t:slim X2™ Insulin Pump

Dexcom G5® Mobile CGM Enabled

User Guide

℞ Only

TANDEM® DIABETES CARE

touch simplicity®

Congratulations on the purchase of your new t:slim X2 System. Your decision to use insulin pump therapy and continuous glucose monitoring is a sign of your commitment to your diabetes care. We recognize and respect the importance of your decision. We also recognize that your t:slim X2 System purchase is only the beginning of your relationship with Tandem. Our commitment goes much deeper than simply supplying products to help you in your diabetes management. We pledge to be here to support you with training and education through our network of Clinical Diabetes Specialists. We also pledge to be here to support you with our dedicated Customer Technical Support.

This User Guide is designed to assist you with the features and functions of the t:slim X2 System. It provides important warnings and cautions on proper operation as well as technical information to ensure your safety. It also provides step-by-step instructions on how to properly program, manage and care for your t:slim X2 System.

Changes in equipment, software, or procedures occur periodically; information describing these changes will be included in future editions of this User Guide. Please contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901 to obtain a replacement copy of the User Guide that is the correct version for your pump.

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Need help? We are here for you 24 hours a day, 7 days a week at (877) 801-6901.

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Section 1

Before You Begin

Chapter 1

Introduction

1.1 System Description

The t:slim X2 Insulin Pump is made up of the t:slim® Insulin Pump and the t:slim 3mL (300 units) cartridge. The t:slim X2 Insulin Pump delivers insulin in two ways: continuous, or basal insulin delivery, and bolus insulin delivery to cover carbohydrates eaten (food bolus) and to lower high blood glucose (correction bolus). The disposable cartridge is filled with up to 300 units of U-100 insulin and attached to the pump. The cartridge is replaced every few days.

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

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

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

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

1.2 About this User Guide

This User Guide covers important information on how to operate your t:slim X2 System. It provides step-by-step instructions to help you properly program, manage and care for the System. It also provides important warnings and cautions on proper operation and technical information to ensure your safety.

In this Guide, the t:slim X2 Pump may be referred to as “your pump” or “your t:slim X2 Pump.” The Dexcom G5 Mobile Transmitter may be referred to as “your transmitter.” The Dexcom G5 Mobile Sensor may be referred to as “your sensor.” Together, the Dexcom G5 Mobile Transmitter and Dexcom G5 Mobile Sensor may be referred to as “your CGM.”

The User Guide is organized into sections. Section 1 provides important information you need to know before you start using the System. Sections 2–4 cover instructions for using the t:slim X2 Insulin Pump. Sections 5–6 cover instructions for using Dexcom G5

Mobile CGM with your t:slim X2 Insulin Pump.

Pump screens used in this Guide to demonstrate how to use features are examples only. They should not be considered suggestions for your individual needs.

Product information, including electronic versions of the User Guide, a Guide to Successful Pumping, t:connect Getting Started and User Guides, and a CGM training tutorial, are available at www.tandemdiabetes.com.

1.3 Important User Information

Review all instructions in this User Guide before using the System.

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

If you are currently using the t:slim X2 Pump without Dexcom G5 Mobile CGM, or if you are currently using Dexcom G5 Mobile CGM with the Dexcom G5 Mobile Receiver, it is still very important that you review all instructions in this User Guide before using the combined System.

Pay special attention to Warnings and Precautions in this User Guide. Warnings and Precautions are identified with ⚠.

If you still have questions after reading this User Guide, contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901. We are here for you 24 hours a day, 7 days a week.

1.4 Important Pediatric User Information

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

Younger children may inadvertently press or tap the pump, leading to unintentional delivery of insulin.

It is the responsibility of the healthcare provider and caregiver to determine if the user is appropriate for treatment with this device.

We recommend reviewing the Quick Bolus and Feature Lock capabilities of the Tandem pump and determining how they best fit with your care plan. These features are detailed in Chapters 10 and 11 of this User Guide.

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

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

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

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

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

If the Feature Lock is turned on, the Quick Bolus feature is automatically disabled. Inadvertent button presses or tampering with the insulin pump could result in over delivery or under delivery of insulin. This can cause very low or very high blood glucose which could result in serious injury or death.

1.5 Conventions of this Guide

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

Convention	Explanation
Bolded Text	Text that is in bold and in a different font than the rest of the sentence or step indicates an onscreen or physical button name.
Touch Screen	The front glass screen of your pump, which displays all programming, operating, and alarm/alert information.
Tap	Quickly and lightly touch the screen with your finger.
Press	Use your finger to depress a physical button (the Screen On/Quick Bolus Button is the only physical/hardware button on your t:slim Pump).
Hold	Keep pressing a button or touching an icon or menu until its function is complete.
Menu	A list of options on your touch screen that allow you to perform specific tasks.
Icon	An image on your touch screen that indicates an option or item of information, or a symbol on the back of your t:slim Pump or its packaging.

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Chapter 2

Important Safety Information

2.1 Indications for Use

Indications for Use

The t:slim X2 Insulin Pump with Dexcom G5 Mobile CGM ("t:slim X2 System") consists of the t:slim X2 Insulin Pump paired with the Dexcom G5 Mobile Sensor and Transmitter.

The t:slim X2 Insulin Pump is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The t:slim X2 Insulin Pump can be used solely for continuous insulin delivery and as part of the t:slim X2 System to receive and display continuous glucose measurements from the Dexcom G5 Mobile Sensor and Transmitter.

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

The t:slim X2 System is indicated for use in individuals 6 years of age and greater.

The t:slim X2 System is intended for single patient use and requires a prescription.

The device is indicated for use with NovoLog or Humalog U-100 insulin.

2.2 Contraindications

Contraindications

The t:slim X2 System is not intended for anyone unable or unwilling to:

- Test blood glucose (BG) levels as recommended by your healthcare provider
- Demonstrate adequate carbohydrate-counting skills (preferred, not required)
- Maintain sufficient diabetes self-care skills
- See your healthcare provider(s) regularly

You must also have adequate vision and/or hearing in order to recognize your System alerts.

The t:slim X2 Pump, Dexcom G5 Mobile Transmitter, and Dexcom G5 Mobile Sensor must be removed before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or

diathermy treatment. Exposure to MRI, CT, or diathermy treatment can damage the System.

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

2.3 System Warnings

WARNINGS – t:slim X2 Insulin Pump

DO NOT start to use your t:slim X2 System before reading the User Guide. Failure to follow the instructions in the User Guide can result in over delivery or under delivery of insulin. This can cause very low or very high blood glucose which could result in serious injury or death. If you have questions or need further clarification on your System use, ask your healthcare provider or call our around-the-clock Customer Technical Support Department at (877) 801-6901.

DO NOT start to use your t:slim X2 System before you have been appropriately trained on its use by a certified t:slim X2 System trainer. Consult with your healthcare provider for your individual training needs for the entire t:slim X2 System. Failure to complete the necessary training on the System could result in serious injury or death.

DO NOT use any other insulin with your System other than U-100 Humalog® or NovoLog®. Only Humalog® and NovoLog® have been tested and found to be compatible for use in the System. Use of insulin with lesser or greater concentration can result in under delivery or over delivery of insulin. This can cause very high or a very low blood glucose.

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

DO NOT start to use your System 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 very low or very high blood glucose.

DO be prepared to inject insulin with an alternative method if delivery is interrupted for any reason. Your t:slim X2 System 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 blood glucose or Diabetic Ketoacidosis (DKA).

DO use only FDA cleared insulin infusion sets with a tubing connector and follow their instructions for use. Failure to do so may result in over delivery or under delivery of insulin and may cause very low or very high blood glucose.

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 blood glucose.

DO NOT ignore infusion set cannula fractures. Infusion set cannulas may fracture on rare occasions. If an infusion set cannula breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken infusion set cannula, please report this to Tandem Customer Technical Support at (877) 801-6901.

NEVER fill your tubing while your infusion set is connected to your body. Always ensure that the infusion set is disconnected from your body before filling the tubing. Failure to disconnect your infusion set from your body before filling the tubing can result in over delivery of insulin. This can cause serious injury or death from very low blood glucose.

DO NOT reuse cartridges or use cartridges other than those manufactured by Tandem Diabetes Care, Inc. Use of cartridges not manufactured by Tandem Diabetes Care, Inc. or reuse of cartridges may result in over delivery or under delivery of insulin. This can cause very low or very high blood glucose.

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

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

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

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

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

The System 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.

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

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

If the Feature Lock is turned on, the Quick Bolus feature is automatically disabled. Inadvertent button presses or tampering with the insulin pump could result in over delivery or under delivery of insulin. This can cause very low or very high blood glucose which could result in serious injury or death.

WARNING – Radiology and Medical Procedures and your t:slim X2 System

ALWAYS notify the provider/technician about your diabetes and your t:slim X2 System. If you need to discontinue use of the System for medical procedures, follow your healthcare provider's instructions to replace missed insulin when you reconnect to the pump. Check your blood glucose before disconnecting from the pump and again when you reconnect and treat high blood glucose levels as recommended by your healthcare provider.

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

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

The t:slim X2 System is magnetic resonance (MR) Unsafe. You must take off your pump, transmitter, and sensor and leave them outside the procedure room if you are going to have any of the above procedures.

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

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

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

There are other procedures where you should proceed with caution:

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

There is no need to disconnect for electrocardiograms (EKGs) or colonoscopies. If you have questions, contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901

WARNINGS – Using Dexcom G5 Mobile CGM with your t:slim X2 Insulin Pump

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

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

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

report this to Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

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

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

DO NOT insert the sensor in sites other than the abdomen (belly) or upper buttocks (for ages 6–17 only). Other sites have not been studied and are not approved. Use in other sites might cause sensor glucose readings to be inaccurate and could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

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

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

STORE the Dexcom G5 Mobile CGM sensor at temperatures between 36°F to 77°F for the length of the sensor's shelf life. You may store the sensor in the refrigerator if it is within this temperature range. The sensor should not be stored in a freezer. Storing the sensor improperly might cause the sensor glucose readings to be inaccurate, and you might miss severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

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

2.4 System Precautions

PRECAUTIONS – t:slim X2 Insulin Pump

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

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.

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

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.

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.

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.

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

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.

CHECK your System'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.

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

CONFIRM that the screen display

turns on, you can hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the Screen On Button when you connect a power source to the USB port. These features are used to notify you about alerts, alarms, and other conditions that require your attention. If these features are not working, discontinue use of the System and contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

CHECK your System 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.

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

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

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 System is working properly by plugging a power source into the USB port and confirming that the display turns on, you hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the Screen On Button. If you are unsure about potential damage, discontinue use of the System and contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

AVOID exposure of your System to temperatures below 40°F (5°C) or above 99°F (37°C). Insulin can freeze at low temperatures or degrade at high temperatures. Insulin that has been exposed to conditions outside of the manufacturer's recommended ranges can affect the safety and performance of the System.

AVOID submersing your pump in fluid beyond a depth of 3 feet or for more than 30 minutes (IPX7 rating). If your pump has been exposed to fluid beyond these limits, check for any signs of fluid ingress. If there are signs of fluid entry, discontinue use of the pump and contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

AVOID areas where there may be flammable anesthetics or explosive gases. The System 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.

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

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.

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.

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.

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

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 blood glucose before disconnecting from the pump and again when you reconnect, and treat high blood glucose (BG) levels as recommended by your healthcare provider.

ENSURE that your personal insulin delivery settings are programmed into the pump before you use the System if you receive a warranty replacement. Failure to enter your insulin delivery settings could result in over delivery or under delivery of insulin. This can cause very low or very high blood glucose which could result in serious injury or death. Consult your healthcare provider as needed.

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

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

PRECAUTIONS – Using Dexcom G5 Mobile CGM with your t:slim X2 Insulin Pump

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

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

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

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

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

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

To calibrate the CGM System, **DO** enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Do not enter sensor glucose readings for calibration. Entering incorrect blood glucose values, blood glucose 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 blood glucose) or hyperglycemia (high blood glucose) events.

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

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

AVOID separating the transmitter and pump by more than 20 feet. The transmission range from the transmitter to the pump is up to 20 feet without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and pump are farther than 20 feet 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 blood glucose) or hyperglycemia (high blood glucose) events.

DO NOT use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration. Alternative site blood glucose values may be different than those taken from a fingerstick blood glucose value and may not represent the timeliest blood glucose value. Use a blood glucose value taken only from a fingerstick for calibration.

Alternative site blood glucose values might affect sensor accuracy and result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

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

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

The Dexcom G5 Mobile Sensor, Transmitter, and Receiver are not compatible with the SEVEN/SEVEN PLUS Transmitter and Receiver. Different generations will not connect with each other and will not work.

2.5 Potential Benefits From Using the System

- The t:slim X2 System provides an automated way to deliver basal and bolus insulin. Delivery can be fine-tuned based on up to 6 customizable Personal Profiles, each with up to 16 time-based settings for Basal Rate, Carb Ratio, Correction Factor, and Target BG. In addition, the Temp Rate feature allows you to program a temporary basal rate change for up to 72 hours.

- The t:slim X2 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, and can be programmed in increments of either units of insulin or grams of carbohydrate.

- From the bolus screen, the "calculator within a calculator" feature allows you to enter multiple carbohydrate values and add them together. The System's bolus calculator will recommend a bolus based on the entire amount of carbohydrates entered, which can help eliminate guesswork.

- The System keeps track of the amount of active insulin from food and correction boluses (IOB). When programming additional food or correction boluses, the pump will subtract the amount of IOB from the recommended bolus if your BG is below the target set in your active Personal Profile. This can help prevent insulin stacking, which can lead to hypoglycemia.

- 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 blood glucose or bolus for meals.

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

- When paired with Dexcom G5 Mobile Transmitter and Sensor, your t:slim X2 System can receive CGM readings every 5 minutes, which are displayed as a trend graph on the Home Screen. You can also program your pump to alert you when your CGM readings are above or below a given level, or are rising or falling quickly. Unlike the readings from a standard blood glucose meter, CGM readings allow you to view trends in real time, as well as capture information when you would otherwise be unable to check your blood sugar, such as while you are asleep. This information can be useful for you and your health care provider when considering changes to your therapy. In addition, the programmable alerts can help you to spot potential low or high blood glucose sooner than you would using a only a blood glucose meter.

- CGM use has been shown to increase time in your target glucose range, without increasing time spent above or below your target range. Real-time CGM can help improve diabetes control (lower A1c values, reducing glycemic variability and time spent in low and high blood glucose ranges)[1, 2, 3] which can help reduce diabetes related complications.[4, 5] These benefits can be seen especially with using real-time CGM at least 6 days per week[2] and can be sustained over time.[6] In some cases, patients perceived an increase in their quality of life and peace of mind when using real-time CGM as well as reporting a high satisfaction with CGM.[7]

[1] Garg S, Zisser H, Schwartz S, Bailey T, Kaplan R, Ellis S, Jovanovic L. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. *Diabetes Care.* 2006; 29:44-50.

[2] JDRF CGM Study Group. Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes. *NEJM* 2008;359:1464-76.

[3] Battelino. Effect of continuous glucose monitoring of hypoglycemia in type 1 diabetes. *Diabetes Care* 2011; 34(4): 795-800.

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

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

[6] JDRF CGM Study Group. Sustained Benefit of Continuous Glucose Monitoring on A1c, Glucose Profiles, and Hypoglycemia in Adults With Type 1 Diabetes, *Diabetes Care* 2009; 32: 2047-2049.

[7] JDRF CGM Study Group. Quality-of-Life Measures in Children and Adults With Type 1 Diabetes. *Diabetes Care* 2010; 33: 2175-2177.

2.6 Possible Risks From Using the System

As with any medical device, there are risks associated with using the t:slim X2 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 health care provider about how these risks may impact you.

Risks associated with using the pump functionality of the System

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

There is a remote chance that an infusion set cannula fragment could remain under your skin if the cannula breaks while you are wearing it. If you think a cannula has broken under your skin, contact your healthcare provider and call Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

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

Risks that could result from pump failure include the following:

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

Risks associated with using the CGM functionality of the System

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

There is a remote chance that a sensor fragment could remain under your skin if the sensor breaks while you are wearing it. If you think a sensor has broken under your skin, contact your healthcare provider and call Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

Other risks associated with CGM use include the following:

- You will not get sensor glucose alerts when the alert function is turned off, your transmitter and pump are out of range, or when your pump is not showing sensor glucose readings. You might not notice alerts if you are unable to hear them or feel the vibration.

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

2.7 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.

Monitor your blood glucose (BG) with the guidance of your healthcare provider. According to the American Association of Diabetes Educators' white paper *Insulin Pump Therapy: Guidelines for Successful Outcomes*, patients should routinely check their BG levels at least 4 times daily (optimally 6 to 8 times daily) in order to detect hyperglycemia (high blood glucose) and hypoglycemia (low blood glucose) early. Undetected hyperglycemia or hypoglycemia can result without proper monitoring.

Consult your healthcare provider before using the System to determine which features are most appropriate for you. Only your healthcare provider can de-

termine and help you adjust your basal rate(s), insulin-to-carbohydrate ratio(s), correction factor(s), blood glucose (BG) target, and duration of insulin action. In addition, only your healthcare provider can determine your CGM settings and how you should use your sensor trend information to help you manage your diabetes.

2.8 Emergency Kit

Make sure that you always have an insulin syringe and vial of insulin with you as a backup for emergency situations. You should also always have an appropriate emergency kit with you. Talk with your healthcare provider regarding what items this kit should include.

Supplies to carry every day:

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

2.9 Verification of Proper Functionality

A power supply (AC adapter with micro-USB connector) is provided as part of the System. Before using your System, ensure that the following occur when you connect a power supply into the USB port of your t:slim X2 Pump:

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

In addition, before using the System, ensure the following:

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

⚠ PRECAUTION

CONFIRM that the screen display turns on, you can hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the Screen On Button when you connect a power source to the USB port. These features are used to notify you about alerts, alarms, and other conditions that require your attention. If these features are not working, discontinue use of the System and contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

2.10 Wireless Co-existence and Data Security

The t:slim X2 System is designed to work safely and effectively in the presence of wireless devices typically found at home, work, retail stores, and places of leisure where daily activities occur. See Section 30.11 for more information.

The t:slim X2 System is designed to accept Bluetooth™ Low Energy (BLE) communication only from a linked Dexcom G5 Mobile Transmitter. BLE communication is not established until you enter the unique Dexcom Transmitter ID into your pump.

The t:slim X2 System and system components ensure data security via proprietary means and ensure data integrity using error checking processes, such as cyclic redundancy checks.

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Chapter 3

Getting to Know Your t:slim X2 System

3.1 What your t:slim X2 System Package Includes

Your t:slim X2 System should include the following items:

1. t:slim X2 Insulin Pump
2. Pump Case
3. t:slim X2 System User Guide
4. t:connect Getting Started Guide
5. USB Cable
6. Wall Power USB Adapter
7. Cartridge Removal Tool
8. Dexcom G5 Mobile Sensors and Transmitter in separate Dexcom packaging

If any of these items are missing, contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

Your t:slim X2 Pump is shipped from Tandem Diabetes Care, Inc. with a clear screen protector. Do not remove the screen protector.

Your t:slim X2 Pump comes from Tandem Diabetes Care, Inc. with a protective cover in the place where the cartridge is normally inserted. This cover must be removed and replaced with a cartridge prior to initiating insulin delivery.

Your t:slim X2 Pump also includes consumable components that may require replacement during the life of your pump, including:

- Pump case(s)/clip(s)
- Screen protector
- USB rubber door
- USB cable

Supply Reordering

To order cartridges, infusion sets, supplies, accessories, screen protectors, sensors and transmitter, please contact Tandem Diabetes Care, Inc. at (877) 801-6901 or your usual supplier of diabetes products.

3.2 System Terminology

Pump Terminology

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

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

BG Target
BG target is a specific blood glucose goal, an exact number, not a range. When a BG is entered in the t:slim X2 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 a high BG. With the t:slim X2 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
Carbs or Carbohydrates are 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 BG.

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 with your t:slim X2 Pump, enter the DELIVER NOW portion to dose a percentage of insulin immediately and the remaining percentage over a period time.

Grams
Grams are a unit of measurement for carbohydrates.

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

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

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

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

Quick Bolus
Quick bolus (using the Quick Bolus Button) is a way to deliver a bolus by following beep/vibration commands without navigating through or viewing the t:slim X2 Pump screen.

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

Units
Units are the measurement for insulin.

USB Cable
USB is the abbreviation for Universal Serial Bus. The USB cable connects into the t:slim X2 Pump's micro USB port.

CGM Terminology

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

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

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

CGM
Continuous glucose monitoring.

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

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

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

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

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

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

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

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

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

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

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

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

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

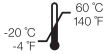
Transmitter Latch
The transmitter latch is a small disposable piece that snaps the transmitter into the sensor pod. It is removed after the transmitter is snapped in.

Trend (Rate of Change) Arrows
Trend arrows show how fast your glucose levels are changing. There are 7 different arrows that show when your glucose direction and speed change.

3.3 Explanation of System Symbols

The following are symbols (and their descriptions), which you may find on your t:slim X2 System and/or its packaging. These symbols tell you about the proper and safe use of the system. Some of these symbols may not have meaning in the United States, and are listed for informational purposes only.

Symbol	Meaning
	Caution; Consult Manual for Important Safety Documentation
	See Instructions for Use
SN	Serial Number of Device
REF	Part Number
IPX7	Watertight Equipment (protected against the effects of temporary immersion in water)
	Type BF Applied Part (patient isolation, not defibrillator protected)
	Manufacturer
Rx Only	For sale by or on the order of a physician only (U.S.)
	Direct Current (DC) voltage

Symbol	Meaning
	Use By Date
	Do Not Re-Use
STERILE R	Sterile by Radiation
	Non Pyrogenic
	Two-sided Temperature Limits
LOT	Lot Number
	Non-ionizing Radiation
	Date of Manufacture
	Class II Equipment

Symbol	Meaning
~	Alternating Current
IP28	Temporary Submersion
IP22	Vertically Falling Drops
	Two-Sided Humidity Limits
	European Union WEEE Directive 2006-66-EC
	Electrical Equipment Designed Primarily for Indoor Use
	Input
	Keep Dry
	Bluetooth

Symbol	Meaning
EC REP	Authorized Representative in the European Community
CE XXXX	Marking Certifies That the Device Meets the European Council Directive 93/42/EEC
	Do Not Use if Package is Damaged
SB	Ship By Date
	MR Unsafe

3.4 Explanation of System Icons

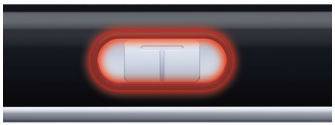
The following icons may appear in the status area (to the left or right of the time and date) on your t:slim X2 Pump Home Screen:

Icon	Meaning
	CGM sensor session is active, and the transmitter is communicating with the pump.
	CGM sensor session is active, but the transmitter is not communicating with the pump.
	CGM calibration is required.
	A system reminder, alert, error, or alarm is active.
	Basal insulin is programmed and being delivered.
	A temporary basal rate is active.
	A basal rate of 0 u/hr is active.
	A temporary basal rate of 0 u/hr is active.
	A bolus is being delivered.
	All insulin deliveries are stopped.

If a CGM session is active, the following icons may appear on the screen in the place where your sensor glucose reading is normally shown:

Icon	Meaning
	CGM sensor session is active, but the transmitter is not communicating with the pump.
	Replace CGM sensor.
	CGM sensor session has been stopped.
	Wait 15 minutes calibration error.
	Startup calibration is required (2 BG values).
	Additional startup calibration is required.
	Unknown sensor reading.
	CGM calibration is required.
	Transmitter error
	Sensor startup 0–30 minutes.
	Sensor startup 31–60 minutes.
	Sensor startup 61–90 minutes.
	Sensor startup 91–119 minutes.

3.5 Explanation of System Colors



Red LED

» 1 red blink every 30 seconds indicates a malfunction or alarm condition.

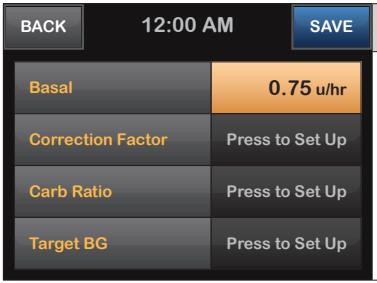
Yellow LED

» 1 yellow blink every 30 seconds indicates an alert or reminder condition.

Green LED

» 1 green blink every 30 seconds indicates the pump is functioning normally.

» 3 green blinks every 30 seconds indicate the pump is charging.



Orange Highlight

» When editing settings, changes are highlighted in orange for review before saving.

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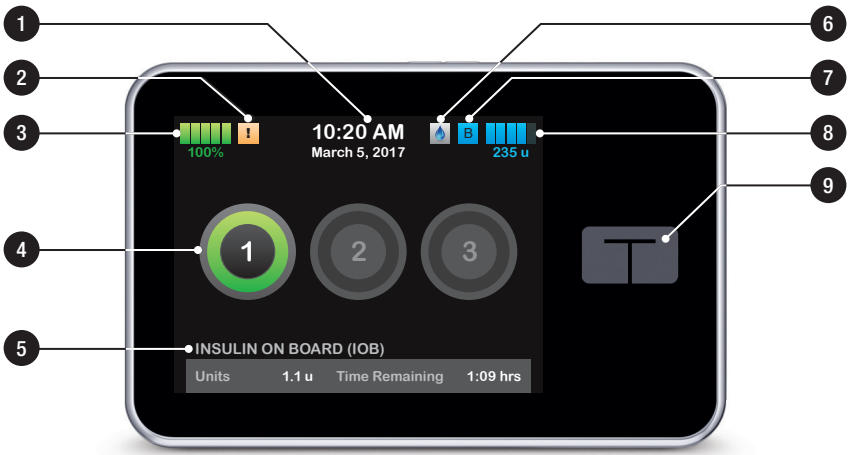
3.6 Screen Lock

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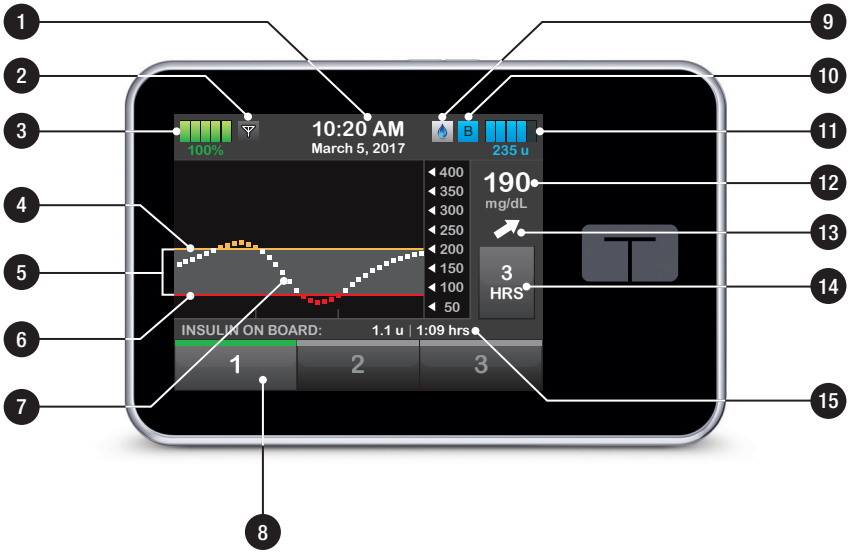
3.7 CGM Screen Lock

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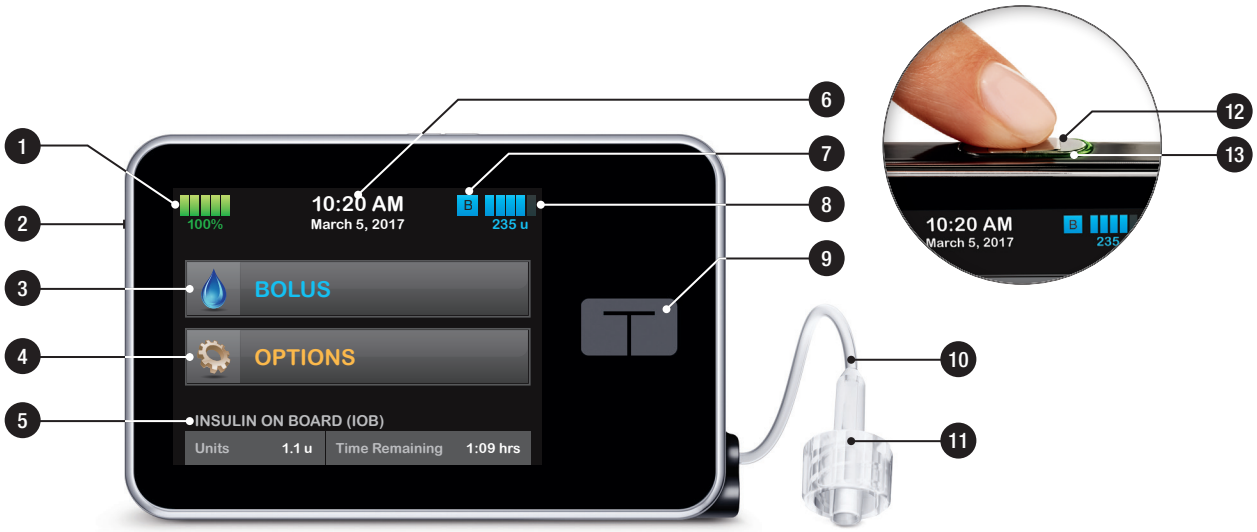
3.8 Home Screen

1. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
2. **USB Port:** Port to charge your t:slim X2 Pump battery. Close the cover when not in use.
3. **Bolus:** Program and deliver a bolus.
4. **Options:** Stop/Resume insulin delivery, manage Pump and CGM Settings, program a Temp Rate, Load cartridge, and view History.
5. **Insulin On Board (IOB):** Amount and time remaining of any active insulin on board.
6. **Time and Date Display:** Displays the current time and date.
7. **Status:** Displays current system settings and insulin delivery status.
8. **Insulin Level:** Displays the current amount of insulin in the cartridge.
9. **Tandem Logo:** Returns to the Home Screen.
10. **Cartridge Tubing:** Tubing that is attached to the cartridge.
11. **Tubing Connector:** Connects the cartridge tubing to the infusion set tubing.
12. **Screen On/Quick Bolus Button:** Turns the t:slim X2 Pump screen on/off or programs a Quick Bolus (if activated).
13. **LED Indicator:** Illuminates when connected to a power supply and indicates proper functionality.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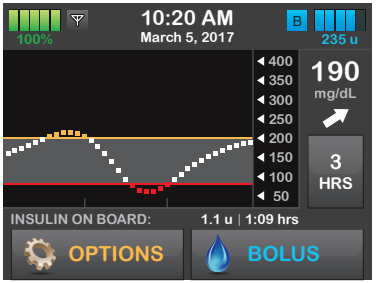
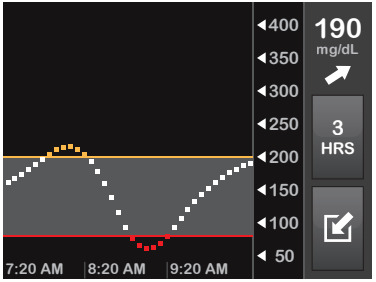
3.9 CGM Home Screen

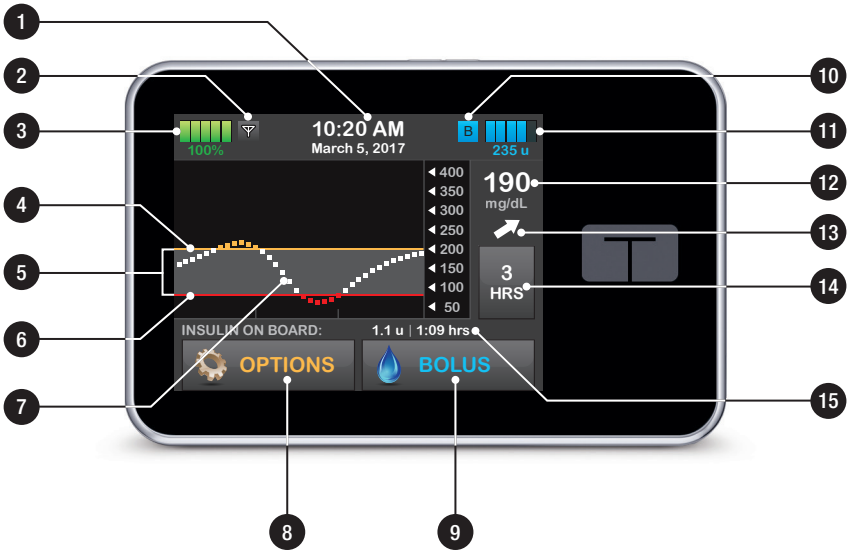
1. **Time and Date Display:** Displays the current time and date.
2. **Antenna:** Indicates communication status between pump and transmitter.
3. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
4. **High Glucose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

To view CGM information on the full screen:
From the Home Screen tap anywhere on the CGM trend graph.



Tap the “minimize” icon to return to the Home Screen.

