minutes after starting your sensor session to make sure your pump and CGM are communicating. The antenna symbol is displayed to the right of the battery indicator.

7. If you see the out of range symbol below the battery level indicator, and the antenna symbol is grayed out, follow these troubleshooting tips:

   a. 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.

b. If the pump and CGM are still not communicating, check the *Dexcom G6* screen to make sure the correct transmitter ID is entered.

c. If the correct transmitter ID is entered and the pump and CGM are still not communicating, contact Customer Technical Support.

4.5 Dexcom G6 Sensor Startup Period

The Dexcom G6 sensor needs a 2-hour startup period to adjust to being under your skin. You will not get sensor glucose readings or alerts until the 2-hour startup period ends.

During the startup period, the *Dashboard* screen shows a 2-hour countdown notification below the battery level indicator. The notification updates over time to show that you are getting closer to the active sensor session..

If you entered a sensor code when you started the CGM sensor session, at the end of the 2-hour startup period, the notification message will be replaced with the current CGM reading.

If you skipped the step to enter a sensor code when you started the CGM sensor session, follow the instructions in the next chapter to calibrate your sensor. You may enter a calibration into the pump at any time, even if you have already entered sensor code. Pay attention to your symptoms, and if they do not match the current CGM readings, you may choose to use a BG meter reading and enter a calibration.

4.6 Ending a Dexcom G6 Sensor Session Before Automatic Shut-Off

You can end your sensor session at any time before the automatic sensor shut-off. To end your sensor session early:

1. From the *Dashboard* screen, tap **Settings**, then tap **CGM**, and then tap **Stop G6 Sensor**.

2. Tap **Yes** to confirm.

✓ The *Sensor Session Stopped* banner is displayed at the top of the Tandem Mobi mobile app.

✓ The **Replace Sensor** icon will appear on the *Dashboard* in the

place where sensor glucose readings normally show.

4.7 Start the Dexcom G7 Sensor

To start a CGM session, follow the steps below.

1. From the *Dashboard* screen, tap **Settings**, then tap **CGM**, and then tap **Dexcom G7**.
2. Tap the *Pairing Code* field to enter the 4-digit pairing code.
3. Tap the *Verify Pairing Code* field to enter the 4-digit pairing code again.
4. Tap **Done** or ✔ .
5. Tap **Save**.

✓ The *Sensor Paired* window displays.

6. Tap **Done** or ✔ .
7. Check your *Dashboard* screen 10 minutes after starting your sensor session to make sure your pump and CGM are communicating. The antenna symbol is displayed to the right of the battery indicator.
8. If you see the out of range symbol below the battery level indicator, and the antenna symbol is grayed out, follow these troubleshooting tips:

   a. 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.

   b. If the pump and CGM are still not communicating, contact Customer Technical Support.

✓ Once you start a sensor session, the Start G7 Sensor option is replaced with Stop G7 Sensor on the *Dexcom G7* screen.

4.8 Dexcom G7 Sensor Startup Period

The Dexcom G7 sensor requires a startup period to adjust to being under your skin. This startup period begins automatically as soon as the sensor is inserted. You will not get sensor glucose readings or alerts until the startup period ends.

During the startup period, the *Dashboard* screen shows a countdown notification below the battery level indicator. The countdown notification displays the time in minutes that are remaining in the startup period. The notification messages show that you are getting closer to the active sensor session.

At the end of the startup period, the notification will be replaced with the current CGM reading.

4.9 Ending a Dexcom G7 Sensor Session Before Automatic Shut-Off

You can end your sensor session at any time before the automatic sensor shut-off. To end your sensor session early:

1. From the *Dashboard* screen, tap **Settings**, then tap **CGM**, and then tap **Stop G7 Sensor**.
2. Tap **Stop Sensor** to confirm.

✓ The *Sensor session stopped* banner is displayed at the top of the Tandem Mobi mobile app.

✓ The **Replace Sensor** icon will appear on the *Dashboard* in the place where sensor glucose readings normally show.

4.10 Setting Your High Glucose Alert and Repeat Feature

1. From the *Dashboard* screen, tap **Settings**, then tap **Alerts & Sounds**, and then tap **CGM Alerts**.
2. To set the High Alert, tap the **High Alert** toggle on.

   The default setting for the High Alert is 200 mg/dL.
3. Tap **Alert Me Above** to update the sensor glucose value at which you will be notified.

   NOTE
   To turn the alert off, tap the **High Alert** toggle off.
4. Using the on-screen keyboard, 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 **Done** or ✔ .

You can set up a repeat feature so that this alert sounds again. The default is never.

To Set Up the Repeat Feature:

6. Tap **Repeat**.
7. 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.

   Scroll down to view all Repeat options.
8. Tap **Done** or ✔ .
9. Tap **Save**.

4.11 Setting Your Low Glucose Alert and Repeat Feature

1. From the *Dashboard* screen, tap **Settings**, then tap **Alerts & Sounds**, and then tap **CGM Alerts**.
2. To Set the Low Alert, tap **Low Alert**.

   The default setting for the Low Alert is 80 mg/dL.
3. Tap **Alert Me Below**.

NOTE
To turn the alert off, tap the **Low Alert** toggle off.

4. Using the on-screen keyboard, 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 **Done** or ✔ .

You can set up a repeat feature so that this alert sounds again. The default is never.

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.

   Scroll down to view all repeat options.

3. Tap **Done** or ✔ .

4. Tap **Save**

4.12 Rate Alerts

Rate alerts tell you when your sensor 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.

4.13 Setting Your Rise Alert

1. From the *Dashboard* screen, tap **Settings**, then tap **Alerts & Sounds**, and then tap **CGM Alerts**.

2. Tap **Rise Alert**.

3. Tap the toggle next to **Rise Alert**.

4. To select the default of 3 mg/dL/min, tap **Save**.

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

5. Tap **2 mg/dL/min** to select, then tap **Done**, then tap **Save**.

✓ Once a value is saved, the Tandem Mobi mobile app will return to the previous screen.

4.14 Setting Your Fall Alert

1. From the *Dashboard* screen, tap **Settings**, then tap **Alerts & Sounds**, and then tap **CGM Alerts**.

2. Tap **Fall Alert**.

3. Tap the toggle next to **Fall Alert**.

4. To select the default of 3 mg/dL/min, tap **Save**.

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

5. Tap **2 mg/dL/min** to select, then tap **Done**, then tap **Save.**

✓ Once a value is saved, the Tandem Mobi mobile app will return to the previous screen.

4.15 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 it on.

Control-IQ+ technology will continue to 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 *Dashboard* screen, tap **Settings**, then tp **Alerts & Sounds**, 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 Me After**.

3. Select the time after which you want to be alerted. You may select a value between 20 minutes and 3 hours and 20 minutes in one minute increments.

4. Tap **Done** or ✔ .

5. Tap **Save**.

4.16 CGM Graphs

You can view the prior 24 hours of sensor glucose information by swiping right on the graph.

If your sensor glucose reading is between your High and Low glucose threshold settings, it is shown in green.

If your sensor glucose reading is above your High glucose threshold setting, it is shown in orange.

If your sensor glucose reading is below your Low glucose threshold setting, it is shown in red.

If the Low Alert is not set and your sensor glucose reading is 55 mg/dL or lower, it is shown in red.

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

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.

4.17 Rate of Change Arrows

Your rate of change arrows add detail about the direction and speed of sensor

glucose change over the last 15 to 20 minutes.

The trend arrows show next to 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 to 20 minutes due to being out of range or due to an error condition, an arrow may not display on the *Dashboard* screen. 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 your Tandem Mobi mobile app displays:

Trend Arrow Definitions

	Constant: Your sensor glucose is steady (not increasing/decreasing more than 1 mg/dL each minute). Your sensor glucose could increase or decrease by up to 15 mg/dL in 15 minutes.
	Slowly rising: Your sensor glucose is rising 1–2 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase up to 30 mg/dL in 15 minutes.
	Rising: Your sensor glucose is rising 2–3 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase up to 45 mg/dL in 15 minutes.
	Rapidly rising: Your sensor glucose is rising more than 3 mg/dL each minute. If it continued rising at this rate, your sensor glucose could increase more than 45 mg/dL in 15 minutes.

	Slowly falling: Your sensor glucose is falling 1–2 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease up to 30 mg/dL in 15 minutes.
	Falling: Your sensor glucose is falling 2–3 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease up to 45 mg/dL in 15 minutes.
	Rapidly falling: Your sensor glucose is falling more than 3 mg/dL each minute. If it continued falling at this rate, your sensor glucose could decrease more than 45 mg/dL in 15 minutes.
No Arrow	No rate of change information: The CGM cannot calculate how fast your sensor glucose is rising or falling at this time.

4.18 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 *Dashboard* screen. The pump will automatically attempt to backfill missing data points in the Tandem Mobi mobile app up to 3 hours in the past when connectivity is restored and readings begin to appear. If the sensor glucose number or trend arrow is missing, and you are concerned that your BG level may be rising or falling, take a BG measurement using your BG meter.

4.19 Calibration Overview

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 Tandem Mobi™ mobile app to calibrate. You must enter one BG value to calibrate every 24 hours after your first startup calibration. The pump and Tandem Mobi mobile app 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 Tandem Mobi mobile app 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 if 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 left portion of the *Dashboard* screen before calibrating.
- Make sure the antenna symbol is visible to the right of the battery

level indicator on the *Dashboard* 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.

4.20 Startup Calibration

If you did not enter a sensor code when starting the Dexcom G6 CGM, the system 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 8 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** icon will appear on the *Dashboard* screen, letting you know that two separate BG values from your BG meter must be entered. You will not see sensor glucose readings until the Tandem Mobi mobile app accepts the BG values.

1. 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).
2. Take a BG measurement using your BG meter. Carefully apply the blood sample to the test strip following your BG meter manufacturer's instructions.
3. Tap **Settings**, then tap **CGM**, and then tap **Calibrate CGM**.
4. Using the on-screen keyboard, enter the BG value from your BG meter into the *BG value* field.
5. Tap **Done**.
6. Tap **Confirm**.

✓ A banner is displayed at the top of the Tandem Mobi mobile app to confirm the calibration entry.

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

✓ The on-screen keyboard will appear.

8. 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).
9. Take a BG measurement using your BG meter. Carefully apply the blood sample to the test strip following your BG meter manufacturer's instructions.

10. Follow steps 4 – 6 to enter your second BG value.

4.21 Calibration BG Value and Correction Bolus

Your Tandem Mobi pump uses the BG value entered into the Tandem Mobi mobile app 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 off, tap **Yes** to go to the *Bolus* screen. Tap **Yes** again add the correction bolus. Follow the instructions in Section 9.2 Correction Bolus Calculation to deliver a correction bolus.
  - If Control-IQ+ technology is on, the Tandem Mobi mobile app will return to the *Dexcom G6* or *Dexcom G7* screen.
- If you enter a calibration value that is below your Target BG in Personal Profiles, tap **OK** and follow the on-screen instructions.

If you enter your Target BG as a calibration value, the Tandem Mobi mobile app will return to the *Dexcom G6* or *Dexcom G7* screen.

4.22 Reasons You May Need to Calibrate

You may need to calibrate if your symptoms do not match the sensor glucose values provided by your CGM.

If you see either the *CGM Low Calibration Error* or the *CGM High Calibration Error* alert, you will be prompted to enter a BG value to calibrate in either 15 minutes or 1 hour, depending on the error.

You may also choose to enter a calibration code at any time, even when it is not required.

CHAPTER 5

Reminders, Alerts, and Alarms

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

If multiple reminders, alerts, and alarms happen at the same time, alarms will be displayed first, alerts will be displayed second, and reminders will be displayed third. Each must be acknowledged separately until all have been acknowledged. Notifications may be cleared in any order.

Reminders notify you with a single sequence of three notes or a single vibration depending on the beep/vibrate setting in Alerts & Sounds. They repeat every 10 minutes until acknowledged. Reminders do not escalate.

Alerts notify you with 2 sequences of 3 notes or 2 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds, and the pump status lights will light up in yellow in the pattern listed in the tables in this chapter. They repeat regularly until acknowledged. Alerts do not escalate.

Alarms notify you with 3 sequences of 3 notes or 3 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds, and the pump status lights will light up in red in the pattern listed in the tables in this chapter. If not acknowledged, alarm patterns escalate. Alarms repeat regularly until the condition that caused the alarm is corrected.

5.1 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 Duration for each reminder.

1. From the *Navigation* bar, tap **Settings**, then tap **Alerts & Sounds**, 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. Tap the toggle next to **Reminder 1**.

    c. Tap **Start Time**, and using the on-screen time picker select the start time and time of day, then tap **Done**.

    d. Tap **Duration**, and using the on-screen time picker select the end time and time of day, then tap **Done**.

    e. Tap each day of the week in the *Repeat* area below to add a

checkmark to all the day(s) you want the reminder to be on.

f. Tap **Save** when all changes are complete.

✓ A *Missed Meal Bolus Reminder 1 (or 2, 3,4) saved* banner is displayed at the top of the Tandem Mobi mobile app.

To Respond to the Missed Meal Bolus Reminder

To clear the reminder from the *Notifications* screen, tap on or slide the reminder message to the left, and tap **Delete** to clear the reminder. Deliver a bolus if necessary.

5.2 Bolus Confirmation Reminder

The Bolus Confirmation Reminder lets you know when a bolus command from the Tandem Mobi mobile app or a Quick Bolus starts and completes delivery.

1. From the *Navigation* bar, tap **Settings**.
2. Tap **Alerts & Sounds**.
3. Tap **Pump Sounds**.
4. Select between Beep or Vibrate for both General and Quick Bolus.
5. Tap **Save**.

If you do not hear or feel the confirmation, the bolus may be incomplete. The Tandem Mobi mobile app will display a notification.

5.3 Low Insulin Alert

Your t:slim X2™ pump keeps track of how much insulin remains in the cartridge and alerts you when it is low. The default for this alert is preset to 20 units. You can set this alert setting anywhere between 15 and 40 units. When the insulin amount goes below the set value, the Low Insulin Alert beeps/ vibrates and also appears on the Tandem Mobi mobile app screen. After the alert is cleared, the low insulin indicator (a single red bar on the insulin level indicator on the *Dashboard* screen) appears.

