GUARDIAN CONNECT

SYSTEM USER GUIDE

Medtronic

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Introduction

Thank you for choosing Medtronic as your diabetes management partner.

The Guardian™ Connect Continuous Glucose Monitoring (CGM) system helps you manage your diabetes by:

- recording your glucose values throughout the day and night
- displaying your glucose values in a convenient and discrete manner using your smartphone
- alerting you to glucose events using your smartphone
- showing the effects that diet, exercise, and medication can have on your glucose levels
- giving 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.

System description

The Guardian Connect system includes the Guardian Connect app (CSS7200), Guardian Connect transmitter (MMT-7821), 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 values are then displayed on the Guardian Connect app. The Guardian Connect app can also provide alerts based on senor glucose 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 allows users to 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 home glucose monitor 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 monitoring devices. The sensor is intended for single use and 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 glucose 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 sensor glucose data, and also provides a user interface for sensor calibration, entering data such as exercise and meals, and uploading information to the CareLink Personal website. It allows users to 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 multiple 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 blood glucose 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 Enlite® Sensor or Guardian Sensor (3). Medtronic cannot guarantee the safety or efficacy of this product if used with other products.

Safety Warnings

App and Mobile Device

- Missing alerts from the Guardian Connect app may result in undetected low and high glucose levels. Follow the instructions and safety warnings in this user guide to make sure you receive alerts as intended.
- 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) even if the audio override feature is on.
- 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 sensor glucose alerts.
- Make sure Bluetooth is on, even if your mobile device is in Airplane mode. If Bluetooth is off, you will not get sensor glucose 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 sensor glucose alerts and sensor glucose information may not be shown correctly.
- If you turn off the override feature in the Guardian Connect app, the alerts will be based on the ringer setting of your mobile device. If your ringer is set to Do Not Disturb, silent, or a low volume, you may not hear sensor glucose alerts.
- 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 sensor glucose alerts.
- Do not close the Guardian Connect app. If the app is closed, you will not get sensor glucose information or alerts.
- 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 sensor glucose alerts. Check the Guardian Connect app occasionally to make sure it is running.
- If your mobile device restarts, the Guardian Connect app will not restart automatically. If you do not open the app again, you will not get sensor glucose alerts. Always make sure to open the app after your mobile device restarts.
- Do not let your mobile device shut down due to low battery, or you will not get sensor glucose alerts. Make sure you have a charger available so you can charge your battery if needed.

- When you snooze a sensor glucose alert, you won't get that alert again during the length of the snooze time you set. Make sure to set the snooze to a short enough time so that you can be sure to get an alert again if your glucose level doesn’t improve.
- Do not make therapy decisions based on sensor glucose values because sensor glucose and blood glucose (BG) values may be different. Confirm your glucose level with your blood glucose meter before making treatment decisions, such as dosing insulin before a meal or taking carbs to treat a low.
- Do not root or jailbreak your mobile device. Rooting or jailbreaking means to change the software of your mobile device in a way the manufacturer did not intend. If you change your mobile device in this way, you may not get sensor glucose alerts and your sensor glucose information may not be shown correctly.

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 7*.
- 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 the 24 Hour HelpLine and discard the device according to local regulations for battery disposal (nonincineration), 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.

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 using a different serter may result in improper insertion, pain, or injury.
- 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.
- 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.

Sensor

- Taking medications with acetaminophen or paracetamol including but not limited to Tylenol®, fever reducers, cold medicine while wearing the sensor may falsely raise your sensor glucose 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 blood glucose 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 products.
- 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 sensor glucose 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 sensor glucose 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 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 site infection.

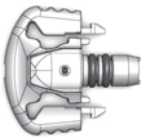
2 If bleeding stops, connect the transmitter (or recorder) to the sensor.
If bleeding does not stop, do not connect the transmitter to the sensor because blood can get into the transmitter connector, and could damage the device.

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 the 24 Hour HelpLine 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 (for example, 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 the 24 Hour HelpLine for further assistance.

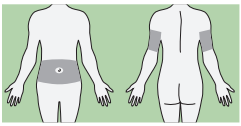
Precautions

- You must test your blood glucose levels at least two times per day, or as indicated by the system. If the app indicates that your sensor glucose is not within your glucose target range, check your blood glucose using your blood glucose meter.
- Do not use any other sensor. Other sensors are not intended for use with the transmitter, and will damage the transmitter and the sensor.
- Only use the green colored 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 cleaning 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 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.
- Do not clean the o-rings on the tester with any substances. Cleaning the o-rings can damage the tester.
- Wash your hands with soap and water before inserting the sensor to help prevent site infection.
- Wear gloves when inserting 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.

Where to insert the sensor

CAUTION: Avoid the 2 inch (5.0 cm) area around the navel to help ensure a comfortable insertion site and to help with sensor adhesion.