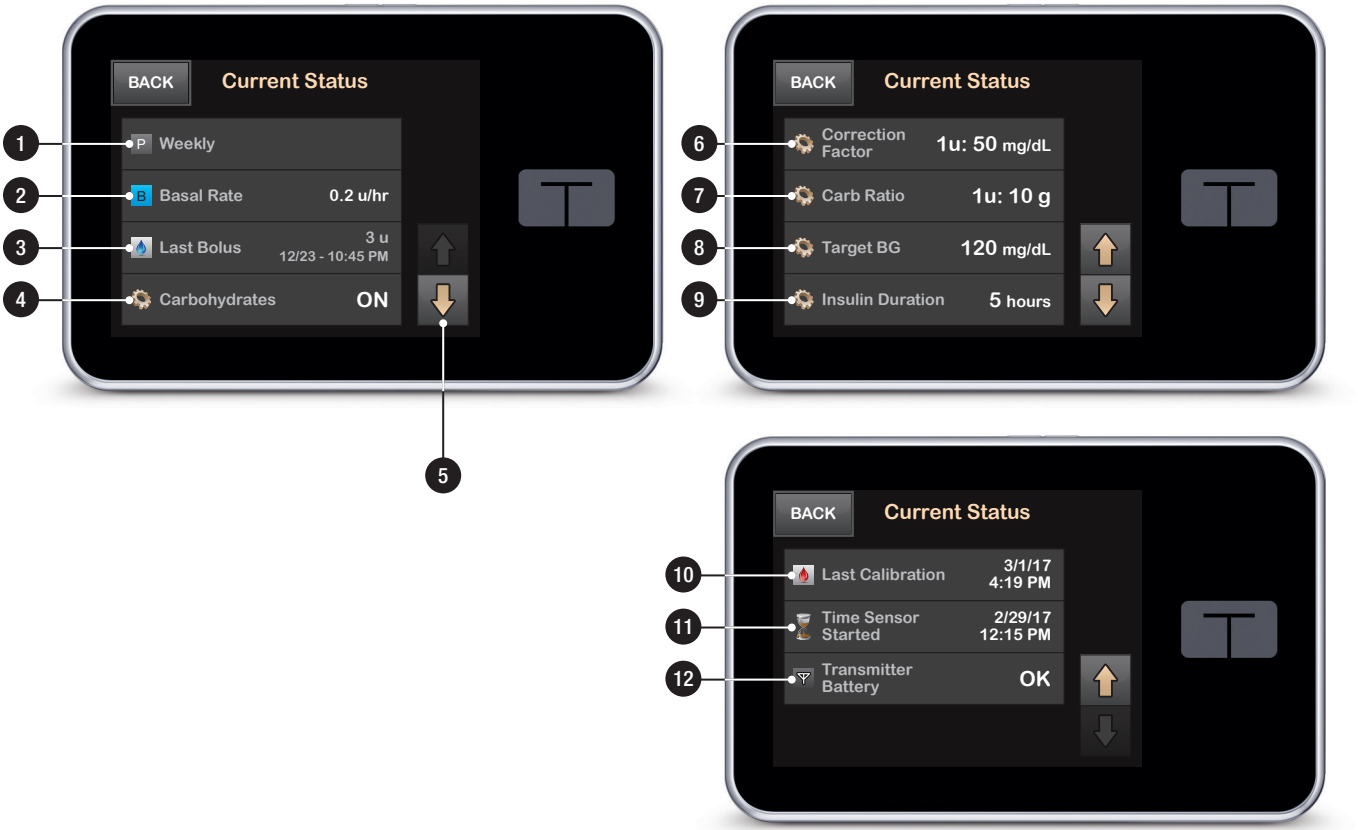



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
10:20 AM
March 5, 2017
100%
B
235 u
190
mg/dL
400
350
300
250
200
150
100
50
3
HRS
INSULIN ON BOARD:
1.1 u | 1:09 hrs
OPTIONS
BOLUS

3.10 Status Screen

The status screen can be accessed from the lock screen and the Home Screen. It is for display only, no changes can be made from this screen.

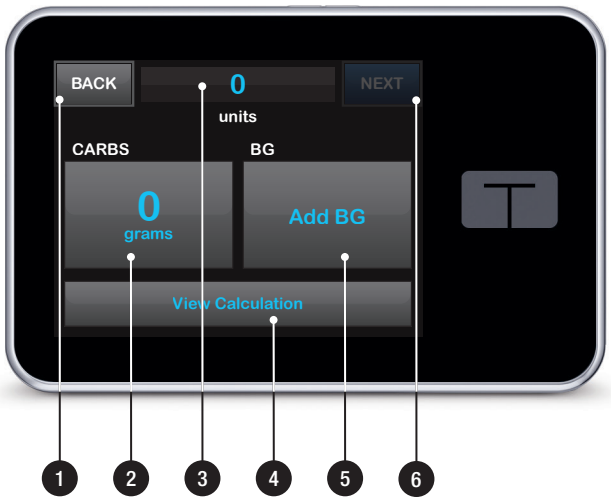
1. **Profile:** Displays current active Personal Profile.
2. **Basal Rate:** Displays current basal rate being delivered. (If a Temp Rate is active, it is displayed in units/hr.)
3. **Last Bolus:** Displays the amount, date and time of last bolus.
4. **Carbohydrates:** Indicates whether feature is on or off.
5. **Up/Down Arrow:** Indicates there is more information.
6. **Correction Factor:** Displays current correction factor used to calculate a bolus.
7. **Carb Ratio:** Displays current carb ratio used to calculate a bolus.
8. **Target BG:** Displays current BG target used to calculate a bolus.
9. **Insulin Duration:** Displays current insulin duration setting used to calculate insulin on board.
10. **Last Calibration:** Displays date and time of last calibration.
11. **Time Sensor Started:** Displays date and time of last time sensor started.
12. **Transmitter Battery:** Displays transmitter battery status.


BACK
Current Status
1
P
Weekly
2
B
Basal Rate
0.2 u/hr
3
Last Bolus
3 u
12/23 - 10:45 PM
4
Carbohydrates
ON
5
BACK
Current Status
6
Correction Factor
1u: 50 mg/dL
7
Carb Ratio
1u: 10 g
8
Target BG
120 mg/dL
9
Insulin Duration
5 hours
BACK
Current Status
10
Last Calibration
3/1/17
4:19 PM
11
Time Sensor Started
2/29/17
12:15 PM
12
Transmitter Battery
OK

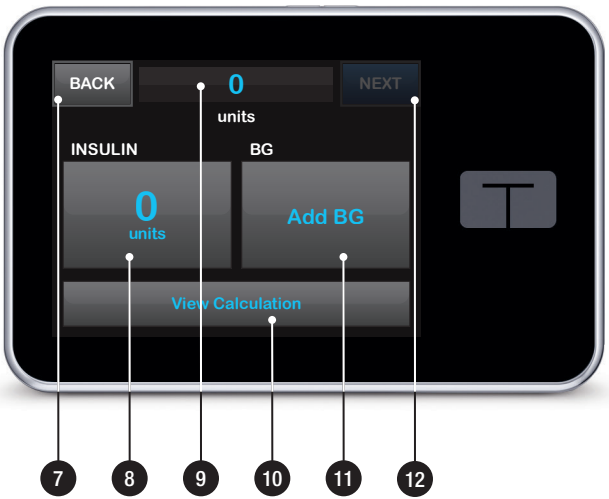
3.11 Bolus Screen

1. **Back:** Returns to the Home Screen.
2. **Carbs:** Enter grams of carb.
3. **Units:** Displays total units calculated. Tap to enter a bolus request or change (override) a calculated bolus.
4. **View Calculation:** Displays how the insulin dose was calculated using the current settings.
5. **Add BG:** Enter blood glucose level.
6. **Next:** Moves to next step.
7. **Back:** Returns to the Home Screen.
8. **Insulin:** Enter units of insulin.
9. **Units:** Displays total units calculated. Tap to enter a bolus request or change (override) a calculated bolus.
10. **View Calculation:** Displays how the insulin dose was calculated using the current settings.
11. **Add BG:** Enter blood glucose level.
12. **Next:** Moves to next step.

Using Grams

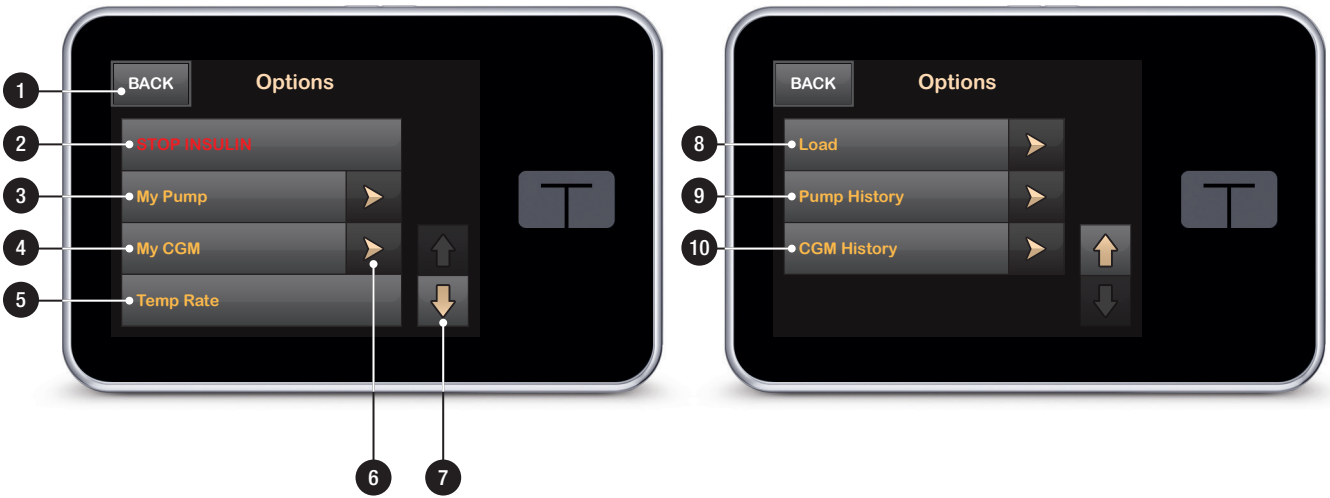


Using Units



3.12 Options Screen

1. **Back:** Returns to the Home Screen.
2. **Stop Insulin:** Stops insulin delivery. If insulin delivery is stopped, RESUME INSULIN will be displayed.
3. **My Pump:** Personal Profiles, Alert Settings, Pump Settings, and Pump Info.
4. **My CGM:** Start/Stop Sensor, Calibrate CGM, CGM Alerts, and CGM Settings.
5. **Temp Rate:** Programs a temporary basal rate.
6. **Menu Arrows:** Indicates additional menu options are available.
7. **Up/Down Arrow:** Indicates there is more information.
8. **Load:** Change Cartridge, Fill Tubing, Fill Cannula, and Site Reminder.
9. **Pump History:** Displays historical log of pump events.
10. **CGM History:** Displays historical log of CGM events.


1
BACK
Options
2
STOP INSULIN
3
My Pump
4
My CGM
5
Temp Rate
6
7
8
BACK
Options
Load
9
Pump History
10
CGM History

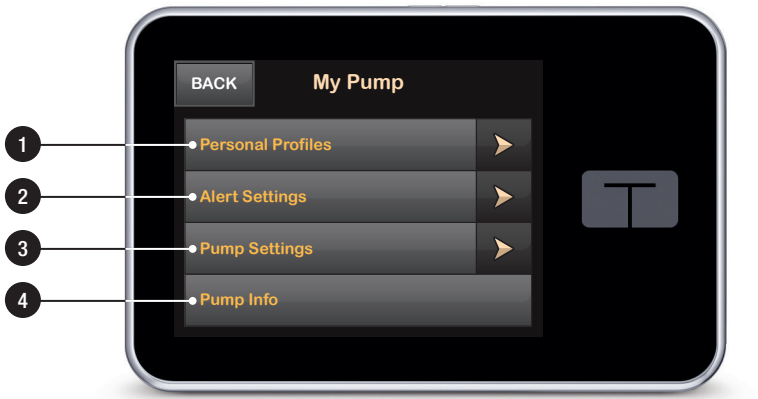
3.13 My Pump Screen

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

2. **Alert Settings:** Customize Pump Reminders and Alerts.

3. **Pump Settings:** Customize Quick Bolus, Pump Volume, Screen Options, and Time and Date.

4. **Pump Info:** Displays t:slim X2 Pump serial number, Tandem Diabetes Care Customer Technical Support phone number, website, and other technical information.


BACK
My Pump
Personal Profiles
Alert Settings
Pump Settings
Pump Info
1
2
3
4

3.14 My CGM Screen

1. **Start Sensor:** Starts a CGM session. If sensor is active, STOP SENSOR will be displayed.

2. **Calibrate CGM:** Enter a calibration blood glucose value. Only active when sensor session is active.

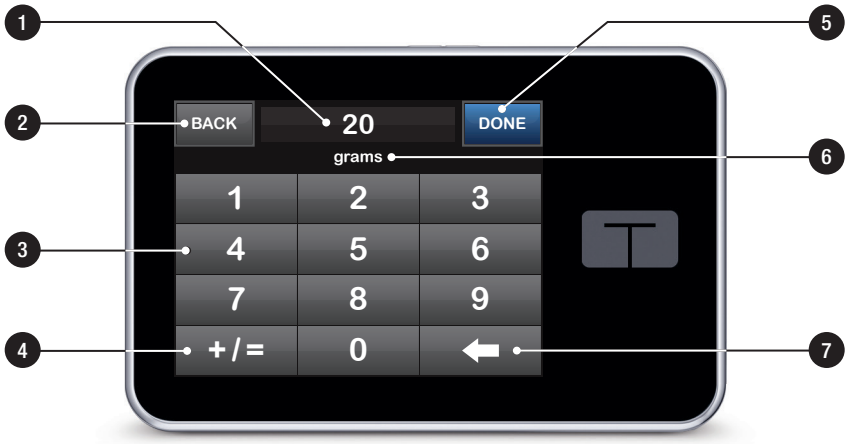
3. **CGM Alerts:** Customize CGM Alerts.

4. **CGM Settings:** Enter transmitter ID, customize CGM volume, and view CGM info.


BACK
My CGM
START SENSOR
Calibrate CGM
CGM Alerts
CGM Settings
1
2
3
4

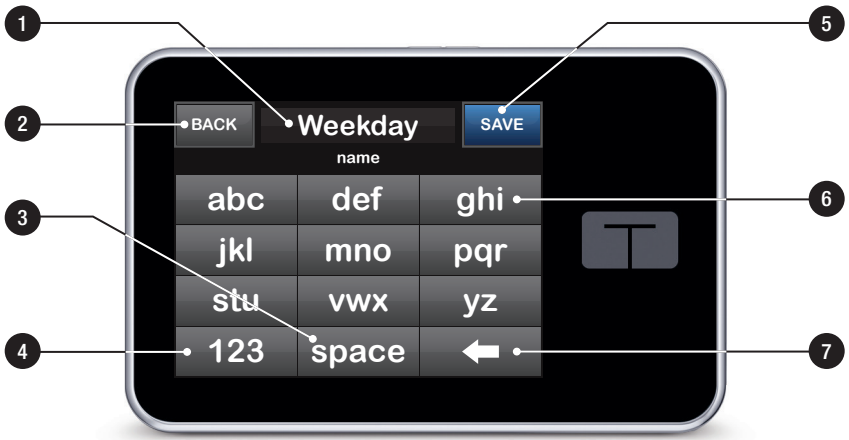
3.15 Number Keypad Screen

1. **Value Entered.**
2. **Back:** Returns to previous screen.
3. **Keypad Numbers.**
4. **+/=:** Allows numbers to be added on gram screen. If in units, this displays as a decimal point.
5. **Done:** Completes task and saves information entered.
6. **Units/Grams:** Value of what is entered.
7. **⬅:** Deletes last number entered.


1
2
3
4
5
6
7
BACK
20
DONE
grams
1
2
3
4
5
6
7
8
9
+/=
0

3.16 Letter Keypad Screen

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


1
2
3
4
5
6
7
BACK
Weekday
SAVE
name
abc
def
ghi
jkl
mno
pqr
stu
vwx
yz
123
space

Section 2

Key Pump Features

Chapter 4

Getting Started

4.1 Charging the t:slim X2 Pump

The t:slim X2 Pump is powered by an internal lithium polymer rechargeable battery. A full charge will last up to 7 days with normal use (5 days when using CGM). Accessories for charging from wall and automobile outlets, as well as from a PC USB port are included with the pump. Use only the accessories provided with the System to charge your t:slim X2 Pump. If you lose any of the accessories, or need a replacement, contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

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

When you first receive your t:slim X2 Pump, you will need to connect it to a charging source before it can be used. Charge the pump until the battery level indicator on the upper left portion of the Home Screen reads 100% (initial charge can take up to 2.5 hours).

The t:slim X2 Pump continues to operate normally while charging. You do not need to disconnect from the pump while charging.

⚠ PRECAUTION

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

If you choose to disconnect from the pump while charging, check with your healthcare provider for specific guidelines. Depending on the length of time you are disconnected, you may need to replace missed basal and/or bolus insulin. Check your blood glucose before disconnecting from the pump and again when you reconnect.

To charge the pump from an AC Power Outlet:

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

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

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

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

To charge the pump using a USB port on a Personal Computer (PC):

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

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

Before using a Mac or PC to charge the t:slim X2 Pump, it is recommended that a driver be installed on the computer by downloading the t:connect Uploader Software from our website at www.tandemdiabetes.com. This will also allow communication between the pump, the PC, and the t:connect Application. Depending on your computer, charging time will vary. The pump will display a CONNECTION ERROR ALERT message if it is not charging properly.

When you charge the t:slim X2 Pump, you will notice the following:

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

⚠ PRECAUTION
CONFIRM that the screen display turns on, you can hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the Screen On Button when you connect a power source to the USB port. These features are used to notify you about alerts, alarms, and other conditions that require your attention. If these features are not working, discontinue use of the System and contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

Charging Tips

Tandem Diabetes Care, Inc. recommends periodically checking the battery level indicator, charging the pump for a short period of time every day (10 to 15 minutes), and also avoiding frequent full discharges.

NOTE: Fully Discharged Battery
If the battery is fully discharged, the screen may not power on immediately when connected to a charging source. The LED around the Screen On/Quick Bolus Button will blink green until there is enough charge to power on the touch screen.

4.2 Using the Touch Screen

To turn on your t:slim X2 Pump screen, first press the Screen On/Quick Bolus Button, then use the pad of your finger to quickly and lightly tap on the screen. Do not use your finger nail or other object to interact with the screen. It will not activate the screen or its functions.

Your t:slim X2 Pump is designed to give you quick and easy access to the functions that you will use in your day-to-day diabetes management - whether basic or advanced.

The t:slim X2 Pump has several safety features to prevent unintentional interaction with the touch screen. The screen must be unlocked by tapping 1–2–3 in sequence. On all screens, if three non-active areas of the touch screen are tapped before an active area is tapped, the screen will turn off to prevent accidental button presses.

NOTE: Touch Screen Tips

When using the t:slim X2 Pump, tap the Tandem Logo to return to the Home Screen or tap BACK to return to the previous screen.

4.3 Turning on the t:slim X2 Pump Screen

1. To turn on your t:slim X2 Pump screen, press the **Screen On/Quick Bolus Button**, located on the top of the pump, once.

▷ The Screen Lock screen will be displayed.

NOTE: Turning off the Pump Screen

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

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

4.4 Unlocking the t:slim X2 Pump Screen

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

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

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

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

4.5 Edit Time

After powering up your t:slim X2 Pump for the first time, set the current time and date. Refer back to this section if you need to edit the time for either traveling in a different time zone or adjusting for Daylight Savings Time.

⚠ PRECAUTION

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

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Pump Settings**.
4. Tap **Time and Date**.
5. Tap **Edit Time**.
6. Tap **Time**.
7. Using the onscreen keypad, enter the hour and minutes. Verify and tap **DONE**.
8. Tap **Time of Day** to set AM or PM.
9. Verify the correct time is set and tap **SAVE**.

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

4.6 Edit Date

1. From the Time and Date screen tap **Edit Date**.
2. Tap **Month**.
3. Find and tap the current month displayed on the right. Use **Up/ Down Arrow** to view months not displayed.
4. Tap **Day**. Using the onscreen keypad enter the current day. Verify and tap **DONE**.
5. Tap **Year**.
6. Using the onscreen keypad enter the current year. Verify and tap **DONE**.
7. Verify the correct date is set and tap **SAVE**.
8. Tap **Tandem Logo** to return to the Home Screen.

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Chapter 5

Infusion Site Care and Loading Cartridge

5.1 Infusion Site Selection and Care

⚠ WARNING
DO use only FDA cleared insulin infusion sets with a tubing connector and follow their instructions for use. Failure to do so may result in over delivery or under delivery of insulin and may cause very low or very high blood glucose.

⚠ WARNING
DO NOT ignore infusion set cannula fractures. Infusion set cannulas may fracture on rare occasions. If an infusion set cannula breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken infusion set cannula, please report this to Tandem Customer Technical Support at (877) 801-6901.

⚠ 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.

General Guidelines

⚠ 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 blood glucose.

Site Selection:

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

Site Rotation:

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

- The infusion set must be replaced and rotated every 48–72 hours, or more often if needed.
- With experience, you will find areas that not only provide

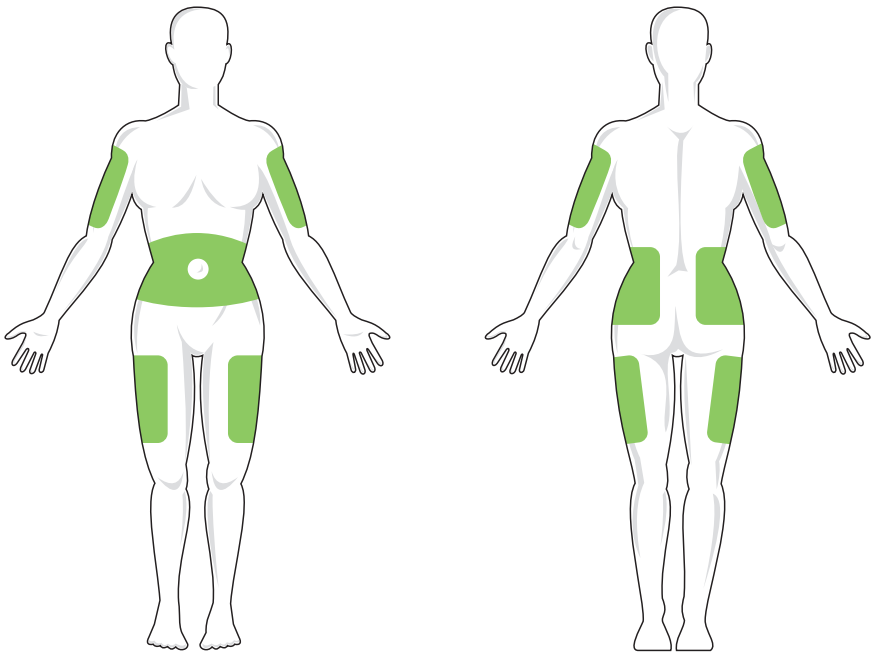
better absorption, but are more comfortable. Keep in mind, using the same areas may cause scarring or lumps which can affect insulin absorption.

- Consult your healthcare provider to establish a rotation schedule that best fits your needs.

Keep it clean:

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

Areas of Body for Infusion Set Insertion



5.2 Cartridge Instructions for Use

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

5.3 Filling and Loading a t:slim Cartridge

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

⚠ WARNING

DO NOT use any other insulin with your System other than U-100 Humalog® or NovoLog®. Only Humalog® and NovoLog® have been tested and found to be compatible for use in the System. Use of insulin with lesser or greater concentration can result in under delivery or over delivery of insulin. This can cause very high or a very low blood glucose.

⚠ WARNING

DO NOT reuse cartridges or use cartridges other than those manufactured by Tandem Diabetes Care, Inc. Use of cartridges not manufactured by Tandem Diabetes Care, Inc. or reuse of cartridges may result in over delivery or under delivery of insulin. This can cause very low or very high blood glucose.

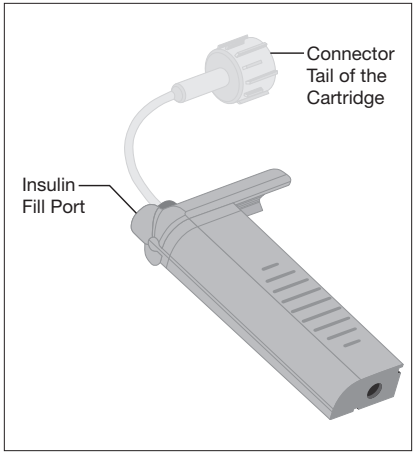
Before you begin, make sure you have the following items:

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

NOTE: Removing the Cartridge

Do NOT remove the used cartridge from the pump during the load process until prompted on the t:slim X2 Pump screen.

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



⚠ PRECAUTION

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

Instructions for Drawing Insulin from Vial into Syringe

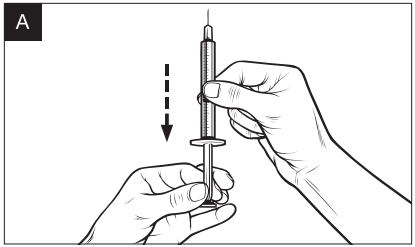
⚠ PRECAUTION

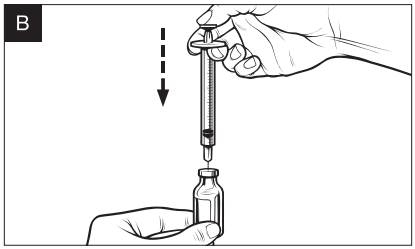
ALWAYS remove all air bubbles from the System before beginning insulin delivery. Ensure there are no air bubbles when drawing insulin into the filling syringe, hold the pump with the white fill port pointed up when filling the tubing, and ensure that there are no air bubbles in the tubing when filling.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

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

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

1. Inspect the needle and syringe package for any signs of damage. Discard any damaged product.
2. Wash your hands thoroughly.
3. Wipe the rubber septum of the insulin vial with an alcohol swab.
4. Remove the needle and syringe from their packaging. Securely twist needle onto syringe. Safely remove protective cap from needle by pulling outward.
5. Draw air into syringe up to the amount of insulin desired *(see image A)*.
6. With insulin vial upright, insert needle into vial. Inject air from syringe into vial. Maintain pressure on syringe plunger *(see image B)*.





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

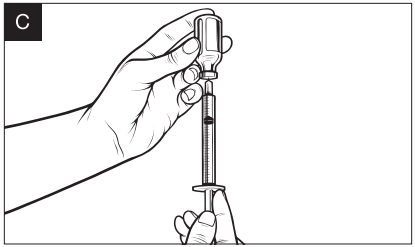
8. Slowly pull back the plunger to the desired amount of insulin *(see image C)*.

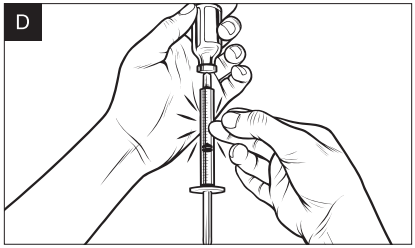
9. While the filling needle is still in the vial and upside down, tap the syringe so that any air bubbles rise to the top *(see image D)*. Then slowly push the plunger upwards, forcing any air bubbles back into the vial.

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

    » If there are air bubbles present, repeat step 9.

    » If no air bubbles are present, remove the filling needle from the vial.





Instructions for Filling the Cartridge

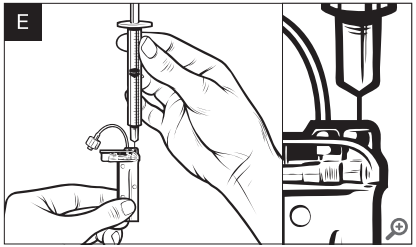
1. Inspect the cartridge package for any signs of damage. Discard any damaged product.

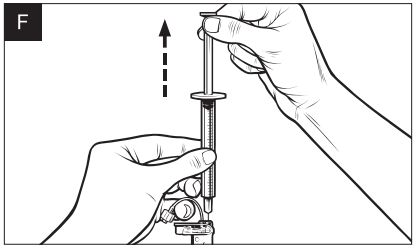
2. Open the package and remove the cartridge.

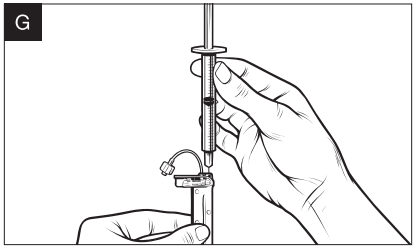
3. Hold the cartridge upright and gently insert the needle into the white insulin fill port on the cartridge *(see image E)*. The needle is not intended to go all the way in, so do not force it.

4. Keeping the syringe vertically aligned with the cartridge, and the needle inside the fill port, pull back on the plunger until it is fully retracted *(see image F)*. This will remove any residual air from the cartridge. Bubbles will rise toward the plunger.

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







6. Withdraw the needle from the fill port.

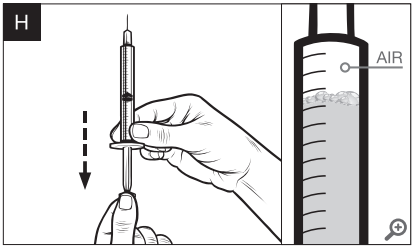
7. Turn the syringe upright and pull down on the plunger *(see image H)*. Flick the barrel to make sure that any air bubbles rise to the top.

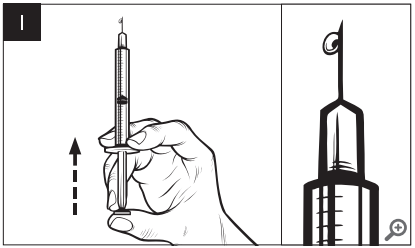
8. Gently press on the plunger to remove air bubbles until insulin fills the needle hub and you see a drop of insulin at the tip of the needle *(see image I)*.

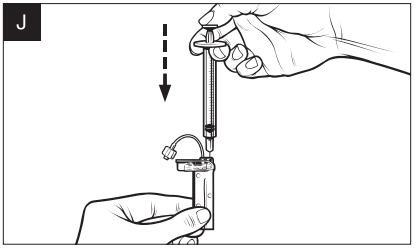
9. Re-insert the needle in the fill port and slowly fill the cartridge with insulin *(see image J)*. It is normal to feel some back pressure as you slowly press on the plunger.

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

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







Instructions on How to Install a Cartridge

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

1. From the Home Screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Load**.

   During the load sequence, the Tandem Logo is disabled. Tapping it will not return to the Home Screen.
4. Tap **Change Cartridge**.
5. Screen will display that all insulin deliveries will be stopped. Tap **YES** to continue.

NOTE: First Time Use

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

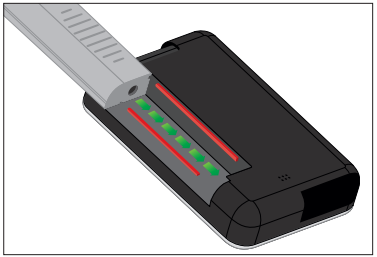
6. Disconnect the infusion set from your body and tap **NEXT** to continue.

▷ "Preparing for Cartridge" screen is displayed.

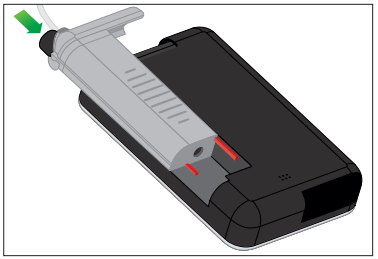
7. Remove the used cartridge.

   If needed, place the cartridge removal tool or the edge of a coin in the slot at the bottom of the cartridge and twist to aid in the removal of the cartridge.
8. Install filled cartridge.

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



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



Tap **UNLOCK** icon when completed.

9. Tap **NEXT** to continue.

▷ "Detecting Cartridge" screen is displayed.

⚠ WARNING

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

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

5.4 Filling Tubing

Filling the Infusion Set Tubing with Insulin

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

To fill the tubing without changing the cartridge, from the Home Screen tap OPTIONS, tap Down Arrow, tap Load, tap Fill Tubing and then follow the instructions. Tap NEW if you installed a new cartridge. Tap FILL if you did not install a new cartridge and want to continue with filling the tubing.

⚠ WARNING
NEVER fill your tubing while your infusion set is connected to your body. Always ensure that the infusion set is disconnected from your body before filling the tubing. Failure to disconnect your infusion set from your body before filling the tubing can result in over delivery of insulin. This can cause serious injury or death from very low blood glucose.

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

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

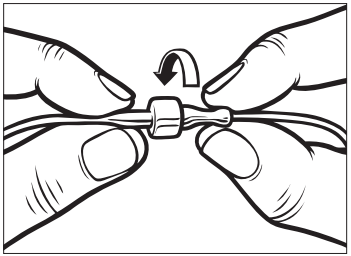
1. Verify that the infusion set is disconnected from your body.

2. Connect the infusion set tubing to the tubing connector on the cartridge:

   a. 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.

   b. Remove the infusion set tubing cap from the tubing connector. Be careful to keep the tubing connector away from unclean areas.

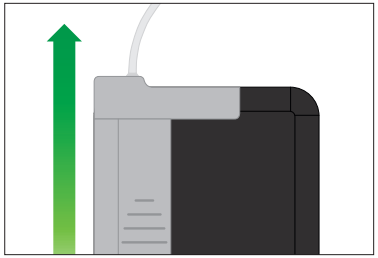
   c. Attach the infusion set tubing to the tubing connector on the cartridge tubing. Twist clockwise until finger tight and then twist another quarter of a turn to ensure a secure connection.



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

Tap **NEXT**.

3. Hold the pump vertically to ensure any air in the cartridge will be dispelled first. Tap **START**. The pump will beep and vibrate regularly while the tubing is being filled.



▷ "Starting Fill" screen is displayed.

The following are approximate amounts of insulin to fill different tubing lengths:

» 15–20 units for 23 inch tubing
» 20–25 units for 32 inch tubing
» 25–30 units for 42 inch tubing

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

▷ "Stopping Fill" screen is displayed.

▷ "Detecting Insulin" screen is displayed.

5. Verify that drops are seen and tap **DONE**.

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

- If you did not tap STOP, the "Max fill amount reached!" screen will appear. Do one of the following:

  a. If you are finished filling the tubing, tap **DONE**.

  b. If you want to fill the tubing with more than 30 units, tap **FILL** to go back to the Fill Tubing screen.

6. Fill Tubing is complete.

NOTE: Initial Display of Insulin Level

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

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

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

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

5.5 Filling Cannula

Filling the Infusion Set Cannula with Insulin

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

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

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

To Fill the Cannula

1. Tap **Fill Cannula**.
2. Insert a new infusion set and connect filled tubing to site, then tap **NEXT**.
3. Tap **Edit Fill Amount**.

   The cannula fill amount displayed is based on your last cannula fill amount. Filling stops at this amount.
4. Select amount needed for cannula fill.

   Refer to your infusion set instructions for use for proper cannula fill amount.

   If the amount needed is not listed, tap Other amount and use the onscreen keypad to enter a value between 0.1 to 1.0 unit.
5. Tap **START**.

▷ “Starting Fill” screen is displayed.

▷ After fill is complete, “Stopping Fill” screen is displayed.

NOTE: Stopping Fill
You can tap STOP at any time during the fill process if you want to stop filling the cannula.

The screen will return to the Load menu if the Site Reminder is turned off. Tap DONE 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 (refer to next section).

5.6 Setting Site Reminder

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

To set the Site Reminder without filling the cannula, from the Home Screen, tap OPTIONS, tap Down Arrow, tap Load, tap Site Reminder then follow the instructions below.

⚠ PRECAUTION

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

1. Tap SAVE if correct. Tap **Edit Reminder** if settings need to be changed.
2. Tap **Remind Me In** and select the number of days (1–3).

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

3. Tap **Remind Me At**. Use the onscreen keypad to enter time and tap **DONE**.
4. Tap **Time of Day** to change AM or PM. Tap **DONE**.
5. Verify Site Reminder is set correctly and tap **SAVE**.

▷ "Setting Saved" screen is displayed.

6. Load screen is displayed. Tap **DONE**.

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

7. Tap **RESUME**.

NOTE: First Time Use

If this is the first time using your t:slim X2 Pump and a Personal Profile has not been defined, a screen will notify you that a profile must be activated to resume insulin. Tap CLOSE.

8. **RESUMING INSULIN** screen is temporarily displayed.

