Tandem Mobi™ System

Technical 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. It provides important warnings and cautions on proper operation as well as technical information to ensure your safety. It also provides step-by-step instructions on how to properly program, manage and care for your Tandem Mobi system.

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

Please contact Customer Technical Support to obtain a replacement copy of the user guide that is the correct version for your system. For contact information see the back cover of this user guide.

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WARNINGS:
Control-IQ+™ technology should not be used in anyone under the age of 2 years old. Control-IQ+ technology should also not be used in patients who require less than a total daily insulin dose of 5 units per day or who weigh less than 20 pounds (9 kilograms), as those are the required minimum values needed in order for Control-IQ+ technology to operate safely.

SIX-DIGIT PAIRING PIN: _____

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

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1 Before You Begin

CHAPTER 1

Introduction

1.1 Conventions of This Guide

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

Formatting Conventions

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

Terminology Definitions

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

Symbol Definitions

Symbol	Definition
	Calls out an important note regarding the use or operation of the system.
	Calls out safety precautions which, if ignored, could result in minor or moderate injury.
	Calls out critical safety information which, if ignored, could result in serious injury or death.
✓	Indicates how the system responds to the previous instruction.

1.2 Explanation of Symbols

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

Explanation of 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
	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

1.3 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.

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.

1.4 System Description

The “system” consists of the Tandem Mobi insulin pump, the embedded Control-IQ+™ technology algorithm, the Tandem Mobi 2mL (200 units) cartridge, and the Tandem Mobi mobile app. The system must be used with a compatible infusion set. The Tandem Mobi pump is controllable by the Tandem Mobi mobile app. The Tandem Mobi mobile app also displays pump information.

The Tandem Mobi mobile app allows you to connect a compatible smartphone to the pump, using *Bluetooth*® wireless technology, to view data from your Tandem Mobi pump and perform pump functions directly on your smartphone. The Tandem Mobi mobile app also provides messages and alerts from your Tandem Mobi pump as push notifications on your smartphone. The Tandem Mobi mobile app can transmit pump and therapy data from the pump to the cloud as long as your smartphone is connected to the Internet. Download the Tandem Mobi mobile app from Google Play™ or from the App Store® and visit tandemdiabetes.com/support for installation instructions.

NOTE

For an up-to-date list of compatible smartphones, 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.

The Tandem Mobi system may be used in combination with a compatible continuous glucose monitoring (CGM) sensor. Both the Dexcom G6 and the Dexcom G7 CGM are compatible with the Tandem Mobi system. The Dexcom G6 transmitter may be referred to as a "transmitter." The Dexcom G6 sensor may be referred to as a "compatible sensor." Together, the Dexcom G6 transmitter and Dexcom G6 sensor may be referred to as a "compatible CGM." The Dexcom G7 CGM has a built-in transmitter and sensor. This will also be referred to as a "compatible CGM."

The sensor is a disposable device that is inserted under the skin to continuously monitor glucose levels. The CGM wirelessly sends readings to the pump every 5 minutes. The pump sends information to the Tandem Mobi mobile app which shows sensor glucose readings, a trend graph, as well as the direction and rate of change arrows.

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

The system delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The disposable cartridge is filled with up to 200 units of U-100 insulin and attached to the pump. The cartridge is replaced every 72 hours.

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

The Control-IQ+ automated insulin dosing feature is an algorithm embedded in the Tandem Mobi insulin pump. This feature enables the Tandem Mobi pump to automatically adjust the delivery of insulin based on CGM sensor readings; however, the feature is not a substitute for your own active diabetes management. Control-IQ+ technology utilizes the CGM sensor readings to calculate a predicted sensor glucose value 30 minutes into the future. For more information on how to turn on Control-IQ+ technology, see Chapter 28 Introduction to Control-IQ+ Technology.

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

1.5 About this User Guide

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

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

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

Product information, including electronic versions of this user guide, the Tandem Source™ Getting Started Guide, the Tandem Source Personal User Guide, and a CGM training tutorial, are available at tandemdiabetes.com.

1.6 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.

1.7 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.

1.8 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.

NOTE

Dexcom CGMs currently allow pairing with one medical device at a time (either the Tandem Mobi system or the Dexcom receiver), but you can still use the Dexcom G6 CGM app or the Dexcom G7 CGM app and your Tandem Mobi system.

NOTE

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

1.9 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. For more information on using a pump without the Tandem Mobi mobile app see Section 4.21 Using the Pump Without the Tandem Mobi Mobile App.

1.10 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.

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.

1.11 Important Pediatric User Information

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

Younger children may inadvertently press 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 8.9 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.

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

⚠ WARNING
The Tandem Mobi insulin pump with Control-IQ+ technology should not be used in children under the age of 2 years old.

⚠ WARNING
DO NOT allow small children (either pump users or non-users) to ingest small parts, such as the 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
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 of insulin. 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.

1.12 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

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CHAPTER 2

Important Safety Information

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

2.1 Insulin Pump Warnings

⚠ 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 Section 1.7 Compatible Insulins. Only U-100 insulin analogs listed in Section 1.7 Compatible Insulins have been tested and found to be compatible for use in the pump. Use of insulin with greater or lesser concentration can result in an over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING
DO NOT put any other drugs or medications inside your pump cartridge. The pump is designed only for continuous subcutaneous insulin infusion (CSII) with U-100 insulin analogs listed in Section 1.7 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 7.3 Filling and Loading a 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.

2.2 Magnetic Resonance Imaging Safety

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

2.3 Radiology and Medical Procedures and Your 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.

2.4 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 from the App Store®. See Chapter 4 Getting to Know the Tandem Mobi Mobile App 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.

2.5 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.

2.6 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
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 15.2 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.

2.7 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/mobilesupport. 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.

2.8 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.

2.9 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.

2.10 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 15.2 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.

2.11 Potential Benefits From Using Your System

- The system provides an automated way to deliver basal and bolus insulin. Delivery can be fine-tuned based on up to six customizable Personal Profiles, each with up to 16 time-based settings for Basal Rate, Carb Ratio, Correction Factor, and Target BG. In addition, the temp rate feature allows you to program a temporary Basal Rate change for up to 72 hours.
- The system gives you the option of delivering a bolus all at once, or delivering a percentage over an extended period of time without navigating to different menus. You can also program a bolus more discreetly using the Quick Bolus feature, which can be used without looking at the pump or Tandem Mobi mobile app, and can be programmed in increments of either units of insulin or grams of carbohydrate.
- The system keeps track of the amount of active insulin from food and correction boluses, or insulin on board (IOB). When programming additional food or correction boluses, the amount of IOB will be subtracted from the recommended bolus if your BG is below the target set in your active Personal Profile. This can help prevent insulin stacking, which can lead to hypoglycemia (low BG).
- You can program a number of reminders that will prompt you to retest your BG after a low or high BG is entered, as well as a Missed

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

- You have the ability to view a variety of data on your Tandem Mobi mobile app screen, including the time and amount of your last bolus, your total insulin delivery by day, as well as broken into basal, food bolus, and correction bolus.

2.12 Possible Risks From Using Your System

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

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

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

Other risks associated with infusion sets include occlusions and air bubbles in the tubing or dislodged cannula, which can affect insulin delivery. If your BG does not decrease after initiating a bolus, or you have other unexplained high BG, it is recommended that you check your infusion set for an occlusion or air bubbles, and verify that the cannula has not dislodged. If the condition persists, call Customer Technical Support or seek medical attention as required.

Risks that could result from system failure include the following:

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

2.13 Working with Your Healthcare Provider

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

Consult your healthcare provider before using the system to determine which

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

2.14 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.

CHAPTER 3

Getting to Know Your Tandem Mobi System

3.1 What Your Package Includes

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
- wall power USB adapter

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

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

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

The 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 allows a secure connection between the cartridge and 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)

NOTE
Avoid using a case with delicate fabrics or material that can be misshaped by force.

Supply Reordering

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

3.2 Pump Components/Diagram

1. **Pump status lights:** Illuminates to indicate pumping status and when charging.

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.

3.3 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.

3.4 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.

⚠ WARNING

Test your BG if you are unable to check your Tandem Mobi mobile app for messaging about any alert, alarm, or malfunction.

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

3.5 Check Status

Above the **Pump** button, there are two lights. These are the pump status lights. To check your pump status, press and release the **Pump** button once. The pump status lights will light up in the colors and patterns listed in Section 3.3 Pump Status Light Colors.

3.6 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.

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

⚠ WARNING

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.

NOTE

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

NOTE

Once the battery is fully charged, the pump status lights will turn off.

PRECAUTION

CONFIRM that you can feel the pump vibrate, and see the pump status lights blinking above the **Pump** button when placing the pump on a powered 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 the Tandem Mobi pump and contact Customer Technical Support.

Charging Tips

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

NOTE

If the battery is fully discharged, the pump status lights may not power on immediately when placed on a charging pad.

3.7 Turning the Pump On

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.

3.8 Turning the Pump Off

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.

3.9 Updating the Pump Software

For warnings and precautions associated with updating your pump software, see Section 2.5 Mobile Tandem Device Updater Warnings and Section 2.7 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.

Before you begin, make sure:

- You have updated your Tandem Mobi mobile app to the most recent version available from Google Play™ or in the App Store®
- You are logged in to your Tandem account on your Tandem Mobi mobile app
- Your pump battery is at least 30% full
- Your smartphone battery is at least 50% full
- Your smartphone is connected to the Internet
- Your smartphone has at least 4 MB of storage

- Your cartridge is ready to change and you have a new cartridge set on hand
- All alerts and alarms have been cleared

Follow these steps in the Tandem Mobi mobile app to update your pump software:

1. From the *Navigation* bar, tap **Settings**.
2. Tap **Pump**.
3. Tap **Pump Software Update**.
4. If your software update requires any actions in Tandem Source, tap **Go to Tandem Source**. Otherwise, you will automatically proceed to Step 5.

   A new Internet window opens on your smartphone and displays the Tandem Source platform. Complete all required steps on the Tandem Source platform to proceed.
5. Resume on the Tandem Mobi mobile app, and tap **Download**.

   The Tandem Mobi mobile app will begin to download the pump software update.
6. Tap **Next**.
7. Complete the items in the Important Safety Information checklist. Tap the radio button next to each statement to check all items.
8. Tap **Next**.
9. Stop all insulin delivery. Tap **Actions** from the *Navigation* bar. Then tap **Stop Insulin** , and then tap **Yes**.
10. Disconnect the infusion site from your body.
11. Return to the pump software update steps. From the *Navigation* bar, tap **Settings**.
12. Your Tandem Mobi mobile app will return you to the *Software Update* screen. Tap **Next**.
13. Tap **Install**.
14. Tap **Install & Restart**. The pump software update process will begin.
15. Once the update is successful, tap **Dismiss**.

The pump will need to reset the cartridge before you may resume insulin delivery. Tap **Load Cartridge** to do this now, or tap **Go to Dashboard** to do this later.

> See Chapter 7 Infusion Site Care and Loading Cartridge to follow the required steps.
>
> Once the cartridge has been reset, you may resume insulin delivery. See Section 9.3 Resuming Insulin Delivery for more information.

If you had an active CGM sensor session when you started the update process, you will need to resume your CGM sensor session.

> See Chapter 22 Starting or Stopping a CGM Sensor Session for more information.

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CHAPTER 4

Getting to Know the Tandem Mobi Mobile App

4.1 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.

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4.2 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.

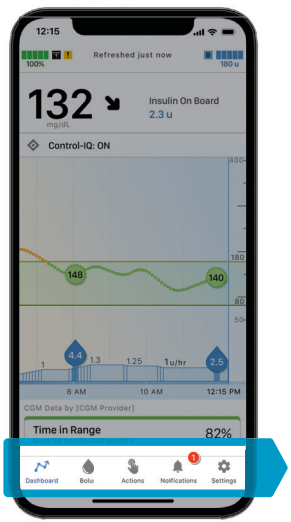
2. Bolus: Program and deliver a bolus.

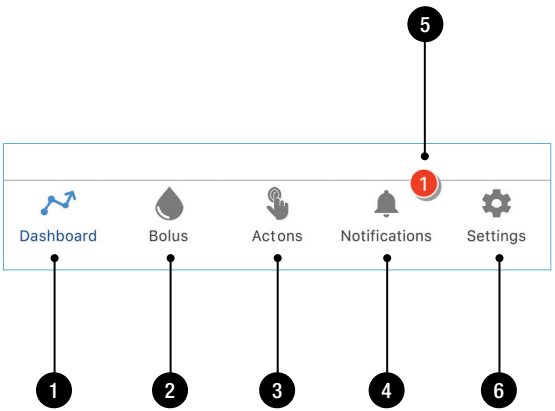
3. Actions: Stop and resume insulin delivery, start and stop activities, load and change a cartridge.

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.


12:15
Refreshed just now
132
mg/dL
Insulin On Board
2.3 u
Control-IQ: ON
148
140
8 AM
10 AM
12:15 PM
CGM Data by (CGM Provider)
Time in Range
82%
Dashboard
Bolus
Actions
Notifications
Settings


5
1
Dashboard
Bolus
Actons
Notifications
Settings
1
2
3
4
6

4.3 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.

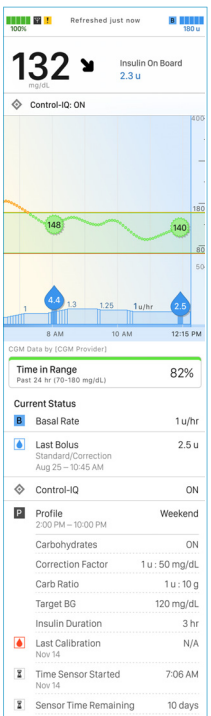
4. Graph: Displays CGM readings, estimated glucose value, BG thresholds, BG events, bolus events, and basal events.

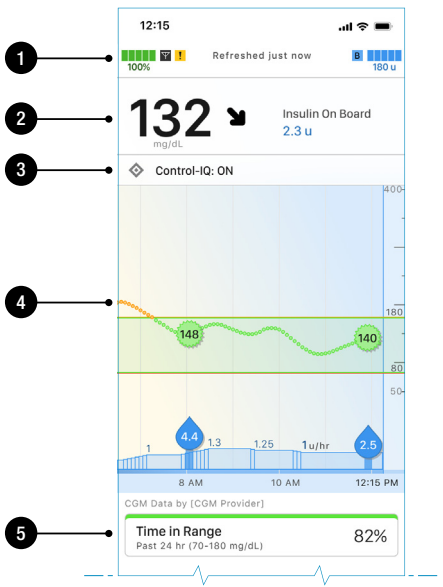
5. Time in Range Tile: Displays the current duration and percentage of time within recommended CGM thresholds.

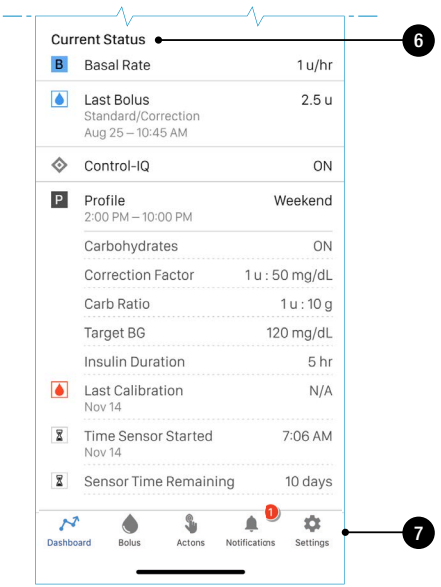
6. Current Status: Displays the time in range information, current basal rate, bolus information, Control-IQ+ technology status, active Personal Profile settings, and CGM settings.

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

Expanded view showing full dashboard screen







4.4 Dashboard Screen – Pump Status Bar

1. Battery Level: Displays the level of battery power remaining of the pump in green. When charging, the charging icon (lightning bolt) will display. The pump battery level indicator on the Tandem Mobi mobile app *Dashboard* screen will increase or decrease by 5% at a time (for example, you will see 100%, 95%, 90%, 85%). When the charge amount is less than 5%, it will begin decreasing 1% at a time (for example, you will see 4%, 3%, 2%, 1%).

2. CGM Antenna: Indicates communication status between pump and CGM.

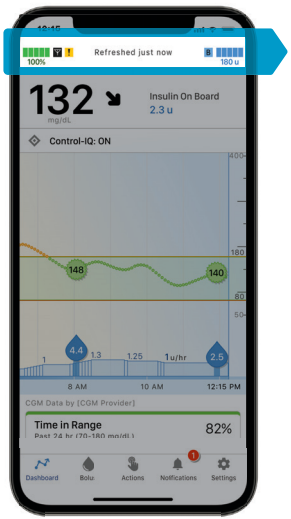
3. Alert Icon: Indicates a reminder, alert or alarm is active.

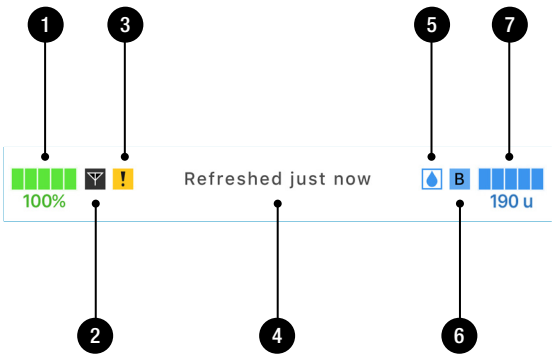
4. Data Refresh: Displays amount of time since pump and Tandem Mobi mobile app last synced.

5. Active Bolus Icon: Indicates a bolus is being delivered.

6. Status: Displays current pump settings and insulin delivery status.

7. Insulin Level: Displays the level of insulin remaining of the pump in blue. Insulin levels will decrease in 5 unit increments. When the insulin level reaches 40 units, the increments will decrease 1 unit at a time. When the insulin level reaches 1 unit, the insulin level will display LOW in red.


100%
Refreshed just now
180 u
132
mg/dL
Insulin On Board
2.3 u
Control-IQ: ON
400
180
60
50
148
140
4.4
1.3
1.25
1 u/hr
2.5
8 AM
10 AM
12:15 PM
CGM Data by (CGM Provider)
Time in Range
82%
Dashboard
Bolus
Actions
Notifications
Settings

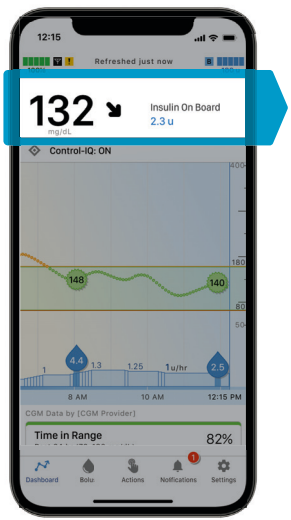

1
3
5
7
100%
Refreshed just now
B
190 u
2
4
6

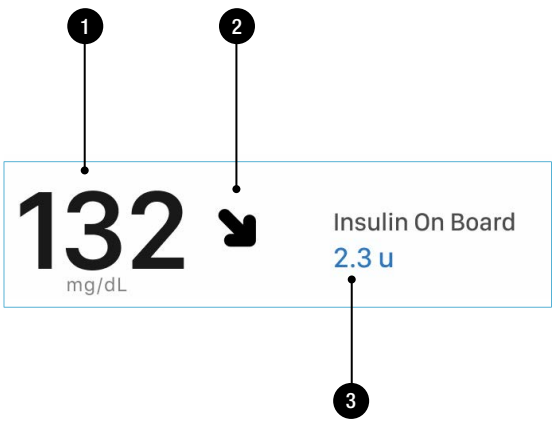
4.5 Dashboard Screen – Glucose & IOB Bar

1. Most Recent 5-Minute Sensor Glucose Reading.

2. Trend Arrow: Indicates direction and rate of change.

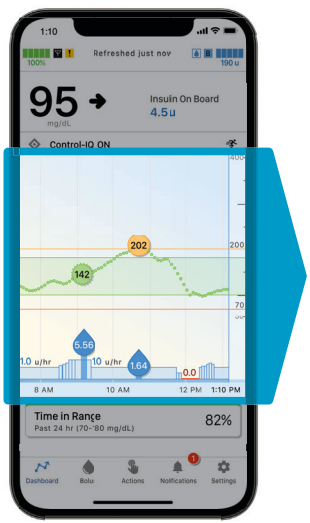
3. Insulin On Board: Amount and time remaining of any active insulin on board.

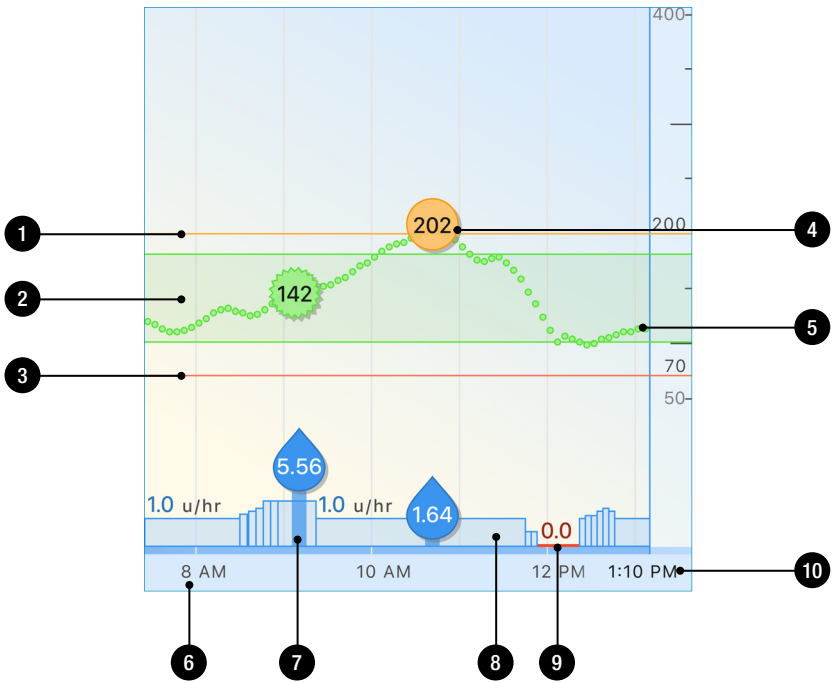

12:15
Refreshed just now
132
mg/dL
Insulin On Board
2.3 u
Control-IQ: ON
400
180
80
50
148
140
4.4
1.3
1.25
1u/hr
2.5
1
8 AM
10 AM
12:15 PM
CGM Data by [CGM Provider]
Time in Range
82%
Dashboard
Bolus
Actions
Notifications
Settings


1
2
132
mg/dL
Insulin On Board
2.3 u
3

4.6 Dashboard Screen – Graph

1. High Glucose Threshold. The upper bound of your target glucose range, shown on your *Dashboard* graph as an orange line.
2. Glucose Target Range. A green zone on your *Dashboard* graph that shows your target glucose range.
3. Low Glucose Threshold. The lower bound of your target glucose range, shown on your *Dashboard* graph as a red line.
4. Active BG Entry: Large circles with a number in the center represents a BG value that has been manually entered into the Tandem Mobi mobile app.
5. Plot of Most Recent Sensor Glucose Readings: Each “dot” on the graph is a sensor glucose reading reported every 5 minutes.
6. X-Axis Divider: Displays the time.
7. Bolus Delivery Icon: Appears when bolus delivery has completed.
8. Basal Rate Delivery Bar: Indicates a time period when a basal rate is being delivered.
9. Insulin Suspension Bar: Indicates a time period when insulin is being delivered at 0 units/hour.
10. Time: Displays the current time of day.


1:10
Refreshed just now
95
mg/dL
Insulin On Board
4.5u
Control-IQ ON
202
142
5.56
1.64
0.0
1.0 u/hr
1.0 u/hr
8 AM
10 AM
12 PM
1:10 PM
Time in Range
Past 24 hr (70-180 mg/dL)
82%
Dashboard
Bolus
Actions
Notifications
Settings


400
200
70
50
202
142
5.56
1.64
0.0
1.0 u/hr
1.0 u/hr
8 AM
10 AM
12 PM
1:10 PM
1
2
3
4
5
6
7
8
9
10

4.7 Dashboard Screen – Current Status

1. Basal Rate: Displays current basal rate of insulin delivery in units/hour. If a temp rate is active, this row will change to display current temp rate being delivered in units/hour.

2. Bolus Status: Displays amount, date and time of last bolus, or the status of a bolus in progress.

3. Control-IQ Status: Displays Control-IQ+™ technology status.

4. Carbohydrates: Indicates if the Carbs feature is turned on or off in the active Personal Profile.

5. Correction Factor: Displays current correction factor used to calculate a bolus.

6. Carb Ratio: Displays current carb ratio used to calculate a bolus.

7. Target BG: Displays current BG target used to calculate a bolus.

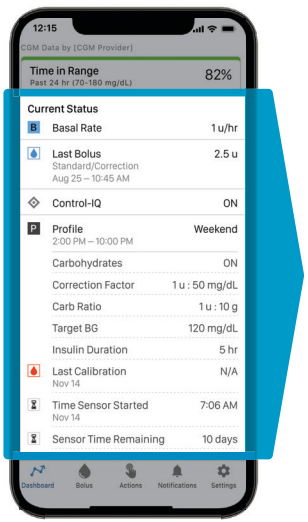
8. Insulin Duration: Displays current insulin duration setting used to calculate insulin on board.

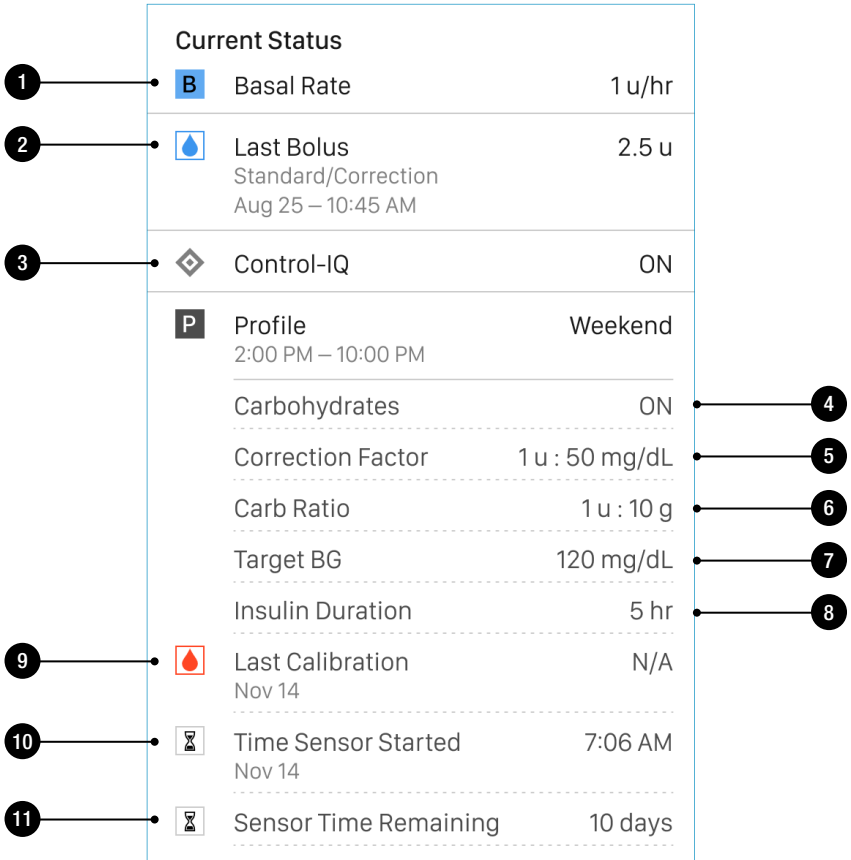
9. Last CGM Calibration: Displays date and time of the last CGM calibration.

10. Time Sensor Started: Displays date and time of the last time a CGM sensor started.

11. Sensor Time Remaining (Dexcom G7 Only): Displays the amount of time left on the current CGM sensor session.

    If you are using a Dexcom G6 CGM, this area will display Transmitter Battery and show the CGM transmitter battery status.


12:15
CGM Data by [CGM Provider]
Time in Range
Past 24 hr (70-180 mg/dL)
82%
Current Status
Basal Rate 1 u/hr
Last Bolus 2.5 u
Standard/Correction
Aug 25 – 10:45 AM
Control-IQ ON
Profile Weekend
2:00 PM – 10:00 PM
Carbohydrates ON
Correction Factor 1 u : 50 mg/dL
Carb Ratio 1 u : 10 g
Target BG 120 mg/dL
Insulin Duration 5 hr
Last Calibration N/A
Nov 14
Time Sensor Started 7:06 AM
Nov 14
Sensor Time Remaining 10 days
Dashboard
Bolus
Actions
Notifications
Settings


Current Status
1
Basal Rate 1 u/hr
2
Last Bolus 2.5 u
Standard/Correction
Aug 25 – 10:45 AM
3
Control-IQ ON
Profile Weekend
2:00 PM – 10:00 PM
Carbohydrates ON
4
Correction Factor 1 u : 50 mg/dL
5
Carb Ratio 1 u : 10 g
6
Target BG 120 mg/dL
7
Insulin Duration 5 hr
8
9
Last Calibration N/A
Nov 14
10
Time Sensor Started 7:06 AM
Nov 14
11
Sensor Time Remaining 10 days

4.8 Bolus Screen

The *Bolus* screen can be accessed from the *Navigation* bar and will default to use grams of carbohydrate in calculating a bolus. You may change this setting in your Personal Profile to use units of insulin instead. The screen on the following page uses grams of carbohydrate as an example. You must use your smartphone security feature before accessing any of the features on this 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 6.5 Creating a New Personal Profile for more information.

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

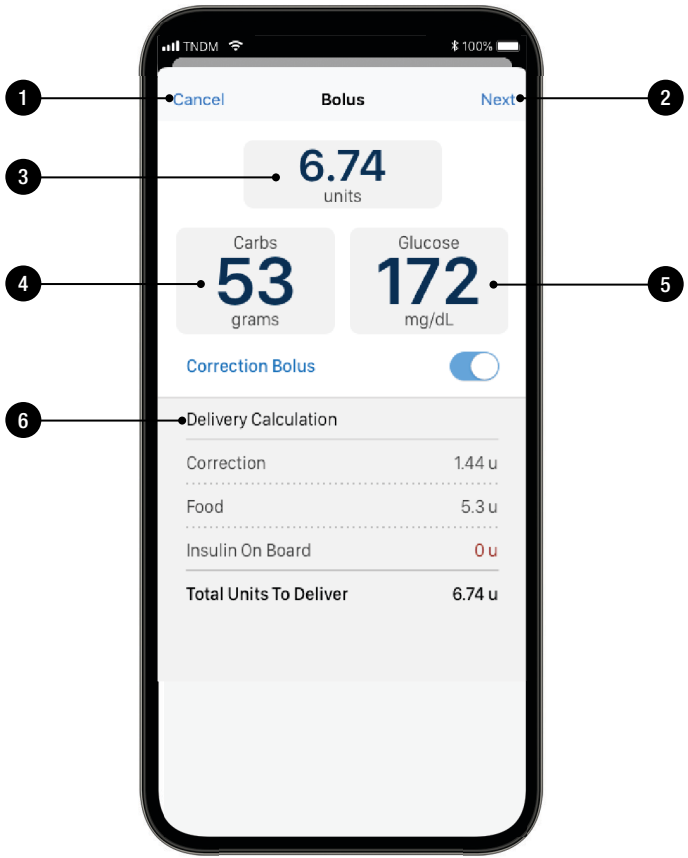
   - Control-IQ+ technology is turned on and available
   - A CGM session is active
   - A CGM value is present
   - A CGM trend arrow is available on the *Dashboard* screen

   NOTE

   For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's user guide. You can also see Section 24.3 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.


TNDM
100%
Cancel
Bolus
Next
6.74
units
Carbs
53
grams
Glucose
172
mg/dL
Correction Bolus
Delivery Calculation
Correction
1.44 u
Food
5.3 u
Insulin On Board
0 u
Total Units To Deliver
6.74 u
1
2
3
4
5
6

4.9 Actions Screen

The *Actions* screen can be accessed from the *Navigation* bar and allows you to control aspects of your pump. You must use your smartphone security feature before accessing any of the features on this screen.

1. Insulin Delivery: Start, stop, and resume insulin delivery. If insulin is stopped, Resume Insulin will be displayed.

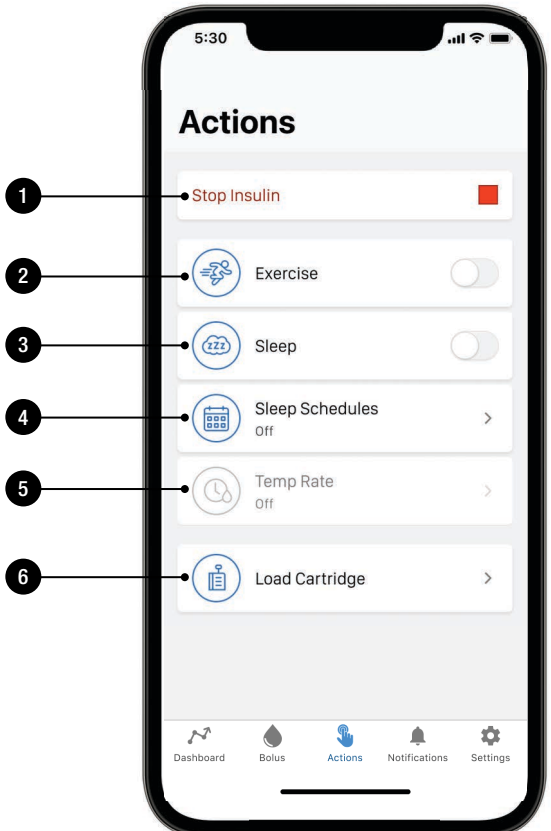
2. Exercise: If Control-IQ+ technology is on, start or stop Exercise.

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.


5:30
Actions
1
Stop Insulin
2
Exercise
3
Sleep
4
Sleep Schedules
Off
5
Temp Rate
Off
6
Load Cartridge
Dashboard
Bolus
Actions
Notifications
Settings

4.10 Notifications Screen

The *Notifications* screen informs you when information related to your pump or CGM requires attention. The outline color of the notification indicates the importance of the information.

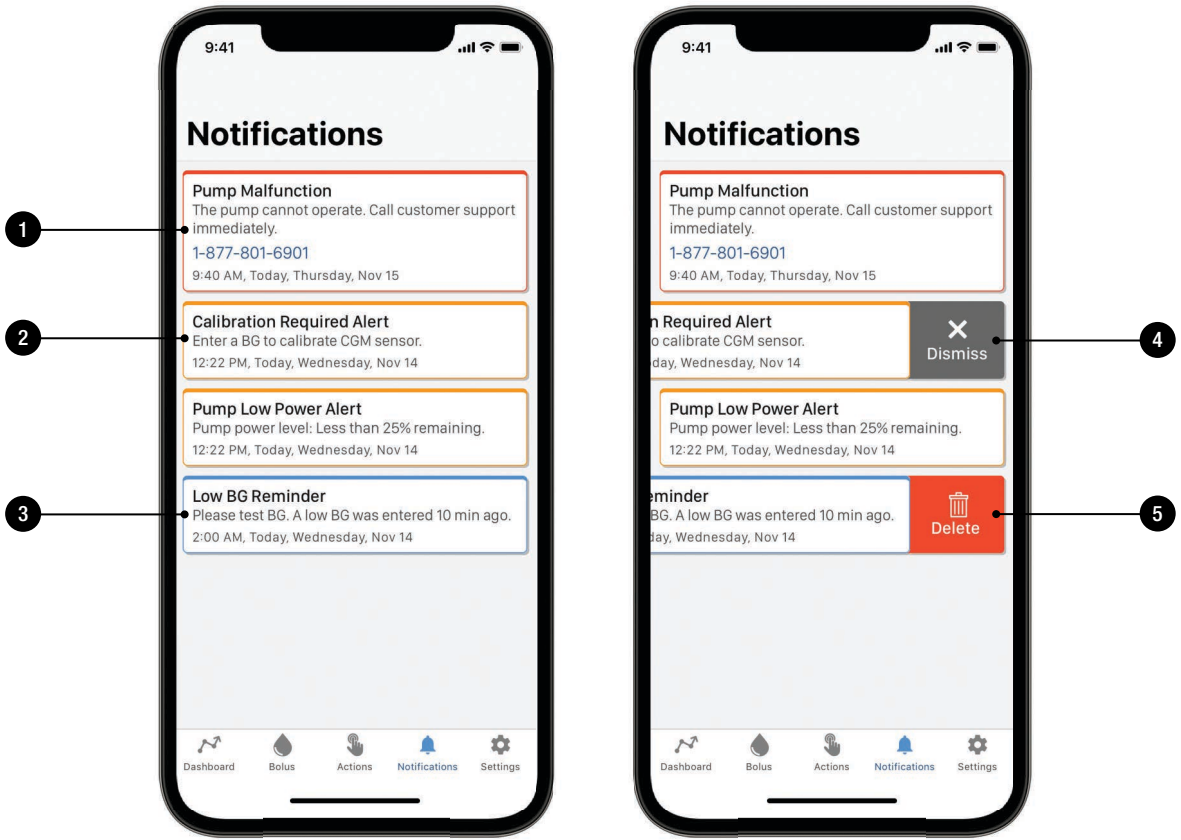
1. Red Outline: A malfunction has occurred on the pump and insulin delivery has been stopped.