Choose an insertion site that has an adequate amount of subcutaneous fat. Shown here are the best body areas (shaded) 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 in muscle or areas constrained by clothing or accessories, areas with tough skin or scar tissue, sites subjected to rigorous movement during exercise, or in sites under a belt or on the waistline for best sensor performance and to avoid accidental sensor removal.

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

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 is receiving or emitting 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 1999/5/EC

Medtronic declares that this product is in conformity with the essential requirements of Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment.

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

IEC60601-1-2:2007; 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, WiFi, Bluetooth, 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 as well. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that is causing the interference.

Assistance

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

Department	Telephone number
24 Hour HelpLine (calls within the United States)	800 646 4633
24 Hour HelpLine (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 test your blood 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™ emergency kit

How to use this guide

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

Convention	Description
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	Indicates an item on the screen that you select with your finger or tap to open.
>	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	Provides additional helpful information.
CAUTION	Notifies you of a potential hazard which, if not avoided, may result in minor or moderate injury or damage to the equipment.
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

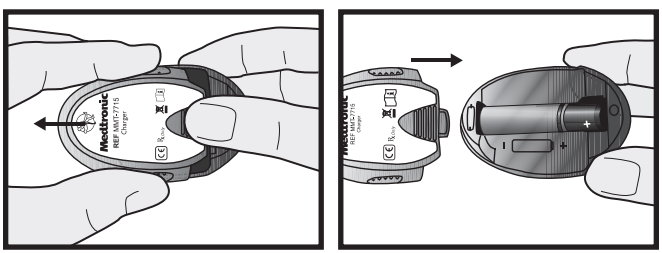
The transmitter contains a non-replaceable, rechargeable battery that you can recharge as needed with the charger. The transmitter will need to be charged before you use it. The charger has a green light that shows the charging status and a red light that communicates any problems during charging. If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

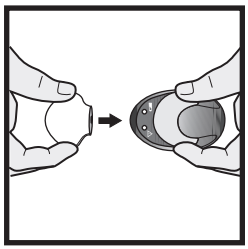


Charging the transmitter

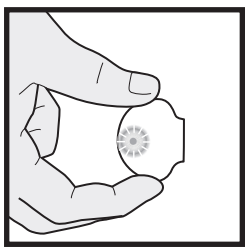
CAUTION: Always charge the transmitter before inserting your sensor. A depleted transmitter does not function. A fully charged transmitter works at least seven days without recharging. A depleted transmitter can take up to two hours to recharge.

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: 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) even if the audio override feature is on.

Pairing your transmitter

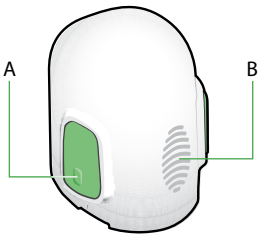
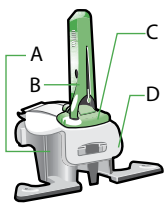
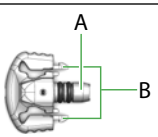
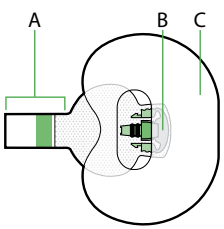
Follow the instructions on your screen to pair your transmitter to your mobile device.

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 completing setup.*

Components

	One-press serter A. bump on both buttons B. thumbprint marking
	Glucose sensor assembly A. pedestal B. needle housing C. sensor D. clear liner
	Sensor base A. sensor connector B. sensor snaps
	Transmitter
	Tape and sensor components A. adhesive tab B. sensor base C. oval tape

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.

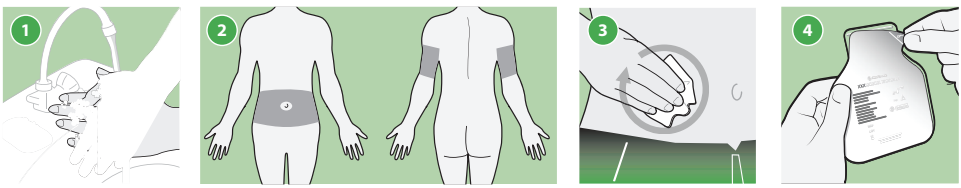
1 Wash your hands.

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.

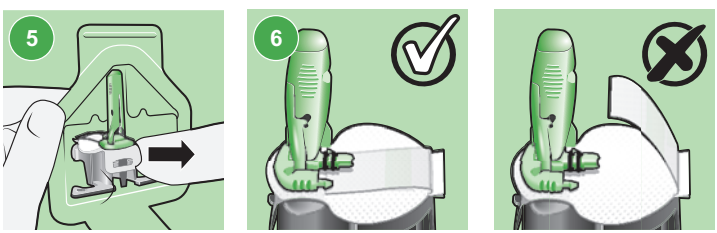
4 Open the sensor package.



