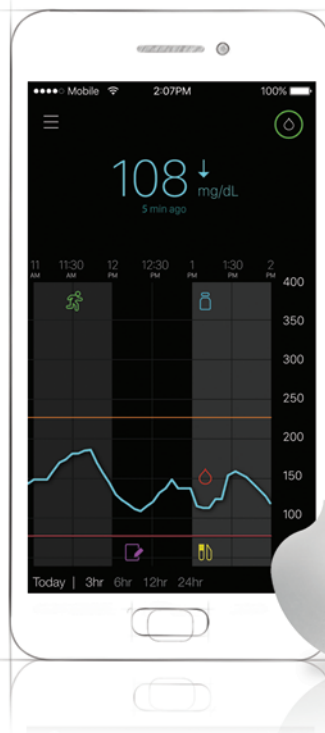# GUARDIAN™ CONNECT

SYSTEM USER GUIDE

Medtronic

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Introduction

Thank you for choosing Medtronic as your diabetes management partner.

The Guardian^TM Connect Continuous Glucose Monitoring (CGM) system helps you manage your diabetes. The Guardian Connect CGM system has the following features:

- Records your glucose values throughout the day and night
- Displays your glucose values in a convenient and discrete manner using your smartphone
- Alerts you to glucose events using your smartphone
- Shows the effects that diet, exercise, and medication can have on your glucose levels
- Gives you additional tools, such as alerts and the ability to record diet, exercise, and insulin intake, to help you prevent high and low glucose levels

This user guide is designed to help you understand the setup and operation of your Guardian Connect system.

Note: The user guide contains some instructions that are specific to the Android™ or iOS platform. Where applicable, follow the instructions specific to your platform.

System description

The Guardian Connect system includes the Guardian Connect app (iOS: CSS7200, Android^TM: CSS7201), Guardian Connect transmitter (MMT-7821L), Guardian Sensor (3) (MMT-7020), charger (MMT-7715), tester (MMT-7736L), one-press serter (MMT-7512), and oval tape (MMT-7015). This guide describes how to set up and use the system.

CGM is a tool that lets you continuously view your sensor glucose values. The Guardian Connect system uses a glucose sensor, the Guardian Sensor (3), placed below your skin, to continuously measure the amount of glucose in your interstitial fluid. The Guardian Connect transmitter collects these glucose measurements, which are then converted to sensor glucose values. These sensor glucose (SG) values are then displayed on the Guardian Connect app. The Guardian Connect app can also provide alerts based on SG levels.

Note: This product should only be used with supported mobile devices. You can access the supported mobile device list in the FAQ section at https:// www.medtronicdiabetes.com/customer-support/guardian-connect-faqs

Indications for Use

The Guardian Connect system is indicated for continuous or periodic monitoring of glucose levels in the interstitial fluid under the skin, in patients 14 to 75 years of age with diabetes mellitus.

The Guardian Connect system provides real-time glucose values and trends through a Guardian Connect app installed on a compatible consumer electronic mobile device. It lets users detect trends and track patterns in glucose concentrations. The Guardian Connect app alerts if a Guardian Sensor (3) glucose level reaches, falls below, rises above, or is predicted to surpass set values.

The Guardian Sensor (3) glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a blood glucose meter and not on values provided by the Guardian Sensor (3).

The Guardian Connect system is comprised of the following devices: Guardian Connect app, Guardian Sensor (3), and the Guardian Connect transmitter.

Guardian Sensor (3)
The Guardian Sensor (3) is intended for use with Medtronic Diabetes glucose-sensing systems to continuously monitor glucose levels in persons with diabetes. The Guardian Sensor (3) is indicated for 7 days of continuous use. It is indicated for use as an adjunctive device to complement, not replace, information obtained from standard blood glucose (BG) monitoring devices. The sensor is intended for single-use. The Guardian Sensor (3) requires a prescription.

Guardian Connect transmitter
The Guardian Connect transmitter is intended for use with the Guardian Connect system. The Guardian Connect transmitter powers the sensor, collects and calculates sensor data, and sends the data via Bluetooth version 4.0 to the Guardian Connect app installed on a compatible mobile device. The transmitter is only compatible with the Guardian Sensor (3). The transmitter is indicated for multiple uses on a single patient as a component of the Guardian Connect system. The Guardian Connect transmitter requires a prescription.

Guardian Connect app

The Guardian Connect app is intended for use only by patients using a compatible mobile device, and who have sufficient experience to adjust mobile device audio and notification settings. The app displays SG data, and also provides a user interface for sensor calibration, entering data such as exercise and meals, and uploading information to the CareLink^TM Personal website. The app can detect trends and track patterns in glucose concentrations. The Guardian Connect app provides alerts if a Guardian Sensor (3) glucose level reaches, falls below, rises above, or is predicted to surpass set values.

The Guardian Connect app is available over-the-counter (OTC) but requires the Guardian Sensor (3) and Guardian Connect transmitter to function.

Charger

The charger is used to charge your transmitter battery. For best results, recharge your transmitter between each use to ensure full transmitter battery life.

Tester

The tester is intended for use with the Guardian Connect transmitter. It is a device used as a watertight cleaning plug during transmitter cleaning. It is also used for simulating a sensor to test that the transmitter is working properly.

One-press serter

The serter is used as an aid for inserting the sensor. It is indicated for single-patient use and is not intended for multi-patient use.

Oval tape

The tape is indicated for use with Medtronic glucose sensor products. It is indicated for one-time use.

User Safety

This section includes important safety information such as indications, contraindications, safety warnings, potential adverse reactions, and how to protect the system from radiation exposure damage.

Contraindications

Continuous glucose monitoring is not recommended for people who are unwilling or unable to perform a minimum of two meter BG tests per day or for people who are unable or unwilling to maintain contact with their healthcare professional. Successful CGM use requires sufficient vision or hearing to allow recognition of the alerts generated by the Guardian Connect app.

Do not use serter on products other than the Guardian Sensor (3). Medtronic cannot guarantee the safety or efficacy of this product if used with other products.

Safety Warnings

App and Mobile Device

- Follow the instructions and safety warnings in this user guide to make sure you receive alerts as intended. Missing alerts from the Guardian Connect app may result in undetected low and high glucose levels.
- Always allow notifications for the Guardian Connect app. If notifications are turned off, you will not receive any alerts, including Urgent Low glucose alerts.
- **Android Users:** You must allow "Do Not Disturb Permission" and "Alerts" for the Guardian Connect app. If "Do Not Disturb Permission" or "Alerts" are turned off, you will not receive any alerts, including Urgent Low sensor glucose alerts.
- **iOS Users:** You must allow "Critical Alerts" for the Guardian Connect app. If "Critical Alerts" is turned off, you will not receive any alerts, including Urgent Low sensor glucose alerts.
- Do not use any phone settings or apps such as "Digital Wellbeing" (in Android^{TM}) or "Screen Time" (in iOS) that may prevent Guardian Connect from sending you alerts.

  If you set the app timer in "Digital Wellbeing" (Android^{TM}) for your Guardian Connect app and let it expire, your Guardian Connect app will shut down and you will not get any sensor glucose alerts.
- Do not use the Guardian Connect app unless you understand how your mobile device settings work. If your mobile device settings are not set up correctly, you may not receive SG alerts.
- Make sure Bluetooth is on, even if your mobile device is in Airplane mode. If Bluetooth is off, you will not get SG information or alerts.
- Do not use the Guardian Connect app if your mobile device screen or speakers are damaged. If your mobile device is damaged, you may not get SG alerts and SG information may not be shown correctly.

- If you use Screen Time, you must add Guardian Connect as an "Always Allowed" app. If you do not add Guardian Connect as an "Always Allowed" app, you will not receive any alerts, including Urgent Low glucose alerts.
- **iOS Users:** Do not turn off vibration in the iOS Accessibility menu. You will not get any vibrations with your alerts, including Urgent Low.
- **Android^TM Users:** Do not lower the vibration feedback to the lowest level in the Android^TM Vibration intensity menu. You will not get any vibrations with your alerts, including Urgent Low.
- Alerts for the Guardian Connect app will sound through your headphones when headphones are connected. If you leave your headphones connected when not in use, you may not hear SG alerts.
- Do not close the Guardian Connect app. If the app is closed, you will not get SG information or alerts.
- Check the Guardian Connect app occasionally to make sure it is running. Your mobile device may close the Guardian Connect app automatically when you are using another app, such as a game. If the Guardian Connect app is closed, you will not get SG alerts.
- Always make sure to open the app after your mobile device restarts to ensure you receive your SG alerts.
- Do not let your mobile device shut down due to low battery, or you will not get SG alerts. Make sure you have a charger available so you can charge your battery if needed.
- Make sure to set the snooze to a short enough time so that you will get an alert again if your glucose level does not improve. When you snooze a SG alert, you do not get that alert again during the length of the snooze time you set.
- Do not make therapy decisions based on sensor glucose values because sensor glucose and BG values may be different. Confirm your glucose level with your BG meter before making treatment decisions, such as dosing insulin before a meal or taking carbs to treat a low.
- Do not root or jailbreak the mobile device. Rooting the Android^TM device or jailbreaking the iOS device means to change the software in a way the manufacturer did not intend. If the mobile device is changed in this way, the Guardian Connect app will display an error message when launched and will not continue to operate.

Transmitter

- Do not use the transmitter adjacent to other electrical equipment that may cause interference with the normal system operation. For more information on other electrical equipment that may compromise normal system operation, see *Exposure to magnetic fields and radiation, on page 8*.
- Do not use the device if you see any cracking, flaking, or damage to the housing. Cracking, flaking, or damage to the housing are signs of deterioration. Deterioration of the housing can affect the ability to properly clean the transmitter and result in serious injury. Call your local Medtronic support representative and discard the device according to local regulations for battery disposal (non-incineration), or contact your healthcare professional for disposal information.
- Do not discard the transmitter in a medical waste container or expose it to extreme heat. The transmitter contains a battery that may ignite and result in serious injury.
- Do not allow children to put small parts in their mouth. This product poses a choking hazard for young children.
- Do not change or modify the device unless expressly approved by Medtronic Diabetes. Modifying the device can cause serious injury, interfere with your ability to operate the device, and void your warranty.
- Do not use the transmitter with any other sensor. Other sensors are not intended for use with the transmitter, and will damage the transmitter and the sensor.

Charger
- Dispose of the charger according to the local regulations for battery disposal, or contact your healthcare professional for disposal information. The charger may ignite upon incineration.

Tester
- Do not use the tester if it comes in contact with blood. Touching blood can cause infection. Dispose of the tester according to the local regulations for medical waste disposal, or contact your healthcare professional for disposal information.

Serter
- Read this entire user guide before attempting to insert the sensor. The one-press serter (MMT-7512) does not work the same as other Medtronic insertion devices. Failure to follow directions or use of a different serter may result in improper insertion, pain, or injury.
- Wear gloves when you insert the sensor into someone other than yourself to avoid contact with patient blood. Minimal bleeding may occur. Contact with patient blood can cause infection.
- Never point a loaded serter toward any body part where insertion is not desired. An accidental button-push may cause the needle to inject the sensor in an undesired location and cause minor injury.
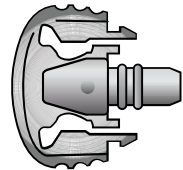
Sensor

- Taking medications with acetaminophen or paracetamol including but not limited to Tylenol™, fever reducers, cold medicine while you wear the sensor may falsely raise your SG readings. The level of inaccuracy depends on the amount of acetaminophen or paracetamol active in your body and may be different for each person. Always use BG meter readings to verify your glucose level before making therapy decisions.
- The Guardian Sensor (3) should only be used with the one-press serter. Medtronic cannot guarantee the safety or effectiveness of this product if used with other insertion devices.
- The Guardian Sensor (3) was developed for use with and the performance evaluated with the approved system only. The sensor should not be used as part of unapproved systems, as it may provide inaccurate SG readings.
- The sensor is designed to work with approved transmitters only. It is not interchangeable with transmitters and recorders that are not compatible with the sensor. Connecting your sensor to a transmitter or recorder that is not approved for use with the sensor may cause damage to the components or inaccurate SG values.
- A retractable needle is attached to the sensor and minimal blood splatter may occur. If you are a healthcare professional or caregiver, wrap sterile gauze around the sensor to minimize contact with blood. Keep as much distance as possible between you and the patient when removing the needle.
- Keep the needle housing within sight at all times to avoid an accidental needlestick or puncture.
- Always inspect the packaging for damage prior to use. Sensors are sterile and non-pyrogenic, unless the package has been opened or damaged. Do not use the sensor if the sterile package has been opened or damaged. Use of an unsterile sensor can cause site infection.
- Watch for bleeding at the insertion site (under, around, or on top of the sensor).

If bleeding occurs, do the following:

1 Use sterile gauze or a clean cloth and place it on top of the sensor. Apply steady pressure for up to three minutes. The use of unsterile gauze can cause site infection.
2 If bleeding stops, connect the transmitter (or recorder) to the sensor.
   If bleeding does not stop, do not connect the transmitter to the sensor because blood can get into the transmitter connector and could damage the device.

If bleeding continues, causes excessive pain or discomfort, or is significantly visible in the plastic base of the sensor, do the following:

1 Remove the sensor and continue to apply steady pressure until the bleeding stops. Discard the sensor in a sharps container.
2 Check the site for redness, bleeding, irritation, pain, tenderness, or inflammation. Treat based on instructions from your healthcare professional.
3 Insert a new sensor in a different location.

plastic base

Contact your local Medtronic support representative if you experience any adverse reactions associated with the transmitter or sensor. Adverse reactions can cause serious injury.

Exposure to magnetic fields and radiation

• Do not expose your sensor or transmitter to Magnetic Resonance Imaging (MRI) equipment, diathermy devices, or other devices that generate strong magnetic fields such as, x-ray, CT scan, or other types of radiation. Always remove your sensor and transmitter before entering a room that has x-ray, MRI, diathermy, or CT scan equipment. Exposure to a strong magnetic field has not been evaluated and can cause the device to malfunction, result in serious injury, or be unsafe. If your sensor or transmitter is exposed to a strong magnetic field, discontinue use and contact your local Medtronic support representative for further assistance.

Precautions

Testing Your Blood Glucose

• Always test your BG a minimum of two times a day or as indicated by the system. Do not enter your SG readings for calibration.

Tester

• Only use the green tester (MMT-7736L) with the transmitter. Do not use any other tester. Other testers are not intended for use with the transmitter, and will damage the transmitter and the tester.
• Always use the tester when you clean the transmitter. Do not use any other tester with the transmitter. Use of another tester can allow water to get into the transmitter or can prevent proper cleaning. Water can damage the transmitter.
• Do not twist the tester or sensor while attached to the transmitter. Twisting the tester or sensor will damage the transmitter.
• Do not allow the tester to come in contact with any liquid when not connected to the transmitter. A wet tester can damage the transmitter.

- Do not clean the O-rings on the tester with any substances. Cleaning the O-rings can damage the tester.

Transmitter

- Do not allow the transmitter to come in contact with any liquid when not connected to a sensor or to the tester. Moisture will damage the transmitter and a wet transmitter can damage the sensor.

Sensor Application

- Wash your hands with soap and water before you insert the sensor to help prevent site infection.
- Wear gloves when you insert the sensor into someone other than yourself to avoid contact with patient blood.
- Do not insert the sensor through tape. Inserting the sensor through tape may cause improper sensor insertion and function.
- Only use alcohol to prepare the insertion site to ensure that residue is not left on the skin.
- Rotate the sensor insertion site so that sites do not become overused.
- Discard used sensors and needle housings in a sharps container after each use to avoid accidental needlestick or puncture.
- Do not clean, resterilize, or try to extract the needle from the needle housing. An accidental needlestick or puncture may occur.
- Do not reuse sensors. Reuse of a sensor may cause damage to the sensor surface and lead to inaccurate glucose values, site irritation, or infection.

Potential risks related to sensor use

General risks with sensor use include:

- Skin irritation or other reactions
- Bruising
- Discomfort
- Redness
- Bleeding
- Pain
- Rash
- Infection
- Raised bump
- Appearance of a small "freckle-like" dot where needle was inserted
- Allergic reaction
- Fainting secondary to anxiety or fear of needle insertion
- Soreness or tenderness

- Swelling at insertion site
- Sensor fracture, breakage or damage
- Minimal blood splatter associated with sensor needle removal
- Residual redness associated with adhesive or tapes or both
- Scarring

Reagents
The sensor contains two biological reagents: glucose oxidase and human serum albumin (HSA). Glucose oxidase is derived from Aspergillus niger and manufactured to meet industry requirements for extraction and purification of enzymes for use in diagnostic, immunodiagnostic, and biotechnical applications. The HSA used on the sensor consists of purified and dried albumin fraction V, derived from pasteurized human serum which is cross-linked via glutaraldehyde. Approximately 3 µg of glucose oxidase and approximately 10 µg of HSA are used to manufacture each sensor. HSA is approved for IV infusion in humans at quantities much larger than in the sensor.

Where to insert the sensor
Choose an insertion site that has an adequate amount of fat. The Guardian Sensor (3) has been studied and is approved for use only in the following sensor insertion sites for the corresponding specified ages.

The sensor insertion site should be at least:

- 2 inches (5 centimeters) from your navel.
- 1 inch (2.5 centimeters) from any manual insulin injection site.

The shaded areas shown below are the best body areas for sensor insertion.
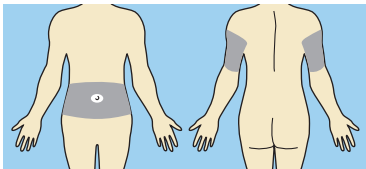
Note: Assistance may be needed for sensor insertion into the back of the upper arm. Some users found it difficult to insert the sensor into their arm by themselves.

Do not insert the sensor into muscle. For best sensor glucose performance and to avoid accidental sensor removal, **avoid** sites:

- Where your clothing may rub or be too tight, such as your belt-line
- That are scarred, have hardened tissue, or stretch marks
- Where there is a lot of movement or rubbing, such as the inside of your arm
- Where your body naturally bends a lot

Radio Frequency (RF) communication

This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility. This device complies with Part 15 of the FCC Rules. Operation is subject to 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.

This device 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 device 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 device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the device and the receiver.
- Decrease the distance between the transmitter and the compatible mobile device to 20 feet (6.1 meters) or less.
- Increase the separation between the transmitter and the equipment that receives or emits interference.

  Note: Harmful interference is defined by the FCC as follows. Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with FCC rules.

Changes or modifications made to this equipment not expressly approved by Medtronic Diabetes could void the user's authority to operate the equipment.

Directive 2014/53/EU
Medtronic declares that this product is in conformity with the essential requirements of Directive 2014/53/EU on Radio and Equipment.

For additional information, contact Medtronic MiniMed at the address or phone number provided on the back cover.

IEC 60601-1-2:2014, 4th Edition; Special EMC Precautions for Medical Electrical Equipment

1   Special Precautions regarding Electromagnetic Compatibility (EMC): This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment where common levels of radiated "E" (V/m) or "H" fields (A/m) exist, such as cellular phones, Wi-Fi, Bluetooth wireless technology, electric can openers, microwave and induction ovens. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.