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Chapter 6

Personal Profiles

6.1 Personal Profiles Overview

⚠ WARNING

DO NOT start to use your System 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 very low or very high blood glucose.

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

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

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

Up to 6 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, and exercise, etc.

6.2 Creating a New Profile

Creating Personal Profiles

You can create up to 6 Personal Profiles, however, only 1 can be active at a time. In the Personal Profiles screen, the active profile is positioned at the top of the list and is marked as ON. When you create a Personal Profile, you can set any or all of the following Timed Settings:

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

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

set up any required settings before you can continue.

The ranges you can set for Timed Settings are:

- Basal (range: 0 and 0.1 to 15 units/hr)
- Correction Factor (range: 1 unit:1 mg/dL to 1 unit:600 mg/dL)
- Carb Ratio (range: 1 unit:1 gram to 1 unit:300 grams)

  Below a carb ratio of 1:10, increments can be entered in 0.1 g. For example a carb ratio of 1:8.2 can be programmed.
- Target BG (range: 70 mg/dL to 250 mg/dL)

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

- Carbs (on indicates entering grams of Carb; off indicates entering units of insulin)
- Insulin Duration (how long a bolus lowers your BG)
- Max Bolus (the maximum amount for a single bolus)

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

- Carbs (default: off if no Carb Ratio is defined)
- Insulin Duration (default: 5 hrs; range: 2 to 8 hrs)
- Max Bolus (default: 10 units; range: 1 to 25 units)

Insulin Duration and Insulin on Board (IOB)

Your t:slim X2 Pump remembers how much insulin you have taken from previous boluses. It does this by relying on the Insulin Duration. The Insulin Duration reflects the amount of time that insulin is actively lowering your BG.

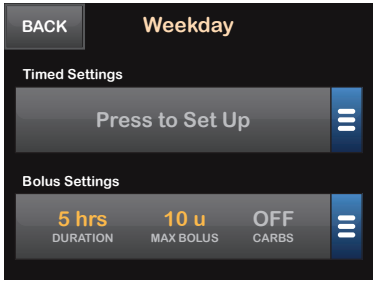
Consult your healthcare provider to accurately set your Insulin Duration.

While the Insulin Duration setting reflects how long insulin from previous boluses lowers your BG, the IOB feature reflects how much insulin is remaining in your body from previous boluses. IOB is always displayed on the Home Screen and is used in bolus delivery calculations when applicable. When a BG is entered during bolus programming, your t:slim X2 Pump will consider any active IOB and calculate an adjusted bolus if necessary.

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap **NEW** to create a new profile.
5. Using the onscreen keypad, enter a profile name (up to 16 characters) and tap **SAVE**.

Tap once for first letter displayed, 2 quick taps for middle letter; and 3 quick taps for the third letter.

6. Tap **Press to Setup** to begin setting insulin delivery settings.



6.3 Programming a New Personal Profile

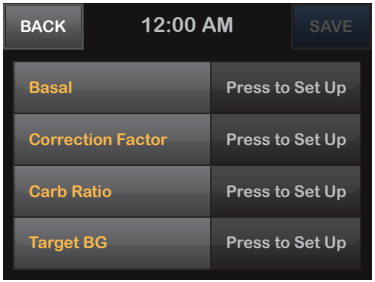
Once the Personal Profile has been created, the settings must be programmed. The first time segment will start at 12:00 AM (midnight).

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

⚠ PRECAUTION

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

Timed Settings



1. Once the new profile has been created, Tap **Basal**.
2. Using the onscreen keypad, enter your basal rate and tap **DONE**.
3. Tap **Correction Factor**.
4. Using the onscreen keypad, enter your correction factor (the mg/dL that 1 unit of insulin will lower BG) and tap **DONE**.
5. Tap **Carb Ratio**.

6. Using the onscreen keypad, enter your insulin-to-carbohydrate ratio (the grams of carb to be covered by 1 unit of insulin) and tap **DONE**.

7. Tap **Target BG**.

8. Using the onscreen keypad, enter your target BG and tap **DONE**.

9. Review entered values and tap **SAVE**.

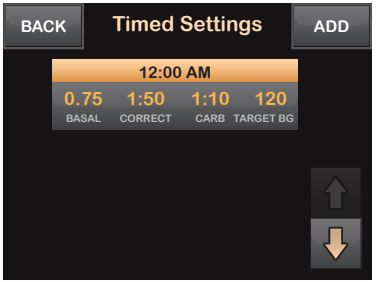
10. Confirm Settings.

    Tap **YES** if entered data is correct.

    Tap **NO** to make changes.

11. Tap **BACK** to set the Bolus Settings.

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



Adding More Time Segments

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

1. On the “Add Segment” screen, tap **Start Time**.

2. Using the onscreen keypad, enter the time (hour and minutes) that you want the segment to begin, and tap **DONE**.

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

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

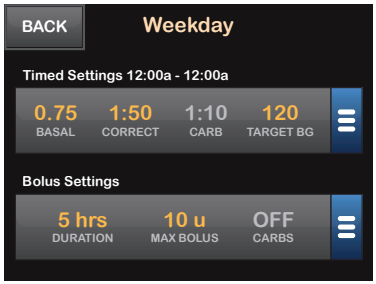
4. Tap **NEXT**.

5. Repeat steps 1 to 10 from the “Programming a New Personal Profile” section above for each segment you want to set up (up to 16).

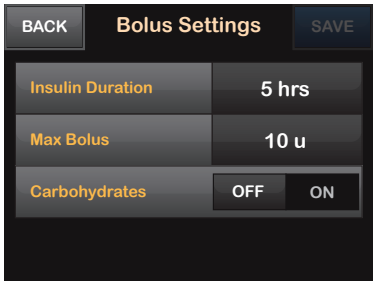
   To find time segments in the list that are not displayed on the first screen, tap the Down Arrow.

Bolus Settings

1. Tap the **Bolus Settings Panel**.



2. Tap **Insulin Duration**.



3. Using the onscreen keypad, enter the desired time for the duration of insulin action (2–8 hrs) and tap **DONE**.

4. Tap **Max Bolus**.

5. Using the onscreen keypad, enter the desired amount for maximum bolus (1–25 units) and tap **DONE**.

> **NOTE: 25 Unit Max Bolus**
> If you set the max bolus to 25 units and a bolus larger than 25 units is calculated using your Carb Ratio or Correction Factor, after the bolus is delivered a reminder screen will appear. The option of delivering the remaining amount of the bolus up to an additional 25 units will be given (refer to Max Bolus Alert in chapter 15.9).

6. Tap **Carbohydrates** to turn on and use the carb ratio when calculating boluses.

7. Review entered values and tap **SAVE**.

8. Confirm Settings.

   Tap **YES** if entered data is correct.

   Tap **NO** to make changes.

9. Tap **Tandem Logo** to return to the Home Screen.

Adding More Personal Profiles

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

2. Tap **My Pump**.

3. Tap **Personal Profiles**.

4. Tap **NEW**.

5. Name the new profile and repeat steps for Timed Settings and Bolus Settings.

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

6.4 Editing or Reviewing an Existing Profile

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to edit or review.
5. Tap **Edit**.
6. Tap **Timed Settings Panel**.
7. Tap the desired time segment to edit.
8. Tap **Basal**, **Correction Factor**, **Carb Ratio** or **Target BG** to make changes as needed and use the onscreen keypad to enter changes. Tap **DONE**.
9. View recent changes and tap **SAVE**.
10. Confirm Settings.

    Tap **YES** if entered data is correct.

    Tap **NO** to make changes.
11. Edit other time segments within the Timed Settings by tapping on them and using the same steps described above.
12. Tap **BACK** after editing all of the time segments.
13. Tap the **Bolus Settings Panel** to change DURATION, MAX BOLUS or CARBS as needed. Use the onscreen keypad to enter desired changes. Tap **SAVE**.
14. Confirm Settings.

    Tap **YES** if entered data is correct.

    Tap **NO** and make changes.
15. Tap **Tandem Logo** to return to the Home Screen.

NOTE: Adding or Deleting Time Segments

To Add a time segment:

» Tap ADD.

» Enter desired start time.

To Delete a time segment:

» Tap on the X to the left of the time segment.

» Tap YES to confirm.

6.5 Duplicating an Existing Profile

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to duplicate.
5. Tap **Duplicate**.
6. Confirm profile to duplicate by tapping **YES**.
7. Using the onscreen keypad, enter the name (up to 16 characters) for the new profile and tap **SAVE**.

▷ "Profile Duplicated" screen is displayed.

▷ A new Personal Profile will be created with the same settings as the profile copied.

8. Tap the **Timed Settings** or **Bolus Settings Panel** to make changes to the new profile.

6.6 Activating an Existing Profile

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to be activated.

   » The Activate and Delete options are disabled for the active profile because the profile is already activated. You cannot delete a profile until you have activated another profile.

   » If you have only 1 profile defined, you do not need to activate it (that profile is automatically activated).

5. Tap **Activate**.

▷ A screen to confirm the activation request is displayed.

6. Tap **YES**.

▷ "Profile Activated" screen is displayed.

6.7 Renaming an Existing Profile

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to be renamed.
5. Tap **Down Arrow**, and then **Rename**.
6. Using the onscreen keypad, rename the profile name (up to 16 characters) and tap **SAVE**.
7. Tap **Tandem Logo** to return to the Home Screen.

6.8 Deleting an Existing Profile

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Personal Profiles**.
4. Tap the name of the Personal Profile to be deleted.

   The active Personal Profile cannot be deleted.
5. Tap **Delete**.
6. Tap **YES**.

▷ "Profile Deleted" screen is displayed.

7. Tap **Tandem Logo** to return to the Home Screen.

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Chapter 7

Bolus

7.1 Bolus Overview

⚠ WARNING

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

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

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

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

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

You can always override the calculated bolus by tapping the area above "units" located at the top of the bolus screen between BACK and NEXT. The override function is always active.

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

⚠ PRECAUTION

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

7.2 Food Bolus Using Units

If bolusing using a carb ratio skip to the next chapter, Food Bolus Using Grams.

1. From the Home Screen, tap **BOLUS**.
2. Tap **0 units**.
3. Using the onscreen keypad enter units of insulin to be delivered, then tap **DONE**.

   ⚠ 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. Tap **NEXT** to confirm the units of insulin to be delivered.
5. Confirm Request.

   Tap **YES** if entered data is correct.

   Tap **NO** to go back to make changes or view calculations.

6. Tap **DELIVER**.

7. The bolus initiated screen is temporarily displayed.

7.3 Food Bolus Using Grams

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

2. Tap **0 grams**.

3. Using the onscreen keypad enter grams of carb and tap **DONE**.

   To add multiple carb values enter first value, then tap +/=, enter second value, tap +/=. Continue until done.

   To clear the value entered and start over, tap the back arrow.

4. Check that the grams of carb are entered in the correct location on the screen.

5. Tap **NEXT** to confirm the units of insulin to be delivered.

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

6. Confirm Request.

   Tap **YES** if entered data is correct.

   Tap **NO** to go back to make changes or view calculations.

7. Tap **DELIVER**.

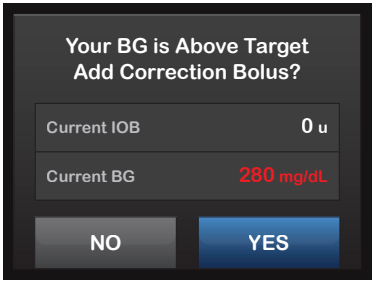
8. The bolus initiated screen is temporarily displayed.

7.4 Correction Bolus

1. From the Home Screen, tap **BOLUS**.
2. Tap **Add BG**.
3. Using the onscreen keypad, enter BG value and tap **DONE**.

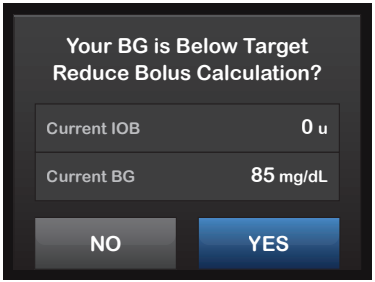
   Once DONE is tapped, the BG value is saved in pump History whether or not a bolus is delivered.

If BG is above the Target BG, a message screen will indicate BG is above Target.



To add a correction bolus tap YES.

If BG is below Target BG, a message screen will indicate BG is below Target.



To reduce bolus calculation tap YES.

When your blood glucose is:

» Above Target BG: the insulin for the food bolus and the correction bolus will be added together. If IOB is present, it will only be used in the calculation of the correction portion of the bolus.

» Between 70 mg/dL and Target BG: You will be given an option to reduce the food bolus to correct for the low blood glucose. In addition, if IOB is present, it will also be used to reduce the bolus calculation.

» Below 70 mg/dL: The food bolus will be reduced to automatically correct for the low blood glucose. In addition, if IOB is present, it will also be used to reduce the bolus calculation.

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

4. Tap **NEXT** to confirm the units of insulin to be delivered.

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

5. Confirm Request.

   Tap **YES** if entered data is correct.

   Tap **NO** to go back to make changes or view calculations.

6. Tap **DELIVER**.

7. The bolus initiated screen is temporarily displayed.

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

Only 1 extended bolus can be active at any given time. However, if the DELIVER LATER portion of an extended bolus is active, you can request another standard bolus.

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

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

3. Using the onscreen keypad enter grams of carb (or units of insulin). Tap **DONE**.

4. If desired, tap **Add BG** and using the onscreen keypad enter BG value. Tap **DONE**.

5. Tap **NEXT** to confirm the units of insulin to be delivered.

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

6. Confirm Request.

   Tap **YES** if entered data is correct.

   Tap **NO** to go back to make changes or view calculations.

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

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

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

9. Use the onscreen keypad to enter the percentage of the bolus to DELIVER NOW and tap **DONE**.

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

10. Tap **2 hrs** under DURATION.

    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 will be notified and the duration of the DELIVER LATER portion will be adjusted.

11. Use the onscreen keypad to adjust the length of time the bolus is to be delivered, then tap **DONE**.

12. Tap **NEXT**.

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

13. Confirm Request.

    Tap **YES** if entered data is correct.

    Tap **NO** to go back to make changes or view calculations.

14. Tap **DELIVER**.

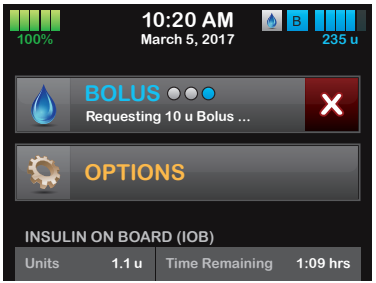
15. The bolus initiated screen is temporarily displayed.

7.6 Canceling or Stopping a Bolus

Canceling a Bolus If delivery <u>Has Not Started</u>

1. Tap **1–2–3** to access the Home Screen.

2. Tap **X** (stop icon) to cancel the bolus.



- ▷ The bolus button will remain inactive while the bolus is being canceled.
- ▷ Once canceled, the bolus button will become active again on the Home Screen.

Stopping a Bolus if delivery of the bolus <u>Has Started</u>:

1. Tap **1–2–3** to access the Home Screen.
2. Tap **X** (stop icon) to stop delivery.
3. Tap **YES**.

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

4. Units requested and delivered are shown. Tap **CLOSE**.

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Chapter 8

Stop/Resume Insulin

8.1 Stopping Insulin Delivery

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

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

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

8.2 Resuming Insulin Delivery

1. If pump screen is not on, press **Screen On/Quick Bolus Button** once to turn on your t:slim X2 Pump screen.
2. Tap **1–2–3** to access the Home Screen.
3. Tap **RESUME**.
4. The RESUMING INSULIN screen is temporarily displayed.

– OR –

1. From the Home Screen, tap **OPTIONS**.
2. Tap **RESUME INSULIN**.
3. Tap **RESUME**.
4. The RESUMING INSULIN screen is temporarily displayed.

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Section 3

Additional Pump Operations

Chapter 9

Temporary Basal Rate

9.1 Setting a Temp Rate

A Temp Rate is used to increase or decrease (by percentage) the current basal rate for a period of time. This feature can be helpful for situations such as exercise or illness.

When you enter the Temp Rate screen, the default values are 100% (current basal rate) and a Duration of 0:15 min. The Temp Rate can be set from a minimum of 0% of current basal rate to a maximum of 250% of current basal rate in increments of 1%.

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

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

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

1. From the Home Screen, tap **OPTIONS**.
2. Tap **Temp Rate**.
3. Tap **Temp Rate**.
4. Using the onscreen keypad enter desired percentage. The current rate is 100%. An increase is greater than 100% and decrease is less than 100%. Tap **DONE**.
5. Tap **Duration**. Using the onscreen keypad enter desired length of time for Temp Rate. Tap **DONE**.

   You can always tap **View Units** to see the actual units to be delivered.
6. Verify settings and tap **START**.
7. The “TEMP RATE STARTED” screen is temporarily displayed.
8. The Screen Lock screen will be displayed with the icon indicating a Temp Rate is active.

   An orange “T” means a Temp Rate is active. A red “T” means a Temp Rate of 0 is active.

9.2 Stopping a Temp Rate

To stop an active temp rate:

1. From the Home Screen, tap **OPTIONS**.
2. On the Options screen, tap **X** (stop icon) on the right side of Temp Rate.
3. On the confirmation screen, tap **STOP**. The “TEMP RATE STOPPED” screen appears before returning to the Options screen.

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Chapter 10

Quick Bolus

10.1 Setting Up Quick Bolus

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

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

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

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Pump Settings**.
4. Tap **Quick Bolus**.
5. Tap **Increment Type**.
6. Tap **units of insulin** or **grams of carbohydrate** to select.
7. Tap **Increment Amount**.
8. Select the preferred increment amount.

   NOTE
   The increment amount is added with each press of the Quick Bolus Button when delivering a quick bolus.

9. Review entered values and tap **SAVE**.
10. Confirm Settings.

    Tap **YES** if entered data is correct.

    Tap **NO** to go back to make changes.

11. Tap **Tandem Logo** to return to the Home Screen.

10.2 Delivering Quick Bolus

If the Quick Bolus function is turned On, you can deliver a bolus without having to look at the t:slim X2 Pump's screen. Simply use the Quick Bolus Button to deliver your bolus. Quick boluses are delivered as standard boluses (there is no BG entry or extended bolus).

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

1. Press and hold **Quick Bolus Button**. The Quick Bolus screen will appear. Listen for 2 beeps (if Pump Volume is set to beep) or feel for vibrations (if Pump Volume is set to vibrate).
2. Press **Quick Bolus Button** for each increment until desired amount is reached. The pump will beep/vibrate for each button press.

3. The pump will beep/vibrate once for each increment pressed to confirm desired amount.

4. After the pump beeps/vibrates, press and hold **Quick Bolus Button** to deliver the bolus.

NOTE: Safety Features

» If you want to cancel the bolus and return to the Home Screen, tap CANCEL on the QUICK BOLUS screen.

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

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

» You cannot exceed 20 button presses when using the Quick Bolus feature. Once you reach 20 button presses, a different tone will sound to notify you (if Quick Bolus is set to vibrate, the pump will stop vibrating in response to additional button presses to notify you). Look at the screen to confirm the bolus amount.

» If you hear a different tone at any point during programming or the pump stops vibrating in response to button presses, look at the screen to confirm the bolus amount. If the Quick Bolus screen does not display the correct bolus amount, use the touch screen to enter bolus information.

5. The bolus initiated screen is temporarily displayed.

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Chapter 11

t:slim X2 Pump Settings

11.1 t:slim X2 Pump Volume

Pump Volume is pre-set to high. A change to the Pump Volume can be made in Pump Settings.

Pump Volume can be personalized for the Button taps, Quick Bolus, Bolus, Reminders, Alerts, and Alarms. Options for Pump Volume include high, medium, low and vibrate.

⚠ PRECAUTION

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

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

   Tap **SAVE** when all changes are complete.
8. Tap **Tandem Logo** to return to the Home Screen.

11.2 Screen Options

The Screen Options for your t:slim X2 Pump include Screen Timeout and Feature Lock.

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

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

Feature Lock is pre-set to off. With the Feature Lock turned on, you cannot deliver a bolus, change any pump settings or access any Personal Profiles.

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Pump Settings**.
4. Tap **Screen Options**.

5. Tap desired option.

For Screen Timeout

1. Tap **Screen Timeout**.
2. Select preferred time and tap **SAVE**.
3. Tap **Tandem Logo** to return to the Home Screen.

For Feature Lock

1. Tap **Feature Lock** to turn On or Off and tap **SAVE**.

▷ A screen to verify that you want to activate the Feature Lock will be displayed.

2. Tap **YES** to confirm.
3. Tap **SAVE**.
4. Tap **Tandem Logo** to return to the Home Screen.

NOTE: Pump Volume

When Feature Lock is turned on, Pump Volume will be set to high until the Feature Lock is turned off.

To Turn the Feature Lock Off

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Pump Settings**.
4. Tap **Screen Options**.
5. Tap **Feature Lock**.
6. Tap **YES**.
7. Tap **SAVE**.

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Chapter 12

t:slim X2 Pump Info and History

12.1 t:slim X2 Pump Info

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

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

12.2 t:slim X2 Pump History

Pump History displays a historical log of pump events. At least 90 days of data can be viewed in History. When the maximum number of events is reached, the oldest events are removed from the history log and replaced with the most recent events.The following can be viewed in History:

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

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

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

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

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

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

1. From the Home Screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **Pump History**.
4. Tap desired option.
5. Tap **Tandem Logo** to return to the Home Screen.

Chapter 13

t:slim X2 Pump Reminders

Your t:slim X2 Pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check you BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

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

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

Reminders notify you with a single sequence of 3 notes or a single vibration depending on the volume/vibrate setting in Pump Volume. They repeat every 10 minutes until acknowledged. Reminders do not escalate.

13.1 Low BG Reminder

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

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

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alert Settings.**
4. Tap **Pump Reminders**.
5. Tap **Low BG**.
6. Low BG is set to on; to turn off, tap **LOW BG**.

    a. Tap **Remind Me Below** and

using the onscreen keypad, enter a Low BG value (from 70 to 120 mg/dL) that you want to trigger the reminder, then tap **DONE**.

b. Tap **Remind Me After** and using the onscreen keypad, enter the time (from 10 to 20 min), then tap **DONE**.

c. Tap **SAVE** when all changes are complete.

d. Tap **Tandem Logo** to return to the Home Screen.

To Respond to the Low BG Reminder

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

13.2 High BG Reminder

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

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

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alert Settings**.
4. Tap **Pump Reminders**.
5. Tap **High BG**.
6. High BG is set to on; to turn off, tap **High BG**.

   a. Tap **Remind Me Above** and using the onscreen keypad, enter a High BG value (from 150 to 300 mg/dL) that you want to trigger the reminder, then tap **DONE**.

   b. Tap **Remind Me After** and using the onscreen keypad, enter the time (from 1 to 3 hours), then tap **DONE**.

   c. Tap **SAVE** when all changes are complete.

7. Tap **Tandem Logo** to return to the Home Screen.

To Respond to the High BG Reminder

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

13.3 After Bolus BG Reminder

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

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alert Settings**.
4. Tap **Pump Reminders**.
5. Tap **After Bolus BG**.
6. After Bolus BG is set to on; to turn off, tap **After Bolus BG**.
   a. Tap **Remind Me After** and using the onscreen keypad, enter the time (from 1 to 3 hours) that you want to trigger the reminder, then tap **DONE**.
7. Tap **SAVE** when all changes are complete.
8. Tap Tandem Logo to return to the Home Screen.

To Respond to the After Bolus BG Reminder

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

13.4 Missed Meal Bolus Reminder

The Missed Meal Bolus Reminder lets you know if a bolus was not delivered during a specified time period. 4 separate reminders are available. When programming this reminder you need to select the Days, the Start Time, and End Time for each reminder.

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alert Settings**.
4. Tap **Pump Reminders**.
5. Tap **Missed Meal Bolus**.

6. On the Missed Meal Bolus screen, tap which reminder you want to set (Reminder 1 to 4) and do the following:

   a. Tap **Reminder 1** (or 2, 3, 4).

   b. Reminder 1 is set to on; to turn **off**, tap **Reminder 1**.

   c. Tap **Selected Days** and tap the day(s) you want the reminder to be on, then tap **BACK**.

   d. Tap **Start Time**, tap **Time** and using the onscreen keypad enter the start time, then tap **DONE**.

   e. Tap **Time of Day** to select AM or PM, then tap **DONE**.

   f. Tap **End Time**, tap **Time** and using the onscreen keypad enter the end time, then tap **DONE**.

   g. Tap **Time of Day** to select **AM** or **PM**, then tap **DONE**.

   h. Tap **SAVE** when all changes are complete.

7. Tap **Tandem Logo** to return to the Home Screen.

To Respond to the Missed Meal Bolus Reminder

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

13.5 Site Reminder

The Site Reminder prompts you to change your infusion set. The default for this reminder is pre-set 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, refer to Chapter 5.6.

To Respond to the Site Reminder

To clear the reminder tap **CLOSE** and change your infusion set.

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Chapter 14

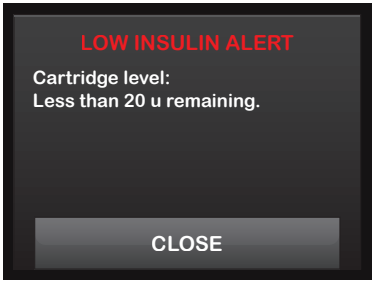
User Settable Alerts and Alarms

14.1 Low Insulin Alert

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

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alert Settings**.
4. Tap **Pump Alerts**.
5. Tap **Low Insulin**.
6. Using the onscreen keypad, enter the number of units (from 10 to 40 units) that you want the Low Insulin Alert value to be set, and tap **DONE**.
7. Tap **SAVE** when all changes are complete.

To Respond to the Low Insulin Alert



To clear the alert, tap **CLOSE**.

14.2 Auto-Off Alarm

Your t:slim X2 Pump can stop insulin delivery and alert you (or whoever is with you) if there has been no interaction with the pump within a specified period of time. The default for this alarm is pre-set to 12 hours. You can set it anywhere between 5 and 24 hours, or off. This alarm notifies you that there has been no interaction with the pump in the specified number of hours and the pump will shut down after 30 seconds.

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

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My Pump**.
3. Tap **Alert Settings**.
4. Tap **Pump Alerts**.

5. Tap **Auto-Off**.

   A confirmation screen will appear. Tap **YES** to continue. Tap **NO** to go back.

6. Verify Auto-Off is set to on, then tap **Time**.

7. Using the onscreen keypad, enter the number of hours (from 5 to 24 hrs) that you want the Auto-Off Alarm to be triggered, and tap **DONE**.

8. Tap **DONE**, then tap **SAVE** when all changes are complete.

9. Tap **Tandem Logo** to return to the Home Screen.

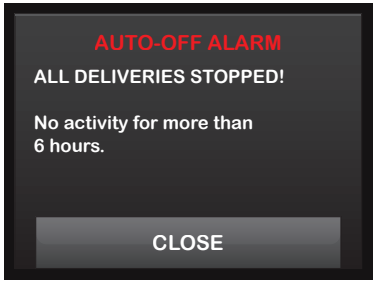
To Respond to Auto-Off Warning

1. Tap **DO NOT SHUT DOWN**.

The warning clears and the pump returns to normal operation.

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

Auto-Off Alarm Screen



1. Tap **CLOSE**. The Home Screen then appears, indicating a status of “All Deliveries Stopped.” You must resume delivery to continue therapy, (refer to Chapter 8.2).

Section 4

t:slim X2 Pump Safety Alerts and Alarms

Chapter 15

t:slim X2 Pump Alerts

Your t:slim X2 Pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check you BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

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

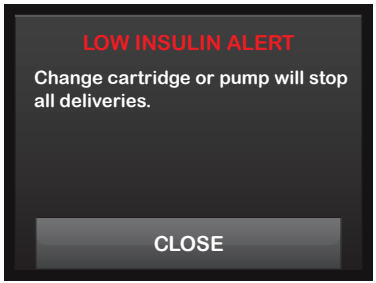
Information in this section will help you learn how to respond to Alerts.

Alerts notify you with 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume. They repeat regularly until acknowledged. Alerts do not escalate.

NOTE: CGM Alerts

There is an additional list of Alerts and Errors related to CGM use in Chapter 26.

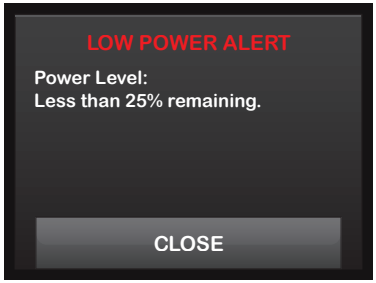
15.1 Low Insulin Alert

What will I see on the Screen?	What does it mean?
	5 units or less of insulin remain in the cartridge.
	How will the System notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the System re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap CLOSE. Change your cartridge as soon as possible to avoid the EMPTY CARTRIDGE ALARM and running out of insulin.

15.2 Low Power Alerts

Low Power Alert 1

What will I see on the Screen?



What does it mean?

Less than 25% of battery power remains.

How will the System notify me?

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

Will the System re-notify me?

Yes, every 5 minutes until acknowledged.

How should I respond?

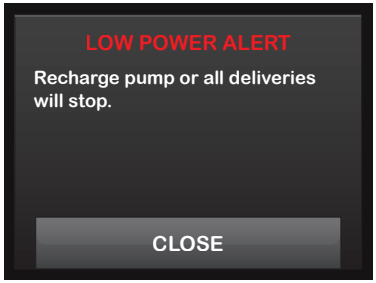
Tap **CLOSE**. Charge your pump as soon as possible to avoid the second LOW POWER ALERT.

NOTE: Low Battery Display

Once the LOW POWER ALERT occurs, the low-power indicator (a single red bar on the battery level display on the Home Screen) appears.

Low Power Alert 2

What will I see on the Screen?



What does it mean?

Less than 5% of battery power remains. Insulin delivery will continue for 30 minutes and then the pump will power off and insulin delivery will stop.

How will the System notify me?

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

Will the System re-notify me?

Yes, every 5 minutes until acknowledged.

How should I respond?

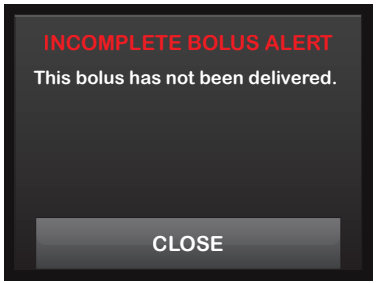
Tap CLOSE. Charge your pump immediately to avoid the LOW POWER ALARM and system power off.

NOTE: Low Battery Display

Once the second LOW POWER ALERT occurs, the low-power indicator (a red 5% on the battery level display on the Home Screen) appears.

15.3 Incomplete Bolus Alert

What will I see on the Screen?



What does it mean?

You started a bolus request but did not complete the request within 90 seconds.

How will the System notify me?

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

Will the System re-notify me?

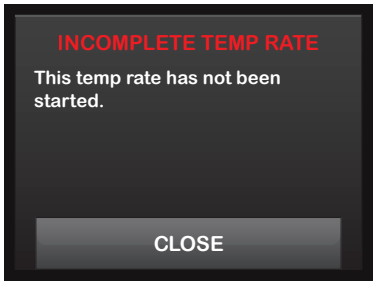
Yes, every 5 minutes until acknowledged.

How should I respond?

Tap CLOSE. The Bolus screen will appear. Continue with your bolus request, or tap BACK if you do not want to continue your bolus request.

15.4 Incomplete Temp Rate Alert

What will I see on the Screen?



What does it mean?

You started to set up a temp rate but did not complete the request within 90 seconds.

How will the System notify me?

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

Will the System re-notify me?

Yes, every 5 minutes until acknowledged.

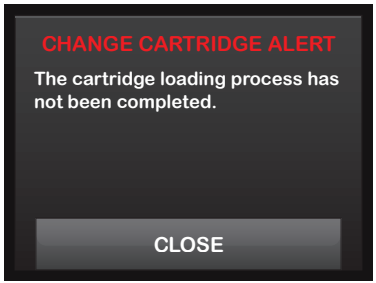
How should I respond?

Tap CLOSE. The Temp Rate screen will appear. Continue setting up your temp rate, or tap BACK if you do not want to continue setting up your temp rate.

15.5 Incomplete Load Sequence Alerts

Incomplete Cartridge Change Alert

What will I see on the Screen?



What does it mean?

You selected Change Cartridge from the Load menu but did not complete the process within 3 minutes.

How will the System notify me?

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

Will the System re-notify me?

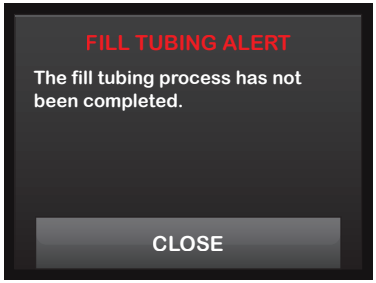
Yes, every 5 minutes until acknowledged.

How should I respond?

Tap CLOSE. Complete the cartridge change process.

Incomplete Fill Tubing Alert

What will I see on the Screen?



What does it mean?

You selected Fill Tubing from the Load menu but did not complete the process within 3 minutes.

How will the System notify me?

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

Will the System re-notify me?

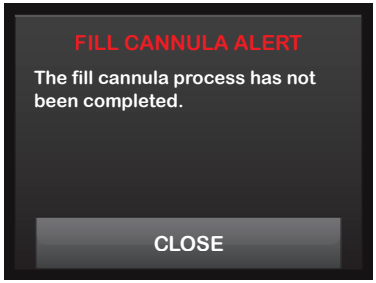
Yes, every 5 minutes until acknowledged.

How should I respond?

Tap CLOSE. Complete the fill tubing process.

Incomplete Fill Cannula Alert

What will I see on the Screen?



What does it mean?

You selected Fill Cannula from the Load menu but did not complete the process within 3 minutes.

How will the System notify me?

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

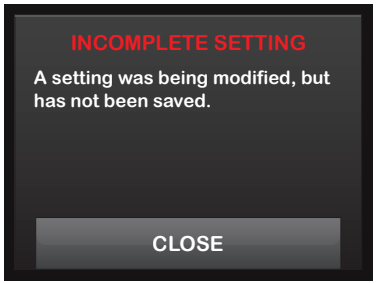
Will the System re-notify me?

Yes, every 5 minutes until acknowledged.

How should I respond?

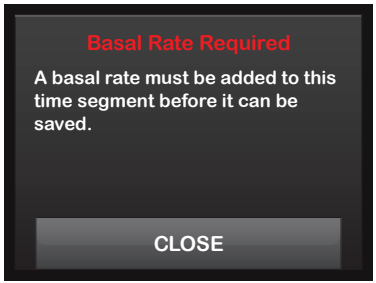
Tap CLOSE. Complete the cannula fill process.