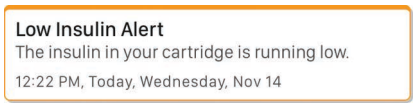
1. From the *Navigation* bar, tap **Settings**.
2. Tap **Alerts & Sounds**.
3. Tap **Pump Alerts & Alarms**.
4. Tap **Low Insulin**.
5. Using the on-screen keyboard, enter the number of units (from 15 to 40 units) that you want the Low Insulin Alert value to be set to, and tap **Done** or ✔ .
6. Tap **Save** when all changes are complete.

✓ A *Pump Alerts saved* banner is displayed at the top of the Tandem Mobi mobile app.

To Respond to the Low Insulin Alert

To clear the alert from the *Notifications* screen, swipe the alert to the left, and tap the **Dismiss** icon. Change your insulin cartridge following the

instructions in Section 7.1 Cartridge Instructions for Use.



5.4 Auto-Off Alarm

Your pump can stop insulin delivery and alert you or whoever is with you if there has been no interaction with the pump or Tandem Mobi mobile app within a specified period of time. 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 system in the specified number of hours and the pump will stop all insulin deliveries.

The Auto-Off Alarm beeps and appears on the lock screen of your smartphone. Insulin delivery stops when you exceed the set number of hours without any of the following actions:

- Use the Tandem Mobi mobile app to send a command to the pump.
- Deliver a Quick Bolus.
- Snooze the pump.

Enable and configure the Auto-Off Alarm as follows:

1. From the *Navigation* bar, tap **Settings**.
2. Tap **Alerts & Sounds**.
3. Tap **Pump Alerts & Alarms**.
4. The **Auto-Off** toggle is off by default.
   - To turn this alert on, tap the toggle next to **Auto-Off**.
   - Tap **Yes** to confirm this feature, and then tap **Save**.
5. Tap **Auto-Off Time**.
6. Using the on-screen number picker, select the number of hours (from 5 to 24 hours) that you want the Auto-Off Alarm to be triggered, and tap **Done**.
7. Tap **Save** when all changes are complete.

✓ A *Pump Alerts & Alarms saved* banner is displayed at the top of the Tandem Mobi mobile app.

5.5 Max Basal Alert

Your pump allows you to set a limit to the Basal Rate. The pump will not allow you to exceed this Basal Rate Limit during a Temp Rate.

Once the Basal Rate Limit in the Pump Settings has been set up (see Section 3.6 Basal Rate Limit), you will receive an alert if the following scenarios occur.

1. A Temp Rate was requested that exceeds the Basal Rate 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 Rate Limit.

5.6 Pump Alerts

Alert	Explanation
Low Insulin Alert	10 or less units of insulin remain in the cartridge. Pump will notify with 2 sequences of 3 notes or 2 vibrations and will re-notify every 5 minutes until acknowledged. Both lights will blink yellow twice in a row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Change your cartridge as soon as possible to avoid the Empty Cartridge Alarm and running out of insulin.
Low Power Alert 1	Less than 20% of battery power remains. Pump will notify with 2 sequences of 3 notes or 2 vibrations and repeat every 5 minutes until acknowledged. Both lights will blink yellow twice in a row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. 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 2 sequences of 3 notes or 2 vibrations and repeat every 5 minutes until acknowledged. Both lights will blink yellow twice in a row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Charge your pump immediately to avoid the Low Power Alarm and pump power off.
Incomplete Bolus Alert	You did not complete a bolus request within 90 seconds. Only notifies on Tandem Mobi Mobile app screen. App will re-notify every 5 minutes until action is completed or canceled. To respond, tap **OK**. The *Bolus* screen will appear. Either continue with your bolus request, or tap the Dashboard icon to return to the *Dashboard* to cancel the bolus request.
Incomplete Temp Rate Alert	You did not complete Temp Rate set up within 90 seconds. Only notifies on Tandem Mobi Mobile app screen. App will re-notify every 5 minutes until action is completed or canceled. To respond, tap **OK**. The *Temp Rate* screen will appear. Continue setting up your temp rate or tap **Cancel** if you wish to cancel set-up.
Incomplete Cartridge Change Alert	You did not complete the Change Cartridge process within 3 minutes. Only notifies on Tandem Mobi Mobile app screen. App will re-notify every 5 minutes until action is completed. To respond, tap **OK**. Complete the cartridge change process.
Incomplete Fill Tubing Alert	You did not complete the Fill Tubing process within 3 minutes. Only notifies on Tandem Mobi Mobile app screen. App will re-notify every 5 minutes until action is completed. To respond, tap **OK**. Complete the fill tubing process.

Alert	Explanation
Incomplete Fill Cannula Alert	You did not complete the Fill Cannula process within 3 minutes. Only notifies on Tandem Mobi Mobile app screen. App will re-notify every 5 minutes until action is completed. To respond, tap **OK**. Complete the fill cannula process.
Incomplete Setting Alert	You did not complete your Personal Profile or Control-IQ+ technology setting within 5 minutes. Only notifies on Tandem Mobi Mobile app screen. App will re-notify every 5 minutes until action is completed. To respond, tap **OK**. Complete programming.
Basal Rate Required Alert	You did not enter a Basal Rate in a time segment in Personal Profiles. A rate must be entered and can be 0 units/hour. Only notifies on the Tandem Mobi mobile app screen. To respond, tap **OK** and enter a Basal Rate in the time segment.
Basal and Carb Ratio Required Alert	You did not enter a Basal Rate or a Carb Ratio in a time segment in Personal Profiles, and the Carbs setting is turned on. Both must be entered and can be 0 units/hour. Only notifies on the Tandem Mobi mobile app screen. To respond, tap **OK** and enter a Basal Rate and Carb ratio in the time segment.
Max Hourly Bolus Alert	In the last 60 minutes, you requested a total bolus delivery that is more than 1.5 times your Max Bolus setting. Only notifies on the Tandem Mobi mobile app screen. To respond, you must tap **No** to return to the *Bolus* screen and adjust the bolus delivery amount or tap **Yes** to confirm the bolus.
Max Bolus Alert	You requested a bolus larger than the Max Bolus setting in your active Personal Profile. Only notifies on the Tandem Mobi mobile app screen. To respond, you must tap **Cancel** to return to the *Bolus* screen and adjust the bolus delivery amount, or tap **Continue** to deliver the amount of your Max Bolus setting.
Max Basal Alert	An active Temp Rate exceeds your Basal Rate Limit setting due to a new timed segment activation within Personal Profiles. Pump will notify with 2 sequences of 3 notes or 2 vibrations and re-notify every 5 minutes until acknowledged. Both lights will blink yellow twice in a row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. The Temp Rate value is reduced to the same Basal Rate Limit value that was set up in Personal Profiles.
Min Basal Alert	An active temp rate dropped below half of your lowest basal setting defined in your Personal Profile. Pump will notify with 2 sequences of 3 notes or 2 vibrations and re-notify every 5 minutes until acknowledged. Both lights will blink yellow twice in a row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Review your Basal Rate settings in Personal Profiles. Review your Temp Rate settings from the *Actions* screen.

Alert	Explanation
Pump Button Alert	The **Pump** button on your pump has been pressed too many times during a Quick Bolus request. Pump will notify with 2 sequences of 3 notes or 2 vibrations and re-notify every 5 minutes until acknowledged. Both lights will blink yellow twice in a row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Check the **Pump** button to see if it is stuck. Contact Customer Technical Support if the issue persists.
Quick Bolus Alert	A Quick Bolus has been requested 3 times but not delivered successfully. Pump will notify with 2 sequences of 3 notes or 2 vibrations and re-notify every 5 minutes until acknowledged. Both lights will blink yellow twice in a row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Check the **Pump** button to see if it is stuck. Contact Customer Technical Support if the issue persists.
Data Error Alert	Your pump has encountered a condition that could result in a loss of data. Pump will notify with 2 sequences of 3 notes or 2 vibrations and re-notify every 5 minutes until acknowledged. Both lights will blink yellow twice in a row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Check your Personal Profiles and pump settings to verify that they are accurate.
Temperature Alert	The internal temperature of your pump is too high or too low. Pump will notify with 2 sequences of 3 notes or 2 vibrations and re-notify every 5 minutes until acknowledged. Both lights will blink yellow twice in a row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Remove pump from extreme temperatures.

5.7 Pump Alarms

Alarm	Explanation
Resume Insulin Alarm 1	You selected **Stop Insulin** from the Actions screen and insulin delivery has been stopped for more than 15 minutes. Pump will notify with 3 sequences of 3 notes or 3 vibrations and re-notify every 3 minutes if not dismissed. If alarm is dismissed, pump will re-notify in 15 minutes. Both lights will blink red twice in a row, turn off, and repeat 5 times. To resume insulin, from the *Actions* screen, tap **Resume Insulin** and tap Yes to confirm.
Resume Insulin Alarm 2	Insulin has been stopped by a separate alarm event. Pump will notify with 3 sequences of 3 notes or 3 vibrations and re-notify every 3 minutes if not dismissed. If alarm is dismissed, pump will re-notify in 15 minutes. Both lights will blink red twice in a row, turn off, and repeat 5 times. To resume insulin, from the *Actions* screen, tap **Resume Insulin** and tap Yes 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 re-notify every 3 minutes until no power remains. Both lights will blink red twice in a row, turn off, and repeat 5 times. To respond, tap **Dismiss** and charge your pump immediately.
Empty Cartridge Alerm	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 re-notify every 3 minutes until you change the cartridge. Both lights will blink red twice in a row, turn off, and repeat 5 times. To respond, tap **Dismiss**. Change your cartridge immediately by following the **Load Cartridge** sequence.
Cartridge Error Alarm	Your pump detected that the cartridge could not be used. All deliveries are stopped. Pump will notify with 3 sequences of 3 notes or 3 vibrations and re-notify every 3 minutes until you change the cartridge. Both lights will blink red twice in a row, turn off, and repeat 5 times. To respond, tap **Dismiss**. Change your cartridge immediately by following the **Load Cartridge** sequence.
Temperature Alarm - Pump	Your pump detected an internal temperature below -31ºF (-35ºC) or above 176ºF (80ºC) and all deliveries have stopped. Pump will notify with 3 sequences of 3 notes or 3 vibrations and re-notify every 3 minutes until a temperature within operating range is detected. Both lights will blink red twice in a row, turn off, and repeat 5 times. To respond, tap **Dismiss**. 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 re-notify every 3 minutes until you resume insulin delivery. Both lights will blink red twice in a row, turn off, and repeat 5 times. To respond, tap **Dismiss**. Check the cartridge, tubing, and infusion site for any sign of damage or blockage and correct the condition. To resume insulin tap **Resume Insulin** from the *Actions* screen.
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 re-notify every 3 minutes until you resume insulin delivery. Both lights will blink red twice in a row, turn off, and repeat 5 times. To respond, tap **Dismiss**. Change the cartridge, tubing, and infusion site to ensure proper delivery of insulin. Resume insulin after changing the cartridge, tubing, and infusion site.
Pump and IOB Reset Alarm	Your pump experienced a reset and IOB has been reset to 0 units/hour. All basal and bolus deliveries have been stopped. You may have IOB that is not displayed if you recently delivered a bolus. **DO NOT** rely on the IOB displayed on your Tandem Mobi mobile app after a restart. **DO NOT** rely on the Max Hourly Bolus Alert for 60 minutes following a pump restart. Pump will notify with 3 sequences of 3 notes or 3 vibrations and re-notify every 3 minutes until you tap **Dismiss**. Both lights will blink red three times in a row, turn off, and repeat five times. To respond, tap **Dismiss** and contact Customer Technical Support. Check the *Dashboard* screen for current pump status. You will need to manually restart insulin delivery. Consult with your healthcare provider for how long you need to wait after a pump restart before you can rely on the IOB calculation.

5.8 Pump Malfunction

Alert	Explanation
Pump Malfunction	Your pump detected a critical error and all deliveries have been stopped. Use your backup insulin delivery method, or contact your healthcare provider for an alternate insulin delivery plan. Pump will notify with 3 sequences of 3 notes and 3 vibrations and re-notify every 3 minutes until you acknowledge the malfunction by tapping **Dismiss**. Both lights will blink red three times in a row, turn off, and repeat five times. To respond: » Write down the Malfunction Code number that appears on the screen. » Tap the phone number on the touchscreen to call Customer Technical Support. Provide the Malfunction Code number that you wrote down. » Tap **Dismiss** to acknowledge the malfunction. » Follow your alternate insulin delivery plan as discussed with your healthcare provider and continue to monitor your BG.

5.9 CGM Alerts and Errors

Alerts and Errors	Explanation
Start-Up Calibration Alert – Dexcom G6 Only	2-hour CGM startup period is complete. Only appears if you did not enter a sensor code. Pump will notify with 1 sequence of 1 note or 1 long vibration and re-notify every 5 minutes until acknowledged and then every 15 minutes until you calibrate. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Follow instructions in Section 4.20 Startup Calibration and enter 2 separate BG values to calibrate the CGM and start your CGM session.
Second Start-Up 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 sequence of 1 note or 1 long vibration and re-notify very 5 minutes until acknowledged and then every 15 minutes until second calibration is entered. Both lights will blink yellow twice in row, turn off, and repeat 5 times. o respond, tap on or slide the alert message left. Tap **Dismiss**. Follow instructions in Section 4.20 Startup Calibration and enter 2 separate BG values to calibrate the CGM and start your CGM session.
12-Hour Calibration Alert	The CGM needs a BG value to calibrate. This will only appear if you did not enter a sensor code. Pump will notify with 1 long vibration and re-notify every 15 minutes with 1 sequence of 1 note or 1 long vibration until acknowledged. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap **Dismiss**. Follow steps 1 – 9 in Section 4.20 Startup Calibration and enter a BG value to calibrate the CGM.
Incomplete Calibration	If you start to enter a calibration value using the keyboard and do not complete the entry within 90 seconds, this screen appears. Only notifies on Tandem Mobi Mobile app screen. App will re-notify every 5 minutes until action is completed. To respond, tap **OK** and complete your calibration by entering the value using the on-screen keyboard.
Calibration Timeout	If you start to enter a calibration value using the keyboard and do not complete the entry within 5 minutes, this screen appears. Only notifies on Tandem Mobi Mobile app screen. App will re-notify every 5 minutes until action is completed. Tap **OK** and obtain a new BG value using your BG meter. Follow steps 1 – 9 in Section 4.20 Startup Calibration to calibrate the CGM.