2   Portable and mobile RF communications equipment can affect medical electrical equipment. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that causes the interference.

3   Be careful when you use your transmitter closer than 12 in (30 cm) to portable radio frequency (RF) equipment or electrical equipment. If you must use your transmitter next to portable RF equipment or electrical equipment, observe the transmitter to verify correct system operation. Degradation of the performance of the transmitter could result.

Assistance

Medtronic provides a 24-Hour Technical Support line for assistance. When calling Technical Support, please have the serial number of your device available. The serial number and 24-Hour Technical Support phone number are listed on the back of your device.

Department	Telephone number
24-Hour Technical Support (calls within the United States)	800 646 4633
24-Hour Technical Support (calls outside the United States)	+1 818 576 5555
Website	www.medtronicdiabetes.com

Emergency kit

Keep an emergency kit with you at all times to make sure that you always have necessary supplies. Tell a family member, co-worker, or friend where you keep your emergency kit.

It is important that you monitor your glucose more frequently while you are traveling. Issues encountered during travel, such as stress; changes in time zones, schedules, activity levels, and meal times; and eating different types of food, can all affect your diabetes.

Your emergency kit should include these items:

- Fast-acting glucose tablets
- Blood glucose monitoring supplies
- Ketone monitoring supplies
- Insulin syringe and rapid-acting insulin with dosage instructions from your healthcare professional
- Adhesive dressing
- Glucagon^{TM} emergency kit

How to use this guide

The following table describes terms and conventions used in this guide.

Convention	Description
Toggle	Toggle indicates that the same feature on the screen can be used to switch between two options. For example, "Toggle an alert on" means that you slide a switch right to turn on an alert. To turn it off, you need to slide the same switch left.
Bold	Bold indicates an item on the screen that you select with your finger or tap to open.
>	> is a shorthand to indicate a series of selections you make on the screen. For example, **Alert Settings** > **Rate Alerts** means that you need to tap **Alert Settings**, and then on the next screen tap **Rate Alerts**.
Note	A note provides additional helpful information.
CAUTION	A caution notifies you of a potential hazard which, if not avoided, may result in minor or moderate injury or damage to the equipment.
WARNING	A warning notifies you of a potential hazard which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.

Preparing your transmitter

The transmitter contains a non-replaceable, rechargeable battery that you can recharge as needed with the charger. The transmitter will need to be charged before you use it. The charger has a green light that shows the charging status and a red light that communicates any problems during charging. If you see a red light, see *Troubleshooting, on page 56*. The charger needs one AAA alkaline battery.

Note: If the battery is installed incorrectly or is low, the charger will not work. Repeat the battery installation steps using a new battery.

Installing a battery in the charger

To install a battery in the charger:

1 Push the battery cover in and slide it off (as shown in the image in step 3).

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2   Insert a new AAA alkaline battery. Make sure the + and - symbols on the battery align with these same symbols shown on the charger.

3   Slide the cover back on the charger until it clicks into place.
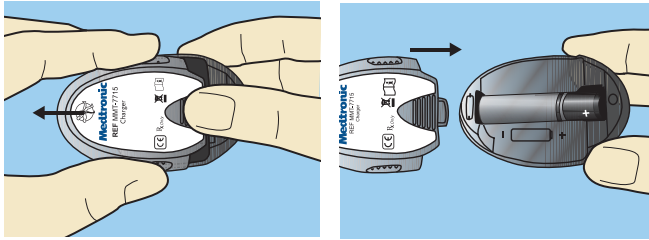
Charging the transmitter

CAUTION: Always charge the transmitter before you insert your sensor. A depleted transmitter does not function. A fully charged transmitter works at least seven days without recharging. A depleted transmitter can take up to two hours to recharge.

CAUTION: Do not store the transmitter on the charger. If the transmitter is left on the charger for more than 60 days, the battery will be permanently damaged.

To charge the transmitter:

1   Push the transmitter and the charger together to connect the transmitter to the charger.

2   Within 10 seconds after the transmitter is connected, a green light on the charger will flash for one to two seconds as the charger powers on. For the rest of the charging time, the green light on the charger will continue to flash in a pattern of four flashes with a pause between the four flashes.

3   When charging is complete, the green light on the charger will stay on, without flashing, for 15 to 20 seconds and then turn off.

4   After the green charger light turns off, disconnect the transmitter from the charger. The green light on the transmitter will flash 10 times and then turn off.
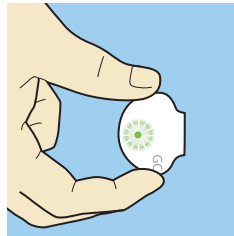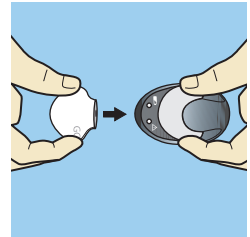
Guardian Connect app setup

When you open the app for the first time, it walks you through the setup process. Simply follow the instructions on your screen.

WARNING: **For iOS users, you must allow "Critical Alerts" and "Notifications" for the Guardian Connect app. If "Critical Alerts" or "Notifications" are turned off, you will not receive any alerts, including Urgent Low glucose alerts. If you use Screen Time, you must add Guardian Connect as an "Always Allowed" app. If you do not add Guardian Connect as an "Always Allowed" app, you will not receive any alerts, including Urgent Low glucose alerts.**

WARNING: **For AndroidTM users, you must allow "Do Not Disturb Permission", "App Notifications" and the "Alerts" category for the Guardian Connect app. If "Do Not Disturb Permission", "App Notifications", or the "Alerts" category are turned off, you will not receive any alerts, including Urgent Low sensor glucose alerts.**

Pairing your transmitter

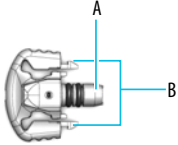Follow the instructions on your screen to pair your transmitter to your mobile device.
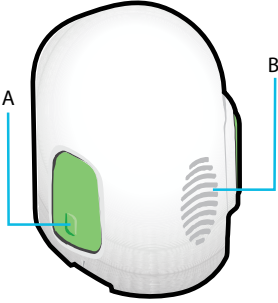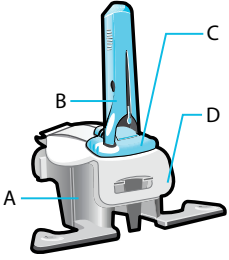
Note: For Android users, make sure to enable the location feature on your mobile device while you pair the transmitter with your mobile device.
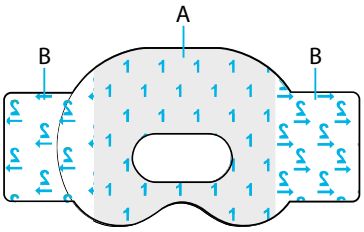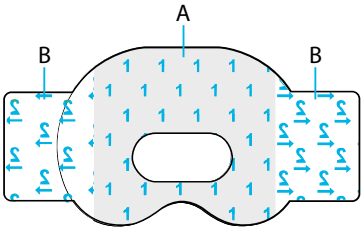
New sensor setup

Follow the instructions on how to insert the sensor. Then follow the on-screen instructions to complete the sensor start up.

Note: You must connect your transmitter to your sensor before you complete setup.

Components

	One-press serter A. green buttons B. thumbprint marking
	Glucose sensor assembly A. pedestal B. needle housing C. sensor base D. clear liner
	Sensor base A. sensor connector B. sensor snaps
	Transmitter

|	
	Charger
	First Piece of Oval Tape A. liner 1 B. liner 2
	Second Piece of Oval Tape A. liner 1 B. liner 2

Inserting the sensor

WARNING: Wear gloves when inserting the sensor into someone other than yourself to avoid contact with patient blood. Minimal bleeding may occur. Contact with patient blood can cause infection.

1 Wash your hands.
2 Choose an insertion site on the abdomen or back of the upper arm that has an adequate amount of fat.

Note: *Assistance may be needed for sensor insertion into the back of the upper arm. Some users found it difficult to insert the sensor into their arm by themselves.*

3 Clean the insertion site with alcohol. Let the area air dry.

4 Open the sensor package.
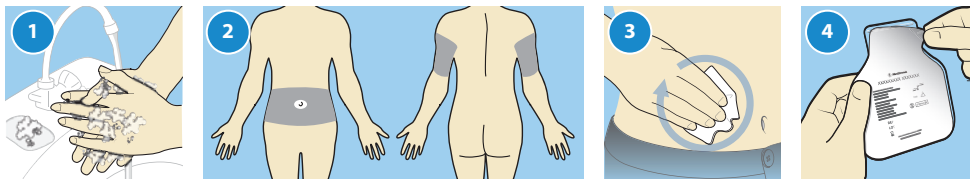
5 Hold the pedestal and remove the glucose sensor assembly from the package. Place the pedestal on a flat surface.

   Note: *The pedestal and glucose sensor assembly are the established definitions in the component table.*

6 Make sure that the adhesive tab of the sensor is tucked under the sensor connector and sensor snaps.
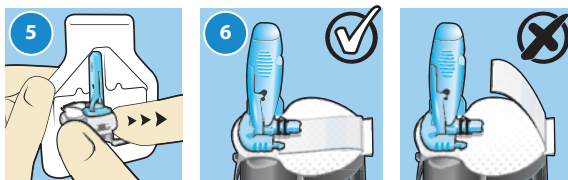
7 Place your thumb on the thumbprint marking to hold the serter without touching the buttons.
   Your fingers should not be touching the buttons.
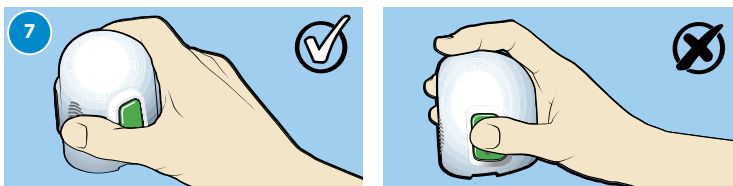

Holding serter correctly   Holding serter incorrectly

8

    a. Grip the serter, placing your thumb on the thumbprint marking, **without holding the buttons**.

    b. Carefully push the serter down onto the pedestal until the base of the serter sits flat on the table and you hear a click.

9

    a. To detach the serter from the pedestal, place the thumb of one hand on the thumbprint marking and grip the serter **without touching any buttons**. With your other hand, place two fingers on the pedestal arms.

    b. Slowly pull the serter straight up without holding the buttons. Do not detach the pedestal from the serter in midair, as this might damage the sensor.
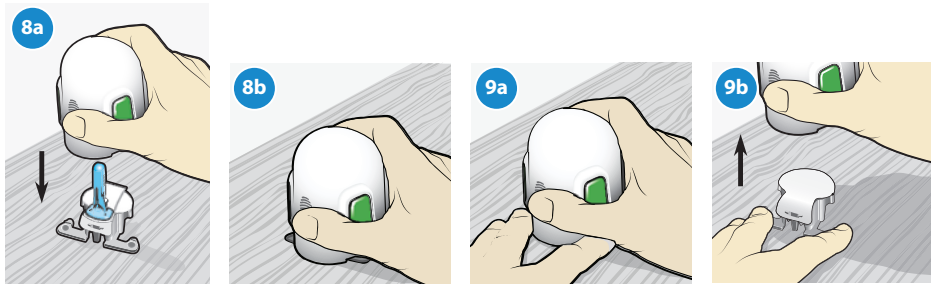
Note: *The arrow on the side of the serter aligns with the needle inside the serter.*
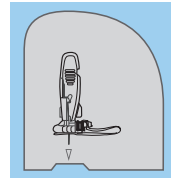

    WARNING: **Never point a loaded serter toward any body part where insertion is not desired. An accidental button-push may cause the needle to inject the sensor in an undesired location, causing minor injury.**

10

   a. Hold the serter steady against your cleaned insertion site, without pushing the serter too deeply into your skin.

     Note: Failing to hold the serter securely flat against your body during insertion may let the serter spring back after pressing the buttons, and result in improper insertion of the sensor.

   b. Press the bump on both buttons at the same time, while holding the serter flat against your body.

   c. Release the bump on both buttons at the same time, while holding the serter flat against your body.

   d. Continue holding the serter flat against your body for at least five seconds to let the adhesive stick to your skin.

   e. Slowly lift the serter away from your body, making sure that the buttons are not pressed.
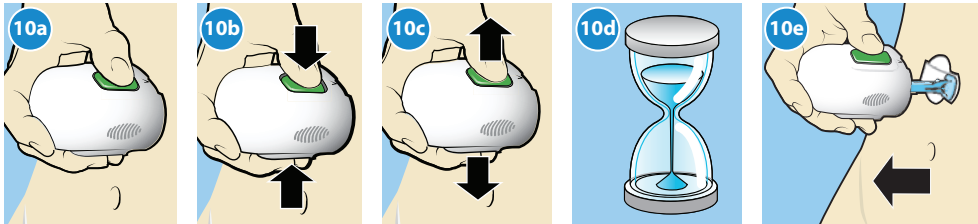
11 If you inserted the sensor into yourself, complete step 11a. If you are a healthcare professional or caregiver who inserted the sensor into a patient, complete step 11b.
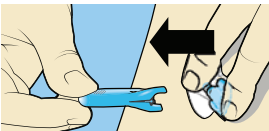
Patient:

a. Gently hold the sensor base against the skin at the sensor connector and the opposite end of sensor base. Hold the needle housing at the top and slowly pull straight out, away from the sensor.

OR
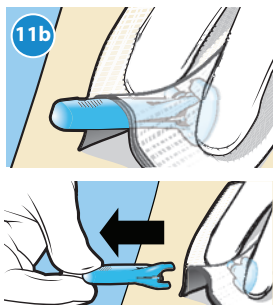
Healthcare professional or caregiver:

b. Wrap sterile gauze around the sensor (as shown in image 11b). Gently hold the sensor base against the skin at the sensor connector and the opposite end of sensor base. Hold the needle housing at the top and slowly pull straight out, away from the sensor.

WARNING: Watch for bleeding at the insertion site. If bleeding occurs under, around, or on top of the sensor, apply steady pressure using sterile gauze or a clean cloth placed on top of the sensor for up to three minutes. The use of unsterile gauze can cause an infection. If bleeding does not stop, remove the sensor and apply steady pressure until the bleeding stops.

Note: *Medtronic adhesives are pressure-sensitive. Pressing the adhesive against the skin ensures that the sensor remains adhered to the skin throughout the wear period.*

Note: *After insertion, use of adhesive products such as Skin Tac^{TM} in addition to the tape is optional. If optional adhesive products are used, apply to the skin under the adhesive pad prior to removing the liner. It can also be applied to the adhesive pad or the skin around the sensor base. Allow for product to dry.*
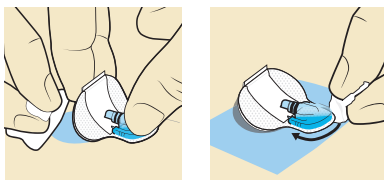
12
- a. Hold the sensor in place and gently remove the adhesive liner from under the adhesive pad. Do not remove the adhesive liner from the rectangular adhesive tab. This tab will be used to secure the transmitter in a later step.
- b. Firmly press the adhesive pad against the skin to make sure that the sensor remains adhered to the skin.

13
- a. Untuck the adhesive tab from under the connector.
- b. Straighten the sensor adhesive tab so that it lies flat against the skin.
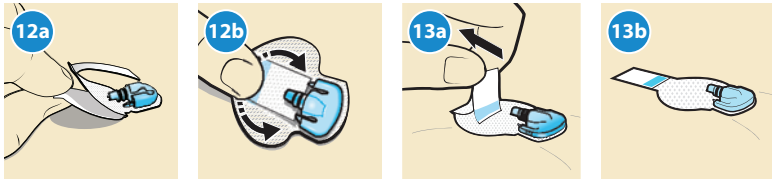
Applying oval tape

1 Remove the liner marked 1.
2 Apply the tape as shown and press down firmly.
3 Remove the liner marked 2 from each side.

Wide part of tape covers end of the transmitter and also the skin.
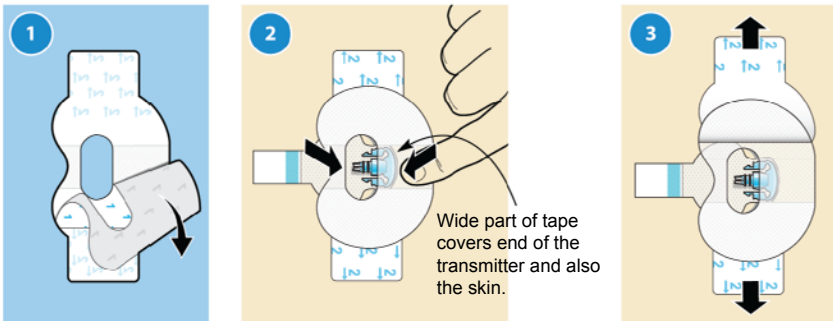
4 Smooth the tape.
5 Connect the transmitter to the sensor.

   Note: Wait for the green light on the transmitter to flash. If the green light does not flash, see Troubleshooting, on page 56.

6 Cover the transmitter with the adhesive tab.

Note: *Do not pull the tab too tightly.*
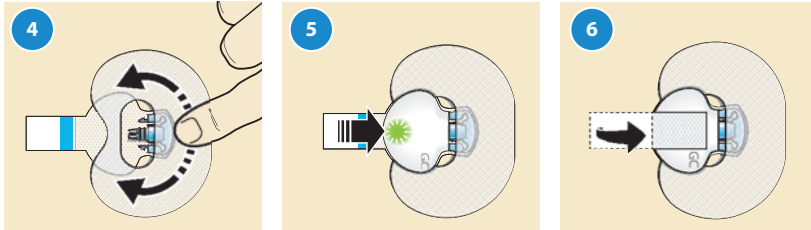
7 To apply a 2nd tape, remove the liner marked 1.
8 Apply the 2nd tape in the opposite direction to the first tape and place it on the transmitter. Press down firmly.

Wide part of tape covers end of the transmitter and also the skin.
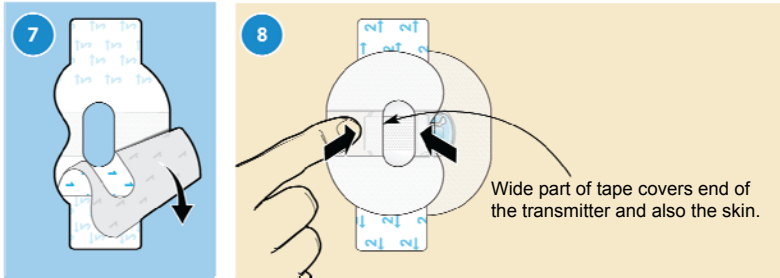
9 Remove the liner marked 2 from each side.
10 Smooth the tape.