15.6 Incomplete Setting Alert

What will I see on the Screen?	What does it mean?
	You started to set up a new Personal Profile but did not save or complete the programming within 5 minutes.
	How will the System notify me? 2 sequences of 3 notes or 2 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the System re-notify me? Yes, every 5 minutes until acknowledged.
	How should I respond? Tap CLOSE. Complete programming the Personal Profile.

15.7 Basal Rate Required Alert

What will I see on the Screen?



What does it mean?

You did not enter a basal rate in a time segment in Personal Profiles. A basal rate must be entered in each time segment (rate can be 0 u/hr).

How will the System notify me?

Prompt screen only.

Will the System re-notify me?

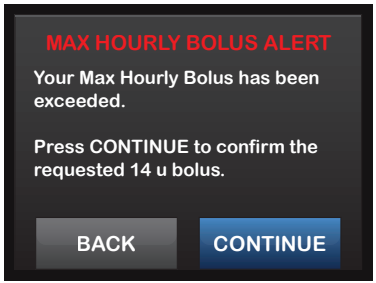
No. A basal rate must be entered to save the time segment.

How should I respond?

Tap CLOSE. Enter a basal rate in the time segment.

15.8 Max Hourly Bolus Alert

What will I see on the Screen?



What does it mean?

In the previous 60 minutes, you requested total bolus delivery that is more than 1.5 times your Max Bolus setting.

How will the System notify me?

Prompt screen only.

Will the System re-notify me?

No. You must tap BACK or CONTINUE to deliver the bolus.

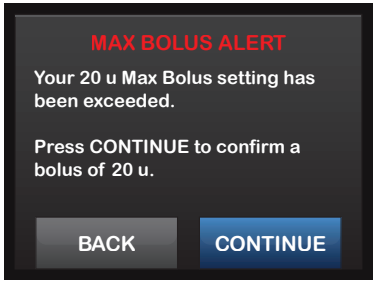
How should I respond?

Tap BACK to return to the Bolus screen and adjust the bolus delivery amount.
Tap CONTINUE to deliver the bolus.

15.9 Max Bolus Alerts

Max Bolus Alert 1

What will I see on the Screen?



What does it mean?

You requested a bolus larger than the Max Bolus setting in your active Personal Profile.

How will the System notify me?

Prompt screen only.

Will the System re-notify me?

No. You must tap BACK or CONTINUE to deliver the bolus.

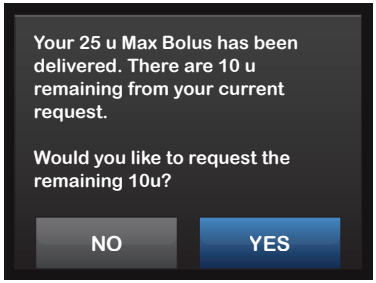
How should I respond?

Tap BACK to return to the Bolus screen and adjust the bolus delivery amount, or tap CONTINUE to deliver the amount of your Max Bolus setting.

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

Max Bolus Alert 2

What will I see on the Screen?



What does it mean?

Your Max Bolus is set to 25 units and you requested a bolus larger than 25 units.

How will the System notify me?

Prompt screen only.

Will the System re-notify me?

No. You must tap NO or YES to deliver the remaining amount of the bolus request.

How should I respond?

Before responding to this Alert, always consider if your bolus insulin needs have changed since you requested the original bolus.

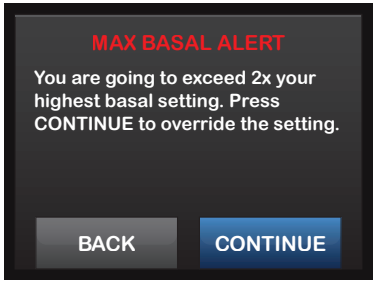
Tap YES to deliver the remaining amount of the bolus request. A confirmation screen will appear.

Tap NO if you do not want to deliver the remaining amount of the bolus request.

15.10 Max Basal Alerts

Max Basal Alert 1

What will I see on the Screen?



What does it mean?

When entering a basal rate or requesting a temp rate, you requested a basal rate more than 2 times the highest basal rate defined in your Personal Profile.

How will the System notify me?

Prompt screen only.

Will the System re-notify me?

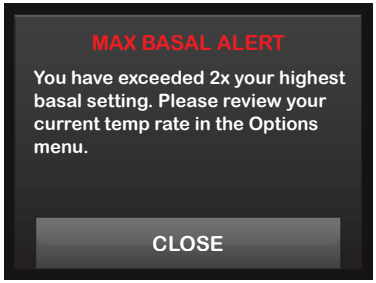
No. You must tap BACK or CONTINUE to move forward.

How should I respond?

Tap BACK to return to the previous screen to adjust the amount, or tap CONTINUE to dismiss the alert and continue with the request.

Max Basal Alert 2

What will I see on the Screen?



What does it mean?

An active temp rate exceeded 2 times your highest basal setting defined in your Personal Profile.

How will the System notify me?

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

Will the System re-notify me?

Yes, every 5 minutes until acknowledged.

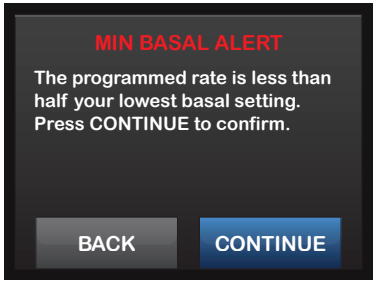
How should I respond?

Tap CLOSE and review your current temp rate in the Options menu.

15.11 Min Basal Alerts

Min Basal Alert 1

What will I see on the Screen?



What does it mean?

When entering a basal rate or requesting a temp rate, you requested a basal rate less than half of the lowest basal rate defined in your Personal Profile.

How will the System notify me?

Prompt screen only.

Will the System re-notify me?

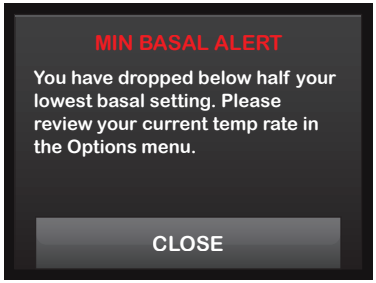
No. You must tap BACK or CONTINUE to move forward.

How should I respond?

Tap BACK to return to the previous screen to adjust the amount, or tap CONTINUE to dismiss the alert and continue with the request.

Min Basal Alert 2

What will I see on the Screen?



What does it mean?

An active temp rate dropped below half of your lowest basal setting defined in your Personal Profile.

How will the System notify me?

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

Will the System re-notify me?

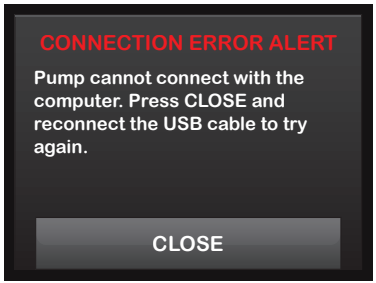
Yes, every 5 minutes until acknowledged.

How should I respond?

Tap CLOSE and review your current temp rate in the Options menu.

15.12 Connection Error Alert

What will I see on the Screen?



What does it mean?

You connected your t:slim X2 Pump to a computer with the USB cable to charge it or upload data to t:connect and a connection could not be made.

How will the System notify me?

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

Will the System re-notify me?

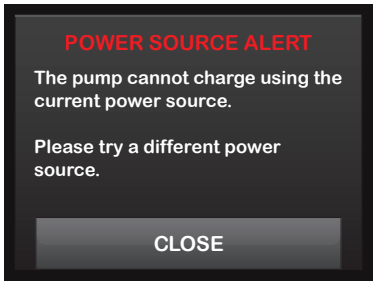
Yes, every 5 minutes until acknowledged.

How should I respond?

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

15.13 Power Source Alert

What will I see on the Screen?



What does it mean?

You connected your t:slim X2 Pump to a power source that does not have enough power to charge the pump.

How will the System notify me?

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

Will the System re-notify me?

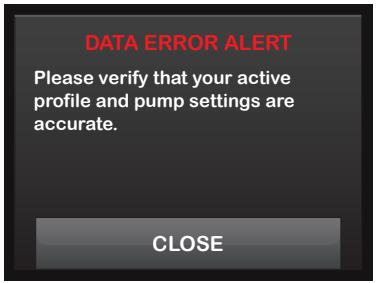
Yes, every 5 minutes until acknowledged.

How should I respond?

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

15.14 Data Error Alert

What will I see on the Screen?



What does it mean?

Your t:slim X2 Pump encountered a condition that could potentially result in a loss of data.

How will the System notify me?

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

Will the System re-notify me?

Yes, every 5 minutes until acknowledged.

How should I respond?

Tap CLOSE. Check your Personal Profiles and pump settings to verify that they are accurate (refer to Chapter 6.4).

Chapter 16

t:slim X2 Pump Alarms

⚠ PRECAUTION

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

Your t:slim X2 Pump lets you know important information about the System with Reminders, Alerts, and Alarms. Reminders are displayed to notify you of an option that you have set (for example, a reminder to check you BG after a bolus). Alerts display automatically to notify you about safety conditions that you need to know (for example, an alert that your insulin level is low). Alarms display automatically to let you know of an actual or potential stopping of insulin delivery (for example, an alarm that the insulin cartridge is empty). Pay special attention to Alarms.

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

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

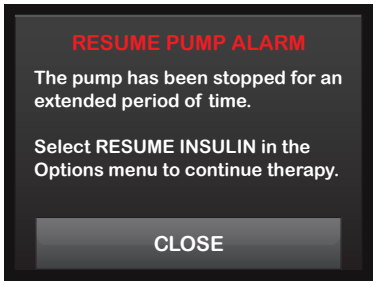
Alarms notify you with 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume. If not acknowledged, alarms escalate to highest volume and vibe. Alarms repeat regularly until the condition that caused the alarm is corrected.

NOTE: CGM Alerts and Errors

There is an additional list of Alerts and Errors related to CGM use in Chapter 26.

16.1 Resume Pump Alarm

What will I see on the Screen?



What does it mean?

You tapped STOP INSULIN in the Options menu and insulin delivery has been stopped for more than 15 minutes.

How will the System notify me?

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

Will the System re-notify me?

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

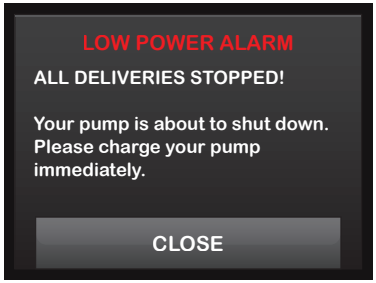
How should I respond?

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

16.2 Low Power Alarms

Low Power Alarm 1

What will I see on the Screen?



What does it mean?

Your t:slim X2 Pump detected a power level of 1% or less remaining and all deliveries have stopped.

How will the System notify me?

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

Will the System re-notify me?

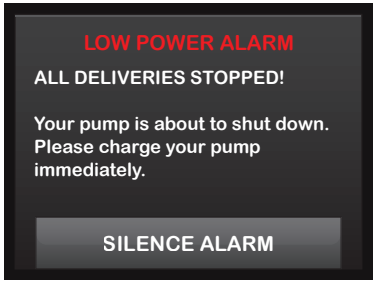
Yes, the System will re-notify you every 3 minutes until no power remains and the pump shuts down.

How should I respond?

Tap CLOSE. Charge your pump immediately to resume insulin delivery.

Low Power Alarm 2

What will I see on the Screen?



What does it mean?

Your t:slim X2 Pump detected a voltage level too low to ensure normal performance and all deliveries have stopped.

How will the System notify me?

A series of rapid beeps at maximum volume for at least 20 seconds before the System shuts down.

Will the System re-notify me?

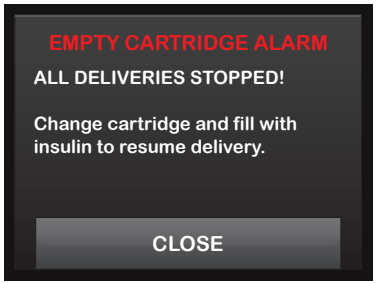
The pump will power back on once it has been plugged into a charging source and has reached an adequate level of charge.

How should I respond?

Tap SILENCE ALARM. Charge your pump immediately to resume insulin delivery.

16.3 Empty Cartridge Alarm

What will I see on the Screen?



What does it mean?

Your t:slim X2 Pump detected that the cartridge is empty and all deliveries have stopped.

How will the System notify me?

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

Will the System re-notify me?

Yes. The system will re-notify you every 3 minutes until you change the cartridge.

How should I respond?

Tap CLOSE. Change your cartridge immediately by tapping OPTIONS from the Home Screen, then Load and follow the instructions in Chapter 5.3.

16.4 Cartridge Error Alarm

What will I see on the Screen?

What does it mean?

Your t:slim X2 Pump detected that the cartridge could not be used and all deliveries have stopped. This can be caused by cartridge defect, not following the proper procedure to load the cartridge, or over filling the cartridge (with more than 300 units of insulin).

How will the System notify me?

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

Will the System re-notify me?

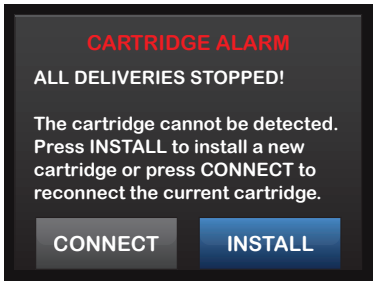
Yes. The system will re-notify you every 3 minutes until you change the cartridge.

How should I respond?

Tap CLOSE. Change your cartridge immediately by tapping OPTIONS from the Home Screen, then Load and follow the instructions in Chapter 5.3.

16.5 Cartridge Removal Alarm

What will I see on the Screen?



What does it mean?

Your t:slim X2 Pump detected that the cartridge has been removed and all deliveries have stopped.

How will the System notify me?

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

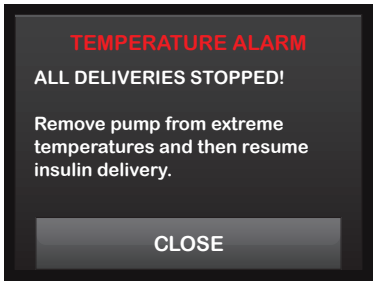
Will the System re-notify me?

Yes. The system will re-notify you every 3 minutes until you reconnect the current cartridge or change the cartridge.

How should I respond?

Tap CONNECT to reattach the current cartridge. Tap INSTALL to load a new cartridge.

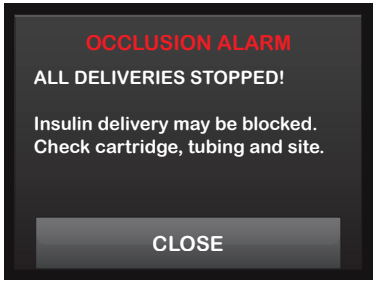
16.6 Temperature Alarm

What will I see on the Screen?	What does it mean?
	Your t:slim X2 Pump detected an internal temperature below 35˚F (2˚C) or above 113˚F (45˚C) or a battery temperature below 35˚F (2˚C) or above 125˚F (52˚C) and all deliveries have stopped.
	How will the System notify me? 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the System re-notify me? Yes. The system will re-notify you every 3 minutes until a temperature in the operating range is detected.
	How should I respond? Tap CLOSE. Remove the pump from the extreme temperature and then resume insulin delivery.

16.7 Occlusion Alarms

Occlusion Alarm 1

What will I see on the Screen?



What does it mean?

Your t:slim X2 Pump detected that insulin delivery is blocked and all deliveries have stopped.

How will the System notify me?

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

Will the System re-notify me?

Yes. The System will re-notify you every 3 minutes until you resume insulin delivery.

How should I respond?

Tap CLOSE. Check the cartridge, tubing, and infusion site for any sign of damage or blockage and correct the condition.

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

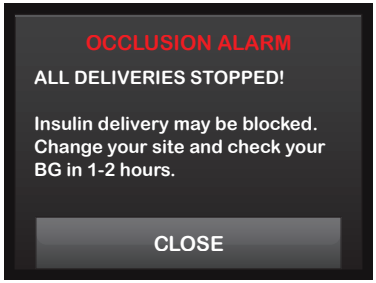
** See Section 30.4 for more information on how long it can take the system to detect an occlusion.*

NOTE: Occlusion During Bolus

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

What will I see on the Screen?



What does it mean?

Your t:slim X2 Pump detected a second occlusion alarm shortly after the first occlusion alarm and all deliveries have stopped.

How will the System notify me?

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

Will the System re-notify me?

Yes. The System will re-notify you every 3 minutes until you resume insulin delivery.

How should I respond?

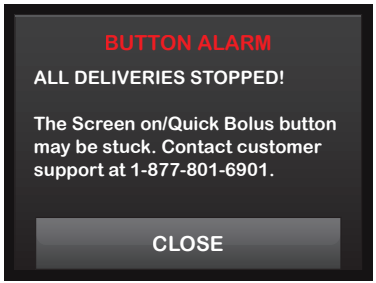
Tap CLOSE. Change the cartridge, tubing, and infusion site to ensure proper delivery of insulin. Resume insulin after changing the cartridge, tubing, and infusion site.

NOTE: Occlusion During Bolus

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

16.8 Screen On/Quick Bolus Button Alarm

What will I see on the Screen?



What does it mean?

The Screen On/Quick Bolus Button (on the top of your t:slim X2 Pump) is stuck or not functioning properly and all deliveries have stopped.

How will the System notify me?

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

Will the System re-notify me?

Yes. The System will re-notify you every 3 minutes until the condition is corrected.

How should I respond?

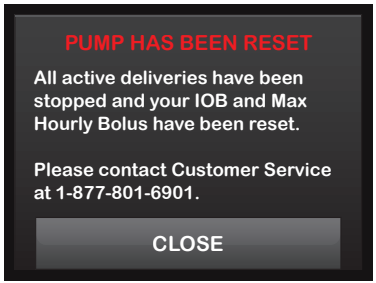
Tap **CLOSE**. Contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

16.9 Altitude Alarm

What will I see on the Screen?	What does it mean?
	Your t:slim X2 Pump detected a pressure difference between inside the cartridge and the surrounding air within the validated operating range of -1,300 feet to 10,000 feet and all deliveries have stopped.
	How will the System notify me? 3 sequences of 3 notes or 3 vibrations depending on the volume/vibrate setting selected in Pump Volume.
	Will the System re-notify me? Yes. The System will re-notify you every 3 minutes until the condition is corrected.
	How should I respond? Tap CLOSE. Remove the cartridge from the pump (this will allow the cartridge to fully vent) and then reconnect the cartridge.

16.10 Reset Alarm

What will I see on the Screen?



What does it mean?

Your t:slim X2 Pump detected that one if its micro-processors experienced a reset and all deliveries have been stopped.

How will the System notify me?

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

Will the System re-notify me?

Yes. The System will re-notify you every 3 minutes until you tap CLOSE.

How should I respond?

Tap **CLOSE**. Contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

Chapter 17

t:slim X2 Pump Malfunction

17.1 Malfunction

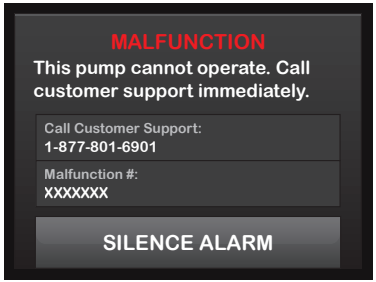
If your t:slim X2 Pump detects a system error, the MALFUNCTION screen appears and all deliveries are stopped. Contact Tandem Diabetes Care Customer Technical Support.

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

⚠ PRECAUTION

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

What will I see on the Screen?



What does it mean?

Your t:slim X2 Pump detected a system error and all deliveries have been stopped.

How will the System notify me?

3 sequences of 3 notes at highest volume and 3 vibrations.

Will the System re-notify me?

Yes, the System will notify you every 3 minutes until you acknowledge the malfunction by tapping SILENCE ALARM.

How should I respond?

Write down the Malfunction Code number that appears on the screen.

Tap SILENCE ALARM. The MALFUNCTION screen will remain on the pump even though the alarm is silenced.

Contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901 and provide the Malfunction Code number that you wrote down.

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Section 5

Getting Started with Your CGM System

Chapter 18

Dexcom G5 Mobile CGM Overview

18.1 CGM System Overview

This section of the User Guide covers instructions for using Dexcom G5 Mobile Continuous Glucose Monitoring (CGM) with your t:slim X2 Pump. Use of Dexcom G5 Mobile CGM is optional and when used, allows readings from your sensor to be displayed on your t:slim X2 Pump screen. Dexcom G5 Mobile CGM uses two parts, a sensor and a transmitter. You will also need a commercially available blood glucose meter to use with your System.

The Dexcom G5 Mobile Sensor is a disposable device that is inserted under the skin to continuously monitor glucose levels for up to 7 days. The Dexcom G5 Mobile Transmitter connects to the sensor pod and wirelessly sends readings to the pump display every 5 minutes. The display shows sensor glucose readings, trend graph, direction and rate of change arrows. You can also program your pump to alert you when your CGM readings are above or below a given level, or are rising or falling quickly.

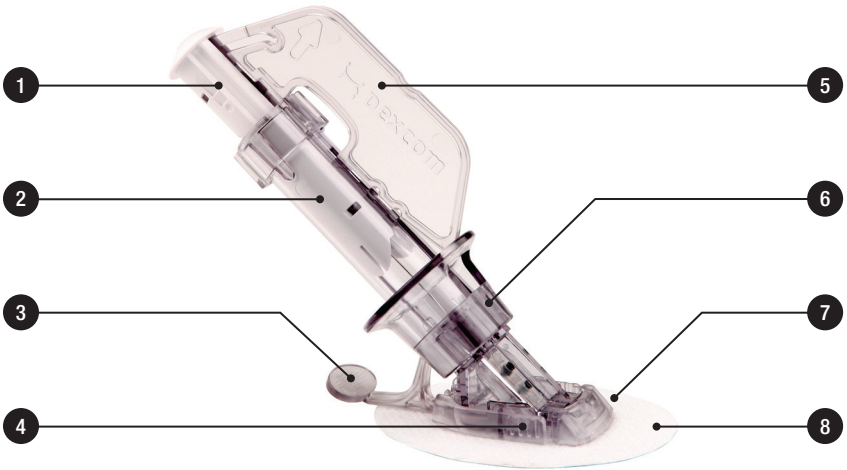
Unlike the readings from a standard blood glucose meter, CGM readings allow you to view trends in real time, as well as capture information when you would otherwise be unable to check your blood sugar, such as while you are asleep. This information can be useful for you and your healthcare provider when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

18.2 Sensor Overview

For your safety, the sensor is packaged in a sterile sealed pack. When you first open the pack, your sensor looks like one item; however, it's actually three: sensor applicator, sensor pod, and sensor wire.

The applicator helps you insert the sensor wire inside the sensor pod under your skin. After inserting the sensor wire, remove the applicator. The sensor wire stays in the sensor pod with the pod attached to your skin by adhesive; the sensor wire is made of silver and platinum with polymer membranes. Once inserted, the thin and flexible wire measures your glucose levels in the fluid between your cells (interstitial fluid) for up to seven days.

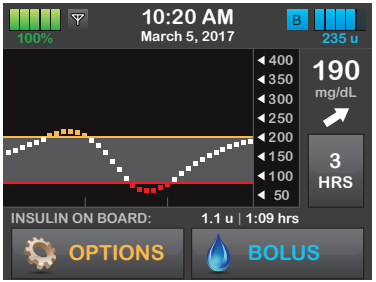
1. Plunger
2. Applicator Barrel
3. Transmitter Latch
4. Release Tab
5. Safety Lock
6. Collar
7. Sensor Pod
8. Adhesive Patch



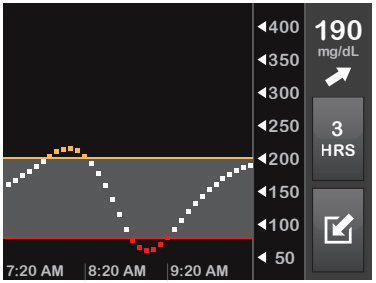
18.3 Receiver (t:slim X2 Pump) Overview

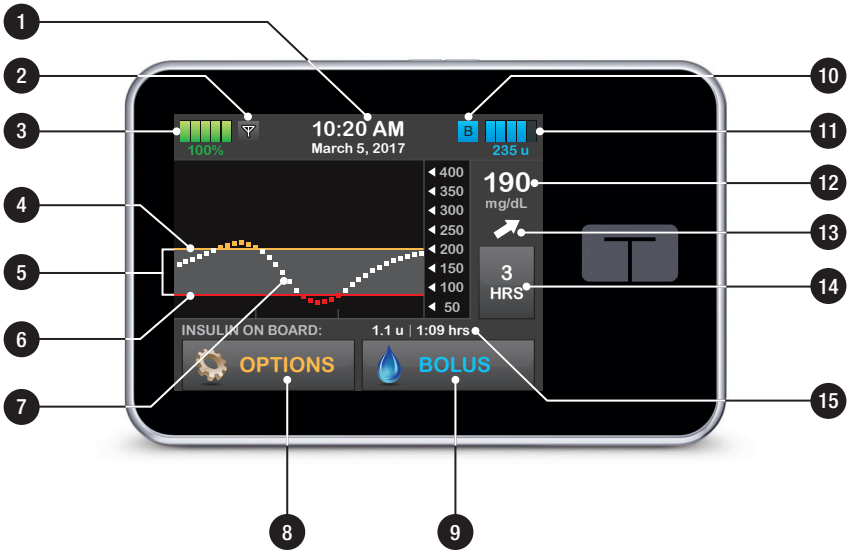
1. **Time and Date Display:** Displays the current time and date.
2. **Antenna:** Indicates communication status between pump and transmitter.
3. **Battery Level:** Displays the level of battery power remaining. When connected for charging, the charging icon (lightning bolt) will display.
4. **High Glucose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

To view CGM information on the full screen:
From the Home Screen tap anywhere on the CGM trend graph.



Tap the “minimize” icon to return to the Home Screen.

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100
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190
mg/dL
3
HRS
INSULIN ON BOARD:
1.1 u | 1:09 hrs
OPTIONS
BOLUS

18.4 Transmitter Overview

Snapping into the sensor pod, the transmitter wirelessly sends your glucose information to your display devices—receiver and/or smart device. If you have a new transmitter, only open the package when you are ready to use it.

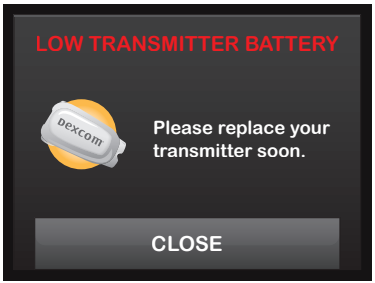
Transmitter features:

- Reusable
  - » Do not discard after sensor session.
  - » Only for you, don't share transmitter.
- Water resistant
- Can transmit data to your display devices for up to 20 feet
  - » Range is less if you are in or under water.
- Battery lasts approximately 90 days
  - » Receiver or smart devices prompts you when battery is running low.
- Serial number is on the back

⚠ PRECAUTION

AVOID separating the transmitter and pump by more than 20 feet. The transmission range from the transmitter to the pump is up to 20 feet without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and pump are farther than 20 feet 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 blood glucose) or hyperglycemia (high blood glucose) events.

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



Chapter 19

CGM Settings

19.1 Entering Your Transmitter ID

Bluetooth™ Low Energy (BLE) is a type of wireless communication used in cell phones and many other devices. Your t:slim X2 Pump and Dexcom G5 Mobile Transmitter wirelessly pair together using BLE communication. This allows the pump and transmitter to communicate securely and only with each other.

To activate the BLE communication, you need to enter the unique transmitter ID into your pump. Once the transmitter ID has been entered into your pump, the two devices can be paired, allowing your sensor glucose readings to be displayed on your t:slim X2 Pump.

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

1. Remove the transmitter from its packaging. Wait 10 minutes for the transmitter to turn on.
2. From the Home Screen, tap **OPTIONS**.
3. Tap **My CGM**.
4. Tap **CGM Settings**.
5. Tap **Transmitter ID**.
6. Using the onscreen keypad, enter the unique transmitter ID.

   The transmitter ID can be found on the bottom (flat surface) of your transmitter.

   The letters I, O, V, and Z are not used in transmitter IDs and should not be entered. If one of these letters is entered, you will be notified that an invalid ID was entered and prompted to enter a valid ID.
7. Tap **NEXT**.
8. To make sure that the correct transmitter ID is entered, you will be prompted to enter it a second time.
9. Repeat step 6 above, then tap **DONE**.

   If the transmitter IDs you entered do not match you will be prompted to start the process again.
10. Once matching values have been entered, you will be returned to the CGM Settings screen and the transmitter ID you entered will be highlighted in yellow.

    Tap **SAVE**.

19.2 Setting CGM Volume

You can set the sound pattern and volume for CGM alerts and prompts to meet your individual needs. Reminders, alerts, and alarms for insulin delivery functions are separate from alerts and errors for CGM functions and do not follow the same pattern and volume. To set your Pump Volume see Chapter 11.1.

CGM Volume options:

Vibrate
When you want to silence CGM volume and be alerted by vibration. The only exception to this is the fixed low alert at 55 mg/dL, which alerts you as a vibration first, followed by beeps 5 minutes later if not confirmed.

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

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

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

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

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

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

1. The first alert is vibrate only.
2. If the alert is not confirmed in 5 minutes, the system vibrates and beeps.
3. If the alert is not confirmed in 5 more minutes, the system vibrates and beeps louder. This continues at the same volume every 5 minutes until confirmed.

For the HypoRepeat Option Only:

If the alert is confirmed and your sensor glucose readings continue to be at or below 55 mg/dL your system repeats the alert sequence in 30 minutes.

CGM Volume Details

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

To Select Your CGM Volume:

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My CGM**.
3. Tap **CGM Settings**.
4. Tap **CGM Volume** to change your setting.

   The default setting is Normal.
5. Tap **Vibrate**, **Soft**, **Normal** or **HypoRepeat** to select.

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

6. Tap **SAVE**.

19.3 CGM Info

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

- Firmware Revision
- Hardware Revision

You can view this information at any time.

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My CGM**.
3. Tap **CGM Settings**.
4. Tap **CGM Info**.

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Chapter 20

Setting CGM Alerts

Setting Your CGM Alerts
You can create personal settings for how and when you want the System to tell you what is happening. The High and Low Alerts tell you when your sensor glucose readings are outside your target glucose range. Rise and Fall (rate of change) Alerts let you know when your glucose levels are changing fast. The System also has a 55 mg/dL Fixed Low Alert that cannot be changed or turned off. This safety feature tells you your glucose level may be dangerously low.

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

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

20.1 Setting Your High Glucose Alert and Repeat Feature

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

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

   NOTE: Turning the Alert Off
   To turn off the High Alert, tap OFF/ON. The screen will indicate that OFF is selected.

7. Using the onscreen keypad, enter the value above which you want to be notified. It can be set between 120 and 400 mg/dL in 1 mg/dL increments.

8. Tap **DONE**.

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

To Set Up the Repeat Feature:

9. Tap **Repeat**.

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

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

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

11. Tap **SAVE**.

20.2 Setting Your Low Glucose Alert and Repeat Feature

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

2. Tap **My CGM**.

3. Tap **CGM Alerts**.

4. Tap **High and Low**.

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

6. Tap **Alert Me Below**.

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

   NOTE: Turning the Alert Off
   To turn off the Low Alert, tap OFF/ON. The screen will indicate that OFF is selected.

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

8. Tap **DONE**.

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

To Set Up the Repeat Feature:

9. Tap **Repeat**.

10. To select the repeat time, tap the time you want the alert to sound again. For instance, if you select 1 hr, the alert will sound every hour as long as your sensor glucose reading remains below the Low Alert Value.

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

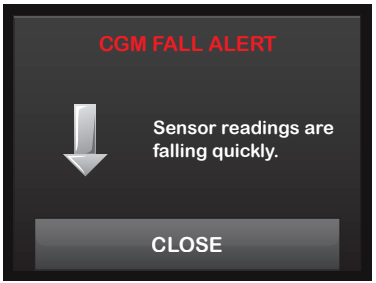
▷ Once a value is selected, the pump will return to the previous screen.

11. Tap **SAVE**.

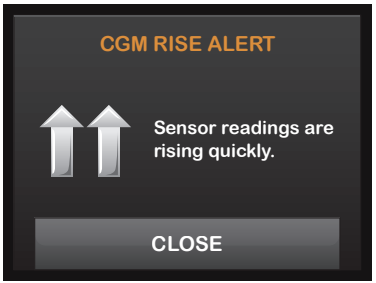
20.3 Rate Alerts

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

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



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



20.4 Setting Your Rise Alert

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

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

   NOTE: Turning the Alert Off
   To turn off the Rise Alert, tap OFF/ON.
7. Tap **2 mg/dL/min** to select.

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

8. Tap **SAVE**.

20.5 Setting Your Fall Alert

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

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

   NOTE: Turning the Alert Off
   To turn off the Fall Alert, tap OFF/ON.
7. Tap **2 mg/dL/min** to select

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

8. Tap **SAVE**.

20.6 Setting Your Out of Range Alert

The range from the transmitter to the pump is up to 20 feet without obstruction.

The Out of Range Alert lets you know when your transmitter and pump are not communicating with each other. Keep the transmitter and the pump within 20 feet of each other without obstruction. When the transmitter and pump are not communicating, you will not get sensor glucose readings or alerts. The default value is off; 30 minutes if on.

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

To Set Your Out of Range Alert:

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My CGM**.
3. Tap **CGM Alerts**.
4. Tap **Out of Range**.

   The default value is off; 30 minutes if on.
5. To select the default of 30 min, tap **SAVE**.

   To change the time, tap **Alert After**.
6. Using the onscreen keypad, enter the time after which you want to be alerted (between 20 minutes and 3 hours and 20 minutes) then tap **DONE**.
7. Tap **SAVE**.

Chapter 21

Inserting the Sensor and Placing the Transmitter

Inserting the Sensor

To use continuous glucose monitoring (CGM) with your t:slim X2 Pump, you need a Dexcom G5 Mobile Sensor and Transmitter. You also need a blood glucose meter and test strips for calibration. After insertion and calibration, the sensor continuously measures and displays your sensor glucose readings for up to 7 days. The following sections will show you how to insert the sensor, attach the transmitter, and start a new continuous glucose monitoring session.

⚠ WARNING

DO NOT ignore sensor fractures. Sensors may fracture on rare occasions. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken sensor, please report this to Tandem Diabetes Care Customer Technical Support at 1-877-801-6901. For patients undergoing an MRI with a retained wire broken off from a Dexcom G5 Mobile Sensor, in-vitro MRI testing did not detect any safety hazards. There was no significant migration or heating of the wire and imaging artifacts were limited to the area around the wire.