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.*

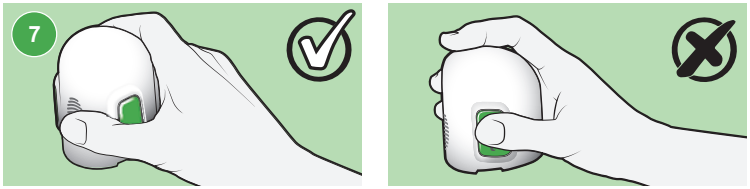
6 Make sure that the adhesive tab of the sensor is tucked under the sensor connector and sensor snaps.



7 **Holding serter correctly**
Place your thumb on the thumbprint marking to hold the serter without touching the buttons.

Holding serter incorrectly

Your fingers should not be touching the buttons.

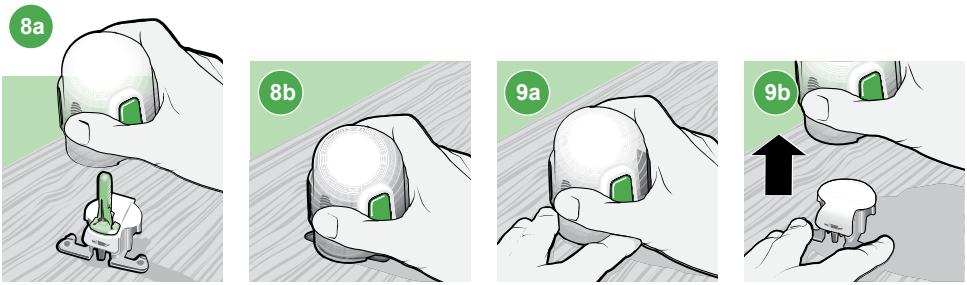


8

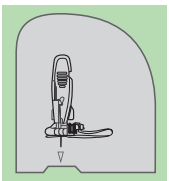
a. Grip the serter, placing your thumb on the thumbprint marking, **without holding the buttons**.
b. Carefully push the serter down onto the pedestal until the base of the serter sits flat on the table and you hear a click.

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.*



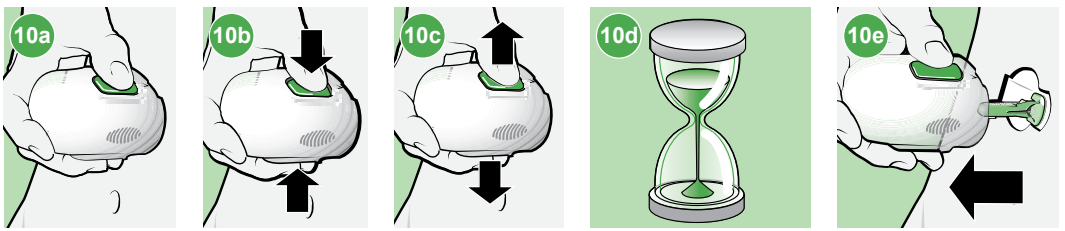
WARNING: **Never point a loaded serter toward any body part where insertion is not desired. An accidental button-push may cause the needle to inject the sensor in an undesired location, causing minor injury.**

10

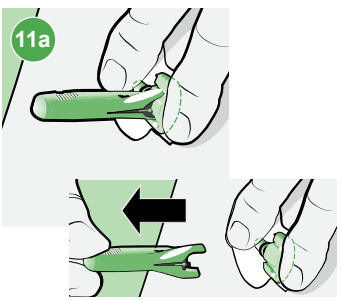
a. Hold the serter steady against your cleaned insertion site, without pushing the serter too deeply into your skin.

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.



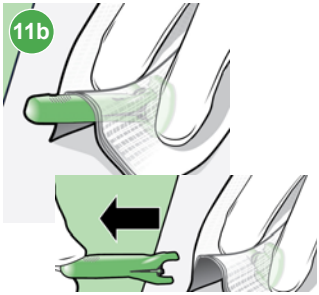
11 If you inserted the sensor into yourself, complete step 11a. If you are a healthcare professional or caregiver who inserted the sensor into a patient, complete step 11b.



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



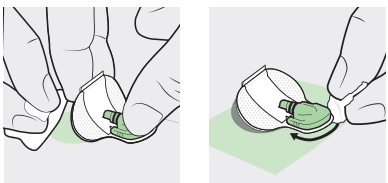
Healthcare professional or caregiver:

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™ 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.*

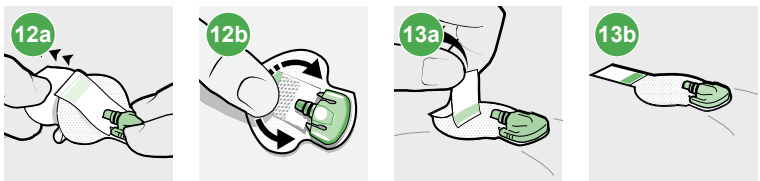


12

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.