2. Yellow Outline: Pump or CGM alert. An alert has occurred on the pump.

3. Blue Outline: Indicates a reminder or informational message. Insulin therapy is not impacted.

4. Dismiss: Appears if you slide an alert notification (yellow outline) with your finger to the left. Tap this icon to dismiss the alert.

5. Delete: Appears if you slide a reminder or informational notification (blue outline) with your finger to the left. Tap this icon to delete the reminder or informational message.


9:41
Notifications
Pump Malfunction
The pump cannot operate. Call customer support immediately.
1-877-801-6901
9:40 AM, Today, Thursday, Nov 15
Calibration Required Alert
Enter a BG to calibrate CGM sensor.
12:22 PM, Today, Wednesday, Nov 14
Pump Low Power Alert
Pump power level: Less than 25% remaining.
12:22 PM, Today, Wednesday, Nov 14
Low BG Reminder
Please test BG. A low BG was entered 10 min ago.
2:00 AM, Today, Wednesday, Nov 14
Dashboard
Bolus
Actions
Notifications
Settings
1
2
3
9:41
Notifications
Pump Malfunction
The pump cannot operate. Call customer support immediately.
1-877-801-6901
9:40 AM, Today, Thursday, Nov 15
Dismiss
Pump Low Power Alert
Pump power level: Less than 25% remaining.
12:22 PM, Today, Wednesday, Nov 14
Delete
Dashboard
Bolus
Actions
Notifications
Settings
4
5

4.11 Settings Screen

The *Settings* screen allows you to adjust settings related to the pump, the CGM, alerts and sounds, and the Tandem Mobi mobile app itself. You must use your smartphone security feature before accessing any of the features on the *Pump* menu.

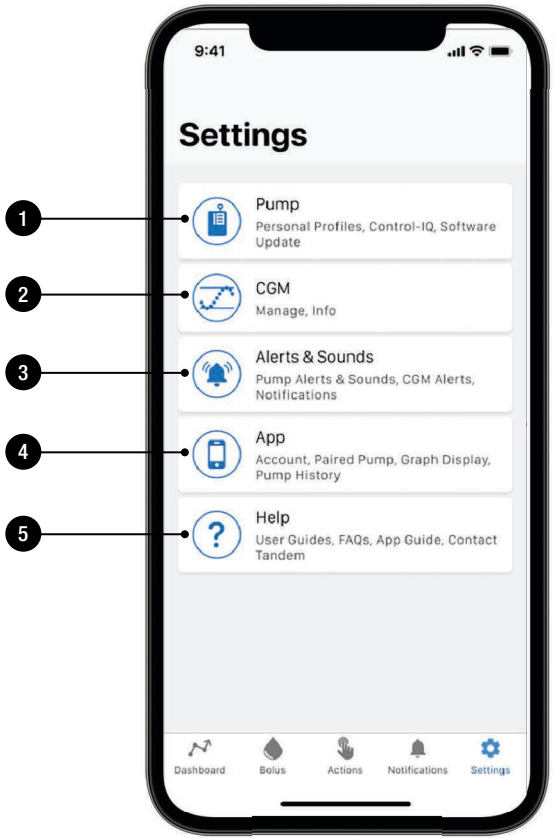
1. Pump: Program Personal Profiles, turn Control-IQ+ technology on or off, program Quick Bolus, program Delivery Limits, set pump time and date, view pump information, and view available pump software updates.

2. CGM: Manage CGM actions and view CGM information.

3. Alerts & Sounds: Set up pump alerts, pump reminders, pump sounds, CGM alerts, app notification settings.

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

5. Help: View user guide links, read FAQs, access the app guide, and view contact information.


1
2
3
4
5
9:41
Settings
Pump
Personal Profiles, Control-IQ, Software Update
CGM
Manage, Info
Alerts & Sounds
Pump Alerts & Sounds, CGM Alerts, Notifications
App
Account, Paired Pump, Graph Display, Pump History
Help
User Guides, FAQs, App Guide, Contact Tandem
Dashboard
Bolus
Actions
Notifications
Settings

4.12 Pump Screen

1. Personal Profiles: Customize settings that define basal and bolus delivery within specific time segments.

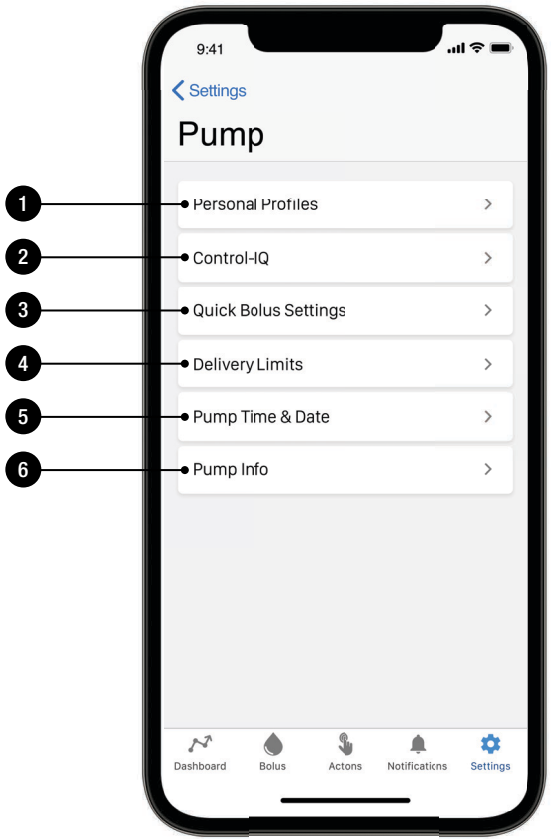
2. Control-IQ: Turn on/off Control-IQ+ technology and enter required values.

3. Quick Bolus Settings: Turn on/off and setup of the Quick Bolus feature.

4. Delivery Limits: Configure Max Bolus and Basal Rate Limit settings for the pump.

5. Pump Time & Date: Set pump time and date.

6. Pump Info: Displays various serial, software, model, and part numbers.


9:41
Settings
Pump
1
Personal Profiles
2
Control-IQ
3
Quick Bolus Settings
4
Delivery Limits
5
Pump Time & Date
6
Pump Info
Dashboard
Bolus
Actons
Notificatıcns
Settings

4.13 Dexcom G6 Screen

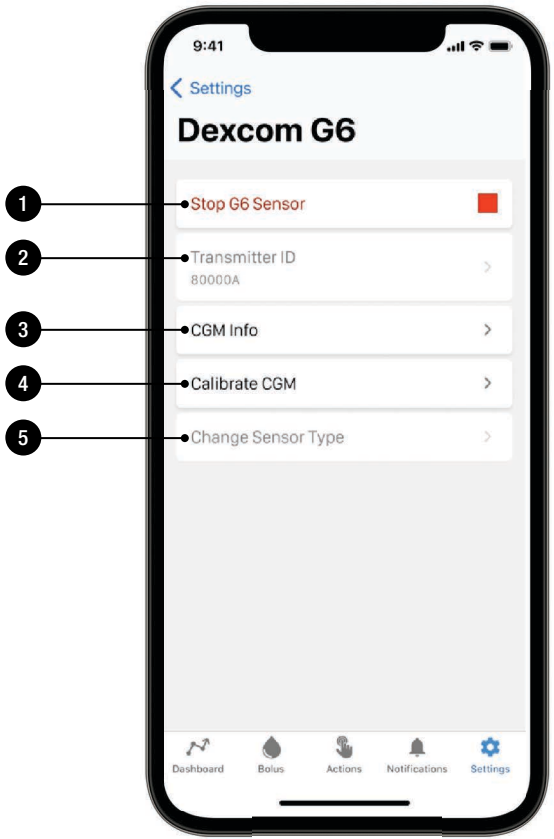
1. **Start G6 Sensor:** Starts or stops a CGM sensor session. If a sensor is active, **Stop G6 Sensor** will be displayed.

2. **Transmitter ID:** Enter the transmitter ID.

3. **CGM Info:** View the CGM information.

4. **Calibrate CGM:** Enter a calibration BG value. Only active when a sensor session is active.

5. **Change Sensor Type:** Return to *Select Sensor* screen to start a new sensor session with a different sensor type.

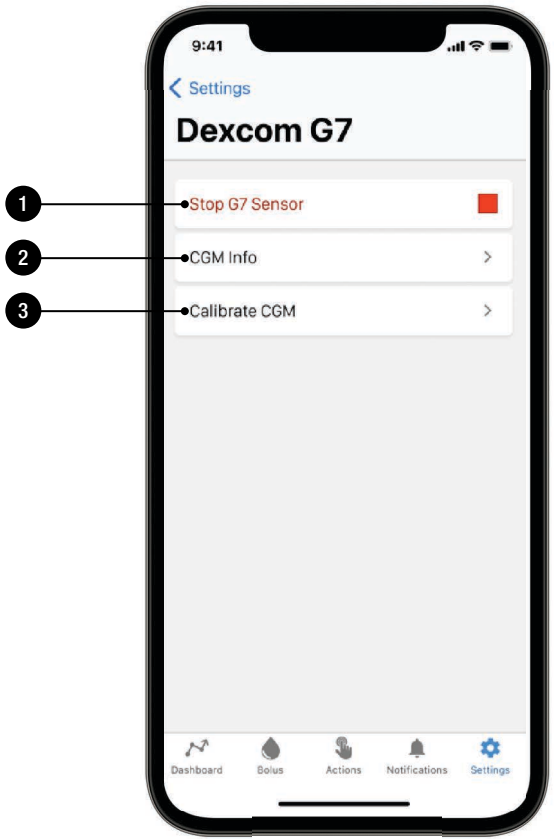

9:41
Settings
Dexcom G6
1
Stop G6 Sensor
2
Transmitter ID
80000A
3
CGM Info
4
Calibrate CGM
5
Change Sensor Type
Dashboard
Bolus
Actions
Notifications
Settings

4.14 Dexcom G7 Screen

1. Start G7 Sensor: Starts or stops a CGM sensor session. If a sensor is active, Stop G7 Sensor will be displayed.

2. CGM Info: View the CGM information.

3. Calibrate CGM: Enter a calibration BG value. Only active when a sensor session is active.


9:41
Settings
Dexcom G7
1
Stop G7 Sensor
2
CGM Info
3
Calibrate CGM
Dashboard
Bolus
Actions
Notifications
Settings

4.15 Control-IQ Screen

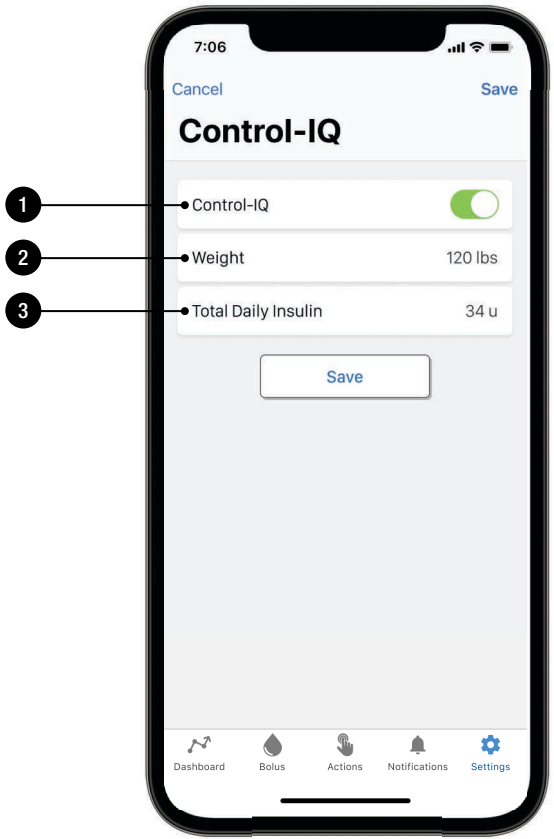
1. Control-IQ: Turns Control-IQ+ technology on or off.

2. Weight: Displays your current weight. This value is manually entered using the on-screen keyboard.

   NOTE
   Your weight should be representative of what you weigh when you turn on Control-IQ+ technology. Weight can be updated when you visit your healthcare provider. The minimum value for weight is 20 pounds (9 kilograms). The maximum value for weight is 440 pounds (200 kilograms).

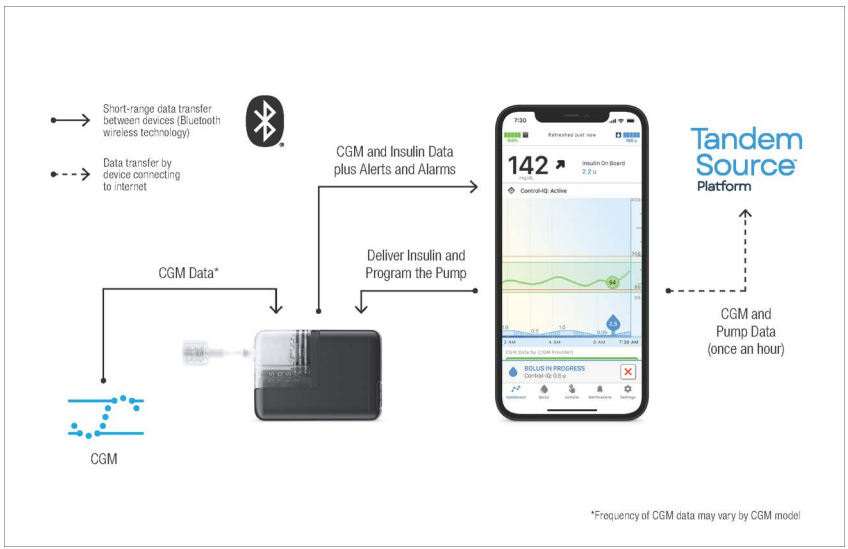
3. Total Daily Insulin: Displays your current total daily insulin value in units. This value is manually entered using the on-screen keyboard.

   NOTE
   If you don't know your Total Daily Insulin (TDI), speak with your healthcare provider to get this value. The minimum value for TDI is 5 units. The maximum value for TDI is 200 units.


1
2
3
7:06
Cancel
Save
Control-IQ
Control-IQ
Weight
120 lbs
Total Daily Insulin
34 u
Save
Dashboard
Bolus
Actions
Notifications
Settings

4.16 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 5.3 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.

4.17 About Bluetooth Technology

Bluetooth Low Energy technology is a type of wireless communication used in cell phones and many other devices. Your Tandem Mobi pump and smartphone wirelessly pair together with other devices using Bluetooth wireless technology communication. This allows the pump and paired devices to communicate securely and only with each other.

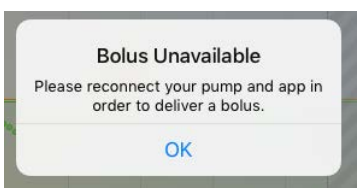
4.18 Disconnection Between Pump and Smartphone

When any of the connections between the pump and your smartphone shown in the diagram in Section 4.16 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 7.3 Filling and Loading a Cartridge and Section 7.4 Filling Tubing.

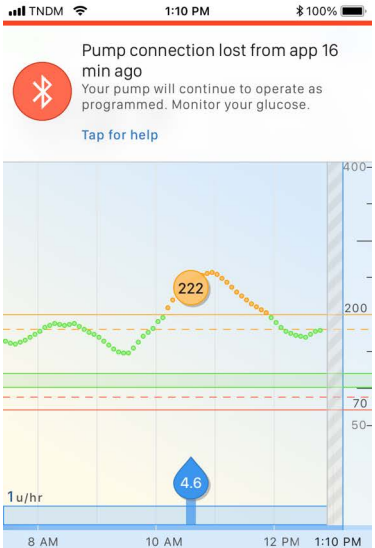
The *Bolus* screen is also inaccessible when disconnected, however, if enabled previously, the **Pump** button that is located on the pump may still be used to deliver a Quick Bolus. See Section 8.9 Quick Bolus on how to setup and deliver a Quick Bolus.

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. See Chapter 13 Alerts, Chapter 14 Alarms, and Chapter 15 Malfunction. If communication cannot be reestablished, attempt to re-pair your pump and smartphone. See Section 5.3 Pairing the Tandem Mobi Mobile App with Your Pump. If the disconnection state cannot be resolved, contact Customer Technical Support.



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.

⚠ PRECAUTION

DO NOT ignore symptoms of high and low glucose. If your Tandem Mobi mobile app readings are unavailable, check your BG using a BG meter and treat any low or high BG readings as necessary.

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.

4.19 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 5.3 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.

⚠ PRECAUTION

DO NOT ignore symptoms of high and low glucose. If your Tandem Mobi mobile app readings do not match your symptoms, check your BG using a BG meter and treat any low or high BG readings as necessary.

4.20 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.

⚠ 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.

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

1. Unpair the pump as shown in Section 5.4 Unpairing the Tandem Mobi Mobile App from Your Pump.
2. Repeat the pairing process as shown in Section 5.3 Pairing the Tandem Mobi Mobile App with Your Pump.

4.21 Using the Pump Without the Tandem Mobi Mobile App

⚑ NOTE

It is important to ensure your pump is connected to your smartphone. If a connection problem occurs, place your pump near your smartphone. See Section 4.18 Disconnection Between Pump and Smartphone for more information.

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

8.9 Quick Bolus for more information. The pump status lights may be used to check your pump status (see Section 3.5 Check Status) and, if enabled, the Snooze feature will remain available (see Section 5.7 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 13 Alerts, Chapter 14 Alarms, or Chapter 15 Malfunction for more information.

4.22 Using the Tandem Mobi Mobile App Without the Pump

⚠ WARNING

Test your BG if you are unable to check your Tandem Mobi mobile app for messaging about any alert, alarm, or malfunction.

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 25.10 CGM Fixed Low Alert 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.

4.23 Tandem Mobi Mobile App Authentication

Ensure that your smartphone security feature (e.g., security PIN, face recognition, fingerprint, or pattern recognition) is configured before using the Tandem Mobi mobile app. These security features are required to adjust insulin and program your pump. The Tandem Mobi mobile app will prompt you to enter in your preferred security feature to protect from inadvertent interactions with your smartphone that could lead to unintentional changes in your delivery of insulin.

2 Tandem Mobi System Features

CHAPTER 5

Getting Started

5.1 Download the Tandem Mobi Mobile App

Before you begin, ensure your smartphone and the Tandem Mobi™ mobile app are compatible and turn off smartphone automatic OS updates.

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.

Ensure your smartphone security feature (e.g., security PIN, face recognition, fingerprint, or pattern recognition) is configured before using the Tandem Mobi mobile app to adjust insulin delivery and control your pump. 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.

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

For more information on the setup and configuration of your smartphone to work with the Tandem Mobi mobile app, please visit tandemdiabetes.com/mobilesupport. 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 Setup** from the index.

⚠ 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 from the App Store®. See Chapter 4 Getting to Know the Tandem Mobi Mobile App for Tandem Mobi mobile app installation.

⚠ PRECAUTION

If your smartphone is incompatible, lost, damaged, or loses connectivity with your pump for any reason, contact your healthcare provider for an alternate insulin delivery plan.

5.2 Log In to the Tandem Mobi Mobile App

After you download the Tandem Mobi mobile app, locate it on your smartphone and open it. The *Sign In* screen appears.

NOTE

The Tandem Mobi mobile app must run in the background in order to receive and transmit data to and from your pump, as well as to the Tandem cloud. When you connect the Tandem Mobi mobile app to your pump, you must disable battery optimization on your smartphone to ensure the Tandem Mobi mobile app can receive alerts and alarms. It is recommended to follow your smartphone manufacturer's instructions for charging.

If you have an existing Tandem Source account, sign in using your credentials. Signing into your Tandem Source account enables the Tandem Mobi

mobile app to upload your data to the Tandem Source platform.

You should allow all permission requests from the Tandem Mobi mobile app so that you receive all notifications from your pump. See Section 5.6 Set Mobile Notifications to configure your notification settings. 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:

1. Tap **Create Account**.
2. Select the country where you live from the *Country Name* drop down menu, and then tap **Continue**.
3. Select the circle next to the account type desired, either **Personal Use** or **Parent/Guardian Use**.

   NOTE

   If you are taking care of or acting on behalf of someone younger than 13, select the **Parent/Guardian Use** account. For **Personal Use** accounts, you must be at least 13 years old in accordance with the Children's Online Privacy Protection Act (COPPA), which prohibits collecting information from people under the age of 13 without parental consent.
4. Tap **Next**.

   ✓ The *Create Account* screen appears.
5. Fill in your account information and tap **Confirm**.

   ✓ An activation email will be sent to the email address provided on the *Create Account* screen.
6. Tap **Open Email App**.

   ✓ The activation email is displayed in email inbox on your smartphone.
7. Select the **Activate Your Account** link provided in the email.

   ✓ A *Create Account* screen is displayed in a browser window on your smartphone.
8. Create a password for your account. Enter the password twice.
9. Tap **Done**.

   ✓ The *Account Login* screen is displayed in the Tandem Mobi mobile app.

   ✓ Enter your email and password and then tap **Sign In**.

Updating the Tandem Mobi Mobile App

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

Updating 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.

5.3 Pairing the Tandem Mobi Mobile App with Your Pump

NOTE

For an up-to-date list of compatible mobile devices and operating systems, please visit tandemdiabetes.com/compatibility.

NOTE

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

NOTE

When you connect the Tandem Mobi mobile app to the pump, you must disable Low Power Mode on your smartphone to ensure the Tandem Mobi mobile app can receive alerts and alarms. It is recommended to follow your smartphone manufacturer's instructions for charging.

NOTE

Your pump may only be paired with one app at a time. Pairing with a new app will remove the connection to previously connected devices.

NOTE

This pairing process is not related to your CGM Bluetooth connection. For CGM Bluetooth information, see Section 20.1 About Bluetooth Technology.

NOTE

Pairing devices such as a CGM or personal smartphone is a sensitive operation. Always perform pairing in a controlled environment, such as your home or at your healthcare provider's office.

In order to program your pump, you must first pair your pump to your smartphone. Ensure that your pump is on, nearby, and not already connected to a device or smartphone. You will also need your pump charging pad connected to a power source.

Pair your pump with your smartphone as follows:

1. Connect your charging pad to a power source using the supplied USB-C cable.

2. Place the pump on the charging pad.

3. Ensure that your pump is turned on. You can check to see if your pump is on by pressing the **Pump** button once. If the pump status lights turn on, your pump is on. If your pump is not on, see Section 3.7 Turning the Pump On for more information.

4. Tap **Begin**.

   a. If the Bluetooth feature is turned off on your smartphone, you will be prompted to turn it on. Tap **OK** and then tap **Continue**, and turn the Bluetooth feature of your smartphone on.

   b. You may be prompted to add Tandem Mobi mobile app permission to use Bluetooth. Tap **OK** and then tap **Go to Tandem Mobi app settings** and enable Tandem Mobi mobile app permissions. Tap **Continue**.

✓ A screen will display to indicate that your pump has been found.

5. Pick up your pump and press the **Pump** button two times. Make sure

you complete this action within 120 seconds.

If you do not complete this action in time, a *Pump Timeout* message will appear. Make sure the pump is on the charging pad, tap **OK**, and repeat step 5.

6. Tap the empty field on the screen. Using the on-screen keyboard, enter the six-digit pairing PIN that 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.

⚠ WARNING
ALWAYS disconnect your infusion set before removing your cartridge.

7. Tap **Done**.
8. Tap **Pair with pump**.
9. Tap **Pair** to confirm the *Bluetooth Pairing Request* message.

✓ A *Pump paired successfully* message will display.

10. Tap **Next**.

✓ A *Set your pump time & date* screen will display.

11. Tap **Set to Now**. This option will sync the pump time and date to what your smartphone is currently using.

    See Section 5.8 Set Time and Date if you would like to change the time and date at any time.

12. Tap **Save**.
13. Tap **Sync pump data**. However, if you did not sign in to or create a Tandem Source account, tap **Go to Dashboard**.

✓ The Tandem Mobi mobile app will display the *Dashboard* screen. A *Welcome Tour* popup window will display shortly afterwards. This series of screens provides Tandem Mobi mobile app navigation tips.

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.

⚑ NOTE
If your smartphone does not pair with your pump, check your smartphone's Bluetooth settings, ensure that your pump is on and near your smartphone, then retry pairing your devices. Note that if your smartphone asks you to allow it to communicate with an external device, you should accept.

⚠ PRECAUTION
Always ensure your pump has established a Bluetooth wireless connection with your

smartphone before you use the Tandem Mobi mobile app to make treatment decisions. Confirm that the information displayed to you matches your signs and symptoms.

5.4 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, you do not have to unpair the old smartphone. You will need to turn off the Bluetooth feature off your old smartphone. Then, you can pair your new smartphone to the pump.

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.

NOTE

It is recommended to disable automatic OS updates on your smartphone when using the Tandem Mobi mobile app. Before you manually update your smartphone operating system, confirm that the Tandem Mobi mobile app is compatible with the new operating system.

5.5 Mobile Connection Security

Only one smartphone may pair with your pump. When pairing your pump with a smartphone, use the unique six-digit pairing PIN found below the serial number, near the QR code of your pump. See Section 5.3 Pairing the Tandem Mobi Mobile App with Your Pump. This unique six-digit pairing PIN will secure communication between the pump and smartphone. All transmissions between the pump and smartphone are encrypted. The pump is designed to deny any unauthorized or unrecognized connections.

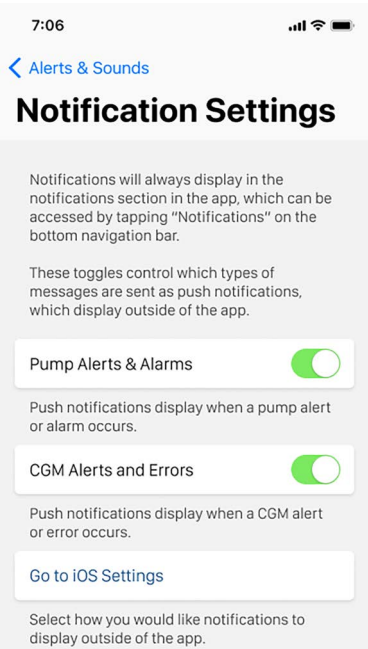
5.6 Set Mobile Notifications

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

The following example shows other smartphone notification settings.



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.

⚠ PRECAUTION

ALWAYS turn on notifications to receive your pump alerts, alarms, and notifications on your smartphone. Notifications must be enabled on your smartphone, and the Tandem Mobi mobile app must be open in the background for pump notifications to be received on your smartphone. For more information about connecting your pump and smartphone, see Section 5.3 Pairing the Tandem Mobi Mobile App with Your Pump, or tap **Help** on the Tandem Mobi mobile app *Settings* screen, then tap **App Guide**.

⚑ NOTE

Check your smartphone's OS push notification settings as well as those in the Tandem Mobi mobile app to ensure your pump and CGM alerts and alarms are set to your preference.

5.7 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**.

5.8 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.

CHAPTER 6

Insulin Delivery Settings

6.1 Overview

This section describes how to program the pump settings that affect insulin delivery. Your smartphone security feature is required to make any insulin delivery settings changes.

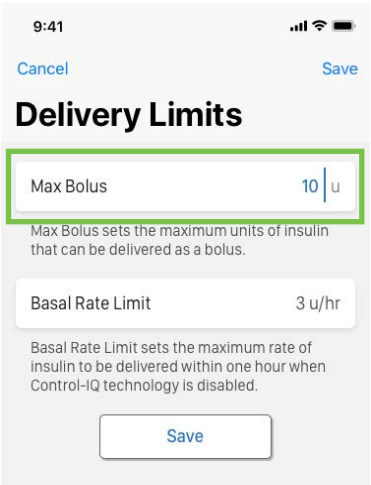
6.2 Max Bolus

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.

6.3 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.

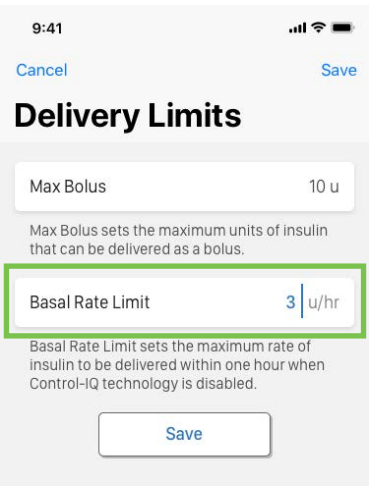
You are unable to set any Basal Rates or temp Basal Rates that exceed the Basal Rate Limit. You can set Basal Rate Limit from 0.2 to 15 units per hour. Work with your healthcare provider to set the proper Basal Rate Limit. The default Basal Rate Limit is 3 units per hour.

⚑ 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 Section 6.5 Creating a New Personal Profile.

To adjust the Basal Rate Limit setting:

1. From the *Navigation* bar, tap **Settings**.
2. Tap **Pump**.
3. Tap **Delivery Limits**.
4. Tap **Basal Rate Limit**.



5. 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.

6. Tap **Done**.
7. 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.

6.4 Personal Profiles Overview

WARNING

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

A Personal Profile is a group of settings that define basal and bolus delivery within specific time segments throughout a 24-hour period. Each 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).

NOTE

In order to turn on Control-IQ+ technology, the Time Segment must be completely filled out, and the Carbohydrates setting must be turned on in the Bolus Settings.

The Tandem Mobi pump uses the settings in your active Personal Profile

to calculate the delivery of basal insulin, food boluses, and correction boluses based on your Target BG. If you only define a Basal Rate in Time Segment, your pump will only be able to deliver basal insulin and standard and extended boluses. Your pump will not calculate correction boluses.

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

NOTE

Some of the Personal Profile settings are overridden when Control-IQ+ technology is turned on. See Chapter 28 Introduction to Control-IQ+ Technology.

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

Although you do not need to define every setting, some pump features require certain settings to be defined and activated. When you are creating a new Personal Profile, the Tandem Mobi mobile app prompts you to set up any required settings before you can continue.

The ranges you can set for Time Segments are:

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

  NOTE

  The Basal Rate may not exceed the Basal Rate Limit set in Pump Settings (Section 6.3 Basal Rate Limit). 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.

  ⚠ 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.

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

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

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

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

- Insulin Duration (amount of time that insulin is active and available in the

body after a bolus has been delivered)

- 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)

  NOTE

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

- Carbs (default: on)

Insulin Duration and Insulin on Board (IOB)

Your pump remembers how much insulin you have taken from previous boluses. It does this by relying on the insulin duration. The insulin duration reflects the amount of time that insulin is actively lowering your BG. While the Insulin Duration setting reflects how long insulin from previous boluses lowers your BG, the IOB feature reflects how much insulin is remaining in your body from previous boluses. IOB is always displayed on the *Dashboard* screen and is used in bolus delivery calculations when applicable. When a glucose value is entered during bolus programming, your pump will consider any active IOB and adjusts the calculated bolus if necessary.

The Insulin Duration time is displayed on the *Dashboard* screen when Control-IQ+ technology is not on.

Consult your healthcare provider to accurately set your Insulin Duration.

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

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

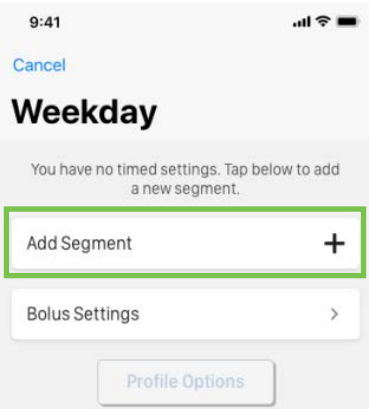
6.5 Creating a New Personal Profile

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.



6.6 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.

- 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.

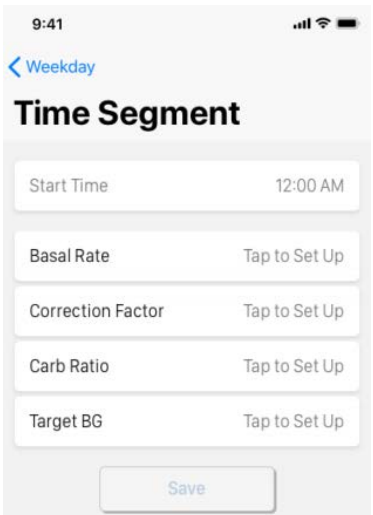
⚠ PRECAUTION

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.

Time Segments

⚑ NOTE

The first time segment is always set to 12:00 AM and cannot be edited.



1. On the *Time Segment* screen, tap **Basal Rate**.
2. Using the on-screen keyboard, enter your Basal Rate and tap **Done**.

NOTE

If you have previously set a Basal Rate Limit in the Pump Settings, then the Basal Rate entered here must be lower then the Basal Rate Limit entered in the Pump Settings.

3. Tap **Correction Factor**.
4. Using the on-screen keyboard, enter your Correction Factor and tap **Done**.
5. Tap **Carb Ratio**.
6. Using the on-screen keyboard, enter your Carb Ratio and tap **Done**.
7. Tap **Target BG**.
8. Using the on-screen keyboard, enter your Target BG and tap **Done**.

NOTE

Once Control-IQ+ technology is turned on, the default Target BG is set to 110 mg/dL. For details about target ranges and how Control-IQ+ technology works, see Chapter 28 Introduction to Control-IQ+ Technology.

9. 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 – 9 from Time Segments for each Time Segment you want to create.

Deleting Time Segments

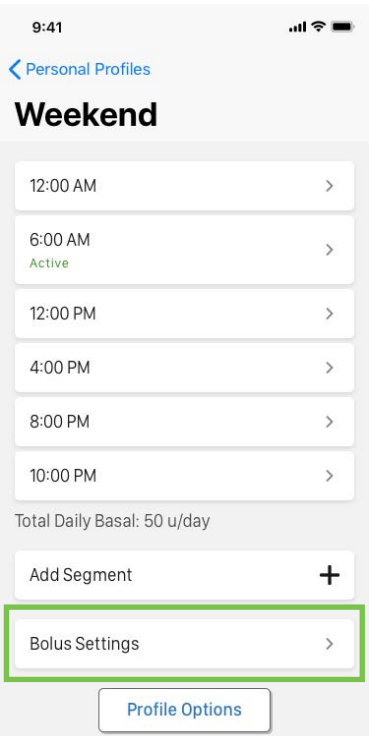
To delete an existing Time Segment:

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**.

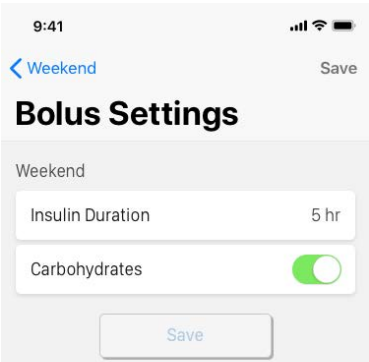
✓ A *Time Segment deleted* banner is displayed at the top of the Tandem Mobi mobile app.

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.

NOTE
The Carbohydrates feature must be turned on in order to use Control-IQ+ technology.

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

NOTE

The Carbohydrates option is turned on by default, but a Basal Rate, Carb Ratio, and Correction Factor will still need to be defined. The Carbohydrates option must be used if Control-IQ+ technology is on.

6.7 Editing or Reviewing an Existing Profile

1. From the *Navigation* bar, tap **Settings**, then tap **Pump**, then tap **Personal Profiles**, and then tap the name of the Personal Profile to edit or review.

   NOTE

   To review settings without editing, skip the remaining steps in this section. You can tap **Personal Profiles** in the upper left corner to return to the *Dashboard* screen.

2. Tap **Time Segments**.

3. Tap the start time of the Time Segment you wish to edit.

4. Tap **Basal Rate**, **Correction Factor**, **Carb Ratio** or **Target BG** to make changes as needed and use the on-screen keyboard to enter changes. Tap **Done**.

5. View recent changes and tap **Save**.

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

6. Edit other time segments within each Time Segment by tapping on them and repeating Steps 2 – 5.

7. Tap **Bolus Settings** to change Insulin Duration or Carbohydrates as needed. Use the on-screen keyboard to enter desired changes. Tap **Save**.

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

NOTE

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

NOTE

To delete a time segment, tap the start time of the time segment you wish to delete and tap **Delete Segment**. Tap **Yes** to confirm.

6.8 Duplicating an Existing Profile

1. From the *Navigation* bar, tap **Settings**, then tap **Pump**, then tap **Personal Profiles**, and then tap the name of the Personal Profile to duplicate.