Alerts and Errors	Explanation
Calibration Error Alert – Dexcom G6 Only	The CGM cannot calibrate using the last BG meter value you entered. Pump will notify with 1 long vibration and re-notify every 5 minutes with 1 sequence of 1 note or 1 long vibration until acknowledged. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Wait at least 15 minutes for glucose and CGM to adjust. If calibration is still desired or readings do not appear, enter 1 more BG value. If sensor glucose readings to not appear after your last calibration, visit the CGM manufacturer's website for applicable product instructions.
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 long vibration and re-notify every 5 minutes until acknowledged and then every 15 minutes until you calibrate, with 1 sequence 1 note or 1 vibration. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Follow steps 1 – 9 in Section 4.20 Startup Calibration to calibrate the CGM.
CGM High Alert	Your most recent sensor glucose reading is at or above the High Alert setting. Pump will notify with 2 long vibrations and re-notify every 5 minutes until acknowledged or your sensor glucose value drops below the Alert level, and again if you have turned on the repeat feature with 1 sequence of 2 notes or 2 long vibrations. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Check your cartridge, tubing, and site, and test your BG. Treat your high sensor glucose as necessary.
CGM Low Alert	Your most recent sensor glucose reading is at or below the Low Alert setting. Pump will notify with 3 long vibrations and re-notify every 5 minutes until acknowledged or your sensor glucose value drops below the Alert level, and again if you have turned on the repeat feature with 1 sequence of 3 notes or 3 long vibrations. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Test your BG and eat carbs if necessary.

Alerts and Errors	Explanation
CGM Fixed Low Alert	Your most recent sensor glucose reading is at or below 55 mg/dL. Pump will notify with 4 long vibrations and re-notify as follows: » Every 5 minutes until acknowledged or your sensor glucose value goes above 55 mg/dL. » If your pump and smartphone are out of range from each other, only the pump will re-notify you every 5 seconds until acknowledged or your sensor glucose value goes above 55 mg/dL. » Additionally, 30 minutes after each acknowledgment until your sensor glucose value goes above 55 mg/dL. Re-notification will be 1 sequence of 4 notes or 4 long vibrations. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Test your BG and eat carbs if necessary.
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 long vibrations and re-notify every 5 minutes with 1 sequence of 2 notes or 2 long vibrations until acknowledged. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Check your cartridge, tubing, and site, and test your BG. Treat your high sensor glucose as necessary, and continue to monitor your BG.
CGM Rapid Rise Alert	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 long vibrations and re-notify every 5 minutes with 1 sequence of 2 notes or 2 long vibrations until acknowledged. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Check your cartridge, tubing, and site, and test your BG. Treat your high sensor glucose as necessary, and continue to monitor your BG.
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 long vibrations and re-notify every 5 minutes with 1 sequence of 3 notes or 3 long vibrations. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Test your BG and eat carbs if necessary. Continue to monitor your BG.
CGM Rapid Fall Alert	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 long vibrations and re-notify every 5 minutes with 1 sequence of 3 notes or 3 long vibrations. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Test your BG and eat carbs if necessary. Continue to monitor your BG.

Alerts and Errors	Explanation
Unknown Sensor Glucose Reading	The sensor is sending sensor glucose readings that the system does not understand, or the pump and the Tandem Mobi mobile app are disconnected. You will not receive sensor glucose readings. Only notifies on Tandem Mobi Mobile app screen. Three dashes will remain on the screen until a new sensor glucose reading is received. If none are received after 20 minutes, the CGM Unavailable Alert will Trigger. The pump will not notify you. To respond, wait 30 minutes for more information from the system. **DO NOT** enter BG values for calibration. The system will not use them in this error state.
Out of Range Alert	The CGM and pump are not communicating. The pump will not receive sensor glucose readings, the Tandem Mobi mobile app will not display the sensor glucose readings, and Control-IQ+ technology is not able to predict sensor glucose levels or adjust insulin delivery. Pump will notify with 1 long vibration and re-notify every 5 minutes until the CGM and pump are back in range with 1 sequence of 1 note or 1 long vibration. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Move the CGM and pump closer together, or remove the obstruction between them.
Low Transmitter Battery Alert – Dexcom G6 Only	Transmitter battery is low. Pump will notify with 1 long vibration and re-notify every 5 minutes with 1 sequence of 1 note or 1 long vibration until acknowledged. Alert will also notify you as battery life is reduced. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Consider replacing the transmitter next time you start a new sensor session.
Transmitter Expired Alert – Dexcom G6 Only	Transmitter battery has expired. Pump will notify with 1 long vibration and re-notify every 5 minutes with 1 sequence of 1 note or 1 long vibration until acknowledged. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Replace the transmitter.
Transmitter Error – Dexcom G6 Only	The transmitter has failed and the CGM session has stopped. Pump will notify with 1 long vibration and re-notify every 5 minutes with 1 sequence of 1 note or 1 long vibration. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. If the transmitter ID is correct, is in range, and is not paired with a Dexcom receiver, replace the transmitter.
Failed Sensor Error	The sensor is not working properly and the CGM session has stopped. Pump will notify with 1 long vibration and re-notify every 5 minutes with 1 sequence of 1 note or 1 long vibration. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Replace sensor and begin a new CGM session.

Alerts and Errors	Explanation
Failed/Incompatible Sensor Alert – Dexcom G7 Only	The Dexcom G7 CGM you are attempting to pair is not compatible with your pump. Pump will notify with 1 beep or 1 vibration and re-notify every 5 minutes until confirmed. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Contact Dexcom customer support.
Invalid Pairing Code – Dexcom G7 Only	Your Dexcom G7 CGM is unable to pair with the Mobi pump for one of the following reasons: » The Dexcom G7 was already paired to a different pump or a Dexcom G7 receiver. » The wrong pairing code was entered. » The Dexcom G7 sensor and pump connection was disrupted. Pump will notify with 1 beep or 1 vibration then re-notify every 5 minutes until acknowledged. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Then, unpair the Dexcom G7 from a different pump or a Dexcom G7 receiver. See Section 4.1 Transferring a Sensor Session to the Tandem Mobi System. » Return to the *Dexcom G7* screen, stop the sensor session, and re-enter the correct pairing code. » Move the pump and CGM within 20 feet (6 meters) of each other.
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 and re-notify with 1 vibration or 1 beep every 5 minutes until acknowledged. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Relocate to an area with fewer sensors to attempt pairing again.
CGM Error – Dexcom G7 Only	Your Dexcom G7 CGM sensor is not working properly. The CGM session has stopped and the CGM can no longer be used. Pump will notify with 1 vibration and re-notify every 5 minutes until acknowledged. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Contact Customer Technical Support.
CGM Unavailable	Your CGM session is still active, but the pump is receiving invalid CGM readings. Pump will notify with 2 long vibrations and re-notify with 1 sequence of 2 notes or 2 long vibrations every 5 minutes. If the condition persists for 3 hours, the Failed Sensor alert will be displayed. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. If no sensor readings continue for more than three hours, contact Dexcom Customer Support.

Alerts and Errors	Explanation
CGM Error	The pump Bluetooth hardware is not working. Pump will notify with 1 vibration and re-notify with 1 vibration or 1 beep every 5 minutes until acknowledged. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Contact Customer Technical Support.

5.10 Control-IQ+ Technology Alerts

Alarm	Explanation
Out of Range Alert – Control-IQ+ Technology Off	The CGM and pump are not communicating. The pump will not receive sensor glucose readings, the Tandem Mobi mobile app will not display the sensor glucose readings, and Control-IQ+ technology is not able to predict sensor glucose levels or adjust insulin delivery. Pump will notify with 1 long vibration and re-notify every 5 minutes with 1 sequence of 1 note or 1 long vibration, if the CGM and pump remain out of range. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Move the CGM and pump closer together, or remove the obstruction between them.
Out of Range Alert – Control-IQ+ Technology On	Control-IQ+ technology is turned on, but the CGM and pump are not communicating. The pump will not receive sensor glucose readings, and the Tandem Mobi mobile app will not display the sensor glucose readings. Control-IQ+ technology will continue to adjust basal rates and deliver automatic correction boluses for the first 20 minutes that the CGM and pump are out of range. Control-IQ+ technology will resume automatic insulin delivery once the CGM and pump are back within range. Pump will notify with 1 long vibration and re-notify every 5 minutes with 1 sequence of 1 note or 1 long vibration, if the CGM and pump remain out of range. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Move the CGM and pump closer together, or remove the obstruction between them.

Alarm	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 on, in the next 15 minutes. Pump will notify with 2 sequences of 3 notes or 2 vibrations and re-notify every 5 minutes until acknowledged, and continue to alert every 2 hours if the issue persists. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Eat carbs and test your BG.
Control-IQ High Alert	Control-IQ+ technology has three hours of CGM data 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 sequences of 3 notes or 2 vibrations and re-notify every 10 minutes until acknowledged, and continue to alert every 2 hours if the issue persists. Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Check your cartridge, tubing, and sit, and test your BG. Treat your high sensor glucose as necessary.
Max Insulin Alert	The pump has delivered the maximum allowable 2 hour insulin amount based on your Total Daily Insulin setting. You see this alert when Control-IQ+ technology has delivered 50% of your Total Daily Insulin (through basal and/or bolus deliveries) over the previous rolling 2 hour window, and detects this condition for 20 minutes in a row. Control-IQ+ technology will suspend insulin delivery for a minimum of 5 minutes, and then resume insulin delivery once the condition is no longer detected. Pump will notify with 2 sequences of 3 notes or 2 vibrations and re-notify every 5 minutes until acknowledged, Both lights will blink yellow twice in row, turn off, and repeat 5 times. To respond, tap on or slide the alert message left. Tap **Dismiss**. Check your Total Daily Insulin settings by tapping **Settings**, **Pump**, **Control-IQ** to ensure they are correct.

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CHAPTER 6

Disconnected States

6.1 Disconnection Between Pump and Smartphone

When any of the connections between the pump and your smartphone shown in the diagram in Section 2.11 Connection Between the Tandem Mobi Mobile App and the Tandem Mobi Insulin Pump become disconnected, some information may no longer be displayed on the Tandem Mobi mobile app, including pump battery level, insulin level, Insulin On Board (IOB), pump history, and estimated glucose value.

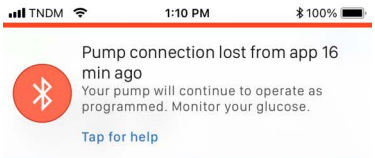
If the pump and smartphone become disconnected during the Loading Cartridge or Fill Tubing process, insulin delivery will be stopped until those steps are complete. See Section 7.1 Cartridge Instructions for Use and Section 7.2 Filling Tubing.

The *Bolus* screen is also inaccessible when disconnected, however, if enabled previously, the **Pump** button that is located on the pump may still be used to deliver a Quick Bolus. See Section 9.8 Quick Bolus on how to setup and deliver a Quick Bolus.

Tapping **Bolus** on the *Navigation* bar generates a *Bolus Unavailable* alert as shown in the following example.

Talk with your healthcare provider to set up an alternate bolus delivery plan if your smartphone is not available and the Quick Bolus feature is not enabled.

While in a disconnection state, when your smartphone and the pump are not communicating, a *Pump connection lost* notification banner will appear at the top of the Tandem Mobi mobile app *Dashboard* screen. This notification will indicate how much time has lapsed since your pump disconnected from your smartphone. Your insulin pump will continue to deliver therapy as intended, receive glucose values if paired to a CGM, and all pump alerts, alarms, reminders, and malfunctions will annunciate on your pump even when disconnected from your smartphone.



The *Notifications* screen will also display this alert, but you will not receive any new notifications on the Tandem Mobi mobile app until the pump reconnects.

You will also see a gray shaded area on the graph since no data can be displayed when the connection is lost.

The Tandem Mobi mobile app also connects with the Tandem Source platform to automatically upload data and receive important notifications.

Make sure your Tandem Mobi mobile app can connect to the Internet via your smartphone and app settings.

6.2 Reconnect Bluetooth Connection

When you see the *Pump connection lost* notification banner:

1. Make sure that your pump and smartphone are within five feet of one another and without any obstruction between the two (including body parts).

2. Confirm that Bluetooth technology is enabled on your smartphone.

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

3. Close or force stop the Tandem Mobi mobile app.

4. Open the Tandem Mobi mobile app.

5. If your connection is lost again, disable your smartphone's Bluetooth connection.

6. Enable your smartphone's Bluetooth connection.

7. If your connection is lost again, sign out of your Tandem Source account.

8. Pair your smartphone with your pump as described in Section 2.13 Pairing the Tandem Mobi Mobile App with Your Pump.

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

6.3 Restart the Tandem Mobi Mobile App

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

For iOS devices:

1. Double-tap the Home button on your smartphone, or swipe up from the bottom of the touchscreen and hold.

2. Find the Tandem Mobi mobile app and swipe up to close or force stop.

3. Reopen the Tandem Mobi mobile app.

For Android devices:

1. Open your smartphone's Settings menu.

2. Open your smartphone's application manager.

3. Tap **Tandem Mobi**. You may need to scroll down your list of applications to locate it among your apps.

4. Tap **Force Stop**.

5. Reopen the Tandem Mobi mobile app.

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

6.4 Using the Pump Without the Tandem Mobi Mobile App

Once setup is complete, the Tandem Mobi insulin pump is designed to continue delivering insulin as programmed when disconnected from your smartphone. The active Personal Profile will remain in effect as well as active Temp Rates or boluses for their programmed duration. If the Quick Bolus function is turned on, you can deliver a standard bolus without the Tandem Mobi mobile app. See Section 9.8 Quick Bolus for more information. The pump status lights may be used to check your pump status (see Section 2.2 Pump Status Light Colors) and, if enabled, the Snooze feature will remain available (see Section 3.7 Enable and Set Snooze) when disconnected from your smartphone.

The pump will also continue to receive sensor glucose readings from a CGM.

Pump alerts, alarms, reminders, and malfunctions will annunciate even when disconnected from your smartphone. See Chapter 5 Reminders, Alerts, and Alarms for more information.

6.5 Using the Tandem Mobi Mobile App Without the Pump

The Tandem Mobi mobile app is required to adjust insulin delivery, view information about alerts, alarms, reminders, and malfunctions, change and load a cartridge, and to adjust pump settings.

When the smartphone and pump are disconnected, the sound setting for CGM Fixed Low alert will automatically be set to HypoRepeat. See Section 5.9 CGM Alerts and Errors for more information.

If turned on, Control-IQ+ technology settings will also remain in effect as long as a CGM sensor session remains active.