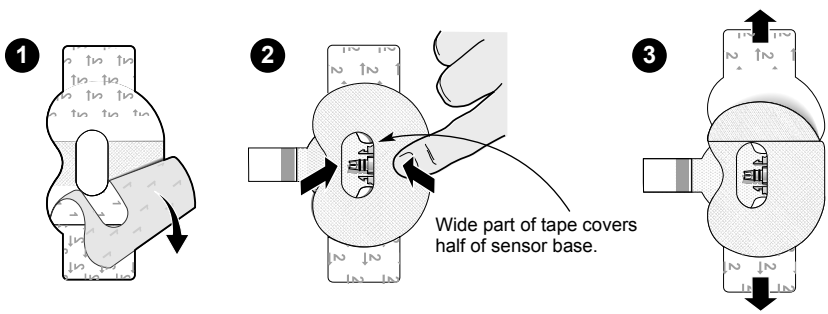
13

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.

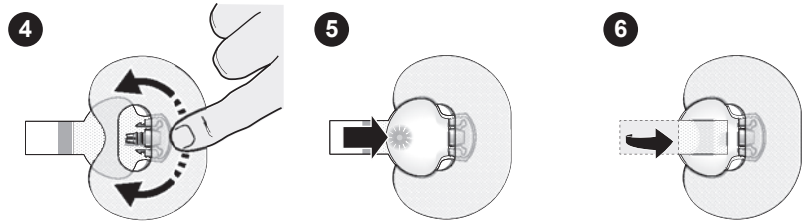


4 Smooth the tape.
5 Connect the transmitter to the sensor.

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

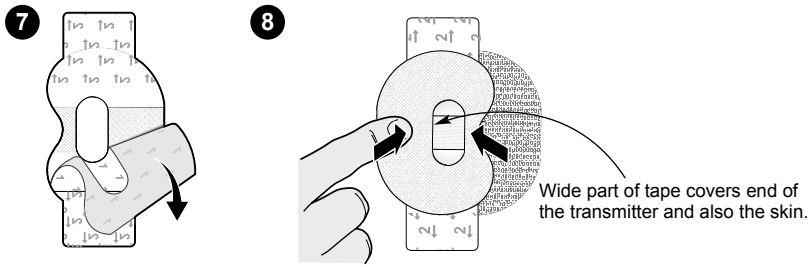
6 Cover the transmitter with the adhesive tab.

Note: *Do not pull the tab too tightly.*



7 To apply a 2nd tape, remove the liner marked 1.

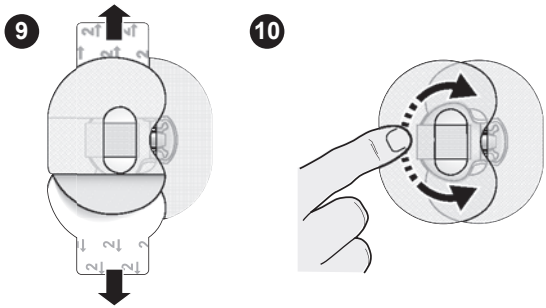
8 Apply the 2nd tape in the opposite direction to the first tape and place it on the transmitter. Press down firmly.



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.*



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.

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.

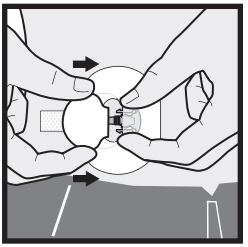
Connecting the transmitter to the sensor

To connect the transmitter to the sensor:

1 After the sensor is inserted, see *Applying oval tape, on page 20* 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.



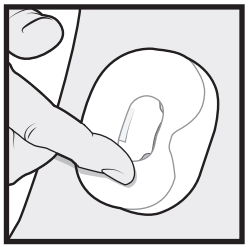
4 Slide the transmitter onto the sensor connector until the sensor arms snap into the notches on the transmitter. If the transmitter is properly connected, and if the sensor has had enough time to become hydrated, the green light on the transmitter will flash 6 times.

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 20*.