2. Tap **Profile Options**.

3. Tap **Duplicate**.

4. Confirm profile to duplicate by tapping **Yes**.

5. Tap the *Profile Name* field, and using the on-screen keyboard, enter the name (up to 16 characters) for the new Personal Profile and tap **Save**.

   ✓ A *Profile duplicated* banner is displayed at the top of the Tandem Mobi mobile app.

✓ A new Personal Profile will be created with the same settings as the duplicated Personal Profile.

6. Tap **Time Segment** or **Bolus Settings** to make changes to the new Personal Profile.

6.9 Activating an Existing Profile

1. From the *Navigation* bar, tap **Settings**, then tap **Pump**, then tap **Personal Profiles**, and then tap the name of the Personal Profile to activate.
   - The Activate and Delete options are disabled for the active Personal Profile because the profile is already activated. You cannot delete a Personal Profile until you have activated another Personal Profile.
   - If you have only one Personal Profile defined, you do not need to activate it. That Personal Profile is automatically activated.
2. Tap **Profile Options**.
3. Tap **Activate**.
4. Confirm profile to activate by tapping **Yes**.

✓ A *Profile activated* banner is displayed at the top of the Tandem Mobi mobile app.

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

6.10 Renaming an Existing Profile

1. From the *Navigation* bar, tap **Settings**, then tap **Pump**, then tap **Personal Profiles**, and then tap the name of the Personal Profile to rename.
2. Tap **Profile Options**.
3. Tap **Rename**.
4. Tap the *Profile Name* field, and using the on-screen keyboard, rename the Personal Profile name (up to 16 characters) and tap **Save**.
5. A *Profile renamed* banner is displayed at the top of the Tandem Mobi mobile app.
6. Tap **Personal Profiles** in the upper left corner to return to the previous screen.

6.11 Deleting an Existing Profile

1. From the *Navigation* bar, tap **Settings**, then tap **Pump**, then tap **Personal Profiles**, and then tap the name of the Personal Profile to delete.
2. Tap **Delete**.

NOTE
The active Personal Profile cannot be deleted.

3. Tap **Yes**.

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

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

6.12 Starting a Temporary Basal Rate

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

The default values for the Temp Rate are 100% (current Basal Rate) and a Duration of 15 minutes. The Temp Rate can be set from a minimum of 0% of current Basal Rate to a maximum of 250% of current Basal Rate in increments of 1%.

Duration can be set from a minimum of 15 minutes to a maximum of 72 hours in increments of 1 minute.

If you program a Temp Rate greater than 0% but less than the minimum allowable Basal Rate of 0.1 units/hour, you will be notified that the selected rate is too low and that it will be set to the minimum allowable rate for delivery.

If you program a Temp Rate more than the Basal Rate Limit defined in your Pump Settings, you will be notified that the selected rate is too high and that it will be set to the maximum allowable rate for delivery.

If you program a Temp Rate more than the maximum allowable Basal Rate of 15 units/hour, you will be notified that the selected rate is too high and that it will be set to the maximum allowable rate for delivery.

1. From the *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.

6.13 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.

CHAPTER 7

Infusion Site Care and Loading Cartridge

7.1 Infusion Site Selection and Care

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

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

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

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

⚠ PRECAUTION
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.

General Guidelines

Site Selection

⚠ 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.

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

Site Rotation

⚠ PRECAUTION
CHANGE your infusion set every 48 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

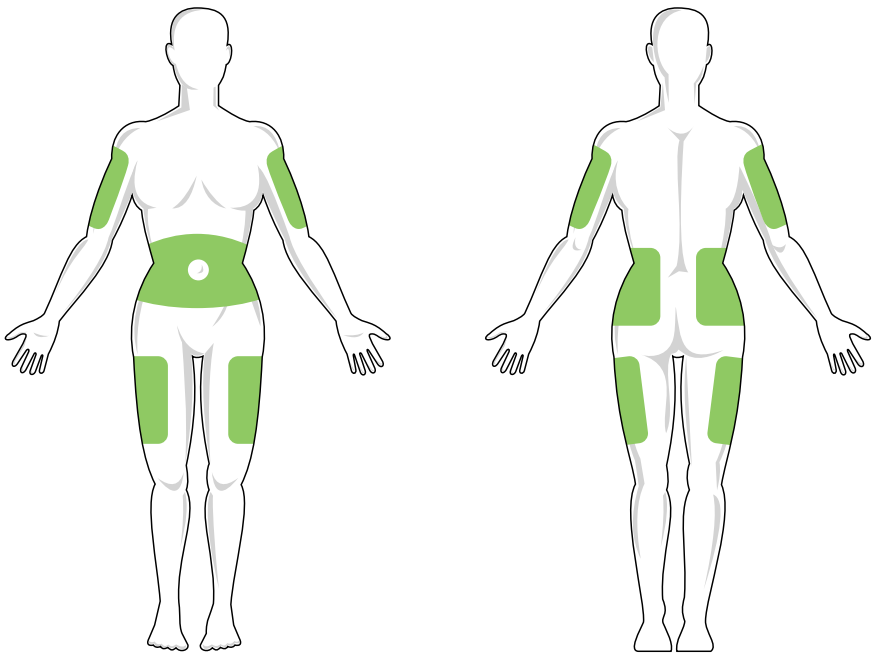
symptoms of infection at your insulin infusion site.

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

Keep it Clean

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

Areas of Body for Infusion Set Insertion



NOTE

If you intend to wear your pump on-body using the optional Tandem Mobi adhesive sleeve, avoid using lotions or moisturizers on skin prior to placement as these substances may affect adhesion of the adhesive sleeve.

7.2 Cartridge Instructions for Use

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

ONLY use insulin analogs that have been tested and found to be compatible for use in the pump, listed in Section 1.7 Compatible Insulins. Use of insulin with greater or lesser concentration can result in an over delivery or under delivery of insulin. This can cause hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING

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

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.

⚠ PRECAUTION

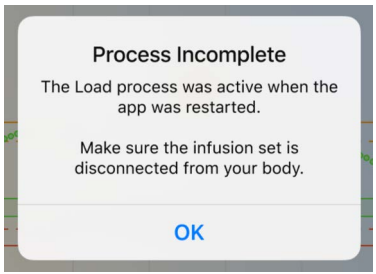
To prevent accidental injury, keep fingers away from the top edge of the vial adapter, as there is a needle inside.

7.3 Filling and Loading a Cartridge

This section describes how to fill the cartridge with insulin and load the cartridge into your Tandem Mobi pump. The single-use disposable cartridge can hold up to 200 units (2.0 mL) of insulin.

If the pump and smartphone become disconnected, or if the Tandem Mobi mobile app is restarted during the

Loading Cartridge process, the following prompt will display.



Tap **OK** to return to the last active screen to complete the Load Cartridge process.

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.

NOTE

The insulin amount displayed on the Tandem Mobi mobile app is the amount of insulin available for delivery. It does not include insulin needed to fill the tubing which may be up to 30 units for longer infusion set tube lengths or as little as 5 units for shorter infusion set tube lengths, and a small amount of insulin that is not available for delivery. When filling the cartridge, add the amount of insulin you want available for delivery, plus the additional amount depending on the tubing length (5 units to 30 units). Use the volume markers on the cartridge to best estimate and add the desired insulin volume you require.

⚠ 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

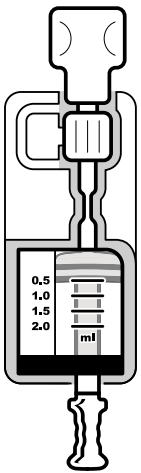
ALWAYS remove all air bubbles from the cartridge before beginning insulin delivery. Make sure that insulin is at room temperature before use or air bubbles could form in the cartridge. Air in the system takes space where insulin should be and can affect insulin delivery.

Before You Begin

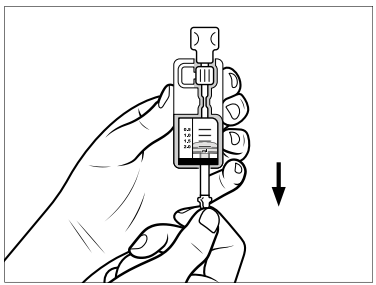
1. Open the Tandem Mobi mobile app.
2. From the *Navigation* bar, tap **Actions**.
3. Tap **Load Cartridge**.
4. Tap **How to fill a cartridge** to view a guided walk-through on how to fill the Tandem Mobi cartridge.
5. Gather an insulin vial, an alcohol swab, an unopened cartridge set, and your smartphone with the Tandem Mobi mobile app.
6. Allow insulin to come to room temperature.
7. Inspect the cartridge set for any signs of damage. Discard any damaged product.
8. Wash your hands and wipe the rubber septum of the insulin vial with an alcohol swab.

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.

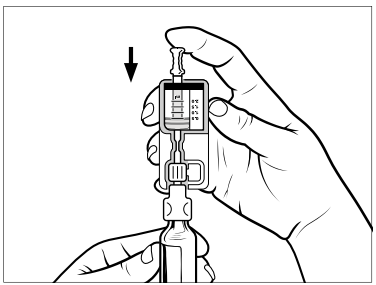


3. Pull the fill rod down to the desired volume. The top ring on the plunger should align with the desired volume marker.

Fill the Cartridge

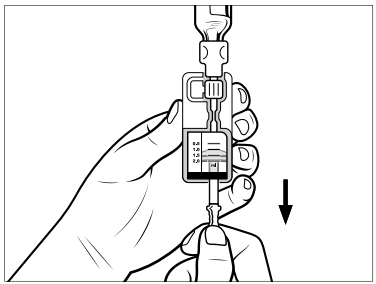
1. With the insulin vial upright and on a flat surface, push the vial adapter down and onto the vial.

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.

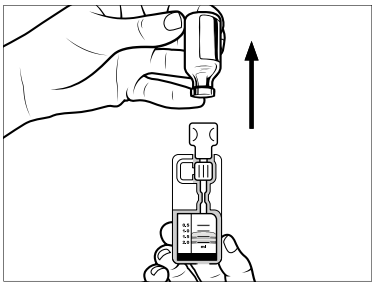
4. Slowly pull back the fill rod to the desired insulin volume.



NOTE

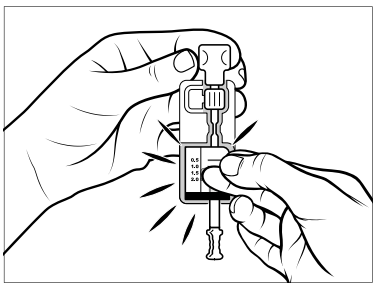
There must be at least 30 units of insulin remaining in the cartridge once the tubing is filled.

5. Pull the vial out from the vial adapter.



Inspect the Cartridge for Air

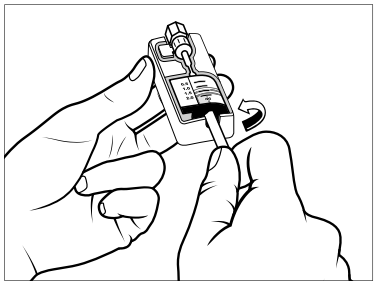
1. Check all sides of the cartridge for air bubbles.
2. Hold the cartridge set completely upright and tap so that any air bubbles rise to the top.



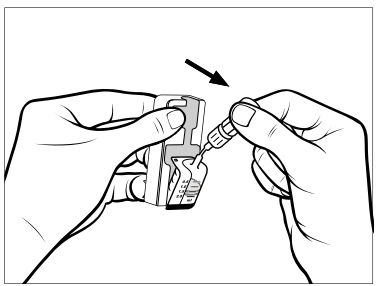
3. Slowly push the fill rod upwards, forcing any air bubbles out of the cartridge.
4. Repeat steps 1 – 3 as needed until no air bubbles are present.

Remove Cartridge From Set

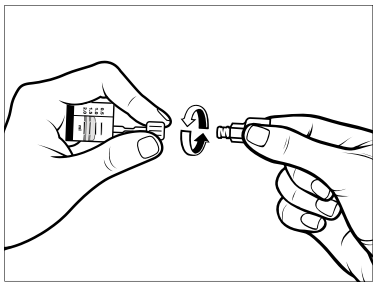
1. Unscrew the fill rod counterclockwise to remove it from the cartridge.



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



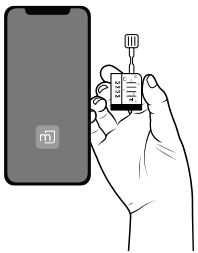
3. Unscrew the vial adapter counterclockwise to remove it from the t:lock™ connector.



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.

NOTE

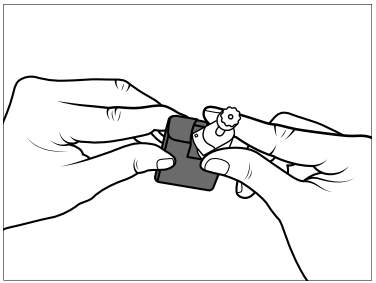
This screen will not be displayed if this is the first time loading a new cartridge and you have not started actively pumping.

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.

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.

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.

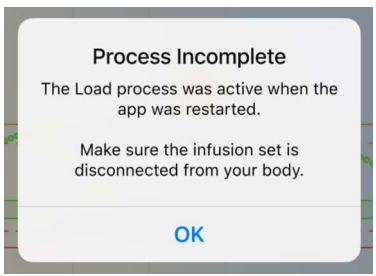
7.4 Filling Tubing

WARNING

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

filling the tubing can result in over delivery of insulin. This can cause hypoglycemia (low BG) events.

If the pump and smartphone become disconnected, or if the Tandem Mobi mobile app is restarted during the Fill Tubing process, the following prompt will display.



Tap **OK** to return to the last active screen to complete the Fill Tubing process.

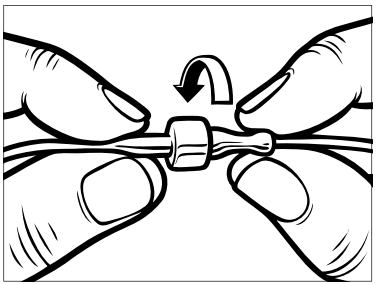
To fill the tubing without changing the cartridge, from the *Navigation* bar, tap **Actions**, tap **Load Cartridge**, tap **Fill Tubing**.

- 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.

⚠ PRECAUTION

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

1. Verify that the infusion set is disconnected from your body.
2. Ensure that the new infusion set package is not damaged, and remove the sterile tubing from the package. If the package is damaged or opened, discard of properly and use another tubing set.
3. 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.

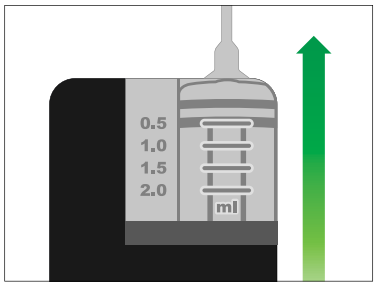


⚠ WARNING

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.

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.

NOTE

The pump will pause the fill tubing process at regular intervals to allow you to check for drops of insulin at the end of your tubing. You may encounter one or more of these pauses before you see drops of insulin.

NOTE

It is important you continue the fill tubing process until you see drops of insulin come out of your tubing. Air in the tubing takes space where insulin should be and can affect insulin delivery.

✓ 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.

7.5 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 7.6 Setting Site Reminder.

7.6 Setting Site Reminder

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

To set the Site Reminder without filling the cannula, from the *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.

NOTE

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

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CHAPTER 8

Manual Bolus

8.1 Manual Bolus Overview

⚠ 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 change the amount of insulin before you deliver your bolus.

⚠ WARNING

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

⚠ WARNING

If you 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.

⚑ NOTE

The information in this chapter does NOT apply to boluses delivered automatically by Control-IQ+™ technology. For information on automatic bolus delivery, see the Automatic Correction Bolus Delivery section in Section 28.2 How Control-IQ+ Technology Works.

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

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

You can deliver different boluses to cover carbohydrate intake (food bolus) and bring your BG back to target (correction bolus). Food and correction boluses can also be programmed together.

If 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.

If your smartphone becomes disconnected from the pump while programming a bolus the *Bolus* screen you may not be able to deliver a bolus.

Before you use the Tandem Mobi mobile app to deliver a bolus, ensure your smartphone's security feature (e.g., security PIN, face recognition, fingerprint, or pattern recognition) is turned on. Never share your security PIN/password or authorize any other person to access your smartphone via their biometric information to avoid unintentional changes in your delivery of insulin.

⚑ NOTE

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

⚠ PRECAUTION

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

8.2 Initiating a Bolus

To request a bolus, from the *Navigation* bar, tap **Bolus**.

⚠ 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 with 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.

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

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

8.3 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

⚠ 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.

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.

NOTE

Retrospective analysis of the pivotal study results indicated that there was an increased incidence of CGM values <70 mg/dL five hours after a bolus was delivered when glucose values were auto-populated.

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

NOTE

For more information about CGM trend arrows and how to use them for treatment decisions, see the CGM manufacturer's product instructions. You can also see Section 24.3 Rate of Change Arrows.

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:

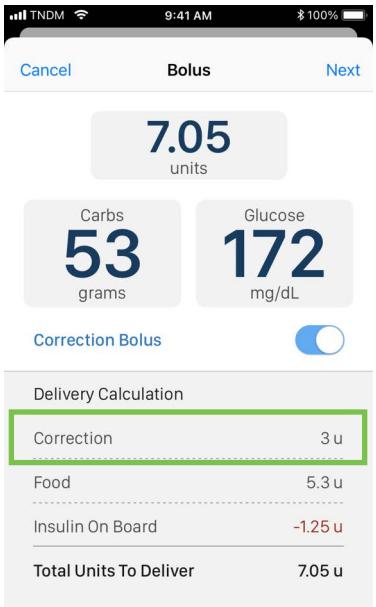
1. Tap the glucose value from the *Glucose* field.

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.

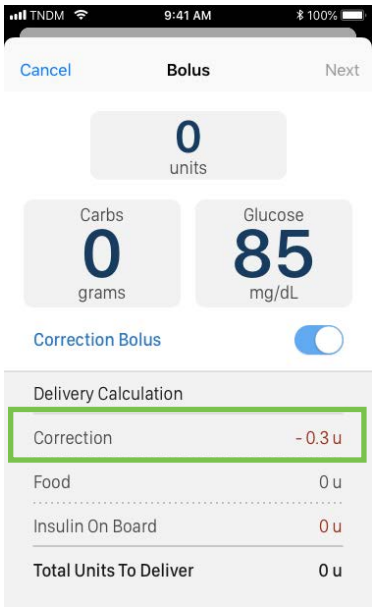
A correction bolus will be added to any other bolus you request.



- 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.

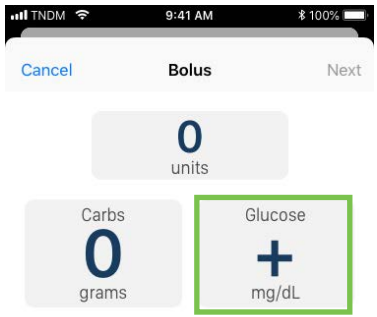
Within Target

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** or ✔.

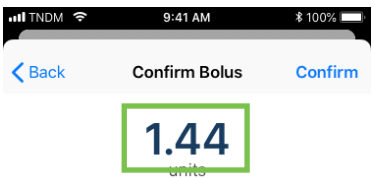
NOTE

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

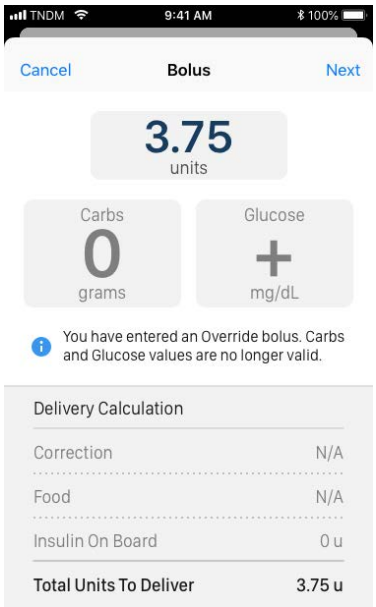
4. Follow the steps in the appropriate Target section above depending on the results of your BG value.

8.4 Bolus Override

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



When you choose to override the calculated bolus, a message will be displayed letting you know that the numbers that were entered for units of insulin (or grams of carb) and the glucose value are not valid, and will not be used for the bolus calculation. The delivery summary will be updated to show the override unit amount that will be delivered.



8.5 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 ✔.

⚠ PRECAUTION

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

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

8.6 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.

8.7 Deliver a Bolus

Once you have entered in your glucose or BG value for a correction bolus, entered in your grams of carbohydrate or units of insulin for a food bolus, or a combination of both, you may deliver the 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.

8.8 Extended Bolus

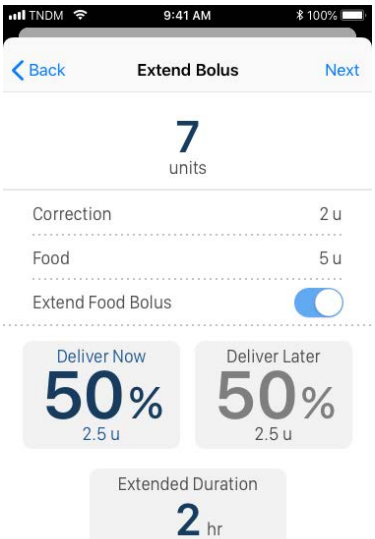
The Extended Bolus feature allows you to deliver part of the bolus now and part of the bolus slowly over a period of up to 8 hours. This can be helpful for high fat meals (such as pizza) or if you have gastroparesis (delayed stomach emptying).

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

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** or ✔.

   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** or ✔.

11. Tap **Next** or ⟶.

12. Confirm request.

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

8.9 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**.
2. Tap **Pump**.
3. Tap **Quick Bolus Settings**.
4. Tap the toggle next to **Quick Bolus** to turn the feature on.
5. Tap **Increment Type**.
6. Select **units of insulin** or **grams of carbohydrate** from the on-screen picker.
7. Tap **Done** or ✔.
8. Tap **Increment Amount**.
9. Select the preferred increment amount from the on-screen picker.

   NOTE

   The increment amount selected here is the amount of insulin delivered with each press of the **Pump** button when delivering a Quick Bolus.

10. Tap **Done** or ✔.
11. 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

⚠ PRECAUTION

You will not be able to deliver a Quick Bolus if certain hypoglycemia alerts or a **Pump** button malfunction is active.

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

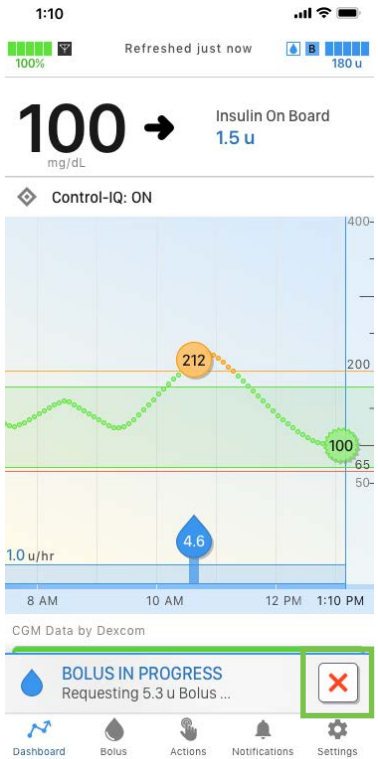
If Control-IQ+ technology is on and has adjusted insulin delivery during a Quick Bolus, the remaining Quick Bolus insulin will be delivered.

8.10 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.

⚠ WARNING

If your smartphone disconnects from your pump when attempting to cancel or stop a bolus, a *Bolus Not Stopped* alert appears on the Tandem Mobi mobile app. Disconnect your infusion set from your body to immediately stop bolus delivery into your body. See Section 4.19 Reconnect Bluetooth Connection to troubleshoot the disconnection.

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2 Tandem Mobi System Features

CHAPTER 9

Starting, Stopping, or Resuming Insulin

9.1 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 6 Insulin Delivery Settings for instructions on creating, configuring, and activating a Personal Profile.

9.2 Stopping Insulin Delivery

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

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

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.

9.3 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.

9.4 Disconnecting When Using Control-IQ+ Technology

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

CHAPTER 10

Pump Information and History

10.1 Pump Info

Your Tandem Mobi™ mobile app allows access to information about your pump. In the *Pump Info* screen you have access to items such as your pump serial number, Customer Technical Support contact information, website, and software/hardware versions.

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

10.2 Pump History

The Tandem Mobi mobile app displays a historical log of pump events. At least 14 days of data can be viewed in Pump History. When the maximum number of events is reached, the oldest events are removed from the history log and replaced with the most recent events. The following can be viewed in the *Pump History* screen:

Bolus, Basal, Load, BG, Alerts and Alarms, Control-IQ, and Complete.

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

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

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

To access Pump History:

1. From the *Navigation* bar, tap **Settings**.
2. Tap **App**.
3. Tap **History**,
4. Tap **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.

NOTE

You must be logged into your Tandem account on your Tandem Mobi mobile app and have the app running in the background in order to send data to Tandem Source.

CHAPTER 11

Reminders

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.

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

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.

11.1 Low BG Reminder

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

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

1. From the *Navigation* bar, tap **Settings**.
2. Tap **Alerts & Sounds**.
3. Tap **Pump Reminders**.
4. Tap **Low BG**.
5. Tap the toggle next to **Low BG Reminder**.
   a. Tap **Remind Me Below** and using the on-screen keyboard, enter a low BG value (from 70 to 120 mg/dL) that you want to trigger the reminder, then tap **Done** or ✔.
   b. Tap **Remind Me After** and using the on-screen number picker, select the time, in minutes (from 10 to 20 minutes), then tap **Done** or ✔.
   c. Tap **Save** when all changes are complete.

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

To Respond to the Low BG Reminder

To clear the reminder from the *Notifications* screen, tap on or slide the reminder message to the left, and tap **Delete**. Check your BG.

11.2 High BG Reminder

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

The default for this reminder is preset to off. If on, the defaults are Remind Me Above 200 mg/dL, and Remind Me After 2 hr, but you can set these values from 150 to 300 mg/dL and 1 to 3 hours.

1. From the *Navigation* bar, tap **Settings**.
2. Tap **Alerts & Sounds**.
3. Tap **Pump Reminders**.
4. Tap **High BG**.
5. Tap the toggle next to **High BG Reminder**.
   a. Tap **Remind Me Above** and using the on-screen keyboard, enter a high BG value (from 150 to 300 mg/dL) that you want to trigger the reminder, then tap **Done** or ✔.
   b. Tap **Remind Me After** and using the on-screen number picker, select the time, in hours and minutes (from 1 to 3 hours), then tap **Done** or ✔.
   c. Tap **Save** when all changes are complete.

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

To Respond to the High BG Reminder

To clear the reminder from the *Notifications* screen, tap on or slide the reminder message to the left, and tap **Delete**. Check your BG.

11.3 After Bolus BG Reminder

The After Bolus BG Reminder prompts you to test your BG at a selected time after bolus delivery. When turning this reminder on, you need to set how much time should pass before the reminder occurs. The default is 1 hour and 30 minutes. It can be set from 1 to 3 hours.

1. From the *Navigation* bar, tap **Settings**.
2. Tap **Alerts & Sounds**.
3. Tap **Pump Reminders**.
4. Tap **After Bolus BG**.
5. Tap the toggle next to **After Bolus BG Reminder**.
6. Tap **Remind Me After** and using the on-screen number picker, enter the time, in hours and minutes (from 1 to 3 hours) that you want to trigger the reminder, then tap **Done** or ✔.

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

✓ An *After Bolus BG Reminder saved* banner is displayed at the top of the Tandem Mobi mobile app.

To Respond to the After Bolus BG Reminder

To clear the reminder from the *Notifications* screen, tap on or slide the reminder message to the left, and tap **Delete**. Check your BG using your BG meter.

11.4 Missed Meal Bolus Reminder

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

1. From the *Navigation* bar, tap **Settings**.
2. Tap **Alerts & Sounds**.
3. Tap **Pump Reminders**.
4. Tap **Missed Meal Bolus**.
5. 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** or ✔.
   d. Tap **Duration**, and using the on-screen time picker select the end time and time of day, then tap **Done** or ✔.
   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.

11.5 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. See Section 13.3 Incomplete Bolus Alert for more information.

11.6 Site Reminder

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

For detailed information on the Site Reminder feature, see Section 7.6 Setting Site Reminder.

To Respond to the Site Reminder

To clear the reminder from the *Notifications* screen, tap on or slide the reminder message to the left, and tap **Delete**. Change your infusion set.

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CHAPTER 12

User Settable Alerts and Alarms

12.1 Low Insulin Alert

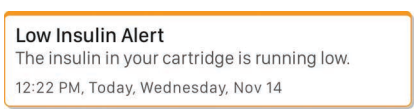
Your Tandem Mobi™ pump keeps track of how much insulin remains in the cartridge and alerts you when it is low. The default for this alert is preset to 20 units. You can set this alert setting anywhere between 15 and 40 units. When the insulin amount goes below the set value, the Low Insulin Alert beeps/ 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 7.3 Filling and Loading a Cartridge.



12.2 Auto-Off Alarm

Your pump can stop insulin delivery and alert you or whoever is with you if there has been no interaction with the pump 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**.

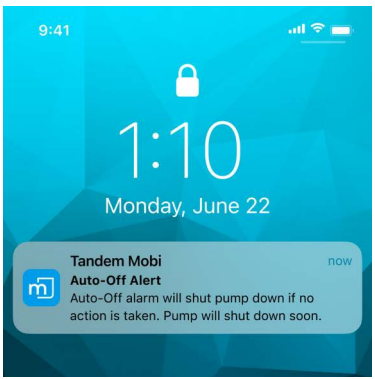
6. Using the on-screen number picker, select the number of hours (from 5 to 24 hours) that you want the Auto-Off Alarm to be triggered, and tap **Done** or ✔.

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.

To Respond to Auto-Off Warning

Five minutes before the specified time you set up for the Auto-Off Alarm, a push notification will appear on the lock screen of your smartphone.You will only receive this notification if the Tandem Mobi mobile app is running on your smartphone and if you have set up notifications as described in Section 5.6 Set Mobile Notifications.



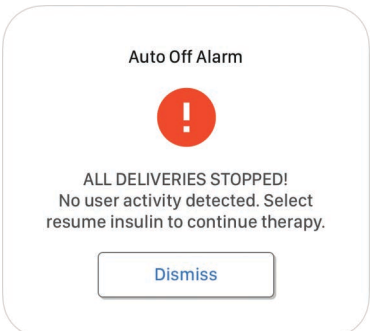
Unlock your smartphone and open or navigate to the Tandem Mobi mobile app. The Auto-Off Alarm timer will reset automatically once the Tandem Mobi mobile app is open.

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

If you do not clear the warning within the 5-minute countdown period, the Auto-Off Alarm occurs, accompanied by an audible alarm. This alarm notifies you that your pump has stopped delivering insulin.

Auto-Off Alarm Screen

Tap **Dismiss**.



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

You must resume delivery to continue therapy, see Section 9.3 Resuming Insulin Delivery.

12.3 Max Basal Alert

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

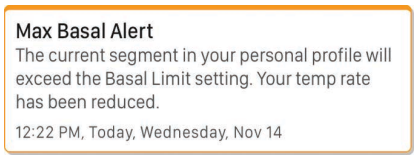
Once the Basal Rate Limit in the Pump Settings has been set up (see Section 6.3 Basal Rate Limit), you will receive an alert if the following scenarios occur.

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.

To Respond to Max Basal Alert

From the *Notifications* screen, swipe the alert to the left, and tap the **Dismiss** icon. The Temp Rate value is reduced to the same Basal Rate Limit value that was set up in Personal Profiles.



CHAPTER 13

Alerts

Your Tandem Mobi™ pump lets you know important information about its performance with reminders, alerts, and alarms. Reminders notify you of an option that you have set (for example, a reminder to check you BG after a bolus). Alerts annunciate automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms annunciate 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 push notifications are enabled on your smartphone, and the Tandem Mobi mobile app is open, you will get the alert notification on your lock screen of your smartphone.

⚠ 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.

If you are in the Tandem Mobi mobile app, you will see a red circle with the number of notifications waiting for your acknowledgment next to the Notifications area of the *Navigation* bar.

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 within the *Notifications* screen. Each must be acknowledged separately until all have been acknowledged. Notifications may be cleared in any order.

Information in this chapter will help you learn how to respond to alerts.

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.

If multiple alerts happen at the same time, you may clear them in any order.

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 enable and set up Snooze, see Section 5.7 Enable and Set Snooze.

⚑ NOTE

There is an additional list of alerts and errors related to CGM use in Chapter 25 CGM Alerts and Errors.

⚑ NOTE

There is an additional list of alerts related to Control-IQ+™ technology use in Chapter 30 Control-IQ+ Technology Alerts.

13.1 Low Insulin Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? Low Insulin Alert The insulin in your cartridge is running low. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	10 units or less of insulin remain in the cartridge.
	What sound setting will I hear or feel?	2 sequences of 3 notes or 2 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Change your cartridge as soon as possible to avoid the Empty Cartridge Alarm and running out of insulin.

13.2 Low Power Alerts

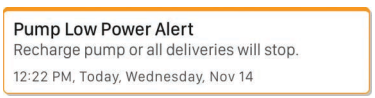
Low Power Alert 1

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? Pump Low Power Alert Pump power level: Less than 20% remaining. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	Less than 20% of battery power remains.
	What sound setting will I hear or feel?	2 sequences of 3 notes or 2 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Charge your pump as soon as possible to avoid the second Low Power Alert.

NOTE

Once the Low Power Alert occurs, the low-power indicator (a single red bar on the battery level indicator on the *Dashboard* screen) appears.

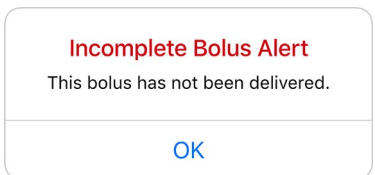
Low Power Alert 2

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	Less than 5% of battery power remains. Insulin delivery will continue for 30 minutes and then the pump will power off and insulin delivery will stop.
	What sound setting will I hear or feel?	2 sequences of 3 notes or 2 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Charge your pump immediately to avoid the Low Power Alarm and pump power off.

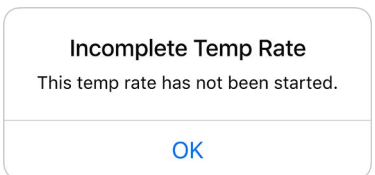
NOTE

Once the Low Power Alert occurs, the low-power indicator (a single red bar on the battery level indicator on the *Dashboard* screen) appears.

13.3 Incomplete Bolus Alert

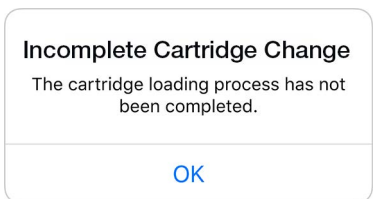
Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	You started a bolus request but did not complete the request within 90 seconds.
	What sound setting will I hear or feel?	Displays on the Tandem Mobi mobile app screen only, the pump will not beep or vibrate.
	Will the Tandem Mobi mobile app and pump re-notify me?	The Tandem Mobi mobile app will re-notify you every 5 minutes until the action is completed or cancelled. The pump will not notify you.
	How should I respond?	Tap **OK**. The *Bolus* screen will appear. » Continue with your bolus request » Tap the **Dashboard** icon to return to the *Dashboard* to cancel the bolus request.

13.4 Incomplete Temp Rate Alert

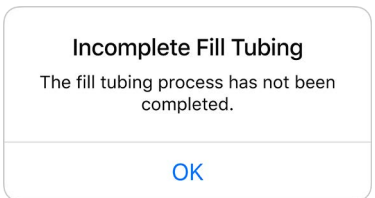
Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	You started to set up a temp rate but did not complete the request within 90 seconds.
	What sound setting will I hear or feel?	Displays on the Tandem Mobi mobile app screen only, the pump will not beep or vibrate.
	Will the Tandem Mobi mobile app and pump re-notify me?	The Tandem Mobi mobile app will re-notify you every 5 minutes until the action is completed or cancelled. The pump will not notify you.
	How should I respond?	Tap **OK**. The *Temp Rate* screen will appear. » Continue setting up your temp rate. » Tap **Cancel** if you do not want to continue setting up your temp rate.

13.5 Incomplete Load Sequence Alerts

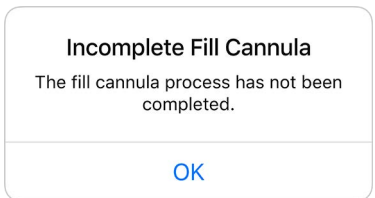
Incomplete Cartridge Change Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	You selected **Change Cartridge** from the *Load Cartridge* screen but did not complete the process within 3 minutes.
	What sound setting will I hear or feel?	Displays on the Tandem Mobi mobile app screen only, the pump will not beep or vibrate.
	Will the Tandem Mobi mobile app and pump re-notify me?	The Tandem Mobi mobile app will re-notify you every 5 minutes until the action is completed. The pump will not notify you.
	How should I respond?	Tap **OK**. Complete the cartridge change process.