Any compatible CGM pairs directly with the Tandem Mobi insulin pump. This allows the pump to continue receiving sensor glucose readings in the event that your smartphone with the Tandem Mobi mobile app is out of range from the pump.

If you cannot find your pump, you can use the Tandem Mobi mobile app to send a signal to your pump. The signal will cause your pump to beep two times and then vibrate two times so that you are able to locate it. This signal is also helpful when two or more pumps are in the same area. The signal can be used to identify your pump from other pumps nearby. To find or identify your pump:

1. From the *Navigation* bar, tap **Settings**.
2. Tap **App**.
3. Tap **Paired Pump**.
4. Tap **Play Sound**. Keep tapping until you locate the pump.

CHAPTER 7

Loading Cartridge

7.1 Cartridge Instructions for Use

For complete cartridge labeling, consult the cartridge instructions for use included in the Tandem Mobi™ cartridge box.

Filling and Loading a Cartridge

To prepare, make sure you have the following items:

- 1 unopened cartridge
- 2.0 mL syringe and fill needle
- 1 vial of room temperature compatible insulin, listed in Section 1.2 Compatible Insulins
- Alcohol prep swap
- 1 new infusion set
- Infusion set Instructions for Use (IFU), found in infusion set product box

Before you begin:

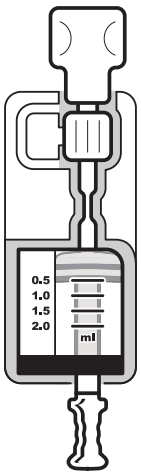
1. Wash your hands with soap and water.
2. Clean the top of the insulin vial with an alcohol prep swab.
3. Inspect all packaging and materials for signs of damage before using. Discard any damaged materials.
4. Open the Tandem Mobi mobile app, and from the *Navigation* bar, tap **Actions**, then **Load Cartridge**.
5. Tap **How to fill a cartridge** to view a guided walk-through on how to fill the Tandem Mobi cartridge.

NOTE

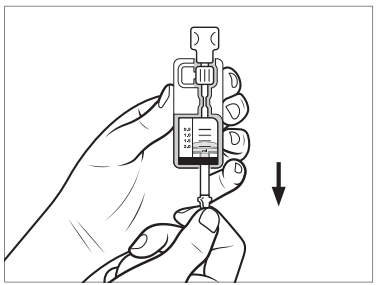
Control-IQ+™ technology will continue to make calculations based on CGM values while the cartridge is being loaded. Since there is no insulin delivered during the cartridge load process, there will be no actual Basal Rate adjustments until the cartridge is filled and loaded back onto the pump. Control-IQ+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

Prepare the Cartridge

1. Remove the cartridge set from its sterile packaging.



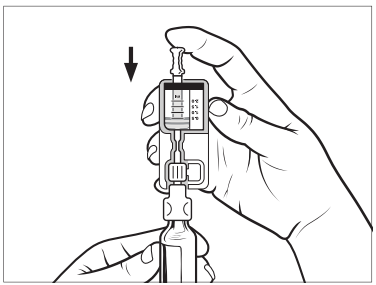
2. Pull the fill rod down completely and then push it back up to force the air out of the cartridge.



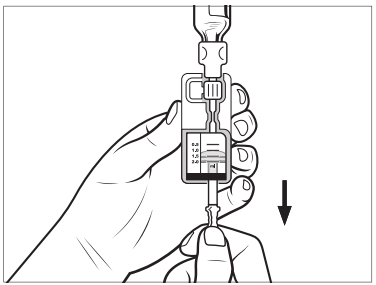
3. Pull the fill rod down to the desired volume. The top ring on the plunger should align with the desired volume marker.

Fill the Cartridge

1. With the insulin vial upright and on a flat surface, push the vial adapter down and onto the vial.
2. Push the fill rod down to force air from the cartridge into the vial and maintain pressure on the fill rod.



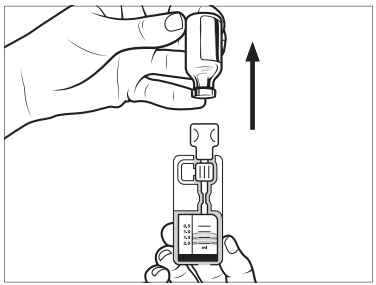
3. Turn the set with the vial still secured upside down, and slowly release the fill rod. Insulin may begin to flow from the vial into the cartridge.
4. Slowly pull back the fill rod to the desired insulin volume.



NOTE

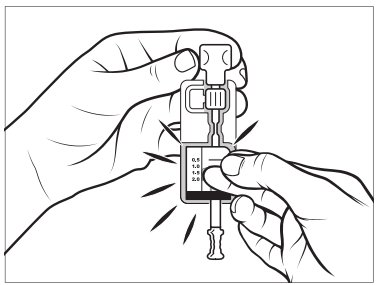
There must be at least 30 units of insulin remaining in the cartridge once the tubing is filled.

5. Pull the vial out from the vial adapter.



Inspect the Cartridge for Air

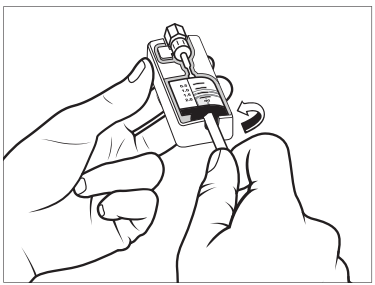
1. Check all sides of the cartridge for air bubbles.
2. Hold the cartridge set completely upright and tap so that any air bubbles rise to the top.



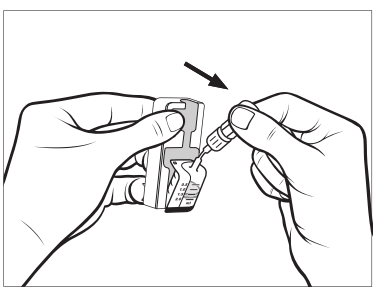
3. Slowly push the fill rod upwards, forcing any air bubbles out of the cartridge.
4. Repeat steps 1 – 3 as needed until no air bubbles are present.

Remove Cartridge From Set

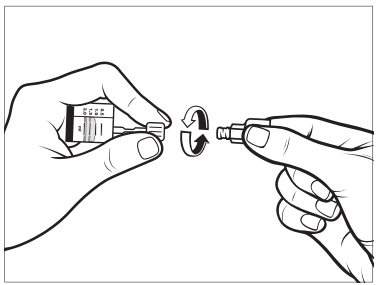
1. Unscrew the fill rod counterclockwise to remove it from the cartridge.



2. Press the release tab and pull the vial adapter forward to remove the cartridge from the set.



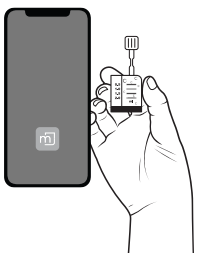
3. Unscrew the vial adapter counterclockwise to remove it from the t:lock™ connector.



4. Dispose of used needles, cartridges, set components, and infusion sets properly and follow the instructions from local regulations.

Open the Tandem Mobi Mobile App and Follow Instructions for Loading the New Cartridge

1. Open the Tandem Mobi mobile app on your smartphone.

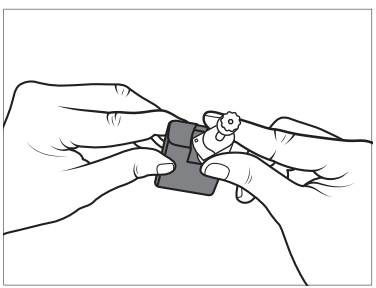


2. From the *Navigation* bar, tap **Actions**.
3. Tap **Load Cartridge**.
4. Tap **Change Cartridge**.
5. A screen will display to notify you that all insulin deliveries will be stopped. Tap **Yes** to continue. This screen does not appear if you have not actively started pumping.
6. Disconnect the infusion set from your body and tap **Continue**.

✓ *Preparing for Cartridge* screen is displayed.

✓ The pump status lights blink blue in an alternating pattern.

7. When prompted, remove the empty cartridge from the pump by rotating it counterclockwise. Place the filled cartridge on the pump and rotate clockwise until it clicks into place.



8. Tap **Continue** when the new cartridge has been placed.

✓ *Cartridge Changed* screen is displayed.

✓ The pump status lights blink with two blue lights.

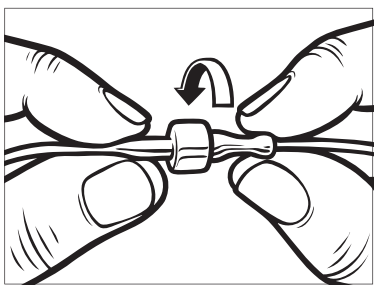
✓ After completing the cartridge change, the Tandem Mobi mobile app will automatically prompt you to fill the tubing.

7.2 Filling Tubing

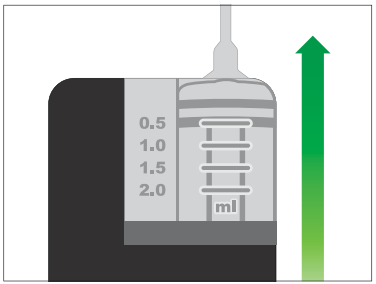
To fill the tubing without changing the cartridge, from the *Navigation* bar, tap **Actions**, tap **Load Cartridge**, tap **Fill Tubing**.

- Tap **Fill** if you did not load a new cartridge and want to continue with filling the tubing.
- Tap **New** if you loaded a new cartridge.

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



5. Hold the pump completely upright to ensure any air in the cartridge will be dispelled first. The t:lock connector should be on top.



6. Tap **Continue** on the Tandem Mobi mobile app.
7. Press and hold the **Pump** button to start filling the tubing with insulin.

✓ *Filling* screen is displayed.

✓ The pump status lights blink blue in an alternating pattern

8. Keep the **Pump** button pressed down and the pump upright until you see drops of insulin at the end of the infusion set.
9. Release the **Pump** button.

✓ The *Filling Stopped* screen is displayed.

a. Check for insulin drops at the end of your tubing.

b. Tap **No** if you do not see drops.

c. Press and hold the **Pump** button again until you see drops of insulin at the end of the tubing.

d. Tap **Yes** if you see drops of insulin at the end of your tubing.

✓ A *Release the Pump Button* prompt is displayed.

a. Release the **Pump** button.

b. Tap **OK**.

✓ The *Filling Stopped* screen is displayed.

c. Check for insulin drops at the end of your tubing.

d. Tap **No** if you do not see drops.

e. Press and hold the **Pump** button again until you see drops of insulin at the end of the tubing.

f. Tap **Yes** if you see drops of insulin at the end of your tubing.

✓ The Tandem Mobi mobile app returns to the *Load Cartridge* screen and the pump status lights blink a pattern of blue, green, and red for approximately one second.

NOTE

There must be at least 30 units of insulin remaining in the cartridge once the tubing is filled.

After tubing fill is complete, when you return to the *Dashboard* screen, the amount of insulin is in the cartridge is displayed in the upper right portion of the screen. You will see the following on the screen:

Each bar on the insulin indicator represents 20% of the total cartridge volume or approximately 40 units of insulin per bar.

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

7.3 Filling Cannula

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

If you already filled tubing previously, and only need to fill the cannula, from the *Navigation* bar, tap **Actions**, tap **Load Cartridge**, tap **Fill Cannula**.

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

1. Tap **Fill Cannula**.
2. Tap the current *Fill Amount* field.

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

3. Enter the amount needed for cannula fill.
   - See your infusion set instructions for use for proper cannula fill amount.
   - Using the on-screen keyboard enter the fill amount needed as a value between 0.1 to 1.0 unit, then tap **Done**.
4. Tap **Start**.

✓ The *Filling Cannula* screen is displayed.

✓ The pump status lights blink blue in an alternating pattern.

✓ After fill is complete, the *Cannula Filled* screen is displayed.

✓ The Tandem Mobi mobile app will return to the *Load Cartridge* screen if the Site Reminder is turned off.

5. Tap **Done** in the upper left corner to go back to the *Actions* screen in order to resume insulin if finished. Or tap **Site Reminder** to set reminder. If Site Reminder is on, the pump will automatically display the *Site Reminder* screen. See Section 7.4 Setting Site Reminder.

7.4 Setting Site Reminder

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

To set the Site Reminder without filling the cannula, from the *Navigation* bar, tap **Actions**, tap **Load Cartridge**, tap **Site Reminder** then follow the instructions below.

1. Tap the toggle next to the **Site Reminder** text to turn the feature on or off.
2. Tap **Remind Me In**. Using the on-screen number picker, select the number of days (1 to 3). Tap **Done**.

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

3. Tap **Remind Me At**. Using the on-screen number picker, select the time (hour, minutes, and time of day) that you would like to be reminded. Tap **Done**.
4. Verify Site Reminder is set correctly and tap **Save**.

✓ A *Site Reminder setting saved* banner is displayed at the top of the Tandem Mobi mobile app.

✓ *Load Cartridge* screen is displayed.

CHAPTER 8

Infusion Sets

8.1 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.

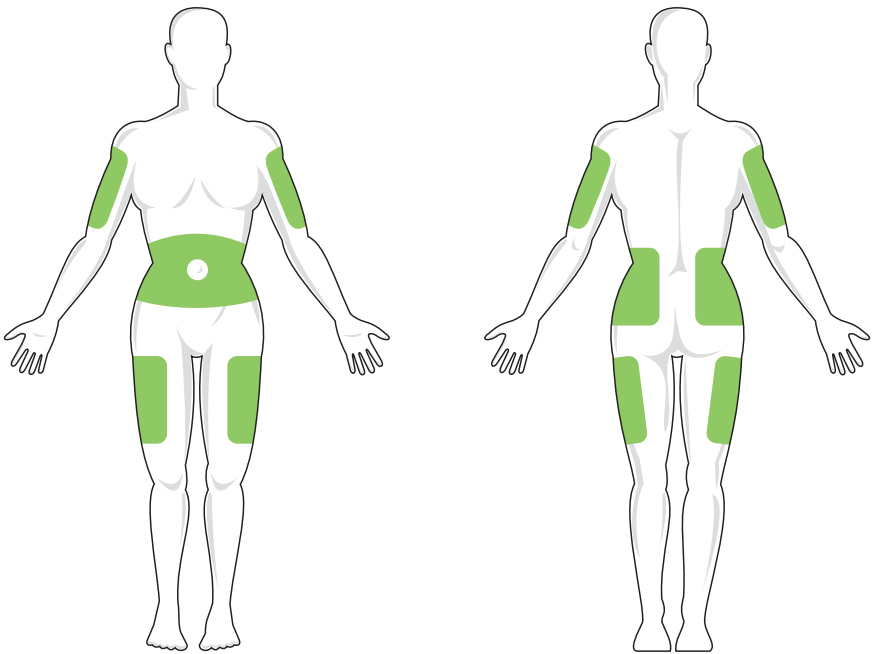
Site Rotation

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

Keep it Clean

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

Areas of Body for Infusion Set Insertion



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CHAPTER 9

Delivering Boluses

9.1 Overview

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

- A bolus can be a minimum of 0.05 units and a maximum of 25 units.
- If Carbs is turned on in your active Personal Profile, you will enter grams of carbohydrate and the bolus will be calculated using your Carb Ratio.
- If you are not using Control-IQ+ technology and Carbs is turned off in your active Personal Profile, you will enter units of insulin to request the bolus.