21.1 Before You Start

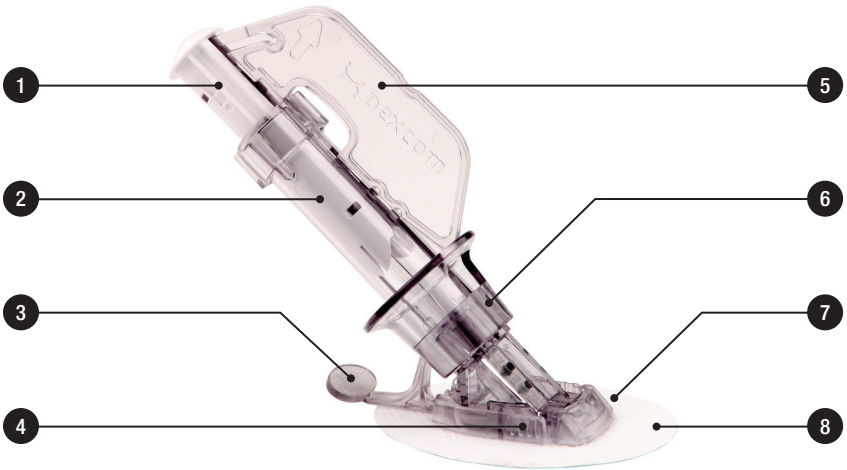
- Wash your hands thoroughly.
- Make sure that the date and time on your t:slim X2 Pump are correct.
- Make sure that the correct transmitter ID has been entered into your pump (see Section 19.1). You only need to enter a new transmitter ID if the pump or transmitter have been replaced.
- Check the expiration date on the sensor package label. The format is YYYY-MM-DD. Insert sensors on or before the end of the expiration date.
- Follow your blood glucose meter manufacturer's instructions to make sure you are getting accurate blood glucose values for calibration and treatment decisions (check code and use control solution).
- Wipe the bottom of the transmitter with a damp cloth or alcohol wipe. Place the transmitter on a clean, dry cloth to dry before you start a new sensor session.
- Make sure that the time on your pump and your blood glucose meter are the same.
- Closely inspect pouch, check it has not been damaged. If yes, do not use
- Remove sensor applicator from pouch.
- Closely inspect sensor, check it has not been damaged. If yes, do not use.
- Keep sensor packaging until sensor session is complete.

⚠ WARNING

STORE the sensor at temperatures between 36°F and 77°F for the length of the sensor's life. You may store the sensor in the refrigerator if it is within this temperature range. The sensor should not be stored in a freezer. Storing the sensor improperly might cause the sensor glucose readings to be inaccurate, and you might miss severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

Review the CGM Sensor Applicator Picture Before Using a New Sensor

1. Plunger
2. Applicator Barrel
3. Transmitter Latch
4. Release Tab
5. Safety Lock
6. Collar
7. Sensor Pod
8. Adhesive Patch



21.2 Removing the Sensor From its Packaging

⚠ PRECAUTION

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

- Wash your hands thoroughly, and dry them.
- Carefully remove the sensor from its packaging. Look closely at the sensor to make sure it is not damaged.
- The applicator is for single use and is disposable.
- The safety lock prevents you from releasing the needle accidentally before you are ready.

21.3 Choosing an Insertion Site

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

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

For adults (ages 18+) only sites on the belly are approved for sensor insertion. For children (ages 6–17) both sites on the belly and upper buttocks are approved for sensor insertion.

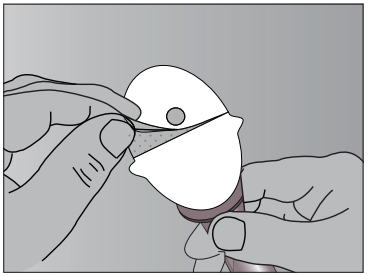
No other sensor insertion sites have been tested and it is not known how well the sensor will work in other sites. The best areas to insert your sensor are usually flat, “pinchable,” and free from where rubbing can occur, such as along the waist band or seat belt strap.

- Choose an area at least 3 inches from your insulin pump infusion set or injection site.
- You may need to shave the area where you plan to put the sensor so the adhesive patch sticks securely.
- Make sure there are no traces of lotions, perfumes, or medications on the area.

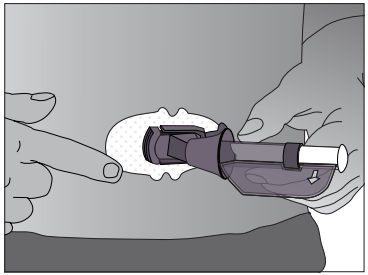
⚠ PRECAUTION
AVOID using the same spot repeatedly for sensor insertion. Rotate your sensor placement sites, and do not use the same site for 2 sensor sessions in a row. Using the same site might cause scarring or skin irritation.

21.4 Placing the CGM Sensor

1. Clean your skin at the sensor placement site with an alcohol wipe. Make sure the area is clean and completely dry before you insert the sensor.
2. Remove the adhesive backing from the sensor pod one half at a time, using the white tabs on the backing. Hold the sensor by the applicator barrel, and try not to touch the sticky adhesive patch.

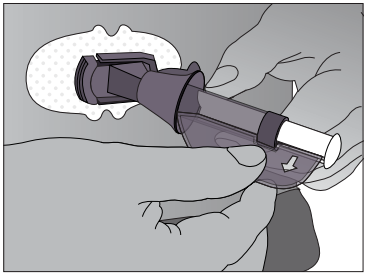


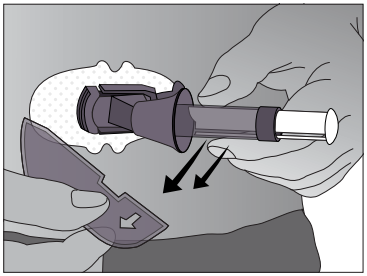
3. Place the sensor horizontally (side to side) as shown in the picture. Do not place the sensor vertically (up and down) on your skin.



4. Move your fingers around the adhesive patch to remove any wrinkles and secure the tape firmly to your skin.

5. Hold the applicator and pull the safety lock straight out away from the applicator, in the direction of the arrows in the picture.





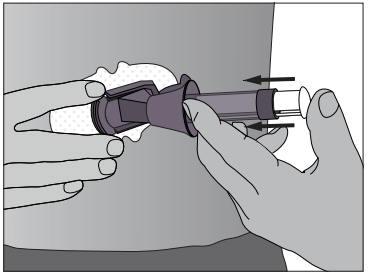
6. Save the safety lock to help you remove the transmitter at the end of your sensor session. The safety lock can be used for transmitter removal but is not required.

21.5 Inserting the CGM Sensor

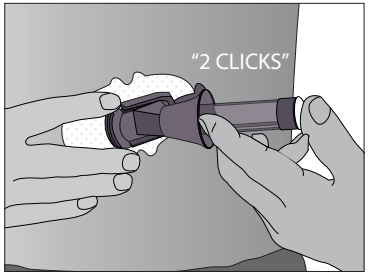
After you place the applicator on your skin and remove the safety lock, you are ready to insert the sensor. Follow the steps below to insert your sensor.

1. Place the fingers of one hand at the edge of the white adhesive (at the opposite side of the sensor from the transmitter latch). You may pinch up on the skin using this hand. Do not pinch up in the middle section of the plastic base.

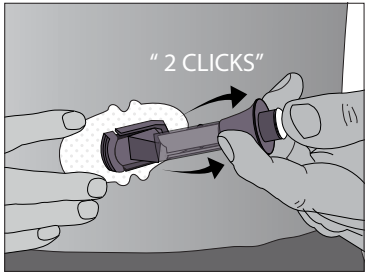
2. While still pinching, use your other hand to place two fingers above the collar on the applicator barrel so they are resting above the collar.



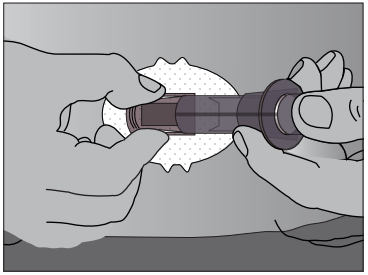
3. Place your thumb on the white plunger. Push the plunger down completely, making sure it is flush against the applicator barrel. You should hear 2 clicks. This inserts the needle and sensor under your skin. **When you are pushing down on the plunger, do not pull back on the collar.**



4. Keep pinching up on your skin with one hand. Place two fingers under the collar. Keep your thumb lightly on top of the white plunger, and pull the collar back towards your thumb until you hear 2 clicks or cannot pull back any more. This leaves the sensor under your skin and removes the needle from your body.



5. Squeeze the center of the ribbed release tabs on the sides of the sensor pod to remove the applicator barrel. Only the sensor pod will be left on your body.



» Make sure the transmitter latch is down (against your body) before squeezing the tabs to remove the applicator barrel.

» Squeeze the center of the ribbed part of the release tabs.

» While squeezing the tabs, rock the applicator barrel forward and out away from your body.

If you have any problems with insertion, save the sensor and applicator and contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

21.6 Attaching the CGM Transmitter

The CGM transmitter wirelessly sends your sensor glucose readings to your t:slim X2 Pump. You must snap the transmitter into the sensor pod after you insert your sensor. Follow the steps below to attach your transmitter.

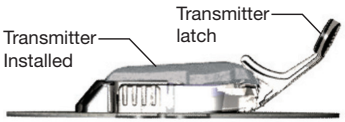
1. Wipe and dry the bottom of the transmitter with a damp cloth or an alcohol wipe before every use.

   » Do not touch the metal circles on the bottom of the transmitter with your skin.

   » Do not scratch the bottom of the transmitter as scratches may compromise the waterproof seal.

2. Place the transmitter in the sensor pod with the flat side down, and the narrower side away from the transmitter latch.

3. Snap in the transmitter:



   » You may want to pinch up on your skin at the front edge of the white adhesive with one hand.

   » Place one finger on the transmitter to keep it in place.

   » With your other hand, pull the latch up and forward, over the transmitter to snap it into place. The transmitter should lie flat in the sensor pod.

   Make sure you hear 2 clicks when you snap the transmitter in place. If it is not fully snapped in, this may lead to a poor connection, allowing fluid to get under the transmitter. This can lead to inaccurate sensor glucose readings.

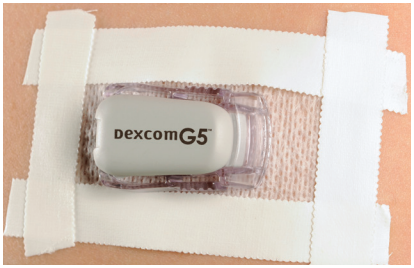
   » Release your pinch on the adhesive edge at this time.

» Make sure the transmitter is secure by sliding your fingers under each long side of the sensor pod and pressing down on the transmitter with your thumb of the same hand, like you are pinching it.

4. **Remove the transmitter latch by holding the sides of your sensor pod with one hand and quickly twisting off the latch away from your body with your other hand.**

5. **Do not remove the transmitter from the sensor pod while the pod is attached to your skin**

The sensor pod should stay on your skin using its own adhesive. But, if the patch is peeling up, you can use medical tape for extra support. If you use tape, only tape over the white adhesive patch on all sides for even support. Do not tape over the transmitter or any of the plastic parts of the sensor pod. Do not tape under the sensor pod or leave any substance on the skin where you insert the sensor.



Chapter 22

Starting a CGM Sensor Session

22.1 Starting Sensor

Once you have entered your transmitter ID, inserted your sensor, and attached your transmitter, you are ready to start a CGM session. Follow the steps below.

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My CGM**.
3. Tap **START SENSOR**.

   Once you start a sensor session, the START SENSOR option is replaced with STOP SENSOR.
4. Tap **YES** to confirm.
5. The "SENSOR STARTED" screen will appear to let you know your 2-hour sensor startup has begun.
6. Your t:slim X2 Pump will return to the CGM Home Screen with the 3 hour trend graph displayed.
7. Check your t:slim X2 Pump CGM Home Screen 10 minutes after starting your sensor session to make sure your pump and transmitter are communicating. The antenna symbol should be to the right of the battery indicator and should be white.
8. If you see the out of range symbol below the insulin level indicator, and the antenna symbol is greyed out, follow these troubleshooting tips:

   a. Make sure your t:slim X2 Pump and transmitter are within 20 feet of each other without obstruction. Re-check in 10 minutes to see if the out of range symbol is still active.

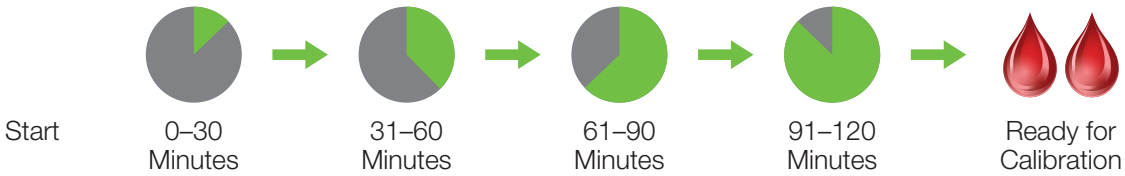
   b. If the pump and transmitter are still not communicating, check the CGM Info screen to make sure the correct transmitter ID is entered.

   c. If the correct transmitter ID is entered and the pump and transmitter are still not communicating, contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

22.2 Sensor Startup Period

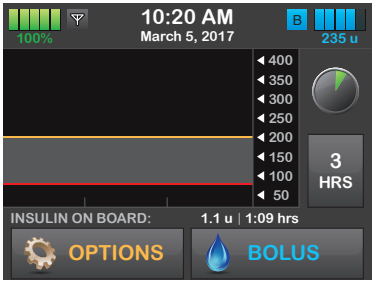
The sensor needs a 2-hour startup period to adjust to being under your skin. You will not get sensor glucose readings or alerts until the 2-hour startup period ends and you complete your first calibrations.

During the startup period, the CGM Home Screen on your t:slim X2 Pump shows a 2-hour countdown symbol in the upper right portion of the screen. The countdown symbol fills in over time to show that you are getting closer to the first calibration time.

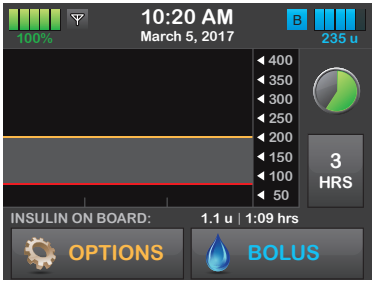


NOTE:
Once your sensor session has completed, you must end the current session before you can start a new session.

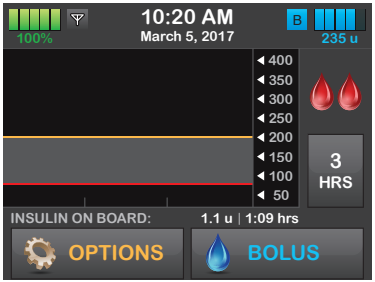
For example, if you started your sensor session 20 minutes ago, you would see this countdown symbol on the CGM Home Screen.



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



At the end of the 2-hour startup period, you will be prompted to enter 2 calibration values and 2 blood drops will appear in the place where the countdown symbol was.



Follow the instructions in the next section to calibrate your sensor.

NOTE:

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

Chapter 23

Calibrating Your CGM System

23.1 Calibration Overview

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

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

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

⚠ CONTRAINDICATION

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

⚠ WARNING

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

⚠ PRECAUTION

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

When calibrating, you must enter your blood glucose values into the pump by hand. You can use any commercially available blood glucose meter. You must calibrate with accurate blood glucose meter values to get accurate sensor glucose readings.

Follow these important instructions when obtaining blood glucose values for calibration:

- Blood glucose values used for calibration must be between 40 to 400 mg/dL and must have been taken within the past 5 minutes.
- Your sensor cannot be calibrated if the glucose value from your meter is less than 40 mg/dL. For safety reasons, if your blood glucose is low, first treat your low blood glucose.
- Make sure a sensor glucose reading shows in the upper right portion of the CGM Home Screen before calibrating.

- Make sure the antenna symbol is visible to the right of the battery indicator on the CGM Home Screen and is active (white, not greyed out) before calibrating.
- Always use the same meter to calibrate that you routinely use to measure your blood glucose. Do not switch your meter in the middle of a sensor session. Blood glucose meter and strip accuracy vary between blood glucose meter brands.
- The accuracy of the blood glucose meter used for calibration may affect the accuracy of sensor glucose readings. Follow your blood glucose meter manufacturer's instructions for blood glucose testing.

23.2 Startup Calibration

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

1. From the Calibrate CGM Screen, Tap **CLOSE**.
2. The CGM Home Screen will appear with two blood drops in the upper right portion of the screen. The two blood drops will stay on the screen until you enter 2 separate blood glucose values to calibrate.
3. Wash and dry your hands, make sure your glucose test strips are not expired and have been stored properly, and make sure your meter is properly coded (if required).
4. Take a blood glucose measurement using your meter. Carefully apply the blood sample to the test strip following your meter manufacturer's instructions.

⚠ PRECAUTION

DO NOT use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration. Alternative site blood glucose values may be different than those taken from a fingerstick blood glucose value and may not represent the timeliest blood glucose value. Use a blood glucose value taken only from a fingerstick for calibration. Alternative site blood glucose values might affect sensor accuracy and result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

5. Tap **OPTIONS**.
6. Tap **My CGM**.
7. Tap **Calibrate CGM**.

8. Using the onscreen keypad, enter the blood glucose value from your meter.

   ⚠ PRECAUTION
   To calibrate the System, DO enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Do not enter sensor glucose readings for calibration. Entering incorrect blood glucose values, blood glucose 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 blood glucose) or hyperglycemia (high blood glucose) events.

9. Tap **DONE**.

10. Tap **YES** to confirm the calibration.

    Tap **NO** if the BG value does not exactly match the reading from your meter. The onscreen keypad will reappear. Enter the exact reading from your meter.

11. The "CALIBRATION ACCEPTED" screen will appear.

    The **My CGM** screen will appear.

12. Tap **Calibrate CGM** to enter your second blood glucose value.

13. The onscreen keypad will appear.

14. Wash and dry your hands, make sure your glucose test strips are not expired and have been stored properly, and make sure your meter is properly coded (if required).

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

16. Follow steps 8–10 to enter your second blood glucose value.

    Carefully apply the blood sample to the test strip following your meter manufacturer's instructions.

17. Follow steps 9–11 to enter your second blood glucose value.

23.3 Calibration Blood Glucose Value and Correction Bolus

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

- If you enter a calibration value that is above your Target BG in Personal Profiles, a message screen will indicate "YOUR BG IS ABOVE TARGET". To add a correction bolus, tap YES. Follow the instructions in Chapter 7.4 to deliver a correction bolus.
- If you enter a calibration value that is below your Target BG in Personal Profiles, a message screen will indicate "YOUR BG IS BELOW TARGET", and other important information will appear on the screen.
- If you enter your Target BG as a calibration value, the pump will return to the CCM Home Screen.

23.4 12 Hour Calibration Update

Calibrate your CGM System at least every 12 hours after your first calibration (2-hour startup calibration) to make sure your sensor glucose readings remain accurate and close to your blood glucose values. You can enter blood glucose values sooner than 12 hours if you want. If you have not entered any blood glucose values in the past 12 hours, the pump will ask you to enter a blood glucose value to update its calibration.

⚠ WARNING

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

2 hours after you start the sensor session, and every 12 hours after that, the "CALIBRATE CGM" screen will appear, letting you know that a blood glucose value from your meter must be entered to calibrate. In addition, a blood drop will appear to the right of the antenna symbol and will remain there until a blood glucose value is entered to calibrate.

1. From the Calibrate CGM Screen, Tap **CLOSE**.

   ⚠ PRECAUTION

   DO NOT use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration. Alternative site blood glucose values may be different than those taken from a fingerstick blood glucose value and may not represent the timeliest blood glucose value. Use a blood glucose value taken only from a fingerstick for calibration. Alternative site blood glucose values might affect sensor accuracy and result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

2. Tap **OPTIONS**.
3. Tap **My CGM**.
4. Tap **Calibrate CGM**.

5. Using the onscreen keypad, enter the blood glucose value from your meter.

   ⚠ PRECAUTION
   To calibrate the System, DO enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Do not enter sensor glucose readings for calibration. Entering incorrect blood glucose values, blood glucose 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 blood glucose) or hyperglycemia (high blood glucose) events.

6. Tap **DONE**.

7. Tap **YES** to confirm the calibration.

   Tap **NO** if the BG value does not exactly match the reading from your meter. The onscreen keypad will appear. Enter the exact reading from your meter.

8. The "CALIBRATION ACCEPTED" screen will appear, followed by the CGM Home Screen or bolus prompt.

23.5 Other Reasons You May Need to Calibrate

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

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

If you see the CALIBRATION ERROR screen, you will be prompted to enter a blood glucose value to calibrate in either 15 minutes or 1 hour, depending on the error.

Chapter 24

Viewing CGM Data on Your t:slim X2 Pump

24.1 Overview

During an active sensor session, CGM readings are sent to your t:slim X2 Pump every 5 minutes. This section teaches you how to view your sensor glucose readings and trend information. The trend graph provides additional information that your blood glucose meter does not. It shows your current glucose value, the direction it is changing and how fast it is changing. The trend graph can also show you where your glucose has been over time.

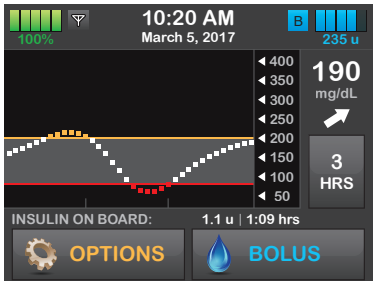
Your blood glucose meter measures glucose in your blood. Your sensor measures glucose from interstitial fluid (the fluid under your skin). Because glucose from different fluids is measured, readings from your blood glucose meter and sensor may not match.

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

⚠ CONTRAINDICATION

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

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



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

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

24.2 CGM Trend Graphs

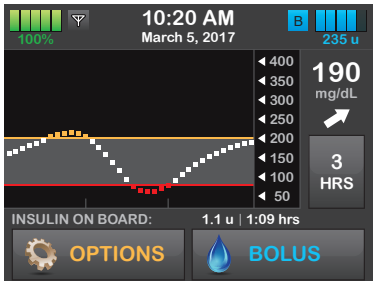
You can view your past sensor glucose trend information on your CGM Home Screen.

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

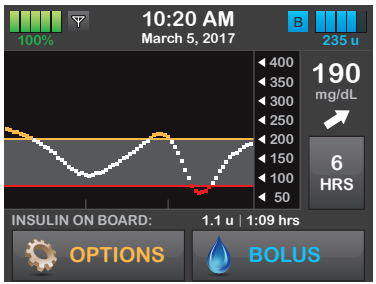
Sensor glucose information is only reported for values between 40 to 400 mg/dL. Your trend graph shows a flat line or dots at 40 or 400 mg/dL when your glucose is outside this range.

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

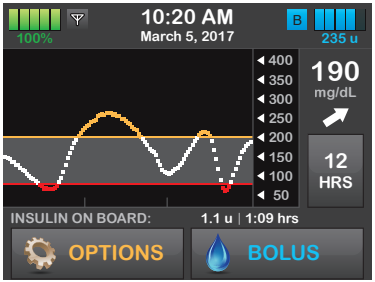
3 Hour Trend Graph (default view) shows you your current glucose reading along with the last 3 hours of sensor glucose readings.



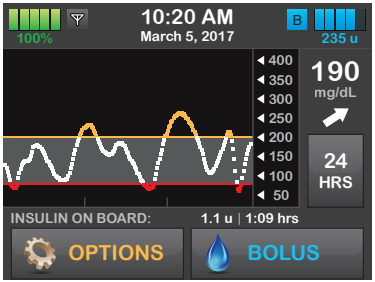
6 Hour Trend Graph shows you your current glucose reading along with the last 6 hours of sensor glucose readings.



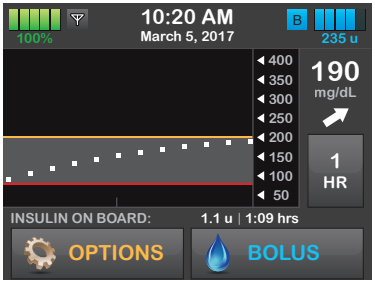
12 Hour Trend Graph shows you your current glucose reading along with the last 12 hours of sensor glucose readings.



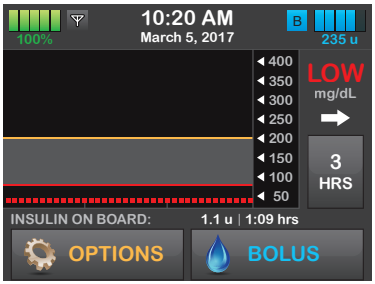
24 Hour Trend Graph shows you your current glucose reading along with the last 24 hours of sensor glucose readings.



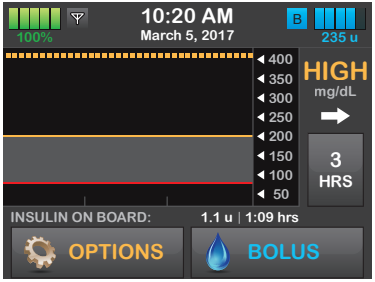
1 Hour Trend Graph shows you your current glucose reading along with the last 1 hour of sensor glucose readings.



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



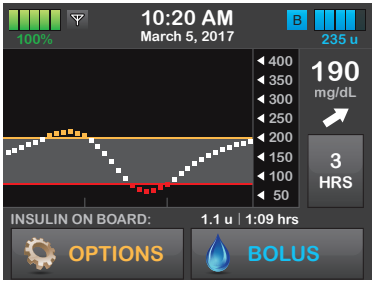
HIGH shows when your most recent sensor glucose reading is greater than 400 mg/dL.



24.3 Rate of Change Arrows

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

The trend arrows show below your current sensor glucose reading.



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

If there are missed communications between the sensor and your t:slim X2 Pump during the last 15–20 minutes due to being out of range or due to an error condition, an arrow may not display. If the trend arrow is missing, and you are concerned that your blood glucose level may be rising or falling, take a blood glucose measurement using your blood glucose meter.

⚠ WARNING

DO NOT ignore symptoms of high and low glucose. If your sensor glucose alerts and readings do not match your symptoms, measure your blood glucose with a blood glucose meter even if your sensor is not reading in the high or low range. Solely relying on the sensor glucose alerts and readings for treatment decisions could result in you missing severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) events.

The table below shows the different trend arrows your receiver displays:

→	**Constant:** Your glucose is steady (not increasing/decreasing more than 1 mg/dL each minute). Your glucose could increase or decrease by up to 15 mg/dL in 15 minutes.
↗	**Slowly rising:** Your glucose is rising 1–2 mg/dL each minute. If it continued rising at this rate, your glucose could increase up to 30 mg/dL in 15 minutes.
↑	**Rising:** Your glucose is rising 2–3 mg/dL each minute. If it continued rising at this rate, your glucose could increase up to 45 mg/dL in 15 minutes.
↑↑	**Rapidly rising:** Your glucose is rising more than 3 mg/dL each minute. If it continued rising at this rate, your glucose could increase more than 45 mg/dL in 15 minutes.
↘	**Slowly falling:** Your glucose is falling 1–2 mg/dL each minute. If it continued falling at this rate, your glucose could decrease up to 30 mg/dL in 15 minutes.
↓	**Falling:** Your glucose is falling 2–3 mg/dL each minute. If it continued falling at this rate, your glucose could decrease up to 45 mg/dL in 15 minutes.
↓↓	**Rapidly falling:** Your glucose is falling more than 3 mg/dL each minute. If it continued falling at this rate, your glucose could decrease more than 45 mg/dL in 15 minutes.
No Arrow	**No rate of change information:** The System cannot calculate how fast your glucose is rising or falling at this time.

24.4 Additional CGM Status Symbols

The following symbols may also appear on your CGM Home Screen in the place where sensor glucose readings normally show. They let you know important information about the System.

You will not get sensor glucose readings during the time a status symbol shows except during the regular 12-hour calibration prompt.

	**Startup Calibration Needed** This symbol in the place where sensor glucose readings normally show means that you need to enter startup calibrations. It remains on the screen until you calibrate with BG values.
	**Additional Calibration Required** This symbol in the place where sensor glucose readings normally show means that you need to enter another startup calibration. It remains on the screen until you calibrate with a BG value.
	**Calibration Needed** This symbol to the right of the antenna means that you need to enter a calibration. It shows when it is time for your 12-hour calibration update or any other time an additional calibration is needed.
	**Out of Range** This symbol in the place where sensor glucose readings normally show means that your transmitter and pump are not communicating. The trend graph will not display sensor glucose readings. Make sure the transmitter and pump are within 20 feet of each other without obstruction.
	**Glucose Reading Error** This symbol in the place where sensor glucose readings normally show means that the pump does not understand the sensor signal but it likely to recover. This symbol relates to the sensor only. You should wait for more prompts and do not enter any calibrations when you see this symbol.

	**Sensor Session Ended** This symbol in the place where sensor glucose readings normally show means that your sensor session has ended.
 	**Wait 15 Minute Calibration Error** Either symbol will be shown in place of where the sensor glucose readings normally show means that the sensor cannot calibrate right now. If you see this, enter at least one more calibration blood glucose value after 15 minutes. If the sensor still cannot calibrate after that, the sensor needs to be removed and a new sensor needs to be inserted.
	**Failed Sensor** This symbol in the place where sensor glucose readings normally show means that the sensor has failed. The sensor needs to be removed and a new sensor needs to be inserted.
	**Failed Transmitter** This symbol in the place where sensor glucose readings normally show means that the transmitter has failed. The transmitter needs to be replaced.

24.5 CGM History

CGM History displays the historical log of CGM events. At least 90 days of data can be viewed in History. When the maximum number of events is reached, the oldest events are removed from the history log and replaced with the most recent events. The following history sections can be viewed:

- Sessions and Calibrations
- Alerts and Errors
- Complete

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

The Sessions and Calibrations section includes the start time and date for each Sensor Session, the stop time and date for each Sensor Session, and all calibration blood glucose 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 history section includes all information from the Sessions and Calibrations and Alerts and Errors sections as well as any changes to Settings.

1. From the Home Screen, tap **OPTIONS**.
2. Tap the **Down Arrow**.
3. Tap **CGM History**.
4. Tap section you want to view.
5. Each section is organized by date. Tap the **date** to view events from that day. Use the **Down Arrow** to scroll to more dates.

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Chapter 25

Ending Your CGM Sensor Session

Ending Your Sensor Session

Your sensor gives you sensor glucose readings for up to 7 days. The performance of the sensor has not been tested beyond 7 days. When the sensor session ends, you will need to replace the sensor and start a new sensor session. In some cases your sensor session may end before you have finished a full 7 day period. You may also choose to end the sensor session early.

Glucose alerts and alarms do not work after the sensor session ends.

25.1 Automatic Sensor Shut-Off

Your t:slim X2 Pump tells you how much time you have left until your sensor session is complete. The "SENSOR EXPIRING SOON" screen shows at 6 hours remaining, 2 hours remaining, and 30 minutes remaining before your 7 day session ends. You will continue to receive sensor glucose readings after reach reminder.

When you see the SENSOR EXPIRING SOON Screen:

1. Tap **CLOSE** to return to the previous screen.

▷ The "SENSOR EXPIRING SOON" screen will show again when there are 2 hours remaining, and when there are 30 minutes remaining.

After the final 30 minutes, the "REPLACE SENSOR" screen is displayed.

2. Tap **CLOSE**.

3. The Home Screen will appear with the Replace Sensor icon in the place where sensor glucose readings normally show.

New sensor glucose readings do not show on your t:slim X2 Pump after your sensor session ends. You must remove your sensor and insert a new sensor.

25.2 Ending a Sensor Session Before Automatic Shut-Off

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

1. From the Home Screen, tap **OPTIONS**.
2. Tap **My CGM**.
3. Tap **STOP SENSOR**.
4. Tap **YES** to confirm.

▷ The "SENSOR STOPPED" screen is temporarily displayed.

5. The Home Screen will appear with the Replace Sensor icon in the place where sensor glucose readings normally show.

   New sensor glucose readings do not show on your t:slim X2 Pump after your sensor session ends. You must remove your sensor and insert a new sensor.

25.3 Removing the Sensor and Transmitter

⚠ WARNING

DO NOT ignore sensor fractures. Sensors may fracture on rare occasions. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken sensor, please report this to Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

Do not remove the transmitter from the sensor pod while the pod is attached to your skin. When you remove the sensor, make sure to pull out the sensor pod while the transmitter is still attached.

Gently peel up the sensor pod adhesive patch from your skin. This will pull out your sensor.

⚠ PRECAUTION

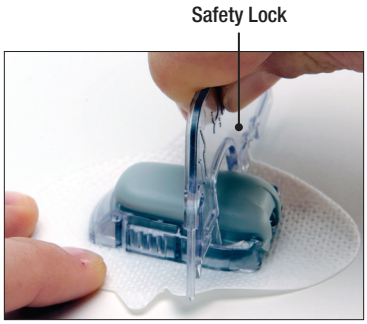
DO NOT discard your transmitter. It is reusable. The same transmitter is used for each session until you have reached the end of the transmitter battery life.

After the sensor pod is off your body, you must remove the transmitter to reuse it. Use either of the two transmitter removal methods below.

Method 1

The safety lock that you removed from the applicator (see Chapter 21.4) can be used as a tool to remove the transmitter.

1. Grasp the end of the adhesive patch. Peel adhesive patch up and away from your body to remove sensor pod and transmitter.
2. Put sensor pod on flat surface.
3. Place the sensor pod on a flat surface.
4. Hold the rounded edge of the safety lock.
5. Make sure the jagged edge of the safety lock is facing down, with the arrow pointing up.
6. Push the safety lock down until it will go no further. The transmitter will “pop” out of the sensor pod.



Method 2

If you did not save the safety lock when you inserted the sensor, you can use your fingers to spread out the tabs at the back of the sensor pod.

1. Grasp the end of the adhesive patch. Peel adhesive patch up and away from your body to remove sensor pod and transmitter.
2. Put sensor pod on flat surface.
3. Grasp sensor pods wide end with two fingers and place fingers in sides’ open slots.
4. Pull tabs away from transmitter.

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Section 6

CGM Alerts, Errors and Troubleshooting

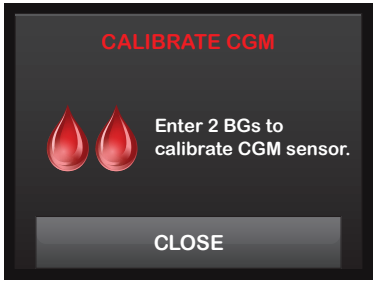
Chapter 26

CGM Alerts and Errors

This section describes CGM alerts and errors that appear on your t:slim X2 Home Screen. It applies only to the CGM portion of your System. CGM alerts and errors do not follow the same pattern of vibration and beeps as insulin delivery reminders, alerts, and alarms. For information on insulin delivery reminders, alerts, and alarms, see Chapters 14–16.