Note: *Be sure to regularly check your sensor site. If the device is not secure, apply an additional off–the–shelf adhesive.*
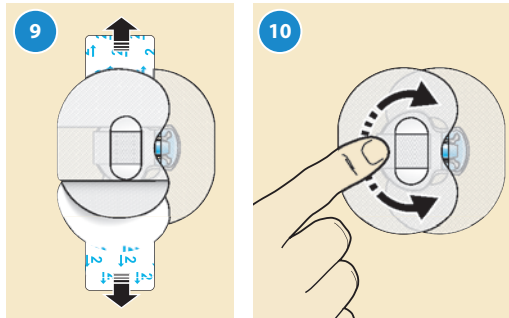
Storage and handling

CAUTION: Do not freeze the sensor, or store it in direct sunlight, extreme temperatures, or humidity. These conditions may damage the sensor.

Only store sensors at room temperature between 36°F to 80°F (2°C to 27°C).

Discard sensor after the "Use by date" indicated on the label, if the package is damaged, or the seal is broken.

Connecting the transmitter to the sensor

To connect the transmitter to the sensor:

1   After the sensor is inserted, see *Applying oval tape, on page 22* for details on applying the required tape before connecting the transmitter.
2   Hold the rounded end of the inserted sensor to prevent it from moving during connection.
3   Hold the transmitter as shown. Line up the two notches on the transmitter with the side arms of the sensor. The flat side of the transmitter should face the skin.

4   Slide the transmitter onto the sensor connector until the sensor arms snap into the notches on the transmitter. If the transmitter is properly connected and if the sensor has had enough time to become hydrated, the green light on the transmitter will flash 6 times.
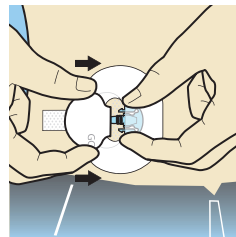
> *Note: If the transmitter does not flash, see Troubleshooting, on page 56.*

5   When the transmitter light flashes green after connecting to the sensor, use the app to start the sensor, follow the prompts on the app to select new or existing sensor.
6   Attach the adhesive tab of the sensor to the transmitter.
7   For instructions on how to apply a second tape, see *Applying oval tape, on page 22*.
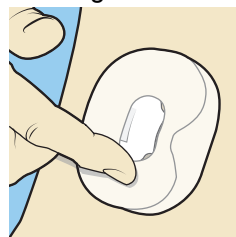
Completing your app setup

Continue to follow the on-screen instructions to enable notifications and setup alerts. For more information, see *Alert settings, on page 35*.

WARNING: **You must allow notifications for the Guardian Connect app during setup. Also, do not turn off notifications for the Guardian Connect app in your mobile device settings. If notifications are off, you will not receive any alerts, including the Urgent Low glucose alert.**

Home screen

The following figure shows the Home screen of the app.

- menu screen
- current sensor glucose reading
- high sensor glucose alert limit
- low sensor glucose alert limit
- day indicator
- time interval
- calibration
- rate of change arrow
- sensor glucose graph
- continuous sensor glucose trace
- add event

101↓ mg/dL
1 minute ago

1 PM   1:30 PM   2 PM   2:30 PM   3 PM   3:30 PM

400
350
300
250
200
150
100
50

Now | 3hr 6hr 12hr 24hr
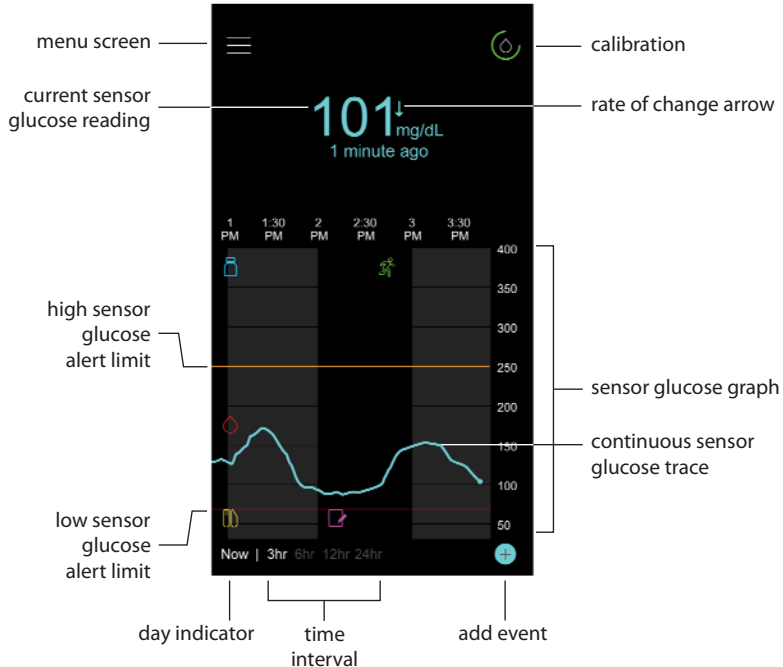
Note: *When you open your app for the first time, there will be no sensor information displayed on the Home screen. Your first sensor glucose reading appears after you have successfully paired your transmitter and calibrated your sensor.*

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Item	Description
Calibration	Displays the Calibration screen where you enter a blood glucose (BG) meter reading for sensor calibration. For details, see *Calibrating your sensor, on page 30*. The color of the ring and the size of its displayed segment indicate calibration status and the approximate time left until your next sensor calibration is due. When your sensor is fully calibrated, the ring is solid green. As the time for your next sensor calibration approaches, segments of the ring disappear, and the color of the ring changes, until a red blood drop appears instead of the ring, as shown: A full green circle ⬤ indicates 12 hours remaining to the next calibration. Half green circle ⬤ indicates 6 hours remaining to the next calibration. Orange ⬤ indicates 3 hours remaining. Red ⬤ indicates one hour remaining. When the red blood drop ⬤ appears, an alert is displayed instructing you to calibrate your system. The question mark ⬤ indicates that the calibration status is unknown. Three dots ⬤ indicate that a calibration currently is not permitted. Selecting any of the blue icons depicted above will provide the user with more information about the calibration status.
Trend arrows	Display your glucose trend and the rate at which the most recent SG level has risen or fallen. For details on setting the rate of change for falling and rising SG values, see *Setting rate alerts, on page 38*.
Menu screen	Provides access to the menu screen, which displays the Guardian Connect system status information and allows you to set up your sensor, define alert settings, view the logbook, and access CareLink Personal settings. For details, see *Menu screen, on page 28*.
Continuous sensor glucose trace	Displays your current and previous SG readings. Tap any point on the graph to view the details of the selected SG reading or event in a box that appears above. For more navigating tips, see *Navigating through the sensor glucose graph, on page 41*.
System status icons	Display the corresponding status icon if the transmitter battery is empty, the life of your sensor has expired, the connection with the transmitter is lost, potential notifications are silenced, or the status of these features is unknown. For details, see *System status icons, on page 29*.
Time interval	Displays preset time intervals of 3, 6, 12, and 24 hours. Tap this icon to switch between time intervals.
Current sensor glucose reading	Displays your current SG reading, which the transmitter calculates and sends wirelessly to the app.

Item	Description
High and low sensor glucose alert limits	Display a line showing the high and low SG limits on the sensor graph. The orange line indicates your SG high limit; the red line indicates your SG low limit.
Sensor status message	Displays the latest active status notification. If a current SG reading is not available, the sensor status message will appear where the SG information would be displayed.
Sensor glucose graph	Displays a blue line representing your SG readings over a selected time interval. It also indicates your high and low glucose limits. For details on the sensor graph, see *Sensor graph, on page 41*.
Day indicator	Displays the date of the data shown in the graph. As you scroll further back into historical data, the date is displayed as Today, Yesterday, days of the previous week.
Add event	Displays the events screen where you can enter additional information, such as exercise, BG readings, meals you eat, or insulin you take. Certain BG readings entered here may be also used for sensor calibration. For details, see *Events, on page 42*.

Menu screen

The Menu screen appears when you tap ☰ in the upper left hand corner of the Home screen.
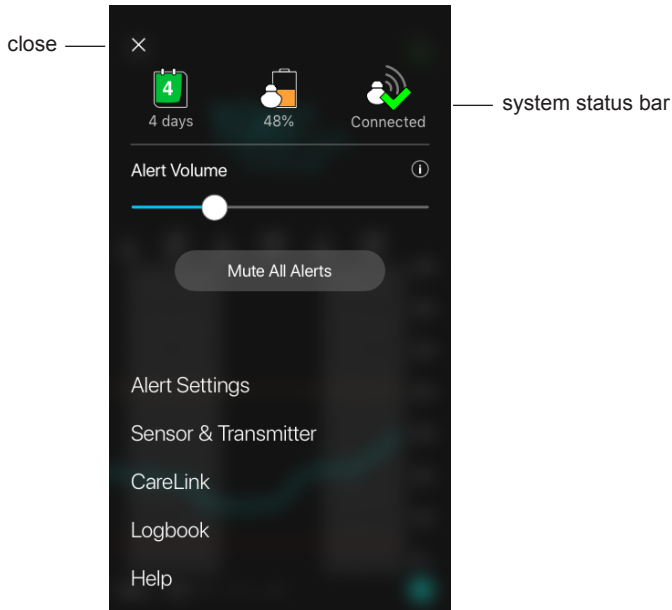
Item	Description
Close (X)	Closes the menu screen and returns you to the Home screen.
System status bar	Displays icons that show a quick status of your Guardian Connect system, including transmitter battery, sensor life, and transmitter communication. For details on the individual icons and their status, see *System status icons, on page 29*.
Alert Volume	Allows you to adjust the volume of alerts. Alerts will sound louder and repeat if not acknowledged. For details, see *Adjusting Alert Volume, on page 40*.
Alert Volume Information	Displays a description of Alert Volume slider and Mute All Alerts button. For details, see *Adjusting Alert Volume, on page 40*.
Mute All Alerts	Allows you to mute all alerts for a specified duration. Urgent Low Alerts will always vibrate. For details, see *Muting Alerts, on page 40*.
Alert Settings	Display the options for setting glucose monitoring alerts and calibration reminders. For details, see *Alert settings, on page 35*.

Item	Description
Sensor and Transmitter Setup	Displays the instructions for starting a new sensor. For details, see *New sensor setup, on page 15*.
CareLink	Provides access to a menu for changing your CareLink user login information.
Logbook	Displays a history of alerts and events that have occurred in the Guardian Connect system. For details, see *Logbook, on page 46*.
Help	Provides the user with software version information, access to the user guide, and reference to the end user license agreement.

System status icons

The system status icons appear at the top of the Menu screen. These icons provide a way for you to quickly check the status of your system. If any condition becomes critical and requires your immediate attention, the corresponding status icon also is displayed on the Guardian Connect Home screen next to the Calibration icon. The icons displayed on the Home screen are interactive and provide more information about the current status.

Icon name	Description
Transmitter battery	As the battery life is used, the icon changes in the following order. This indicates that the charge level of your battery is decreasing from 100% to 0%. When your battery is full, the icon is solid green indicating that approximately 100% of your battery capacity remains, which means you can expect at least 7 days of use remaining. Orange icon indicates that approximately 50% of your battery capacity remains. Single red bar indicates you have up to one day of use remaining. When the battery is empty, the icon is a red outline . The question mark indicates that the battery status is unknown.

Icon name	Description
Sensor life	As your sensor life is used, the number on the icon indicates the number of days left before you need to replace your sensor, and the color of the icon changes as shown:
	When you insert a new sensor, the icon is solid green. When there is less than one day left, the 1-day icon remains red, and the text below it indicates the number of hours that remain. The question mark indicates that the sensor life is unknown. When the sensor is expired, you will see an "X".
Transmitter communication	The communication status between your transmitter and the app:
	— the transmitter is active and connected
	— there is a communication error, the transmitter is not paired to your mobile device, or Bluetooth is off

Calibrating your sensor

Calibration is the process of entering a BG meter reading to calculate SG values. You must calibrate your sensor regularly to ensure you continue to receive accurate SG data. For details, see *Calibrating guidelines, on page 31*.

Note: *The Guardian Connect system requires up to a two-hour warm-up, from the time the sensor is connected to the transmitter, before you can calibrate your sensor. The calibration icon remains hidden until the sensor has completed its warm-up.*

Whenever a sensor calibration is due, you receive an alert that instructs you to calibrate your sensor now. After you calibrate the sensor, it may take up to five minutes to receive updated SG values. If you do not calibrate after receiving a calibration alert, your transmitter stops calculating your SG values until you calibrate your sensor.

The following table describes when a sensor calibration is required.

Required calibration	When?	Description
First	Within two hours after connecting a new sensor.	Sensor will take up to two hours to become operational. As soon as it is initialized, you will be asked to calibrate your sensor.
Second	Within six hours after your first calibration.	If you do not calibrate for more than six hours after the first calibration, your transmitter stops calculating your SG values until you calibrate your sensor.

Required calibration	When?	Description
Subsequent	Within 12 hours after your second calibration and at least every 12 hours thereafter.	If you do not calibrate for more than 12 hours, your transmitter stops calculating your SG values until you calibrate your sensor. You must calibrate the sensor at least every 12 hours throughout its life. For details, see *Calibrating guidelines, on page 31*.

Note: You may also receive an additional calibrate alerts (Calibrate Now) to let you know that another calibration is required to improve sensor performance. If you do not calibrate after receiving an additional Calibrate Now alert, your transmitter stops calculating your SG values until you calibrate your sensor and your app may stop displaying SG values.

Calibrating guidelines

Follow these guidelines for best sensor calibration results:

- Calibrate three to four times at regular intervals throughout the day to improve accuracy. If necessary, set a calibration reminder as explained in *Setting calibration reminders, on page 39*.
- Enter your BG meter reading into the app immediately after testing your BG.
- Review your BG meter instructions for guidance on how to test your BG.

CAUTION: Do not use Alternative Site Testing under the following conditions. Use fingertip testing in any of these cases:
- If you think your BG is low (hypoglycemia).
- When BG is changing rapidly, such as after a meal, insulin dose, or exercise.
- If you have hypoglycemic unawareness (lack of symptoms).
- If you get alternative site BG results that do not agree with how you feel.
- During illness or times of stress.
- If you will be driving a car or operating machinery.
- For calibration of CGM system.

- Always wash your hands before testing your BG.
- Use only your fingertips when obtaining blood samples for calibration.
- Avoid using an old BG reading or reusing BG readings from previous calibrations.
- If for some reason calibration is unsuccessful, you must wait at least 15 minutes before attempting another calibration.

Note: If your BG meter readings are significantly different from your SG readings, wash your hands and calibrate again.

Entering BG meter readings for calibration

You can enter a BG meter reading for calibration from the Calibration screen as described in this section or when you enter a BG meter reading on the Events screen, as described in *Entering BG meter readings, on page 43*.

To enter a BG meter reading for sensor calibration:

1   Take a BG meter reading.
2   On the Home screen of the app, tap the calibration icon.
3   Using the number pad, enter the BG value between 40 and 400 mg/dL.
4   Make sure the value displayed above the number pad is correct. If not, tap ⌫ to clear it and enter the correct value.
5   Tap **Calibrate** at the bottom.
    The App returns to the Home screen, and a blood drop appears on the SG graph at the time of the entry. Your SG reading appears within five minutes after calibration.

Alerts

The Guardian Connect app provides **system status alerts** and **glucose alerts**. These alerts can inform you about your glucose levels and the status of your Guardian Connect system.

Glucose Alerts

You can set **glucose alerts** to notify you if your SG values:

•   Are rising or falling above a particular rate.
•   Have gone above or below limits that you set.
•   Are predicted to go above or below a limit that you set.

The **glucose alerts** in the Guardian Connect system are listed below:

Alert type	Description
High Sensor Glucose	Your SG level has gone above the high limit you set.
High Predicted	Your SG is predicted to go above the high limit you set, within a period of time that you set (up to 60 minutes ahead).
Rise Alert	Your SG is rising faster than a rate you set (corresponding to the rising arrows displayed next to your SG level).
Low Sensor Glucose	Your SG level has gone below the low limit you set.

Alert type	Description
Low Predicted	Your SG is predicted to go below the low limit you set, within a period of time that you set (up to 60 minutes ahead).
Fall Alert	Your SG is falling faster than a rate you set (corresponding to the falling arrows displayed next to your SG level).
Urgent Low Sensor Glucose	Your SG level has gone below 55 mg/dL.

Note: *You will always receive an Urgent Low Glucose alert when your SG value is 55 mg/dL or below, except if the Guardian Connect app is in "Alerts Disabled". However, if the Guardian Connect app is in "Alerts Disabled", you will not receive any alerts, including the Urgent Low glucose alert.*

Glucose alerts can be customized and are set up during system setup, or as described in *Alert settings, on page 35*.

System Status Alerts

The Guardian Connect system also has system **status alerts** that inform you about actions needed to ensure the correct functioning of the system. See the Status Alerts table below for a complete listing of these alerts. For more information on how to address these alerts, see *Troubleshooting, on page 56*.

The **status alerts** in the Guardian Connect system are listed below:

When you receive the following status alerts, you still receive SG information but you should act on these alerts so you can continue to receive SG information in the future.

Alert type	Description
Calibrate by	You programmed the Calibration Reminder setting to alert you when a calibration will be due.
Mobile device battery low	Your mobile device battery has fallen at or below 20% of its power.

The **status alerts** in the Guardian Connect system are listed below:

When you receive the following status alerts, you **no longer receive** SG information.

Alert type	Description
Calibrate Now	You need to calibrate your sensor in order to get SG readings.
Calibration not accepted	Your BG meter value could not be used to calibrate.
Change sensor	You may have received a second Calibration not accepted alert or the sensor is not working properly.

Alert type	Description
Lost Communication	Your Guardian Connect app and transmitter haven't been communicating for 30 minutes. Your app may have closed if there are too many apps running at the same time or if there is radio frequency interference.
Sensor end of life	Sensor has reached its maximum life of 7 full days.
Sensor glucose not available	There is no sensor information due to several possible causes. Some causes include the sensor pulling out of your skin or your sensor not working properly.
Transmitter battery empty	Your transmitter battery is empty and needs to be recharged. You are no longer receiving sensor information.
Transmitter error	The transmitter is trying to fix a problem.
Jailbroken device detected	The operating software on the iOS mobile device has been changed such that it no longer works in the way the manufacturer intended. The app cannot be used with a jailbroken device. Changing the mobile device operating software causes the app to stop working.
Rooted device detected	The operating software on the Android^{TM} mobile device has been changed such that it no longer works in the way the manufacturer intended. The app cannot be used with a rooted device. Changing the mobile device operating software causes the app to stop working.

How Guardian Connect App Will Alert You

Your mobile device has several options for adjusting notification sounds, such as silent/mute mode and Do Not Disturb. These options might stop Guardian Connect from sending you Guardian Connect alerts. Guardian Connect will be in "Alerts Disabled" when it is unable to send you Guardian Connect alerts. To make sure you get all the alerts you want, keep in mind the following:

- **For iOS**, keep Critical Alerts and Notifications on for the Guardian Connect app. Also, if you use Screen Time, add Guardian Connect to "Always Allowed" apps.
- **For Android**, keep Do Not Disturb Permission, App Notifications, and Alerts on for the Guardian Connect app.
- You need to keep these items on for the Guardian Connect app to receive any alerts from the app. When these features are turned off, Guardian Connect will be in "Alerts Disabled" and you will not receive any alerts, including Urgent Low glucose alerts.
- To turn on Critical Alerts, Notifications, Alerts, and Do Not Disturb Permission follow the instructions on the pop-ups in the app.
- **For iOS users**, to add Guardian Connect to "Always Allowed" apps in Screen Time, go to your phone **Settings**>**Screen Time**>**Always Allowed**, and select Guardian Connect.