You can initiate a bolus when the following three things are all true:

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

9.2 Correction Bolus Calculation

Once the pump knows your glucose value, either from the CGM or from manual entry, it will determine whether to recommend that a correction bolus to be added to any other bolus requested on the *Bolus* screen. The pump can receive your glucose value from manual entry into the Tandem Mobi mobile app or from 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 Tandem Mobi insulin pump can automatically use CGM readings in the bolus calculator when Control-IQ+ technology is on 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 CGM with your BG meter, you should follow the instructions to calibrate your 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:

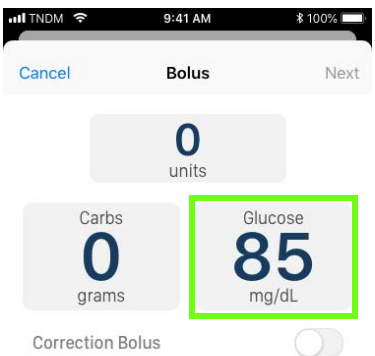
- Control-IQ+ technology is turned on and available
- A CGM session is active
- A CGM value is present
- A CGM trend arrow is available on the *Dashboard* screen

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:

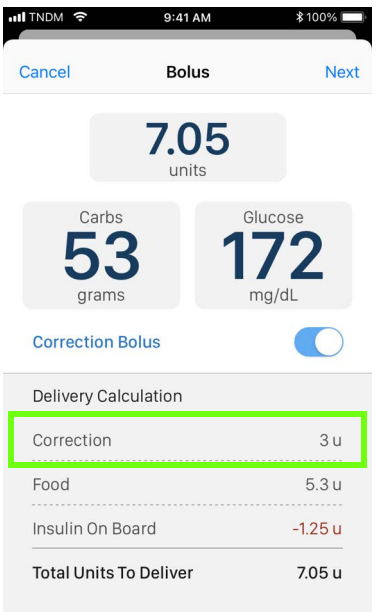
1. Tap the glucose value from the *Glucose* field.



2. Using the on-screen keyboard, enter your BG value and tap **Done**.

Above Target

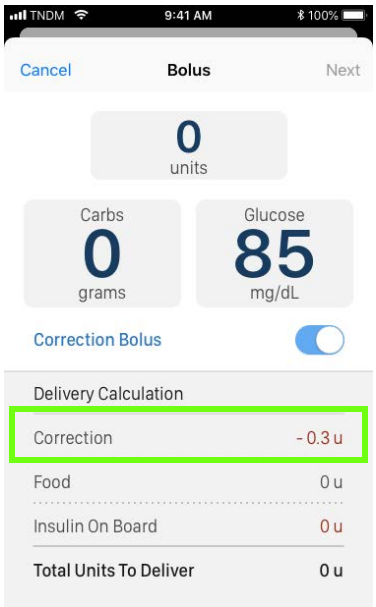
If your BG or sensor glucose value is above your Target BG, the pump displays information in the *Delivery Calculation* portion of the *Bolus* screen. A correction bolus will be added to any other bolus you request.



- To accept the correction bolus tap **Next** in the upper right-hand corner.
- To decline the correction bolus, tap the toggle above *Delivery Calculation* off. Then, tap **Next** in the upper right-hand corner.
- To decline the bolus entirely, tap **Cancel** in the upper left-hand corner to return to the *Dashboard* screen.

Below Target

If your BG or sensor glucose value is below your Target BG, the pump displays information in the *Delivery Calculation* portion of the *Bolus* screen. If your BG is below your Target BG, but greater than or equal to 70 mg/dL, a prompt will appear to confirm a reverse correction is needed. If your BG is less than 70 mg/dL, a reverse correction bolus will automatically be added to any other bolus you request.



- To accept the correction bolus tap **Next** in the upper right-hand corner.
- To decline the correction bolus, tap **Cancel** in the upper left-hand corner to return to the *Dashboard* screen.

Within Target

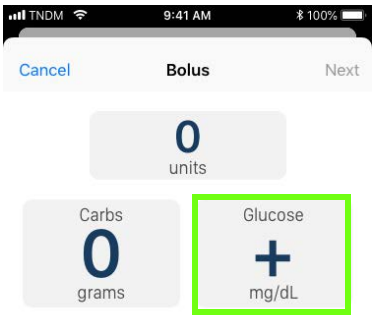
If your BG or sensor glucose value is the same value as your Target BG, no *Correction Bolus* screen is displayed.

BG Value Manual Entry

If your sensor glucose value was not auto-populated on the *Bolus* screen based on the conditions needed for that feature, you will need to enter your BG value into the Tandem Mobi mobile app manually. The Tandem Mobi mobile app displays information in the *Delivery Calculation* portion of the *Bolus* screen, if appropriate, after you manually enter your BG value on the *Bolus* screen. Manually enter your BG value as follows:

1. From the *Navigation* bar, tap **Bolus**.

2. Tap **Glucose**.

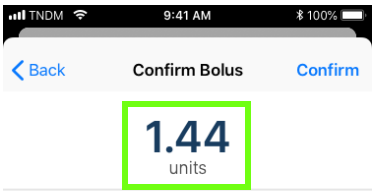


3. Using the on-screen keyboard, enter your BG value and tap **Done**. Once **Done** is tapped, the BG value is saved in your pump history whether or not a bolus is delivered.

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

9.3 Bolus Override

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



9.4 Food Bolus Using Units

1. From the *Navigation* bar, tap **Bolus**.

2. Tap **0 units** on the left side of the screen.

3. Using the on-screen keyboard enter units of insulin to be delivered, then tap **Done** or ✔.

4. Check that the units of insulin for your meal are entered correctly.

9.5 Food Bolus Using Grams

1. From the *Navigation* bar, tap **Bolus**.

2. Tap **0 grams**.

3. Using the on-screen keyboard enter grams of carb and tap **Done** or ✔.

4. Check that the grams of carb for your meal are entered correctly.

9.6 Deliver a Bolus

1. Check that the values are entered correctly.

   - Tap **Next** or → in the upper right-hand corner if entered data is correct.
   - Tap **Cancel** or X in the upper left-hand corner to go back to the *Dashboard* screen.

2. Confirm request.

   - Tap **Confirm** or ✔ in the upper right-hand if entered data is correct.
   - Tap **Back** or **Bolus** or **X** in the upper left-hand corner to go

back to make changes or view calculations.

3. Tap the *Deliver Bolus* icon.

4. Use your smartphone security feature to authorize the bolus delivery.

✓ The *Dashboard* screen is displayed.

✓ A *BOLUS IN PROGRESS* message is displayed below the graph on the *Dashboard* screen until the bolus delivery is complete.

✓ Once the bolus delivery is complete, a blue droplet icon appears on the graph, and the IOB value is updated.

9.7 Extended Bolus

The Extended Bolus feature allows you to deliver part of the bolus now and part of the bolus slowly over a period of up to 8 hours.

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 *Navigation* bar, tap **Bolus**.

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

3. Using the on-screen keyboard enter grams of carb (or units of insulin). Tap **Done** or ✔.

4. If desired, tap the *Glucose* field and using the on-screen keyboard enter a BG or override an auto-populated sensor glucose value. Tap **Done** or ✔.

5. Check that the values are entered correctly.

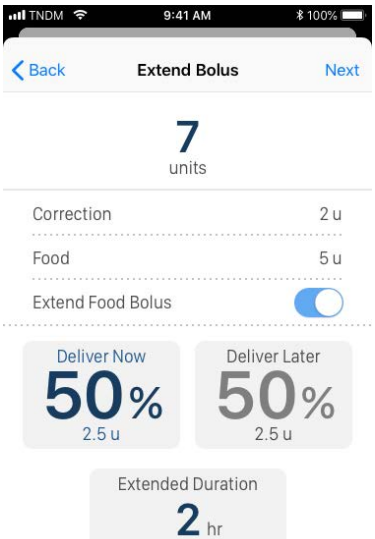
   - Tap **Next** or ⟶ in the upper right-hand corner if entered data is correct.
   - Tap **Cancel** or X in the upper left-hand corner to go back to the *Dashboard* screen.

6. Tap the toggle next to **Extend Food Bolus**.

7. The extended bolus information appears on the screen. Tap **50%** in the *Deliver Now* field to adjust the percentage of the food bolus that is to be delivered immediately.

   The percentage value for *Deliver Later* is automatically calculated by the pump. The default is 50% Deliver Now and 50% Deliver Later.

The default for the *Extended Duration* field is 2 hours.



8. Use the on-screen number picker to select the percentage of the bolus to Deliver Now and tap **Done**.

   For the Deliver Now portion, the minimum amount is 0.05 units. You may set this amount to 0 units if you would like the entire bolus to be 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.

9. Tap **2 hr** in the *Extended Duration* field.

   The maximum duration for extended bolus delivery is 8 hours.

10. Use the on-screen number picker to select the length of time the bolus is to be delivered. You can choose between 15 minutes and 8 hours in one minute increments. Tap **Done**.

11. Tap **Next**.

12. Confirm request.

    - Tap **Confirm** in the upper right-hand corner if entered data is correct.
    - Tap **Back** or **Bolus** in the upper left-hand corner to go back to make changes or view calculations.

13. Tap the *Deliver Bolus* icon.

14. Use your smartphone security feature to authorize the bolus delivery.

✓ The *Dashboard* screen is displayed.

✓ A *BOLUS IN PROGRESS* message is displayed below the graph on the *Dashboard* screen until the bolus delivery is complete.

✓ A blue droplet icon immediately appears on the graph which represents the Deliver Now portion of the extended bolus. This icon is followed by a blue shaded area which represents the Deliver Later portion of the extended bolus. The droplet will display the total units

being delivered over the entire extended bolus duration.

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.

9.8 Quick Bolus

The Quick Bolus function enables you to deliver a bolus by simply pressing the **Pump** button. If enabled, it is a way to deliver a bolus by following beep/vibration commands without navigating through or viewing the Tandem Mobi mobile app screen. Your smartphone security feature is required to change Quick Bolus settings.

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

NOTE

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

Configure Quick Bolus

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

1. From the *Navigation* bar, tap **Settings**, then tap **Pump**, and then tap **Quick Bolus Settings**.
2. Tap the toggle next to **Quick Bolus** to turn the feature on.
3. Tap **Increment Type**.
4. Select **units of insulin** or **grams of carbohydrate** from the on-screen picker.
5. Tap **Done**.
6. Tap **Increment Amount**.
7. Select the preferred increment amount from the on-screen picker.

   NOTE

   This increment is the amount of insulin delivered with each press of the **Pump** button when delivering a Quick Bolus.
8. Tap **Done**.
9. Review entered values and tap **Save**.

✓ A *Quick Bolus Settings have been saved* banner is displayed at the top of the Tandem Mobi mobile app.

Delivering a Quick Bolus

If the Quick Bolus function is turned on, you can deliver a bolus without the Tandem Mobi mobile app by pressing the **Pump** button on your pump to deliver your bolus. Quick boluses are delivered as standard boluses (there is no glucose value entry or extended bolus).

1. Press and hold the **Pump** button on your pump. Listen for two beeps (if Sound setting is set to beep) or feel for vibrations (if Sound setting is set to vibrate) on the pump.

2. Press the **Pump** button for each set 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 **Pump** button for several seconds until a confirmation beep/vibration occurs to deliver the bolus.

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

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

   You cannot exceed 20 consecutive button presses when using the Quick Bolus feature. Once you reach 20 button presses, a different tone will sound to notify you. If Quick Bolus is set to vibrate, the pump will stop vibrating in response to additional button presses to notify you.

   If you hear a different tone at any point during programming or the pump stops vibrating in response to button presses, check the Tandem Mobi mobile app screen.

✓ The pump status lights pulsate blue in an alternating pattern while the bolus is being delivered.

✓ The *BOLUS IN PROGRESS* message displays on the *Dashboard* screen.

NOTE

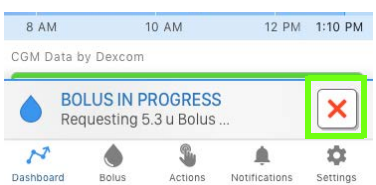
If Control-IQ+ technology is on and has adjusted insulin delivery during a Quick Bolus, the remaining Quick Bolus insulin will be delivered.

9.9 Canceling or Stopping a Bolus

Canceling a Bolus if delivery HAS NOT STARTED

Any time you request a bolus, you have 10 seconds to cancel the bolus after requesting it to completely avoid any bolus delivery.

Tap ☒ to cancel the bolus while the *Dashboard* displays the “Requesting Bolus” message. Your pump and the Tandem Mobi mobile app need to be connected in order to cancel the bolus.



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

✓ Once canceled, **Bolus** will become active again.

Stopping a Bolus if delivery of the BOLUS HAS STARTED

You are able to cancel a bolus that has already started delivery.

1. Tap ☒ to stop bolus delivery.

2. Tap **Yes**.

✓ The *BOLUS IN PROGRESS* message on the *Dashboard* screen displays an additional *Stopping Bolus...* message.

✓ A *Bolus Stopped* window appears, and the units requested and delivered are shown.