26.1 Startup Calibration Alert

What will I see on the Screen?



What does it mean?

2-hour CGM startup period is complete.

How will the System notify me?

1 vibration, then vibration/beep every 5 minutes until confirmed.

Will the System re-notify me?

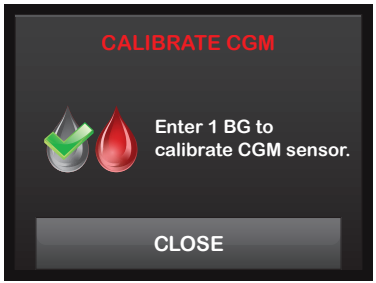
Yes, every 15 minutes until you calibrate.

How should I respond?

Tap **CLOSE** and enter 2 separate blood glucose values to calibrate the system and start your CGM session.

26.2 Second Startup Calibration Alert

What will I see on the Screen?



What does it mean?

The System needs an additional blood glucose value to complete startup calibration.

How will the System notify me?

1 vibration, then vibration/beep every 5 minutes until confirmed.

Will the System re-notify me?

Yes, every 15 minutes until second calibration is entered.

How should I respond?

Tap CLOSE and enter a blood glucose value to calibrate the System and start your CGM session.

26.3 12 Hour Calibration Alert

What will I see on the Screen?

What does it mean?

The System needs a blood glucose value to calibrate.

How will the System notify me?

On screen only with no vibration or beep.

Will the System re-notify me?

Yes, every 15 minutes.

How should I respond?

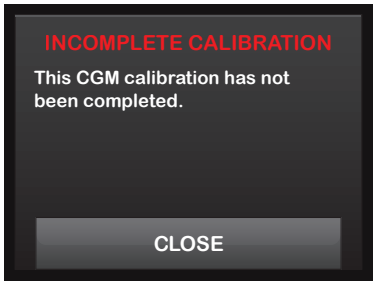
Tap CLOSE and enter a blood glucose value to calibrate the system.

⚠ WARNING

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

26.4 Incomplete Calibration

What will I see on the Screen?



What does it mean?

If you start to enter a calibration value using the keypad and do not complete the entry within 90 seconds, this screen appears.

How will the System notify me?

2 beeps or vibrations depending on Pump Volume selected.

Will the System re-notify me?

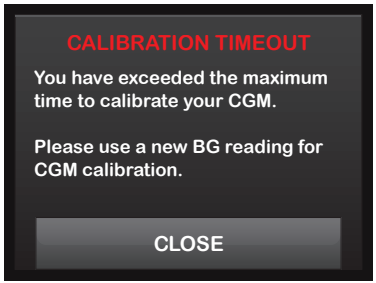
Yes, every 5 minutes until confirmed.

How should I respond?

Tap CLOSE and complete your calibration by entering the value using the onscreen keypad.

26.5 Calibration Timeout

What will I see on the Screen?



What does it mean?

If you start to enter a calibration value using the keypad and do not complete the entry within 5 minutes, this screen appears.

How will the System notify me?

2 beeps or vibrations depending on Pump Volume selected.

Will the System re-notify me?

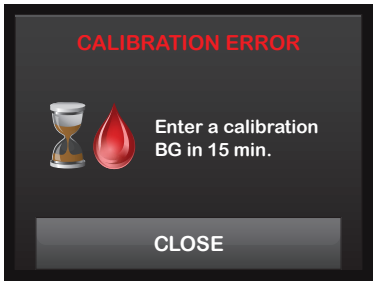
Yes, every 5 minutes until confirmed.

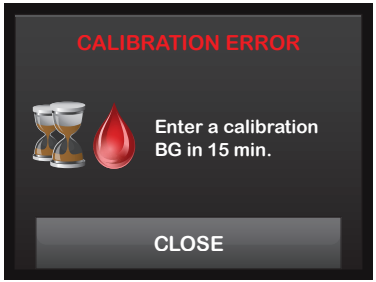
How should I respond?

Tap CLOSE and obtain a new blood glucose value using your meter. Enter the value using the onscreen keypad to calibrate the System.

26.6 Wait 15 Minute Calibration Error Alert

What will I see on the Screen?





What does it mean?

The sensor cannot calibrate.

How will the System notify me?

1 vibration, then vibration/beep every 5 minutes until confirmed.

Will the System re-notify me?

No.

How should I respond?

Tap CLOSE to confirm. Wait 15 minutes then enter 1 more blood glucose value. Wait 15 more minutes. If error screen still appears, enter 1 more blood glucose value. Wait 15 minutes. If no sensor glucose readings appear, the sensor needs to be replaced.

26.7 Calibration Required Alert

What will I see on the Screen?

What does it mean?

The System needs a blood glucose value to calibrate. Sensor glucose readings will not be displayed at this time.

How will the System notify me?

1 vibration, then vibration/beep every 5 minutes until confirmed.

Will the System re-notify me?

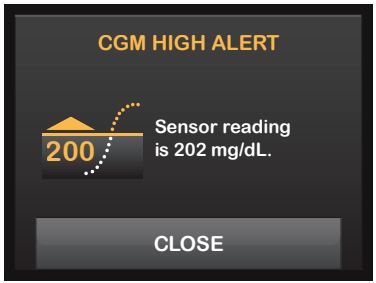
Yes, every 15 minutes.

How should I respond?

Tap CLOSE and enter a blood glucose value to calibrate the System.

26.8 CGM High Alert

What will I see on the Screen?



What does it mean?

Your most recent sensor glucose reading is at or above the High Alert setting.

How will the System notify me?

2 vibrations, then 2 vibrations/beeps every 5 minutes until confirmed or your glucose value drops below the Alert level.

Will the System re-notify me?

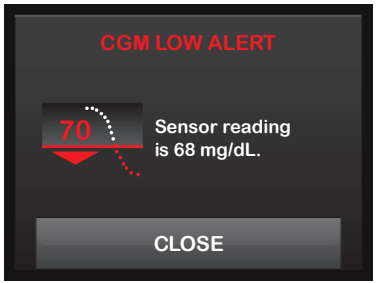
No, unless you have turned on the Repeat feature.

How should I respond?

Tap CLOSE to confirm.

26.9 CGM Low Alert

What will I see on the Screen?



What does it mean?

Your most recent sensor glucose reading is at or below the Low Alert setting.

How will the System notify me?

3 vibrations, then 3 vibrations/beeps every 5 minutes until confirmed or your glucose value goes above the Alert level.

Will the System re-notify me?

Only if you have turned on the Repeat feature.

How should I respond?

Tap CLOSE to confirm.

26.10 CGM Fixed Low Alert

What will I see on the Screen?

What does it mean?

Your most recent sensor glucose reading is at or below 55 mg/dL.

How will the System notify me?

4 Vibrations, then 4 vibrations/beeps every 5 minutes until confirmed or your glucose value goes above 55 mg/dL.

Will the System re-notify me?

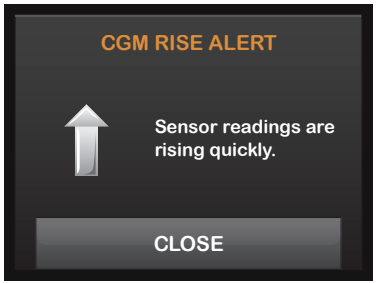
Yes, 30 minutes after each confirmation until your glucose value goes above 55 mg/dL.

How should I respond?

Tap CLOSE to confirm.

26.11 CGM Rise Alert

What will I see on the Screen?



What does it mean?

Your glucose levels are rising at 2 mg/dL per minute or faster (at least 30 mg/dL in 15 minutes).

How will the System notify me?

2 vibrations, then 2 vibrations/beeps every 5 minutes or until confirmed.

Will the System re-notify me?

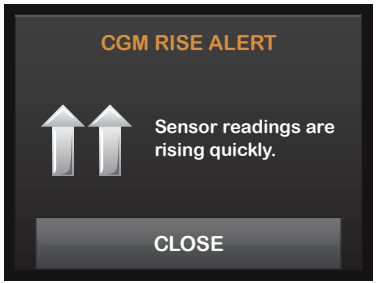
No.

How should I respond?

Tap CLOSE to confirm.

26.12 CGM Rapid Rise Alert

What will I see on the Screen?



What does it mean?

Your glucose levels are rising at 3 mg/dL per minute or faster (at least 45 mg/dL in 15 minutes).

How will the System notify me?

2 vibrations, then 2 vibrations/beeps every 5 minutes or until confirmed.

Will the System re-notify me?

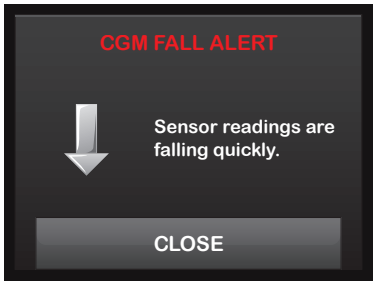
No.

How should I respond?

Tap CLOSE to confirm.

26.13 CGM Fall Alert

What will I see on the Screen?



What does it mean?

Your glucose levels are falling at 2 mg/dL per minute or faster (at least 30 mg/dL in 15 minutes).

How will the System notify me?

3 vibrations, then 3 vibrations/beeps every 5 minutes or until confirmed.

Will the System re-notify me?

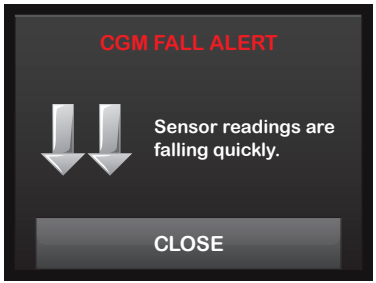
No.

How should I respond?

Tap CLOSE to confirm.

26.14 CGM Rapid Fall Alert

What will I see on the Screen?



What does it mean?

Your glucose levels are falling at 3 mg/dL per minute or faster (at least 45 mg/dL in 15 minutes).

How will the System notify me?

3 vibrations, then 3 vibrations/beeps every 5 minutes or until confirmed.

Will the System re-notify me?

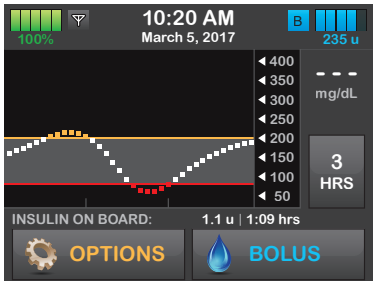
No.

How should I respond?

Tap CLOSE to confirm.

26.15 Unknown Sensor Reading

What will I see on the Screen?



What does it mean?

The sensor is sending sensor glucose readings that the System does not understand. You will not receive sensor glucose readings.

How will the System notify me?

On screen only with no vibration or beep.

Will the System re-notify me?

The 3 dashes will remain on the screen until a new glucose reading is received and displayed in their place.

How should I respond?

Wait 30 minutes for more information from the system. Do not enter blood glucose values for calibration. The system will not use blood glucose values for calibration when "- - -" appears on the screen.

26.16 Out of Range Alert

What will I see on the Screen?

What does it mean?

The transmitter and pump are not communicating and you will not receive sensor glucose readings.

How will the System notify me?

1 vibrate, then vibration/beep every 5 minutes until the transmitter and pump are back in range.

Will the System re-notify me?

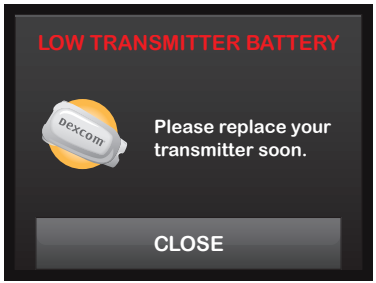
Yes, if the transmitter and pump remain out of range.

How should I respond?

Tap CLOSE to confirm and move the transmitter and pump closer together, or remove the obstruction between them.

26.17 Low Transmitter Battery Alert

What will I see on the Screen?



What does it mean?

Transmitter battery is low.

How will the System notify me?

1 vibration, then vibration/beep every 5 minutes until confirmed.

Will the System re-notify me?

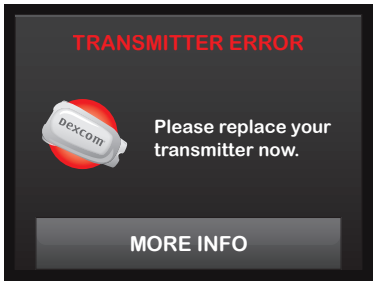
Yes, the alarm will notify you when there are 21, 14, and 7 days of transmitter battery life remaining.

How should I respond?

Tap CLOSE to confirm. Replace the transmitter as soon as possible.

26.18 Transmitter Error

What will I see on the Screen?



What does it mean?

The transmitter has failed and the CGM session has stopped.

How will the System notify me?

1 vibration, then vibration/beep every 5 minutes.

Will the System re-notify me?

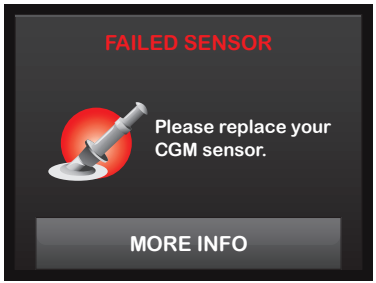
No.

How should I respond?

Tap MORE INFO. A screen notifying you that your CGM session has stopped but insulin delivery continues will appear. Replace the transmitter immediately.

26.19 Failed Sensor Error

What will I see on the Screen?



What does it mean?

The sensor is not working properly and the CGM session has stopped.

How will the System notify me?

1 vibration, then vibration/beep every 5 minutes.

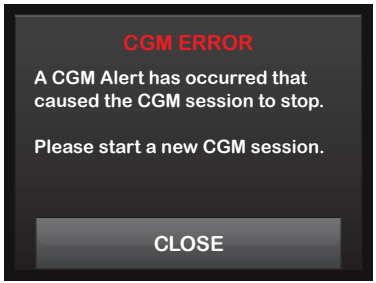
Will the System re-notify me?

No.

How should I respond?

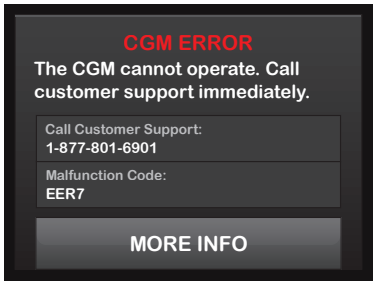
Tap MORE INFO. A screen notifying you that your CGM session has stopped but insulin delivery continues will appear. Replace the sensor and begin a new CGM session.

26.20 CGM Error

What will I see on the Screen?	What does it mean?
	Your CGM System is not working properly and the CGM session has been stopped.
	How will the System notify me? 1 vibration, then vibration/beep every 5 minutes.
	Will the System re-notify me? No.
	How should I respond? Tap CLOSE and start a new CGM session.

26.21 CGM System Error

What will I see on the Screen?



What does it mean?

Your CGM System is not working properly; the CGM session has stopped and the system can no longer be used.

How will the System notify me?

1 vibration, then vibration/beep every 5 minutes.

Will the System re-notify me?

No.

How should I respond?

Tap MORE INFO. A screen notifying you that your CGM System cannot operate but insulin delivery continues will appear. Call Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

Chapter 27

CGM Troubleshooting

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

If the troubleshooting steps in this chapter do not fix your issue, contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901 for additional help.

27.1 Sensor Insertion Troubleshooting

Possible issue:

You are having trouble taking the safety lock off the sensor applicator barrel.

Troubleshooting tip:

- Make sure to pull the safety lock straight out away from your body. Use the arrows on the safety lock as a guide.

Possible issue:

You are not able to pull the collar up the applicator barrel after inserting the sensor.

Troubleshooting tips:

- Make sure the white plunger is completely pressed down before pulling the collar up.
- Try using more force when pulling the collar up.

Possible Issue:

You are not able to remove the applicator barrel from the sensor pod.

Troubleshooting tips:

- Make sure the collar is pulled all the way up. When pulling the collar up you should hear 2 “clicks”. The collar should be as close to the top of the applicator as possible.
- Make sure the transmitter latch is flat against the adhesive on your body before squeezing the release tabs.
- Squeeze the center of the ribbed release tabs on the sides of the sensor pod and lift the applicator away from your body.

Possible Issue:

You are not able to remove the transmitter latch from the sensor pod.

Troubleshooting tips:

- Hold the sensor pod with one hand

and twist the transmitter latch with the other hand to remove it.

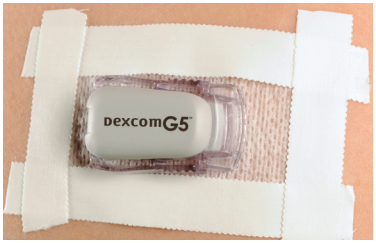
- Do not try to snap it straight off.

Possible Issue:

The sensor pod is not sticking long enough on your body.

Troubleshooting tips:

- Make sure your skin is clean, clear of any cream or lotion, and completely dry before you insert the sensor.
- If hair is preventing the sensor pod from sticking, shave your skin before you insert the sensor.
- You may use medical tape (such as Blenderm, Tegaderm, IV 3000, 3M tape) over the white adhesive patch of the sensor pod, but do not place the tape over the transmitter or the plastic parts of the sensor pod.



27.2 Calibration Troubleshooting

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

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

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

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

Do not calibrate if your blood glucose value is below 40 mg/dL or above 400 mg/dL.

Make sure you have not taken any medications containing acetaminophen (such as Tylenol).

27.3 Unknown Sensor Reading Troubleshooting

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

Often the System can correct the problem and continue providing sensor glucose readings. If it has been at least 3 hours since your last sensor glucose reading, contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

Do not enter any blood glucose values for calibration when you see "- - -" on your screen. The System will not use a blood glucose value for calibration when this symbol is on your screen.

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

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

27.4 Out of Range/No Antenna Troubleshooting

⚠ PRECAUTION

AVOID separating the transmitter and receiver by more than 20 feet. The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and receiver are farther than 20 feet 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 blood glucose) or hyperglycemia (high blood glucose) events.

If you see the Out of Range icon on your screen in the place where your sensor glucose reading normally shows, then your t:slim X2 Pump is not communicating with your transmitter and sensor glucose readings will not show on your screen. Each time you start a new sensor session, wait 10 minutes for your t:slim X2 Pump to start communicating with your transmitter. When a sensor session is active, you may sometimes experience loss of communication for 10 minutes at a time. This is normal.

If you see the Out of Range icon for more than 10 minutes, move your t:slim X2 Pump and CGM transmitter closer together and remove any obstructions. Wait 10 minutes and communication should be restored.

You must enter your transmitter ID correctly into your pump to receive sensor glucose readings (see Chapter 19.1). Make sure you have removed your sensor and stopped your sensor session before checking or changing your transmitter ID. You cannot change your transmitter ID during a sensor session.

If you are still having trouble getting sensor glucose readings, contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

27.5 Failed Sensor Troubleshooting

The System may detect issues with your sensor where it cannot determine your glucose reading. The sensor session ends and the “FAILED SENSOR” screen shows on your t:slim X2 Pump. If you see this screen, it means your CGM session has ended.

Remove your sensor and insert a new sensor.

To help improve future sensor performance, follow the troubleshooting tips below.

- Make sure your sensor is not expired.
- Make sure your sensor pod is not dislodged or peeling up.
- Make sure your transmitter is snapped in completely.
- Make sure nothing is rubbing the sensor pod (i.e. clothing, seat belts, etc.).

- Make sure you have selected a good insertion site.
- Make sure your insertion site is clean and dry before sensor insertion.

27.6 Sensor Inaccuracies

Inaccuracies are usually related to your sensor only and not to your transmitter or pump. Your sensor glucose readings are meant to be used for trending purposes only. The sensor measures glucose in the fluid under the skin - not in blood, and sensor glucose readings are not identical to readings from your blood glucose meter.

⚠ WARNING

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

⚠ PRECAUTION

To calibrate the System, **DO** enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Do not enter sensor glucose values for calibration. Entering incorrect blood glucose values, blood glucose 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 blood glucose) or hyperglycemia (high blood glucose) events.

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

- Make sure your sensor is not expired.
- Make sure you do not calibrate

when "- - -" or the Out of Range icon are on the screen.

- Do not use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration as alternative site readings may be different than those from a blood glucose value. Use a blood glucose value only from your fingers for calibration.
- Use only blood glucose values between 40–400 mg/dL for calibration. If one or more of your values is outside of this range, the receiver will not calibrate.
- Use the same meter you routinely use to measure your blood glucose to calibrate. Do not switch your meter in the middle of a sensor session. Blood glucose meter and strip accuracy vary between blood glucose meter brands.
- Before taking a blood glucose measurement for calibration, wash your hands, make sure your glucose test strips have been stored properly and are not expired and make sure that your meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions provided with your meter or test strips.
- Make sure you are using your blood glucose meter following the manufacturer's instructions to get accurate blood glucose values for calibration.
- Make sure you have not taken any medications containing acetaminophen (such as Tylenol) to ensure you are getting accurate blood glucose values for calibration.

Section 7

Living With and Caring for Your System

Chapter 28

Lifestyle Issues and Travel

28.1 Overview

While the convenience and flexibility of the t:slim X2 System 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 t:slim X2 System can be worn during most forms of exercise, such as running, cycling, hiking, and resistance training. During exercise, the pump can be worn in the provided case, your pocket, or other third-party "sport cases." 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 blood glucose levels. Even if you disconnect your tubing from your infusion site, the t:slim X2 Pump should continue to receive data from the transmitter as long as it is within the 20-foot range without obstruction.

Aquatic Activities

⚠ PRECAUTION

AVOID submersing your pump in fluid beyond a depth of 3 feet or for more than 30 minutes (IPX7 rating). If your pump has been exposed to fluid beyond these limits, check for any signs of fluid ingress. If there are signs of fluid entry, discontinue use of the pump and contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

Your t:slim X2 Pump is watertight to a depth of 3 feet for up to 30 minutes (IPX7 rating), but it is not waterproof. Your pump should not be worn while swimming, scuba diving, surfing, or during any other activities that could submerge the pump for an extended period of time. Your pump should not be worn in hot tubs or Jacuzzis.

The Dexcom G5 Mobile Sensor is water resistant when showering, bathing or swimming if the transmitter is fully snapped in. The sensor has been tested to be water resistant when submerged for up to 8 feet and up to 24 hours. Underwater use will affect the ability to communicate with the t:slim X2 pump, so the range will be much less than during normal use. Extended contact with water could weaken the adhesive used by your infusion sets and Dexcom CGM Sensors and cause them to fall off prematurely.

Extreme Altitudes

Some activities, such as hiking, skiing or snowboarding, could expose your pump to extreme altitudes. The t:slim X2 Pump has been tested at altitudes up to 10,000 feet at standard operating temperatures.

Extreme Temperatures

You should avoid activities which could expose your System to temperatures below 40˚F (5˚C) or above 99˚F (37˚C), as insulin can freeze at low temperatures or degrade at high temperatures.

Other Activities Which Require Removing Your Pump

There are other activities, such as bathing and intimacy, when it may be more convenient for you to remove your pump. It is safe to do so for short periods of time. If planning to disconnect from your pump, discuss a plan with your health care provider for compensating for any basal delivery you miss while disconnected, and be sure to check your blood glucose levels frequently. Missing basal delivery could cause your blood sugar 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 2.8.
- 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 HCP explaining the medical need for your insulin pump and other supplies.

Traveling by Air

⚠ PRECAUTION

DO NOT expose your System 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 System should not be exposed to them. Notify the Transportation Security Administration (TSA) Agent that your System cannot be exposed to X-ray machines and request an alternate means of screening.

Visit TSA's website if you have any questions or concerns.

www.tsa.gov
Email:
TSA-ContactCenter@tsa.dhs.gov
Phone:
(866) 289-9673.

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

The System is safe for use on U.S. commercial airlines. The Dexcom G5 Mobile Transmitter is an M-PED with emission levels that meet FAA standards and may be used onboard the aircraft without any further testing by the operator.

Pack your pump supplies in your carry-on luggage. DO NOT pack your supplies in checked luggage as it could get delayed or lost.

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

Chapter 29

Taking Care of Your t:slim X2 System

29.1 Overview

This section provides information on caring for and maintaining your System.

Cleaning Your System

When cleaning your t:slim X2 Pump, use a damp lint-free cloth. Do not use household or industrial cleaners, solvents, bleach, scouring pads, chemicals, or sharp instruments. Never submerge the pump in water or use any other liquid to clean it. Do not place the pump in the dishwasher or use hot water to clean it. If needed, use only a very mild detergent, such as a bit of liquid soap with warm water. When drying your pump, use a soft towel; never place your pump in a microwave oven or baking oven to dry it.

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

Inspecting Your System 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 System is working properly by plugging a power source into the USB port and confirming that the display turns on, you hear audible beeps, feel the pump vibrate, and see the green LED light blinking around the edge of the Screen On Button. If you are unsure about potential damage, discontinue use of the System and contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

If you drop your t:slim X2 Pump or it has been hit against something hard, ensure that it is still working properly. Check that the touch screen is working and clear, and that the cartridge and infusion set are properly in place. Check for leaks around the cartridge and at the tubing connector to the infusion set. Immediately contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901 if you notice any cracks, chips, or other damage.

If your transmitter is damaged or cracked, do not use it. Immediately contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901 if you notice any cracks or other damage.

Do not use the sensor if its sterile package has been damaged or opened.

Storing Your System

If you need to stop using your t:slim X2 Pump for a long period of time, you can place the pump in storage mode. To place the pump in storage mode, connect the pump to a power source and then press and hold down the Screen On/Quick Bolus Button for 25 seconds. The pump will beep 3 times before going into storage mode. Disconnect the pump from the power source.

Keep the pump protected when not in use. Store at temperatures between -4°F and 140°F and at relative humidity levels between 20% and 90%.

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

Keep the sensor in its sterile packaging until you are ready to use it. Store at temperatures between 36°F and 77°F and at relative humidity levels between 15% and 85%. Storing outside of this temperature range may result in reduced sensor response to glucose and may cause inaccurate CGM readings. You may store your sensors in the refrigerator if it is within the temperature range above. Sensors should not be stored in a freezer.

Do not insert sensors past the expiration date. The expiration date format is YYYY-MM-DD. Insert sensors on or before the end of the calendar day printed on the sensor package label.

Keep the transmitter protected when not in use. Store at temperatures between 32°F and 113°F and humidity levels between 10% and 95% relative humidity.

Disposing of System Components

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

Section 8

Technical Specifications and Warranty

Chapter 30

Technical Specifications

30.1 Overview

This section provides tables of technical specifications, performance characteristics, options, settings, and electromagnetic compliance information for the t:slim X2 System. The specifications in this section meet the international standards set forth in IEC 60601-1 and IEC 60601-2-24.

30.2 t:slim X2 System Specifications

t:slim X2 System Specifications (including the t:slim X2 Pump, and Dexcom G5 Mobile Sensor and Transmitter)

Specification Type	Specification Details
Operating Conditions	Temperature: 41°F (5°C) to 98.6° F (37°C) Humidity: 20% to 90% RH non-condensing
Storage Conditions	Temperature: 36° F (2°C) to 77° F (25°C) Humidity: 20% to 85% RH non-condensing
Operating Altitude	-500 feet to 10,000 feet
Moisture Protection	IPX7: Watertight to a depth of 3 feet for up to 30 minutes
Protection Against Electrical Shock	Type BF applied part

t:slim X2 Pump Specifications

Specification Type	Specification Details
Classification	External PSU: Class II, Infusion Pump. Internally-powered equipment, Type BF applied part. The risk of ignition of flammable anesthetics and explosive gases by the pump is remote. While this risk is remote, it is not recommended to operate the t:slim X2 Pump in the presence of flammable anesthetics or explosive gases.
Size	3.13˝ x 2.0˝ x 0.6˝ (L x W x H) - (7.95 cm x 5.08 cm x 1.52 cm)
Weight (with full disposable)	3.95 ounces (112 grams)
Operating Conditions	Temperature: 41°F (5°C) to 98.6°F (37°C) Humidity: 20% to 90% RH non-condensing
Storage Conditions	Temperature: -4°F (-20°C) to 140°F (60°C) Humidity: 20% to 90% RH non-condensing
Atmospheric Pressure	-1,300 feet to 10,000 feet
Moisture Protection	IPX7: Watertight to a depth of 3 feet for up to 30 minutes
Reservoir Volume	3.0 mL or 300 units
Cannula Fill Amount	0.1 to 1.0 units of insulin
Insulin Concentration	U-100
Alarm Type	Visual, audible, and vibratory

table continued on next page …

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Specification Type	Specification Details
Basal Delivery Accuracy at all Flow Rates (tested per IEC 60601-2-24)	±5% **The System is designed to vent automatically when there is a pressure difference between inside the cartridge and the surrounding air. In certain conditions, such as a gradual elevation change of 1,000 feet, the System may not vent immediately and delivery accuracy can vary up to 15% until 3 units have been delivered or elevation changes by more than 1,000 feet.**
Bolus Delivery Accuracy at all Volumes (tested per IEC 60601-2-24)	±5%
Patient Protection from Air Infusion	The pump provides subcutaneous delivery into interstitial tissue and does not deliver intravenous injections. Clear tubing aids in detecting air.
Maximum Infusion Pressure Generated and Occlusion Alarm Threshold	30 PSI
Frequency of Basal Delivery	5 minutes for all Basal Rates
Retention Time of Electronic Memory when Internal System Battery is Fully Discharged (including Alarm Settings and Alarm History)	Greater than 30 days
Infusion Set used for Testing	Unomedical Comfort™ Infusion Set

table continued on next page …

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Specification Type	Specification Details
Internal System Battery Life	4 years minimum under normal use conditions
Typical Operating Time when System is Operating at Intermediate Rate	During normal use, the intermediate rate is 2 units/hr; battery charge can be reasonably expected to last up to 7 days (5 days if using CGM) from a fully charged state to a totally discharged state
Handling of Over-Infusion or Under-Infusion	The method of delivery isolates the insulin chamber from the patient and the software performs frequent monitoring of system status. Multiple software monitors provide redundant protection against unsafe conditions. Over-infusion is mitigated by continuous self-tests, layering of redundancies and confirmations, and numerous other safeguard alarms. Users are required to review and confirm the details of all bolus deliveries, basal rates, and temp rates to ensure certainty before initiating a delivery. In addition, once bolus deliveries are confirmed, the user is given 5 seconds to cancel the delivery before it is started. An optional Auto-Off alarm triggers when the user has not interacted with the pump's user interface for a pre-defined period of time. Under-infusion is mitigated by occlusion detection and blood glucose monitoring as blood glucose entries are recorded. Users are prompted to treat high blood glucose conditions with a correction bolus.
Bolus Volume at Release of Occlusion (2 units per hour Basal)	Less than 3 units with Unomedical Comfort™ (110cm) Infusion Set
Residual Insulin Remaining in the Cartridge (unusable)	Approximately 15 units
Minimum Audible Alarm Volume	45 dBA at 1 meter

Dexcom G5 Mobile Product Specifications

User is the single use operator in the home environment. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Do not touch the metal connectors on the bottom of the transmitter and other open connectors on the receiver, charging cable and charger.

Dexcom G5 Mobile Sensor Specifications

Glucose Range	40 - 400 mg/dL
Sensor Life	Up to 7 days
Calibration	Commercially available blood glucose meter
Calibration Range	40 - 400 mg/dL
Storage Condition	Temperature: 36°F to 77°F Humidity: 15% - 85% RH
Sterilization	Sterile by radiation

Dexcom G5 Mobile Transmitter Specifications

Part Number	P/N 9438-01	P/N 9438-05
Dimensions (including sensor pod)	Length: 1.5 inches Width: 0.9 inches Thickness: 0.5 inches	Length: 1.5 inches Width: 0.9 inches Thickness: 0.4 inches
Weight (including sensor pod)	0.4 ounces	0.3 ounces
Power Supply	Silver oxide batteries (not replaceable)	Silver oxide batteries (not replaceable)
Operational Conditions	Temperature: 50°F to 108°F Humidity: 10% to 95% RH	Temperature: 50°F to 108°F Humidity: 10% to 95% RH
Storage Conditions	Temperature: 32°F to 113°F Humidity: 10% to 95% RH	Temperature: 32°F to 113°F Humidity: 10% to 95% RH
Operating Altitude	-500 to 12000 feet	-500 to 12000 feet
Limited Warranty	3 months	3 months
Moisture Protection	IP28: temporary submersion	IP28: temporary submersion
Protection Against Electrical Shock	Type BF applied part	Type BF applied part

USB Charging/Download Cable Specifications

Tandem P/N	004113
Length	6 feet
Type	USB A to USB Micro B

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

Tandem P/N	03933
Input	100 to 240 Volts AC, 50/60 Hz
Output Voltage	5 Volts DC
Max Output Power	5 Watts
Output Connector	USB type A

Car Adapter (not included), Specifications

Tandem P/N	003934
Input	12 Volts DC
Output Voltage	5 Volts DC
Max Output Power	5 Watts minimum
Output Connector	USB type A

PC, USB Connector, Specifications

Output Voltage	5 Volts DC
Output Connector	USB type A
Safety Standard Compliance	60950-1 or 60601-1 or equivalent

The t:slim X2 System is designed to be connected to a host PC for battery charging and data transfer to t:connect. The following minimum characteristics are required of the host PC:

- USB 1.1 port (or later)
- t:connect Uploader Software (available for download at www.tandemdiabetes.com)
- PC compliant with 60950-1 or equivalent safety standard

Connecting the t:slim X2 System to a host PC that is attached to other equipment could result in previously unidentified risks to the patient, operator, or a third party. The user should identify, analyze, evaluate, and control these risks.

Subsequent changes to the host PC could introduce new risks and require additional analysis. These changes can include but are not limited to changing the configuration of the PC, connecting additional items to the PC, disconnecting items from the PC, and updating or upgrading equipment connected to the PC.