WARNING: **For iOS users, you must allow "Critical Alerts" and "Notifications" for the Guardian Connect app. If "Critical Alerts" or "Notifications" are turned off, the Guardian Connect app is in "Alerts Disabled" and you will not receive any alerts, including Urgent Low glucose alerts. If you use "Screen Time", you must add Guardian Connect as an "Always Allowed" app. If you do not add Guardian Connect as an "Always Allowed" app, you will not receive any alerts, including Urgent Low glucose alerts.**

WARNING: **For Android^TM users, you must allow "Do Not Disturb Permission", "App Notifications" and the "Alerts" category for the Guardian Connect app. If "Do Not Disturb Permission", "App Notifications", or the "Alerts" category are turned off, the Guardian Connect app is in "Alerts Disabled" and you will not receive any alerts, including Urgent Low sensor glucose alerts.**

WARNING: **Alerts for the Guardian Connect app will sound through your headphones when headphones are connected. If you leave your headphones connected when not in use, you may not hear SG alerts.**

WARNING: **Do not close the Guardian Connect app. If the app is closed, you will not get SG alerts.**

WARNING: **Your mobile device may close the Guardian Connect app automatically when you are using another app, such as a game. If the Guardian Connect app is closed, you will not get SG alerts. Check the Guardian Connect app occasionally to make sure it is running.**

WARNING: **Do not let your mobile device shut down due to low battery, or you will not get SG alerts. Make sure you have a charger available so you can charge your battery if needed.**

CAUTION: **Use of the app will deplete the mobile device battery more quickly.**

Alert settings

Setting low alerts
Low alert settings include the following:

Low alert setting	Description
Day Starts at	The Day time alert setting is where you set when your day begins, what your low limit is during the day, and when to alert you.
Night Starts at	The Night time alert setting is where you set when your night begins, what your low limit is during the night, and when to alert you.
Low Limit	Your Low Limit is the value on which your other low settings are based. Your low limit can be set from 60 to 90 mg/dL. On your SG graph, your low limit appears as a red horizontal line at the value that you set.
Don't Alert Me	When Don't Alert Me is selected, you do not receive any alerts for low glucose. You still receive an Urgent Low Alert since this alert is always on.
At Low Limit	When At Low Limit is selected, your system displays a Low Sensor Glucose Alert when your SG value reaches or falls below your low limit.
Before Low Limit	When Before Low Limit is selected, you receive a Low Predicted alert any time the SG is predicted to reach your low limit. This makes you aware of potential lows before they occur.
Before and at Low Limit	When Before and at Low Limit is selected, you receive a Low Predicted Alert any time the SG is predicted to reach your low limit and when your SG value reaches or falls below your low limit. This makes you aware of potential lows before they occur and when you reach or fall below your low limit.
Time Before Low	Time Before Low is available only when Alert Before Low is selected. Time Before Low determines when you will receive a Low Predicted Alert, if your SG values continue to decrease at the current rate of change. You can set a time between ten minutes and one hour.
Max Volume at Night	Max Volume at Night is available only in the Night time section and when you select Alert me. Toggling **Max Volume at Night** on for Low Alerts makes all Low Alerts sound at max volume at night.

To set your low alerts:

1 On the Home screen, tap ☰ and select **Alert Settings** > **Low Alerts**.
2 Tap **Day starts at** and set the desired start time. Tap **Save**.
3 Tap **Low Limit** and set the desired limit between 60 and 90 mg/dL. Tap **Save**.
4 If you want to receive alerts when your SG approaches your low limit, tap **Alert me** and choose one of the following:

a. At Low Limit
b. Before Low Limit
c. Before and at Low Limit

5 If you select **Before Low Limit** or **Before and at Low Limit**, the **Time Before Low** appears. Set the desired time when you want to receive a Low Predicted alert and tap **Save**.

6 Return to the Low Alerts screen and tap **Night starts at**. Set the desired start time and tap **Save**. Repeat steps 3 through 5 to set your night time alerts.

7 You can toggle **Max Volume At Night**. When **Max Volume At Night** is toggled on, your Low Alerts sound at max volume at night.

8 When you complete alert set up, tap Alert Settings back button to return to Alert Settings screen.

9 Tap the Menu back button to return to the Menu screen.

10 Tap **X** to close the menu and return to the Home screen.

Setting high alerts

High alert settings include the following:

High alert setting	Description
Day Starts at	The Day time alert setting is where you set when your day begins, what your high limit is during the day, and when to alert you.
Night Starts at	The Night time alert setting is where you set when your night begins, what your high limit is during the night, and when to alert you.
High Limit	Your high limit is the value on which your other high settings are based. Your high limit can be set from 100 to 400 mg/dL. On your SG graph, your high limit appears as an orange horizontal line at the value that you set.
Don't Alert Me	When Don't Alert Me is selected, you do not receive any alerts for high glucose. You still receive an Urgent Low Alert since this alert is always on.
At High Limit	When At High Limit is selected, your system displays a High Sensor Glucose alert when your SG value reaches or exceeds your high limit.
Before High Limit	When Before High Limit is selected, you receive a High Predicted alert any time the SG is predicted to reach your high limit. This makes you aware of potential high glucose levels before they occur.
Before and at High Limit	When Below and at High Limit is selected, you receive a High Predicted Alert any time the SG is predicted to reach your high limit and when your SG value reaches or falls below your high limit. This makes you aware of potential highs before they occur and when you reach or fall below your high limit.

High alert setting	Description
Time Before High	The Time Before High option is available only when the Alert Before High feature is selected. This option determines when you receive a High Predicted alert if your SG values continue to increase at the current rate of change. You can set a time between ten minutes and one hour.
Max Volume at Night	Max Volume at Night is available only in the Night time section and when you select Alert me. Toggling **Max Volume at Night** on for High Alerts makes all High Alerts sound at max volume at night.

To set your high alerts:

1 On the Home screen, tap ▤ and select **Alert Settings** > **High Alerts**.

2 Tap **Day starts at** and set the desired start time. Tap **Save**.

3 Tap **High Limit** and set the desired limit between 100 and 400 mg/dL. Tap **Save**.

4 If you want to receive alerts when your SG approaches your high limit, tap **Alert me** and choose one of the following:
   a. At High Limit
   b. Before High Limit
   c. Before and at High Limit

5 If you select **Before High Limit** or **Before and at High Limit**, the **Time Before High** appears. Set the desired time when you want to receive a High Predicted alert and tap **Save**.

6 Return to the High Alerts screen and tap **Night starts at**. Set the desired start time and tap **Save**. Repeat steps 3 through 5 to set your night time alerts.

7 You can toggle **Max Volume At Night**. When **Max Volume At Night** is toggled on, your High Alerts sound at max volume at night.

8 When you complete alert set up, tap Alert Settings back button to return to Alert Settings screen.

9 Tap the Menu back button to return to the Menu screen.

10 Tap **X** to close the menu and return to the Home screen.

Setting rate alerts

Rate alerts notify you when your SG falls (Fall Alert) or rises (Rise Alert) equal to or faster than a specified rate. These alerts help you understand how your glucose levels are affected, for example, by meals or exercise.

On the Home screen, these rapidly falling or rising trends are indicated by arrows, as shown in *Home screen, on page 25*. The more arrows, the higher the rate of change. The following table shows the trend arrows and their corresponding rates.

↑	SG has been rising at a rate of 1 mg/dL or more per minute, but less than 2 mg/dL per minute.
↓	SG has been falling at a rate of 1 mg/dL or more per minute, but less than 2 mg/dL per minute.
↑↑	SG has been rising at a rate of 2 mg/dL or more per minute, but less than 3 mg/dL per minute.
↓↓	SG has been falling at a rate of 2 mg/dL or more per minute, but less than 3 mg/dL per minute.
↑↑↑	SG has been rising at a rate of 3 mg/dL or more per minute.
↓↓↓	SG has been falling at a rate of 3 mg/dL or more per minute.

To set your rate alerts:

1   On the Home screen, tap ☰ and select **Alert Settings** > **Fall & Rise Alerts**.

2   Toggle **Fall Alert** on.
    Three options appear with the number of arrows corresponding to a specific fall rate that is equal to or faster than the alerts you set.

3   Tap the arrow option with the fall rate you want to use.

4   Toggle **Rise Alert** on.
    Three options appear with the number of arrows corresponding to a specific rise rate that is equal to or faster than the alerts you set.

5   Tap the arrow option with the rise rate you want to use.

6   When you complete Fall & Rise set up, tap **Alert Settings** back button to return to Alert Settings screen.

Setting calibration reminders
Calibration reminders remind you of an upcoming calibration. You can set a reminder for yourself that sensor calibration is due within a specified period of time. For example, if you set your reminder to 30 minutes, you will receive a Calibrate By alert 30 minutes before you need to enter a BG meter reading for calibration.

To set a calibration reminder:

1   On the Home screen, tap ☰ , and select **Alert Settings** > **Calibration**.

2   Tap **Alert Settings** and then tap **Calibration**.

3   Toggle the **Reminder** setting. This will give you the **Time before calibration** option.

4   Tap **Time before calibration** and set your calibration reminder time. Tap **Save**.

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Setting alert snooze time

The snooze feature lets you set a snooze time for your alerts. This feature reminds you of the alert condition after a set period of time, if the alert condition still persists. You can set snooze time for high and rise alerts that is different from snooze time for low and fall alerts.

To set your alert snooze time:

1   On the Home screen, tap ☰ , and select **Alert Settings** > **Snooze Time**.
2   Tap **Low & Fall Alerts** and set the desired snooze time for Low & Fall Alerts. Tap **Save**.
3   Tap **High & Rise Alerts** and set the desired snooze time for High & Rise Alerts. Tap **Save**.

Adjusting Alert Volume

All Guardian Connect alerts sound at the volume you set here. Alerts sound louder and repeat if not acknowledged.

To adjust alert volume:

1   On the Home screen, tap ☰ .
2   At the top, there is a slider. Swipe left to turn the volume down. Swipe right to turn the volume up.

*Note: If you set the volume at 0%, a popup appears stating: "Alert volume set at 0%. If you don't respond to the initial alert, it will sound and repeat. Your alerts are NOT muted. To mute alerts, tap **Mute All Alerts**."*

Muting Alerts

All Guardian Connect alerts will be muted for the time you select. Urgent Low Alert will always vibrate.

To mute alerts:

1   On the Home screen, tap ☰ .
2   Tap **Mute All Alerts** and 4 options appear.
    a.   30 min
    b.   1 hour
    c.   4 hours (max)
    d.   Custom
    If you select Custom, adjust your mute time to the desired length and tap **Mute**.

3   A popup appears to confirm the alerts are muted. If you want to cancel the mute, tap **Cancel Mute**.

Acting On Guardian Connect Alerts

When you get a Guardian Connect alert, you get a notification on your mobile device like you do for other apps. All alerts vibrate according to your phone vibration settings. For more details on Guardian Connect Alerts, see *How Guardian Connect App Will Alert You, on page 34*.

When you get a Guardian Connect alert, you must open the app to address the alert. Dismissing the notification only removes it from the list of notifications on your mobile device. If you dismiss the notification from your mobile device, but don't act on it in the Guardian Connect app, the alert may repeat.

When you open the app, you will see the alert on your screen. For system status alerts, you can clear the alert by clicking **OK**. For SG alerts, you can either swipe the alert up, which will snooze the alert for the pre-set snooze period, or you can drag the alert down to set a new snooze period.

Sensor graph

The sensor graph displays your current SG reading. It also allows you to view a history of SG readings and events you have entered.

Navigating through the sensor glucose graph

• Swipe the center of the graph right and left to view historical data and to return to the current graph location.
• Pinch and stretch the center of the graph with your fingers to zoom in and out on the graph data.
• Tap the graph twice to view the graph at the selected 3-hour, 6-hour, 12-hour, and 24-hour zoom levels.
• Tap the horizontal time axis above the graph to center the selected time point on the graph. This lets you view the details of the selected SG reading or event in an information box that appears above the graph. For details, see *Graph information boxes, on page 42*.
• Double tap the vertical SG values axis to the right of the graph to return to the current SG reading displayed on the graph.

Graph information boxes

When you tap any point on the graph, the tapped time is marked by a vertical cursor on the graph, and a box with the information about the tapped event or SG reading appears above the graph. The following figure provides an example:
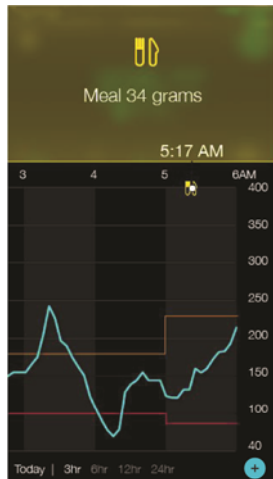
For SG readings, information boxes display the SG value, its date and time, and rate of change arrows, similar to the current SG value information displayed on the Home screen. If there is no SG value for the selected time point, the information box displays the sensor status message for that point.

For event markers, information boxes display the details specific to each event type. For details, see *Events, on page 42*.

You can drag the cursor across the graph, skipping at five-minute intervals to pinpoint a specific SG value on the graph.

Information boxes appear for a few seconds and then close.

Events

Events help you capture information that may affect your glucose levels. You can use the Events screen on the app to enter and save certain types of events.

Event icon	Event name	Description
	Blood Glucose	Blood glucose meter readings. These can be used either to calibrate the system or simply to manage your diabetes without calibrating the system.
	Insulin	The type and amount of insulin you have delivered.
	Meal	The amount of carbohydrates you eat or drink.
	Exercise	The intensity and duration of your exercise routine.
	Notes	This event can be used to enter any other information relevant to your diabetes management. For example, you can record information such as when you take medications, feel ill, or are under stress.

Note: Make it a practice to enter events when they happen. If you make a mistake when entering an event, you can always delete the event and enter it again.

Entering BG meter readings

If you measure your BG, for example, when you eat or when your BG rises or falls rapidly, you can enter these measurements into the app.

You also have the option of using the entered BG meter reading for calibration purposes, if calibration is allowed at the time when you entered the event. To use the BG meter reading for calibration, the value must be between 40 and 400 mg/dL. When calibrating your sensor from the BG screen, you may enter your current BG values, or values that are up to ten minutes old.

Note: You can enter a BG value between 20 and 600 mg/dL into the Events feature. For BG calibration, you can enter a value between 40 and 400 mg/dL.

To enter a BG meter reading into the Events feature:

1   Measure your BG with a BG meter.

2 Tap ⊕ at the bottom of the Home screen.

3 Tap 🔴 on the Events screen.

4 If you need to change the date or time for the entry, tap **Time** and make the appropriate changes.

5 Using the number pad, enter the BG meter reading.

6 Make sure the value displayed above the number pad is correct. If the value is incorrect, tap ⌫ to clear it and enter the correct value.

7 Tap **Save** at the bottom of the screen.

8 If you receive a message instructing you to calibrate now:
   • To update the sensor with the entered BG meter reading, select **Calibrate**.
   • If you do not want to update the sensor with this reading, select **Just save**.
   • If you need to make a correction or need to cancel, tap **X**.

   The app returns to the Home screen, and 🔴 appears on the graph at the selected time.

Entering insulin injection information

If you deliver insulin using an insulin pump, insulin pen, or a syringe, you can use the app to record the amount of insulin you inject.

To enter the type and amount of insulin you delivered:

1 Make a note of the amount and type of injection you took.

2 At the bottom of the Home screen, tap ⊕.

3 On the Events screen, tap 🔵.

4 If you need to change the date or time for the entry, tap **Time** and make the appropriate changes.

5 Using the number pad, enter the insulin amount.

6 Make sure the value displayed above the number pad is correct. If not, tap ⌫ to clear it and enter the correct value.

7 Tap **Type** and select the type of insulin you took:
   • Rapid-acting
   • Long-acting
   • Unspecified

8 Tap **Back** at the top to return to the Insulin Event screen.

9 The app returns to the Home screen, and 🔵 appears on the graph at the selected time.

Entering meal information
You can use the app to record information about the carbohydrates you eat or drink with meals or snacks.

To enter your meal information:

1 Determine the total amount, in grams, of carbohydrates in the meal, snack, or drink that you plan to consume.
2 At the bottom of the Home screen, tap ⊕.
3 On the Events screen, tap 🔵.
4 If you need to change the date or time for the entry, tap **Time** and make the appropriate changes.
5 Using the number pad, enter the amount of carbohydrates you have consumed.
6 Make sure the value displayed above the number pad is correct. If not, tap ⌫ to clear it and enter the correct value.
7 Tap **Save** at the bottom.
 The app returns to the Home screen, and 🟡 appears on the graph at the selected time.

Entering exercise information
You can use the app to enter information about your exercise regimen. Make sure you are consistent and enter the marker either before or after each time you exercise.

To enter your exercise information:

1 Make a note about how long you exercised (duration), and how difficult or easy the exercise was (intensity).
2 At the bottom of the Home screen, tap ⊕.
3 On the Events screen, tap 🟢.
4 If you need to change the date or time, tap **Time** and set the desired day and time for this exercise entry.
5 Tap **Intensity** and select Low, Medium, or High to indicate how intensely you have exercised.
6 Tap **Duration**.
7 Tap **Save** at the bottom.
 The app returns to the Home screen, and 🏃 appears on the graph at the selected time.

Entering notes

You can use the app to enter events other than BG measurements, insulin injections, carbohydrates consumed, and exercise information. For example, you can record information such as when you take medications, feel ill, or are under stress.

To enter notes:

1   At the bottom of the Home screen, tap ⊕ .
2   On the Events screen, tap 🔲 .
3   Using the text field, enter the relevant information.
4   Tap **Save** at the bottom.
    The app returns to the Home screen, and 🔲 appears on the graph at the selected time.

Logbook

The Logbook screen displays a history of alerts and events that occurred on the selected day, with the most recent entries at the top of the list.

To view Logbook entries:

1   On the Home screen, tap ▤ and select **Logbook**.
2   Do any of the following to view the desired information:
    • Tap **Alerts** or **Events** to filter the list by the specific type. You also can select **All** to view the entire list.
    • Swipe down and up on the list to view the entries.
    • If you wish to delete an event entry, swipe it left and tap **Delete**.

        Note: You cannot delete alerts or calibration events.

    • Tap the desired entry to expand it and view the details. You can also use ∧ and ∨ arrows at the top of the expanded view to scroll through the list entries.
3   If you are viewing a specific event or alert on a details screen, tap **Logbook** > **Menu** to return to the Menu screen. If you are on the main Logbook screen, tap **Menu** to return to the Menu screen.

Syncing your data to CareLink Personal website

Guardian Connect offers remote monitoring by Care Partners and daily uploads to the CareLink Personal website. This is done using an automatic feature called "Sync to CareLink".