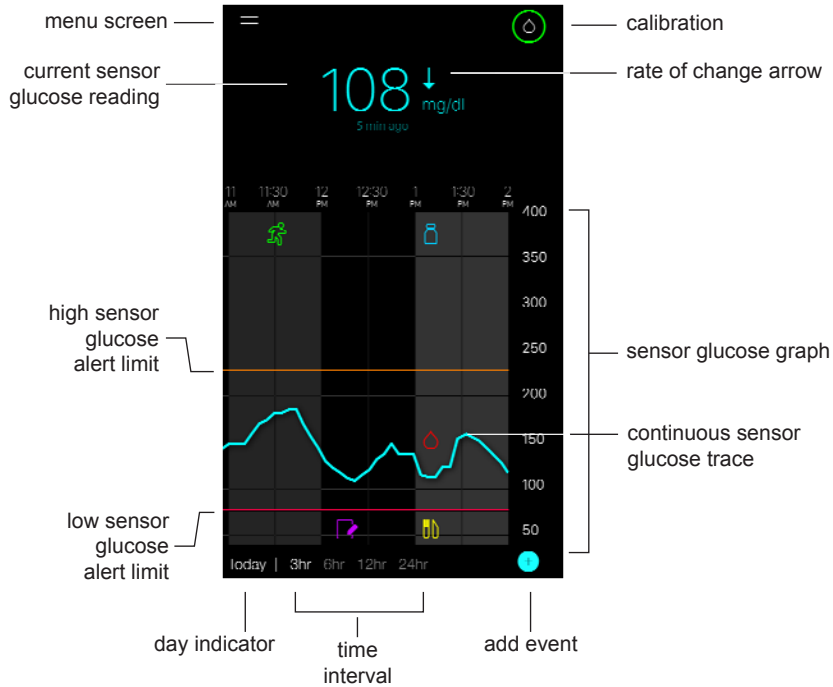
Completing your app setup

Continue to follow the on-screen instructions to enable notifications and setup alerts. For more information, see *Alert settings, on page 36*.

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) even if the audio override feature is on.

Home screen

The following figure shows the Home screen of the app.



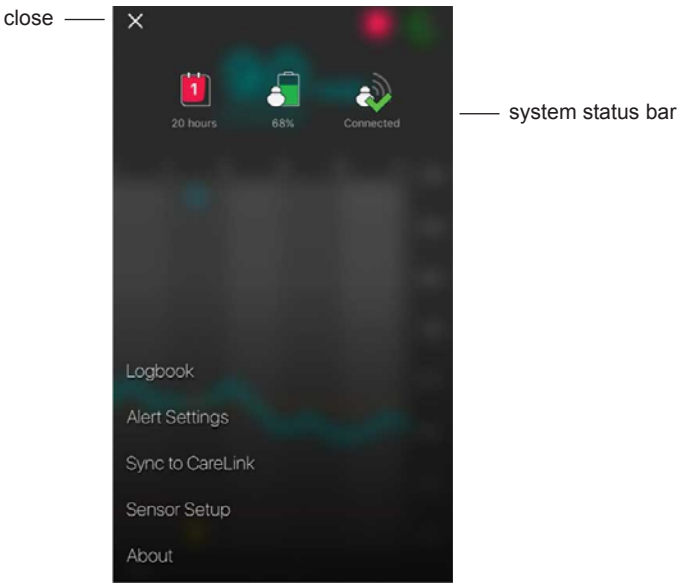
Note: *When you open your app for the first time, there will be no sensor information displayed on the Home screen. Your first sensor glucose reading appears after you have successfully paired your transmitter and calibrated your sensor.*

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 29*. 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.
Rate of change arrows	Display your glucose trend and the rate at which the most recent sensor glucose level has risen or fallen. For details on setting the rate of change for falling and rising sensor glucose 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 27*.
Continuous sensor glucose trace	Displays your current and previous SG readings. Tap any point on the graph to view the details of the selected sensor glucose 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 28*.
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 sensor glucose 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 sensor glucose limits on the sensor graph. The orange line indicates your sensor glucose high limit; the red line indicates your sensor glucose low limit.
Sensor status message	Displays the latest active status notification. If a current sensor glucose reading is not available, the sensor status message will appear where the sensor glucose information would be displayed.
Sensor glucose graph	Displays a blue line representing your sensor glucose 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 40*.
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, blood glucose readings, meals you eat, or insulin you take. Certain blood glucose 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 ☰ on 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 28*.
Logbook	Displays a history of alerts and events that have occurred in the Guardian Connect system. For details, see *Logbook, on page 45*.
Alert Settings	Display the options for setting glucose monitoring alerts and calibration reminders. For details, see *Alert settings, on page 36*.
Sync to CareLink	Provides access to a menu for changing your CareLink Personal user login information.
Sensor Setup	Displays the instructions for starting a new sensor. For details, see *New sensor setup, on page 14*.

Item	Description
About	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.
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 remaining. 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

Icon name	Description
Notification	The notification icon indicates that alerts may be missed because the override feature is turned off. The notification icon will display on the Home screen of the app when the override feature is turned off and your device is set to silent or notifications are disabled. 

Calibrating your sensor

Calibration is the process of entering a blood glucose meter reading to calculate sensor glucose values. You must calibrate your sensor regularly to ensure you continue to receive accurate sensor glucose data. For details, see *Calibrating guidelines, on page 30*.

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 will receive an alert instructing you to calibrate your sensor now. After you calibrate the sensor, it may take up to five minutes to receive updated sensor glucose values. If you do not calibrate after receiving a calibration alert, your transmitter stops calculating your sensor glucose 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 sensor glucose values until you calibrate your sensor.
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 sensor glucose 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 30*.