30.3 t:slim X2 Pump Options and Settings

Option/Setting Type	Option/Setting Details
Time	12-hour clock
Maximum Basal Rate	15 units/hr
Insulin Delivery Profiles (Basal and Bolus)	6
Basal Rate Segments	16 per delivery profile
Basal Rate Increment	0.001 at programed rates equal to or greater than 0.1 units/hr
Temp Basal Rate	15 minutes to 72 hours with 1 minute resolution with a range of 0% to 250%
Bolus Setup	Can deliver based on carb input (grams) or insulin input (units). Default is units. (The range for carbs is 1 to 999 grams; the range for insulin is 0.05 to 25 units)
Insulin-to-Carb (IC) Ratio	16 time segments per 24-hour period; Ratio: 1 unit of insulin per x grams of carbs; 1:1 to 1:300 (can be set by 0.1 below 10)
BG Correction Target Value	16 time segments. 70 to 250 mg/dL in 1 mg/dL increments
Insulin Sensitivity Factor (ISF)	16 time segments; Ratio: 1 unit of insulin reduces glucose x mg/dL; 1:1 to 1:600 (1 mg/dL increments)
Duration of Insulin Action	1 time segment; 2 to 8 hours in 1-minute increments (default is 5 hrs)
Bolus Increment	0.01 at volumes greater than 0.05 units

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Option/Setting Type	Option/Setting Details
Quick Bolus Increments	When set to units: 0.5, 1, 2, 5 units (default is 0.5 units); or when set to grams/carbs: 2, 5, 10, 15 grams (default is 2 g)
Maximum Extended Bolus Time	8 hours
Maximum Bolus Size	25 units
Low Reservoir Volume Indicator	Status indicator visible on Home Screen; Low Insulin Alert is user adjustable from 10 to 40 units (default is 20 units).
Auto-Off Alarm	On or Off (default is On); user-adjustable (5 to 24 hours; default is 12 hours, which you can change when option is set to On).
History Storage	At least 90 days of data
Language	English
Feature Lock	Blocks access to insulin delivery screens and pump setting screens (default is Off).
Screen Lock	Protects from unintentional taps.
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).

30.4 t:slim X2 Pump Performance Characteristics

The t:slim X2 insulin pump delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The following accuracy data was collected on both types of delivery in laboratory studies performed by Tandem.

Basal Delivery

To assess basal delivery accuracy, thirty-two t:slim X2 pumps were tested by delivering at low, medium, and high basal rates (0.1, 2.0, and 15 U/hr). Sixteen of the pumps were new, and sixteen had been aged to simulate four years of regular use. For both aged and unaged pumps, eight pumps were tested with a new cartridge, and eight with a cartridge which underwent two years of real time aging. Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid at various time points was used to assess pumping accuracy.

The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for low, medium, and high basal rate settings for all pumps tested. For the medium and high basal rates, accuracy is reported from the time basal delivery started with no warm-up period. For the minimum basal rate, accuracy is reported after a 1-hour warm-up period. For each time period, the tables show the volume of insulin requested in the first row and the volume that was delivered as measured by the scale in the second row.

Low Basal Rate Delivery Performance (0.1 U/hr)

Basal Duration (Number of Units Delivered with 0.1 U/hr Setting	1 hour (0.1 U)	6 hours (0.6 U)	12 hours (1.2 U)
Amount Delivered [min, max]	0.12 U [0.09, 0.16]	0.67 U [0.56, 0.76]	1.24 U [1.04, 1.48]

Medium Basal Rate Delivery Performance (2.0 U/hr)

Basal Duration (Number of Units Delivered with 2 U/hr Setting	1 hour (2 U)	6 hours (12 U)	12 hours (24 U)
Amount Delivered [min, max]	2.1 U [2.1, 2.2]	12.4 U [12.0, 12.8]	24.3 U [22.0, 24.9]

High Basal Rate Delivery Performance (15 U/hr)

Basal Duration (Number of Units Delivered with 15 U/hr Setting	1 hour (15 U)	6 hours (90 U)	12 hours (180 U)
Amount Delivered [min, max]	15.4 U [14.7, 15.7]	90.4 U [86.6, 93.0]	181 U [175.0, 187.0]

Bolus Delivery

To assess bolus delivery accuracy, thirty-two t:slim X2 pumps were tested by delivering consecutive low, medium, and high bolus volumes (0.05, 2.5, and 25 units). Sixteen of the pumps were new, and sixteen had been aged to simulate 4 years of regular use. For both aged and unaged pumps, 8 pumps were tested with a new cartridge, and 8 with a cartridge which underwent 2 years of real time aging. Water was used as a substitute for insulin for this testing. The water was pumped into a container on a scale, and the weight of the liquid at various times points was used to assess pumping accuracy.

Delivered bolus volumes were compared to the requested bolus volume delivery for minimum, intermediate, and maximum bolus volumes. The tables below show average, minimum and maximum bolus sizes observed as well as the number of boluses which were observed to be within the specified range of each target bolus volume.

Summary of Bolus Delivery Performance (n=32 pumps)

Individual Bolus Accuracy Performance	Target Bolus Size [Units]	Mean Bolus Size [Units]	Min Bolus Size [Units]	Max Bolus Size [Units]
Min Bolus Delivery Performance (n=800 boluses)	0.050	0.050	0.000	0.114
Intermediate Bolus Delivery Performance (n=800 boluses)	2.50	2.46	0.00	2.70
Max Bolus Delivery Performance (n=256 boluses)	25.00	25.03	22.43	25.91

Low Basal Delivery Performance (0.05 U) (n=800 boluses)

	Units of Insulin Delivered After a 0.05 U Bolus Request									
	< 0.0125 (< 25%)	0.0125–0.0375 (25–75%)	0.0375–0.045 (75–90%)	0.045–0.0475 (90–95%)	0.0475–0.0525 (95–105%)	0.0525–0.055 (105–110%)	0.055–0.0625 (110–125%)	0.0625–0.0875 (125–175%)	0.0875–0.125 (175–250%)	> 0.125 (> 250%)
Number and Percent of Boluses Within Range	21/800 (2.6%)	79/800 (9.9%)	63/800 (7.9%)	34/800 (4.3%)	272/800 (34.0%)	180/800 (22.5%)	105/800 (13.1%)	29/800 (3.6%)	17/800 (2.1%)	0/800 (0.0%)

Intermediate Basal Delivery Performance (2.5U) (n=800 boluses)

	Units of Insulin Delivered After a 2.5 U Bolus Request									
	<0.625 (<25%)	0.625–1.875 (25–75%)	1.875–2.25 (75–90%)	2.25–2.375 (90–95%)	2.375–2.625 (95–105%)	2.625–2.75 (105–110%)	2.75–3.125 (110–125%)	3.125–4.375 (125–175%)	4.375–6.25 (175–250%)	>6.25 (>250%)
Number and Percent of Boluses Within Range	9/800 (1.1%)	14/800 (1.8%)	11/800 (1.4%)	8/800 (1.0%)	753/800 (94.1%)	5/800 (0.6%)	0/800 (0.0%)	0/800 (0.0%)	0/800 (0.0%)	0/800 (0.0%)

High Basal Delivery Performance (25 U) (n=256 boluses)

	Units of Insulin Delivered After a 25 U Bolus Request									
	< 6.25 (< 25%)	6.25–18.75 (25–75%)	18.75–22.5 (75–90%)	22.5–23.75 (90–95%)	23.75–26.25 (95–105%)	26.25–27.5 (105–110%)	27.5–31.25 (110–125%)	31.25–43.75 (125–175%)	43.75–62.5 (175–250%)	> 62.5 (> 250%)
Number and Percent of Boluses Within Range	0/256 (0.0%)	0/256 (0.0%)	1/256 (0.4%)	3/256 (1.2%)	252/256 (98.4%)	0/256 (0.0%)	0/256 (0.0%)	0/256 (0.0%)	0/256 (0.0%)	0/256 (0.0%)

Rate of Delivery

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

Bolus Duration

25 Unit Bolus Duration	8 minutes 26 seconds Typical
2.5 Unit Bolus Duration	1 minute 45 seconds Typical

Time to Occlusion Alarm

Operating Rate	Typical	Maximum
Bolus (3 units or Greater)	1 minute 2 seconds	3 Minutes
Basal (2 units/hr)	1 Hour 4 Minutes	2 Hours
Basal (0.1 units/hr)	19 Hours 43 Minutes	36 Hours

The time to occlusion alarm is based on insulin volume not delivered. During an occlusion event, boluses of less than 3 units may not trigger an occlusion alarm if no basal insulin is being delivered. The bolus amount will reduce the time to occlusion depending on the basal rate.

30.5 Dexcom G5 Mobile CGM Transmitter Performance Characteristics

Parameter	Performance Characteristics
TX/RX Frequencies	2.402-2.480 GHz
Bandwidth	1.02 MHz
Maximum Output Power	1.0 mW EIRP
Modulation	Gaussian Frequency-Shift Keying
Data Rate	1 Mbps
Data Communication Range	20 feet

The Dexcom G5 Mobile CGM is safe for use on U.S. commercial airlines. The Dexcom G5 Mobile Transmitter is an M-PED with emission levels that meet RTCA/DO160, Section 21, Category M. Per FAA Advisory, Circular #91-21, 1B, dated 8/25/06, any M-PED that meets this standard in all modes may be used onboard the aircraft without any further testing by the operator. This device can withstand exposure to common electrostatic (ESD) and electromagnetic interference (EMI).

30.6 Dexcom G5 Mobile CGM Sensor Performance Characteristics

We recommend that you review the information in this chapter with your healthcare provider to understand how well Dexcom G5 Mobile CGM performs.

Dexcom G5 Mobile CGM uses a glucose sensor to continuously measure and monitor your glucose levels. The sensor is "calibrated" using a commercially available blood glucose meter. Once calibrated, the CGM reports glucose readings up to every 5 minutes. The CGM was evaluated in clinical studies in which CGM sensor readings were compared to blood glucose values to assess its performance and how well the CGM readings compare to a laboratory test method that measures blood glucose values. Additionally, patients performed self-monitoring blood glucose meter tests at home to assess the CGM performance in real use environment.

Although the performance characteristics of the CGM are presented in the following, there is no commonly accepted statistical approach for capturing performance of continuous glucose monitors (CGMs), such as the Dexcom G5 Mobile CGM.

Clinical Study Overview

The CGM performance was evaluated in four separate prospective clinical studies. In all four studies, subjects were required to confirm glucose readings with their SMBG meters before making any treatment decisions. Two studies included adults, and two studies included pediatrics. In the following sections and tables, the studies will be identified as follows:

Adult Studies (18 years and older)
Original Adult Study: the Receiver included software version SW10050

Software 505 Adult Study: the Receiver included software version SW10505

Pediatric Studies (2 to 17 years)
Original Pediatric Study: the Receiver included software version SW10050

Software 505 Pediatric Study: the Receiver included software version SW10505

The Dexcom G5 Mobile CGM incorporates the algorithm from software version SW10505 and has a new software number.

Overview of Adult Studies

The CGM performance for adults was evaluated in two separate prospective clinical studies:

Original Adult Study (software SW10050) and the **Software 505 Adult** Study (software SW10505).

Differences between the studies include the number of subjects enrolled, the number of sensors worn by each participant, the SMBG meter used, and the number of clinic days each subject participated in during the study. An overview of each study is provided here.

The **Original Adult** Study enrolled 72 subjects, and the **Software 505 Adult** Study enrolled 51 subjects. All

subjects had Type 1 or Type 2 diabetes mellitus, and required insulin or oral medication to manage their diabetes. In the **Original Adult** Study, 83% of subjects had Type 1 diabetes, and 17% of subjects had Type 2 diabetes. In the **Software 505** Adult Study, 86% of subjects had Type 1 diabetes, and 14% of subjects had Type 2 diabetes. Both studies included subjects greater than 18 years of age.

Subjects in both studies used the CGM for seven days. In the **Original Adult** Study, thirty-six subjects each wore 2 sensors; in the **Software 505 Adult** Study, all subjects wore 1 sensor only. Throughout the 7-day wear period, the sensor was calibrated with an average of 2 fingersticks per day (approximately once every 12 hours). In the **Original Adult** Study, subjects used the LifeScan® OneTouch® Ultra®2 meter and in the **Software 505** Adult Study, subjects used Bayer's CONTOUR® NEXT USB meter.

In the **Original Adult** Study, all subjects were evaluated in a controlled clinic environment on all three clinic days: Day 1, Day 4, and Day 7 of the 7-day wear period. In the **Software 505 Adult** Study, subjects were evaluated in one of the three clinic days so there are fewer data samples than in the **Original Adult** Study. While using the CGM in the clinic, subjects had their blood glucose measured every 15 minutes with a reliable laboratory method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer. This instrument is referred to as the "YSI." Readings from the CGM were reported every 5 minutes and paired with YSI values in order to characterize how well the CGM readings agreed with laboratory standard blood glucose results. The remainder of the study took place at home, and the CGM performance was also paired with the comparative meter results, referred to as the "SMBG."

Overview of Pediatric Studies

The CGM performance for children and adolescents was evaluated in two separate prospective clinical studies: the **Original Pediatric** Study (SW10050) and the **Software 505 Pediatric** Study (SW10505). Differences between the studies include the number of subjects enrolled, the number of sensors worn by each participant, the SMBG meter used, the length of time subjects were evaluated in a controlled clinic environment and whether or not subjects ages 13-17 had their glucose levels intentionally manipulated during the study. An overview of each study is provided here.

The **Original Pediatric** Study enrolled 176 subjects, with 16% of subjects younger than 6-years old, and the **Software 505 Pediatric** Study enrolled 79 subjects, with 20% of subjects younger than 6-years old. All subjects had Type 1 or Type 2 diabetes mellitus and required insulin or oral medication to manage their diabetes. In the **Original Pediatric** Study, about 99% of subjects had Type 1 diabetes and 1% had Type 2 diabetes. In the **Software 505** Pediatric Study, all subjects had Type 1 diabetes. Sensors were inserted in either the abdomen or upper buttocks.

Subjects in all studies used the CGM for seven days. In the **Original Pediatric** Study, all subjects wore 2 sensors; in the **Software 505 Pediatric**

Study, all subjects wore 1 sensor only. Throughout the 7-day wear period, the sensors were calibrated with an average of 2 fingersticks per day (approximately once every 12 hours), using self-monitoring blood glucose (SMBG) meter values. The **Original Pediatric** Study used the LifeScan® OneTouch® Verio® IQ meter; the **Software 505 Pediatric** Study used Bayer's CONTOUR® NEXT USB meter.

All subjects were evaluated in a controlled clinic environment on Day 1, Day 4 or Day 7 of the 7-day wear period. While using the CGM in the clinic, subjects provided at least two fingerstick measurements per hour, and subjects ages 6-17 also provided venous blood for comparison to a laboratory method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer. This instrument is referred to as the "YSI." In the **Original Pediatric** Study, subjects' glucose levels were not intentionally manipulated during this study; in the **Software 505 Pediatric** Study, subjects ages 13-17 had their glucose levels intentionally manipulated during the clinic session. Readings from the CGM were reported every 5 minutes and paired with YSI values collected every 15 minutes in order to characterize how well the CGM readings agreed with laboratory standard blood glucose results. The remainder of the study took place at home, and the CGM performance was also paired with the comparative meter results, referred to as the "SMBG."

Table 1-A. Agreement to YSI within CGM Glucose Ranges (Adult)

CGM Glucose Range[1] (mg/dL)	Study[2]	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent Greater than 40/40% YSI
Overall	Original	9152	71%	82%	92%	3%
	Software 505	2263	86%	93%	98%	1%
40–60	Original	512	67%	78%	88%	6%
	Software 505	120	89%	94%	98%	0%
61–80	Original	781	73%	85%	94%	2%
	Software 505	226	91%	96%	99%	0%
81–180	Original	3853	67%	78%	91%	3%
	Software 505	738	84%	92%	98%	1%
181–300	Original	2784	72%	84%	93%	4%
	Software 505	798	86%	93%	98%	1%
301–350	Original	775	82%	91%	97%	2%
	Software 505	229	86%	94%	98%	1%
351–400	Original	447	74%	84%	91%	5%
	Software 505	152	80%	92%	97%	0%

1. CGM readings are within 40–400 mg/dL, inclusive.
2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 1-B. Agreement to YSI within CGM Glucose Ranges (Pediatric)

CGM Glucose Range[1] (mg/dL)	Study[2]	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent Greater than 40/40% YSI
Overall	Original	2922	55%	68%	85%	7%
	Software 505	2262	81%	91%	96%	2%
40–60	Original	19	63%	74%	79%	21%
	Software 505	86	54%	74%	91%	3%
61–80	Original	76	61%	82%	92%	4%
	Software 505	142	77%	82%	90%	3%
81–180	Original	1155	56%	69%	84%	6%
	Software 505	805	78%	88%	97%	1%
181–300	Original	1380	55%	68%	85%	7%
	Software 505	957	89%	96%	99%	1%
301–350	Original	206	48%	62%	80%	11%
	Software 505	209	81%	91%	94%	5%
351–400	Original	86	48%	61%	79%	12%
	Software 505	63	64%	81%	83%	8%

1. CGM readings are within 40–400 mg/dL, inclusive.
2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Agreement Relative to YSI

Agreement between the CGM and blood glucose values is characterized using paired CGM and YSI values. The CGM and YSI results were compared by pairing the YSI blood glucose value to a CGM glucose reading that occurred immediately after the YSI was collected.

The agreement of the CGM to blood glucose values was assessed by calculating the percentage of CGM readings that were within 15%, 20%, 30% and greater than 40% of the YSI values. For readings less than or equal to 80 mg/dL the absolute difference in mg/dL between the two glucose results was calculated. For values greater than 80 mg/dL the absolute percent difference (%) from the YSI values was calculated. The percentages of total readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30% or greater than 40 mg/dL or 40% are provided in Tables 1-A and 1-B. The tables are categorized within CGM glucose ranges. When you see a CGM reading on your receiver, this table shows you how likely that reading matches your blood glucose level (measured by YSI in the study).

For example, in the **SW10505 Adult** Study (Table 1-A), the total number of data pairs considered in the analysis was 2263. Of these, 93% of the CGM readings fall within ± 20 mg/dL of the YSI blood glucose values ≤ 80 mg/dL and within ± 20% of YSI blood glucose values > 80 mg/dL.

Table 2-A. Number and Percentage of YSI Values When CGM Readings are "Low" or "High" (Adult)

			YSI (mg/dL)					Total
CGM Readings	Study[1]	CGM-YSI Pairs	< 55	< 60	< 70	< 80	≥ 80	
"LOW"	Original	n	66	84	123	142	13	155
		Cumulative Percent	42%	54%	79%	92%	8%	
	Software 505	n	11	16	17	18	0	18
		Cumulative Percent	61%	89%	94%	100%	0%	

			YSI (mg/dL)					Total
CGM Readings	Study[1]	CGM-YSI Pairs	> 340	> 320	> 280	> 240	≤ 240	
"High"	Original	n	189	220	238	246	2	248
		Cumulative Percent	76%	89%	96%	99%	1%	
	Software 505	n	40	43	45	45	0	45
		Cumulative Percent	89%	96%	100%	100%	0%	

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 2-B. Number and Percentage of YSI Values When CGM Readings are "Low" or "High" (Pediatric)

			YSI (mg/dL)					Total
CGM Readings	Study[1]	CGM-YSI Pairs	< 55	< 60	< 70	< 80	≥ 80	
"LOW"	Original	n	0	0	0	0	13	13
		Cumulative Percent	0%	0%	0%	0%	100%	
	Software 505	n	3	5	10	15	1	16
		Cumulative Percent	19%	31%	63%	94%	6%	

			YSI (mg/dL)					Total
CGM Readings	Study[1]	CGM-YSI Pairs	> 340	> 320	> 280	> 240	≤ 240	
"High"	Original	n	38	51	68	69	1	70
		Cumulative Percent	54%	73%	97%	99%	1%	
	Software 505	n	14	19	22	23	1	24
		Cumulative Percent	58%	79%	92%	96%	4%	

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Agreement When CGM Reads "LOW" or "HIGH"

The CGM reports glucose readings between 40 and 400 mg/dL. When the CGM determines the glucose reading is below 40 mg/dL, it displays "LOW" on the pump home screen. When the CGM determines that the glucose level is above 400 mg/dL, it displays "HIGH" on the pump home screen. Because the CGM does not display glucose values below 40 mg/dL or above 400 mg/dL, the comparisons to the actual blood glucose levels (as determined by the YSI analyzer) when CGM is classified as "LOW" or "HIGH" are included separately in Tables 2-A and 2-B. The tables include the numbers and the cumulative percentages when YSI values were less than certain glucose levels (for "LOW"), and when YSI values were greater than certain glucose levels (for "HIGH").

For example, in the **Software 505 Adult** Study (Table 2-A), when the CGM displayed "LOW" (18 occasions), 100% (18 out of 18) of the YSI values were less than 80 mg/dL, and 94% (17 out of 18) of the YSI values were less than 70 mg/dL. When the CGM displayed "HIGH" (45 occasions), 100% (45 out of 45) of the YSI values were greater than 240 mg/dL, and 100% (45 out of 45) of the YSI values were greater than 280 mg/dL.

Table 3-A. Concurrence of CGM Readings and YSI Values (Original Adult Study)

CGM mg/dL	YSI (mg/dL) Row Percentage of Matched Pairs in Each CGM Glucose Range											Number of Paired CGM-YSI
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	
< 40	6%	48%	37%	7%	1%	0%	0%	0%	0%	0%	0%	155
40–60	4%	49%	36%	11%	1%	0%	0%	0%	0%	0%	0%	512
61–80	0%	22%	51%	24%	1%	0%	0%	0%	0%	0%	0%	781
81–120	0%	2%	17%	66%	13%	1%	0%	0%	0%	0%	0%	1706
121–160	0%	0%	1%	25%	60%	13%	2%	0%	0%	0%	0%	1492
161–200	0%	0%	0%	2%	28%	53%	16%	2%	0%	0%	0%	1240
201–250	0%	0%	0%	0%	3%	21%	51%	21%	3%	1%	0%	1181
251–300	0%	0%	0%	0%	0%	4%	19%	49%	24%	3%	0%	1018
301–350	0%	0%	0%	0%	0%	0%	3%	28%	51%	16%	1%	775
351–400	0%	0%	0%	0%	0%	0%	3%	10%	43%	38%	7%	447
> 400	0%	0%	0%	0%	0%	0%	1%	6%	21%	57%	15%	248

Table 3-B. Concurrence of CGM Readings and YSI Values (Software 505 Adult Study)

CGM mg/dL	YSI (mg/dL) Row Percentage of Matched Pairs in Each CGM Glucose Range											Number of Paired CGM-YSI
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	
< 40	6%	83%	11%	0%	0%	0%	0%	0%	0%	0%	0%	18
40–60	2%	74%	22%	3%	0%	0%	0%	0%	0%	0%	0%	120
61–80	0%	19%	68%	13%	0%	0%	0%	0%	0%	0%	0%	226
81–120	0%	0%	19%	72%	8%	1%	0%	0%	0%	0%	0%	347
121–160	0%	0%	0%	17%	72%	11%	0%	0%	0%	0%	0%	246
161–200	0%	0%	0%	0%	25%	59%	16%	0%	0%	0%	0%	286
201–250	0%	0%	0%	0%	0%	16%	70%	13%	1%	0%	0%	376
251–300	0%	0%	0%	0%	0%	2%	16%	61%	14%	7%	0%	281
301–350	0%	0%	0%	0%	0%	0%	2%	28%	59%	10%	1%	229
351–400	0%	0%	0%	0%	0%	0%	0%	4%	47%	45%	5%	152
> 400	0%	0%	0%	0%	0%	0%	0%	0%	20%	38%	42%	45

Table 3-C. Concurrence of CGM Readings and YSI Values (Original Pediatric Study)

CGM mg/dL	YSI (mg/dL) Row Percentage of Matched Pairs in Each CGM Glucose Range											Number of Paired CGM-YSI
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	
< 40	0%	0%	0%	54%	31%	15%	0%	0%	0%	0%	0%	13
40–60	0%	21%	58%	16%	5%	0%	0%	0%	0%	0%	0%	19
61–80	0%	21%	45%	30%	4%	0%	0%	0%	0%	0%	0%	76
81–120	0%	1%	20%	66%	12%	1%	0%	0%	0%	0%	0%	338
121–160	0%	0%	1%	36%	54%	7%	1%	0%	0%	0%	0%	511
161–200	0%	0%	0%	4%	40%	48%	6%	1%	0%	0%	0%	596
201–250	0%	0%	0%	1%	9%	44%	41%	5%	0%	0%	0%	658
251–300	0%	0%	0%	0%	2%	7%	50%	36%	3%	0%	2%	432
301–350	0%	0%	0%	0%	0%	2%	18%	59%	21%	0%	0%	206
351–400	0%	0%	0%	0%	0%	0%	3%	28%	50%	16%	2%	86
> 400	0%	0%	0%	0%	0%	0%	1%	14%	41%	36%	7%	70

Table 3-D. Concurrence of CGM Readings and YSI Values (Software 505 Pediatric Study)

CGM mg/dL	YSI (mg/dL) Row Percentage of Matched Pairs in Each CGM Glucose Range											Number of Paired CGM-YSI
	< 40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	> 400	
< 40	6%	25%	63%	6%	0%	0%	0%	0%	0%	0%	0%	16
40–60	0%	33%	60%	6%	1%	0%	0%	0%	0%	0%	0%	86
61–80	0%	8%	64%	26%	2%	0%	0%	0%	0%	0%	0%	142
81–120	0%	1%	15%	69%	13%	1%	1%	0%	0%	0%	0%	314
121–160	0%	0%	0%	15%	66%	18%	1%	0%	0%	0%	0%	313
161–200	0%	0%	0%	1%	18%	66%	15%	0%	0%	0%	0%	355
201–250	0%	0%	0%	0%	1%	17%	68%	14%	0%	0%	0%	444
251–300	0%	0%	0%	0%	0%	0%	26%	58%	16%	0%	0%	336
301–350	0%	0%	0%	0%	0%	0%	4%	40%	46%	9%	0%	209
351–400	0%	0%	0%	0%	0%	0%	3%	14%	62%	21%	0%	63
> 400	0%	0%	0%	0%	0%	0%	4%	13%	29%	38%	17%	24

Concurrence of CGM and Laboratory Reference

Table 3-A (Original Adult Study), 3-B (Software 505 Adult Study), 3-C (Original Pediatric Study) and 3-D (Software 505 Pediatric Study) are categorized by ranges of CGM glucose readings. These tables describe, for each range of CGM glucose readings, what percentage of paired YSI values were in the same glucose range (shaded) or in glucose ranges above and below the paired CGM readings.

For example, based on the **Software 505 Adult**, when CGM readings are within 81 to 120 mg/dL, you can expect your blood glucose levels are within 81 to 120 mg/dL 72% of time.

Table 4-A. Difference to YSI within CGM Glucose Ranges (Adult)

CGM Glucose Range[1] (mg/dL)	Study[2]	Number of Paired CGM-YSI	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	9152	2.9%	1.7%	13.3%	9.8%
	Software 505	2263	2.5%	2.4%	9.0%	7.0%
*40–60	Original	512	-10.0	-8.2	13.5	9.7
	Software 505	120	-3.3	-2.1	6.9	4.8
*61–80	Original	781	-2.4	-0.4	11.4	8.6
	Software 505	226	0.8	1.4	6.7	5.4
81–180	Original	3853	4.8%	3.0%	13.8%	9.8%
	Software 505	738	3.9%	4.1%	9.6%	8.2%
181–300	Original	2784	2.1%	0.0%	11.9%	9.2%
	Software 505	798	0.6%	0.4%	8.0%	6.1%
301–350	Original	775	3.8%	2.8%	9.8%	7.9%
	Software 505	229	4.1%	3.4%	8.0%	5.8%
351–400	Original	447	10.4%	7.7%	12.8%	9.1%
	Software 505	152	7.2%	6.3%	9.2%	7.2%

1. CGM readings are within 40–400 mg/dL, inclusive. 2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).
** For CGM ≤ 80 mg/dL, the difference and absolute difference in mg/dL are included instead of percent differences (%).*

Table 4-B. Difference to YSI within CGM Glucose Ranges (Pediatric)

CGM Glucose Range[1] (mg/dL)	Study[2]	Number of Paired CGM-YSI	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	2922	13.5%	11.6%	17.4%	13.5%
	Software 505	2262	1.8%	1.2%	10.4%	7.9%
*40–60	Original	19	-18.1	-9.1	19.2	9.1
	Software 505	86	-15.3	-13.2	16.1	13.2
*61–80	Original	76	-3.7	-2.3	13.4	10.6
	Software 505	142	-4.8	-1.0	11.8	7.7
81–180	Original	1155	11.9%	9.7%	17.0%	13.0%
	Software 505	805	1.9%	0.7%	10.6%	8.1%
181–300	Original	1380	14.8%	12.4%	17.4%	13.3%
	Software 505	957	2.2%	1.0%	8.1%	6.5%
301–350	Original	206	19.2%	15.9%	19.4%	15.9%
	Software 505	209	7.8%	6.5%	11.0%	7.9%
351–400	Original	86	18.5%	15.5%	19.1%	15.5%
	Software 505	63	14.9%	11.6%	15.2%	11.6%

1. CGM readings are within 40–400 mg/dL, inclusive. 2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).
** For CGM ≤ 80 mg/dL, the difference and absolute difference in mg/dL are included instead of percent differences (%).*

Accuracy Relative to YSI

Accuracy between matched pairs was also estimated by calculating the percent difference between the CGM reading and the YSI value. For example, if the YSI value is 100 mg/dL and the CGM reading is 90 mg/dL, a 10% difference between the CGM and the YSI is reported. The CGM and YSI values were compared by pairing the CGM reading that fell immediately after the YSI value was collected.

In the example above, the CGM reading is less than the YSI value, so the percent difference reading is negative. The mean percent difference is the average of all positive and negative percent differences between the two devices; it tells you if the CGM reads higher or lower on average than the YSI within each glucose range.

Another estimate used to show the accuracy of the CGM is the absolute percent difference. The absolute percent difference tells you the percent difference or "distance" between the CGM and YSI values, but does not tell you whether the CGM is reading, on average, higher or lower than the YSI laboratory standard. The mean absolute percent difference is the average "distance" (regardless if positive or negative) between CGM readings and YSI values.

Accuracy measures in differences for both the **Original Adult** and **Software 505 Adult** Studies are summarized in Table 4-A. Accuracy measures in differences for both the **Original Pediatric** and **Software 505 Pediatric** Studies are summarized in Table 4-B. Tables 4-A and 4-B are categorized within CGM glucose ranges.

For example, in the **Software 505 Adult** Study (Table 4-A), overall, on average, the CGM reads 2.5% different (Mean Percent Difference) than the reference and 9.0% absolute different (Mean Absolute Difference) than the reference values. The Median Percent Difference shows that half of the time the CGM reads 2.4% or less than the YSI blood glucose values and the Median Absolute Percent Difference shows that half of the time the CGM reads about 7.0% or less than the YSI blood glucose values.

Table 5-A. Hypoglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Adult)

Hypoglycemic Alert Level (mg/dL)	Study[1]	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	50%	50%	71%	29%
	Software 505	71%	29%	68%	32%
60	Original	64%	36%	75%	25%
	Software 505	85%	15%	83%	17%
70	Original	79%	21%	83%	17%
	Software 505	92%	8%	91%	9%
80	Original	87%	13%	86%	14%
	Software 505	95%	5%	90%	10%
90	Original	90%	10%	89%	11%
	Software 505	96%	4%	94%	6%

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 5-B. Hypoglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Pediatric, Ages 6-17 Years)

Hypoglycemic Alert Level (mg/dL)	Study[1]	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	0%	100%	0%	100%
	Software 505	22%	78%	75%	25%
60	Original	11%	89%	25%	75%
	Software 505	42%	58%	78%	23%
70	Original	47%	53%	50%	50%
	Software 505	68%	32%	75%	25%
80	Original	55%	45%	55%	45%
	Software 505	86%	14%	91%	9%
90	Original	69%	31%	62%	38%
	Software 505	90%	10%	93%	7%
100	Original	75%	25%	62%	38%
	Software 505	91%	9%	93%	7%

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 5-C. Hypoglycemic Alert and Detection Rate Evaluation in Reference to SMBG 30 Minutes Before and After (Pediatric, Ages 2-5 Years)

Hypoglycemic Alert Level (mg/dL)	Study[1]	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55	Original	3%	97%	57%	43%
	Software 505	25%	75%	100%	0%
60	Original	11%	89%	62%	38%
	Software 505	20%	80%	100%	0%
70	Original	29%	71%	77%	23%
	Software 505	20%	80%	100%	0%
80	Original	35%	65%	85%	15%
	Software 505	61%	39%	100%	0%
90	Original	51%	49%	89%	11%
	Software 505	78%	22%	100%	0%
100	Original	64%	36%	91%	9%
	Software 505	82%	18%	100%	0%

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Low and High Glucose Alerts

The ability of the CGM to detect high and low glucose levels is assessed by comparing CGM results to YSI results at low and high blood glucose levels and determining if the alert may have sounded. The CGM and YSI values were compared by pairing the CGM reading that occurred immediately after the YSI value was collected. We suggest that you ask your doctor what alert settings would be best for you.

The Low Glucose Alert

Estimates of how well the adjustable Low Glucose Alert performs are presented in Tables 5-A, 5-B and 5-C. Table 5-A represents the hypoglycemic alert evaluation within 15 minutes of the YSI value in the adult studies. Table 5-B represents the alert evaluation within 15 minutes of the YSI value for a subset of the pediatric population—subjects age 6 to 17 years who had YSI measurements every 15 minutes. Table 5-C represents the alert evaluation within 30 minutes of an SMBG reading for 2- to 5-year old subjects in the pediatric studies.

Hypoglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or below the alert setting within 15 or 30 minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the blood glucose level was above the alert setting within 15 or 30 minutes before or after the device alarmed.

For example, if you set the Low Glucose Alert to 70 mg/dL and your alarm sounds, how often can you expect your blood sugar to actually be low? In the **Software 505 Adult** Study (Table 5-A), when your alarm sounds, you can expect your blood sugar to be below 70 mg/dL approximately 92% of the time and above 70 mg/dL approximately 8% of the time within the 15 minute period before or after your alarm sounds.

Hypoglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hypoglycemia or how often it misses such an event. The Hypoglycemia Detection Rate is the % of time the blood glucose level was at or below the alert setting and device alarmed within 15 or 30 minutes before or after the blood glucose was at or below the alert settings. The Hypoglycemia Missed Detection Rate is the % of time the blood glucose was at or below the alert setting, but the device did not alarm within 15 or 30 minutes before or after the blood glucose was at or below the alert setting.

For example, if you set the Low Glucose alert to 70 mg/dL, how often will your alarm alert you if your blood glucose goes below 70 mg/dL? In the **Software 505 Adult** Study (Table 5-A), when your blood sugar goes below 70 mg/dL, you can expect your alarm to sound 91% of the time and not to sound approximately 9% of time within the 15 minute period before or after your blood sugar goes below 70 mg/dL.