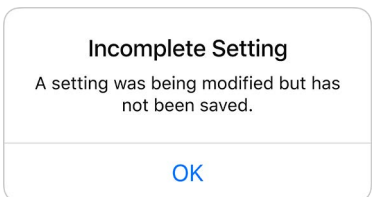
Incomplete Fill Tubing Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	You selected **Fill Tubing** from the *Load Cartridge* screen but did not complete the process within 3 minutes.
	What sound setting will I hear or feel?	Displays on the Tandem Mobi mobile app screen only, the pump will not beep or vibrate.
	Will the Tandem Mobi mobile app and pump re-notify me?	The Tandem Mobi mobile app will re-notify you every 5 minutes until the action is completed. The pump will not notify you.
	How should I respond?	Tap **OK**. Complete the fill tubing process.

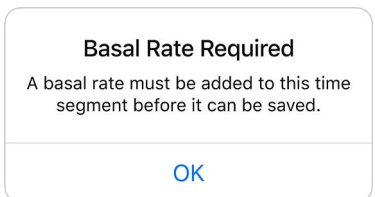
Incomplete Fill Cannula Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	You selected **Fill Cannula** from the *Load Cartridge* screen but did not complete the process within 3 minutes.
	What sound setting will I hear or feel?	Displays on the Tandem Mobi mobile app screen only, the pump will not beep or vibrate.
	Will the Tandem Mobi mobile app and pump re-notify me?	The Tandem Mobi mobile app will re-notify you every 5 minutes until the action is completed. The pump will not notify you.
	How should I respond?	Tap **OK**. Complete the cannula fill process.

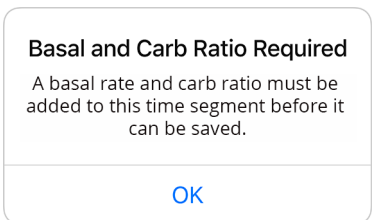
13.6 Incomplete Setting Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	You started to set up a new Personal Profile or Control-IQ+ technology setting but did not save or complete the programming within 5 minutes.
	What sound setting will I hear or feel?	Displays on the Tandem Mobi mobile app screen only, the pump will not beep or vibrate.
	Will the Tandem Mobi mobile app and pump re-notify me?	The Tandem Mobi mobile app will re-notify you every 5 minutes until the action is completed. The pump will not notify you.
	How should I respond?	Tap **OK**. Complete programming the Personal Profile or Control-IQ+ technology setting.

13.7 Basal Rate Required Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen?  	What does it mean?	You did not enter a Basal Rate in a time segment in Personal Profiles. A Basal Rate must be entered in each time segment (rate can be 0 units/hour).
	What sound setting will I hear or feel?	Displays on the Tandem Mobi mobile app screen only, the pump will not beep or vibrate.
	Will the Tandem Mobi mobile app and pump re-notify me?	No, a Basal Rate must be entered to save the time segment.
	How should I respond?	Tap **OK**. Enter a Basal Rate in the time segment.

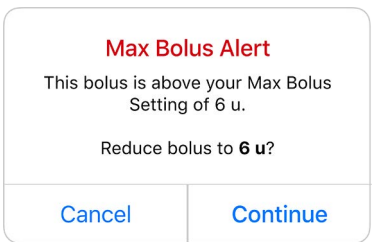
13.8 Basal and Carb Ratio Required Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	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. A Basal Rate and a Carb Ratio must be entered in each time segment (rate can be 0 units/hour).
	What sound setting will I hear or feel?	Displays on the Tandem Mobi mobile app screen only, the pump will not beep or vibrate.
	Will the Tandem Mobi mobile app and pump re-notify me?	No, a Basal Rate and Carb Ratio must be entered to save the time segment.
	How should I respond?	Tap **OK**. Enter a Basal Rate and a Carb Ratio in the time segment.

13.9 Max Hourly Bolus Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	In the previous 60 minutes, you requested total bolus delivery that is more than 1.5 times your Max Bolus setting.
	What sound setting will I hear or feel?	Displays on the Tandem Mobi mobile app screen only, the pump will not beep or vibrate.
	Will the Tandem Mobi mobile app and pump re-notify me?	No, you must tap **No** or **Yes** to deliver the bolus.
	How should I respond?	» Tap **No** to return to the *Bolus* screen and adjust the bolus delivery amount. » Tap **Yes** to confirm the bolus.

13.10 Max Bolus Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen?  	What does it mean?	You requested a bolus larger than the Max Bolus setting in your active Personal Profile.
	What sound setting will I hear or feel?	Displays on the Tandem Mobi mobile app screen only, the pump will not beep or vibrate.
	Will the Tandem Mobi mobile app and pump re-notify me?	No, you must tap **Cancel** or **Continue** to deliver the bolus.
	How should I respond?	» Tap **Cancel** to return to the *Bolus* screen and adjust the bolus delivery amount. » Tap **Continue** to deliver the amount of your Max Bolus setting.

13.11 Max Basal Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? **Max Basal Alert** The current segment in your personal profile will exceed the Basal Limit setting. Your temp rate has been reduced. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	An active Temp Rate exceeds your Basal Rate Limit setting due to a new timed segment activation within Personal Profiles. This alert will only display once your timed segment changes.
	What sound setting will I hear or feel?	2 sequences of 3 notes or 2 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. The Temp Rate value is reduced to the same Basal Rate Limit value that was set up in Personal Profiles.

13.12 Min Basal Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? Min Basal Alert Your current rate is less than the lowest allowable basal setting. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	An active temp rate dropped below half of your lowest basal setting defined in your Personal Profile.
	What sound setting will I hear or feel?	2 sequences of 3 notes or 2 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Review your Temp Rate settings from the *Actions* screen. » Review your Basal Rate settings in Personal Profiles. » Review your Temp Rate settings from the *Actions* screen.

13.13 Pump Button Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? **Button Alert** The pump has detected too many button presses during a quick bolus request. Please check the pump button to see if it is stuck. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	The **Pump** button on your pump has been pressed too many times during a Quick Bolus request.
	What sound setting will I hear or feel?	2 sequences of 3 notes or 2 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Check the **Pump** button to see if it is stuck in the pressed down position. Contact Customer Technical Support if the issue persists.

13.14 Quick Bolus Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? **Quick Bolus Alert** A quick bolus has been requested three times without delivery. Please check the pump button to see if it is stuck. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	A Quick Bolus has been requested three times, but has not been delivered successfully.
	What sound setting will I hear or feel?	2 sequences of 3 notes or 2 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Check the **Pump** button to see if it is stuck in the pressed down position. Contact Customer Technical Support if the issue persists.

13.15 Data Error Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? Data Error Alert Please verify that your active profile and pump settings are accurate. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	Your pump encountered a condition that could potentially result in a loss of data.
	What sound setting will I hear or feel?	2 sequences of 3 notes or 2 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Check your Personal Profiles and pump settings to verify that they are accurate. See Section 6.7 Editing or Reviewing an Existing Profile.

13.16 Temperature Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? Temperature Alert Remove the pump from extreme temperatures. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	The internal temperature of your pump is too high or too low.
	What sound setting will I hear or feel?	2 sequences of 3 notes or 2 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Remove the pump from extreme temperatures.

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CHAPTER 14

Alarms

⚠ 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.

Your Tandem Mobi pump lets you know important information about its performance with reminders, alerts, and alarms. Reminders notify you of an option that you have set (for example, a reminder to check your BG after a bolus). Alerts annunciate automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms annunciate 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 push notifications are enabled on your smartphone, and the Tandem Mobi mobile app is open, you will get the alert notification on the lock screen of your smartphone.

⚠ 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.

If you are in the Tandem Mobi mobile app, you will see a red circle with the number of notifications waiting for your acknowledgment next to the Notifications area of the *Navigation* bar.

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 within the *Notifications* screen. Each must be acknowledged separately until all have been acknowledged. Notifications may be cleared in any order.

Information in this chapter will help you learn how to respond to alarms.

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.

If multiple alarms happen at the same time, you may clear them in any order.

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 enable and set up Snooze, see Section 5.7 Enable and Set Snooze.

⚑ NOTE

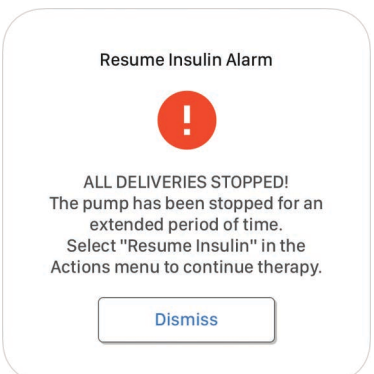
There is a list of alerts and errors related to CGM use in Chapter 25 CGM Alerts and Errors.

⚑ NOTE

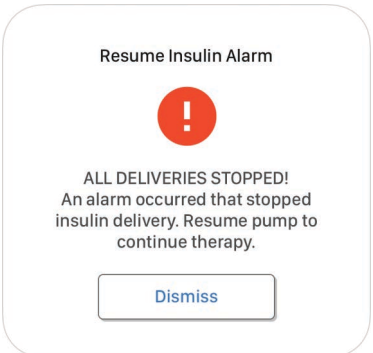
There is a list of alerts related to Control-IQ+™ technology use in Chapter 30 Control-IQ+ Technology Alerts.

14.1 Resume Insulin Alarms

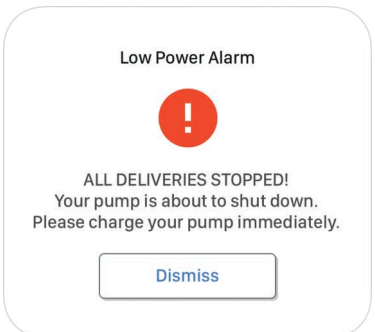
Resume Insulin Alarm 1

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	You selected **Stop Insulin** from the *Actions* screen and insulin delivery has been stopped for more than 15 minutes.
	What sound setting will I hear or feel?	3 sequences of 3 notes or 3 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink red three times in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes. » If not acknowledged by tapping **Dismiss**, the system will re-notify you every 3 minutes. » If acknowledged by tapping **Dismiss**, the system will re-notify you in 15 minutes.
	How should I respond?	To resume insulin, from the *Actions* screen, tap **Resume Insulin** and tap **Yes** to confirm.

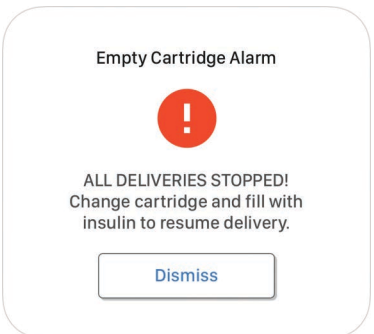
Resume Insulin Alarm 2

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it means?	Insulin has been stopped by a separate alarm event.
	What sound setting will I hear or feel?	3 sequences of 3 notes or 3 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink red three times in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes. » If not acknowledged by tapping **Dismiss**, the system will re-notify you every 3 minutes. » If acknowledged by tapping **Dismiss**, the system will re-notify you in 15 minutes.
	How should I respond?	To resume insulin, from the *Actions* screen, tap **Resume Insulin** and tap **Yes** to confirm.

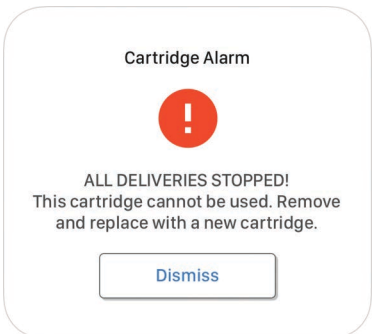
14.2 Low Power Alarm

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	Your pump detected a power level of 1% or less remaining and all deliveries have stopped.
	What sound setting will I hear or feel?	3 sequences of 3 notes or 3 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink red three times in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 3 minutes until no power remains and the pump shuts down.
	How should I respond?	Tap **Dismiss**. Charge your pump immediately to resume insulin delivery.

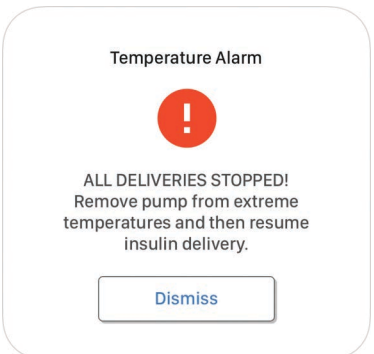
14.3 Empty Cartridge Alarm

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	Your pump detected that the cartridge is empty and all deliveries have stopped.
	What sound setting will I hear or feel?	3 sequences of 3 notes or 3 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink red three times in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 3 minutes until you change the cartridge.
	How should I respond?	Tap **Dismiss**. Change your cartridge immediately by tapping **Actions** from the *Navigation* bar, then **Load Cartridge** and follow the instructions in Section 7.3 Filling and Loading a Cartridge.

14.4 Cartridge Error Alarm

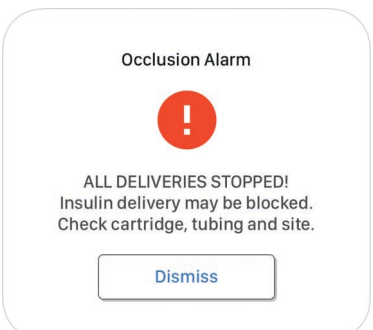
Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	Your pump detected that the cartridge could not be used and all deliveries have stopped. This can be caused by cartridge defect or not following the proper procedure to load the cartridge. It's not possible to overfill the Mobi cartridge.
	What sound setting will I hear or feel?	3 sequences of 3 notes or 3 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink red three times in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 3 minutes until you change the cartridge.
	How should I respond?	Tap **Dismiss**. Change your cartridge immediately by tapping **Actions** from the *Navigation* bar, then **Load Cartridge** and follow the instructions in Section 7.3 Filling and Loading a Cartridge.

14.5 Temperature Alarm – Pump

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	Your pump detected an internal temperature below -31ºF (-35ºC) or above 176ºF (80ºC) and all deliveries have stopped.
	What sound setting will I hear or feel?	3 sequences of 3 notes or 3 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink red three times in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 3 minutes until a temperature in the operating range is detected.
	How should I respond?	Tap **Dismiss**. Remove the pump from the extreme temperature and then resume insulin delivery.

14.6 Occlusion Alarms

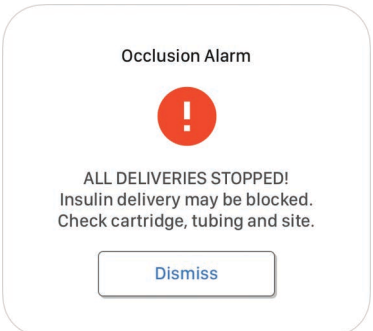
Occlusion Alarm 1

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	Your pump detected that insulin delivery is blocked and all deliveries have stopped. See Section 32.5 Pump Performance Characteristics for more information on how long it can take the system to detect an occlusion.
	What sound setting will I hear or feel?	3 sequences of 3 notes or 3 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink red three times in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 3 minutes until you resume insulin delivery.
	How should I respond?	Tap **Dismiss**. Check the cartridge, tubing, and infusion site for any sign of damage or blockage and correct the condition. To resume insulin, from the *Actions* screen, tap **Resume Insulin**.

NOTE

If the occlusion alarm occurs during bolus delivery, after tapping **Dismiss**, a screen will appear letting you know how much of the requested bolus was delivered before the occlusion alarm. When the occlusion is cleared, some or all of the previously requested insulin volume may be delivered. Test your BG at the time of alarm and follow your healthcare provider's instructions for managing potential or confirmed occlusions.

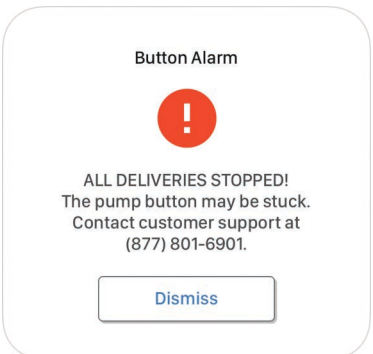
Occlusion Alarm 2

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	Your pump detected a second occlusion alarm shortly after the first occlusion alarm and all deliveries have stopped.
	What sound setting will I hear or feel?	3 sequences of 3 notes or 3 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink red three times in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 3 minutes until you resume insulin delivery.
	How should I 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.

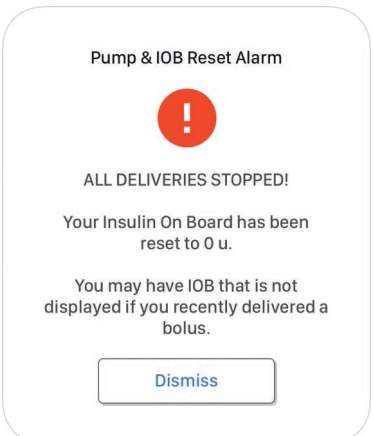
NOTE

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

14.7 Pump Button Alarm

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	The **Pump** button on your pump is stuck or not functioning properly and all deliveries have stopped.
	What sound setting will I hear or feel?	3 sequences of 3 notes or 3 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink red three times in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 3 minutes until the condition is corrected.
	How should I respond?	Tap **Dismiss**. Contact Customer Technical Support.

14.8 Pump & IOB Reset Alarm

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	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. Additionally, **DO NOT** rely on the Max Hourly Bolus Alert for 60 minutes following a pump restart.
	What sound setting will I hear or feel?	3 sequences of 3 notes or 3 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink red three times in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 3 minutes until you tap **Dismiss**.
	How should I respond?	Tap **Dismiss**. 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.

CHAPTER 15

Malfunction

15.1 Malfunction

If your pump detects a critical error, the *Pump Malfunction* screen appears on the Tandem Mobi™ mobile app and all deliveries are stopped. Contact Customer Technical Support.

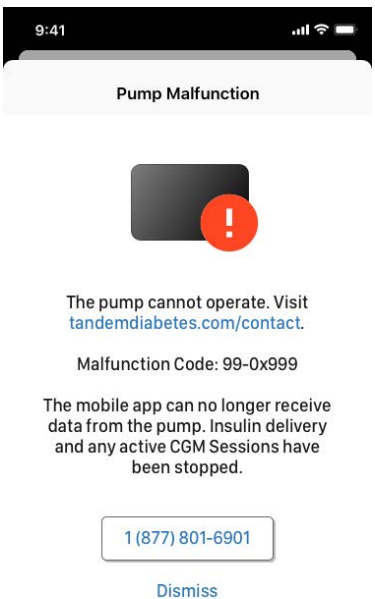
Malfunctions notify you with 3 sequences of 3 notes and 3 vibrations and the pump status lights will light up in red in the pattern listed in the table in this chapter. They repeat at regular intervals until acknowledged by tapping Dismiss in the Tandem Mobi mobile app.

For pump malfunctions, the vibrations and pump status lights display will continue until the pump runs out of battery. Beeps are silenced when the user taps Dismiss in the Tandem Mobi mobile app.

⚠ PRECAUTION

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

15.2 Pump Malfunction

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	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.
	What sound setting will I hear or feel?	3 sequences of 3 notes and 3 vibrations.
	What pump status lights will I see?	Both lights will blink red three times in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 3 minutes until you acknowledge the malfunction by tapping **Dismiss**.
	How should I 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.

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CHAPTER 16

Taking Care of Your Pump

16.1 Taking Care of Your Pump

Cleaning Your Pump

It is recommended that you routinely clean your pump. Before starting, always suspend your insulin, disconnect your infusion set, and remove the cartridge from the pump. If your pump is exposed to common household chemicals such as sunscreen or bug sprays, be sure to clean the pump immediately. When cleaning your pump, use a damp lint-free cloth with a 9:1 water to dish detergent solution. 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

⚠ PRECAUTION

DO NOT use your pump if you think it might be damaged due to dropping it or hitting it against a hard surface. Check that the pump is working properly by placing it on the charging pad, you feel the pump vibrate, and see the pump status lights blinking above the **Pump** button. If you are unsure about potential damage, discontinue use of the pump and contact Customer Technical Support.

If you drop your pump or it has been hit against something hard, ensure that it is still working properly. Check that the 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

If you need to stop using your pump for a long period of time, you can place the pump in storage mode. To place the pump in storage mode, 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.

Keep the pump protected when not in use. Store at temperatures 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. The pump will beep four times and the pump status lights will flash two green lights four times. However, if the pump was in storage mode for an extended amount of time, the pump battery may become fully depleted and it may take longer than usual to hear the beeps and see the pump status lights. See Section 3.6 Charging the Pump for more information.

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.

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CHAPTER 17

Lifestyles Issues and Travel

17.1 Lifestyle Issues and Travel for Your Pump

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

⚠ PRECAUTION

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

Physical Activity

The pump can be worn during most forms of exercise, such as running, cycling, hiking, and resistance training. During exercise, the pump can be worn in the provided case, the Tandem Mobi adhesive sleeve, your pocket, or other third-party "sport cases."

⚠ 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.

⚑ NOTE

Avoid using a case with delicate fabrics or material that can be misshaped by force.

For activities where contact is a concern, such as baseball, hockey, martial arts, or basketball, you can disconnect from your pump for short periods of time. If planning to disconnect from your pump, discuss a plan with your healthcare provider to compensate for any basal insulin delivery you miss while disconnected, and be sure to continue to check your BG levels. Even if you disconnect your tubing from your infusion site, the pump should continue to receive data from the CGM as long as it is within the 20-foot (6-meter) range without obstruction. The Tandem Mobi™ mobile app should also continue to receive data from the pump within this range.

Aquatic Activities

⚠ 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.

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

⚠ 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.

There are other activities, such as bathing and intimacy, when it may be more convenient for you to remove your pump. It is safe to do so for short periods of time. If planning to disconnect from your pump, discuss a plan with your healthcare provider for compensating for any basal delivery you miss while disconnected, and be sure to check your BG levels frequently. Missing basal delivery could cause your BG to rise.

Travel

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

- The items listed in the Emergency Kit described in Section 1.12 Emergency Kit.
- A prescription for both rapid-acting and long-acting insulin of the type recommended by your healthcare provider in case you need to take insulin by injection.
- A letter from your healthcare provider explaining the medical need for your insulin pump and other supplies.

Traveling by Air

⚠ PRECAUTION

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

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

The pump 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.

If you enable Airplane mode on your smartphone, you must maintain an active Bluetooth connection between your smartphone and your pump to use the Tandem Mobi mobile app. You can use the Quick Bolus feature on your pump, if enabled, to deliver a bolus if you cannot connect your smartphone and pump. Please check with your airline carrier and smartphone manufacturer instructions prior to traveling to determine conditions for using Bluetooth technology.

NOTE

The Tandem Mobi mobile app requires an active Bluetooth connection to connect with your pump. If you turn on Airplane mode, make sure you keep Bluetooth technology enabled to connect to your pump.

3 CGM Features

CHAPTER 18

Important CGM Safety Information

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

18.1 CGM Warnings

Using a Dexcom CGM with Your Tandem Mobi™ Insulin Pump

⚠ WARNING

DO NOT ignore symptoms of high and low glucose. If your sensor glucose alerts and readings do not match your symptoms, measure your BG with a 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.

18.2 CGM Precautions

Using a Dexcom CGM with Your Tandem Mobi Insulin Pump

⚠ 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.

18.3 Potential Benefits From Using the Tandem Mobi Insulin Pump with CGM

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

18.4 Possible Risks From Using the Tandem Mobi Insulin Pump with CGM

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

Other risks associated with CGM use include the following:

- You will not get sensor glucose alerts when the alert function is turned off, your CGM and pump are out of range, or when your pump is not showing sensor glucose readings. You might not notice alerts if you are unable to hear them or feel the vibration.
- There are a number of risks as a result of the fact that the Dexcom CGM takes readings from fluid below the skin (interstitial fluid) instead of blood. There are differences in how glucose is measured in the blood compared to

how it is measured in interstitial fluid, and glucose is absorbed into the interstitial fluid slower than it is absorbed into the blood, which can cause CGM readings to lag behind readings from a BG meter.

3 CGM Features

CHAPTER 19

CGM Overview

19.1 CGM System Overview

This section of the user guide covers instructions for using a CGM with your Tandem Mobi™ system. Use of a CGM is optional, but in order to use Control-IQ+™ technology, CGM is required. When used, a CGM allows readings from your sensor to be sent to your pump and then displayed on your Tandem Mobi mobile app. To make treatment decisions during a new sensor startup period, you will also need a commercially available BG meter to use with your System.

Compatible CGMs are the Dexcom G6 CGM, which consists of a sensor and transmitter, and the Dexcom G7 CGM, which consists of a sensor with a built-in transmitter. The Dexcom receiver is sold separately.

Both CGM systems are devices that are inserted under the skin to continuously monitor glucose levels from interstitial fluid (the fluid under your skin). The CGM uses Bluetooth wireless technology communication and sends readings to the pump every 5 minutes. The Tandem Mobi mobile app *Dashboard* screen shows sensor glucose readings, a graph, and the direction and rate of change arrows. For information about inserting a Dexcom CGM sensor, connecting and pairing to a CGM, and Dexcom product specifications, visit the manufacturer's website for applicable product instructions and training information.

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

19.2 Device Connection Overview

CGM readings in the Tandem Mobi mobile app are provided through the Tandem Mobi insulin pump connection. Ensure your CGM is connected to the Tandem Mobi pump before pairing the CGM with any other devices or mobile apps.

Unlike the readings from a standard BG meter, CGM readings allow you to view trends in near real time, while capturing information and glucose patterns when you would otherwise be unable to check your BG, such as while you are asleep. This information can be useful for you and your healthcare provider when considering changes to your therapy. In addition, the programmable alerts can help you to spot potential low or high sensor glucose sooner than you would using a only a BG meter.

19.3 Receiver (Insulin Pump) Overview

To review the icons and controls displayed on the *Dashboard* screen with CGM enabled, see Section 4.3 Dashboard Screen.

19.4 Dexcom G6 Transmitter Overview

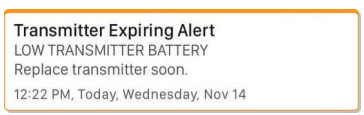
For information about the Dexcom G6 transmitter, visit the manufacturer's website for applicable product instructions.

⚠ PRECAUTION

DO keep your CGM and pump within 20 feet (6 meters) with no obstacles (like walls or metal)

between them. Otherwise, they may not be able to communicate. If water is between your CGM and the pump (for example, if you're showering or swimming) keep them closer to each other. The range is reduced because Bluetooth technology doesn't work as well through water. To ensure communication, it is suggested that you wear the pump on the same side of the body that you wear your CGM.

Once you see the *Low Transmitter Battery* alert, consider replacing the transmitter the next time you start a new sensor session.



19.5 Sensor Overview

For information about Dexcom sensors, visit the manufacturer's website for applicable product instructions.

The Tandem Mobi mobile app alerts you when your CGM sensor session has expired.

You will also get alerts from the Tandem Mobi mobile app to let you know how much time remains in your CGM sensor session. These alerts vary depending on which sensor you are using.

Dexcom G6 Sensor

If you are using the Dexcom G6 sensor, the Tandem Mobi mobile app will alert you at the following times:

- 24 hours remaining
- 2 hours remaining
- 30 minutes remaining

Dexcom G7 Sensor

If you are using the Dexcom G7 sensor, the Tandem Mobi mobile app will alert you at the following times:

- 24 hours remaining
- 2 hours remaining

The Dexcom G7 sensor provides an additional 12-hour grace period. The Tandem Mobi mobile app will alert you when your grace period will end at the following times:

- 2 hours remaining
- 30 minutes remaining

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3 CGM Features

CHAPTER 20

CGM Settings

20.1 About Bluetooth Technology

Bluetooth Low Energy technology is a type of wireless communication used in cell phones and many other devices. Your Tandem Mobi™ system uses Bluetooth wireless technology communication to wirelessly pair together with other devices, such as a CGM or a smartphone running the Tandem Mobi mobile app. This allows the pump to wirelessly communicate with paired devices securely and only with each other.

20.2 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.

20.3 Setting CGM Volume

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

CGM Volume options:

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

Beep
The default profile when you receive your pump. This sets all alerts and alarms to beep.

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

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

The Fixed Low Alert at 55 mg/dL cannot be turned off or changed.

The beep and HypoRepeat options have the following sequence:

- The first alert is vibrate only.
- If the alert is not acknowledged in 5 minutes, the pump vibrates and beeps.
- If the alert is not acknowledged in 5 more minutes, the pump vibrates and beeps again. This continues every 5 minutes until acknowledged.
- If the alert is acknowledged and your sensor glucose readings continue to be at or below 55 mg/dL your pump repeats the alert sequence in 30 minutes (HypoRepeat option only).

Sound Option Descriptions

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

To Select Your CGM Volume:

1. From the *Navigation* bar, tap **Settings**.
2. Tap **Alerts & Sounds**.
3. Tap **Pump Sounds**.
4. Tap **CGM Alerts**.
5. Tap **Beep**, **Vibrate**, or **HypoRepeat** to select, and tap **Done** (iOS) or **OK** (Android).
6. Tap **Save**.

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

20.4 CGM Info

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

- Firmware Revision
- Hardware Revision
- BLE Hardware ID
- Software Number

You can view this information at any time.

1. From the *Navigation* bar, tap **Settings**.
2. Tap **CGM**.
3. Tap **CGM Info**.

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3 CGM Features

CHAPTER 21

Setting CGM Alerts

Setting Your CGM Alerts

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

NOTE

The following applies to setting CGM alerts on the pump. Any alerts that have been set up in a separate CGM app are not automatically transferred to the pump and must be set up in the CGM mobile app.

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

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

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

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

21.1 High and Low Glucose Alerts

You can personalize the High and Low Alerts which tell you when your sensor glucose readings are outside of your target sensor glucose range. When you have both your High and Low Alerts turned on, dashed lines appear on the *Dashboard* graph indicating the alert limits. The default for the High Alert is on, 200 mg/dL. The default for the Low Alert is on, 80 mg/dL. Consult with your healthcare provider before setting the High and Low Glucose Alert setting.

21.2 Setting Your High Glucose Alert and Repeat Feature

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

   The default setting for the High Alert is 200 mg/dL.
5. 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.
6. 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.
7. Tap **Done** or ✔.

   The repeat feature allows you to set a time for the High Alert to sound again and display on your Tandem Mobi™ mobile app as long as your sensor glucose reading remains above the High Alert value. The default value is: Never (the alert will not sound again). You can set the repeat feature to sound again every

15 minutes, 30 minutes, 1 hour, 2 hours, 3 hours, 4 hours, or 5 hours when your sensor glucose reading remains above the High Alert value.

To Set Up the Repeat Feature:

8. Tap **Repeat**.
9. 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.
10. Tap **Done** or ✔.
11. Tap **Save**.

21.3 Setting Your Low Glucose Alert and Repeat Feature

1. From the *Dashboard* screen, tap **Settings**.
2. Tap **Alerts & Sounds**.
3. Tap **CGM Alerts**.
4. To Set the Low Alert, tap **Low Alert**.

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

   NOTE
   To turn the alert off, tap the **Low Alert** toggle off.
6. 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.
7. Tap **Done** or ✔.

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

To Set Up the Repeat Feature:

8. Tap **Repeat**.
9. 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.
10. Tap **Done** or ✔.
11. Tap **Save**.

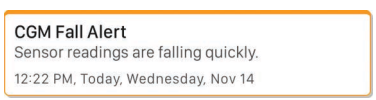
21.4 Rate Alerts

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

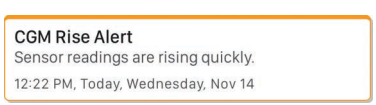
mg/dL or more per minute. The default value for both the Fall Alert and the Rise Alert is off. When turned on, the default is 3 mg/dL. Consult with your healthcare provider before setting the Rise and Fall Alerts.

Examples

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



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



21.5 Setting Your Rise Alert

1. From the *Dashboard* screen, tap **Settings**.
2. Tap **Alerts & Sounds**.
3. Tap **CGM Alerts**.
4. Tap **Rise Alert**.
5. Tap the toggle next to **Rise Alert**.
6. To select the default of 3 mg/dL/min, tap **Save**.

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

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

7. Tap **2 mg/dL/min** to select, then tap **Done** or ✔, then tap **Save**.

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

21.6 Setting Your Fall Alert

1. From the *Dashboard* screen, tap **Settings**.
2. Tap **Alerts & Sounds**.
3. Tap **CGM Alerts**.
4. Tap **Fall Alert**.
5. Tap the toggle next to **Fall Alert**.
6. To select the default of 3 mg/dL/min, tap **Save**.

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

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

7. Tap **2 mg/dL/min** to select, then tap **Done** or ✔, then tap **Save**.

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

21.7 Setting Your Out of Range Alert

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

The Out of Range Alert lets you know when your CGM and pump are not communicating with each other. This alert is on by default.

⚠ PRECAUTION

We recommend that you keep the CGM Out of Range Alert turned on to notify you if your CGM is disconnected from your pump whenever you are not actively monitoring your pump status. Your CGM is providing the data that Control-IQ+™ technology requires to make predictions to automate insulin delivery.

Keep the CGM and the pump within 20 feet (6 meters) of each other without obstruction. To ensure communication, it is suggested that you wear the pump on the same side of the body that you wear your CGM. When the CGM and pump are not communicating, you will not get sensor glucose readings or alerts. The default value is on and will alert after 20 minutes.

The Out Of Range symbol appears on the *Dashboard* screen (if turned on) when the CGM and pump are not communicating. It will continue to re-alert until the CGM and pump are back in range.

⚑ NOTE

Control-IQ+ technology will continue to operate for the first 15 minutes that the CGM and pump are out of range. Once the Out of Range condition is present for 20 minutes, Control-IQ+ technology will stop operation until the two devices are within range.

To Set Your Out of Range Alert:

1. From the *Dashboard* screen, tap **Settings**.
2. Tap **Alerts & Sounds**.
3. Tap **CGM Alerts**.
4. Tap **Out of Range**.

   The default is set to on and the time is set to 20 minutes.
5. To change the time, tap **Alert Me After**.
6. 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.
7. Tap **Done** or ✔.
8. Tap **Save**.

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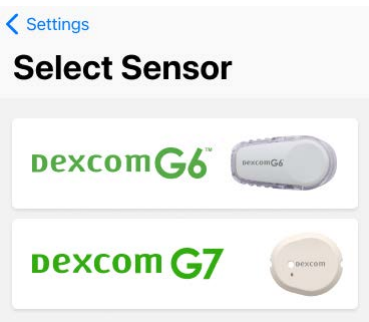
3 CGM Features

CHAPTER 22

Starting or Stopping a CGM Sensor Session

22.1 Choosing Your Sensor Type

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



You may switch CGM types at any time.

NOTE

Ensure your CGM is connected to the Tandem Mobi pump before pairing the CGM with any other devices or mobile apps.

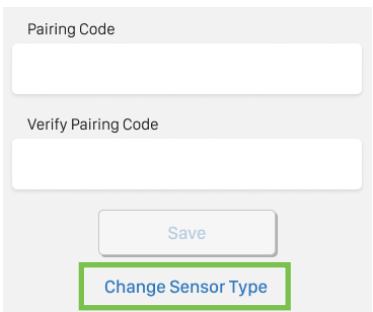
To switch from a Dexcom G6 CGM:

1. From the *Dashboard* screen, tap **Settings**.
2. Tap **CGM**.
3. Tap **Change Sensor Type** at the bottom of the *Dexcom G6* screen.

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

To switch from a Dexcom G7:

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



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

22.2 Enter Your Dexcom G6 Transmitter ID

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

If you need to replace your transmitter, you will need to enter the new transmitter ID into your Tandem Mobi mobile app.

If you need to replace your pump, you will need to re-enter the transmitter ID into your Tandem Mobi mobile app after you re-pair your replacement pump to the Tandem Mobi mobile app.

1. Remove the transmitter from its packaging.

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

2. From the *Dashboard* screen, tap **Settings**.
3. Tap **CGM**.
4. Tap **Dexcom G6**.
5. Tap the **Transmitter ID** field.
6. 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. If one of these letters is entered, you will be notified that an invalid ID was entered and prompted to enter a valid ID.

7. Using the on-screen keyboard, verify your transmitter ID by entering it again in the **Verify Transmitter ID** field.
8. Tap **Done** or ✔.
9. 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.

22.3 Start the Dexcom G6 Sensor

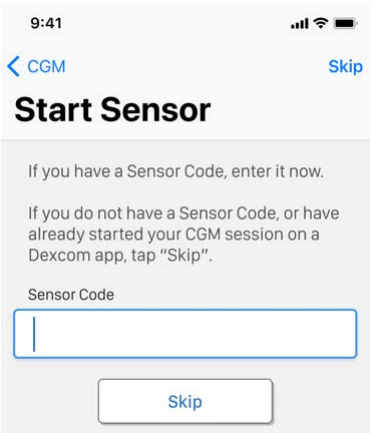
The following information is specific to the Dexcom G6 sensor. For information on starting a sensor session for the Dexcom G7 CGM, see Section 22.8 Start the Dexcom G7 Sensor.