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 sensor glucose values until you calibrate your sensor and your app may stop displaying sensor glucose 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 blood glucose meter reading into the app immediately after testing your blood glucose.
- Review your BG meter instructions for guidance on how to test your blood glucose.

Caution: **Do not use Alternative Site Testing under the following conditions. Use fingertip testing in any of these cases:**

- If you think your blood glucose is low (hypoglycemia).
- When blood glucose is changing rapidly (after a meal, insulin dose or exercise).
- If you have hypoglycemic unawareness (lack of symptoms).
- If you get alternative site blood glucose 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 blood glucose.
- Use only your fingertips when obtaining blood samples for calibration.
- Avoid using an old blood glucose reading or reusing blood glucose 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 blood glucose meter readings are significantly different from your sensor glucose readings, wash your hands and calibrate again.*

Entering blood glucose meter readings for calibration
You can enter a blood glucose meter reading for calibration from the Calibration screen as described in this section or when you enter a blood glucose meter reading on the Events screen, as described in *Entering blood glucose meter readings, on page 42*.

To enter a blood glucose meter reading for sensor calibration:

1 Take a blood glucose meter reading.
2 On the Home screen of the app, tap the calibration icon.
3 Using the number pad, enter the blood glucose value between 40 mg/dL 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 top. Confirm the value, and then tap **Calibrate sensor XXX mg/dL**.
The App returns to the Home screen, and a blood drop appears on the sensor glucose graph at the time of the entry. Your sensor glucose reading appears within five minutes after calibration.

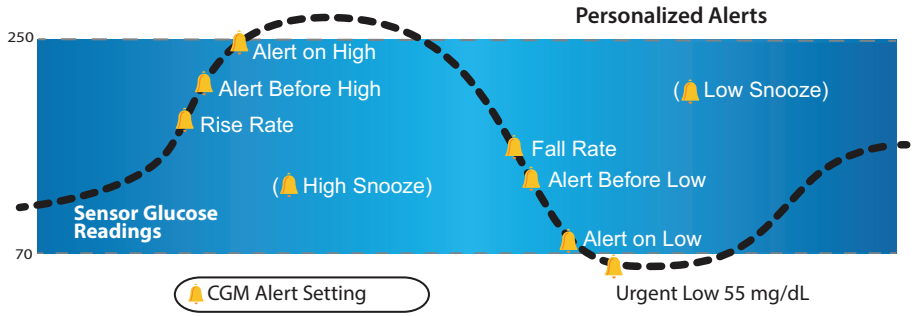
Alerts

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 sensor glucose 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 sensor glucose level has gone above the high limit you set.
High Predicted	Your sensor glucose 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 sensor glucose is rising faster than a rate you set (corresponding to the rising arrows displayed next to your sensor glucose level).
Low Sensor Glucose	Your sensor glucose level has gone below the low limit you set.
Low Predicted	Your sensor glucose 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 sensor glucose is falling faster than a rate you set (corresponding to the falling arrows displayed next to your sensor glucose level).
Urgent Low Sensor Glucose	Your sensor glucose level has gone below 55 mg/dL.

Note: *You will always receive an Urgent Low Glucose Alert when your sensor glucose value is 55 mg/dL or below. This alert will also produce a sound regardless of your mobile device's volume or audio override. But remember, notifications for the Guardian Connect app must be kept on.*

Glucose alerts can be customized and are set up during system setup, or as described in *Alert settings, on page 36*.

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 will still receive sensor glucose information but you should act on these alerts so you can continue to receive sensor glucose 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 will no longer receive sensor glucose information.

Alert type	Description
Calibrate Now	You need to calibrate your sensor in order to get sensor glucose 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.
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.

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. Your Guardian Connect app has features to make sure you can receive Guardian Connect alerts, even if these modes are active. To make sure you get all the alerts you want, keep in mind the following:

1 Keep notifications on for the Guardian Connect app.
You need to keep notifications turned on for the Guardian Connect app to receive any alerts from the app.

To turn on notifications, go to your mobile device's Settings app by tapping on  and then tap the message.

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) even if the audio override feature is on.

2 Audio override helps make sure you hear alerts, even when your mobile device is set to silent or Do Not Disturb.
The app has an audio override feature that allows your app alerts to sound at maximum volume, even if your mobile device's ringer volume is set to Do Not Disturb, low volume, or silent (vibrate). **The audio override feature is already turned ON** for all app alerts when you first start using your app.

After initial setup, you can choose which alerts (Low, High, and/or Status Alerts) will override the ringer volume. You can also turn off the override entirely, if you prefer. Your override setting won't affect the Urgent Low Glucose Alert.

3 Urgent Low Glucose Alert will sound even if audio override is turned off.
Your Guardian Connect app has an Urgent Low Glucose Alert, which will always alert you when your glucose level goes below 55 mg/dL. As long as notifications are turned on, you will always get this alert – even if your phone is set to Do Not Disturb or silent (vibrate), or the ringer volume is low.