This automatic Sync to CareLink feature sends data displayed in the app to the CareLink Connect tab of the CareLink Personal website. This data is sent approximately every five minutes when an Internet connection to the website is available. This feature also automatically sends sensor history information used to create CareLink Personal reports roughly every 24 hours. This information can be viewed by you or a care partner on the CareLink Personal website at carelink.minimed.com. Please note that your mobile device must be connected to the Internet to send data to the website. If using a cellular connection, your provider's data rates may apply.

If the Sync to CareLink toggle is turned off, the app no longer sends sensor information to the CareLink Personal website.

The **Upload Now** button allows you to immediately send sensor history data to the website for generating reports.

Sending a care partner access to CareLink Personal website

Now that your app is synced with CareLink Personal website, you can invite a family member, friend, or care partner to track your diabetes information on the website. Visit carelink.minimed.com on your personal computer or tap the **Manage Care Partners** button within the app to access the CareLink Personal website. There you can create a username and temporary password for each care partner. Your care partners use this login information to access your diabetes information on the website.

Note: Your care partners use the CareLink Personal website login information you create for them to access the CareLink Personal website.

For more information on the CareLink Connect tab, please refer to the *CareLink Connect User Guide* found in the CareLink Connect tab of the CareLink Personal website.

Disconnecting the transmitter from the sensor

To disconnect the transmitter from the sensor:

1   Carefully remove any tape from the transmitter and sensor.
2   Remove the adhesive tab from the top of the transmitter.
3   Hold the transmitter as shown, and pinch the flexible side arms of the sensor between your thumb and forefinger.
4   Gently pull the transmitter away from the sensor.
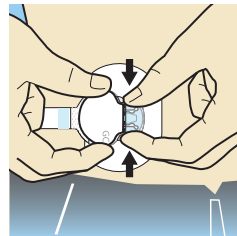
Removing the sensor

When you are ready to change your sensor, disconnect the transmitter from the sensor. See *Disconnecting the transmitter from the sensor, on page 48*. Gently pull the sensor from your body to remove it. Place the sensor in a sharps container.

Reconnecting the existing sensor

If necessary, you can reconnect your transmitter to an existing sensor. Simply connect your transmitter to your sensor. When the app detects the connection, confirm that the sensor is an existing sensor. It may take a few seconds to establish a connection when connecting an existing sensor. If you reconnect an existing sensor, the sensor goes through another warm-up period before you can calibrate.

Tester

The tester is used to test the transmitter to make sure it works. It is also used as a required component for cleaning the transmitter. Properly connecting the tester to the transmitter ensures that fluids do not come in contact with the connector pins inside the transmitter. Fluids can cause connector pins to corrode and affect the performance of the transmitter.

Do not twist the tester while attached to the transmitter. This damages the transmitter.

The tester can be used 61 times. If you use the tester more than 61 times, the connector pins inside the transmitter could be damaged because the tester cannot continue to provide a waterproof seal. For instructions on how to check the connector pins, see *Inspecting the transmitter connector pins, on page 49*.

CAUTION: Only use the green tester (MMT-7736L) with the transmitter. Pockets on the transmitter are visible when connected to the tester. Do not use any other tester. Other testers are not intended for use with the transmitter and will damage the transmitter and the tester.

green tester

pockets
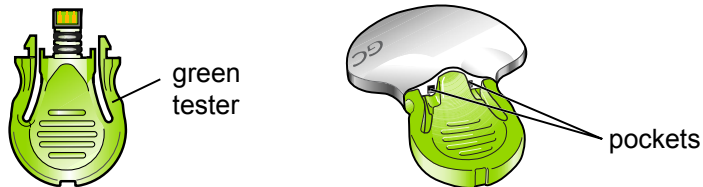
Inspecting the transmitter connector pins

This image is an example of how the connector pins should look.

connector opening

connector pins

housing
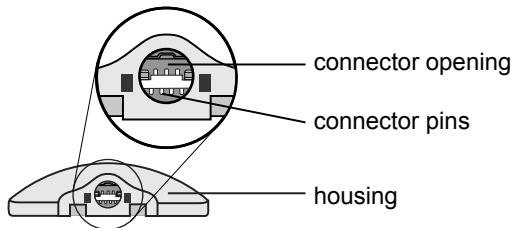
Look inside the connector opening of the transmitter to make sure that the connector pins are not damaged or corroded. If the connector pins are damaged or corroded, the transmitter cannot communicate with the charger or the app on your compatible mobile device. Contact your local Medtronic support representative. It may be time to replace your transmitter.

Also look for moisture inside the connector opening. If you see any moisture, allow the transmitter to dry for at least one hour. Moisture inside the connector opening could cause the transmitter to not work properly and could cause corrosion and damage over time.

Connecting the tester for testing or cleaning

To connect the tester:

1 Hold the transmitter and the tester as shown. Line up the flat side of the tester with the flat side of the transmitter.
2 Push the tester into the transmitter until the flexible side arms of the tester click into the notches on both sides of the transmitter. When properly connected, the green light on the transmitter flashes 6 times.
3 To test the transmitter, check the sensor icon in the app to ensure that the transmitter is sending a signal, see *System status icons, on page 29*.
4 To clean the transmitter, see *Cleaning the transmitter, on page 50*.
5 After testing or cleaning, disconnect the tester from the transmitter.
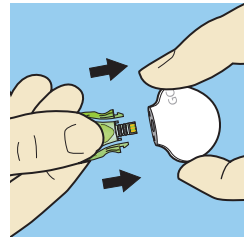
Disconnecting the tester

To disconnect the tester:

1 Hold the transmitter body as shown and pinch the side arms of the tester.
2 With the tester arms pinched, gently pull the transmitter away from the tester.

> *Note: To save transmitter battery life, do NOT leave the tester connected after cleaning or testing.*
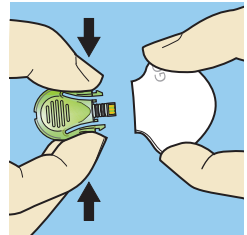
Cleaning the transmitter

The transmitter is a single-patient use device and not intended for multi-patient use.

WARNING: Do not discard the transmitter in a medical waste container or expose it to extreme heat. The transmitter contains a battery that may ignite and result in serious injury.

Note: The tester is a required component for cleaning the transmitter.

Always clean the transmitter after each use.

To clean the transmitter, you need the following materials:

• mild liquid soap
• soft-bristled toddler toothbrush
• container
• clean, lint-free dry cloths

Use life

The transmitter can be cleaned up to 122 times or one year, whichever comes first. Discard the transmitter at this point. If you continue to use the transmitter beyond 122 times or one year, the cleaning process may damage the device. Contact Medtronic to order a new transmitter.

WARNING: **Do not use the device if you see any cracking, flaking, or damage to the housing. Cracking, flaking, or damage to the housing are signs of deterioration. Deterioration of the housing can affect the ability to properly clean the transmitter, and result in serious injury. Call your local Medtronic support representative and discard the device according to local regulations for battery disposal (non-incineration), or contact your healthcare professional for disposal information.**

To clean the transmitter:

1 Wash your hands thoroughly.
2 Attach the tester to the transmitter to create a waterproof seal.
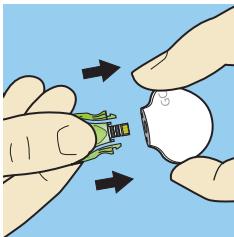
3 If there is adhesive residue on the transmitter, see *Removing adhesive residue, on page 53*.
4 Rinse the transmitter under room temperature tap water for at least one minute, and until visibly clean. Make sure all hard-to-reach areas are rinsed completely.
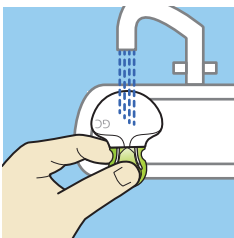
5 Prepare a mild liquid soap solution using 1 teaspoon (5 milliliters) of mild liquid soap per 1 gallon (3.8 liters) of room temperature tap water.

6 With the tester still attached, submerge the transmitter in the mild liquid soap solution and soak for one minute.
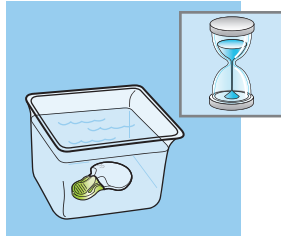
7 Holding the tester, brush the entire surface of the transmitter using a soft-bristled toddler toothbrush. Make sure to brush all hard-to-reach areas until visibly clean.
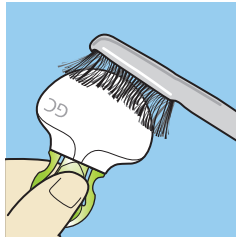
8 Rinse the transmitter under running room temperature tap water for at least one minute, and until all visible liquid soap is gone.
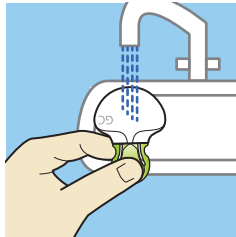
9 Dry the transmitter and tester with a clean, dry cloth.
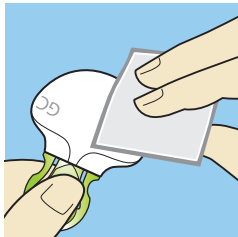
10 Place the transmitter and tester on a clean, dry cloth and air dry them completely.
11 Disconnect the tester from the transmitter by gently squeezing the arms of the tester.
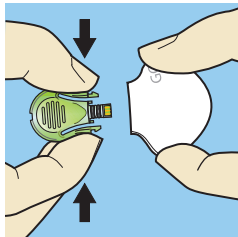
Removing adhesive residue

You may need to perform this procedure if there is adhesive residue present on the transmitter. If you visually inspect the transmitter and see adhesive residue on it, follow these instructions.

To remove adhesive residue, you need cotton swabs and a medical adhesive remover such as Detachol^{TM}, which is a mineral spirit.

Note: *During testing, Medtronic MiniMed used Detachol^{TM} to remove the adhesive residue from the transmitter.*

To remove adhesive residue:

1 Make sure the tester is attached to the transmitter.
2 Soak a cotton swab in the medical adhesive remover.

3   Hold the tester and gently rub the adhesive residue on the transmitter until it is fully removed.
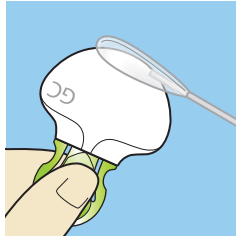
4   Continue with the cleaning procedure. See *Cleaning the transmitter, on page 50* for details.

Bathing and swimming

After the transmitter and sensor are connected, they form a waterproof seal to a depth of 8 feet (2.4 meters) for up to 30 minutes. You can shower and swim without removing them.

Cleaning the charger

This procedure is for general cleaning as required, based on physical appearance.

CAUTION: Do not immerse the charger in water or any other cleaning agent. The charger is not waterproof. Water can damage the charger and cause the device to malfunction.

WARNING: Dispose of the charger according to the local regulations for battery disposal, or contact your healthcare professional for disposal information. The charger may ignite upon incineration.

To clean the charger:

1   Wash your hands thoroughly.
2   Use a damp cloth with mild cleaning solution, such as a dishwashing detergent, to clean any dirt or foreign material from the outside of the charger. Never use organic solvents, such as paint thinner or acetone, to clean the charger.
3   Place the charger on a clean, dry cloth and air dry for two to three minutes.

Serter

Storage and handling
Store the serter in the released position, at room temperature, to maintain optimum product performance and life.

Serter life of use
The serter has a minimum service life of one year.

Serter maintenance
The serter is intended for single-patient use. The serter needs to be cleaned after every use or whenever there is debris, blood, or other contaminants.

Cleaning
To clean the serter, you need the following materials: mild liquid soap, a soft-bristled toddler toothbrush, and a container.

To clean the serter:

1 Prepare a mild liquid soap solution using 1 teaspoon (5 milliliters) of mild liquid soap per 1 gallon, which is equal to 16 cups (3.8 liters) of tap water.
2 Rinse the serter under running tap water at room temperature for at least one minute. Rinse until the serter is visibly clean. Make sure all hard-to-reach areas are rinsed completely.
3 When rinsing the serter, press and release the mechanism on the underside of the serter to ensure that the entire device is completely rinsed with water.
4 Submerge the serter in the mild liquid soap solution and soak it for at least 10 minutes.
5 Brush the entire surface of the serter using a soft-bristled toddler toothbrush until visibly clean. Pay close attention to brushing the hard-to-reach areas.
6 Rinse the serter under running tap water at room temperature for at least one minute, and until all visible liquid soap is gone.
7 Shake off any excess water or moisture and place the serter upright on a clean, dry, cloth to air dry.

Troubleshooting

The following table contains troubleshooting information for the transmitter, charger, and tester. For more information about troubleshooting, see your system user guide.

Transmitter

Problem	Likely Cause(s)	Resolution
You connected the transmitter to the charger and no lights came on.	The transmitter connector pins are damaged or corroded. Your charger battery has no power or no battery is inserted.	1 Check the transmitter connector pins for damage or corrosion. For more information about your connector pins, see *Inspecting the transmitter connector pins, on page 49*. If the pins are damaged or corroded, contact your local Medtronic support representative. It may be time to replace your transmitter. 2 If there is no damage to the connector pins, replace the battery in the charger. For instructions on replacing your charger battery, see *Installing a battery in the charger, on page 13*.
During charging, the flashing green light on the charger turns off and you see a longer flashing red light on the charger.	Your charger battery is low on power.	Replace the battery in the charger. For instructions on replacing your charger battery, see *Installing a battery in the charger, on page 13*.
During charging, the flashing green light on the charger turns off and you see a series of quick flashing red lights on the charger for two seconds at a time.	Your transmitter is low on power.	1 Charge the transmitter continuously for one hour. If flashing does not stop, proceed to step 2. 2 Charge the transmitter continuously for eight hours. If flashing does not stop, call your local Medtronic support representative. It may be time to replace your transmitter.

Problem	Likely Cause(s)	Resolution
During charging, a mix of quick and long flashing red lights appear on the charger.	Your charger *and* your transmitter are low on power.	1 Replace the battery in the charger. For instructions on replacing your charger battery, see *Installing a battery in the charger, on page 13*. 2 Charge the transmitter continuously for one hour. If the quick flashing red lights do not stop, proceed to step 3. 3 Charge the transmitter continuously for eight hours. If flashing does not stop, call your local Medtronic support representative. It may be time to replace your transmitter.
The green light on the transmitter does not flash when you connect it to the sensor.	Your transmitter is not fully connected. Your transmitter is low on power. Your sensor is not properly inserted into your body.	1 Disconnect the transmitter from the sensor. 2 Wait for five seconds and reconnect them. If the green light still does not flash, proceed to step 3. 3 Fully charge the transmitter and connect it to the tester. If the green light still does not flash, see troubleshooting on "The green light on the transmitter does not flash when you connect it to the tester". If the green light flashes, proceed to step 4. 4 Disconnect the transmitter from the tester, wait at least five seconds, and connect the transmitter to the sensor. If the green light still does not flash, proceed to step 5. 5 The sensor may not be properly inserted into your body. Remove the sensor from your body and insert a new sensor.
The green light on the transmitter does not flash when you connect it to the tester.	Your transmitter is not fully connected. Your transmitter is low on power.	1 Check the connection between the transmitter and the tester. If the green light still does not flash, proceed to step 2. 2 Fully charge the transmitter. 3 Test the transmitter with the tester again. If you still do not see the green light flash, call your local Medtronic support representative. It may be time to replace your transmitter.

Problem	Likely Cause(s)	Resolution
Your transmitter battery does not last for seven days.	Your transmitter is not fully charged when you connect it to the sensor. The transmitter and the app on your compatible mobile device frequently lose wireless connection.	1 Fully charge the transmitter before connecting it to the sensor. If the transmitter battery still does not last for seven days, proceed to step 2. 2 Move away from any equipment that can cause RF interference. For more information on RF interference, see *Radio Frequency (RF) communication, on page 11*. 3 Make sure your compatible mobile device and your transmitter are located on the same side of your body to minimize any RF interference. If your fully charged transmitter battery continues to lose power before a full seven days, call your local Medtronic support representative. It may be time to replace your transmitter.
Your transmitter does not pair or re-pair with Guardian Connect App.	The transmitter and the app on your compatible mobile device frequently lose wireless connection. The transmitter paired to the phone but is not recognized by Guardian Connect App.	Follow the steps on the Pair Transmitter screen in the Sensor & Transmitter menu screen. If the transmitter is not found, make sure your phone and transmitter are near each other and try the following steps: For Android™: 1 Go to your phone settings and tap **Connections**. 2 Tap **Bluetooth** and unpair any Medtronic transmitter. The transmitter is identified by "GT" followed by a series of numbers. 3 Turn Bluetooth **Off** and back **On**. 4 Retry the directions on Pair Transmitter screen. For iOS: 1 Go to your phone settings and tap **Bluetooth**. 2 Tap **Forget** to forget any Medtronic transmitters. The transmitter is identified by "GT" followed by a series of numbers. 3 Retry the directions on Pair Transmitter screen.

CareLink

Problem	Likely Cause(s)	Resolution
Receiving a connection error when trying to up-load data to CareLink.	Your phone has lost con-nection to the internet. You have changed your password through the CareLink website. CareLink servers are temporarily not respond-ing.	1 Check that your phone is connected to Wi-Fi or mobile network data. Go to a web browser and try to access any web page to see if internet connection is working through WiFi or through mobile network data. 2 If you are able to access the internet, go to Menu screen > CareLink screen and re-log into CareLink again with your latest CareLink credentials. 3 If your credentials are updated, you have internet connection, and upload is still fail-ing, CareLink servers may be temporarily not responding. Please try again later.