To start a sensor session, follow the steps below.

1. From the *Dashboard* screen, tap **Settings**.
2. Tap **CGM**.
3. Tap **Dexcom G6**.
4. 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.



5. 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.

6. Tap **Done** or ✔.

7. Tap **Next** or →.

8. 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.

9. 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.

10. 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.

22.4 Dexcom G6 Sensor Startup Period

The Dexcom G6 sensor requires a 2-hour startup period to adjust to being under your skin. You will not get sensor glucose readings or alerts until the 2-hour startup period ends. For information about Dexcom G6 CGM sensor startup periods, visit the manufacturer's website for applicable product instructions.

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

⚠ WARNING

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

⚑ NOTE

During the sensor startup period, Control-IQ+™ technology will not adjust Basal Rates or deliver automatic correction boluses. The sensor must be actively providing readings for Control-IQ+ technology to operate.

Examples

For example, if you started your sensor session 65 minutes ago, you would see this countdown message on the *Dashboard* screen.

If you entered a sensor code when you started the CGM sensor session, at the end of the 2-hour startup period, the countdown 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.

22.5 Dexcom G6 Automatic Sensor Shut-Off

Your Tandem Mobi mobile app tells you how much time you have left until your sensor session is complete. The *CGM Sensor Expiring Soon* alert shows at 24

hours remaining, 2 hours remaining, and 30 minutes remaining before your session ends. You will continue to receive sensor glucose readings after each reminder.

After the final 30 minutes, the *Replace Sensor* alert is displayed.

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

Sensor glucose alerts and alarms do not work after the sensor session ends. New sensor glucose readings do not show on your Tandem Mobi mobile app after your sensor session ends. If you are using Control-IQ+ technology, it becomes inactive when a CGM sensor session is ended. You must remove your sensor, insert a new sensor, and start a new sensor session.

22.6 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. However, if you end a sensor session early, you cannot re-start the session with that same sensor. A new sensor must be used.

NOTE

DO NOT throw away the transmitter at the end of a sensor session. Continue use of the transmitter until the pump notifies you that the transmitter battery is about to expire. Wipe the outside of the transmitter with isopropyl alcohol between sensor sessions.

Sensor glucose alerts and alarms do not work after the sensor session ends. New sensor glucose readings do not show on your Tandem Mobi mobile app after your sensor session ends. If you are using Control-IQ+ technology, it becomes inactive when a CGM sensor session is ended. You must remove your sensor, insert a new sensor, and start a new sensor session.

To end your sensor session early:

1. From the *Dashboard* screen, tap **Settings**.
2. Tap **CGM**.
3. Tap **Stop G6 Sensor**.
4. 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.

22.7 Removing the Dexcom G6 Sensor and Transmitter

⚠ WARNING

DO NOT ignore broken or detached sensor wires. A sensor wire could remain under your skin. If a sensor wire breaks off under your skin and you can't see it, don't try to remove it. Contact your healthcare provider. Also seek professional medical help if you have symptoms of infection or inflammation (redness, swelling, or pain) at the insertion site. If you experience a broken sensor, please report this to Customer Technical Support.

For information about removing the Dexcom G6 sensor and Dexcom G6 transmitter, visit the manufacturer's

website for applicable product instructions.

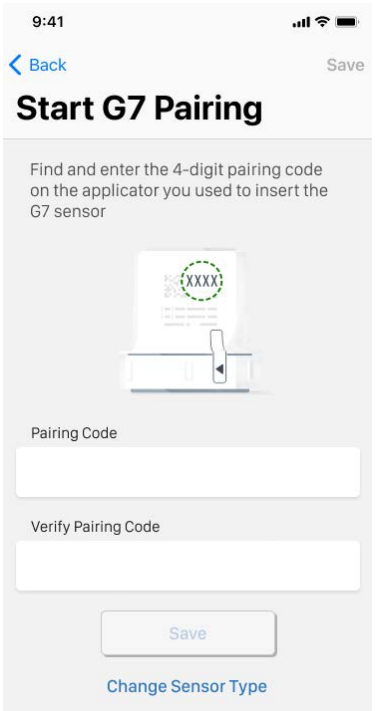
22.8 Start the Dexcom G7 Sensor

The following information is specific to the Dexcom G7 sensor. For information on starting a sensor session for the Dexcom G6 sensor, see Section 22.3 Start the Dexcom G6 Sensor.

To start a CGM session, follow the steps below.

1. From the *Dashboard* screen, tap **Settings**.
2. Tap **CGM**.
3. Tap **Dexcom G7**.

   The following screen displays prompting you to enter the pairing code. For information about Dexcom G7 CGM pairing codes, visit the manufacturer's website for applicable product instructions.



4. Tap the *Pairing Code* field to enter the 4-digit pairing code.
5. Tap the *Verify Pairing Code* field to enter the 4-digit pairing code again.
6. Tap **Done** or ✔.
7. Tap **Save**.

✓ The *Sensor Paired* window displays.

8. Tap **Done** or ✔.
9. 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.
10. 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.

22.9 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. For information about Dexcom G7 CGM sensor startup periods, visit the manufacturer's website for applicable product instructions.

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 text changes to show that you are getting closer to the active sensor session.

⚠ WARNING

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

⚑ NOTE

During the sensor startup period, Control-IQ+ technology will not adjust Basal Rates or deliver automatic correction boluses. The sensor must be actively providing readings for Control-IQ+ technology to operate.

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

22.10 Dexcom G7 Automatic Sensor Shut-Off

Your Tandem Mobi mobile app tells you how much time you have left until your sensor session is complete. The *CGM Sensor Expiring Soon* alert shows at 24 hours remaining and 2 hours remaining before your session ends. After the sensor has expired, a 12-hour grace period begins. You will continue to receive sensor glucose readings after each reminder. During the grace period, the Tandem Mobi mobile app tells you when there are 2 hours remaining, and again when there are 30 minutes remaining.

If you do not want to stop your sensor you will see the *CGM Sensor Expiring Soon* alert in the *Notifications* screen. If you do not dismiss this alert, it will continue to display the updated time remaining in the sensor session time.

Once the CGM sensor is expired, you will see the *Sensor Expired* alert in the *Notifications* screen. This alert indicates that the 12 hour grace period has begun.

If you still do not want to stop your sensor, you will see the *Replace Sensor Soon* alert in the *Notifications* screen. This alert will show when there are two hours left in the grace period and again when there are 30 minutes left in the grace period.

After the final 30 minutes, the *Replace Sensor* alert is displayed.

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

Sensor glucose alerts and alarms do not work after the sensor session ends. New sensor glucose readings do not show on your Tandem Mobi mobile app after your sensor session ends. If you are using Control-IQ+ technology, it becomes inactive when a CGM sensor session is ended. You must remove your sensor, insert a new sensor, and start a new sensor session.

22.11 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. However, if you end a sensor session early, you cannot re-start the session with that same sensor. A new sensor must be used.

Sensor glucose alerts and alarms do not work after the sensor session ends. New sensor glucose readings do not show on your Tandem Mobi mobile app after your sensor session ends. If you are using Control-IQ+ technology, it becomes inactive when a CGM sensor session is ended. You must remove your sensor, insert a new sensor, and start a new sensor session.

To end your sensor session early:

1. From the *Dashboard* screen, tap **Settings**.
2. Tap **CGM**.
3. Tap **Stop G7 Sensor**.
4. 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.

22.12 Removing the Dexcom G7 Sensor

⚠ WARNING

DO NOT ignore broken or detached sensor wires. A sensor wire could remain under your skin. If a sensor wire breaks off under your skin and you can't see it, don't try to remove it. Contact your healthcare provider. Also seek professional medical help if you have symptoms of infection or inflammation (redness, swelling, or pain) at the insertion site. If you experience a broken sensor, please report this to Customer Technical Support.

For information about removing the Dexcom G7 CGM, visit the manufacturer's website for applicable product instructions.

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3 CGM Features

CHAPTER 23

Calibrating Your Dexcom CGM System

Calibration is required for the Dexcom G6 CGM if you did not enter a sensor code when starting the sensor session. It is optional at all other times.

Calibration is optional for the Dexcom G7 CGM and can be performed if you have symptoms that do not align with your posted CGM values.

23.1 Calibration Overview

If you are using the Dexcom G6 and did not enter a CGM sensor code when starting a sensor session, you will be prompted to calibrate at the following intervals:

- 2-hour startup: 2 calibrations 2 hours after you start your sensor session
- 12-hour update: 12 hours after the 2 hour start up calibration
- 24-hour update: 24 hours after the 2 hour start up calibration
- Every 24 hours: every 24 hours after the 24-hour update
- When notified

On the first day of your sensor session, you must enter four BG values into your 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.

23.2 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 10 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.

⚠ PRECAUTION

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

3. Tap **Settings**.
4. Tap **CGM**.
5. Tap **Calibrate CGM**.
6. Using the on-screen keyboard, enter the BG value from your BG meter into the *BG value* field.

⚠ PRECAUTION

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

7. Tap **Done** or ✔.
8. Tap **Confirm**.

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

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

✓ The on-screen keyboard will appear.

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

your BG meter manufacturer's instructions.

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

23.3 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 8.3 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.

23.4 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.

NOTE

Although it is not required, and you will not be prompted to calibrate, you may enter a calibration into the pump at any time, even if you have already entered a sensor code. Pay attention to your symptoms, and if they do not match the current CGM readings, you may choose to enter a calibration.

3 CGM Features

CHAPTER 24

Viewing CGM Data on Your Tandem Mobi Mobile App

24.1 Overview

⚠ WARNING

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

The pump screens in this section illustrate the screen when Control-IQ+™ technology is off. For information about CGM screens when Control-IQ+ technology is on, see Section 29.8 Control-IQ+ Technology Information on Your Screen.

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

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

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

24.2 CGM Graphs

You can view the prior 24 hours of sensor glucose information by swiping right on the graph. For more information on what displays on the graph, see Section 4.6 Dashboard Screen – 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.

24.3 Rate of Change Arrows

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

24.4 CGM History

CGM History displays the historical log of CGM events. At least 14 days of data can be viewed in History. When the maximum number of events is reached, the oldest events are removed from the history log and replaced with the most recent events. The following history sections can be viewed:

- Sessions and Calibrations
- Alerts and Errors
- Complete

Each section above is organized by date. If there are no events associated with a date, the day will not be shown in the list.

The Sessions and Calibrations section includes the start time and date for each Sensor Session, the stop time and date for each Sensor Session, and all calibration BG values entered.

The Alerts and Errors section includes the date and time for all Alerts and Errors that occurred. The letter “D” (D: Alert) before an Alert or Alarm indicates the time it was declared. The letter “C” (C: Alert) indicates the time it was cleared.

The Complete section includes all information from the Sessions and Calibrations and Alerts and Errors sections as well as any changes to settings.

1. From the *Navigation* bar, tap **Settings**.
2. Tap **App**.
3. Tap **History**.
4. Tap **CGM History**.
5. Tap the section you want to view. Each section is organized by date. Tap the date to view events from that day.

24.5 Missed Readings

If your pump misses CGM readings for a period of time, you will see three dashes where the CGM reading typically displays on the *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.

NOTE

Control-IQ+ technology will continue to operate for the first 15 minutes after CGM readings become unavailable. If connectivity between the pump and CGM is not restored after 20 minutes, Control-IQ+ technology will stop operation until CGM readings are available. While Control-IQ+ technology is not operating, your pump will continue to deliver insulin according to your Personal Profile settings. Once CGM readings are available, Control-IQ+ technology will automatically resume. For more information, see Chapter 28 Introduction to Control-IQ+ Technology.

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CHAPTER 25

CGM Alerts and Errors

Information in this chapter will help you learn how to respond to CGM alerts and errors. It applies only to the CGM portion of your system. CGM alerts and errors do not follow the same pattern of vibration and beeps as insulin delivery reminders, alerts, and alarms.

If push notifications are enabled on your smartphone, and the Tandem Mobi™ mobile app is open, you will get the alert notification on the lock screen of your smartphone.

NOTE

Not all alerts are applicable to all CGM types. An alert screen may vary slightly depending on the type of CGM you are using.

⚠ 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.

If you are using the Tandem Mobi mobile app, you will see a red circle with the number of notifications waiting for your acknowledgment next to the Notifications area of the *Navigation* bar. Notifications may be cleared in any order.

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 enable and set up Snooze, see Section 5.7 Enable and Set Snooze.

For information on insulin delivery reminders, alerts, and alarms, see Chapter 13 Alerts, Chapter 14 Alarms, and Chapter 15 Malfunction.

For information on Control-IQ+™ technology alerts, see Chapter 30 Control-IQ+ Technology Alerts.

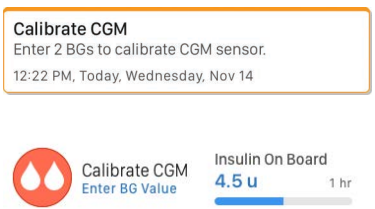
⚠ WARNING

If a sensor session is ended, either automatically or manually, Control-IQ+ technology is unavailable and will not adjust insulin. In order for Control-IQ+ technology to be enabled, a sensor session must be started and transmitting sensor values to the pump based on a sensor code, pairing code, or sensor calibration.

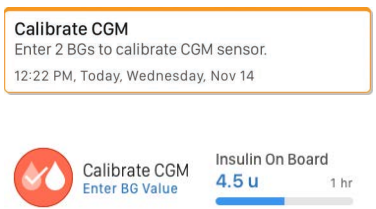
⚠ PRECAUTION

You must customize the CGM alert settings on the Tandem Mobi mobile app and the Dexcom G6 CGM app separately. The alert settings apply to the Tandem Mobi mobile app and the Dexcom G6 CGM app separately.

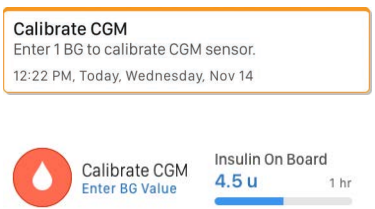
25.1 Startup Calibration Alert – Dexcom G6 Only

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	The CGM startup period is complete. This will only appear if you did not enter a sensor code.
	What sound setting will I hear or feel?	1 sequence of 1 note or 1 long vibration depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged and then every 15 minutes until you calibrate.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Follow instructions in Section 23.2 Startup Calibration and enter 2 separate BG values to calibrate the CGM and start your CGM session.

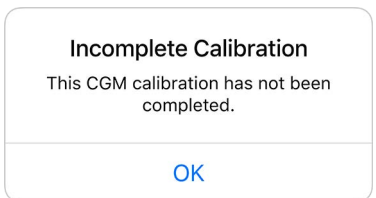
25.2 Second Startup Calibration Alert – Dexcom G6 Only

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	The CGM needs an additional BG value to complete startup calibration. This will only appear if you did not enter a sensor code.
	What sound setting will I hear or feel?	1 sequence of 1 note or 1 long vibration depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged and then every 15 minutes until second calibration is entered.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Follow instructions in Section 23.2 Startup Calibration and enter a second BG value to calibrate the CGM and start your CGM session.

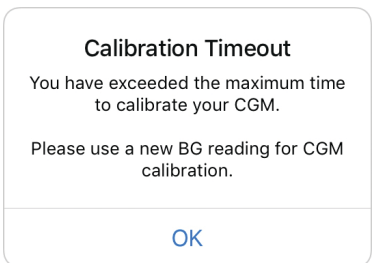
25.3 12 Hour Calibration Alert – Dexcom G6 Only

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	The CGM needs a BG value to calibrate. This will only appear if you did not enter a sensor code.
	What sound setting will I hear or feel initially?	1 long vibration.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 15 minutes with 1 sequence of 1 note or 1 long vibration depending on the beep/vibrate setting selected in Alerts & Sounds until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Follow steps 1 – 8 in Section 23.2 Startup Calibration and enter a BG value to calibrate the CGM.

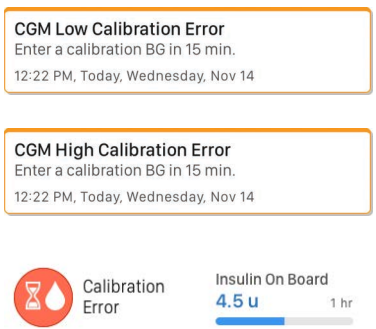
25.4 Incomplete Calibration

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	If you start to enter a calibration value using the keyboard and do not complete the entry within 90 seconds, this screen appears.
	What sound setting will I hear or feel?	Displays on the Tandem Mobi mobile app screen only, the pump will not beep or vibrate.
	Will the Tandem Mobi mobile app and pump re-notify me?	The Tandem Mobi mobile app will re-notify you every 5 minutes until the action is completed. The pump will not notify you.
	How should I respond?	Tap **OK** and complete your calibration by entering the value using the on-screen keyboard.

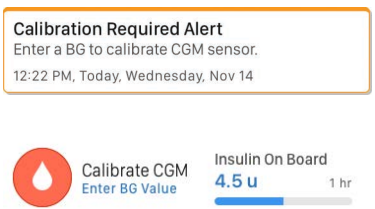
25.5 Calibration Timeout

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	If you start to enter a calibration value using the keyboard and do not complete the entry within 5 minutes, this screen appears.
	What sound setting will I hear or feel?	Displays on the Tandem Mobi mobile app screen only, the pump will not beep or vibrate.
	Will the Tandem Mobi mobile app and pump re-notify me?	The Tandem Mobi mobile app will re-notify you every 5 minutes until the action is completed. The pump will not notify you.
	How should I respond?	Tap **OK** and obtain a new BG value using your BG meter. Follow steps 1 – 8 in Section 23.2 Startup Calibration to calibrate the CGM.

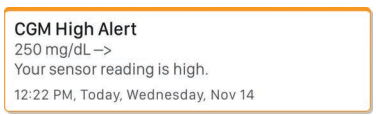
25.6 Calibration Error Alert – Dexcom G6 Only

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	The CGM cannot calibrate using the last BG meter value you entered.
	What sound setting will I hear or feel initially?	1 long vibration.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes with 1 sequence of 1 note or 1 long vibration depending on the beep/vibrate setting selected in Alerts & Sounds until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Give the CGM and your glucose value time to adjust by waiting at least 15 minutes. 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.

25.7 Calibration Required Alert – Dexcom G6 Only

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	The CGM needs a BG value to calibrate. Sensor glucose readings will not be displayed at this time.
	What sound setting will I hear or feel initially?	1 long vibration.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged and then every 15 minutes until you calibrate, with 1 sequence of 1 note or 1 long vibration depending on the beep/vibrate setting selected in Alerts & Sounds.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Follow steps 1 – 8 in Section 23.2 Startup Calibration to calibrate the CGM.

25.8 CGM High Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen?  	What does it mean?	Your most recent sensor glucose reading is at or above the High Alert setting.
	What sound setting will I hear or feel initially?	2 long vibrations.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, 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. See Section 21.2 Setting Your High Glucose Alert and Repeat Feature. The re-notification will be 1 sequence of 2 notes or 2 long vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Check your cartridge, tubing, and site, and test your BG. Treat your high sensor glucose as necessary.

25.9 CGM Low Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? CGM Low Alert 60 mg/dL –> Your sensor reading is low. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	Your most recent sensor glucose reading is at or below the Low Alert setting.
	What sound setting will I hear or feel initially?	3 long vibrations.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, 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. See Section 21.3 Setting Your Low Glucose Alert and Repeat Feature. The re-notification will be 1 sequence of 3 notes or 3 long vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Test your BG and eat carbs and if necessary.

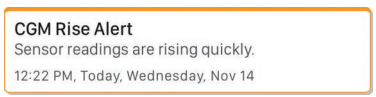
25.10 CGM Fixed Low Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? CGM Low Alert 54 mg/dL –> Your sensor reading is low. Check BG and eat carbs if necessary. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	Your most recent sensor glucose reading is at or below 55 mg/dL.
	What sound setting will I hear or feel initially?	4 long vibrations.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	» 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. » The re-notification will be 1 sequence of 4 notes or 4 long vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Test your BG and eat carbs and if necessary.

25.11 CGM Rise Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? CGM Rise Alert Sensor readings are rising quickly. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	Your sensor glucose levels are rising at 2 mg/dL per minute or faster (at least 30 mg/dL in 15 minutes).
	What sound setting will I hear or feel initially?	2 long vibrations.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes with 1 sequence of 2 notes or 2 long vibrations depending on the beep/vibrate setting selected in Alerts & Sounds until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Check your cartridge, tubing, and site, and test your BG. Treat your high sensor glucose as necessary, and continue to monitor your BG.

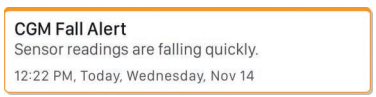
25.12 CGM Rapid Rise Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen?  	What does it mean?	Your sensor glucose levels are rising at 3 mg/dL per minute or faster (at least 45 mg/dL in 15 minutes).
	What sound setting will I hear or feel initially?	2 long vibrations.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes with 1 sequence of 2 notes or 2 long vibrations depending on the beep/vibrate setting selected in Alerts & Sounds until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Check your cartridge, tubing, and site, and test your BG. Treat your high sensor glucose as necessary, and continue to monitor your BG.

25.13 CGM Fall Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? CGM Fall Alert Sensor readings are falling quickly. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	Your sensor glucose levels are falling at 2 mg/dL per minute or faster (at least 30 mg/dL in 15 minutes).
	What sound setting will I hear or feel initially?	3 long vibrations.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes with 1 sequence of 3 notes or 3 long vibrations depending on the beep/vibrate setting selected in Alerts & Sounds until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Test your BG and eat carbs if necessary. Continue to monitor your BG.

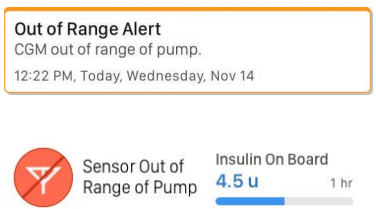
25.14 CGM Rapid Fall Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen?  	What does it mean?	Your sensor glucose levels are falling at 3 mg/dL per minute or faster (at least 45 mg/dL in 15 minutes).
	What sound setting will I hear or feel initially?	3 long vibrations.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes with 1 sequence of 3 notes or 3 long vibrations depending on the beep/vibrate setting selected in Alerts & Sounds until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Test your BG and eat carbs if necessary. Continue to monitor your BG.

25.15 Unknown Sensor Glucose Reading

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	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.
	What sound setting will I hear or feel?	Displays on the Tandem Mobi mobile app screen only, the pump will not beep or vibrate.
	Will the Tandem Mobi mobile app and pump re-notify me?	The 3 dashes will remain on the screen until a new sensor glucose reading is received and displayed in their place. If no sensor glucose readings are received after 20 minutes, the CGM Unavailable Alert will trigger. See Section 25.25 CGM Unavailable. The pump will not notify you.
	How should I respond?	Wait 30 minutes for more information from the system. Do not enter BG values for calibration. The system will not use BG values for calibration when “- - -” appears on the screen.

25.16 Out of Range Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	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.
	What sound setting will I hear or feel initially?	1 long vibration.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until the CGM and pump are back in range with 1 sequence of 1 note or 1 long vibration depending on the beep/vibrate setting selected in Alerts & Sounds.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Move the CGM and pump closer together, or remove the obstruction between them.

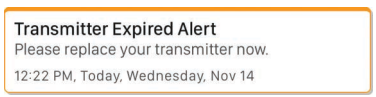
⚠ WARNING

Control-IQ+ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate setting in your active Personal Profile.

25.17 Low Transmitter Battery Alert – Dexcom G6 Only

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? Low Transmitter Battery Please replace your transmitter soon. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	Transmitter battery is low.
	What sound setting will I hear or feel initially?	1 long vibration.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	» Yes, every 5 minutes until acknowledged. » Additionally, the alert will notify you as the battery life is reduced. » The re-notification will be 1 sequence of 1 note or 1 long vibration depending on the beep/vibrate setting selected in Alerts & Sounds.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Consider replacing the transmitter the next time you start a new sensor session.

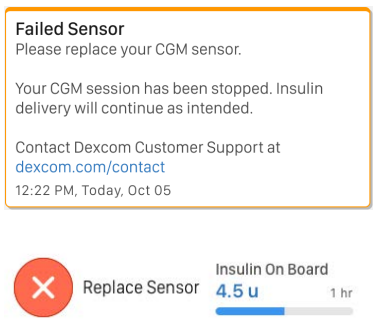
25.18 Transmitter Expired Alert – Dexcom G6 Only

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen?  	What does it mean?	Transmitter battery has expired.
	What sound setting will I hear or feel initially?	1 long vibration.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes with 1 sequence of 1 note or 1 long vibration depending on the beep/vibrate setting selected in Alerts & Sounds until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Replace the transmitter.

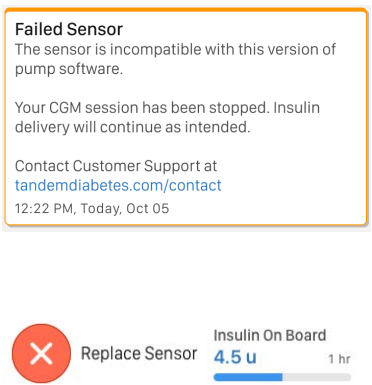
25.19 Transmitter Error – Dexcom G6 Only

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? **Transmitter Alert** Make sure your ID is correct, your transmitter is in range, and that your transmitter is not paired with a Dexcom receiver. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	The transmitter has failed and the CGM session has stopped.
	What sound setting will I hear or feel initially?	1 sequence of 1 long vibration.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes with 1 sequence of 1 note or 1 long vibration depending on the beep/vibrate setting selected in Alerts & Sounds until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. If the transmitter ID is correct, is in range, and is not paired with a Dexcom receiver, replace the transmitter.

25.20 Failed Sensor Error

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	The sensor is not working properly and the CGM session has stopped.
	What sound setting will I hear or feel initially?	1 long vibration.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes with 1 sequence of 1 note or 1 long vibration depending on the beep/vibrate setting selected in Alerts & Sounds until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Replace the sensor and begin a new CGM session.

25.21 Failed/Incompatible Sensor Alert – Dexcom G7 Only

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	The Dexcom G7 CGM you are attempting to pair is not compatible with your pump.
	What sound setting will I hear or feel initially?	1 beep/vibration, then beep/vibration every 5 minutes until confirmed.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	No.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Contact Dexcom Customer Support.

25.22 Invalid Pairing Code – Dexcom G7 Only

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? **Invalid Pairing Code** Make sure your Pairing Code is correct, your sensor is in range, and that your sensor is not paired with a Dexcom receiver. Pairing Code entered: 1234 If you entered the wrong pairing code, please stop your session and pair with the correct code. 9:07 AM, Today, Oct 05	What does it mean?	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.
	What sound setting will I hear or feel initially?	1 vibration, then vibration/beep every 5 minutes.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. » Unpair the Dexcom G7 from a different pump or a Dexcom G7 receiver. See Section 20.2 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.

25.23 Unable to Pair – Dexcom G7 Only

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? Unable to Pair There are too many Dexcom G7 sensors nearby. Move your pump and sensor to a location with fewer sensors in the area. 12:22 PM, Today, Oct 05	What does it mean?	Your Dexcom G7 CGM has attempted to pair too many times while in an area with too many Dexcom G7 sensors.
	What sound setting will I hear or feel initially?	1 vibration, then vibration/beep every 5 minutes.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Relocate to an area with fewer sensors to attempt pairing again.

NOTE

If the alert is displayed and the pump joins a CGM session, the alert will clear.

25.24 CGM Error – Dexcom G7 Only

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? CGM Error There is an error with the CGM software update. Insulin delivery will continue as intended. Contact Customer Support at tandemdiabetes.com/contact. 12:22 PM, Today, Oct 05	What does it mean?	Your Dexcom G7 CGM sensor is not working properly. The CGM session has stopped and the CGM can no longer be used.
	What sound setting will I hear or feel initially?	1 vibration, then vibration/beep every 5 minutes.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Contact Customer Technical Support.

25.25 CGM Unavailable

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? CGM Unavailable You will not receive any CGM alerts, errors or sensor glucose readings. If no sensor reading continue for more than 3 hours Contact Dexcom Customer Support at dexcom.com/contact 12:22 PM, Today, Oct 05	What does it mean?	Your CGM session is still active, but the pump is receiving invalid CGM readings.
	What sound setting will I hear or feel initially?	2 long vibrations.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged and then every 20 minutes, with 1 sequence of 2 notes or 2 long vibrations depending on the beep/vibrate setting selected in Alerts & Sounds. If the condition persists for 3 hours, the Failed Sensor alert will be displayed. See Section 25.20 Failed Sensor Error.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. If no sensor readings continue for more than three hours, contact Dexcom Customer Support.

25.26 CGM Error

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? CGM Error Bluetooth cannot operate. Insulin delivery will continue as intended. Contact Customer Support at tandemdiabetes.com/contact. 12:22 PM, Today, Oct 05	What does it mean?	The pump Bluetooth hardware
	What sound setting will I hear or feel initially?	1 vibration, then vibration/beep every 5 minutes.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Contact Customer Technical Support.

3 CGM Features

CHAPTER 26

CGM Troubleshooting

This chapter provides helpful tips and instructions to help you fix issues you may have while using the CGM portion of your system.

If the troubleshooting steps in this chapter do not fix your issue, contact Customer Technical Support.

The following tips are specific to troubleshooting the Dexcom CGM connected to your pump. For more information about Dexcom CGM troubleshooting, visit the manufacturer's website for applicable product instructions.

26.1 CGM Pairing Troubleshooting

Possible issue:

Difficulty pairing your Dexcom CGM with your Tandem Mobi™ insulin pump.

Troubleshooting tip:

Ensure your CGM is connected to the Tandem Mobi pump before pairing the CGM with any other devices or mobile apps. See Section 20.2 Transferring a Sensor Session to the Tandem Mobi System.

26.2 Calibration Troubleshooting

To ensure proper calibration of your CGM, follow these important tips:

Before you take a BG value for calibration, wash your hands, make sure your BG test strips have been stored properly and are not expired, and make sure that your BG meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions that came with your BG meter or test strips.

Do not calibrate if you see the Out of Range symbol in the place where your sensor glucose readings are normally shown on the *Dashboard* screen.

Do not calibrate if you see "- - -" in the place where you sensor glucose readings are normally shown on the *Dashboard* screen.

Do not calibrate if your BG value is below 20 mg/dL or above 600 mg/dL.

26.3 Unknown Sensor Reading Troubleshooting

When your CGM cannot provide a sensor glucose reading "- - -" shows in the place where your sensor glucose is normally shown on the *Dashboard* screen. This means that the pump does not understand the sensor signal temporarily.

Often the pump can correct the problem and continue providing sensor glucose readings. If it has been at least 3 hours since your last sensor glucose reading, contact the CGM manufacturer.

Do not enter any BG values for calibration when you see "- - -" on your *Dashboard* screen. The pump will not use a BG value for calibration when this symbol is on your *Dashboard* screen.

If you see "- - -" often during a sensor session, follow the troubleshooting tips below before inserting another sensor.

- Make sure your sensor is not expired.

- Make sure your sensor pod is not dislodged or peeling up.
- Dexcom G6 Only: Make sure your transmitter is snapped in completely.
- Make sure nothing is rubbing the sensor pod (e.g., clothing, seat belts, etc.).
- Make sure to select a good insertion site.
- Make sure your insertion site is clean and dry before sensor insertion.
- Dexcom G6 Only: Wipe the bottom of the transmitter with a damp cloth or isopropyl alcohol wipe. Place the transmitter on a clean, dry cloth and air dry for 2 to 3 minutes.

26.4 Out of Range/No Antenna Troubleshooting

⚠ WARNING

Control-IQ+™ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate setting in your active Personal Profile.

⚠ PRECAUTION

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

If you see the Out of Range icon on your *Dashboard* in the place where your sensor glucose reading normally shows, then your Tandem Mobi pump is not communicating with your CGM and sensor glucose readings will not show on your *Dashboard*. Each time you start a new sensor session, wait 10 minutes for your Tandem Mobi pump to start communicating with your CGM. When a sensor session is active, you may sometimes experience loss of communication for 10 minutes at a time. This is normal.

If you see the Out of Range icon for more than 10 minutes, move your Tandem Mobi pump and CGM closer together and remove any obstructions. Wait 10 minutes and communication should be restored.

You must enter your transmitter ID or pairing code correctly into your Tandem Mobi mobile app to receive sensor glucose readings (see Section 22.2 Enter Your Dexcom G6 Transmitter ID or Section 22.8 Start the Dexcom G7 Sensor). Make sure you have removed your sensor and stopped your sensor session before checking or changing your transmitter ID or pairing code. You cannot change your transmitter ID or pairing code during a sensor session.

If you are still having trouble getting sensor glucose readings, contact Customer Technical Support.

26.5 Failed Sensor Troubleshooting

The pump may detect issues with your sensor where it cannot determine your

sensor glucose reading. The sensor session ends and the *Failed Sensor* alert displays on your Tandem Mobi mobile app. If you see this alert, it means your CGM session has ended.

- Remove your sensor and insert a new sensor.
- To help improve future sensor performance, follow the troubleshooting tips below.
  - Make sure your sensor is not expired.
  - Make sure your sensor pod is not dislodged or peeling up.
  - If using a Dexcom G6 sensor, make sure your transmitter is snapped in completely.
  - Make sure nothing is rubbing the sensor pod (e.g., clothing, seat belts, etc.).
  - Make sure you have selected a good insertion site.

26.6 Sensor Inaccuracies

Inaccuracies are usually related to your sensor only and not to your CGM or pump. The sensor measures glucose in the fluid under the skin—not in blood, and sensor glucose readings are not identical to readings from your BG meter.

⚠ PRECAUTION

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

If the difference between your sensor glucose reading and BG value is greater than 20% of the BG value for sensor readings >80 mg/dL or greater than 20 mg/dL for sensor readings <80 mg/dL, wash your hands and take another BG measurement. If the difference between this second BG measurement and the sensor is still greater than 20% for sensor readings >80 mg/dL or greater than 20 mg/dL for sensor readings <80 mg/dL, recalibrate your sensor using the second BG value. The sensor glucose reading will correct over the next 15 minutes. If you see differences between your sensor glucose readings and BG values outside of this acceptable range, follow the troubleshooting tips below before inserting another sensor:

- Make sure your sensor is not expired.
- Make sure you do not calibrate when "- - -" or the Out of Range icon are on the *Dashboard* screen.
- Do not use alternative BG site testing (blood from your palm or forearm, etc.) for calibration as alternative site readings may be different than those from a BG value. Use a BG value only from your fingers for calibration.
- Use only BG values between 20 to 600 mg/dL for calibration. If one or more of your values is outside of

this range, the pump will not calibrate.

- Use the same BG meter you routinely use to measure your BG to calibrate. Do not switch your BG meter in the middle of a sensor session. BG meter and strip accuracy vary between BG meter brands.
- Before taking a BG measurement for calibration, wash your hands, make sure your BG test strips have been stored properly and are not expired, and make sure that your BG meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions provided with your BG meter or test strips.
- Make sure you are using your BG meter following the manufacturer's instructions to get accurate BG values for calibration.

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CHAPTER 27

Control-IQ+ Technology Important Safety Information

The following includes important safety information related to Control-IQ+™ technology. The information presented in this chapter does not represent all warnings and precautions related to the pump. Pay attention to other warnings and precautions listed throughout this user guide as they relate to special circumstances, features, or users.

27.1 Responsible Use of Control-IQ+ Technology

Systems like the Tandem Mobi™ insulin pump with Control-IQ+ technology are not substitutes for the active management of diabetes, including manually bolusing for meals. There are common scenarios in which automated systems cannot prevent a hypoglycemic event. Control-IQ+ technology relies on current CGM sensor readings to function and will not be able to predict sensor glucose values and suspend insulin delivery if a patient's CGM is not functioning properly or their pump is unable to receive the CGM signal. Patients should be instructed to always use the components of the pump system (pump, Tandem Mobi mobile app, cartridges, CGM, and infusion sets) according to the applicable instructions for use and check them regularly to make sure they are functioning as expected. Patients should always pay attention to their sensor glucose values, actively monitor and manage BG, and treat accordingly.

27.2 Control-IQ+ Technology Warnings

⚠ WARNING
Control-IQ+ technology has not been evaluated in pregnant women or persons on dialysis. Sensor glucose readings may be inaccurate in these populations and could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

⚠ WARNING
Control-IQ+ technology has not been evaluated in critically ill patients. It is not known how different conditions or medications common to the critically ill population may affect the performance of the Control-IQ+ technology. Sensor glucose readings may be inaccurate in critically ill patients, and solely relying on the sensor glucose alerts and readings for treatment decisions could result in you missing severe hypoglycemia (low BG) or hyperglycemia (high BG) events.