3. Tap **OK**.

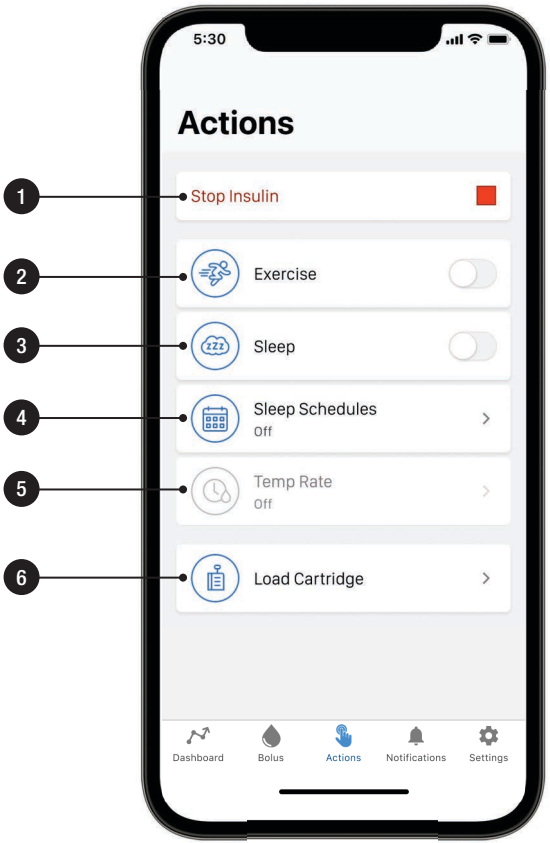
✓ A blue droplet icon appears on the graph which displays the partial amount delivered, and the IOB value is updated.

CHAPTER 10

Actions

10.1 Actions Screen

1. **Insulin Delivery:** Start, stop, and resume insulin delivery. If insulin is stopped, Resume Insulin will be displayed.
2. **Exercise:** If Control-IQ+ technology is on, start or stop Exercise.
3. **Sleep:** If Control-IQ+ technology is on, start or stop Sleep.
4. **Sleep Schedules:** If Control-IQ+ technology is on, program Sleep to start and stop at scheduled times.
5. **Temp Rate:** Program a temporary basal rate.
6. **Load Cartridge:** Change Cartridge, Fill Tubing, Fill Cannula, and Site Reminder.



10.2 Insulin Delivery

Starting Insulin Delivery

Insulin delivery starts once you have a Personal Profile configured and activated. Your smartphone security feature is required to start insulin delivery. See Chapter 3 Pump Settings for instructions on creating, configuring, and activating a Personal Profile.

Stopping Insulin Delivery

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

1. From the *Navigation* bar, tap **Actions**.
2. Tap **Stop Insulin** ■.
3. Tap **Yes**.

✓ An *All deliveries have been stopped* banner appears at the top of the Tandem Mobi™ mobile app. From the *Dashboard* screen, a message displays the status *All Deliveries Stopped!* under the sensor glucose value. A red exclamation mark icon appears next to this message and also in the upper right portion of the Tandem Mobi mobile app, next to the insulin level indicator.

NOTE

A paired smartphone with the Tandem Mobi mobile app is required to start or stop insulin delivery. If your smartphone becomes disconnected from your pump for an extended period, or is not accessible to you for any reason, disconnect your infusion set from your body to stop insulin delivery.

Resuming Insulin Delivery

1. From the *Navigation* bar, tap **Actions**.
2. Tap **Resume Insulin** ▶.
3. Tap **Yes**.

✓ An *Insulin has been resumed* banner appears at the top of the Tandem Mobi mobile app.

10.3 Exercise, Sleep, and Sleep Schedules

Please see Chapter 29 Configuring and Using Control-IQ+ Technology.

10.4 Starting a Temporary Basal Rate

- A Temp Rate changes current basal rate by percentage, for a set period of time.
- Default is 100% (current basal rate) and 15 minutes.
- Can be set from 0% to 250% in 1% increments.
- Duration can be set 15 minutes to 72 hours, in 1 minute increments
- If the rate is set below the minimum Basal Rate of 0.1 units/hour, the pump will be automatically set to the minimum allowable rate.

- If the rate set is more than the Basal Rate defined in your Pump Settings, or above 15 units/hour, the Temp Rate will automatically be set to the maximum allowable rate.

1. From the *Navigation* bar, tap **Actions**.
2. Tap **Temp Rate**.
3. Tap **Temp Rate** again.
4. Using the on-screen number picker enter desired percentage. The current rate is 100%. An increase is greater than 100% and decrease is less than 100%.
5. Tap **Done**.
6. Tap **Duration**.
7. Using the on-screen number picker enter desired length of time in hours and minutes for the Temp Rate.
8. Tap **Done**.

   Below the Temp Rate settings, the affected Time Segments and adjusted basal rates are displayed.
9. Verify settings and tap **Start**.

✓ The *Temp Rate started* banner is displayed at the top of the Tandem Mobi mobile app.

✓ Tap **Dashboard** on the *Navigation* bar to view the *Dashboard* screen and confirm the icon indicating a Temp Rate is active.

- A T in an yellow box means a Temp Rate is active.
- A T in a red box means a Temp Rate of 0 units/hour is active.
- The basal rate delivery bar on the bottom of the graph will be yellow.

NOTE

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

10.5 Stopping a Temp Rate

To stop an active Temp Rate:

1. From the *Navigation* bar, tap **Actions**.
2. Tap **Temp Rate**.
3. At the bottom of the *Temp Rate* screen, tap **Stop**.
4. Tap **Yes**.

✓ The *Temp Rate stopped* banner is displayed at the top of the Tandem Mobi mobile app.

Tap **Dashboard** on the *Navigation* bar to view the *Dashboard* screen and confirm the icon indicating a Temp Rate is removed.

10.6 Load Cartridge

Please see Section 7.1 Cartridge Instructions for Use.

CHAPTER 11

Control-IQ+ Technology

11.1 Control-IQ+ Technology Overview

Control-IQ+™ technology is a feature of the Tandem Mobi™ pump that automatically adjusts insulin dosing in response to readings from a CGM. The pump can be used with or without Control-IQ+ technology turned on. The following sections describe how Control-IQ+ technology works and how it responds to CGM values while you are awake, sleeping, and exercising.

Control-IQ+ technology responds to the actual CGM readings as well as predicts CGM values 30 minutes in the future. Insulin delivery is automatically adjusted based on the predicted CGM value, your active Personal Profile, and whether or not a Control-IQ+ technology activity is on.

NOTE

Once you have used Control-IQ+ technology, it will maintain and use the actual total insulin delivered, including the adjustments made to basal and all types of boluses while using the pump. It is important to update the Total Daily Insulin setting in the *Control-IQ* menu when you visit your healthcare provider. This value is used for the 2-hour maximum insulin alert.

Personal Profile Basal Rate Delivery

When the predicted CGM value is within the treatment value range (112.5–160 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 3 Pump Settings for more information about Personal Profiles.

11.2 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

11.3 Set Weight

1. Tap the **Weight Units** field on the *Control-IQ* screen.
2. Tap the **Weight** field.
3. Using the on-screen keyboard, enter the accurate weight value. Weight can be set from a minimum of 20 pounds (9 kilograms) to a maximum of 440 pounds (200 kilograms).
4. Tap **Done** to close the on-screen keyboard.

11.4 Set Total Daily Insulin

An estimate of Total Daily Insulin should be entered. Include all types of insulin (basal and bolus) delivered in a 24-hour period. Consult your healthcare

provider if you need assistance estimating your insulin requirements.

1. Tap the **Total Daily Insulin** field on the *Control-IQ* screen.
2. Using the on-screen keyboard, enter the accurate total daily insulin value. Total Daily Insulin can be set from a minimum of 5 units to a maximum 200 units.
3. Tap **Done** to close the on-screen keyboard.
4. Tap **Save**.

✓ A *Control-IQ saved* banner is displayed at the top of the Tandem Mobi™ mobile app.

5. When you are done setting up Control-IQ+ technology, tap **Dashboard** on the *Navigation* bar.

11.5 Turn Control-IQ+ Technology On or Off

To turn on:

1. From the *Navigation* bar, tap **Settings**.
2. Tap **Pump**.
3. Tap **Control-IQ**.
4. To turn Control-IQ+ technology on, tap the toggle next to **Control-IQ**.

To turn off:

1. To turn Control-IQ+ technology off, tap the toggle next to **Control-IQ**.
2. Tap **Yes** to turn Control-IQ+ technology off.
3. Tap **Save.**

✓ A *Control-IQ saved* banner is displayed at the top of the Tandem Mobi mobile app.

Control-IQ+ technology cannot be turned on unless Weight and Total Daily Insulin are entered. The Weight value is used by Control-IQ+ technology to maintain safe and effective increases and decreases in insulin dose. The Total Daily Insulin value is used by Control-IQ+ technology to calculate the maximum insulin delivery rate and to maintain a safe and effective increase in insulin dose.

These values may be updated when you visit your healthcare provider.

11.6 Maximum Insulin Delivery

When Control-IQ+ technology predicts that your sensor glucose value will be above a preset treatment value (160 mg/dL) 30 minutes in the future, but the maximum rate of insulin delivery has been reached, Control-IQ+ technology stops increasing the insulin delivery rate. The maximum insulin delivery rate is a calculated value that is dependent on an individual's Correction Factor setting (found in the active Personal Profile), the Total Daily Insulin estimated by Control-IQ+ technology based on actual total daily insulin values, and the current insulin on board (IOB).

11.7 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:

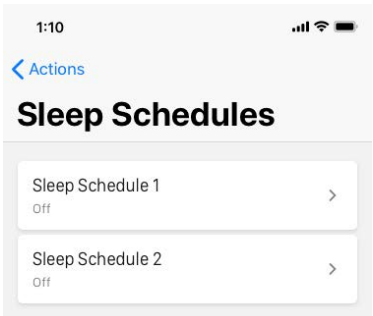
				zzz
Delivers	AutoBolus	180	180	×
Increases	Basal Insulin	160	160	120
Maintains	Profile Settings	112.5	140	112.5
Decreases	Basal Insulin	70	80	70
Stops	Basal Insulin			

11.8 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 *Navigation* bar, tap **Actions**.
2. Tap **Sleep Schedules**.
3. 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 sleep schedule you want to edit.



4. Tap the toggle next to the Sleep Schedule. More options will appear to set up the Sleep Schedule.
5. Tap **Start Time**.
6. Using the on-screen time picker, select the time (hour, minutes, and time of day) that you want the Sleep Schedule to begin.
7. Tap **Done**.
8. Tap **End Time**.
9. Using the on-screen time picker, select the time (hour, minutes, and time of day) that you want the Sleep Schedule to end.
10. Tap **Done**.
11. On the REPEAT section of the screen, tap the day of the week that you want included in the Sleep Schedule. The day that appears at the top of this list is the current day of the week.

    A blue checkmark will display next to the corresponding day of the week when it is active. To deactivate a day, tap the day of the week again to remove the checkmark.
12. When you are finished selecting the days, tap **Save**. If no days are selected, the schedule is set to off.

✓ A *Sleep Schedule saved* banner is displayed at the top of the Tandem Mobi mobile app.

13. When you are done setting up the Sleep Schedules, tap **Dashboard** on the *Navigation* bar.

11.9 Start or Stop a Sleep Schedule

Once a Sleep Schedule is configured, it is on by default when it is saved. If you have multiple Sleep Schedules configured, you can change which Sleep Schedule is on or turn them off completely.

Start a Sleep Schedule

1. From the *Navigation* bar, tap **Actions**.
2. Tap **Sleep Schedules**.
3. Tap the Sleep Schedule you want to turn on. (If no sleep schedules are configured, see Section 11.8 Schedule Sleep.)
4. Tap the toggle next to the Sleep Schedule title.
5. Tap **Save**.

Stop a Sleep Schedule

1. From the *Navigation* bar, tap **Actions**.
2. Tap **Sleep Schedules**.

   Tap the Sleep Schedule you want to turn off.
3. Tap the toggle next to the Sleep Schedule title.
4. Tap **Save**.

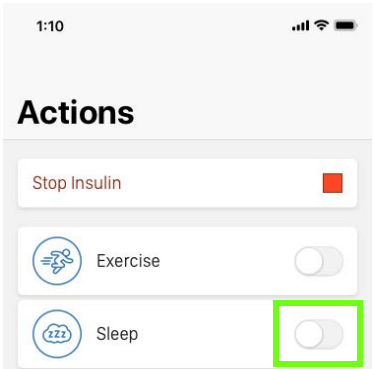
11.10 Manually Start or Stop Sleep

In addition to scheduling sleep, Sleep can be manually started and/or stopped.

Sleep time determines when Control-IQ+ technology, if started, switches to Sleep activity. Control-IQ+ technology must be on and a CGM session must be active to start Sleep.

Manually Start Sleep

1. From the *Navigation* bar, tap **Actions**.
2. Tap the toggle next to **Sleep**.



✓ A *Sleep started* banner is displayed at the top of the Tandem Mobi mobile app. The Sleep icon is displayed on the *Dashboard* screen. Sleep will automatically be stopped if Exercise is started.

Manually Stop Sleep

1. From the *Navigation* bar, tap **Actions**.
2. Tap the toggle next to **Sleep**.

✓ A *Sleep stopped* banner is displayed at the top of the Tandem Mobi mobile app. The Sleep icon is removed from the *Dashboard* screen.

11.11 Manually Stop or Start Exercise

Manually Start Exercise

1. From the *Navigation* bar, tap **Actions**.
2. Tap the toggle next to **Exercise**.

✓ An *Exercise started* banner is displayed at the top of the Tandem Mobi mobile app. The Exercise icon is displayed on the *Dashboard* screen.

Manually Stop Exercise

1. From the *Navigation* bar, tap **Actions**.
2. Tap the toggle next to **Exercise**.

✓ An *Exercise stopped* banner is displayed at the top of the Tandem Mobi mobile app. The Exercise icon is removed from the *Dashboard* screen. Exercise will automatically be stopped if Sleep in started.

11.12 Disconnecting When Using Control-IQ+ Technology

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

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CHAPTER 12

Important Safety Information

12.1 Insulin Pump Warnings

The following includes important safety information related to your Tandem Mobi™ pump and its components.

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

⚠ WARNING
DO NOT start to use your pump before you have been appropriately trained on its use by a certified trainer or through the training materials available online. 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 1.2 Compatible Insulins. Only U-100 insulin analogs listed in 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 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 Tandem Mobi 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:

- Use the pump, CGM, and all other system components in accordance with their respective instructions for use
- Test BG levels as recommended by a healthcare provider
- Demonstrate adequate carbohydrate-counting skills
- Maintain sufficient diabetes self- care skills
- See a healthcare provider(s) regularly

The user must also have adequate vision and/or hearing in order to recognize 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
Test your BG if you are unable to check your Tandem Mobi mobile app for messaging about any alert, alarm, or malfunction.