Alerts

Problem	Likely Cause(s)	Resolution
Lost Communication alert	You are using another app, such as a game, that takes up a lot of the memory on your mobile device. This means that your Guardian Connect app stops running and can't communicate with the transmitter.	Open the app to ensure it is running properly. You should check periodically to see if the app is still running in the background in order to receive alerts and SG values.
	The app has been closed. Your Guardian Connect app has stopped running and can't communicate with the transmitter. Potential causes include using other apps and features (for example task manager apps), or by selecting Force Stop for Guardian Connect from an Android^{TM} device Settings menu.	
	Your mobile device is out of range.	Make sure your mobile device and your transmitter are located within 20 feet (6 meters). It is helpful to keep your devices on the same side of your body to minimize any radio frequency (RF) interference.
	There is radio frequency (RF) interference from other devices.	Move away from any equipment that can cause radio frequency (RF) interference, such as cordless phones or routers.
	Your sensor disconnected from your transmitter.	Reconnect your sensor to your transmitter. Be careful not to pull the sensor out. ***Note:*** *When you have reconnected your transmitter to your sensor, your sensor goes through a warm-up period which may last up to 2 hours.*

Problem	Likely Cause(s)	Resolution
Lost Communication alert	Your sensor pulled out from your skin.	You cannot continue using this sensor. You must insert a new sensor to continue receiving SG values. For best results, recharge your transmitter before you start using a new sensor to ensure full transmitter battery life.
		If your transmitter is still not communicating with the app, contact your local Medtronic support representative for assistance.
Transmitter Battery Empty alert	Your transmitter battery is empty and needs to be recharged.	See *Guardian Connect Transmitter* user guide for instructions on how to disconnect your transmitter from your sensor. For best results, recharge your transmitter between each use to ensure full transmitter battery life.
		Note: When reconnecting your transmitter to your sensor, your sensor will go through a warm-up period which may last up to 2 hours.
Mobile Device Battery Low alert	Your mobile device battery level is at 20% or lower, the battery needs to be recharged soon.	Recharge your mobile device battery to ensure that your Guardian Connect system can function and send alerts. Remember to always carry a charger for your mobile device to ensure continuous use of the Guardian Connect system.
Change Sensor alert	The current sensor is not working properly and needs to be replaced.	To continue receiving SG values, a new sensor must be used. See your *Guardian Connect Transmitter* user guide for instructions on how to change your sensor. For best results, recharge your transmitter between each use to ensure full transmitter battery life.
Sensor End of Life alert	The current sensor has reached the end of its life and no longer displays SG values on the Guardian Connect app.	To continue receiving SG values, a new sensor must be used. See *Guardian Connect Transmitter* user guide for instructions on how to change your sensor. For best results, recharge your transmitter between each use to ensure full transmitter battery life.
Calibration Not Accepted alert	The last calibration value entered was not accepted by the Guardian Connect system.	The Guardian Connect system will request another calibration when it is ready. This can take up to 15 minutes from when the Calibration Not Accepted alert was received. Review your BG meter instructions for use on how to test your BG. Enter this new value in the app for calibration. For details on how to calibrate your sensor, see *Calibrating guidelines, on page 31*.

Problem	Likely Cause(s)	Resolution
Calibrate Now alert	A calibration is required by the system.	Review your BG meter instructions for guidance on how to test your BG. Enter this new value in the app for calibration. For details on how to calibrate your sensor, see *Calibrating guidelines, on page 31*.
Sensor Glucose Not Available alert	There is an error with the sensor.	No action is required. The sensor is trying to fix a problem. This may take up to 3 hours. Do not calibrate during this time. During this time, you should not rely on alerts from the system and you should use other methods to monitor your glucose values.
Transmitter Error alert	There is an error with the transmitter.	Disconnect the transmitter from the sensor and reconnect it. Upon reconnecting your transmitter to your sensor, your sensor goes through a warm-up period which may last up to 2 hours. If you still experience issues, you may need to replace your transmitter. Contact your local Medtronic representative for more assistance.

Storage

Store the transmitter, charger, and tester in a clean, dry location at room temperature. If the transmitter is not in use, you must charge the transmitter at least once every 60 days.

CAUTION: Do not store the transmitter on the charger. If the transmitter is left on the charger for more than 60 days, the battery will be permanently damaged.

Disposal

Do not dispose transmitter in unsorted municipal waste stream. Discard the transmitter according to local regulations for battery disposal, or contact your healthcare professional for disposal information.

Specifications

Biocompatibility	Transmitter: Complies with EN ISO 10993-1
Applied parts	Transmitter Sensor
Operating conditions	Transmitter temperature: 32°F to 113°F (0°C to 45°C) **CAUTION: When operating the transmitter on a tester in air temperatures greater than 106°F (41°C), the temperature of the transmitter may exceed 109°F (43°C)** Transmitter relative humidity: 10% to 95% with no condensation Transmitter pressure: 8.4 to 15.4 psi (57.60 to 106.17 kPa) Charger temperature: 50°F to 104°F (10°C to 40°C) Charger relative humidity: 30% to 75% with no condensation
Storage conditions	Transmitter temperature: -4°F to 131°F (-20°C to 55°C) Transmitter relative humidity: up to 95% with no condensation Transmitter pressure: 8.4 to 15.4 psi (57.60 to 106.17 kPa) Charger temperature: 14°F to 122°F (-10°C to 50°C) Charger relative humidity: 10% to 95% with no condensation
Battery life	Transmitter: Seven days of continuous glucose monitoring immediately following a full charge. Charger: The charger uses one new AAA battery to charge the transmitter.
Transmitter frequency	2.4 GHz band, Bluetooth Smart (version 4.0)
Effective radiated power (ERP)	-9.740 dBm
Operating range	Up to 20 feet (6.1 meters)
Transmitter expected service life	The transmitter expected service life is one year depending on patient usage.
Serter approximate dimensions	3.09 x 2.72 x 2.27 inches (7.85 x 6.91 x 5.77 centimeters)
Serter approximate weight	3.97 ounces (112.5 grams)

Essential Performance

The essential performance (EP) of the transmitter is to measure and transmit to a monitoring device the sensing device's signal value(s) within the transmitter's accuracy requirements under the specified use conditions outlined in the system user

guide and for the duration of the expected service life. If the transmitter experiences electromagnetic disturbances, either no or incorrect data may be transmitted. In such situations, refer to the operation, maintenance, and troubleshooting instructions within the applicable user guides. You may also use the tester to test if the transmitter is operating properly. If the transmitter is damaged or if it cannot communicate with the charger or mobile device, contact your local helpline or representative for assistance.

Guardian Connect Quality of service

Guardian Connect can use both Wi-Fi and cellular data to send data to CareLink Connect for remote monitoring, and to upload history to CareLink Personal. Guardian Connect will use Wi-Fi to transmit data when a Wi-Fi connection is available, and cellular data if Wi-Fi is not available. Although all data sent by Guardian Connect is encrypted, a secured Wi-Fi network is recommended.

Transmitter wireless communication

Quality of service
The transmitter and app connect via a BLE network. The transmitter sends glucose data and system related alerts to the app. The transmitter and the app verify the integrity of received data after wireless transmission. Quality of the connection is in accordance with the Bluetooth Specification v4.0.

Data security
The transmitter is designed to only accept radio frequency (RF) communications from recognized and linked devices. You must program the app to accept information from a specific transmitter. Transmitted sensitive data is encrypted to prevent unauthorized receipt or communication. If you use a Wi-Fi connection, it is recommended to connect to a secure Wi-Fi network, such as WPA2 or other newer wireless security protocols.

The app may send anonymous analytic data to Medtronic if permission has been granted in the setup of the app. This access can be revoked or reinstated at any time in the Help section of the app.

Traveling by air
Your transmitter is safe for use on commercial airlines. If airline personnel request that you turn off your system, you must comply.

Guidance and manufacturer's declaration

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	CISPR 11 Group 1, Class B	The transmitter uses RF energy only for system communications. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Not applicable	**Note:** *The preceding statement is required by IEC 60601-1-2 for Group 1, Class B devices. Since the transmitter is battery powered, its emissions will not be affected by the establishment power supply and there is no evidence of any issues associated with the use of the system in domestic establishments.*
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2:2014 Test Level**	**Max foreseeable use condition per IEC 60601-1-2:2014**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	For use in a typical domestic, commercial, or hospital environment.
Conducted disturbances induced by RF fields	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM bands between 150 kHz to 80 MHz	Not applicable	Requirement does not apply to this battery powered device.
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100 kHz repetition frequency	Not applicable	Requirement does not apply to this battery powered device.
Surge IEC 61000-4-5	Line to Line: ±0.5 kV, ±1 kV Line to Ground: ±0.5 kV, ±1 kV, ±2 kV	Not applicable	Requirement does not apply to this battery powered device.
Note: *U_T is the a.c. mains voltage prior to application of the test level.*			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2:2014 Test Level**	**Max foreseeable use condition per IEC 60601-1-2:2014**	**Electromagnetic Environment Guidance**
Voltage dips, short interruptions, and voltage variations on power supply lines IEC 61000-4-11	0% U_T; 0.5 cycles (at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°) 0% U_T; 1 cycle (at 0°) 70% for 25/30 cycles (at 0°) 0% for 250/300 cycles	Not applicable	Requirement does not apply to this battery powered device.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	For use in a typical domestic, commercial, or hospital environment.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	IEC 60601-1-2:2014, Table 9	IEC 60601-1-2:2014, Table 9	For use in a typical domestic, commercial, or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 6 GHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the transmitter, including cables, than the recommended separation distance of 12 in (30 cm). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2:2014 Test Level**	**Max foreseeable use condition per IEC 60601-1-2:2014**	**Electromagnetic Environment Guidance**
Note: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.*			

Guardian Sensor (3) Performance

CGM performance

The use of the Guardian Sensor (3) with the Guardian Connect transmitter enables CGM (Continuous Glucose Monitoring) technology. The transmitter transmits SG values calculated by the real-time algorithm to a primary display device, which allows you to monitor your SG values.

Clinical study description

The performance of the Guardian Sensor (3) was evaluated in a clinical study. This inpatient (in-clinic) and outpatient (at home) study included subjects 14 to 75 years in age. The study design was a multi-center, prospective single-sample correlational design without controls. All subjects were assigned to treatment. 3 sensors were worn at the same time by each subject.[1]

Each subject was instructed to wear 2 real-time CGM systems in the abdomen area.

*   1 Guardian Sensor (3) connected to the Guardian Link (3) transmitter, which transmitted to the insulin pump (for display purposes only); and,
*   1 Guardian Sensor (3) connected to the Guardian Connect transmitter, which transmitted to the Guardian Connect app, a standalone CGM display device.

Each subject was also instructed to wear another Guardian Sensor (3) in the arm that was connected to a blinded glucose sensor recorder (GSR).

The SG data collected by the blinded GSRs were retrospectively processed through the real-time CGM algorithm. This is the same algorithm used in the Guardian Connect and pump CGM systems. Thus, all data is representative of real-time sensor usage.

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[1] Medtronic Inc., A Performance Evaluation of the   Enlite™ 3 Glucose Sensor to Support a Full 168 hours (7 Days) of Use, CER292DOC/F. Oct 2016.

The CONTOUR[TM] NEXT LINK 2.4 Wireless Meter was the study meter used for all calibrations in this study, and was the only meter evaluated with the Guardian Sensor (3) CGM systems. The sensor has not been tested with other meters. Therefore, the performance with other BG meters may differ from the performance with the CONTOUR[TM] NEXT LINK 2.4 Wireless Meter described below.

Frequent Sample Testing (FST) was performed on days 1, 3, and 7 over the life of the sensor. Reference blood (plasma) glucose values were obtained with a Yellow Springs Instrument (YSI[TM]) Glucose Analyzer every 5 to 15 minutes. During the FSTs, the subjects were instructed to calibrate the sensors once every 12 hours, or as requested by the display device. During home use (outside the clinic), subjects were instructed to calibrate both sensors 3 to 4 times spread throughout the day.

A total of 93 subjects previously diagnosed with type 1 or 2 diabetes were enrolled in the study, and 88 subjects participated in at least one day of FST. The overall number of subjects that participated in FST procedures on days 1, 3, and 7 were 88, 87, and 79, respectively. During each FST period, subjects with an established insulin sensitivity ratio and insulin carbohydrate ratio underwent a hypoglycemic challenge and a hyperglycemic challenge to evaluate performance at high and low glycemic ranges.

During the study, subjects were instructed to continue with their current diabetes regimen (including glucose monitoring with their own meter when appropriate) independent of their use of the study devices. The insulin pumps were not used to infuse insulin, and neither 2 real-time CGM systems nor the blinded GSR system was used to manage diabetes during this study. The study meter was used for confirmation of alerts, treatment decisions and sensor calibrations.

Results

Sensor accuracy
The following information highlights the Guardian Sensor (3) performance from 88 subjects only during frequent sample testing (FST).

Mean absolute relative difference, by number of daily calibrations
Table 1 shows the mean absolute relative difference (MARD). MARD represents the average relative difference, regardless if positive or negative, between the SG values and the paired BG values measured by YSI™.

Table 1. SG MARD Versus YSI™ (within YSI™ glucose ranges).

YSI™ glucose ranges (mg/dL)	Abdomen Insertion Site				Arm Insertion Site			
	Calibration every 12 hours		Calibration 3 to 4 times a day		Calibration every 12 hours		Calibration 3 to 4 times a day	
	Number of paired SG-YSI	Mean Absolute Relative Difference (%)	Number of paired SG-YSI	Mean Absolute Relative Difference (%)	Number of paired SG-YSI	Mean Absolute Relative Difference (%)	Number of paired SG-YSI	Mean Absolute Relative Difference (%)
Overall	12090	10.55	11664	9.64	10526	9.09	10771	8.68
<40*	12	17.03	11	16.41	7	17.24	7	17.24
40–60*	353	7.96	324	7.53	335	6.44	349	6.42
61–80*	1445	9.44	1403	8.81	1345	7.76	1372	7.44
81–180	6505	9.94	6342	9.33	5644	8.64	5795	8.35
181–300	3277	10.00	3114	8.57	2766	8.58	2785	7.95
301–350	366	9.63	341	8.13	308	9.09	338	8.27
351–400	117	9.58	114	8.56	111	8.47	115	8.23
>400	15	10.85	15	10.92	10	10.71	10	11.44

For YSI reference range ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).

Note: SG Readings are within 40–400 mg/dL.

Percent agreement, by number of daily calibrations
In Tables 2 through 9, the agreement of the SG values to paired YSI values was assessed by calculating the percentage of YSI values that were within 15%, 20%, 30%, 40% and greater than 40% of the paired SG values. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI values was calculated.

Results are shown for defined SG ranges when calibrating every 12 hours and calibrating three to four times a day for sensors.

Table 2. Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	12090	76.6	85.7	94.3	97.3	2.7
≥40–60*	781	57.7	73.2	90.7	96.9	3.1
>60-80*	1350	76.1	83.4	93.4	96.8	3.2
>80-180	6769	76.5	85.3	93.5	96.5	3.5
>180-300	2833	80.8	90	97.1	98.9	1.1
>300-350	286	86.4	95.1	99.7	100	0
>350-400	71	93	100	100	100	0

* *For reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*

Note: *SG Readings are within 40–400 mg/dL.*

Table 3. Agreement (%) of SG paired points within SG ranges on FST Day 1; Calibration every 12 hours, Abdomen.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	4294	65.3	76.6	89.5	94.7	5.3
≥40–60*	278	46.8	61.9	83.5	94.2	5.8
>60–80*	474	61	71.7	88	93.5	6.5
>80–180	2443	64.9	75.4	87.6	93.2	6.8
>180–300	985	71.6	83.8	95.5	98.5	1.5
>300–350	90	82.2	95.6	100	100	0
>350–400	24	91.7	100	100	100	0

* *For reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*

Note: *The overall number of available paired SG-YSI points on FST Day 1 was from 88 subjects. SG Readings are within 40–400 mg/dL.*

Table 4. Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	11664	80.6	88.9	95.9	98.2	1.8
≥40–60*	686	60.2	75.1	92	98.1	1.9
>60–80*	1303	78.7	85.7	93.5	96.7	3.3
>80–180	6549	79.9	88.5	95.7	98	2
>180–300	2782	86.4	93.5	98	99.4	0.6
>300–350	279	92.5	97.8	99.6	100	0
>350–400	65	95.4	100	100	100	0

* For reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: *The overall number of available paired SG-YSI points on FST Day 1 was from 88 subjects. SG Readings are within 40–400 mg/dL.*

Table 5. Agreement (%) of SG paired points within SG ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	4136	71.4	81.9	92.3	96.3	3.7
≥40–60*	247	50.2	64.4	84.6	95.5	4.5
>60–80*	429	66.2	73.9	86.5	92.8	7.2
>80–180	2353	70.6	81.4	91.8	95.5	4.5
>180–300	988	78.6	89.1	97.2	99.5	0.5
>300–350	97	88.7	96.9	100	100	0
>350–400	22	100	100	100	100	0

* For reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: *The overall number of available paired SG-YSI points on FST Day 1 was from 85 subjects. SG Readings are within 40–400 mg/dL.*

Table 6. Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Arm.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	10526	82.5	90.3	96.3	98.7	1.3
≥40–60*	520	77.1	86.9	96	99.6	0.4
>60–80*	1238	88.2	92.5	96.4	99	1
>80–180	5957	80.3	88.5	95.5	98.2	1.8
>180–300	2495	85	93.2	98	99.4	0.6
>300–350	256	90.6	96.9	100	100	0
>350–400	60	90	93.3	100	100	0

* *For reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*

Note: SG Readings are within 40–400 mg/dL.

Table 7. Agreement (%) of SG-YSI paired points within SG ranges on FST Day 1; Calibration every 12 hours, Arm.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	3390	74.7	84.2	93.2	97.8	2.2
≥40–60*	168	60.1	73.2	90.5	98.8	1.2
>60–80*	339	75.5	79.4	88.8	97.3	2.7
>80–180	2017	73.2	83.1	92	97	3
>180–300	760	80.5	90.8	98.2	99.6	0.4
>300–350	91	84.6	93.4	100	100	0
>350–400	15	60	73.3	100	100	0

* *For reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.*

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 82 subjects. SG Readings are within 40–400 mg/dL.

Table 8. Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Arm.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	10771	84.3	91.6	97.3	99.1	0.9
≥40–60*	503	77.1	87.5	96.6	99.6	0.4
>60–80*	1291	89.3	93.4	97.7	99.1	0.9
>80–180	6076	82	90	96.7	98.7	1.3
>180–300	2569	87	94.4	98.3	99.7	0.3
>300–350	271	94.8	98.5	100	100	0
>350–400	61	95.1	96.7	100	100	0

* For reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: *SG Readings are within 40–400 mg/dL.*

Table 9. Agreement (%) of SG-YSI paired points within SG ranges on FST Day 1; Calibration 3 or 4 times a day, Arm.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	3591	76.8	86	95	98.5	1.5
≥40–60*	162	62.3	75.3	91.4	98.8	1.2
>60–80*	346	76.3	81.5	92.8	97.4	2.6
>80–180	2108	75.1	85	94.2	98	2
>180–300	869	81.8	91	97.7	99.9	0.1
>300–350	93	92.5	96.8	100	100	0
>350–400	13	84.6	84.6	100	100	0

* For reference range ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: *The overall number of available paired SG-YSI points on FST Day 1 was from 83 subjects. SG Readings are within 40–400 mg/dL.*

Agreement when CGM reads "Below 40 mg/dL" or "Above 400 mg/dL"

The real-time CGM systems display glucose values between 40 mg/dL and 400 mg/dL. It displays "Below 40 mg/dL" when the SG value detected is below 40 mg/dL. It displays "Above 400 mg/dL" when the SG value detected is above 400 mg/dL. Tables 10, 11, 12 and 13 illustrate the number and percentage of the paired YSI values in different blood glucose levels when the CGM system displays "Below 40 mg/dL" (LOW) or "Above 400 mg/dL" (HIGH).

Table 10. The number and percentage of YSI values collected when CGM displays 'Below 40 mg/dL' (LOW); Calibration every 12 hours.

CGM Display	Insertion Site	CGM-YSI pairs	<55	<60	<70	<80	>80	Total
					YSI (mg/dL)			
LOW	Abdomen	Cumulative, n	42	77	139	150	4	154
		Cumulative %	27%	50%	90%	97%	3%	100%
	Arm	Cumulative, n	17	35	67	74	1	75
		Cumulative %	23%	47%	89%	99%	1%	100%

Table 11. The number and percentage of YSI values collected when CGM displays 'Below 40 mg/dL' (LOW); Calibration 3 or 4 times a day.