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

⚠ WARNING
Control-IQ+ technology is not a substitute for understanding and being ready at any time to take over manual control of your current or future diabetes therapy.

⚠ WARNING
Control-IQ+ technology is not designed to prevent all hypoglycemia (low BG) or hyperglycemia (high BG).

⚠ WARNING
Control-IQ+ technology adjusts the delivery of insulin, but does not treat low BG. Always pay attention to your symptoms, manage your BG level, and treat according to the recommendations of your healthcare provider.

⚠ WARNING
Do not use Control-IQ+ technology unless recommended by your healthcare provider.

⚠ WARNING
Do not use Control-IQ+ technology until you have received training.

⚠ WARNING
The 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.

27.3 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 28

Introduction to Control-IQ+ Technology

28.1 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.

⚠ PRECAUTION
You must continue to take boluses to cover food eaten or to correct a high sensor glucose value. Read all Control-IQ+ technology instructions before activating Control-IQ+ technology.

⚑ NOTE
The target CGM ranges used by Control-IQ+ technology are not customizable.

⚑ NOTE
The Insulin On Board (IOB) Time Remaining, which indicates how long the total units of insulin from food and correction boluses will be active in the body, is not displayed when Control-IQ+ technology is on due to the variability of insulin delivery when automatically responding to CGM values. The IOB units will always be displayed on the *Dashboard* screen of the Tandem Mobi mobile app.

28.2 How Control-IQ+ Technology Works

⚠ WARNING
Control-IQ+ technology is not a substitute for understanding and being ready at any time to take over manual control of your current or future diabetes therapy.

⚠ WARNING
Control-IQ+ technology is not designed to prevent all hypoglycemia (low BG) or hyperglycemia (high BG).

⚠ WARNING
Control-IQ+ technology adjusts the delivery of insulin, but does not treat low BG. Always pay attention to your symptoms, manage your BG level, and treat according to the recommendations of your healthcare provider.

⚠ WARNING
Do not use Control-IQ+ technology unless recommended by your healthcare provider.

⚠ WARNING
Do not use Control-IQ+ technology until you have received training.

⚠ WARNING
Control-IQ+ technology relies on current CGM sensor readings and will not be able to accurately predict BG levels and adjust insulin delivery if for any reason your CGM is not functioning properly, or the pump has not received any CGM sensor values in 21 minutes.

⚠ PRECAUTION
We recommend that you enable the High Glucose Alert and the Low Glucose Alert when using Control-IQ+ technology so that you will be notified if sensor glucose readings are outside of your target range, and you can treat high or low BG according to your healthcare provider's recommendations.

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

NOTE

Control-IQ+ technology activity types are not automatically turned on, and must be set up as a scheduled occurrence or turned on as needed. For more information, see Section 29.4 Schedule Sleep, Section 29.6 Manually Start or Stop Sleep, and Section 29.7 Manually Stop or Start Exercise.

Control-IQ+ technology adjusts insulin delivery in several ways to help keep your actual glucose value within the target range. It will decrease or suspend insulin delivery when predicted sensor glucose values are below a preset treatment value, increase insulin delivery when predicted sensor glucose values are above a preset treatment value, and automatically deliver a correction bolus once per hour, as needed. The automatic correction bolus is based on a predicted sensor glucose value. There are maximum insulin delivery limits based on your Personal Profile settings. These different insulin delivery actions are described below. Each of the insulin delivery adjustments occurs in different ways depending on whether you start Sleep, start Exercise, or stop both. For more detail on how insulin adjustments are made for different activities see the Control-IQ+ Technology Without Sleep or Exercise, Control-IQ+ Technology During Sleep, and Control-IQ+ Technology During Exercise sections in this chapter.

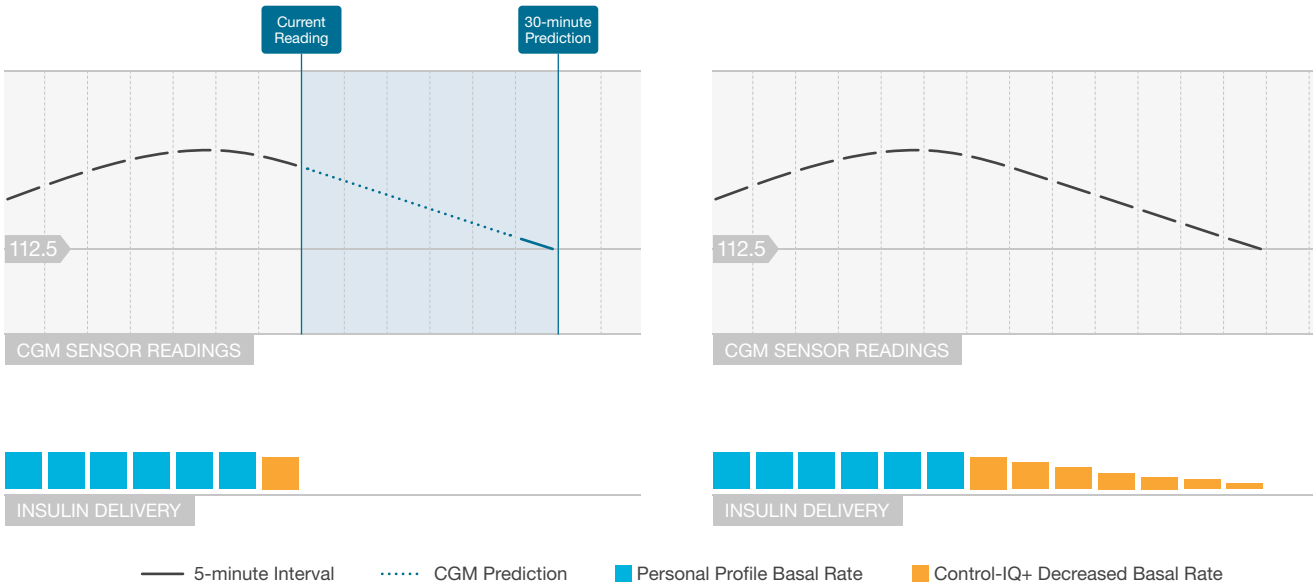
Personal Profile Basal Rate Delivery

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 6 Insulin Delivery Settings for more information about Personal Profiles.

Decreased Insulin Delivery

When Control-IQ+ technology predicts that your sensor glucose value will be at or below a preset treatment value (112.5 mg/dL) 30 minutes in the future, the rate of insulin delivery will start decreasing to attempt to keep the actual sensor glucose values within the target range. The following diagrams depict how the pump uses 30 minute predictions to gradually decrease insulin delivery compared to the personal profile Basal Rate. The diagram on the left depicts the prediction. The diagram on the right depicts how the insulin and CGM readings might look if the CGM graph continued on the trend.



NOTE

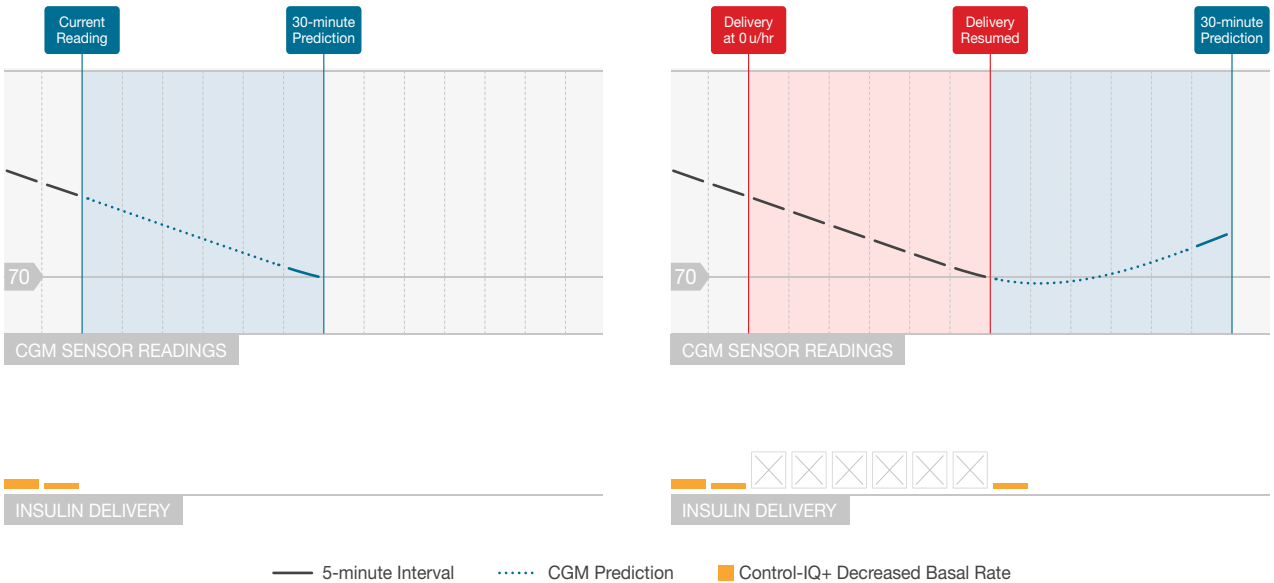
Diagrams are for illustrative purposes only and are not intended to reflect actual results.

Insulin Decreased or Delivering 0 Units per Hour

Control-IQ+ technology can reduce the basal delivery to a percent of the Basal Rate in addition to completely suspending. When Control-IQ+ technology predicts that your sensor glucose value will be lower than a preset treatment value (70 mg/dL) 30 minutes in the future, insulin delivery will decrease and will set the Basal Rate at 0 units per hour if necessary to attempt to keep the actual sensor glucose values within the target range. Manual boluses can still be delivered when Control-IQ+ technology is decreasing or suspending insulin. The following diagrams depict an illustration of when Control-IQ+ technology might set the insulin delivery rate to 0 units per hour, and when it will resume at a decreased rate after the 30 minute prediction is above the target sensor glucose value.

NOTE

When Control-IQ+ technology sets the Basal Rate to 0 units per hour, bolus deliveries will continue. This includes starting a new bolus and any remaining bolus from an extended bolus delivery.



NOTE

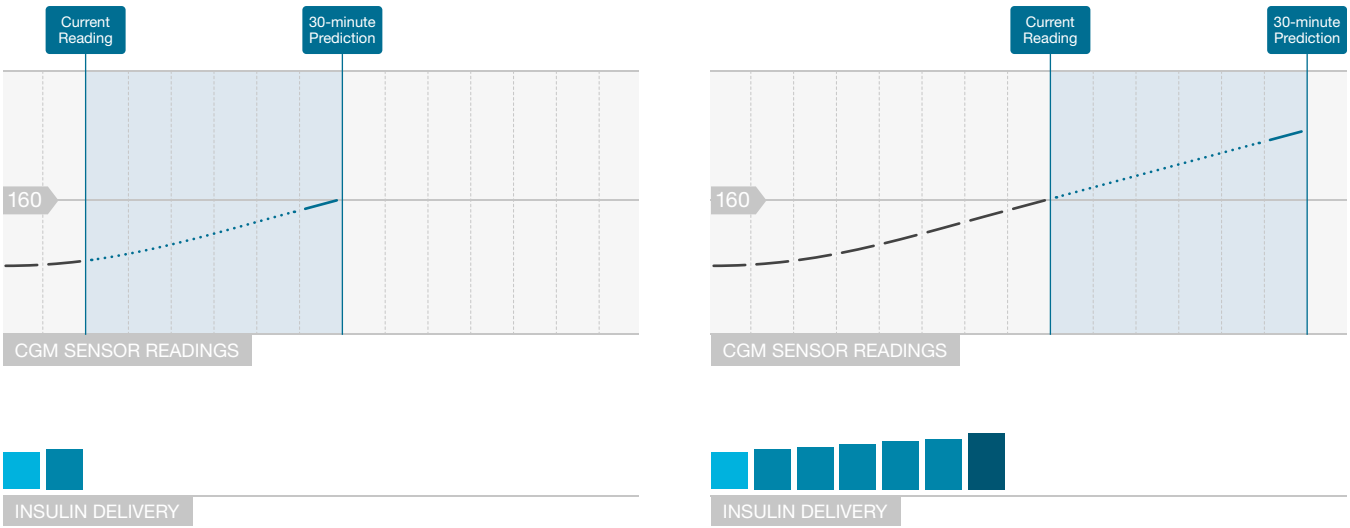
Diagrams are for illustrative purposes only and are not intended to reflect actual results.

Increasing Insulin Delivery

When Control-IQ+ technology predicts that your sensor glucose value will be at or above a preset treatment value (160 mg/dL) 30 minutes in the future, the rate of insulin delivery will start increasing to attempt to keep the actual CGM values within the target CGM range. The following diagrams depict when Control-IQ+ technology might be increasing and delivering at the maximum increased Basal Rate.

Maximum Insulin Delivery

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



NOTE

Diagrams are for illustrative purposes only and are not intended to reflect actual results.

Automatic Correction Bolus Delivery

When Control-IQ+ technology predicts that your CGM value will be at or above a preset treatment value (180 mg/dL) 30 minutes in the future, and when Control-IQ+ technology is either increasing insulin delivery or delivering maximum insulin delivery, the pump will automatically deliver correction boluses to attempt achieve the target range.

The automatic correction bolus will deliver a correction bolus calculated based on the Personal Profile Correction Factor and predicted CGM reading. The target sensor glucose value for the automatic correction bolus is 110 mg/dL. Automatic correction bolus delivery occurs at most once every 60 minutes, and will not be delivered within 60 minutes of the start, cancellation, or completion of an automatic bolus or a manual bolus. For an extended bolus, this 60 minutes does not start until after the DELIVER NOW duration has completed. The percentage and duration between boluses is designed to avoid insulin stacking that may cause unsafe reductions in sensor glucose values.

NOTE

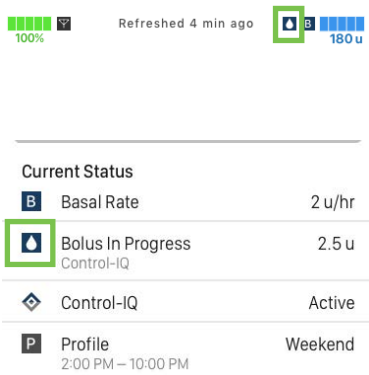
Each automatic correction bolus delivery can be manually canceled or stopped during the delivery in the same way that a manual bolus can be stopped. See Section 8.10 Canceling or Stopping a Bolus.

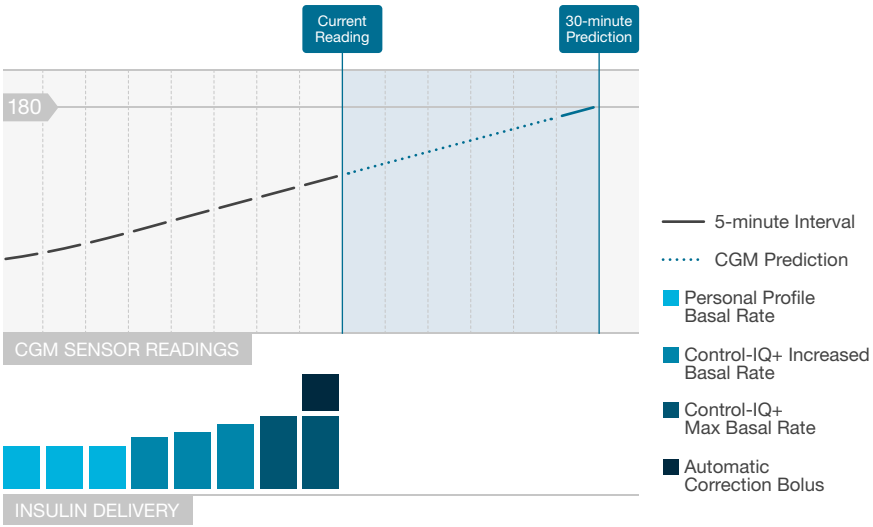
NOTE

The maximum amount of insulin that an automatic correction bolus will deliver is 6 units. This value cannot be increased, but you may choose to deliver a manual bolus after the automatic correction bolus delivery is complete.

⚠ PRECAUTION

The pump does not activate beeps or vibrations to indicate when an automatic correction bolus delivery has started. The following Tandem Mobi mobile app icon and message indicate that an automatic correction bolus is being delivered.





NOTE

Diagrams are for illustrative purposes only and are not intended to reflect actual results.

28.3 Control-IQ+ Technology Actions

When Control-IQ+ technology is turned on you can choose to start Sleep or Exercise to help the pump adjust the automated insulin dosing settings as described in previous sections.

If you have not started either Sleep or Exercise, the pump will use the settings described in the following section.

Control-IQ+ Technology Without Sleep or Exercise

The CGM range targeted by Control-IQ+ technology when Sleep or Exercise are turned off is 112.5 to 160 mg/dL. This range is wider than the Sleep and Exercise ranges to account for the variability of factors that affect CGM values while people are awake and not exercising.

Decreasing Insulin Without Sleep or Exercise

Insulin is decreased when Control-IQ+ technology predicts a CGM reading of ≤112.5 mg/dL 30 minutes in the future.

Suspended Insulin Without Sleep or Exercise

Insulin is set to 0 units/hour when Control-IQ+ technology predicts a CGM reading ≤70 mg/dL 30 minutes in the future.

Increasing Insulin Without Sleep or Exercise

Insulin is increased when Control-IQ+ technology predicts a CGM reading of ≥160 mg/dL 30 minutes in the future.

Automatic Correction Bolus Without Sleep or Exercise

When Sleep or Exercise are turned off, Control-IQ+ technology will deliver automatic correction boluses as described in the Automatic Correction Bolus Delivery section of this chapter.

Control-IQ+ Technology During Sleep

The Control-IQ+ technology Sleep range is targeted during scheduled sleep times and when Sleep is manually started (until it is stopped). See Chapter 29 Configuring and Using Control-IQ+ Technology and see the Start a Sleep Schedule section for instructions on setting the hours you plan to sleep and the Manually Start Sleep section for starting Sleep manually in that chapter.

The CGM range targeted by Control-IQ+ technology during Sleep is 112.5 mg/dL to 120 mg/dL. This range is smaller than the target range when Sleep or Exercise are turned off since there are fewer variables that affect CGM values while you are sleeping. During Sleep, Control-IQ+ technology will not deliver automatic correction boluses.

Decreasing Insulin During Sleep

Insulin is decreased when Control-IQ+ technology predicts a CGM reading of ≤112.5 mg/dL 30 minutes in the future.

Suspended Insulin During Sleep

Insulin is set to 0 units/hour when Control-IQ+ technology predicts a CGM reading ≤70 mg/dL 30 minutes in the future.

Increasing Insulin During Sleep

Insulin is increased when Control-IQ+ technology predicts a CGM reading of ≥120 mg/dL 30 minutes in the future.

Automatic Correction Bolus During Sleep

Automatic correction boluses will not be delivered while Sleep is on.

When Control-IQ+ technology switches back to the settings without Sleep, whether according to scheduled wake time or due to manually stopping Sleep, the transition from the targeted sleep CGM range occurs slowly and can take 30-60 minutes. This helps ensure that actual CGM values transition gradually.

Control-IQ+ Technology During Exercise

During Exercise, Control-IQ+ technology uses the target CGM range 140 mg/dL to 160 mg/dL. This target range is smaller and higher than the target range when Sleep or Exercise are turned off to accommodate the likely natural drop in sensor glucose following exercise.

If Exercise is on when a Sleep Schedule is due to begin, the Sleep Schedule does not start until you stop Exercise manually.

Decreasing Insulin During Exercise

Insulin is decreased when Control-IQ+ technology predicts a CGM reading of ≤140 mg/dL 30 minutes in the future.

Suspended Insulin During Exercise

Insulin is set to 0 units/hour when Control-IQ+ technology predicts a CGM reading ≤80 mg/dL 30 minutes in the future.

Increasing Insulin During Exercise

Insulin is increased when Control-IQ+ technology predicts a CGM reading of ≥160 mg/dL 30 minutes in the future.

Automatic Correction Bolus During Exercise

When Exercise is on, Control-IQ+ technology will deliver automatic correction boluses as described in the Automatic Correction Bolus Delivery section of this chapter.

See Chapter 29 Configuring and Using Control-IQ+ Technology for instructions on starting or stopping Exercise.

For a summary of all treatment values and how they are different, see the diagram on the next page.

		Control-IQ	Sleep Activity	Exercise Activity
Delivers	Delivers an automatic correction bolus if sensor glucose is predicted to be above ___ mg/dL	180	––	180
Increases	Increases basal insulin delivery if sensor glucose is predicted to be above ___ mg/dL	160	120	160
Maintains	Maintains active Personal Profile settings* when sensor glucose is between ___ - ___ mg/dL	112.5 - 160	112.5 - 120	140 - 160
Decreases	Decreases basal insulin delivery if sensor glucose is predicted to be below ___ mg/dL	112.5	112.5	140
Stops	Stops basal insulin delivery if sensor glucose is predicted to be below ___ mg/dL	70	70	80

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CHAPTER 29

Configuring and Using Control-IQ+ Technology

29.1 Required Settings

Required Personal Profile Settings

In order to use Control-IQ+™ technology, the following Personal Profile settings must be configured. See Chapter 6 Insulin Delivery Settings for instructions about setting these values.

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

Required Control-IQ+ Technology Pump Settings

In addition to the required Personal Profile settings, there are two values specific to Control-IQ+ technology that must be set. These are:

- Weight
- Total Daily Insulin

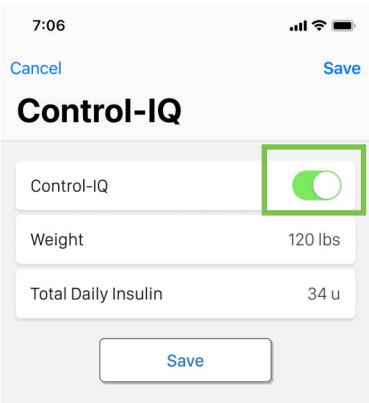
Recommended Control-IQ+ Technology Pump Settings

Although Sleep can be started and stopped manually, it is recommended that you schedule sleep. This chapter explains how to do both. The following settings are required to schedule sleep:

- Start Time
- End Time
- Selected Days

29.2 Turn Control-IQ+ Technology 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**.



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.

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.

Enter Your 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** or ✔ to close the on-screen keyboard.

Enter Your 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** or ✔ 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.

29.3 Turn Control-IQ+ Technology 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.

29.4 Schedule Sleep

Control-IQ+ technology operates differently during Sleep with Exercise turned on, or with both of these turned off. Sleep can be scheduled to turn on and off automatically, or it can be turned on and off manually. This section covers how to set Sleep to turn on and off automatically. For detailed information about how to use Control-IQ+ technology, see Chapter 28 Introduction to Control-IQ+ Technology.

You can configure two different Sleep Schedules to account for changes in lifestyle, such as a weekday Sleep Schedule and a weekend Sleep Schedule. These two Sleep Schedules cannot overlap, which allows you to turn on both Sleep Schedules at the same time.

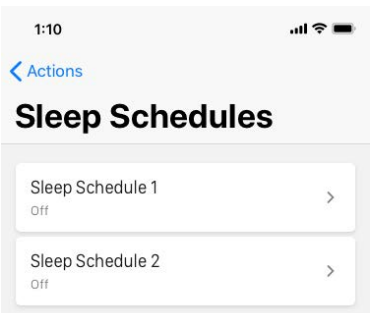
NOTE

If you manually start Sleep before a Sleep Schedule begins, it does not impact the scheduled wake time. For example, if your Sleep Schedule is set from 10pm to 6am (22:00 to 6:00), and you start Sleep manually at 9pm (21:00), Sleep will end at 6am (6:00) as scheduled; unless manually stopped.

NOTE

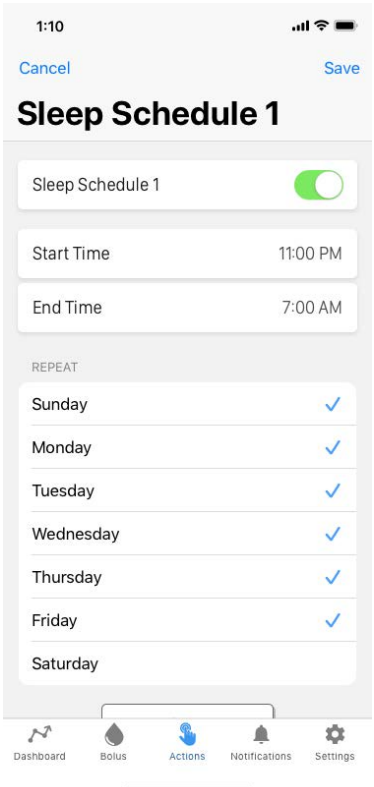
Exercise and Sleep may not be enabled at the same time. If Exercise is active at the time a Sleep Schedule is set to begin, the Sleep Schedule does not start until you stop Exercise manually.

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** or ✔.
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** or ✔.
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**.

    NOTE

    If no days are selected when you tap **Save**, the Sleep Schedule is set to off and the remaining Sleep Schedule settings are not displayed. The remaining instructions do not apply to an incomplete Sleep Schedule.

✓ 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.

29.5 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 29.4 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**.

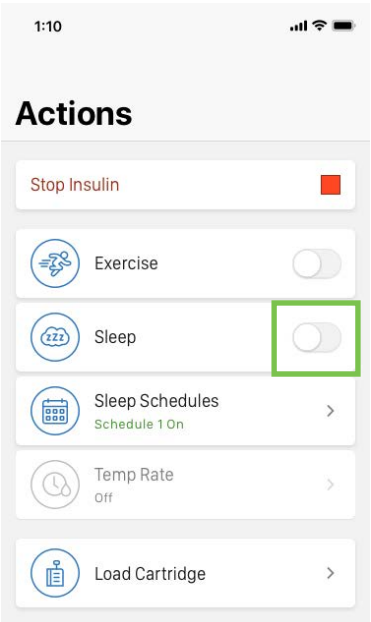
29.6 Manually Start or Stop Sleep

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**.

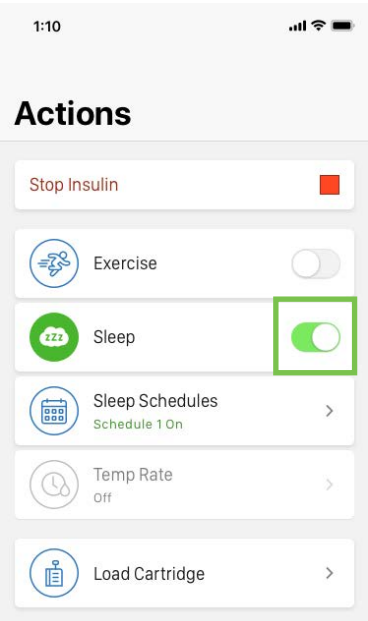


✓ A *Sleep started* banner is displayed at the top of the Tandem Mobi mobile app. The Sleep icon is displayed on the *Dashboard* screen. Sleep will automatically be stopped if Exercise is started.

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.

29.7 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**.

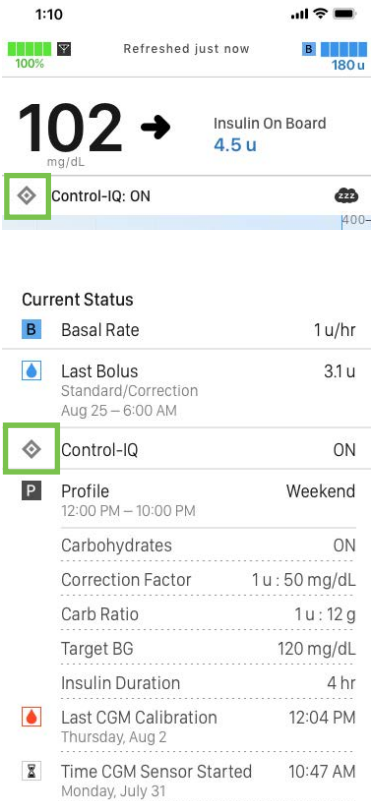
✓ An *Exercise stopped* banner is displayed at the top of the Tandem Mobi mobile app. The Exercise icon is removed from the *Dashboard* screen. Exercise will automatically be stopped if Sleep in started.

29.8 Control-IQ+ Technology Information on Your Screen

Control-IQ+ Technology Status Icon

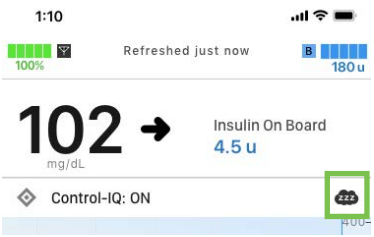
When Control-IQ+ technology is on, a diamond icon is displayed next to the Control-IQ row of the Current Status section of the *Dashboard* screen. This icon uses different colors to communicate information about how Control-IQ+ technology is operating. Each different color and its meaning can be found in Section 4.1 Explanation of Icons.

When Control-IQ+ technology is on but not active (i.e. insulin is being delivered normally), the diamond icon is gray. The Control-IQ+ diamond appears below the CGM reading and in the Current Status areas of the *Dashboard* screen. as depicted below. Regardless of the color, the icon always appears in the same places.



Exercise and Sleep Icons

When Exercise or Sleep is turned on, an icon is displayed near the top of the *Dashboard* screen, directly under the IOB information. The respective icon displays in the same place on the *Dashboard* screen, since Exercise and Sleep can never be on at the same time. The following image shows the Sleep icon on the *Dashboard* screen.

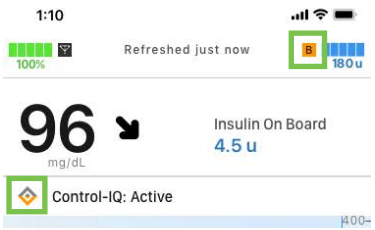


When Exercise is on, the Exercise icon is displayed in the same location.

Basal Status Icons

There are several basal status icons that display in different colors, each of which communicates information about how Control-IQ+ technology is operating. Each different color and its meaning can be found in Section 4.1 Explanation of Icons.

The following image highlights where the basal status icons display at the top of and under the CGM reading on the *Dashboard* screen.



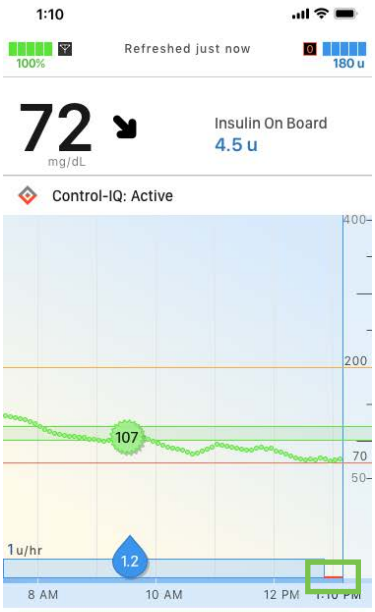
Automatic Correction Bolus Status Icon

When Control-IQ+ technology is on and delivering an automatic correction bolus, an icon displays to the left of the basal status icon. See Section 4.1 Explanation of Icons. The following image shows the location of the bolus icon. This is the same location where the manual bolus icon displays.

The Current Status area of the *Dashboard* also indicates that there is an automatic correction bolus delivered by Control-IQ+ technology. The text **Bolus in Progress**, with **Control-IQ** listed below is displayed. The amount of the bolus is also displayed.

Graph Insulin Delivery Suspended

Portions of the graph that display a red line on the X-axis time indicator lines and labels area indicate the times when Control-IQ+ technology was delivering 0 units/hour. Each dot on the graph represents a five-minute increment.



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CHAPTER 30

Control-IQ+ Technology Alerts

Information in this chapter will help you learn how to respond to Control-IQ+™ technology alerts and errors. It applies only to the Control-IQ+ technology within your pump. The Control-IQ+ technology alerts follow the same pattern as other pump alerts according to your Alerts & Sounds selection.

If push notifications are enabled on your smartphone, and the Tandem Mobi™ mobile app is open, you will get the alert notification on the lock screen of your smartphone.

⚠ 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.

If you are in the Tandem Mobi mobile app, you will see a red circle with the number of notifications waiting for your acknowledgment next to the Notifications area of the *Navigation* bar. Notifications may be cleared in any order.

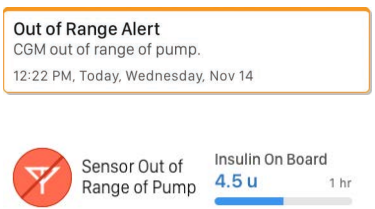
If multiple alerts happen at the same time, you may clear them in any order.

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 enable and set up Snooze, see Section 5.7 Enable and Set Snooze.

For information on insulin delivery reminders, alerts, and alarms see Chapter 13 Alerts, Chapter 14 Alarms, and Chapter 15 Malfunction.

For information on CGM Alerts and Errors, see Chapter 25 CGM Alerts and Errors.

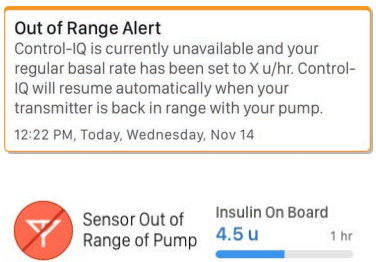
30.1 Out of Range Alert – Control-IQ+ Technology Off

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	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.
	What sound setting will I hear or feel initially?	1 long vibration.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes if the CGM and pump remain out of range with 1 sequence of 1 note or 1 long vibration depending on the beep/vibrate setting selected in Alerts & Sounds.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Move the CGM and pump closer together, or remove the obstruction between them.

⚠ WARNING

Control-IQ+ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate setting in your active Personal Profile.

30.2 Out of Range Alert – Control-IQ+ Technology On

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? 	What does it mean?	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.
	What sound setting will I hear or feel initially?	1 long vibration.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes if the CGM and pump remain out of range with 1 sequence of 1 note or 1 long vibration depending on the beep/vibrate setting selected in Alerts & Sounds.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Move the CGM and pump closer together, or remove the obstruction between them.

⚠ WARNING

Control-IQ+ technology can only adjust insulin delivery when your CGM is in range. If you go out of range during insulin adjustment, your basal insulin delivery will revert to the Basal Rate setting in your active Personal Profile.

⚑ NOTE

It is recommended that you keep the Out of Range Alert turned on and set to 20 minutes. If your pump and CGM are not connected for 20 minutes, Control-IQ+ technology will not work. Control-IQ+ technology will begin working immediately when the CGM and pump are back within range.

30.3 Control-IQ Low Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? **Control-IQ Low Alert** Control-IQ has predicted that you will drop low. Eat carbs and test your BG. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	Control-IQ+ technology Low Alert has predicted that your sensor glucose reading will drop below 70 mg/dL, or below 80 mg/dL if Exercise is on, in the next 15 minutes.
	What sound setting will I hear or feel?	2 sequences of 3 notes or 2 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged, and then every 2 hours if the issue persists.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Eat carbs and test your BG.

30.4 Control-IQ High Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? **Control-IQ High Alert** Control-IQ has increased your insulin, but your sensor readings remain above 200 mg/dL. Check your cartridge, tubing, site, and test your BG. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	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.
	What sound setting will I hear or feel?	2 sequences of 3 notes or 2 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 10 minutes until acknowledged, and then every 2 hours if the issue still persists.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Check your cartridge, tubing, and site, and test your BG. Treat your high sensor glucose as necessary.

30.5 Max Insulin Alert

Screen	Explanation	
What will I see on the Tandem Mobi mobile app screen? **Max Insulin Alert** Control-IQ has delivered the maximum allowable amount of insulin in a 2-hour period. Make sure your Total Daily Insulin is correct in Control-IQ settings. 12:22 PM, Today, Wednesday, Nov 14	What does it mean?	The pump has delivered the maximum allowable 2 hour insulin amount based on your Total Daily Insulin setting. You see this alert when Control-IQ+ technology has delivered 50% of your Total Daily Insulin (through basal and/or bolus deliveries) over the previous rolling 2 hour window, and detects this condition for 20 minutes in a row. Control-IQ+ technology will suspend insulin delivery for a minimum of 5 minutes, and then resume insulin delivery once the condition is no longer detected.
	What sound setting will I hear or feel?	2 sequences of 3 notes or 2 vibrations depending on the beep/vibrate setting selected in Alerts & Sounds.
	What pump status lights will I see?	Both lights will blink yellow twice in a row before turning off. This pattern is repeated for a total of five times. 
	Will the Tandem Mobi mobile app and pump re-notify me?	Yes, every 5 minutes until acknowledged.
	How should I respond?	On the *Notifications* screen, tap on or slide the alert message to the left. Tap **Dismiss** to clear the alert. Check your Total Daily Insulin settings by tapping **Settings**, **Pump**, **Control-IQ** to ensure they are correct.