Table 6-A. Hyperglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Adult)

Hyperglycemic Alert Level (mg/dL)	Study[1]	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	95%	5%	98%	2%
	Software 505	98%	2%	100%	0%
140	Original	94%	6%	97%	3%
	Software 505	97%	3%	99%	1%
180	Original	92%	8%	97%	3%
	Software 505	97%	3%	99%	1%
200	Original	92%	8%	97%	3%
	Software 505	96%	4%	98%	2%
220	Original	91%	9%	95%	5%
	Software 505	94%	6%	98%	2%
240	Original	91%	9%	94%	6%
	Software 505	93%	7%	95%	5%
300	Original	82%	18%	86%	14%
	Software 505	86%	14%	90%	10%

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 6-B. Hyperglycemic Alert and Detection Rate Evaluation in Reference to YSI 15 Minutes Before and After (Pediatric, Ages 6-17 Years)

Hyperglycemic Alert Level (mg/dL)	Study[1]	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	91%	9%	98%	2%
	Software 505	98%	2%	99%	1%
140	Original	87%	13%	99%	1%
	Software 505	97%	3%	98%	2%
180	Original	75%	25%	99%	1%
	Software 505	94%	6%	98%	2%
200	Original	71%	29%	98%	2%
	Software 505	94%	6%	97%	3%
220	Original	67%	33%	97%	3%
	Software 505	93%	7%	96%	4%
240	Original	62%	38%	96%	4%
	Software 505	88%	12%	94%	6%
300	Original	43%	57%	93%	7%
	Software 505	69%	31%	84%	16%

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 6-C. Hyperglycemic Alert and Detection Rate Evaluation in Reference to SMBG 30 Minutes Before and After (Pediatric, Ages 2-5 Years)

Hyperglycemic Alert Level (mg/dL)	Study[1]	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120	Original	92%	8%	98%	2%
	Software 505	97%	3%	99%	1%
140	Original	90%	10%	98%	2%
	Software 505	98%	2%	100%	0%
180	Original	87%	13%	96%	4%
	Software 505	99%	1%	93%	7%
200	Original	85%	15%	96%	4%
	Software 505	98%	2%	93%	7%
220	Original	81%	19%	95%	5%
	Software 505	100%	0%	97%	3%
240	Original	80%	20%	95%	5%
	Software 505	99%	1%	98%	2%
300	Original	71%	29%	90%	10%
	Software 505	95%	5%	96%	4%

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

The High Glucose Alert

Estimates of how well the adjustable High Glucose Alert performs are presented in Tables 6-A, 6-B and 6-C. Table 6-A represents the hyperglycemic alert evaluation within 15 minutes of the YSI value in the adult studies. Table 6-B represents the alert evaluation within 15 minutes of the YSI value for a subset of the pediatric population—subjects age 6 to 17 years who had YSI measurements every 15 minutes. Table 6-C represents the alert evaluation within 30 minutes of an SMBG reading for 2- to 5-year old subjects in the pediatric studies.

Hyperglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or above the alert setting within 15 or 30 minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the blood glucose level was below the alert setting within 15 or 30 minutes before or after the device alarmed.

For example, if you set the High Glucose alert to 200 mg/dL and your alarm sounds, how often can you expect your blood sugar to actually be high? In the **Software 505 Adult** Study (Table 6-A), when your alarm sounds, you can expect your blood sugar to be at or above 200 mg/dL approximately 96% of the time and not be above 200 mg/dL approximately 4% of the time within the 15 minute period before or after your alarm sounds.

Hyperglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hyperglycemia or how often it misses such an event. The Hyperglycemia Detection Rate is the % of time the blood glucose level was at or above the alert setting and the device alarmed within 15 or 30 minutes before or after the blood glucose was at or above the alert settings. The Hyperglycemia Missed Detection Rate is the % of time the blood glucose was at or above the alert setting, but the device did not alarm within 15 or 30 minutes before or after the blood glucose was at or above the alert setting.

For example, if you set your High Glucose alert to 200 mg/dL, how often will your alarm alert you if your blood glucose goes at or above 200 mg/dL? In the **Software 505 Adult** Study (Table 6-A), when your blood sugar goes above 200 mg/dL, you can expect your alarm to sound 98% of the time and not to sound approximately 2% of time within the 15 minute period before or after your blood sugar goes above 200 mg/dL.

Table 7-A. Percentage of CGM Readings[1] Within YSI Values With Data Stratified in 2-Hour Increments After Calibration (Adult)

Time From Calibration	Study[2]	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent Greater than 40/40% YSI
0-2 hours	Original	1929	78%	88%	96%	2%
	Software 505	469	93%	97%	99%	0%
2-4 hours	Original	1516	69%	81%	91%	4%
	Software 505	389	90%	97%	99%	0%
4-6 hours	Original	1547	69%	79%	91%	5%
	Software 505	383	85%	91%	97%	2%
6-8 hours	Original	1520	68%	79%	92%	3%
	Software 505	380	79%	90%	97%	2%
8-10 hours	Original	1555	71%	82%	92%	4%
	Software 505	347	83%	92%	98%	0%
10-12 hours	Original	1068	65%	77%	91%	4%
	Software 505	295	80%	90%	98%	0%
12-14 hours	Original	17	65%	76%	82%	12%
	Software 505	0	--	--	--	--

1. CGM readings are within 40–400 mg/dL, inclusive. 2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 7-B. Percentage of CGM Readings[1] Within YSI Values With Data Stratified in 2-Hour Increments After Calibration (Pediatric)

Time From Calibration	Study[2]	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent Greater than 40/40% YSI
0-2 hours	Original	648	65%	75%	87%	7%
	Software 505	545	83%	91%	97%	1%
2-4 hours	Original	649	51%	67%	86%	7%
	Software 505	460	72%	89%	96%	2%
4-6 hours	Original	630	51%	61%	80%	10%
	Software 505	428	77%	88%	95%	2%
6-8 hours	Original	409	52%	68%	85%	5%
	Software 505	325	88%	92%	94%	3%
8-10 hours	Original	296	53%	69%	84%	7%
	Software 505	305	86%	93%	97%	1%
10-12 hours	Original	253	58%	74%	89%	5%
	Software 505	198	89%	94%	98%	0%
12-14 hours	Original	37	32%	38%	65%	22%
	Software 505	1	100%	100%	100%	0%

1. CGM readings are within 40–400 mg/dL, inclusive. 2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Calibration Stability

The CGM must be calibrated every 12 hours. To demonstrate performance of the CGM over a 12-hour calibration period, sensors were evaluated to verify that performance remains consistent over the 12-hour calibration period. CGMs were evaluated in 2-hour increments after calibration. Performance was estimated at each 2-hour interval and stratified by glucose values by calculating the percentage of CGM readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30%, 40 mg/dL or 40% and greater than 40 mg/dL or 40% of the YSI values in Tables 7-A and 7-B.

Table 8-A. Sensor Stability Relative to YSI (Accuracy Over Time[1]) - (Adult)

Day of Wear	Study[2]	Number of Paired CGM-YSI	Mean Absolute Percent Difference	Median Absolute Percent Difference	Percent Within 15/15% YSI	Percent Within 20/20% YSI	Percent Within 30/30% YSI	Percent Greater Than 40/40% YSI
Day 1	Original	3023	16.7%	13.2%	59%	71%	86%	6%
	Software 505	680	10.7%	7.9%	77%	84%	96%	2%
Day 4	Original	3108	11.4%	8.2%	77%	87%	95%	2%
	Software 505	777	8.0%	6.4%	89%	96%	99%	0%
Day 7	Original	3021	11.9%	8.9%	76%	87%	95%	2%
	Software 505	806	8.5%	7.2%	90%	97%	99%	0%

1. CGM readings are within 40–400 mg/dL, inclusive.
2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 8-B. Sensor Stability Relative to YSI (Accuracy Over Time[1]) - (Pediatric, Ages 6-17 Years)

Day of Wear	Study[2]	Number of Paired CGM-YSI	Mean Absolute Percent Difference	Median Absolute Percent Difference	Percent Within 15/15% YSI	Percent Within 20/20% YSI	Percent Within 30/30% YSI	Percent Greater Than 40/40% YSI
Day 1	Original	1016	21.2%	15.8%	48%	61%	78%	15%
	Software 505	740	12.7%	8.5%	75%	83%	91%	4%
Day 4	Original	810	16.0%	13.9%	52%	66%	87%	3%
	Software 505	795	8.1%	6.7%	89%	97%	100%	0%
Day 7	Original	1096	15.1%	11.3%	63%	76%	89%	4%
	Software 505	727	10.4%	8.4%	80%	91%	98%	1%

1. CGM readings are within 40–400 mg/dL, inclusive.
2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 8-C. Sensor Stability Relative to SMBG (Accuracy Over Time[1]) - (Pediatric, Ages 2-17 Years)

Day of Wear	Study[2]	Number of Paired CGM-SMBG	Mean Absolute Percent Difference	Median Absolute Percent Difference	Percent Within 15/15% SMBG	Percent Within 20/20% SMBG	Percent Within 30/30% SMBG	Percent Greater Than 40/40% SMBG
Day 1	Original	3216	18.8%	14.2%	53%	65%	81%	10%
	Software 505	893	14.8%	10.7%	64%	79%	91%	5%
Day 2	Original	2148	16.2%	12.4%	60%	74%	87%	6%
	Software 505	436	13.2%	10.4%	69%	81%	95%	3%
Day 3	Original	1977	15.2%	11.0%	63%	76%	89%	5%
	Software 505	441	13.8%	11.3%	66%	77%	91%	2%
Day 4	Original	2830	14.0%	10.9%	66%	79%	91%	4%
	Software 505	850	10.7%	8.5%	79%	91%	97%	1%
Day 5	Original	1768	15.4%	10.7%	67%	78%	90%	5%
	Software 505	374	11.4%	8.7%	74%	86%	96%	1%
Day 6	Original	1704	14.3%	9.8%	68%	79%	90%	4%
	Software 505	410	12.3%	9.2%	72%	80%	93%	2%
Day 7	Original	2675	12.4%	9.2%	72%	83%	94%	3%
	Software 505	860	11.3%	8.6%	79%	90%	96%	2%

1. CGM readings are within 40–400 mg/dL, inclusive. 2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Sensor Stability

Relative to YSI

Sensors can be worn for up to 7 days. Performance was estimated by calculating the percentage of CGM readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30%, 40 mg/dL or 40% and greater than 40 mg/dL or 40% of the YSI values at the beginning (Day 1), middle (Day 4) and end (Day 7) of the CGM lifecycle. The average and median of the absolute percent differences are included in Tables 8-A and 8-B showing consistent accuracy and sensor stability over the 7-day life of the sensor.

Relative to SMBG (Pediatric Study)

Performance was also estimated by calculating the percentage of CGM readings within various percentages of the SMBG values at each day of the sensor wear period (Table 8-C). The average and median of the absolute percent differences are included in the table.

Precision of Sensor Readings

A subset of subjects wore two sensors at the same time. This was to look at how similarly two sensors function on the same subject (sensor precision). Precision was evaluated by comparing the glucose readings from the two sensors worn on the same subject at the same time.

In the **Original Adult** Study, 36 subjects wore two sensors. Results showed that sensor readings from the two sensors generally agreed with each other within 9% (absolute percent difference) with a 7% coefficient of variation. In the **Original Pediatric** Study, all subjects wore two sensors. Results showed that sensor readings from the two sensors generally agreed with each other within 10% (absolute percent difference) with a 7% coefficient of variation. Only one sensor was worn in the **Software 505 Adult** and **Software 505 Pediatric** Studies so precision data was not collected.

Sensor Life

Sensors may be worn for up to 7 days (168 hours). To estimate how long a sensor will work over 7 days, all sensors worn were evaluated to determine how many days/hours of readings each sensor provided.

In the **Original Adult** Study, 108 sensors were evaluated. Ninety-four percent (94%) of the sensors lasted until Day 7 (145-168 hours). There were 6 (6%) sensors that ended early, four of which lasted more than 3 days.

In the **Software 505 Adult** Study, 51 sensors were evaluated. Ninety-eight percent (98%) of the sensors lasted until Day 7 (145-168 hours). There was 1 (2%) sensor that ended early, which lasted until day 5 of the sensor wear.

In the **Original Pediatric** Study, 351 sensors were evaluated. Eighty-five percent (85%) of the sensors lasted until Day 7 (145-168 hours).

In the **Software 505 Pediatric** Study, 77 sensors were evaluated. Ninety-four percent (94%) of the sensors lasted until Day 7 (145-168 hours).

Table 9-A. Number of Readings Provided by Each Sensor Over 7-Days (Adult)

% of Total Possible Readings Provided	Study[1]	Total Readings Provided (Min-Max)	% of Systems Providing That Number of Readings
0–25%	Original	167–491	2%
	Software 505	0	0%
26–50%	Original	719–914	4%
	Software 505	856–856	2%
51–75%	Original	1267–1267	1%
	Software 505	1253–1253	2%
76–100%	Original	1811–1992	94%
	Software 505	1497–1992	96%

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 9-B. Number of Readings Provided by Each Sensor Over 7-Days (Pediatric)

% of Total Possible Readings Provided	Study[1]	Total Readings Provided (Min-Max)	% of Systems Providing That Number of Readings
0–25%	Original	103–427	3%
	Software 505	60–223	4%
26–50%	Original	569–954	3%
	Software 505	877–891	3%
51–75%	Original	1006–1484	9%
	Software 505	1131–1342	3%
76–100%	Original	1518–1992	86%
	Software 505	1623–1990	91%

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 10-A. CGM Readings Within Wear Days (Adult)

Statistic	Study[1]	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	All Days[2]
Mean	Original	98%	98%	98%	98%	97%	99%	95%	97%
	Software 505	98%	99%	98%	98%	96%	99%	97%	98%
Median	Original	100%	100%	100%	100%	100%	100%	100%	100%
	Software 505	99%	100%	100%	100%	100%	100%	100%	100%
Standard Deviation	Original	5%	3%	9%	8%	10%	3%	11%	8%
	Software 505	3%	2%	8%	11%	15%	2%	13%	9%

Table 10-B. CGM Readings Within Wear Days (Pediatric)

Statistic	Study[1]	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	All Days[3]
Mean	Original	97%	96%	96%	95%	94%	94%	92%	95%
	Software 505	96%	96%	95%	96%	93%	95%	93%	95%
Median	Original	99%	99%	99%	99%	99%	99%	98%	99%
	Software 505	99%	98%	99%	99%	97%	97%	98%	98%
Standard Deviation	Original	6%	10%	9%	12%	14%	14%	17%	12%
	Software 505	9%	6%	12%	10%	15%	7%	12%	11%

1. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).
2. A total of 108 sensors were included with the Original Study and 51 sensors were included with the Software 505 Study.
3. A total of 108 sensors were included with the Original Study and 77 sensors were included with the Software 505 Study.

Number of Readings Provided

The CGM is capable of providing a reading up to every 5 minutes, or up to 288 readings per day. For a variety of reasons, the CGM may not display a glucose reading and readings are "skipped." Tables 9-A and 9-B estimate the number of readings you can expect to receive from the CGM over the entire 7-day period after calibration. Tables 10-A and 10-B show the number of readings you can expect to receive from the sensor within each system wear day.

For the **Software 505 Adult** Study (SW10505), 96% of CGM provided between 1,497 and 1,992 valid glucose readings (or more than 75% of the expected number of readings) as seen in Table 9-A. Adjusted within each sensor wear-day, the CGM in the **Software 505 Adult** Study provided an average of 98% of all expected glucose readings (288) as seen in Table 10-A.

Table 11-A. Agreement to SMBG within CGM Glucose Ranges (Adult)

CGM Glucose Range[1] (mg/dL)	Study[2]	Number of paired CGM-SMBG	Percent within 15/15% SMBG	Percent within 20/20% SMBG	Percent within 30/30% SMBG	Percent Greater than 40/40% SMBG
Overall	Original	7508	69%	81%	94%	2%
	Software 505	2992	77%	87%	96%	1%
40–60	Original	731	75%	84%	92%	4%
	Software 505	221	73%	80%	87%	7%
61–80	Original	968	78%	86%	95%	1%
	Software 505	336	77%	85%	95%	1%
81–180	Original	3141	65%	78%	93%	2%
	Software 505	1362	74%	85%	96%	1%
181–300	Original	1960	68%	81%	94%	3%
	Software 505	826	80%	90%	97%	1%
301–350	Original	450	77%	88%	98%	1%
	Software 505	161	83%	93%	99%	0%
351–400	Original	258	75%	85%	95%	2%
	Software 505	86	90%	93%	98%	1%

1. CGM readings are within 40–400 mg/dL, inclusive.
2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 11-B. Agreement to SMBG within CGM Glucose Ranges (Pediatric)

CGM Glucose Range[1] (mg/dL)	Study[2]	Number of paired CGM-SMBG	Percent within 15/15% SMBG	Percent within 20/20% SMBG	Percent within 30/30% SMBG	Percent Greater than 40/40% SMBG
Overall	Original	16318	64%	76%	89%	5%
	Software 505	4264	73%	84%	94%	2%
40–60	Original	487	44%	55%	68%	19%
	Software 505	240	54%	71%	86%	7%
61–80	Original	1340	59%	70%	85%	7%
	Software 505	399	64%	76%	92%	2%
81–180	Original	7084	62%	74%	90%	5%
	Software 505	1650	72%	84%	95%	2%
181–300	Original	5627	69%	80%	90%	5%
	Software 505	1526	79%	89%	97%	2%
301–350	Original	1176	65%	77%	90%	4%
	Software 505	319	72%	83%	94%	2%
351–400	Original	604	58%	72%	86%	6%
	Software 505	130	69%	79%	86%	8%

1. CGM readings are within 40–400 mg/dL, inclusive.
2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).

Table 12-A. CGM Difference to SMBG Within CGM Glucose Ranges (Adult)

CGM Glucose Ranges[1] (mg/dL)	Study[2]	Number of Paired CGM-SMBG	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	7508	-0.4%	-1.4%	14.0%	11.0%
	Software 505	2992	-2.6%	-2.7%	11.3%	8.6%
*40–60	Original	731	-9.3	-8.0	11.7	8.0
	Software 505	221	-10.3	-6.0	13.0	8.0
*61–80	Original	968	-1.0	1.0	10.7	8.0
	Software 505	336	-4.0	-2.0	10.1	7.0
81–180	Original	3141	1.4%	0.0%	14.2%	11.0%
	Software 505	1362	-2.6%	-3.1%	11.4%	8.9%
181–300	Original	1960	-0.7%	-2.8%	13.0%	10.3%
	Software 505	826	-1.4%	-2.0%	9.5%	7.4%
301–350	Original	450	-0.7%	-2.6%	10.5%	8.6%
	Software 505	161	0.0%	0.0%	8.3%	6.0%
351–400	Original	258	5.0%	3.0%	11.9%	8.6%
	Software 505	86	3.9%	3.2%	8.1%	6.7%

1. CGM readings are within 40–400 mg/dL, inclusive. 2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).
** For CGM ≤ 80 mg/dL, the differences in mg/dL are included instead of percent differences (%).*

Table 12-B. Difference to SMBG Within CGM Glucose Ranges (Pediatric)

CGM Glucose Ranges[1] (mg/dL)	Study[2]	Number of Paired CGM-SMBG	Mean Percent Difference	Median Percent Difference	Mean Absolute Percent Difference	Median Absolute Percent Difference
Overall	Original	16318	2.2%	0.9%	15.3%	11.1%
	Software 505	4264	-0.7%	-1.1%	12.5%	9.5%
*40–60	Original	487	-22.1	-17.0	23.9	18.0
	Software 505	240	-15.9	-14.0	16.9	14.0
*61–80	Original	1340	-11.8	-8.0	17.0	11.0
	Software 505	399	-7.8	-6.0	13.7	10.0
81–180	Original	7084	1.1%	-1.0%	15.4%	11.4%
	Software 505	1650	-1.2%	-2.6%	12.1%	9.5%
181–300	Original	5627	5.7%	3.4%	13.5%	9.5%
	Software 505	1526	1.7%	0.9%	10.1%	7.7%
301–350	Original	1176	9.6%	7.2%	14.2%	10.4%
	Software 505	319	6.7%	5.9%	11.8%	8.9%
351–400	Original	604	12.7%	10.2%	16.1%	11.9%
	Software 505	130	12.0%	8.9%	15.7%	10.6%

1. CGM readings are within 40–400 mg/dL, inclusive. 2. Both sets of study data are presented and are labeled as Original (SW10050) or Software 505 (SW10505).
** For CGM ≤ 80 mg/dL, the difference and absolute difference in mg/dL are included instead of percent differences (%).*

Agreement and Accuracy Relative to SMBG

Agreement between the CGM and blood glucose values is also characterized using paired CGM and SMBG results (Tables 11-A/B to 12-A/B).

The CGM and SMBG values were compared by pairing the comparative SMBG value to a CGM glucose reading that occurred immediately after the SMBG was collected. These results characterize the performance subjects expect during real-time use of the CGM in their daily diabetes management when comparing the CGM readings to their home blood glucose meter results. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the two glucose results was calculated. For values greater than 80 mg/dL, the absolute percent difference (%) from the SMBG values was calculated. The percentages of total readings within 15 mg/dL or 15%, 20 mg/dL or 20%, 30 mg/dL or 30%, 40 mg/dL or 40% or greater than 40 mg/dL or 40% were then calculated.

For example, if the CGM reads 100 mg/dL, it is between 81-180 mg/dL range and you can expect the CGM readings to be within 20% of the SMBG values 85% of the time for the **Software 505 Adult** Study, as seen in Table 11-A.

Overall, the CGM in the **Software 505 Adult** Study reads, on average, 2.6% lower (Mean Percent Difference) than SMBG values and 11.3% absolute different (Mean Absolute Percent Difference) than the SMBG values. The Median Percent Difference shows that half of the time the CGM reads lower in 2.7% or less than the SMBG values and the Median Absolute Percent Difference shows that half of the time the CGM reads about 8.6% or less different than SMBG values, as seen in Table 12-A.

Adverse Events

No serious adverse events or device-related serious adverse events occurred during the studies. Mild to moderate skin irritation, such as erythema or edema, occurred at the sensor needle insertion area or around the adhesive area. No infection, bruising, or bleeding occurred at the sensor needle insertion area or the adhesive area.

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30.7 Electromagnetic Compatibility

The information contained in this section is specific to the t:slim X2 System. This information provides reasonable assurance of normal operation, but does not guarantee such under all conditions. If the t:slim X2 System must be used in close proximity with other electrical equipment, the System should be observed in this environment to verify normal operation. Special precautions for electromagnetic compatibility must be taken when using medical electrical equipment. The System shall be placed into service with adherence to the EMC information provided here. Using cables and accessories not specified in this User Guide may adversely impact safety, performance, and electromagnetic compatibility, including increased emissions and/or decreased immunity.

For IEC 60601-1 testing, Essential Performance for the t:slim X2 System is defined as follows:

- The System will not over deliver a clinically significant amount of insulin.
- The System will not under deliver a clinically significant amount of insulin without notification to the user.
- The System will not deliver a clinically significant amount of insulin after occlusion release.
- The System will not discontinue reporting CGM data without notification to the user.

This section contains the following tables of information:

- Electromagnetic Emissions
- Electromagnetic Immunity
- Distances Between the t:slim X2 System and RF Equipment

30.8 Electromagnetic Emissions

The t:slim X2 System is intended for use in the electromagnetic environment specified below. Always make sure that the System is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions, CISPR 11	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions, CISPR 11	Class B	The System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions, IEC 61000-3-2	N/A	
Voltage Fluctuations/Flicker Emissions, IEC 61000-3-3	N/A	

30.9 Electromagnetic Immunity

The t:slim X2 System is intended for use in the electromagnetic environment specified below. Always make sure that the System is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines (100 kHz repetition frequency)	± 2 kV for power supply lines ± 1 kV for input/output lines (100 kHz repetition frequency)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	70% UR (30% dip in Ur) for 25 cycles 0% Ur (100% dip in Ur) for 1 cycle at 0 degrees 0% Ur (100% dip in Ur) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% Ur (100% dip in Ur) for 250 cycles	70% UR (30% dip in Ur) for 25 cycles 0% Ur (100% dip in Ur) for 1 cycle at 0 degrees 0% Ur (100% dip in Ur) for 0.5 cycles at 0, 45, 90, 135, 180, 225, 270, and 315 degrees 0% Ur (100% dip in Ur) for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the pump requires continued operation during power mains interruptions, it is recommended that the pump be powered from an uninterruptible power supply or a battery. NOTE: Ur is the a.c. mains voltage prior to application of the test level.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	400 A/m (IEC 60601-2-24)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	Proximity Field from Wireless Transmitters	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 V	Portable and mobile RF communications equipment should be used no closer to any part of the pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 0.35\sqrt{P}$ 80 MHz to 800 MHz, $d = 0.12\sqrt{P}$ 800 MHz to 2.5GHz, $d = 0.23\sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	30 V/m	
Proximity Field from Wireless Transmitters	385MHz: 27V/m @ 18Hz pulse modulation 450MHz: 28V/m @ FM modulation 710MHz, 745MH, 780MHz: 9V/m @ 217 Hz pulse modulation 810MHz, 870MHz, 930MHz: 28V/m @ 18Hz Pulse modulation 1720MHz, 1845MHz, 1970MHz: 28V/m @ 217 Hz Pulse Modulation 2450MHz: 28V/m @ 217Hz Pulse modulation 5240MHz, 5500MHz, 5785MHz: 9V/m @ 217 Hz Pulse modulation	385MHz: 27V/m @ 18Hz pulse modulation 450MHz: 28V/m @ FM modulation 710MHz, 745MH, 780MHz: 9V/m @ 217 Hz pulse modulation 810MHz, 870MHz, 930MHz: 28V/m @ 18Hz Pulse modulation 1720MHz, 1845MHz, 1970MHz: 28V/m @ 217 Hz Pulse Modulation 2450MHz: 28V/m @ 217Hz Pulse modulation 5240MHz, 5500MHz, 5785MHz: 9V/m @ 217 Hz Pulse modulation	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the pump is used exceeds the applicable RF compliance level above, the pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

30.10 Distances Between the t:slim X2 Pump and RF Equipment

The t:slim X2 System is intended for use in an electromagnetic environment typically found in the home, at work, retail stores, and places of leisure, where daily activities occur. The chart below can be used as a guideline for determining the recommended minimum distance to maintain between a radio frequency (RF) transmitter and the t:slim X2 System. For specific concerns about a particular RF transmitter interfering with your System's operation, please contact the transmitter manufacturer for its rated power and frequency.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the t:slim X2 System

The t:slim X2 System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the t:slim X2 System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter in Watts	Separation Distance According to Frequency of Transmitter *inches or feet* (m)		
	150 kHz to 80 MHz (d *in meters* = 0.35√P)	80 MHz to 800 MHz (d *in meters* = 0.12√P)	800 MHz to 2.5 GHz (d *in meters* = 0.23√P)
0.01	1.6 in (0.04)	0.12 in (0.012)	0.9 in (0.023)
0.1	4.3 in (0.11)	1.5 in (0.038)	2.9 in (0.073)
1	1.1 ft (0.35)	4.7 in (0.120)	9.0 in (0.23)
10	3.6 ft (1.11)	14.9 in (0.379)	2.39 ft (0.727)
100	11.5 ft (3.50)	3.94 ft (1.20)	7.54 ft (2.3)

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

The table below provides a list of typical devices for various levels of transmitter power and frequency, and the recommended separation distances from the transmitter and the System.

Rated Maximum Output Power of Transmitter in Watts	Typical Devices	Recommended Separation Distance *Inch (Meters)*	
0.001W	Bluetooth Class 3 (standard 1 meter range) Commonly used as bluetooth headset	0.3 in (0.007 m)	
0.01W	Internet to music adaptor Commonly used for FM wireless music streaming	0.5 in (0.013 m)	
0.1W	Bluetooth Class 1 (100 meter range) Wireless router (WiFi)	2.9 in (0.073 m)	
0.5W	Typical cellular/smart phone*	6.4 in (0.163 m)	
1W	Typical microwave oven RF leakage	9 in (0.23 m)	

* Caution: Interference with pump electronics by cell phones can occur if worn in close proximity. It is recommended that your pump and cell phone be worn at least 6.4 inches apart.

30.11 Quality of Wireless Service

The manufacturer defines the quality of service of the t:slim X2 System as the percent of readings successfully received by the display, where the transmitter and display attempt to communicate every 5 minutes. One of the t:slim X2 System's essential performance requirements states that the system will not discontinue reporting data and/or information from the G5 transmitter to the user without notification.

The system notifies the user of a missed reading, or when the transmitter and pump are out of range of one another in several ways. The first is when a bullet point is missed on the CGM graph which will occur within five minutes of the previous reading. The second indication occurs after 10 minutes when the Out of Range Icon is displayed on the home screen. The third is a user settable alert that will notify the user when the pump and transmitter is out of range of one another. Setting this alert is defined in Section 20.6.

The system performance requirements state that 90% of readings will be successfully transferred to the display while the transmitter and display are within 20 feet of each other, and no more than 12 consecutive readings (1 hour) will be missed.

To improve quality of service when other devices operating in the 2.4 GHz band are around, the t:slim X2 System uses the built-in coexistence features provided by Bluetooth technology.

30.12 FCC Notice Concerning Interference

The transmitter covered by this user's guide has been certified under FCC ID: PH29433.

Although the transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from the transmitter will be free from interference.

Compliance Statement (Part 15.19)

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and

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

Warning (Part 15.21)

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC Interference Statement (Part 15.105 (b))

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This portable transmitter with its antenna complies with FCC/IC RF exposure limits for general population/uncontrolled exposure.

30.13 Warranty Information

Warranty

t:slim X2 Insulin Pump

Tandem Diabetes Care, Inc. ("Tandem") warrants the t:slim X2 Insulin Pump against defects in materials and workmanship, under normal use, for the period of 4 years from the original date of shipment of the pump to the original end use purchaser (the "Warranty Period"). For any defective t:slim X2 Pump covered by the foregoing warranty, Tandem will, at its discretion, repair the pump or replace it with a new or refurbished t:slim X2 Pump, subject to the conditions and exclusions stated herein. Repair or replacement of a t:slim X2 Pump will not extend the original 4 year warranty, which will continue to apply. If your t:slim X2 Pump is replaced, then you must return your original pump to Tandem in accordance with Tandem's instructions. In the event the defective t:slim X2 Pump is not returned, then this warranty shall be void and you will not be entitled to future pump replacement or repairs.

The warranty is valid only if the t:slim X2 Pump is used in accordance with Tandem's instructions for use and user manual and will not apply if:

- damage results from changes or modifications made to the t:slim X2 Insulin Pump by the user or third persons after the date of manufacture;
- damage results from service or repairs performed to any part of the t:slim X2 Pump by any person or entity other than Tandem;
- the t:slim X2 Pump seal is broken;
- a non-Tandem cartridge is used with the t:slim X2 Pump;
- damage consists of scratches and wear to surfaces and other externally exposed parts due to wear and tear;
- damage results from an event or accident beyond the control of Tandem; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse.

From time-to-time Tandem may offer software updates for your t:slim X2 Pump to help to ensure the up-to-date functionality of your pump or software that are intended to add new features to your t:slim X2 Pump. Tandem reserves the right to offer those updates, if any, in its sole discretion either at no charge or for an additional fee to be determined at a future date. To the extent that an update is offered at no charge, it is considered to be included in the original cost of your pump. Any future software updates will be subject to your acceptance of other terms and conditions that may be applicable at that time, including additional terms that may modify or limit the terms of this Warranty.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the t:slim X2 Pump covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate.

This warranty only applies to the t:slim X2 Pump and does not apply to other products or accessories. This warranty is valid only in the United States. No employee of Tandem or any other party is authorized to make any warranty in addition to those made in this Warranty.

The remedies provided for in this warranty are the exclusive remedies available for any warranty claims. Neither Tandem nor its suppliers or distributors shall be liable for losses, liabilities, claims or damages of any kind or nature whatsoever, including, without limitation, any indirect, incidental, consequential, or special damages of any kind caused by or arising out of a defect in the product. All other warranties, express or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

Warranty

t:slim Cartridges

Tandem Diabetes Care, Inc. ("Tandem") warrants its cartridge against defects in materials and workmanship for one use during the period of 3 days after the individual cartridge sterile packaging has been opened, not to exceed 6 months from date of shipment of the cartridge to the end user (the "Warranty Period"). During the Warranty Period, Tandem will replace any defective cartridge, subject to the conditions and exclusions stated herein.

The warranty is valid only if the cartridges are used in accordance with the accompanying instructions for use and user guide and will not apply if:

- the cartridge has been used for more than a single-time use by a single end-user;
- damage results during the improper opening of the sterile package not in conformance with the procedures outlined in the associated Instructions for Use;
- the sterile package is compromised while in the control of the user by any means other than purposeful opening by the user at the time of intended product use;
- damage results from changes or modifications made to the cartridge by the user or third persons after the date of manufacture;
- damage results from service or repairs performed to any part of the cartridge by any person or entity other than Tandem;
- damage is caused by use of the cartridge with any non-Tandem insulin pump;
- damage results from an event or accident beyond the control of Tandem; or
- damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This war¬ranty does not apply to insulin pumps and other accessories. This warranty is valid only in the United States. No employee of Tandem or any other party is authorized to make any warranty in addition to those made in this Warranty.

The remedies provided for in this warranty are the exclusive remedies available for any warranty claims. Neither Tandem nor its suppliers or distributors shall be liable for losses, liabilities, claims or damages of any kind or nature whatsoever, including, without limitation, any indirect, incidental, consequential, or special damages of any kind caused by or arising out of a defect in the product. All other warranties, express or implied, are excluded, including the

warranties of merchantability and fitness for a particular purpose.

Warranty

For more information about Dexcom's warranty, please visit www.dexcom.com.

30.14 Returned Goods Policy

Any insulin pump product ("Pump") that was originally purchased from Tandem Diabetes Care®, Inc. ("Tandem") or one of its authorized distributors may be re-turned to Tandem only for the following reasons: (1) during the applicable warranty period (which is set forth in the user guide for the Pump), the customer experiences an issue with the Pump that is covered by the warranty set forth in the user guide for the Pump, then Tandem will repair or replace the Pump as provided under the applicable warranty above, and (2) during the thirty (30) day period after the shipment of the Pump, if the customer discovers that the Pump is not suited for the customer based on a valid, good faith medical reason which has been confirmed by the customer's physician, then Tandem or the authorized distributor will accept the return of the Pump and provide a refund to the customer and/or its insurance company for the amount actually paid for the Pump. Tandem will not accept or be obligated to accept for return any Pump that is not based on one of the two reasons. To assure prompt handling when returning a Pump, the customer must first obtain a returned materials authorization (RMA) number from Tandem's or its authorized distributor's Customer Service Department. This returned materials authorization number must be clearly written on the outer box. If Tandem or the authorized distributor provides a label, the label must be attached or taped to the outer box. If no label is provided, Tandem recommends shipping via insured ground service with a tracking number. Tandem is not responsible for lost or damaged packages.

To obtain a returned materials authorization (RMA) number and shipping address, please contact Tandem Diabetes Care Customer Technical Support at (877) 801-6901.

Returns pre-authorized by Tandem's authorized distributors should be sent to the distributor authorizing the return, unless other instructions are provided.

Returns made without the returned materials authorization number will be returned to the customer, freight collect. This policy is subject to applicable law.

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