CGM Display	Insertion Site	CGM-YSI pairs	<55	<60	<70	<80	>80	Total
					YSI (mg/dL)			
LOW	Abdomen	Cumulative, n	33	64	108	119	4	123
		Cumulative %	27%	52%	88%	97%	3%	100%
	Arm	Cumulative, n	18	35	66	72	1	73
		Cumulative %	25%	48%	90%	99%	1%	100%

Table 12. The number and percentage of YSI values collected when CGM displays 'Above 400 mg/dL' (HIGH); Calibration every 12 hours.

			YSI (mg/dL)					
CGM Display	Insertion Site	CGM-YSI pairs	<340	<320	<280	<240	>240	Total
HIGH	Abdomen	Cumulative, n	8	9	9	9	0	9
		Cumulative %	89%	100%	100%	100%	0%	100%
	Arm	Cumulative, n	8	8	9	9	0	9
		Cumulative %	89%	89%	100%	100%	0%	100%

Table 13. The number and percentage of YSI values collected when CGM displays 'Above 400 mg/dL' (HIGH); Calibration 3 or 4 times a day.

			YSI (mg/dL)					
CGM Display	Insertion Site	CGM-YSI pairs	<340	<320	<280	<240	>240	Total
HIGH	Abdomen	Cumulative, n	8	9	9	9	0	9
		Cumulative %	89%	100%	100%	100%	0%	100%
	Arm	Cumulative, n	8	8	8	8	0	8
		Cumulative %	100%	100%	100%	100%	0%	100%

Concurrence of SG and YSI values

Tables 14 through 21 show, for each SG range, the percentage of concurring data points where the paired YSI values were in different blood glucose ranges.

Table 14. Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen.

		Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)										
SG Ranges (mg/dL)	Number of paired SG-YSI	YSI glucose range (mg/dL)										
		<40	≥40– 60	>60– 80	>80– 120	>120– 160	>160– 200	>200– 250	>250– 300	>300– 350	>350– 400	>400
A) <40	154	0.0% (0/0)	50.0% (77/154)	47.4% (73/154)	2.6% (4/154)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40–60	781	1.2% (9/781)	30.7% (240/781)	57.2% (447/781)	10.6% (83/781)	0.3% (2/781)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	1350	0.2% (3/1350)	8.3% (112/1350)	60.1% (811/1350)	29.2% (394/1350)	2.1% (28/1350)	0.1% (2/1350)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	2953	0.0% (0/0)	0.0% (1/2953)	6.3% (185/2953)	73.0% (2157/2953)	18.2% (537/2953)	2.0% (60/2953)	0.4% (13/2953)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)

		Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)										
SG Ranges (mg/dL)	Number of paired SG-YSI	YSI glucose range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
E) >120–160	2784	0.0% (0/0)	0.0% (0/0)	0.1% (2/2784)	8.8% (245/2784)	67.7% (1885/2784)	20.3% (565/2784)	2.8% (79/2784)	0.3% (8/2784)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	1875	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.1% (2/1875)	10.0% (188/1875)	60.2% (1128/1875)	28.2% (529/1875)	1.5% (28/1875)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200–250	1382	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (4/1382)	8.0% (111/1382)	61.1% (844/1382)	28.1% (389/1382)	2.3% (32/1382)	0.1% (2/1382)	0.0% (0/0)
H) >250–300	608	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (2/608)	10.9% (66/608)	61.2% (372/608)	25.5% (155/608)	2.1% (13/608)	0.0% (0/0)
I) >300–350	286	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.0% (3/286)	19.9% (57/286)	55.2% (158/286)	22.4% (64/286)	1.4% (4/286)
J) >350–400	71	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	1.4% (1/71)	29.6% (21/71)	53.5% (38/71)	15.5% (11/71)
K) >400	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.1% (1/9)	77.8% (7/9)	11.1% (1/9)

Table 15. Concurrence of YSI values and SG readings using SG ranges on FST Day 1; Calibration every 12 hours, Abdomen.

		Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)										
SG Ranges (mg/dL)	Number of paired SG-YSI	YSI glucose range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	71	0.0% (0/0)	38.0% (27/71)	57.7% (41/71)	4.2% (3/71)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) ≥40–60	278	2.2% (6/278)	23.0% (64/278)	55.8% (155/278)	18.7% (52/278)	0.4% (1/278)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	474	0.4% (2/474)	12.0% (57/474)	47.7% (226/474)	34.8% (165/474)	4.6% (22/474)	0.4% (2/474)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	1071	0.0% (0/0)	0.1% (1/1071)	4.6% (49/1071)	66.6% (713/1071)	23.4% (251/1071)	4.5% (48/1071)	0.8% (9/1071)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	978	0.0% (0/0)	0.0% (0/0)	0.1% (1/978)	8.3% (81/978)	58.4% (571/978)	26.8% (262/978)	5.9% (58/978)	0.5% (5/978)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	662	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (2/662)	9.1% (60/662)	52.6% (348/662)	35.3% (234/662)	2.7% (18/662)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200–250	515	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	6.2% (32/515)	56.3% (290/515)	33.8% (174/515)	3.3% (17/515)	0.4% (2/515)	0.0% (0/0)

	Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)											
SG Ranges (mg/dL)	Number of paired SG-YSI	YSI glucose range (mg/dL)										
		<40	≥40– 60	>60– 80	>80– 120	>120– 160	>160– 200	>200– 250	>250– 300	>300– 350	>350– 400	>400
H) >250–300	202	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	9.4% (19/202)	55.0% (111/202)	32.2% (65/202)	3.5% (7/202)	0.0% (0/0)
I) >300–350	90	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.0% (18/90)	54.4% (49/90)	23.3% (21/90)	2.2% (2/90)
J) >350–400	24	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	4.2% (1/24)	37.5% (9/24)	50.0% (12/24)	8.3% (2/24)
K) >400	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 88 subjects.

Table 16. Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen.

	Percent of matched pairs in each YSI Glucose Range for each SG range (mg/dL)											
SG Ranges (mg/dL)	Number of paired SG-YSI	YSI glucose ranges (mg/dL)										
		<40	>=40– 60	>60– 80	>80– 120	>120– 160	>160– 200	>200– 250	>250– 300	>300– 350	>350– 400	>400
A) <40	123	0.0% (0/0)	52.0% (64/123)	44.7% (55/123)	3.3% (4/123)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) >=40–60	686	1.3% (9/686)	31.6% (217/686)	57.0% (391/686)	9.9% (68/686)	0.1% (1/686)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	1303	0.2% (2/1303)	8.1% (106/1303)	63.4% (826/1303)	26.2% (342/1303)	1.9% (25/1303)	0.2% (2/1303)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	2864	0.0% (0/0)	0.0% (1/2864)	6.5% (186/2864)	74.5% (2133/2864)	17.5% (502/2864)	1.3% (36/2864)	0.2% (6/2864)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	2681	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	9.0% (241/2681)	69.9% (1874/2681)	19.1% (512/2681)	1.8% (49/2681)	0.2% (5/2681)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	1820	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.1% (2/1820)	10.3% (188/1820)	63.6% (1157/1820)	24.9% (454/1820)	1.0% (19/1820)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200–250	1314	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.5% (7/1314)	8.5% (112/1314)	65.3% (858/1314)	24.6% (323/1314)	1.1% (14/1314)	0.0% (0/0)	0.0% (0/0)
H) >250–300	652	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (2/652)	11.3% (74/652)	63.5% (414/652)	22.9% (149/652)	2.0% (13/652)	0.0% (0/0)
I) >300–350	279	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	17.9% (50/279)	59.5% (166/279)	21.1% (59/279)	1.4% (4/279)

Percent of matched pairs in each YSI Glucose Range for each SG range (mg/dL)												
SG Ranges (mg/dL)	Number of paired SG-YSI	YSI glucose ranges (mg/dL)										
		<40	>=40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
J) >350–400	65	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.5% (12/65)	64.6% (42/65)	16.9% (11/65)
K) >400	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.1% (1/9)	77.8% (7/9)	11.1% (1/9)

Table 17. Concurrence of YSI values and SG readings using SG ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	>=40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	62	0.0% (0/0)	37.1% (23/62)	58.1% (36/62)	4.8% (3/62)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) >=40–60	247	2.4% (6/247)	21.5% (53/247)	58.7% (145/247)	17.0% (42/247)	0.4% (1/247)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	429	0.2% (1/429)	12.6% (54/429)	52.0% (223/429)	30.3% (130/429)	4.4% (19/429)	0.5% (2/429)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	1014	0.0% (0/0)	0.1% (1/1014)	5.3% (54/1014)	70.7% (717/1014)	20.4% (207/1014)	3.1% (31/1014)	0.4% (4/1014)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	973	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	9.1% (89/973)	61.6% (599/973)	24.8% (241/973)	4.0% (39/973)	0.5% (5/973)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	633	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (2/633)	10.7% (68/633)	56.7% (359/633)	30.3% (192/633)	1.9% (12/633)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200–250	497	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/497)	7.8% (39/497)	64.6% (321/497)	26.4% (131/497)	1.0% (5/497)	0.0% (0/0)	0.0% (0/0)
H) >250–300	224	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	12.9% (29/224)	58.0% (130/224)	23.7% (53/224)	5.4% (12/224)	0.0% (0/0)
I) >300–350	97	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	19.6% (19/97)	59.8% (58/97)	18.6% (18/97)	2.1% (2/97)
J) >350–400	22	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	27.3% (6/22)	63.6% (14/22)	9.1% (2/22)
K) >400	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 88 subjects.

Table 18. Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Arm.

		Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)										
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	>=40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	75	2.7% (2/75)	44.0% (33/75)	52.0% (39/75)	1.3% (1/75)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) >=40–60	520	1.0% (5/520)	41.9% (218/520)	51.7% (269/520)	5.4% (28/520)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	1238	0.2% (2/1238)	9.2% (114/1238)	70.3% (870/1238)	20.0% (247/1238)	0.4% (5/1238)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	2722	0.0% (0/0)	0.1% (3/2722)	7.5% (203/2722)	74.0% (2014/2722)	17.7% (481/2722)	0.8% (21/2722)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	2348	0.0% (0/0)	0.0% (1/2597)	1.0% (3/2348)	9.2% (215/2348)	70.4% (1652/2348)	18.0% (423/2348)	2.3% (54/2348)	0.0% (1/2348)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	1614	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.1% (2/1614)	9.4% (151/1614)	64.7% (1044/1614)	24.8% (400/1614)	0.9% (14/1614)	0.2% (3/1614)	0.0% (0/0)	0.0% (0/0)
G) >200–250	1212	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.6% (7/1212)	6.8% (83/1212)	63.9% (774/1212)	27.3% (331/1212)	1.4% (17/1212)	0.0% (0/0)	0.0% (0/0)
H) >250–300	556	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/556)	9.4% (52/556)	65.1% (362/556)	23.9% (133/556)	1.4% (8/556)	0.0% (0/0)
I) >300–350	256	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.0% (46/256)	56.6% (145/256)	24.6% (63/256)	0.8% (2/256)
J) >350–400	60	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	3.3% (2/60)	16.7% (10/60)	66.7% (40/60)	13.3% (8/60)
K) >400	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.1% (1/9)	55.6% (5/9)	33.3% (3/9)

Table 19. Concurrence of YSI values and SG readings using SG ranges on FST Day 1; Calibration every 12 hours, Arm.

		Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)										
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	>=40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	54	3.7% (2/54)	29.7% (16/54)	64.8% (35/54)	1.9% (1/54)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) >=40–60	168	1.8% (3/168)	22.0% (37/168)	64.3% (108/168)	11.9% (20/168)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	>=40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
C) >60–80	339	0.6% (2/339)	11.2% (38/339)	58.1% (197/339)	29.2% (99/339)	0.9% (3/339)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	895	0.0% (0/0)	0.3% (3/895)	6.6% (59/895)	69.8% (625/895)	21.6% (193/895)	1.7% (15/895)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	803	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	10.0% (80/803)	64.6% (519/803)	21.4% (172/803)	4.0% (32/803)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	549	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/549)	8.9% (49/549)	61.4% (337/549)	28.1% (154/549)	1.5% (8/549)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200–250	355	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.3% (1/355)	7.9% (28/355)	63.9% (227/355)	27.0% (96/355)	0.8% (3/355)	0.0% (0/0)	0.0% (0/0)
H) >250–300	175	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	10.9% (19/175)	65.7% (115/175)	21.1% (37/175)	2.3% (4/175)	0.0% (0/0)
I) >300–350	91	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.9% (19/91)	52.7% (48/91)	24.2% (22/91)	2.2% (2/91)
J) >350–400	15	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	13.3% (2/15)	33.3% (5/15)	53.3% (8/15)	0.0% (0/0)
K) >400	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 82 subjects.

Table 20. Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Arm.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG Ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	>=40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	73	2.7% (2/73)	45.2% (33/73)	50.7% (37/73)	1.4% (1/73)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) >=40–60	503	1.0% (5/503)	45.9% (231/503)	48.3% (243/503)	4.8% (24/503)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	1291	0.2% (2/1291)	8.9% (115/1291)	72.3% (933/1291)	18.4% (237/1291)	0.3% (4/1291)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	2756	0.0% (0/0)	0.1% (3/2756)	7.0% (194/2756)	75.9% (2092/2756)	16.5% (456/2756)	0.4% (11/2756)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG Ranges (mg/dL)	Num-ber of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	>=40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
E) >120–160	2442	0.0% (0/0)	0.0% (0/0)	0.1% (2/2442)	9.3% (228/2442)	71.4% (1743/2442)	18.0% (439/2442)	1.2% (30/2442)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	1588	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.1% (2/1588)	9.4% (150/1588)	66.3% (1053/1588)	23.5% (373/1588)	0.6% (9/1588)	0.1% (1/1588)	0.0% (0/0)	0.0% (0/0)
G) >200–250	1246	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.5% (6/1246)	7.4% (92/1246)	65.7% (818/1246)	25.1% (313/1246)	1.4% (17/1246)	0.0% (0/0)	0.0% (0/0)
H) >250–300	613	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/613)	8.6% (53/613)	65.1% (399/613)	24.6% (151/613)	1.5% (9/613)	0.0% (0/0)
I) >300–350	271	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.2% (44/271)	59.8% (162/271)	23.2% (63/271)	0.7% (2/271)
J) >350–400	61	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	4.9% (3/61)	11.5% (7/61)	70.5% (43/61)	13.1% (8/61)
K) >400	8	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	62.5% (5/8)	37.5% (3/8)

Table 21. Concurrence of YSI values and SG readings using SG ranges on FST) Day 1; Calibration 3 or 4 times a day, Arm.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	>=40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	54	3.7% (2/54)	29.6% (16/54)	64.8% (35/54)	1.9% (1/54)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
B) >=40–60	162	1.9% (3/162)	25.3% (41/162)	61.7% (100/162)	11.1% (18/162)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60–80	346	0.6% (2/346)	11.6% (40/346)	61.3% (212/346)	25.7% (89/346)	0.9% (3/346)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80–120	899	0.0% (0/0)	0.3% (3/899)	6.3% (57/899)	74.0% (665/899)	18.2% (164/899)	1.1% (10/899)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120–160	878	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	10.0% (88/878)	67.0% (588/878)	21.0% (184/878)	2.1% (18/878)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160–200	571	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/571)	9.3% (53/571)	62.3% (356/571)	27.3% (156/571)	0.9% (5/571)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200–250	427	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.2% (1/427)	8.2% (35/472)	62.5% (267/427)	27.6% (118/427)	1.4% (6/427)	0.0% (0/0)	0.0% (0/0)

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	>=40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
H) >250–300	202	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	9.9% (20/202)	59.9% (121/202)	26.7% (54/202)	3.5% (7/202)	0.0% (0/0)
I) >300–350	93	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.1% (15/93)	59.1% (55/93)	22.6% (21/93)	2.2% (2/93)
J) >350–400	13	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	15.4% (2/13)	7.7% (1/13)	76.9% (10/13)	0.0% (0/0)
K) >400	0	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)

Note: *The overall number of available paired SG-YSI points on FST Day 1 was from 83 subjects.*

Percent agreement post calibration

The agreement of the SG values to paired YSI values was assessed for every 2-hour period post sensor calibration. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI values was calculated.

Tables 22 and 23 show the percent agreement rates post calibration for sensors inserted into the abdomen. Performance when sensors are inserted in the arm is at least comparable to results when sensors are inserted in the abdomen.

Table 22. Agreement rates for every 2-hour period post calibration period; Calibration every 12 hours, Abdomen.

Percent Agreement (%)						
Time after calibration	Number of paired SG-YSI	Percent of SG within 15/15% of YSI	Percent of SG within 20/20% of YSI	Percent of SG within 30/30% of YSI	Percent of SG within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
0-2 hours	2999	85	92.6	97.8	99.6	0.4
2-4 hours	2667	75.1	85.9	95.3	98.8	1.2
4-6 hours	2138	71.4	82	92.7	97.6	2.4
6-8 hours	1521	77.6	88.4	97	99.3	0.7
8-10 hours	1523	84.2	91.1	97.6	99.3	0.7
10-12 hours	1242	79.8	89.5	96.3	98.6	1.4

Note: *SG Readings are within 40–400 mg/dL.*

Table 23. Agreement rates for every 2-hour period post calibration; Calibration 3 or 4 times a day, Abdomen.

Percent Agreement (%)						
Time after calibration	Num- ber of paired SG-YSI	Percent of SG within15/15% of YSI	Percent of SG within 20/20% of YSI	Percent of SG within 30/30% of YSI	Percent of SG within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
0-2 hours	4585	87	93.5	98.1	99.7	0.3
2-4 hours	3949	80.7	89.9	96.7	99	1
4-6 hours	2856	78.7	87.6	95.5	98.5	1.5
6-8 hours	227	74.9	86.3	96.9	99.6	0.4
8-10 hours	35	82.9	85.7	91.4	94.3	5.7
10-12 hours	12	91.7	91.7	91.7	100	0

Note: SG Readings are within 40–400 mg/dL.

Trend accuracy

Tables 24 and 25 show, for each SG rate-of-change range (indicated on display by number of arrows), percentage of SG-YSI paired values that fell into different YSI rate-of-change ranges. The tables show the trend accuracy for sensors inserted into the abdomen. Performance when sensors are inserted in the arm is at least comparable to results when sensors are inserted into the abdomen.

Table 24. Trend accuracy; Calibration every 12 hours, Abdomen.