CHAPTER 31

Control-IQ+ Technology Clinical Study Overview

31.1 Introduction

The following data represents the clinical performance of the t:slim X2™ insulin pump with Control-IQ™ technology in multiple studies.

The first pivotal study (DCLP3) included participants ≥14 years old. A second pivotal study (DCLP5) included participants 6 years to 13 years old. A third pivotal study (PEDAP) included participants 2 years to <6 years old. These three studies used the original version of Control-IQ technology, Control-IQ technology (v1.0), and were all randomized control trials (RCTs).

Three more pivotal trials were subsequently performed. The PEDAP trial was extended for a 3-month extension phase where all participants used the study device. High insulin use was evaluated in the Higher-IQ trial, a single arm study. Control-IQ technology was evaluated in an RCT in adults with type 2 diabetes in the 2IQP study. These three studies used an updated version of Control-IQ technology, Control-IQ+ technology (v1.5).

All participants in these studies used the Dexcom G6 CGM.

Control-IQ technology has not been evaluated in children under 2 years of age. The safety and/or effectiveness of Control-IQ technology in children under 2 years of age is unknown.

31.2 Software Version History

Control-IQ+ technology (v1.5) introduced changes to allow for a wider range of weight and TDI input. Other changes were implemented and are outlined in the table below.

Parameter	Control-IQ 1.0	Control-IQ+ (1.5)
Minimum Total Daily Insulin Entry	10 units	5 units
Maximum Total Daily Insulin Entry	100 units	200 units
Minimum Weight Entry	55 pounds	20 pounds
Maximum Weight Entry	308 pounds	440 pounds
Correction Factor Range Accepted by Algorithm	1:10 to 1:200	1:10 to 1:600
Maximum Extended Bolus Duration	2 hours	8 hours
Temporary Basal Rates with Closed-Loop Active	No	Yes
Basal Rate Clipping*	Yes	No
**Limited to 3 units/hour when delivering programmed basal rate*		

31.3 The DCLP3 Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 6 months under normal conditions in adults and adolescents 14 years of age or older. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to the use of sensor augmented pump (SAP) therapy alone (the control arm), labeled as Control-IQ technology and SAP in the tables in this section.

168 participants were randomly assigned to use Control-IQ technology or SAP for the study in a 2:1 ratio. The Control-IQ technology arm included 112 participants and the SAP arm included 56 participants. All 168 participants completed the trial.

Baseline characteristics of study participants are provided in this section. The study population consisted of patients with a clinical diagnosis of type 1 diabetes, 14 to 71 years of age, treated with insulin via an insulin pump or injections for at least one year. Females known to be pregnant were not included.

The summary statistics presented for the DCLP3 describe the primary outcome measure of the sensor glucose time in range between 70–180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study is not designed to determine difference in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm used the original Control-IQ algorithm (Control-IQ technology v1.0).

The primary outcome sensor time in range 70–180 mg/dL showed a mean adjusted difference 11% improvement with Control-IQ technology use compared to the control arm.

There was one episode of Diabetic Ketoacidosis (DKA), caused by infusion site failure in the Control-IQ technology arm. There were no severe hypoglycemic events in the DCLP3 with Control-IQ technology use. No other serious adverse events related to the device were reported.

Baseline Characteristics

DCLP3: Baseline Characteristics including Demographics at Enrollment (N=168)

Characteristic		Control-IQ (n=112)	SAP (n=56)
Age (years)			
	Mean ± SD	33 ± 16	33 ± 17
	Range	14 to 71	14 to 63
	<18 years	31 (28%)	17 (30%)
	≥18 years	81 (72%)	39 (70%)
Sex – Female n (%)		54 (48%)	30 (54%)
Race / Ethnicity*			
	White non-Hispanic	94 (86%)	53 (95%)
	Black / African American	4 (4%)	0 (0%)
	Asian	3 (3%)	2 (4%)
	Native Hawaiian / Other Pacific Islander	1 (<1%)	0 (0%)
	More than one race	7 (6%)	1 (2%)
Income†			
	<$50,000	10 (11%)	2 (4%)
	$50,000 – <$100,000	24 (27%)	18 (36%)
	≥$100,000	55 (62%)	30 (60%)

DCLP3: Baseline Characteristics including Demographics at Enrollment (N=168) (Continued)

Characteristic		Control-IQ (n=112)	SAP (n=56)
Education‡			
	≤High School Diploma	3 (3%)	6 (11%)
	Associates Degree or Some College	13 (12%)	7 (13%)
	Bachelor's Degree	51 (46%)	21 (38%)
	Master's Degree	32 (28%)	17 (30%)
	Doctoral or Professional Degree	13 (12%)	5 (9%)
Health Insurance§			
	Private	102 (94%)	50 (91%)
	CHP or another government / Medicaid	5 (5%)	5 (9%)
	None	2 (2%)	0 (0%)

**Three subjects in the Control-IQ technology arm did not provide race information.*
†Twenty-three subjects in the Control-IQ technology arm and 6 in SAP arm did not provide income information.
‡Highest level completed by the subject, or the primary caregiver if the participant was <18 years old. One subject in the Control-IQ technology arm did not provide education information.
§Three subjects in the Control-IQ technology arm and one in the SAP arm did not provide insurance information.

Adverse Effects

The following tables provide a full list of adverse events that occurred during the main part of the DCLP3 study:

DCLP3: Types of Adverse Events by Treatment Arm (N=168)

		Number of Events	
		Control-IQ (n=112)	SAP (n=56)
Total Number of Adverse Events		13	3
Adverse Events Related to Study Device			
	Ketosis (Infusion Site Failure)	3	0
	Hyperglycemia (Infusion Site Failure)	4	2
	Hyperglycemia (Defected Cartridge)	1	0
	Diabetic Ketoacidosis (Infusion Set Failure)	1	0
Adverse Effects Not Related to a Study Device			
	Hyperglycemia (User Error)	3	0
	Hyperglycemia (Respiratory Infection)	0	1
	Coronary Bypass Surgery	1	0
	Otitis Externa	1	0
	Concussion	1	0

Adverse Effects

The following table provides a list of only hyperglycemia or ketosis events during the DCLP3 study:

DCLP3: Hyperglycemia/Ketosis Events by Treatment Arm (N=168)

	Number of Events	
	Control-IQ (n=112)	SAP (n=56)
Ketosis (Infusion Site Failure)	3	0
Hyperglycemia (Infusion Site Failure)	4	2
Hyperglycemia (Defected Cartridge)	1	0
Diabetic Ketoacidosis (Infusion Set Failure)	1	0
Hyperglycemia (User Error)*	3	0
Hyperglycemia (Respiratory Infection)	0	1
**Discontinued pump, forgot to replace*		

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used in the Control-IQ technology arm:

DCLP3: Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over the 6-Month Period (n=112)

	Average Pump Use*	Average Time Control-IQ Available**
Weeks 1–4	100%	91%
Weeks 5–8	99%	91%
Weeks 9–12	100%	91%
Weeks 12–16	99%	91%
Weeks 17–20	99%	91%
Weeks 21–End	99%	82%
Overall	99%	89%

**The denominator is the total possible time within the 6-month study period.*
***Control-IQ Available is calculated as the percent of time when Control-IQ technology was available and operating normally during the 6-month study period.*

Primary Analysis

The primary outcome of the DCLP3 was to compare the CGM sensor values in range between 70–180 mg/dL between the Control-IQ technology and the SAP arms. The data represent the overall system performance 24-hours per day.

DCLP3: Comparison of CGM Values Between Control-IQ and SAP Users (N=168)

Characteristic	Control-IQ	SAP	Difference Between Study Arm and Control Arm
Average Sensor Glucose (std dev)	156 mg/dL (19 mg/dL)	170 mg/dL (25 mg/dL)	-14 mg/dL
Average % 70–180 mg/dL (std dev)	71.4% (11.7%)	59.2% (14.6%)	+11%
Average % >180 mg/dL (std dev)	27% (12%)	38.5% (15.2%)	-10%
Average % <70 mg/dL (std dev)	1.59% (1.15%)	2.25% (1.46%)	-0.88%
Average % <54 mg/dL (std dev)	0.29% (0.29%)	0.35% (0.32%)	-0.10%

The following table describes the average time participants in both the Control-IQ technology arm and the SAP arm spent with sensor glucose levels between 70–180 mg/dL by month at baseline and during the study period:

DCLP3: Percentage of Time in Range per Study Arm by Month (N=168)

Month	Control-IQ	SAP
Baseline	61%	59%
Month 1	73%	62%
Month 2	72%	60%
Month 3	71%	60%
Month 4	72%	58%
Month 5	71%	58%
Month 6	70%	58%

Secondary Analysis

The following table shows secondary analysis comparing the percent of time that participants spent at the indicated sensor glucose levels during the daytime and nighttime for the DCLP3:

DCLP3: Secondary Analysis by Time of Day (N=168)

Characteristic	Unit of Measure	Daytime		Nighttime	
		Control-IQ	SAP	Control-IQ	SAP
Overall Sensor Glucose Control	Average Sensor Glucose (std dev)	158 mg/dL (20 mg/dL)	170 mg/dL (26 mg/dL)	150 mg/dL (18 mg/dL)	170 mg/dL (27 mg/dL)
	Average % Sensor Glucose 70–180 mg/dL (std dev)	69.8% (12.4%)	59.4% (14.6%)	76.1% (12.4%)	58.5% (16.2%)

The following table compares the percent of time spent between 70–180 mg/dL across the different baseline HbA1c values observed in the DCLP3 study in both treatment arms:

Percentage of Time in Range per Study Arm by Baseline HbA1c (N=168)

Baseline HbA1c	Time in Range	
	Control-IQ	SAP
≤6.5	85%	78%
6.6–7.0	76%	69%
7.1–7.5	71%	49%
7.6–8.0	69%	56%
≥8.1	60%	47%

The following table compares the average HbA1c values for all DCLP3 participants at baseline, after 13 weeks, and after 26 weeks. There was a relative difference of -0.33% between the Control-IQ technology arm and the SAP arm:

Comparison of HbA1c Values (N=168)

Time Period	Control-IQ	SAP
Baseline	7.40%	7.40%
After 13 Weeks	7.02%	7.36%
After 26 Weeks	7.06%	7.39%

The following table compares the change in HbA1c values for participants over the course of the DCLP3:

DCLP3: Change in HbA1c Values from Randomization to 26 Weeks (N=168)

			Number of Subjects (% of Subjects) with Change in HbA1c									
			Decrease >1%		Decrease 0 to 1%		No Change		Increase 0 to 1%		Increase >1%	
			n	%	n	%	n	%	n	%	n	%
Baseline Central Lab HbA1c		n										
5% ≤ HbA1c < 6%	Treatment	8	0	0%	1	13%	0	0%	7	88%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%
6% ≤ HbA1c < 7%	Treatment	30	0	0%	18	60%	3	10%	9	30%	0	0%
	Control	19	0	0%	10	53%	0	0%	9	47%	0	0%
7% ≤ HbA1c < 8%	Treatment	45	4	9%	33	73%	2	4%	5	11%	1	2%
	Control	22	0	0%	11	50%	1	5%	8	36%	2	9%
8% ≤ HbA1c < 9%	Treatment	22	5	23%	15	68%	1	5%	1	5%	0	0%
	Control	13	0	0%	8	62%	0	0%	4	31%	1	8%
9% ≤ HbA1c < 10%	Treatment	4	1	25%	2	50%	0	0%	1	25%	0	0%
	Control	1	0	0%	0	0%	0	0%	1	100%	0	0%
HbA1c ≥ 10%	Treatment	2	2	100%	0	0%	0	0%	0	0%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%

DCLP3: Change in HbA1c Values from Randomization to 26 Weeks (N=168) (Continued)

			Number of Subjects (% of Subjects) with Change in HbA1c									
Overall	Treatment	111	12	11%	69	62%	6	5%	23	21%	1	<1%
	Control	55	0	0%	29	53%	1	2%	22	40%	3	5%

31.4 The DCLP5 Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in children age 6 to 13 years of age. The system's performance was evaluated in an RCT comparing the use of Control-IQ technology to the use of SAP therapy alone (the control group).

The study design was very similar to DCLP3. In DCLP5, participants (N=101) were randomly assigned to Control-IQ technology or SAP in a 3:1 ratio. In this study, the Control-IQ technology arm included 78 participants. Like the DCLP3, this study population had a clinical diagnosis of type 1 diabetes. Unlike the DCLP3, the DCLP5 had participants 6 to 13 years of age. They were treated with insulin via an insulin pump or injections for at least one year. They weighed ≥55 pounds (25 kilograms) and ≤308 pounds (140 kilograms) and took at least 10 units of insulin a day. Females known to be pregnant were not included. Participants were required to be living with at least one parent or guardian knowledgeable about diabetes and managing diabetes-related emergencies and willing to participate in all training sessions.

No participants were enrolled in the DCLP5 study who had inpatient psychiatric treatment in the past 6 months, the presence of a known adrenal disorder, untreated thyroid disease, cystic fibrosis, severe infectious process not anticipated to resolve prior to study procedures (e.g. meningitis, pneumonia, osteomyelitis), any skin condition in the area of insertion that prevents safe sensor or pump placement (e.g. bad sunburn, pre-existing dermatitis, intertrigo, psoriasis, extensive scarring, cellulitis), abnormal liver function tests (transaminase >3 times the upper limit of normal), or abnormal renal function test results (estimated glomular filtration rate [GFR] <60 mL/minute/1.7m^2). Participants were also excluded for use of any medication, any carcinogenic disease, or other significant medical disorder if that injury, medication, or disease in the judgment of the investigator would affect the completion of the protocol.

The summary statistics presented for the DCLP5 describe the primary outcome measure of the sensor glucose time in range between 70–180 mg/dL, reported by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study is not designed to determine difference in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm use the original Control-IQ algorithm (Control-IQ technology v1.0). There were no episodes of DKA in the DCLP5. There were no severe hypoglycemic events in the DCLP5 with Control-IQ technology use. No other serious adverse events related to the device were reported.

Baseline Characteristics

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
Age (years)			
	6 – 9	21 (27%)	8 (35%)
	10 – 13	57 (73%)	15 (65%)
	Median (IQR)	11 (9, 12)	10 (8, 13)
	Range	6 to 13	6 to 13
Sex – Female n (%)		38 (49%)	12 (52%)
Race / Ethnicity*			
	White non-Hispanic	64 (82%)	18 (78%)
	Hispanic or Latino	6 (8%)	2 (9%)
	Black / African American	0 (0%)	0 (0%)
	Asian	1 (1%)	1 (4%)
	More than one race	7 (9%)	2 (9%)
Annual Household Income			
	<$25,000	0 (0%)	0 (0%)
	$25,000 – <$35,000	2 (3%)	0 (0%)
	$35,000 – <$50,000	1 (1%)	2 (10%)

DCLP5: Baseline Characteristics including Demographics at Enrollment (N=101) (Continued)

Characteristic		Control-IQ (n=78*)	SAP (n=23*)
	$50,000 – <$75,000	5 (7%)	0 (0%)
	$75,000 – <$100,000	13 (18%)	4 (19%)
	$100,000 – <$200,000	27 (36%)	8 (38%)
	≥$200,000	26 (35%)	7 (33%)
Parent Education			
	≤High School Diploma	2 (3%)	0 (0%)
	Associates Degree or Some College	5 (6%)	1 (4%)
	Bachelor's Degree	32 (41%)	9 (39%)
	Master's Degree	34 (44%)	11 (48%)
	Doctoral or Professional Degree	5 (6%)	2 (9%)
Health Insurance			
	Private	102 (94%)	50 (91%)
	CHP or another government / Medicaid	5 (5%)	5 (9%)
	Military	2 (3%)	1 (4%)
	Other	0 (0%)	0 (0%)
	None	0 (0%)	0 (0%)

**Missing data (CLC/SAP): annual household income 4 (5%)/2 (9%), total daily insulin 1 (1%)/0 (0%). All other variables have no missing data.*

Adverse Effects

The following tables provide a full list of adverse events that occurred during the main part of the DCLP5 study:

DCLP5: Types of Adverse Events by Treatment Arm (N=101)

		Number of Events	
		Control-IQ (n=78)	SAP (n=23)
Total Number of Adverse Events		16	3
Adverse Events Related to Study Device			
	Ketosis (Infusion Site Failure)	8	0
	Abscess at Sensor Site (CGM Sensor)	0	2
	Hyperglycemia (Defected Cartridge)	1	0
Adverse Effects Not Related to a Study Device			
	Hypoglycemia (User Error)	1	0
	Ketosis (User Error)	2	1
	Ketosis (Gastroenteritis)	1	0
	Hyperglycemia (User Error)	2	0
	Accidental Over-Delivery of Insulin (User Error)*	1	0

**One subject primed tubing while connected to body. This was a serious adverse event, requiring treatment in the emergency room for hypoglycemia prevention.*

The following table provides a list of only hyperglycemia or ketosis events during the DCLP5 study:

DCLP5: Hyperglycemia/Ketosis Events by Treatment Arm (N=101)

	Number of Events	
	Control-IQ (n=78)	SAP (n=23)
Ketosis (Infusion Site Failure)	8	0
Hyperglycemia (Defected Cartridge)	1	0
Ketosis (User Error)*	2	1
Ketosis (Gastroenteritis)	1	0
Hyperglycemia (User Error)†	2	0

**Improper cartridge fill*
†Failed to recharge pump battery

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used in the Control-IQ technology arm:

DCLP5: Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over the 4-Month Period (n=78)

	Average Time Control-IQ Available*
Weeks 1–4	93.4%
Weeks 5–8	93.8%
Weeks 9–12	94.1%
Weeks 13–End	94.4%
Overall	92.8%

**Control-IQ Available is calculated as the percent of time when Control-IQ technology was available and operating normally during the 4-month study period.*

Primary Analysis

The primary outcome of the DCLP5 was to compare the CGM sensor values in range between 70–180 mg/dL between the Control-IQ technology arm and the SAP arm. The data represent the overall system performance 24 hours per day.

DCLP5: Comparison of CGM Values Between Control-IQ and SAP Users (N=101)

Characteristic	Control-IQ	SAP	Difference Between Study Arm and Control Arm
Average Sensor Glucose (std dev)	162 mg/dL (18 mg/dL)	179 mg/dL (26 mg/dL)	-17 mg/dL
Average % 70–180 mg/dL (std dev)	67% (10%)	55% (13%)	+11%
Average % >180 mg/dL (std dev)	31% (10%)	43% (14%)	-10%
Average % <70 mg/dL (std dev)	1.8% (1.38%)	2.1% (1.18%)	-0.40%
Average % <54 mg/dL (std dev)	0.34% (0.35%)	0.38% (0.35%)	-0.07%

The following table describes the average time participants in both the Control-IQ technology arm and the SAP arm spent with sensor glucose levels between 70–180 mg/dL by month at baseline and during the study period.

DCLP5: Percentage of Time in Range per Study Arm by Month (N=101)

Month	Control-IQ	SAP
Baseline	53%	51%
Month 1	68%	56%
Month 2	68%	54%
Month 3	67%	56%
Month 4	66%	55%

Secondary Analysis

Secondary analysis comparing the percent of time that participants spent at the indicated sensor glucose levels during the daytime and nighttime for the DCLP5 are shown below:

DCLP5: Secondary Analysis by Time of Day (N=101)

Characteristic	Unit of Measure	Daytime		Nighttime	
		Control-IQ	SAP	Control-IQ	SAP
Overall Sensor Glucose Control	Average Sensor Glucose (std dev)	167 mg/dL (21 mg/dL)	179 mg/dL (27 mg/dL)	146 mg/dL (16 mg/dL)	180 mg/dL (27 mg/dL)
	Average % Sensor Glucose 70–180 mg/dL (std dev)	63% (11%)	56% (14%)	80% (9%)	54% (16%)

The following table compares the change in HbA1c values for participants over the course of the DCLP5:

DCLP5: Change in HbA1c Values from Randomization to 16 Weeks (N=101)

			Number of Subjects (% of Subjects) with Change in HbA1c									
			Decrease >1%		Decrease 0 to 1%		No Change		Increase 0 to 1%		Increase >1%	
			n	%	n	%	n	%	n	%	n	%
Baseline Central Lab HbA1c		n										
5% ≤ HbA1c < 6%	Treatment	3	0	0%	0	0%	2	67%	1	33%	0	0%
	Control	0	0	0%	0	0%	0	0%	0	0%	0	0%
6% ≤ HbA1c < 7%	Treatment	18	0	0%	9	50%	1	6%	8	44%	0	0%
	Control	3	0	0%	1	33%	0	0%	2	67%	0	0%
7% ≤ HbA1c < 8%	Treatment	28	3	11%	20	71%	0	0%	5	18%	0	0%
	Control	8	0	0%	5	63%	0	0%	2	25%	1	13%
8% ≤ HbA1c < 9%	Treatment	20	11	55%	9	45%	0	0%	0	0%	0	0%
	Control	10	0	0%	7	70%	0	0%	3	30%	0	0%
9% ≤ HbA1c < 10%	Treatment	7	5	71%	1	14%	0	0%	1	14%	0	0%
	Control	1	0	0%	1	100%	0	0%	0	0%	0	0%
HbA1c ≥ 10%	Treatment	1	0	0%	1	100%	0	0%	0	0%	0	0%
	Control	1	0	0%	1	100%	0	0%	0	0%	0	0%

DCLP5: Change in HbA1c Values from Randomization to 16 Weeks (N=101) (Continued)

			Number of Subjects (% of Subjects) with Change in HbA1c									
Overall	Treatment	77	19	25%	40	52%	3	4%	15	19%	0	0%
	Control	23	0	0%	15	65%	0	0%	7	30%	1	4%

31.5 The PEDAP Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 4 months under normal conditions in preschoolers 2 to <6 years of age. The system's performance was evaluated in an RCT comparing use of Control-IQ technology to Standard Care (SC, the control group), which included SAP therapy and multiple daily injection (MDI) therapy.

In PEDAP, participants (N=102) were randomly assigned to Control-IQ technology or SC in a 2:1 ratio.

The Control-IQ technology arm included 68 participants, and the SC arm included 34 participants. Participants had a clinical diagnosis of type 1 diabetes and were 2 to 5 years of age. They were treated with insulin via an insulin pump or injections for at least 6 months. They weighed at least 20 pounds (9 kilograms) and took at least 5 units of insulin per day.

Participants were required to be living with at least one parent or guardian knowledgeable about diabetes and managing diabetes-related emergencies and willing to participate in all training sessions. No participants had a history of adrenal insufficiency, untreated thyroid disease, used oral or injectable steroids within the last 8 weeks, history of chronic renal disease or currently on hemodialysis, hemophilia or any other bleeding disorder, history of >1 severe hypoglycemic event with seizure or loss of consciousness in the last 3 months, history of >1 DKA event in the last 6 months not related to illness, infusion set failure, or initial diagnosis, known ongoing adhesive intolerance, or condition, in the opinion of the investigator, would put the participant or study at risk. Concurrent use of any non-insulin glucose lowering agent (including GLP-1 agonists, Symlin, DPP-4 inhibitors, and sulfonylureas) was not allowed.

The summary statistics presented describe the primary outcome measure of the sensor glucose time in range 70–180 mg/dL, by treatment arm. Analysis of secondary endpoints was also performed.

Results of all subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income. There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of the t:slim X2 insulin pump with Control-IQ technology. The study was not designed to determine differences in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm used the original Control-IQ algorithm (Control-IQ technology v1.0), modified to allow lower weight and total daily insulin dose entry.

The primary outcome sensor time in range showed a mean adjusted difference 12.4% improvement with Control-IQ technology use compared to SC.

There was one episode of DKA caused by infusion site failure, in the Control-IQ technology arm. There were two cases of severe hypoglycemia in the Control-IQ technology arm and one in the SC arm. No other serious adverse events related to the device were reported.

Baseline Characteristics

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
Age (years)				
	Mean ± SD	3.94 ± 1.24	3.84 (1.23)	4.06 (1.25)
	Range	2.00 to 5.98	2.00 to 5.98	2.02 to 5.90
	2 to <4	47 (46%)	31 (46%)	16 (47%)
	4 to <6	55 (54%)	37 (54%)	18 (53%)
Weight (kg)				
	Mean (SD)	17.7 (4.2)	17.7 (4.7)	17.7 (3.3)
	Range	11.1 to 44.7	11.1 to 44.7	11.8 to 23.9
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase				
	Median (IQR)	0.66 (0.54, 0.79)	0.66 (0.55, 0.77)	0.66 (0.51, 0.80)
	Range	0.26 to 2.12	0.26 to 2.12	0.31 to 1.64
Sex – Female n (%)		52 (51%)	33 (49%)	19 (56%)
Race / Ethnicity				

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102) (Continued)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
	White non-Hispanic	75 (74%)	50 (74%)	25 (74%)
	Black / African American	6 (6%)	4 (6%)	2 (6%)
	Asian	2 (2%)	1 (1%)	1 (3%)
	More than one race	3 (3%)	2 (3%)	1 (3%)
Income*				
	<$50,000	14 (14%)	8 (12%)	6 (19%)
	$50,000 – <$100,000	31 (33%)	19 (30%)	12 (38%)
	≥$100,000	51 (53%)	37 (57%)	14 (44%)
Parent Education				
	≤High School Diploma	9 (9%)	6 (9%)	3 (9%)
	Technical/Vocational	3 (3%)	2 (3%)	1 (3%)
	Associate Degree	11 (11%)	6 (9%)	5 (15%)
	College Graduate (Bachelor's or higher)	35 (34%)	22 (32%)	13 (38%)
	Advanced Degree (Masters, PhD, MD, etc.)	44 (43%)	32 (47%)	12 (35%)

PEDAP: Baseline Characteristics Including Demographics at Enrollment (N=102) (Continued)

Characteristic		Overall (n=102)	CLC (n=68)	SC (n=34)
Health Insurance				
	Private‡	78 (77%)	52 (76%)	26 (79%)
	CHP or another government / Medicaid†	22 (24%)	15 (22%)	7 (21%)
	None	1 (<1%)	1 (1%)	0 (0%)

**Missing data (CLC/SC): Health insurance 0/1, annual household income 4/2, BMI percentile 2/0, HbA1c 4/2. All other variables have no missing data.*
†For participants with Private Insurance, 7 participants also had Medicaid, 1 participant also had Medicare, and 1 participant also had other government insurance.
‡For participants with Medicaid, 1 participant also had other government insurance.

Adverse Effects

The following table provides a full list of adverse events that occurred during the main art of the PEDAP study.

PEDAP: Types of Adverse Events by Treatment Arm (N=102)

		Number of Events	
		Control-IQ (n=68)	SC (n=34)
Total Number of Adverse Events		71	14
Severe Hypoglycemic (SH) Events*		2	1
Diabetic Ketoacidosis (DKA) Events†		1	0
Other Serious Adverse Events‡ (SAEs)		0	1
Other Adverse Events *N Events/N Participants*		68/40	12/9
	Hyperglycemia with or without Ketosis Related to Study Device	39/26	0
	Hyperglycemia with or without Ketosis Not Related to Study Device	12/9	8/7
	Hypoglycemia (not severe)	2/2	0/0
	Burn	1/1	0/0

PEDAP: Types of Adverse Events by Treatment Arm (N=102) (Continued)

		Number of Events	
		Control-IQ (n=68)	SC (n=34)
	COVID-19	3/3	0/0
	Fall	1/1	0/0
	Fractured Finger	1/1	0/0
	Gastroenteritis	2/2	2/2
	Hematuria	1/1	0/0
	Medical Device Site Bleeding	1/1	0/0
	Skin Infection	3/2	0/0
	Streptococcal Sore Throat	1/1	0/0
	Upper Respiratory Infection	1/1	0/0
	Vomiting	0/0	2/1

**A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.*
†*DKA events meeting DCCT criteria.*
‡*One participant in the SC group was hospitalized for an asthma flare.*

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the PEDAP trial in the intervention arm.

PEDAP Percentage of t:slim X2 Insulin Pump with Control-IQ Technology Use Over 13-week Period (n=68)

	Average Time Control-IQ In Use*
Weeks 1–4	92%
Weeks 5–8	95% (n=67)
Weeks 9–13	95% (n=67)
Overall	94%

**The denominator is the number of days between the beginning of the fourth day after randomization and the end of the day before the 13-week visit, or the end of the day before the last contact date for the participant who dropped out.*

Primary Analysis

The primary outcome of PEDAP was to compare the CGM sensor values in range between 70–180 mg/dL between the Control-IQ technology arm and the SC arm. The data represent the overall system performance 24 hours per day.

PEDAP: Percent Time in Range: Primary Endpoint Tested for Superiority (N=101)

Time and Change	Control-IQ (n=67)	SC (n=34)
Baseline	57% (18)	55% (15)
13 Weeks	69% (11) (n=68)	56% (13)
Change from Baseline mean (SD)	12.5% (11.8)	1.0% (6.6)
13 week Adjusted Group Difference (95% CI) [p-value]	12.4% (9.5, 15.3) [<0.001]	

Secondary Analysis

Change in HbA1c values to baseline subgroups follows:

PEDAP: Change in HbA1c Values by Baseline HbA1c Subgroups (Treatment n=59, Control n=31)

		N	Baseline mean (SD)	Change from Baseline Mean (SD)
Baseline HbA1c				
<7.0%	Treatment	21	6.4 (0.5)	-0.08 (0.33)
	Control	8	6.5 (0.3)	-0.18 (0.37)
7% ≤ HbA1c < 8%	Treatment	19	7.5 (0.3)	-0.51 (0.34)
	Control	8	7.4 (0.2)	-0.01 (0.36)
HbA1c ≥ 8%	Treatment	19	8.9 (0.9)	-1.22 (0.81)
	Control	15	8.5 (0.4)	-0.31 (0.40)
Overall	Treatment	59	8.9 (0.9)	-1.22 (0.81)
	Control	15	8.5 (0.4)	-0.31 (0.40)

31.6 The PEDAP Extension Phase

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in preschoolers 2 to <6 years of age. The PEDAP extension phase allowed participants in the preceding PEDAP RCT to continue in the trial for an additional 13 weeks during an Extension Phase (N=96), with all participants using Control-IQ technology use for 3 more months. A subset of participants also performed meal and exercise challenges during the study.

Participants used either Closed-Loop Control (CLC) for the RCT and the extension phase of the study (CLC-CLC), or used Standard Care (SC) for the RCT arm of the study, then switched to CLC during the extension phase (SC-CLC).

Participants in the CLC-CLC arm (N=63, those who continued with Control-IQ technology) were compared to the SC-CLC group (who were in the standard care arm for the RCT, who then switched to Control-IQ technology for the extension, N=33).

The summary statistics presented for the PEDAP Extension Phase describe key CGM outcomes, as well as analysis of secondary endpoints.

All participants in the PEDAP extension phase used the updated Control-IQ algorithm, Control-IQ+ technology (v1.5).

Key CGM outcomes showed, in the CLC-CLC group, time in range 70–180 mg/dL increased from 57% at PEDAP RCT baseline to 70% at the end of the 13-week RCT, and this was sustained during the Extension Phase at 70%, with no significant change comparing the CLC use in the RCT phase to CLC use in the Extension Phase.

In the SC-CLC group, time in range 70–180 mg/dL was 55% at the PEDAP RCT baseline, 56% during the RCT, and 68% during the Extension Phase. Comparing standard care from the RCT with use of CLC in the extension, the mean difference in time in range 70–180 mg/dL was 11.8%.

There were two cases of severe hypoglycemia in the 63 participants in the CLC-CLC group (3%) unrelated to the study device, and no cases among the 33 participants in the SC-CLC group. No cases of DKA were reported. No other serious adverse events related to the device were reported.

Baseline Characteristics

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
Age at Beginning of Extension Phase (years)				
	Mean (SD)	4.17 (1.23)	4.10 (1.23)	4.32 (1.23)
	Range	2.30 to 6.33	2.33 to 6.33	2.35 to 6.22
	2 to <4	44 (46%)	29 (46%)	15 (45%)
	4 to <6	44 (46%)	31 (49%)	13 (39%)
	6 to <7	8 (8%)	3 (5%)	5 (15%)
Sex – Female n (%)		51 (53%)	32 (51%)	19 (58%)
Weight (kg)				
	Mean (SD)	18.5 (4.4)	18.7 (4.9)	18.2 (3.3)
	Range	12.2 to 47.2	12.7 to 47.2	12.2 to 24.4
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase				
	Median (IQR)	0.69 (0.59, 0.82)	0.69 (0.59, 0.80)	0.69 (0.55, 0.94)
	Range	0.42 to 1.70	0.42 to 1.70	0.44 to 1.38

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96) (Continued)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
Race / Ethnicity				
	White non-Hispanic	81 (84%)	53 (85%)	28 (85%)
	Black / African American	5 (5%)	3 (5%)	2 (6%)
	Asian	2 (2%)	1 (2%)	1 (3%)
	More than one race	8 (8%)	6 (10%)	2 (6%)
Hispanic Ethnicity		14 (15%)	9 (14%)	5 (15%)
Income at RCT Baseline*				
	<$50,000	13 (14%)	7 (11%)	6 (19%)
	$50,000 to $100,000	31 (34%)	19 (33%)	12 (39%)
	>$100,000	46 (51%)	33 (56%)	13 (42%)
Parent Education at RCT Baseline				
	High School graduate/diploma/GED	7 (7%)	4 (6%)	3 (9%)
	Technical/Vocational	3 (3%)	2 (3%)	1 (3%)
	Associate Degree	11 (11%)	6 (10%)	5 (15%)
	College Graduate (Bachelor's or equivalent)	34 (35%)	22 (35%)	12 (36%)
	Advanced Degree (Masters, PhD, MD, etc.)	41 (43%)	29 (46%)	12 (36%)

PEDAP Extension Phase: Baseline Characteristics Including Demographics at Enrollment (N=96) (Continued)

Characteristic		Overall (N=96)	CLC-CLC (n=62)	SC-CLC (n=33)
Health Insurance at RCT Baseline*				
	Private‡	74 (78%)	49 (78%)	25 (78%)
	Medicare / Medicaid†	13 (14%)	9 (14%)	4 (12%)
	Other Government Insurance	8 (8%)	5 (8%)	3 (9%)

**Missing data (CLC-CLC/SC-CLC): Health insurance 0/1, annual household income 4/2. All other variables have no missing data.*
†For participants with Private Insurance, 6 participants also had Medicaid, 1 participant also had Medicare, and 1 participant also had other government insurance.
‡For participants with Medicaid, 1 participant also had other government insurance.

Adverse Effects

The following table provides a full list of adverse events that occurred during the PEDAP extension phase. There were no DKA events:

Summary of Adverse Events During PEDAP Extension Phase (N=96)

		Number of Events	
		CLC-CLC (n=63)	SC-CLC (n=33)
Total Number of Adverse Events		46	29
Severe Hypoglycemic (SH) Events* *N Events/N Participants*		2/2	0/0
Other Serious Adverse Events† (SAEs) *N Events/N Participants*		1/1	0/0
Other Adverse Events *N Events/N Participants*		43/34	29/16
	Hyperglycemia with or without Ketosis Related to Study Device	20/18	8/8
	Hyperglycemia with or without Ketosis Not Related to Study Device	10/8	12/4
	Hypoglycemia (not severe)	1/1	0/0
	Allergy NOS	1/1	0/0

Summary of Adverse Events During PEDAP Extension Phase (N=96) (Continued)

		Number of Events	
		CLC-CLC (n=63)	SC-CLC (n=33)
	Cellulitis	0/0	1/1
	COVID-19	3/3	0/0
	Fever	0/0	1/1
	Gastroenteritis	2/2	2/2
	Head Injury	0/0	1/1
	Influenza	1/1	0/0
	Laceration	0/0	1/1
	Pneumonia	1/1	0/0
	Skin Infection	1/1	2/2
	Upper Respiratory Infection	1/1	0/0
	Viral Syndrome	1/1	0/0
	Vomiting	1/1	1/1

**A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.*

†*One participant in the CLC-CLC group was hospitalized for muscle pain*

Intervention Compliance

The following table provides an overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the PEDAP extension phase. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ technology v1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 - 13. In weeks 14 - 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ+ technology v1.5).

PEDAP Extension Phase Median Percentage of Time of Closed-Loop System Use

	CLC-CLC	SC-CLC
Weeks 1–13*	94% (n=63)	NA (n=33)
Weeks 14–17	96% (n=63)	96% (n=33)
Weeks 18–21	96% (n=62)	96% (n=32)
Weeks 22–26	96% (n=61)	96% (n=31)
Weeks 14–26**	96% (n=63)	95% (n=33)

**The denominator for Weeks 1–13 is the number of days between the beginning of the fourth day after the randomization and the end of the day before the 13-week visit.*
***Denominator for Weeks 14–26 is the number of days between the beginning of the fourth day after the Extension Training visit and the end of the day before the 26-week visit, or the end of the day before the last contact date for the participants who dropped out.*

Key CGM Outcomes

Time in range 70–180 mg/dL for all phases of the trial is shown below. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ technology v1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1–13. In weeks 14–26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ+ technology v1.5).