Changing audio override

1 Tap  on your app home screen. Tap **Alert Settings**. Then tap **Audio**.
2 Switch **Override** to On or Off.
3 Switch your **Low**, **High**, and/or **Status Alerts** to On or Off.
4 At the top of the screen, tap **Save**.

WARNING: If you turn off the override feature in the Guardian Connect app, the alerts will be based on the ringer setting of your mobile device. If your ringer is set to Do Not Disturb, silent, or a low volume, you may not hear sensor glucose alerts.

How does the audio override work?

Your app settings	Your mobile device's volume	App alerts you will get
Audio override ON	Ringer volume is ON Vibrate only Do Not Disturb is ON	Sound at maximum volume
Audio override OFF	Ringer volume is ON	Same sound as mobile device's ringer volume
	Vibrate only	No sound but will vibrate
	Do Not Disturb is ON	No sound or vibrate

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 sensor glucose alerts.

WARNING: Do not close the Guardian Connect app. If the app is closed, you will not get sensor glucose 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 sensor glucose 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 sensor glucose 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.

Note: *While the Guardian Connect app is open or running in the background, the side volume buttons on your mobile device will only control the media volume (not the ringer volume). The media volume setting is used to adjust the volume of music, videos, and sounds in some games and other apps. The ringer volume is the setting that is used to adjust the volume of phone calls, text messages, and other notifications. When the audio override is active, your Guardian Connect alerts will always play at the maximum media volume of your device.*

Note: *When an alert is triggered and the audio override feature is active, you may briefly see your phone's volume settings displayed on screen while the Guardian Connect app sets your device volume. You can continue to use your device normally. The volume display may also appear a second time as the Guardian Connect app restores your previous volume level.*

Alert settings

Setting high alerts

High alert settings include the following:

High alert setting	Description
High Limit	Your high limit is the value on which your other high settings are based. Your high limit can be set from 100 mg/dL to 400 mg/dL. On your sensor glucose graph, your high limit appears as an orange horizontal line at the value that you set.
Alert on High	When Alert on High is on, your system displays a High Sensor Glucose alert when your sensor glucose value reaches or exceeds your high limit.
Alert Before High	When Alert Before High is on, you will receive a High Predicted alert any time the sensor glucose is predicted to reach your high limit. This makes you aware of potential high glucose levels before they occur.
Time Before High	The Time Before High option is available only when the Alert Before High feature is on. This option determines when you will receive a High Predicted alert, if your sensor glucose values continue to increase at the current rate of change. You can set a time between ten minutes and one hour.

To set your high alerts:

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

2 Toggle **All Day** to switch between all-day alerts and different alerts for day and night. If you choose to set different alerts for day and night, two sets of settings appear.

3 For daytime alerts, tap **Day starts at** and set the desired start time for the selected day period.

4 Tap **High Limit** and set the desired limit between 100 mg/dL and 400 mg/dL. This toggles **Alert on High** on.

5 Return to the High Alerts screen and tap **Save**.

6 If you want to receive alerts when your sensor glucose is approaching your high limit:
   a. Toggle **Alert Before High** on.
   b. Tap **Time Before High** and set the desired time when you want to receive a High Predicted alert.

7 If you are setting different alerts for day and night, tap **Night starts at**, select the time, and repeat steps 4 and 5 to set your nighttime alerts.

8 Tap **Save** at the top of the screen to save your settings. Then tap **Alert Settings** to define the other alert settings, such as snooze time for the alerts you have just set.

9 When you have completed setting up your alerts, tap **Home** to return to the Home screen.

Setting low alerts

Low alert settings include the following:

Low alert setting	Description
Low Limit	Your Low Limit is the value on which your other low settings are based. Your low limit can be set from 60 mg/dL to 90 mg/dL. On your sensor glucose graph, your low limit appears as a red horizontal line at the value that you set.
Alert on Low	When Alert on Low is on, your system displays a Low Sensor Glucose alert when your sensor glucose value reaches or falls below your low limit.
Alert Before Low	When Alert Before Low is on, you will receive a Low Predicted alert any time the sensor glucose is predicted to reach your low limit. This makes you aware of potential lows before they occur.
Time Before Low	Time Before Low is available only when Alert Before Low is on. Time Before Low determines when you will receive a Low Predicted Alert, if your sensor glucose values continue to decrease at the current rate of change. You can set a time between ten minutes and one hour.

You can define your low alert settings for the entire day or use different settings during the day and at night.

To set your low alerts:

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

2 Toggle **All Day** to switch between all-day alerts and different alerts for day and night. If you choose to set different alerts for day and night, two sets of settings appear.