⚠ 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
DO NOT change your infusion set before bedtime or if you will not be able to test your BG 1 to 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
ALWAYS insert infusion set and connect to the pump before applying the sleeve to ensure the tubing is not stretched. Failure to follow these steps could result in crimping or dislodgement at the infusion site, which could affect the performance of the cannula. This could lead to hyperglycemia (high blood glucose).

⚠ 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 follow the load sequence on your Tandem Mobi mobile app prior to loading a new cartridge on the pump. See Section 7.1 Cartridge Instructions for Use.

⚠ WARNING
DO NOT remove a used cartridge from the pump or load a new cartridge until prompted on the Tandem Mobi mobile app. Failure to do so may result in damage to the pump or possible over or under delivery of insulin. ALWAYS

disconnect your infusion set before removing the cartridge.

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

⚠ WARNING
DO NOT disconnect the tubing connector between the cartridge tubing and the infusion set tubing while delivering insulin. 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 it onto the pump. This may result in an inaccurate display of the insulin level on the *Dashboard* screen, and an over or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING
DO NOT allow small children (either pump users or non-users) to ingest small parts, such as the 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
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 Tandem Mobi insulin 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
ONLY use accessories, cables, adapters, and chargers provided by the manufacturer. Use of third-party equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ WARNING
DO NOT place metal objects on the charging pad.

⚠ WARNING
ALWAYS inspect your cartridge for signs of damage. **ALWAYS** replace the cartridge if it is damaged and **ALWAYS** suspend insulin and disconnect your infusion site before replacing the cartridge.

⚠ WARNING
ALWAYS inspect your cartridge to ensure the cartridge is securely attached to the pump. **ALWAYS** suspend insulin and disconnect your infusion site if the cartridge rotates or is not

securely attached to the pump before adjusting the cartridge.

⚠ WARNING
AVOID excessive exposure of your cartridge when filled with insulin to direct sunlight as this may impact the effectiveness of insulin.

⚠ WARNING
DO NOT expose your pump to a magnet, such as pump cases that have a magnetic clasp or common products which include magnets such as cellphones and wireless charging cases. Exposure to magnets or products with magnets may interfere with the pump motor. Damage to the motor can impact the pump's functionality.

⚠ 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 Tandem Mobi System

Please review your smartphone manufacturer's instructions before using the Tandem Mobi 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
- Magnetic Resonance Imaging (MRI)
- 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 Mobi Mobile App Warnings

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

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

⚠ WARNING
DO NOT start to use the Tandem Mobi mobile app 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 confirm that your smartphone operating system (OS) update is compatible with the Tandem Mobi mobile app before updating your OS. If you update to an incompatible OS, you may lose the ability to adjust insulin and program your pump with the Tandem Mobi mobile app. Your pump will continue to operate as programmed. You will need to pair your pump with a compatible smartphone to be able to control the pump from your smartphone.

⚠ 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 Mobi mobile app on a smartphone that has been jailbroken or rooted,

or uses an unreleased or pre-released operating system. Only download the Tandem Mobi mobile app from Google Play™ or the App Store®. See Chapter 2 Getting to Know Your Tandem Mobi System for Tandem Mobi mobile app installation.

⚠ WARNING

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 Mobi 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 Mobi mobile app, you will not receive these alerts, alarms, or notifications on your smartphone. All alerts and alarms will continue to annunciate on the pump.

⚠ WARNING

Any time you request a bolus, you have 10 seconds to cancel the bolus after requesting it to completely avoid insulin delivery. The Tandem Mobi mobile app will display "BOLUS IN PROGRESS Requesting Bolus" during this time, and the pump status lights pulsate blue in an alternating pattern. You can cancel a bolus from the app regardless of how you requested it as long as your pump and the Tandem Mobi mobile app are connected.

⚠ WARNING

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

⚠ WARNING

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 do not see a reduction in BG after a bolus is complete, 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

The Tandem Mobi mobile app requires the use of the security feature that unlocks your smartphone to adjust insulin delivery and program the pump. ONLY users capable of independently making treatment decisions should have the ability to unlock the smartphone on which the Tandem Mobi mobile app is installed.

⚠ WARNING

For patients whose insulin administration is managed by a caregiver, it is recommended to turn off the Quick Bolus feature to avoid inadvertent bolus delivery. Inadvertent Pump button presses could result in over delivery. This can cause hypoglycemia (low BG) events. However, if your smartphone is lost or damaged, you will NOT be able to deliver a bolus using your pump. Contact your healthcare provider for an alternate insulin delivery plan if your smartphone is not available and the Quick Bolus feature is not enabled.

12.5 Mobile Tandem Device Updater Warnings

⚠ WARNING

DO NOT update your pump before reading the user guide. Incorrect use of the Mobile Tandem

Device Updater or your failure to follow the instructions, precautions and warnings in this user guide, may result in an inoperable pump or expose your pump to cybersecurity risks. If you have questions or need further clarification on the Mobile Tandem Device Updater or pump use, contact Customer Technical Support.

⚠ WARNING
COMPLETE any required training before starting to use the updated software. Failure to complete necessary training could result in serious injury or death.

⚠ WARNING
Be prepared to inject insulin with an alternative method in case you encounter any issues while updating your pump. Failure to have an alternative method of insulin delivery can lead to very high BG or Diabetic Ketoacidosis (DKA).

⚠ WARNING
CHECK your blood glucose (BG) prior to suspending delivery and be sure to treat high or low BG levels as directed by your healthcare provider prior to updating your pump.

⚠ WARNING
SUSPEND all pump insulin delivery prior to using the Mobile Tandem Device Updater.

⚠ WARNING
DO NOT update your pump while your infusion set is connected to your body.

⚠ WARNING
CONFIRM your pump's personal settings, date, time, and serial number are correct immediately after the update. Incorrect settings can result in over delivery or under delivery of insulin. Consult with your healthcare provider as needed to establish appropriate settings. Closely monitor your insulin delivery and BG following an update. Ensure your symptoms match your therapy data.

⚠ WARNING
DO NOT rely on the Insulin On Board (IOB) displayed on your pump after an update until your prior IOB has been depleted. Your IOB will be reset to zero during the update process. Since the calculated bolus amount relies on IOB, it could prompt you to deliver more insulin than needed and result in hypoglycemia. Consult with your healthcare provider for how long you need to wait after an update before you can rely on the IOB calculation.

12.6 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 water resistant and the warranty is voided.

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

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

symptoms of infection at your insulin infusion site.

⚠ PRECAUTION
ALWAYS remove all air bubbles from the pump before beginning insulin delivery. Ensure there are no air bubbles when drawing insulin into the cartridge, hold the pump upright 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
ALWAYS remove all air bubbles from the pump before beginning insulin delivery. Make sure that insulin is at room temperature before use or air bubbles could form in the cartridge. Air in the system takes space where insulin should be and can affect insulin delivery.

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

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

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

⚠ PRECAUTION
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 you can feel the pump vibrate, and see the pump status lights blinking above the Pump button when charging the pump. 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 beep will help ensure that you don't miss an alert or alarm.

⚠ PRECAUTION

ALWAYS look at the Tandem Mobi mobile app screen following confirmation of a Quick Bolus on the pump. Looking at the Tandem Mobi mobile app while you are getting familiar with the Quick Bolus feature 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

ALWAYS monitor your BG for up to four hours after dropping or hitting the pump against a hard surface. Check that the pump is working properly by pressing the **Pump** button and ensuring the LEDs turn on, or placing it on a charging pad connected to a power source and confirming that you feel the pump vibrate, see the pump status lights blinking above the **Pump** button, and by checking the Tandem Mobi mobile app. If your pump is damaged or 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

When fitted with a cartridge, newly manufactured pumps are water resistant (IP28) to a depth of 8 feet (2.4 meters) for up to 2 hours. Over time, the moisture protection capabilities of the pump may be compromised by incidental bumps, drops or other unintentional events the pump may be exposed to over time under normal use conditions. **ALWAYS** inspect your pump for damage. If there are signs of fluid entry, discontinue use of the pump and contact Customer Technical Support.

⚠ PRECAUTION

ALWAYS inspect your pump for damage or signs of fluid entry. If fluid leaks into your pump, it may cause the internal battery to overheat which may result in harm. 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

DO NOT wear or place your pump more than 12 inches (30.5 cm) above your infusion site. Doing so may result in over delivery of insulin.

⚠ 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

MONITOR your glucose levels during any significant changes in environmental temperature, pressure, and altitude as insulin delivery may be impacted. Examples may include snow skiing, driving on a mountain road, or ascending and descending in an airplane. 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

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

⚠ PRECAUTION

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

⚠ PRECAUTION

When exposed to electrostatic discharge, the operation of the pump may be affected. Temporary disruption in wireless communications accompanied by notification may be observed. The pump may indicate a malfunction if wireless communication functionality is unable to recover. See Section 5.8 Pump Malfunction for further information.

⚠ PRECAUTION

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

⚠ PRECAUTION

To prevent accidental injury, keep fingers away from the top edge of the vial adapter, as there is a needle inside.

12.7 Tandem Mobi Mobile App Precautions

⚠ PRECAUTION

DISCONTINUE use of the Tandem Mobi mobile app if your smartphone is damaged, or if a significant portion of its display is damaged or does not illuminate.

⚠ PRECAUTION

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

⚠ PRECAUTION

The Tandem Mobi 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 Mobi mobile app is lost, the Tandem Mobi mobile app will not display current insulin pump information and cannot be used to adjust insulin delivery or to program your pump. To help maintain the wireless connection between the insulin pump and the Tandem Mobi mobile app, it is recommended the smartphone running the Tandem Mobi mobile app is within five feet of the compatible insulin pump.

⚠ PRECAUTION

CHECK your pump and Tandem Mobi mobile app 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

When you force stop or quit your app, it is no longer running in the background on your smartphone. This means that you will not receive any notifications on your smartphone until you reopen your app. However, your pump will remain paired to your smartphone and insulin delivery will continue as programmed.

⚠ PRECAUTION

ALWAYS turn Zoom Mode off when using the Tandem Mobi mobile app. If your smartphone has Zoom Mode turned on, you should not use the information displayed in the Tandem Mobi mobile app to make therapy decisions.

⚠ PRECAUTION

Use of mobile devices not complying with either IEC 60601-1, 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/compatibility. You can also find this information in the Tandem Mobi mobile app from the *Settings* screen. Tap **Help**, then **App Guide**, and then choose **Smartphone Compatibility** from the index.

⚠ PRECAUTION

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

12.8 Mobile Tandem Device Updater Precautions

⚠ PRECAUTION
ONLY use the Mobile Tandem Device Updater to update your pump.

⚠ PRECAUTION
DO NOT close or force stop the Tandem Mobi mobile app during an update. Doing so could interrupt the update, and your pump may not function.

⚠ PRECAUTION
DO NOT turn off your smartphone during an update. Doing so could interrupt the update, and your pump may not function.

⚠ PRECAUTION
DO NOT disconnect from the Internet during an update. Doing so could interrupt the update, and your pump may not function.

⚠ PRECAUTION
If you had an active CGM sensor session when you started the update process, you will need to resume your current session by tapping **Settings**, **CGM**, **Start Sensor** once the update is complete. The CGM sensor session continues to be active, but you will not see your CGM trend graph until you start your CGM sensor session again.

⚠ PRECAUTION
DO NOT rely on the Max Hourly Bolus Alert for 60 minutes following an update. Your Max Hourly Bolus will be reset to zero during the update process.

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.

12.9 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
Continue to use a BG meter and test strips in order to make treatment decisions during the CGM sensor startup period.

⚠ WARNING
If a sensor session is ended, either automatically or manually, you will not receive any CGM alerts. In order to receive CGM alerts, a sensor session must be started and transmitting sensor values to the pump based on a sensor code, pairing code, or sensor calibration.

12.10 CGM Precautions

⚠ PRECAUTION

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

⚠ PRECAUTION

PAY ATTENTION to the trend information on the *Dashboard* 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 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

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 results while taking hydroxyurea could result in missed hypoglycemia alerts or errors in diabetes management, such as giving a higher dose of insulin than necessary to correct falsely high sensor glucose values. It can also result in errors when reviewing, analyzing and interpreting historical patterns for assessing glucose control. **DO NOT** use the Dexcom 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 the Dexcom G6 CGM with Your Tandem Mobi Insulin Pump

⚠ PRECAUTION

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

12.11 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 Tandem Mobi insulin pump with Control-IQ+ technology should not be used in children under the age of 2 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 based on a sensor code, pairing code, or sensor calibration.

⚠ 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 system to over deliver insulin, which can lead to severe hypoglycemia (low BG) events.

⚠ 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.

12.12 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 delivery 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 delivery.

⚠ 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

Pump Care and 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 Tandem Mobi System Symbols

Symbol	Definition
	Caution
	Refer to instruction manual/booklet
	For sale by or on the order of a physician only (U.S.)
LOT	Batch code
REF	Catalogue number
MN	Manufacturer number
#	Model Number
	Manufacturer

Symbol	Definition
	Type BF Applied Part (patient isolation, not defibrillator protected)
	Consult instructions for use or consult electronic instructions for use
	Non-ionizing electromagnetic radiation
SN	Serial number
MD	Medical device
MR	Magnetic Resonance (MR) Unsafe; keep away from magnetic resonance imaging (MRI) equipment
IP28	Ingress Protection (IP) Code
	Date of manufacture

Explanation of Tandem Mobi System Symbols (Continued)

Symbol	Definition
	Direct Current (DC) voltage
	Separate collection for waste electrical and electronic equipment
	Electric equipment designed primarily for indoor use
	IEC Class II equipment
	Wall power USB adapter
	USB cable
	Quick Reference Guide
	User guide
	Quantity

Symbol	Definition
	Regulatory Compliance Mark
	Humidity range
	Temperature range
	Keep dry
	Pump
	Wireless charging pad
	Pump case
	Adhesive sleeve

13.2 Taking Care of Your Pump

Cleaning Your Pump

- Always clean pump after it is exposed to common household items, like sunscreen and bug spray.
- Use a damp, lint free cloth with 9:1 ratio of water to dish detergent.
- 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.
- 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 or hit your pump, ensure that it is still working properly. Check that the pump status lights are working and clear, and that the cartridge and infusion set are properly in place. Check for leaks around the cartridge and at the t:lock™ 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, place the pump on the charging pad and then press and hold down the **Pump** button for 20 seconds. The pump will beep 3 times before going into storage mode. Remove the pump from the power source. Store between -4°F (-20°C) and 113°F (45°C) and at relative humidity levels between 20% and 90%.
- To bring the pump out of storage mode, place the pump on the charging pad and press the **Pump** button for 5 seconds. If the pump has been stored for an extended length of time, the battery may be drained and require charging.
- When the pump battery becomes fully depleted, pump date and time will be reset and need to be reprogrammed. Pump settings and event logs are maintained in storage mode regardless of the pump battery charge state.