PEDAP Extension Phase: Percent Time in Range 70–180 mg/dL: Primary Endpoint Tested for Superiority (N=96)

Time and Change	CLC-CLC (n=63)	SC-CLC (n=33)
RCT Baseline	57% (18) n=62	55% (15)
Weeks 1-13	70% (11)	56% (13)
Weeks 14-26	70% (11)	68% (9)
26 week Adjusted Group Difference (95% CI) [p-value]*	0.1% (-1.2, 1.4) [0.86]	

**The point estimate and 95% confidence interval for the difference were calculated from a direct likelihood model. This model adjusted for the RCT baseline value of the metric, age, prior CGM and pump use, and site as a random effect. P-values and confidence intervals were adjusted to control the false discovery rate.*

Secondary Analysis

The following table shows secondary analysis of HbA1c outcomes. All participants in the CLC-CLC arm used the original Control-IQ algorithm (Control-IQ technology v1.0), modified to allow a lower weight and total daily insulin dose entry in weeks 1 – 13. In weeks 14 – 26, all participants in the extension phase in both the CLC-CLC arm and the SC-CLC arm used the updated Control-IQ algorithm (Control-IQ+ technology v1.5):

PEDAP Extension Phase: HbA1c Outcomes*

		N	Baseline mean (SD)
RCT Baseline	CLC-CLC	59	7.6 (1.2)
	SC-CLC	32	7.7 (0.9)
Week 13	CLC-CLC	58	7.0 (0.7)
	SC-CLC	32	7.5 (0.9)
Week 26	CLC-CLC	55	7.1 (0.8)
	SC-CLC	28	7.2 (0.7)

**CLC-CLC group used closed-loop control for both the RCT and the extension phase. SC-CLC used standard care for the RCT and closed-loop control for the extension phase.*

31.7 The Higher-IQ Trial

The goal of this study was to assess the safety and efficacy of Control-IQ technology when used 24 hours a day for 3 months under normal conditions in adults with high insulin needs.

The Higher-IQ study enrolled adults (N=34) with type 1 diabetes using at least one basal rate greater than 3 units/hour, in a single arm, prospective study of Control-IQ technology use for 13 weeks. All participants also performed meal and exercise challenges during the study.

Participants were at least 18 years of age, had type 1 diabetes for at least 1 year, were users of an insulin pump for at least 3 months, had a hemoglobin AC1c 10.5% and had a weight ≤440 pounds.

Baseline characteristics of study participants are provided below. Participants with more than 1 episode of severe hypoglycemia or DKA in the last 6 months were not included. Females known to be pregnant were not included. Participants with hemophilia or any other bleeding disorder, history of adrenal insufficiency, untreated thyroid disease, chronic kidney disease which could affect CGM accuracy, history of gastroparesis, or a condition, which in the opinion of the investigator or designee, would put the participant or study at risk were not included.

Treatment with sulfonylureas, meglitinides, or Symlin was not permitted. Participants taking GLP-1 receptor agonists, DPP-4 inhibitors, and/or SGLT-2 inhibitors were allowed to continue these medications if they were on a stable dose for the last 3 months.

The summary statistics presented for Higher-IQ describe key CGM outcomes, as well as analysis of change in HbA1c.

All participants in the Higher-IQ study used the updated Control-IQ algorithm, Control-IQ+ technology (v1.5).

Key CGM outcomes showed time in range 70–180 mg/dL was 64.75% overall, with time in hypoglycemia of 1.04%.

HbA1c decreased from 7.69% at baseline to 6.87% after 13 weeks of Control-IQ technology use, a decrease of 0.82%.

There were no DKA or severe hypoglycemia events in the study. No other serious adverse events related to the device were reported.

Baseline Characteristics

Higher-IQ Baseline Characteristics Including Demographics at Enrollment (N=34)

Characteristic		All Participants Used Control-IQ (N=34)
Age (years)		
	Mean (SD)	39.9 (11.9)
	Range	20 to 66
Sex – Female n (%)		(14) 41.2%
Weight (kg)		
	Mean (SD)	114.8 (17.4)
	Range	85.1 to 169.3
Total Daily Insulin (units/kg/day) at Beginning of Extension Phase		
	Median (IQR)	1.2 (0.4)
	Range	0.5 to 2.0
Race / Ethnicity		
	White non-Hispanic	34 (100%)
	Black / African American	2 (5.9%)
	Native Hawaiian or Other Pacific Islander	1 (2.9%)
Hispanic Ethnicity		3 (8.8%)
Highest Level of Education		

Higher-IQ Baseline Characteristics Including Demographics at Enrollment (N=34)

Characteristic		All Participants Used Control-IQ (N=34)
	Less than high school	1 (2.9%)
	High School graduate/diploma/GED	4 (11.8%)
	Some college but no degree	8 (23.5%)
	Associate Degree	3 (8.8%)
	College Graduate (Bachelor's or equivalent)	13 (38.2%)
	Advanced Degree (Masters, PhD, MD, etc.)	5 (14.7%)

Adverse Effects

The following table provides a full list of adverse events that occurred during the Higher-IQ study:

Higher-IQ – All Adverse Events (N=34)

	Number of Events
	All Participants Used Control-IQ
Total Number of Adverse Events	38
Severe Hypoglycemic (SH) Events*	0
Diabetic Ketoacidosis (DKA) Events†	0
Other Serious Adverse Events‡ (SAEs)	1
Other Adverse Events *N Events/N Participants*	37/18

Higher-IQ – All Adverse Events (N=34) (Continued)

		Number of Events
		All Participants Used Control-IQ
	Hyperglycemia with or without Ketosis Related to Study Device	1/1
	Hyperglycemia with or without Ketosis Not Related to Study Device	0/0
	Bronchitis	1/1
	Chronic Kidney Disease	1/1
	Cough	1/1
	COVID-19	2/2
	Dyslipidemia	1/1
	Hypertension	1/1
	Influenza	3/3
	Ligament Sprain	1/1
	Migraine	1/1
	Myalgia	1/1
	Nausea/Vomiting	2/2
	Oropharyngeal Pain	1/1
	Otitis Externa	1/1
	Otitis Media	2/2

Higher-IQ – All Adverse Events (N=34) (Continued)

		Number of Events
		All Participants Used Control-IQ
	Pharyngitis Streptococcal	1/1
	Skin Abrasion	1/1
	Sleep Apnea Syndrome	1/1
	Stiff Person Syndrome	1/1
	Tooth Abscess	1/1
	Tooth Fracture	1/1
	Tympanic Membrane Perforation	1/1
	Upper Respiratory Tract Infection	10/7

**A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.*
†*DKA events meeting DCCT criteria.*
‡*One participant was hospitalized for new onset atrial fibrillation.*

Intervention Compliance

The following table provides and overview of how often the t:slim X2 insulin pump with Control-IQ technology was used during the Higher-IQ trial:

Higher-IQ Intervention Adherence over the 13-week Study Period (N=34)

	Sensor Use (%)	Closed-Loop System Use (%)
Mean (SD)	97.9%	93%

Key CGM Outcomes

Key CGM outcomes are shown below, for overall, daytime, and overnight:

Higher-IQ: Percentage of Time in Glycemic Ranges (N=34)

CGM Time in Range Mean % (SD)	Overall	Daytime	Overnight
BG 70–180 mg/dL	64.75% (10.75)	63.47% (10.89)	68.47% (14.81)
BG >180 mg/dL	34.21% (11.05)	35.62% (11.25)	30.09% (15.01)
BG ≥250 mg/dL	10.45% (6.78)	10.74% (6.29)	9.58% (10.39)
BG 70–140 mg/dL	37.87% (10.75)	36.96% (10.81)	40.55% (14.43)
BG <54 mg/dL	0.20% (0.22)	0.15% (0.17)	0.35% (0.42)
BG <70 mg/dL	1.04% (0.98)	0.90% (0.90)	1.44% (1.48)

Secondary Analysis

Higher-IQ: Change in Central Lab HbA1c at 13 Weeks (N=34)

	Baseline	13 Weeks	Change from Baseline	P Value
HbA1c (%) Mean (SD)	7.69 (1.08)	6.87 (0.57)	-0.82 (0.73)	p<0.001

31.8 The 2IQP Trial

The goal of this study was to assess safety, efficacy, user satisfaction and quality of life with use of Control-IQ technology in adults with type 2 diabetes using insulin therapy with mealtime coverage for 13 weeks. The system's performance was evaluated in a RCT comparing the use of Control-IQ technology to continued use of insulin therapy by injections with a Dexcom G6 sensor (CGM arm).

319 participants were randomly assigned to use Control-IQ technology or CGM for the study in a 2:1 ratio. The Control-IQ technology arm included 215 participants, and the CGM arm included 104 participants. Participants in the Control-IQ technology arm performed meal and exercise challenges.

Baseline characteristics of study participants are provided below. The study population consisted of patients with a clinical diagnosis of type 2 diabetes, age 19 to 87 years of age, using insulin therapy with at least one injection containing rapid-acting insulin per day or an insulin pump for at least 3 months prior to enrollment. Prior use of mixed insulin with a rapid component was allowed. Females known to be pregnant were not included.

Treatment with sulfonylureas, meglitinides or Symlin was not permitted. Participants taking other noninsulin glucose-lowering medications (such as GLP-1 receptor agonists, DPP-4 inhibitors, and/or SGLT-2 inhibitors), or weight-reduction medications, were allowed to continue these medications if on a stable dose for the last 3 months.

At enrollment 9% of participants had HbA1c <7%, 30% had HbA1c from 7.0 to <8.0%, 31% had HbA1c from 8.0 to <9.0%, and 30% had HbA1c >9.0%.

The summary statistics describe the primary outcome measure of change in HbA1c compared between treatment arms. Analysis of CGM endpoints was also performed.

Results of subgroup analyses indicate that the Control-IQ technology treatment effect is similar across the distribution of age, race, and income.

There is no evidence to suggest that baseline demographics are associated with more or less benefit or risk from the use of Control-IQ technology. The study was not designed to determine differences in benefit or risk from each subgroup.

All participants in the Control-IQ technology arm used the updated Control-IQ technology algorithm (Control-IQ+ technology v1.5).

HbA1c improved from 8.2% at randomization to 7.3% at 13 weeks in the Control-IQ technology arm, a change of -0.9%. In the CGM arm, HbA1c improved from 8.1% at randomization to 7.7% at 13 weeks, a change of -0.3%. This represents an adjusted group difference of -0.6% favoring the Control-IQ technology arm. Sensor time in range 70-180 mg/dL showed an adjusted group difference of 14% improvement with Control-IQ technology use compared to the CGM arm at 13 weeks.

There were no DKA or hyperosmolar hyperglycemic syndrome events in the study. There was one severe hypoglycemic event in the Control-IQ

technology arm, and none in the CGM arm. There was one death unrelated to the study in the CGM arm. There were no deaths in the Control-IQ technology arm. No other serious adverse events related to the device were reported.

Baseline Characteristics

2IQP: Baseline Characteristics by treatment group (N=319)

Characteristic		Control-IQ (n=215)	CGM (n=104)
Age (years)			
	Mean ± SD	59 ± 12	57 ± 12
	Range	19 to 87	23 to 80
Sex – Female n (%)		105 (49%)	49 (47%)
Weight (kg)			
	Median (IQR)	99 (84, 117)	103 (87, 117)
	Range	49 to 164	51 to 174
Total Daily Insulin (units/kg/day)			
	Median (IQR)	0.9 (0.6, 1.2)	0.9 (0.6, 1.2)
	Range	0.2 to 2.7	0.2 to 3.6
HbA1c Central Lab at Randomization*			
	Mean ± SD	8.2 (1.4)	8.1 (1.2)
	Range	5.7 to 14.1	5.2 to 12.4
Race*			

2IQP: Baseline Characteristics by treatment group (N=319) (Continued)

Characteristic		Control-IQ (n=215)	CGM (n=104)
	White	148 (69%)	74 (71%)
	Black / African American	45 (21%)	24 (23%)
	Asian	10 (5%)	3 (3%)
	Native Hawaiian / Other Pacific Islanders	2 (<1%)	0 (0%)
	American Indian / Alaskan Native	1 (<1%)	1 (<1%)
	More than one race	6 (3%)	2 (2%)
	Unknown / Not reported	3 (1%)	0 (0%)
Ethnicity			
	Hispanic or Latino	23 (11%)	11 (11%)
	Not Hispanic or Latino	190 (88%)	93 (89%)
	Unknown / Not reported	2 (<1%)	0 (0%)
Annual Household Income[†]			
	<$50,000	60 (28%)	26 (25%)
	$50,000 – <$100,000	52 (24%)	21 (20%)
	≥$100,000	53 (25%)	36 (35%)
	Unknown	11 (5%)	5 (5%)
	Does not wish to provide	39 (18%)	16 (15%)

2IQP: Baseline Characteristics by treatment group (N=319) (Continued)

Characteristic		Control-IQ (n=215)	CGM (n=104)
Education‡			
	≤High School Diploma	8 (4%)	3 (3%)
	High School graduate / diploma / GED	57 (27%)	21 (20%)
	Technical / Vocational	25 (12%)	12 (12%)
	Associate Degree	33 (15%)	16 (15%)
	College Graduate	49 (23%)	32 (31%)
	Advanced Degree (e.g. Master's, PhD, MD)	33 (15%)	16 (15%)
	Unknown	1 (<1%)	0 (0%)
	Does not wish to provide	9 (4%)	4 (4%)
Health Insurance§			
	Private	116 (54%)	65 (63%)
	Medicare	57 (27%)	15 (14%)
	Medicaid	10 (5%)	13 (13%)
	Other government insurance	23 (11%)	8 (8%)
	No coverage	2 (<1%)	2 (2%)
	Unknown / no answer	7 (3%)	1 (<1%)

**Sample not analyzable for one person in the AID group.*

Adverse Effects

The following tables provide a full list of adverse events that occurred during the main part of the 2IQP study.

2IQP: Types of Adverse Events by Treatment Arm (n=319)

		Number of Events	
		Control-IQ (n=215)	CGM (n=104)
Total Number of Adverse Events		106	26
Severe Hypoglycemic (SH) Events*		1	0
Diabetic Ketoacidosis (DKA) Events†		0	0
Hyperosmolar Hyperglycemic Syndrom (HHS) Events		0	0
Other Serious Adverse Events (SAEs)		18	7
	Back Surgery	1	0
	Breast Ductal Carcinoma	1	0
	COVID-19	2	0
	Cardiomyopathy	1	0
	Chest Pressure	1	0
	Congestive Heart Failure	1	1
	Coronary Artery Disease	0	1
	Exacerbation of Asthma	1	0
	Foot Infection	1	0

2IQP: Types of Adverse Events by Treatment Arm (n=319) (Continued)

		Number of Events	
		Control-IQ (n=215)	CGM (n=104)
	Headache	0	1
	Hip Fracture	1	0
	Hypotension	1	0
	Infection (Chronic) of Amputation Stump	1	0
	Knee Surgery NOS	1	0
	Multinodular Goiter	1	0
	Other	1	0
	Pancreatitis	1	0
	Pancreatitis (Fatal)	0	1
	Pneumonia	0	1
	Tooth Abscess	0	1
	Total Knee Replacement	1	0
	Unstable Angina	0	1
	Vitreous Hemmorrhage	1	0
Non-Serious Adverse Events			

2IQP: Types of Adverse Events by Treatment Arm (n=319) (Continued)

		Number of Events	
		Control-IQ (n=215)	CGM (n=104)
	Hyperglycemia with or without Ketosis Related to Study Device	20	0
	Hyperglycemia with or without Ketosis Not Related to Study Device	1	2
	Hypoglycemia (not severe)	10	2
	Other Reported Adverse Events	56	15

**A severe hypoglycemic event is defined as a hypoglycemic event that a) required assistance of another person due to altered consciousness, and b) required another person to actively administer carbohydrate, glucagon, or other resuscitative actions.*

†DKA events meeting DCCT criteria.

Intervention Compliance

The following table provides an overview of the how often Control-IQ technology was active in the Control-IQ technology arm.

2IQP: Closed-Loop System Use Over 13-week Period

	Overall	Weeks 1-4	Weeks 5-8	Weeks 9-13
% Time Closed Loop Use ***Median (Q_1, Q_3)****	93%, (87%, 95%)	93% (86%, 95%)	94% (90%, 96%)	93% (86%, 96%)
**Denominator is the number of days between the first day after initiation of pump use and the last day the pump was used in a non-suspension mode.*				

Primary Analysis

The criterion for superiority in the primary endpoint was met. In the primary analysis, mean HbA1c decreased 0.9% from 8.2±1.4% at baseline to 7.3±0.9% during follow-up in the Control-IQ technology group, and decreased 0.3% from 8.1±1.2% to 7.7±1.1% in the CGM group. The adjusted group difference [Control-IQ technology minus CGM] = -0.6%; 95% confidence interval (CI) -0.8% to 0.4%; p<0.001.

2IQP: Percent Time in Range: Primary Endpoint Tested for Superiority

Time and Change	Control-IQ	CGM
Baseline (n)	n=214*	n=104
Baseline mean (SD)	8.2% (1.4%)	8.1% (1.2%)
13 weeks (n)	n=209†	n=102‡
13 Weeks mean (SD)	7.3% (0.9%)	7.7% (1.1%)
Change from Baseline mean (SD)	-0.9% (1.1%)	-0.3% (0.9%)
13 week Adjusted Group Difference (95% CI)§ [p-value]	-0.6% (-0.8%, -0.4%) [<0.001]	

**Missing (sample not analyzable) for one participant.*
† Four participants dropped prior to 13 weeks final visit. The sample for one participant not analyzable. The sample for one participant was collected outside the pre-specified analysis window and thus not included.
‡ Two participants dropped prior to 13 weeks final visit.
§ The difference is AID – CGM. A direct likelihood model was used. This model adjusted for the baseline value of the metric and for site as a random effect.

Secondary Analysis

Change in time in range 70–180 mg/dL at 13 weeks showed a 14% adjusted group difference improvement in favor of the Control-IQ technology arm.

2IQP: Mean (SD) Change in CGM Time in Rang 70–180 mg/dL During the Study Period

Time and Change	Control-IQ	CGM
Baseline	48% (24%)	51% (21%)
13 Weeks	64% (16%)	52% (21%)
Change from Baseline	16% (19%)	1% (14%)
13 week Adjusted Group Difference (95% CI) [p-value]	14% (11%, 17%) [<0.001]	

CHAPTER 32

Technical Specifications

32.1 Overview

This section provides tables of technical specifications, performance characteristics, options, settings, and electromagnetic compliance information for the Tandem Mobi™ pump. The specifications in this section meet the international standards set forth in IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, and IEC 60601-2-24.

32.2 Tandem Mobi Insulin Pump Specifications

Pump Specifications

Specification Type	Specification Details
Classification	External PSU: Class II, Infusion Pump. Internally-powered equipment, Type BF applied part. The risk of ignition of flammable anesthetics and explosive gases by the pump is remote. While this risk is remote, it is not recommended to operate the Tandem Mobi pump in the presence of flammable anesthetics or explosive gases.
Size	2.02” x 1.47” x 0.56” (L x W x H) - (5.13 cm x 3.73 cm x 1.42 cm)
Weight (with full disposable)	1.06 ounces (30 grams)
Operating Conditions	Temperature: 41°F (5°C) to 99°F (37°C) Humidity: 20% to 85% RH non-condensing
Storage Conditions	Temperature: -4°F (-20°C) to 113°F (45°C) Humidity: 20% to 90% RH non-condensing
Atmospheric Pressure	-1,300 feet to 13,800 feet (-396 meters to 4,206 meters)
Ingress Protection	New pump with a cartridge loaded: IP28 water resistant to a depth of 8 feet (2.4 meters) for up to 2 hours
Cartridge Volume	2.0 mL or 200 units
Cannula Fill Amount	0.1 to 1.0 units of insulin

Pump Specifications (Continued)

Specification Type	Specification Details
Insulin Concentration	U-100
Service Life Conditions	The expected service life of the pump including internal power source and charging accessories is four years.
Alarm Type	Visual, audible, and vibratory
Basal Delivery Accuracy at all Flow Rates (tested per IEC 60601-2-24)	±5% for delivery rates 0.1 units/hour to 15.0 units/hour
Bolus Delivery Accuracy at all Volumes (tested per IEC 60601-2-24)	±5%
Patient Protection from Air Infusion	The pump provides subcutaneous delivery into interstitial tissue and does not deliver intravenous injections. Transparent tubing and syringe housing aids in detecting air bubbles.
Maximum Infusion Pressure Generated and Occlusion Alarm Threshold	70 PSI
Frequency of Basal Delivery	5 minutes for all Basal Rates
Retention Time of Electronic Memory when Internal Pump Battery is Fully Discharged (including Alarm Settings and Alarm History)	Greater than 30 days
Infusion Set used for Testing	Unomedical VariSoft™ Infusion Set
Typical Operating Time when Pump is Operating at Intermediate Rate	During normal use, the intermediate rate is 2 units/hour; battery charge can be reasonably expected to last between 3 and 5 days, depending on your use of CGM and Tandem Mobi mobile app features from a fully charged state to a totally discharged state.

Pump Specifications (Continued)

Specification Type	Specification Details
Handling of Over-Infusion or Under-Infusion	The software performs frequent monitoring of pump status. Multiple software monitors provide redundant protection against unsafe conditions. Over-infusion is mitigated by monitoring glucose, (whether via CGM, BG meter, or both), layering of redundancies and confirmations, and numerous other safeguard alarms. Users are required to review and confirm the details of all bolus deliveries, Basal Rates, and temp rates to ensure certainty before initiating a delivery. In addition, once bolus deliveries are confirmed, the user is given 5 seconds to cancel the delivery before it is started. An optional Auto-Off alarm triggers when the user has not interacted with the system for a predefined period of time. Under-infusion is mitigated by occlusion detection and BG monitoring as BG entries are recorded. Users are prompted to treat high BG conditions with a correction bolus.
Bolus Volume at Release of Occlusion	The bolus volume at occlusion release will not exceed the volume of the programmed insulin intended for delivery.
Residual Insulin Remaining in the Cartridge (unusable)	Maximum 15 units (0.15 mL)
Minimum Audible Alarm Volume	45 dBA at 1 meter

NOTE

Accuracies stated in this table are valid for all Tandem Diabetes Care, Inc. branded infusion sets including: AutoSoft™ 90, AutoSoft XC, AutoSoft 30, VariSoft, and TruSteel™ branded infusion sets.

32.3 Accessory Specifications

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

32.4 Tandem Mobi Insulin Pump Options and Settings

Options and Settings

Option/Setting Type	Option/Setting Detail
Time	User defined with a 12-hour clock
Basal Rate Setting Range	0.1 – 15 units/hour
Insulin Delivery Profiles (Basal and Bolus)	6
Basal Rate Segments	16 per delivery profile
Basal Rate Increment	0.001 at programed rates equal to or greater than 0.1 units/hour
Temp Basal Rate	15 minutes to 72 hours with 1 minute resolution with a range of 0% to 250%
Bolus Setup	Can deliver based on carb input (grams) or insulin input (units). The range for carbs is 1 to 999 grams, the range for insulin is 0.05 to 25 units
Insulin-to-Carb (IC) Ratio	16 time segments per 24-hour period; Ratio: 1 unit of insulin per x grams of carb; 1:1 to 1:300 (can be set by 0.1 below 10)
BG Target Value	16 time segments. 70 to 250 mg/dL in 1 mg/dL increments
Correction Factor	16 time segments; Ratio: 1 unit of insulin reduces BG x mg/dL; 1:1 to 1:600 (1 mg/dL increments)
Duration of Insulin Action	1 time segment; 2 to 8 hours in 1-minute increments (default is 5 hours)
Bolus Increment	0.01 at volumes greater than 0.05 units
Quick Bolus Increments	When set to units of insulin: 0.5, 1, 2, 5 units (default is 0.5 units); or when set to grams of carb: 2, 5, 10, 15 grams (default is 2 g)

Options and Settings (Continued)

Option/Setting Type	Option/Setting Detail
Maximum Extended Bolus Time	8 hours
Maximum Bolus Size	25 units
Maximum Automatic Bolus Size	6 units
Low Cartridge Volume Indicator	Status indicator visible on *Dashboard* screen; Low Insulin Alert is user adjustable from 15 to 40 units (default is 20 units).
Auto-Off Alarm	On or Off (default is off); user-adjustable (5 to 24 hours; default is 12 hours, which you can change when option is set to on).
History Storage	30 days
Language	English
Site Reminder	Prompts user to change infusion set. Can be set for 1 to 3 days at a time selected by user (default is off).
Missed Meal Bolus Reminder	Prompts user if a bolus has not occurred during the period of time the reminder is set for. 4 reminders available (default is off).
After Bolus Reminder	Prompts user to test BG at a selected time period after a bolus has been delivered. Can be set between 1 to 3 hours (default is off).
High BG Reminder	Prompts user to retest BG after a High BG has been entered. User selects High BG value and time for reminder. (default is off).
Low BG Reminder	Prompts user to retest BG after a Low BG has been entered. User selects Low BG value and time for reminder. (default is off).

32.5 Pump Performance Characteristics

The Tandem Mobi insulin pump delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The following accuracy data was collected on both types of delivery in laboratory studies performed by Tandem.

Basal Delivery

To assess basal delivery accuracy, 32 Tandem Mobi pumps were tested by delivering at low, medium, and high Basal Rates (0.1, 2.0, and 15 units/hour). Sixteen of the pumps were new, and 16 had been aged to simulate four years of regular use. For both aged and unaged pumps, eight pumps were tested with a new cartridge, and eight with a cartridge which underwent two years of aging. Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid at various time points was used to assess pumping accuracy.

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for low, medium, and high Basal Rate settings for all pumps tested. For the medium and high basal rates, accuracy is reported from the time basal delivery started with no warm-up period. For the minimum Basal Rate, accuracy is reported after a 1-hour warm-up period. For each time period, the tables show the volume of insulin requested in the first row and the volume that was delivered as measured by the scale in the second row.

Low Basal Rate Delivery Performance (0.1 Units/hour)

Basal Duration (Number of Units Delivered with 0.1 Units/hour Setting)	**1 hour (0.1 units)**	**6 hours (0.6 units)**	**12 hours (1.2 units)**
Amount Delivered [min, max]	0.09 units [0.07, 0.18]	0.60 units [0.37, 0.73]	1.21 units [0.84, 1.38]

Medium Basal Rate Delivery Performance (2.0 Units/hour)

Basal Duration (Number of Units Delivered with 2 Units/hour Setting)	**1 hour (2 units)**	**6 hours (12 units)**	**12 hours (24 units)**
Amount Delivered [min, max]	1.9 units [1.5, 2.1]	12.1 units [10.7, 12.5]	24.4 units [21.8, 25.0]

High Basal Rate Delivery Performance (15 units/hour)

Basal Duration (Number of Units Delivered with 15 Units/hour Setting)	**1 hour (15 units)**	**6 hours (90 units)**	**12 hours (180 units)**
Amount Delivered [min, max]	15.3 units [12.3, 15.6]	90.5 units [84.4, 91.0]	180.0 units [174.2, 181.4]

Bolus Delivery

To assess bolus delivery accuracy, 32 Tandem Mobi pumps were tested by delivering consecutive low, medium, and high bolus volumes (0.05, 2.5, and 25 units). Sixteen of the pumps were new, and 16 had been aged to simulate four years of regular use. For both aged and unaged pumps, eight pumps were tested with a new cartridge, and eight with a cartridge which underwent two years of aging. Water was used as a substitute for insulin for this testing. The water was pumped into a container on a scale, and the weight of the liquid at various time points was used to assess pumping accuracy.

Delivered bolus volumes were compared to the requested bolus volume delivery for minimum, intermediate, and maximum bolus volumes. The tables below show average, minimum and maximum bolus sizes observed as well as the number of boluses which were observed to be within the specified range of each target bolus volume.

Summary of Bolus Delivery Performance (n=32 pumps)

Individual Bolus Accuracy Performance	Target Bolus Size [Units]	Mean Bolus Size [Units]	Min Bolus Size [Units]	Max Bolus Size [Units]
Min Bolus Delivery Performance (n=800 boluses)	0.050	0.051	0.031	0.058
Intermediate Bolus Delivery Performance (n=800 boluses)	2.50	2.493	2.087	2.712
Max Bolus Delivery Performance (n=192 boluses)	25.00	24.625	23.778	25.775

Low Bolus Delivery Performance (0.05 Units) (n=800 boluses)

	Units of Insulin Delivered After a 0.05 Unit Bolus Request									
	<0.0125 (<25%)	0.0125–0.0375 (25–75%)	0.0375–0.045 (75–90%)	0.045–0.0475 (90–95%)	0.0475–0.0525 (95–105%)	0.0525–0.055 (105–110%)	0.055–0.0625 (110–125%)	0.0625–0.0875 (125–175%)	0.0875–0.125 (175–250%)	>0.125 (>250%)
Number and Percent of Boluses Within Range	0/800 (0%)	2/800 (1%)	17/800 (2%)	42/800 (5%)	495/800 (62%)	185/800 (23%)	59/800 (7%)	0/800 (0%)	0/800 (0%)	0/800 (0%)

Intermediate Bolus Delivery Performance (2.5 Units) (n=800 boluses)

	Units of Insulin Delivered After a 2.5 Unit Bolus Request									
	<0.625 (<25%)	0.625–1.875 (25–75%)	1.875–2.25 (75–90%)	2.25–2.375 (90–95%)	2.375–2.625 (95–105%)	2.625–2.75 (105–110%)	2.75–3.125 (110–125%)	3.125–4.375 (125–175%)	4.375–6.25 (175–250%)	>6.25 (>250%)
Number and Percent of Boluses Within Range	0/800 (0%)	0/800 (0%)	2/800 (1%)	19/800 (3%)	736/800 (92%)	43/800 (6%)	0/800 (0%)	0/800 (0%)	0/800 (0%)	0/800 (0%)

High Bolus Delivery Performance (25 Units) (n=192 boluses)

	Units of Insulin Delivered After a 25 Unit Bolus Request									
	<6.25 (<25%)	6.25–18.75 (25–75%)	18.75–22.5 (75–90%)	22.5–23.75 (90–95%)	23.75–26.25 (95–105%)	26.25–27.5 (105–110%)	27.5–31.25 (110–125%)	31.25–43.75 (125–175%)	43.75–62.5 (175–250%)	>62.5 (>250%)
Number and Percent of Boluses Within Range	0/192 (0%)	0/192 (0%)	0/192 (0%)	0/192 (0%)	192/192 (100%)	0/192 (0%)	0/192 (0%)	0/192 (0%)	0/192 (0%)	0/192 (0%)

Rate of Delivery

Characteristic	Value
25 Unit Bolus Delivery Speed	4.93 units/min Typical
2.5 Unit Bolus Delivery Speed	1.72 units/min Typical

Bolus Duration

Characteristic	Value
25 Unit Bolus Duration	5 minutes 4 seconds Typical
2.5 Unit Bolus Duration	1 minute 27 seconds Typical

Time to Occlusion Alarm*

Operating Rate	Typical	Maximum
Bolus (2.5 units or Greater)	46 seconds	3 minutes
Basal (2 units/hour)	40 minutes	2 hours
Basal (0.1 units/hour)	17 hours 11 minutes	72 hours

**The time to occlusion alarm is based on insulin volume not delivered using the worst-case maximum available infusion set length (43 inches). During an occlusion event, boluses of less than 3 units may not trigger an occlusion alarm if no basal insulin is being delivered. The bolus amount will reduce the time to occlusion alarm depending on the Basal Rate.*

32.6 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

32.7 Wireless Co-existence and Data Security

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

⚠ 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.

32.8 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 from the App Store®. See Section 5.1 Download 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 5.3 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.

32.9 Electromagnetic Emissions

The system is intended for use in the electromagnetic environment specified below. Always make sure that the system is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

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

32.10 Electromagnetic Immunity

The system is intended for use in home healthcare electromagnetic environments.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

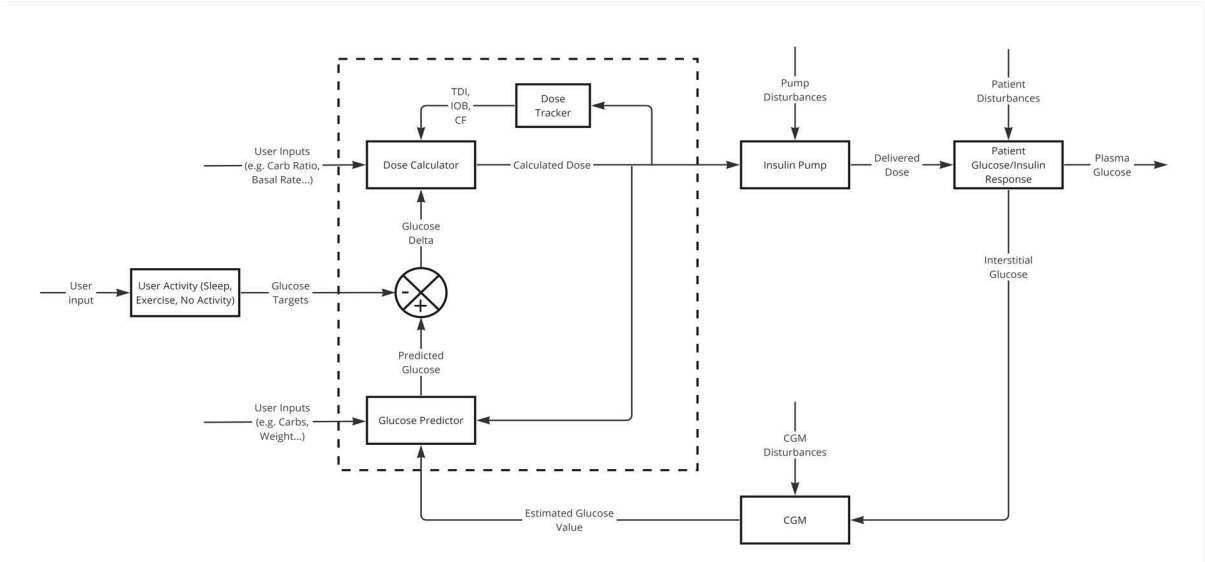
Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air
Electrical Fast Transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines (100 kHz repetition frequency)	± 2 kV for power supply lines ± 1 kV for input/output lines (100 kHz repetition frequency)
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode
Conducted RF IEC 61000-4-6	3V, 0.15 to 80 MHz 6V in ISM bands between 0.15 and 80 MHz	3V, 0.15 to 80 MHz 6V in ISM bands between 0.15 and 80 MHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz, 80% AM @ 1kHz	10 V/m 80 MHz to 2.7 GHz, 80% AM @ 1kHz

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level
Proximity Field from RF Wireless Communications Equipment IEC 61000-4-3	385 MHz: 27 V/m @ 18 Hz Pulse modulation 450 MHz: 28 V/m @ FM modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz Pulse modulation 810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz Pulse modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz Pulse Modulation 2450 MHz: 28 V/m @ 217 Hz Pulse modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz Pulse modulation	385 MHz: 27 V/m @ 18 Hz Pulse modulation 450 MHz: 28 V/m @ FM modulation 710 MHz, 745 MHz, 780 MHz: 9 V/m @ 217 Hz Pulse modulation 810 MHz, 870 MHz, 930 MHz: 28 V/m @ 18 Hz Pulse modulation 1720 MHz, 1845 MHz, 1970 MHz: 28 V/m @ 217 Hz Pulse Modulation 2450 MHz: 28 V/m @ 217 Hz Pulse modulation 5240 MHz, 5500 MHz, 5785 MHz: 9 V/m @ 217 Hz Pulse modulation
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	70% UR (30% dip in Ur) for 25 cycles 0% Ur (100% dip in Ur) for 1 cycle at 0 degrees 0% Ur (100% dip in Ur) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% Ur (100% dip in Ur) for 250 cycles	70% UR (30% dip in Ur) for 25 cycles 0% Ur (100% dip in Ur) for 1 cycle at 0 degrees 0% Ur (100% dip in Ur) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% Ur (100% dip in Ur) for 250 cycles
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m, 50 & 60 Hz	400 A/m, 50 & 60 Hz (IEC 60601-2-24)
Proximity Magnetic Field IEC 61000-4-39	30 kHz @ 8 A/m 134.2 kHz @ 65 A/m 13.56 MHz @ 7.5 A/m	30 kHz @ 8 A/m 134.2 kHz @ 65 A/m 13.56 MHz @ 7.5 A/m

32.11 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.



32.12 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 21.7 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.

32.13 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)

32.14 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.

32.15 Warranty Information

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

32.16 Returned Goods Policy

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

32.17 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.

32.18 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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