Percent of Matched Pairs-in Each YSI Rate-of-Change Range for Each SG Rate-of-Change Range							
SG Rate-of-Change Range (mg/ dL/min)	Number of paired SG-YSI	YSI Rate-of-Change Range (mg/dL/min)					
		<-2	[-2,-1]	[-1, 0]	[0, 1]	[1, 2]	>2
A) <-2	162	38.3% (62/162)	40.1% (65/162)	20.4% (33/162)	0.6% (1/162)	0.6% (1/162)	0.6% (1/162)
B) [-2,-1]	1001	4.8% (48/1001)	39.9% (399/1001)	51.3% (514/1001)	3.7% (37/1001)	0.3% (3/1001)	0.0% (0/1001)
C) [-1,0]	5960	0.5% (30/5960)	3.8% (228/5960)	77.6% (4627/5960)	17.1% (1020/5960)	0.8% (49/5960)	0.1% (6/5960)
D) [0,1]	3517	0.2% (7/3517)	0.5% (18/3517)	25.7% (903/3517)	63.4% (2231/3517)	9.3% (326/3517)	0.9% (32/3517)
E) [1,2]	1059	0.1% (1/1059)	0.4% (4/1059)	4.5% (48/1059)	37.9% (401/1059)	48.6% (515/1059)	8.5% (90/1059)
F) >2	391	0.0% (0/391)	0.0% (0/391)	2.8% (11/391)	7.4% (29/391)	40.9% (160/391)	48.8% (191/391)

Table 25. Trend accuracy; Calibration 3 or 4 times a day, Abdomen.

Percent of Matched Pairs-in Each YSI Rate-of-Change Range for Each SG Rate-of-Change Range							
SG Rate-of-Change Range (mg/dL/min)	Number of paired SG-YSI	YSI Rate of Change Range (mg/dL/min)					
		<-2	[-2,-1]	[-1, 0]	[0, 1]	[1, 2]	>2
A) <-2	159	39.0% (62/159)	39.6% (63/159)	19.5% (31/159)	0.6% (1/159)	1.3% (2/159)	0.0% (0/159)
B) [-2,-1]	967	5.1% (49/967)	38.7% (374/967)	51.9% (502/967)	4.0% (39/967)	0.3% (3/967)	0.0% (0/967)
C) [-1,0]	5753	0.5% (28/5753)	4.0% (228/5753)	77.5% (4456/5753)	17.2% (990/5753)	0.8% (46/5753)	0.1% (5/5753)
D) [0,1]	3387	0.2% (8/3387)	0.5% (18/3387)	26.5% (898/3387)	62.5% (2118/3387)	9.3% (316/3387)	0.9% (29/3387)
E) [1,2]	1024	0.0% (0/1024)	0.2% (2/1024)	5.0% (51/1024)	38.8% (397/1024)	47.5% (486/1024)	8.6% (88/1024)
F) >2	374	0.0% (0/374)	0.0% (0/374)	2.4% (9/374)	8.0% (30/374)	42.8% (160/374)	46.8% (175/374)

Precision
Precision of the System was evaluated by comparing the results from two separate sensors worn in the abdomen on the same subject at the same time. A total of 83 subjects provided 30,350 paired SG-YSI measurements, with a mean Percent Absolute Relative Difference (PARD) of 9.07% with a coefficient of variation (%CV) of 6.5%.

Though precision in the arm has not been specifically assessed, arm vs. arm and arm vs. abdomen is likely comparable to the abdomen precision based on Medtronic's internal evaluation.

Sensor life
After the first successful calibration, 72.3% of sensors operated more than six days and up to the full seven days of wear (144 to 168 hours). The mean functional sensor life for sensors worn in the abdomen insertion site over the course of the study was 144.2 hours, with a median functional life of 167.6 hours.

The mean functional sensor life for sensors worn in the arm insertion site over the course of the study was 146.1 hours, with a median functional life of 167.9 hours.

Safety
There were no moderate or severe device-related or procedure-related adverse events, device-related or procedure-related serious adverse events, or unanticipated adverse device effects after seven days of use.

Alert performance
CGM enables your device to display SG readings, glucose trend arrows, glucose trend graphs, and SG alerts, for example High and Low Sensor Glucose alerts, High and Low Predicted alerts, and Rise and Fall alerts for rate-of-change.

The high and low SG alerts (**Threshold alerts**) let the user know when the SG is at or above the high limit or at or below the low limit. Using only a high or low Threshold alert may reduce the number of false alerts, but does not provide a warning before reaching a high or low limit.

Predicted alerts notify users that their SG level may soon reach a high or low limit setting. Users may select how early they would like to be notified before their SG level reaches a high or low limit. The earliest warning is 60 minutes before reaching a high or low limit, but users can reduce the amount of warning down to 10 minutes. Users receive a Predictive alert when their SG level is predicted to reach their high or low limit in Time Before High or Time Before Low setting they select. In general, the earlier the warning, the more time a user has to react to a potential high or low, but this also increases the potential for false alerts.

A predictive alert is simply an estimation of a future SG level compared to the high or low limit setting. If the predicted future SG value is above the high limit or below the low limit, then a predictive alert is sounded even though the current SG level has not crossed the high or low limit. The predicted SG level is calculated using the current SG level, the derivative of current and previous SG readings (the trend or slope of the SG readings) and the Time Before High or Time Before Low duration the user selects.

The device always alerts the user with an Urgent Low glucose alert when the CGM reads that the user is at or below 55 mg/dL, regardless of the high/low threshold and/or predictive alerts that the user sets.

Glucose TRUE Alert Rate
The glucose true alert rate is the rate at which the BG confirmed that the CGM alert was triggered correctly. For example:

a **True Threshold Hypoglycemic alert rate** is a measure of how often the CGM read that the user was below the low threshold and the user's BG was actually below that low threshold.

b **True Threshold Hyperglycemic alert rate** is a measure of how often the CGM read that the user was above the high threshold and the user's BG was actually above that high threshold.

c **True Predictive Hypoglycemic alert rate** is a measure of how often the CGM predicted that the user would reach below the low threshold and the user's BG was actually below that low threshold within 15 or 30 minutes.

d **True Predictive Hyperglycemic alert rate** is a measure of how oftenn the CGM predicted that the user would reach above the high threshold and the user's BG was actually above that high threshold within 15 or 30 minutes.

The true alert rate is important because it is necessary that users be notified when their blood glucose is low or high so that they can correct the low or high BG. A high true alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's BG is likely to be at or approaching that threshold.

For example, per the following table, the low glucose alerts would have correctly indicated that the user was below (i.e. threshold only), or predicted to reach below the threshold (i.e. predictive only) or both (predictive and threshold) 66.9%, 38.4%, or 47.4% of the time within 30 minutes (or 66.9%, 35.9% or 45.7% of the time within 15 minutes) when the user had BG values lower than 70 mg/dL for a sensor inserted in the abdomen.

Table 1. Glucose TRUE Alert Performance using Calibration every 12 hours

Glucose TRUE Alert Rate						
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
55	Abdomen	38.8%	38.8%	N/A	N/A	N/A	N/A
	Arm	58.7%	58.7%	N/A	N/A	N/A	N/A
60	Abdomen	53.5%	51.9%	27.6%	26.9%	35.6%	34.6%
	Arm	69%	67.8%	29.1%	27.2%	38.9%	37.2%
70	Abdomen	66.9%	66.9%	38.4%	35.9%	47.4%	45.7%
	Arm	77.4%	75.3%	40.4%	35%	51.7%	47.3%
80	Abdomen	69.3%	69.3%	44.5%	40.8%	52.9%	50.5%
	Arm	77.5%	76.4%	43.3%	39.2%	54.2%	51%

Glucose TRUE Alert Rate						
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
90	Abdomen	75.1%	74.4%	48.9%	45.9%	57.9%	55.6%
	Arm	74.9%	74.9%	53.3%	48.7%	60.9%	57.9%
180	Abdomen	93.7%	92.8%	70.5%	66.9%	78.0%	75.4%
	Arm	92.9%	92.9%	68%	63.2%	76.5%	73.7%
220	Abdomen	91.9%	91.9%	68.9%	66.3%	76.6%	74.8%
	Arm	92.2%	92.2%	65.7%	62.2%	74.5%	72.2%
250	Abdomen	90.2%	90.2%	64.0%	60.1%	72.5%	69.8%
	Arm	91.4%	91.4%	62%	59.8%	71.1%	69.6%
300	Abdomen	81.3%	81.3%	57.8%	54.0%	65.4%	62.7%
	Arm	81.9%	80.6%	51.7%	49.7%	61.2%	59.3%

Glucose FALSE Alert Rate

The glucose false alert rate is the rate at which the BG did not confirm that the CGM alert was triggered correctly. For example:

a   **False Threshold Hypoglycemic alert rate** is a measure of how often the CGM read that the user was below the low threshold but the user's BG was actually above that low threshold.

b   **False Threshold Hyperglycemic alert rate** is a measure of how often the CGM read that the user was above the high threshold but the user's BG was actually below that high threshold.

c   **False Predictive Hypoglycemic alert rate** is a measure of how often the CGM predicted that the user would be below the low threshold but the user's BG was actually above that low threshold within 15 or 30 minutes.

d   **False Predictive Hyperglycemic alert rate** is a measure of how often the CGM predicted that the user would be above the high threshold but the user's BG was actually below the high threshold within 15 or 30 minutes.

The false alert rate is important because it is necessary that users be correctly notified when their BG is low or high so that they can correct the low or high BG. A low false alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's BG is likely to be at or approaching that threshold.

For example, per the following table, the high glucose threshold alerts would have incorrectly indicated that the user was above (i.e. threshold only), or predicted to reach above the threshold (i.e. predictive only), or both (threshold and predictive) 6.30%, 29.5% or 22.0% of the time within 30 minutes (or 7.2%, 33.1%, or 24.6% of the time within 15 minutes) when the user had BG less than 180 mg/dL for a sensor inserted in the abdomen.

Table 2. Glucose FALSE Alert Performance Using Calibration Every 12 hours

Glucose FALSE Alert Rate							
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
55	Abdomen	61.2%	61.2%	N/A	N/A	N/A	N/A
	Arm	41.3%	41.3%	N/A	N/A	N/A	N/A
60	Abdomen	46.5%	48.1%	72.4%	73.1%	64.4%	65.4%
	Arm	31%	32.2%	70.9%	72.8%	61.1%	62.8%
70	Abdomen	33.1%	33.1%	61.6%	64.1%	52.6%	54.3%
	Arm	22.6%	24.7%	59.6%	65.0%	48.3%	52.7%
80	Abdomen	30.7%	30.7%	55.5%	59.2%	47.1%	49.5%
	Arm	22.5%	23.6%	56.7%	60.8%	45.8%	49.0%
90	Abdomen	24.9%	25.6%	51.1%	54.1%	42.1%	44.4%
	Arm	25.1%	25.1%	46.7%	51.3%	39.1%	42.1%
180	Abdomen	6.3%	7.2%	29.5%	33.1%	22.0%	24.6%
	Arm	7.1%	7.1%	32%	36.8%	23.5%	26.3%
220	Abdomen	8.1%	8.1%	31.1%	33.7%	23.4%	25.2%
	Arm	7.8%	7.8%	34.3%	37.8%	25.5%	27.8%
250	Abdomen	9.8%	9.8%	36.0%	39.9%	27.5%	30.2%
	Arm	8.6%	8.6%	38.0%	40.2%	28.9%	30.4%
300	Abdomen	18.8%	18.8%	42.2%	46.0%	34.6%	37.3%
	Arm	18.1%	19.4%	48.3%	50.3%	38.8%	40.7%

Glucose Correct Detection Rate

Glucose Correct Detection Rate is the rate that the device alerted when it should have alerted. For example, the BG was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device sounded an alert.

The correct detection rates are important because it is necessary that users be notified when their BG is low or high so that they can correct the low or high BG. A high glucose correct detection rate indicates that users can have confidence that they will be notified by the device if their BG is low or high.

For example, per the following table, the threshold alert, the predictive alert, or both (threshold and predictive) notified the user 90.5%, 98.5% or 98.5% of the time within 30 minutes (or 90.5%, 98.5% or 98.5% within 15 minutes) when the user had blood glucose less than 70 mg/dL in a sensor inserted in the abdomen.

Table 3. Glucose Correct Detection Alert Performance Using Calibration Every 12 hours

Glucose Correct Detection Alert Rate						
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
55	Abdomen	73.6%	73.6%	N/A	N/A	N/A	N/A
	Arm	78.7%	78.7%	N/A	N/A	N/A	N/A
60	Abdomen	83.3%	82.1%	96.4%	95.2%	96.4%	96.4%
	Arm	86.3%	83.6%	100%	97.3%	100%	100%
70	Abdomen	90.5%	90.5%	98.5%	95.6%	98.5%	95.6%
	Arm	90.2%	88.6%	96.7%	91.9%	96.7%	93.5%
80	Abdomen	87.2%	87.2%	95.2%	92.0%	95.7%	93.6%
	Arm	89.0%	88.4%	97.1%	91.3%	97.7%	96.5%
90	Abdomen	91.1%	88.7%	97.3%	93.4%	98.1%	94.6%
	Arm	91.7%	90.4%	98.7%	96.5%	98.7%	97.8%
180	Abdomen	93.1%	91.4%	96.6%	93.4%	96.9%	95.4%
	Arm	93.2%	92.2%	98.1%	94.2%	98.7%	96.4%
220	Abdomen	90.1%	89.2%	94.8%	93.5%	95.3%	94.4%
	Arm	90.1%	89.2%	96.1%	93.6%	96.1%	95.6%
250	Abdomen	81.5%	80.9%	96.5%	91.3%	96.5%	93.6%
	Arm	80.9%	79.6%	96.7%	90.8%	96.7%	91.4%
300	Abdomen	75.3%	75.3%	95.3%	92.9%	95.3%	94.1%
	Arm	74.4%	71.8%	93.6%	89.7%	93.6%	89.7%

Glucose Missed Detection Rate
The Missed Detection Rate is the rate that the device did not alert when it should have. For example, the BG was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device did not sound a threshold or predictive alert.

Missed detection rates are important because it is necessary that users be notified when their BG is low or high, so that they can correct the low or high BG. A low missed detection rate indicates that users can have confidence that they will be notified by the device if their BG is low or high.

For example, per the following table, the threshold alert, predictive alert, or both alerts (threshold and predictive) did not sound 9.5%, 1.5% or 1.5% of the time within 30 minutes (or 9.5%, 4.4% or 4.4% within 15 minutes) when the user had BG less than 70 mg/dL in a sensor inserted in the abdomen.

Table 4. Glucose Missed Detection Alert Performance using Calibration every 12 hours

Glucose Missed Detection Alert Rate							
mg/dL	Insertion Site	Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
55	Abdomen	26.4%	26.4%	N/A	N/A	N/A	N/A
	Arm	21.3%	21.3%	N/A	N/A	N/A	N/A
60	Abdomen	16.7%	17.9%	3.6%	4.8%	3.6%	3.6%
	Arm	13.7%	16.4%	0%	2.7%	0%	0%
70	Abdomen	9.5%	9.5%	1.5%	4.4%	1.5%	4.4%
	Arm	9.8%	11.4%	3.3%	8.1%	3.3%	6.5%
80	Abdomen	12.8%	12.8%	4.8%	8%	4.3%	6.4%
	Arm	11%	11.6%	2.9%	8.7%	2.3%	3.5%
90	Abdomen	8.9%	11.3%	2.7%	6.6%	1.9%	5.4%
	Arm	8.3%	9.6%	1.3%	3.5%	1.3%	2.2%
180	Abdomen	6.9%	8.6%	3.4%	6.6%	3.1%	4.6%
	Arm	6.8%	7.8%	1.9%	5.8%	1.3%	3.6%
220	Abdomen	9.9%	10.8%	5.2%	6.5%	4.7%	5.6%
	Arm	9.9%	10.8%	3.9%	6.4%	3.9%	4.4%
250	Abdomen	18.5%	19.1%	3.5%	8.7%	3.5%	6.4%
	Arm	19.1%	20.4%	3.3%	9.2%	3.3%	8.6%
300	Abdomen	24.7%	24.7%	4.7%	7.1%	4.7%	5.9%
	Arm	25.6%	28.2%	6.4%	10.3%	6.4%	10.3%

Warranty

Medtronic MiniMed, Inc. (or such other legal entity as may be referred to as manufacturer on the labeling of this device "Medtronic MiniMed") warrants the Medtronic transmitter to the purchaser of the product against defects in material and workmanship for a period of one (1) year and the charger for up to one (1) year from the date of purchase.

During the warranty period, Medtronic MiniMed will replace or repair, at its discretion, any defective transmitter or charger, subject to the conditions and exclusions stated herein. This warranty applies only to new devices. In the event a transmitter or charger is replaced, the warranty period will not be extended past its original expiration date.

This warranty is valid only if the Medtronic transmitter or charger is used in accordance with the manufacturer's instructions. Without limitation, this warranty will not apply:

- If damage results from changes or modifications made to the transmitter or charger by the user, or third persons, after the date of purchase;
- If damage results from service or repairs performed by any person or entity other than the manufacturer;
- If damage results from a *Force Majeure* or other event beyond the control of the manufacturer;
- If damage results from negligence or improper use, including but not limited to: improper storage, submersion in water, physical abuse, (such as dropping);
- If damage results from use of the device in a manner other than according to the manufacturer's product labeling, instructions for use, or regulatory notifications.

This warranty shall be personal to the original 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 purchaser shall cause this warranty to immediately terminate. This warranty does not apply to Glucose Sensors and other accessories.

The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Medtronic MiniMed nor its suppliers or distributors shall be liable for any incidental, consequential, or special damage of any nature or kind caused by or arising out of a defect in the product.

All other conditions and warranties, other than mandatory statutory warranties, expressed or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

This warranty gives the purchaser specific legal rights, and the purchaser may also have other rights that vary under local law. This warranty does not affect the purchaser's statutory rights.

Icon table

$\boxed{\text{SN}}$	Serial number
📖ⓘ	Consult instructions for use
⚠	Caution: consult instructions for use for important warnings or precautions not found on the label
$\boxed{\text{REF}}$	Catalogue number
$\boxed{\text{C}\epsilon}$	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union Acts.
(1x)	One transmitter, charger, and serter per container/package
(2x)	Two testers per container/package
⚒	Date of manufacture (YYYY-MM-DD)
🏭	Manufacturer
📖	Consult instructions for use
-XX°C -XX°F / +XX°C +XXX°F	Storage temperature limits
(((•)))	Non-ionizing electromagnetic radiation
🧍	Type BF applied part
FCC ID	Complies with United States Radio communication requirements.
IP48	Transmitter: 4 is the level of protection against solid objects with a diameter above 1mm. 8 is the level of protection against the effects of continuous immersion in water [8 feet (2.4 meters) immersion for 30 minutes]
% XX% / XX%	Storage humidity limit
R$_{X}$ Only	Requires prescription in the USA
⚱	Fragile, handle with care
☂	Keep dry

♻	Recyclable, contains recycled content
🗑	Do not dispose of this product in unsorted municipal waste stream
(MR)	Magnetic Resonance (MR) unsafe
❈®	Bluetooth® wireless technology or Bluetooth® enabled
🔋	Recharge-by date

Icon glossary

For a definition of the symbols displayed on the device and package labels, please see http://www.medtronicdiabetes.com/symbol-definitions.

Medtronic

REF CSS7200, CSS7201, MMT-7821L, MMT-7020,
MMT-7715, MMT-7736L, MMT-7512, MMT-7015

R℞ Only

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