Disposing of System Components

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

13.3 Lifestyle Issues and Travel for Your Pump

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.

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.

Aquatic Activities

- Your pump is water resistant to a depth of 8 feet (2.4 meters) for up to 2 hours (IP28 rating) when a cartridge is loaded, 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

⚠ PRECAUTION

MONITOR your glucose levels during any significant changes in environmental temperature, pressure, and altitude as insulin delivery may be impacted. Examples may include snow skiing, driving on a mountain road, or ascending and descending in an airplane. Changes in delivery accuracy can affect insulin delivery and cause injury.

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, for intimacy, 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 1.11 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

- Your pump has been designed to withstand common electromagnetic interference including airport metal detectors.
- The pump can be used on aircraft according to the directions provided by the operator of the aircraft. The pump is a Medical Portable Electronic Device (M-PED) which meets the RTCA/DO-160 edition G, Section 20, Category T and Section 21, Category M.
- 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.
- The Tandem Mobi mobile app requires an active Bluetooth connection to connect with your pump. If in airplane mode, make sure you keep Bluetooth enabled. Check with your airline carrier and smartphone instructions prior to travel to determine conditions for using Bluetooth technology.

13.4 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 Tandem Mobi system or your failure to follow the instructions, precautions, and warnings in this user guide may result in an inoperable pump or expose your Tandem Mobi system to cybersecurity risks.

- Keep your pump, smartphone, and Tandem Mobi mobile app in your control or on your person at all times.
- Do not share your pump's serial number or Tandem Mobi 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 Mobi system. See Section 1.4 System Description for a full system description.
- Do not use any software or third-party applications which have not been authorized by Tandem as being safe for use with your system.
- Contact Tandem's Customer Technical Support if you suspect your system may have been compromised by any cybersecurity interference or vulnerability.

The Tandem Mobi system includes security features designed to keep the system and data secure. These security features are automatic and don't require configuration. However, you should be aware of the features and their intended purpose. The security features include the following:

- Pump Software Integrity: The Tandem Mobi pump software

(firmware) is protected through code signing to ensure pump software has not been tampered with.

- Mobile App Integrity: The Tandem Mobi mobile app is protected through code signing to ensure the app has not been tampered with.
- Encryption and Authentication of Wireless Communications: All wireless communications are encrypted and authenticated to protect your data and prevent unauthorized wireless connections to the system.
- Mobile Database Encryption: Data stored on the smartphone is encrypted to protect data from unauthorized access.
- Internal Logging of Cybersecurity Events: All events related to cybersecurity such as pairing of a new device or failure of an integrity check are logged internally on the device.
- Enforcement of Single Paired Mobile and CGM Devices: Pairing of more than one smartphone or CGM at a time is prohibited by the Tandem Mobi system.

13.5 Cybersecurity Threat Notification

Tandem Mobi Pump

The Tandem Mobi system will provide notification when a cybersecurity threat is detected. If possible, the pump will force disconnection from unauthorized devices. When a threat is not preventable by other means, the pump will indicate a malfunction (see Section 5.8 Pump Malfunction) and suspend all operation. Contact Customer Technical Support if you suspect your pump may have been compromised by any cybersecurity interference or vulnerability.

Tandem Mobi Mobile App

In the event of a Bluetooth communication authentication failure, the Tandem Mobi mobile app will automatically disconnect from the pump and the disconnection banner will be displayed. When corruption or tampering of the Tandem Mobi mobile app is detected, the app will no longer open and must be uninstalled and reinstalled. Repeated failures to pair the mobile application with the Tandem Mobi pump may also indicate a possible cybersecurity threat. Contact Customer Technical Support if you suspect your app may have been compromised by any cybersecurity interference or vulnerability.

13.6 Specifications and Options

Pump Specifications

Specification Type	Specification Details
Operating Conditions	Temperature: 41°F (5°C) to 99°F (37°C) Humidity: 20% to 85% RH non-condensing

USB Charging Pad Cable Specifications

Specification Type	Specification Detail
Length	5 feet (1.5 meters)
Type	USB A to USB C

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

Specification Type	Specification Detail
Part Number	HDP12-MD5024U
Input	100 to 240 Volts AC, 50/60 Hz
Output Voltage	5 Volts DC
Max Output Power	12 Watts
Output Connector	USB type A

Inductive Charging Pad Specifications

Specification Type	Specification Detail
Part Number	MC-10D
Input	5 Volts DC, 2 Amps
Max Output Power	5 Watts
Wireless Charging Protocol	Qi compatible

Options and Settings

Option/Setting Type	Option/Setting Detail
Language	English

13.7 Electromagnetic Compatibility

The Tandem Mobi system complies with the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2.

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

ONLY use accessories, cables, adapters, and chargers provided by the manufacturer. Use of third-party equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

For IEC 60601-1 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.
- The pump with Control-IQ+™ technology will continue to correctly adjust automated insulin dosing based on received CGM data.

This section contains the following tables of information:

- Wireless Co-existence and Data Security
- Electromagnetic Emissions
- Electromagnetic Immunity
- Wireless Technology

13.8 Wireless Co-existence and Data Security

The system is designed to work safely and effectively in the presence of wireless devices typically found at home, work, retail stores, and places of leisure where daily activities occur.

⚠ 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 Tandem Mobi 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 system.

The system is designed to ensure data security and patient confidentiality using a series of cybersecurity measures, including device authentication,

message encryption, and message validation.

NOTE

The pump only accepts communications from a known linked device such as a CGM or personal smartphone. You must pair each device with your pump. The pump wireless communications are protected with encryption and authentication.

NOTE

Always install pump software updates as they are made available by Tandem. Software updates may contain security enhancements necessary to maintain device cybersecurity. Tandem will notify you by communication channels such as emails and website pages when pump software updates are available.

13.9 Tandem Mobi 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 Mobi mobile app on a smartphone that has been jailbroken or rooted, or uses an unreleased or pre-release operating system. Only download the Tandem Mobi mobile app from Google Play™ or the App Store®. See Section 2.12 Download and Log in to the Tandem Mobi Mobile App for Tandem Mobi mobile app installation.

If the app becomes corrupted or compromised, uninstall the Tandem Mobi mobile app and follow the instructions in Section 2.13 Pairing the Tandem Mobi Mobile App with Your Pump to regain a known configuration of the Tandem Mobi mobile app.

NOTE

Always install Tandem Mobi mobile app updates as they are made available by Tandem. App updates may contain security enhancements necessary to maintain device cybersecurity. Tandem will notify you by communication channels such as emails and website pages when app updates are available.

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.

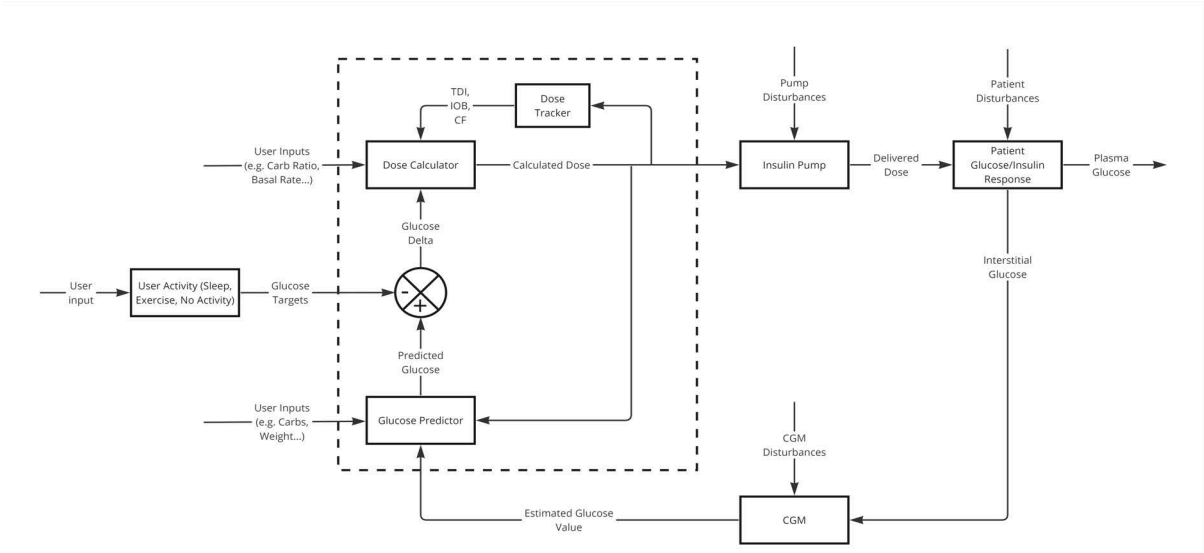
NOTE

For an up-to-date list of compatible mobile devices and operating systems, please visit tandemdiabetes.com/compatibility. You can also find this information in the Tandem Mobi mobile app from the *Settings* screen. Tap **Help**, then **App Guide**, and then choose **Smartphone Compatibility** from the index.

Please report any cybersecurity incident or vulnerability to Tandem Customer Technical Support as soon as you discover it.

13.10 IEC 60601-1-10: Physiological Closed-Loop Controlled System

Control-IQ+ technology manages insulin therapy using a closed-loop control algorithm which modulates basal delivery and initiates periodic automatic correction boluses based on predicted glucose, insulin delivery history, and user input variables. The control algorithm uses continual feedback of Estimated Glucose Values (EGVs) from a Continuous Glucose Monitor (CGM), user-reported carbohydrate entries, insulin delivery history, and user weight to predict estimated blood glucose 30 minutes in the future. The control algorithm then uses this predicted glucose value, the current user mode glucose targets (e.g., exercise, sleep), and user-input pump settings to calculate the insulin delivery dose. All doses are validated by an insulin safety system to prevent over-delivery of insulin. The control algorithm is embedded in the pump application code. EGV values are received by the pump via Bluetooth wireless technology from a compatible CGM sensor. The following block diagram describes this theory of operation.



13.11 Quality of Wireless Service

The quality of wireless service between the pump and CGM is defined as the percent of CGM readings successfully received by the pump. One of the essential performance requirements states that the pump will not discontinue reporting data and/or information from the CGM transmitter 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 *Dashboard* screen. The third is a user settable alert that will notify the user when the transmitter and pump are out of range of one another. Setting this alert is defined in Section 4.15 Setting Your Out of Range Alert.

The minimum quality of wireless service of the pump and CGM assures that the pump does not miss 15 consecutive minutes of CGM readings. The pump is capable of successfully receiving at least 90% of CGM readings while the transmitter and pump are within 20 feet (6 meters) of each other, unobstructed.

For proper use of the Tandem Mobi mobile app, the pump and compatible smartphone should maintain wireless communication 80% of the time. The quality of service of the wireless communication between the Tandem Mobi pump and smartphone running the Tandem Mobi mobile app is assured within 20 feet, unobstructed. Wireless interference caused by other devices in the 2.4 GHz band may impact the CGM or smartphone's ability to maintain this quality of service. To improve the quality of wireless service in the presence of other devices operating in the 2.4 GHz band, decrease the distance between the pump and smartphone or CGM. If connectivity is lost, the Tandem Mobi mobile app will provide notification.

The Tandem Mobi system does not rely upon Wi-Fi or cellular service to function. However, Internet connectivity is recommended for optimal use of the system, allowing for consistent wireless uploading of data to the Tandem cloud. Wi-Fi or cellular services are required to receive software updates to the mobile application or Tandem Mobi pump.

13.12 Wireless Technology

The system utilizes wireless technology with the following characteristics:

Wireless Technology Specifications

Specification Type	Specification Detail
Wireless Technology	Bluetooth Low Energy (BLE) version 5.0
Tx/Rx Frequency Range	2.360 to 2.500 GHz
Bandwidth (per channel)	2 MHz
Radiated Output Power (maximum)	+8 dBm
Modulation	Gaussian Frequency-Shift Keying
Data Rate	2 Mbps
Data Communication Range (maximum)	20 feet (6 meters)

13.13 FCC Notice Concerning Interference

The device covered by this user guide has been certified under FCC ID: 2AA9B05.

This device complies with part 15 of the FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and

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

13.14 Warranty Information

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

13.15 Returned Goods Policy

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

13.16 System Event Data

Your Tandem Mobi pump's event data is monitored and logged on the pump. Your Tandem Mobi mobile app's event data is monitored and logged on the app. The information stored on the pump and app may be obtained and used by Customer Technical Support and other internal Tandem personnel in accordance with our privacy notice for troubleshooting purposes when information is uploaded to a data management application that supports use of the System, or if the pump is returned. Others who may assert a legal right to know, or who obtain your consent to know such information may also have access to read and use this data. The Privacy Notice is available at tandemdiabetes.com/privacy/privacy-policy.

13.17 Product List

For a complete product list, please contact Customer Technical Support.

Insulin Delivery

- Tandem Mobi insulin pump
- Tandem Mobi charging pad
- USB-C charging pad cable
- Tandem Mobi quick reference guide
- Tandem Mobi Insulin System User Guide
- wall power USB adapter

Consumables

- Tandem Mobi cartridge (t:lock connector)
- infusion set (all with t:lock connector)

  Infusion sets are available in different cannula sizes, tubing lengths, insertion angles, and may come with or without an insertion device. Some infusion sets have a soft cannula and others and have a steel needle.

Contact Customer Technical Support for available sizes and lengths of the following infusion sets with t:lock connectors:

- AutoSoft 90 infusion set
- AutoSoft 30 infusion set
- AutoSoft XC infusion set
- VariSoft infusion set
- TruSteel infusion set

Optional Accessories

- Tandem Mobi pump case
- Tandem Mobi adhesive sleeve

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PATENTS AND TRADEMARKS

Covered by one or more patents. For a list of patents, see tandemdiabetes.com/legal/patents.

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