3 For daytime alerts, tap **Day starts at** and set the start time for the selected day period.

4 Tap **Low Limit** and set the desired limit between 60 mg/dL and 90 mg/dL. This toggles **Alert on Low** on.

5 Return to the Low Alerts screen and tap **Save**.

6 If you want to receive alerts when your sensor glucose is approaching your low limit:
   a. Toggle **Alert Before Low** on.
   b. Tap **Time Before Low** and set the desired time when you want to receive a Low Predicted alert.

7 If you are setting different alerts for day and night, tap **Night starts at**, select the time, and repeat steps 4 and 5 to set your nighttime alerts.

8 At the top of the screen, tap **Alert Settings** to save your settings and to define the other alert settings, for example, snooze time for the alerts you have just set.

9 When you have completed setting up your alerts, tap **Home** to return to the Home screen.

Setting rate alerts

Rate alerts notify you when your sensor glucose is rising (Rise Alert) or falling (Fall 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 rising or falling trends are indicated by arrows, as shown in *Home screen, on page 24*. The more arrows, the higher the rate of change.

To set your rate alerts:

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

2 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. One arrow signals a 1 mg/dL rise; two arrows signal a 2 mg/dL rise; and three arrows signal a 3 mg/dL rise.

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

4 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. One arrow signals a 1 mg/dL fall; two arrows signal a 2 mg/dL fall; and three arrows signal a 3 mg/dL fall.

5 Tap the arrow option with the fall rate you want to use.
6 At the top of the screen, tap **Save** > **Alert Settings** to return to the Alert Settings screen. Then tap **Home** to return to the Home screen.

Setting alert snooze time
The snooze feature lets you set a snooze time for your alerts. This feature will remind 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 **High and Rise Alerts** and set the desired amount of time before you are reminded of the existing alert condition.
3 Tap **Low and Fall Alerts** and set the desired amount of time before you are reminded of the existing alert condition.
4 At the top of the screen, tap **Save** > **Alert Settings** to return to the Alert Settings screen. Then tap **Home** to return to the Home 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 Reminder**.
2 Toggle **Reminder** on.
3 Set the desired amount of time to be alerted before sensor calibration is due.
4 At the top of the screen, tap **Save** > **Alert Settings** to return to the Alert Settings screen. Then tap **Home** to return to the Home screen.

Setting audio override

You can set which type of alerts you want to sound regardless of your device ringer setting. When you first start using your app, all of the alerts will override your device ringer setting. You can change these settings if you prefer not to override your device ringer setting.

To set an override:

1 Tap  on your app home screen. Tap **Alert Settings**. Then tap **Audio**.

2 Switch **Override** to On or Off.

3 Switch your **Low**, **High**, and/or **Status Alerts** to On or Off.

4 At the top of the screen, tap **Save**.

Note: *While the Guardian Connect app is open or running in the background, the side volume buttons on your mobile device will only control the media volume (not the ringer volume). The media volume setting is used to adjust the volume of music, videos, and sounds in some games and other apps. The ringer volume is the setting that is used to adjust the volume of phone calls, text messages, and other notifications. When the audio override is active, your Guardian Connect alerts will always play at the maximum media volume of your device.*

Acting On Guardian Connect Alerts

When you get a Guardian Connect alert, you will get a notification on your mobile device (like you do for other apps). You may also get a sound or vibration alert, depending on your mobile device settings, as described in the *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 sensor glucose 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

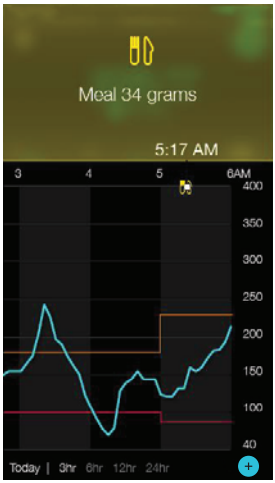
The sensor graph displays your current sensor glucose reading. It also allows you to view a history of sensor glucose readings and events you have entered.

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 sensor glucose reading or event in an information box that appears above the graph. For details, see *Graph information boxes, on page 41*.
- Double tap the vertical sensor glucose values axis to the right of the graph to return to the current sensor glucose 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 sensor glucose reading appears above the graph. The following figure provides an example:



For sensor glucose readings, information boxes display the sensor glucose value, its date and time, and rate of change arrows, similar to the current sensor glucose value information displayed on the Home screen. If there is no sensor glucose 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 sensor glucose 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.
	Other	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 blood glucose meter readings

If you measure your blood glucose, for example, when you eat or when your blood glucose is rising or falling rapidly, you can enter these measurements into the app.

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

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

To enter a blood glucose meter reading into the Events feature:

1 Measure your blood glucose with a blood glucose 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 blood glucose 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 top of the screen.
8 If you receive a message instructing you to calibrate now:
  • To update the sensor with the entered blood glucose meter reading, select **Calibrate sensor XXX mg/dL**.
  • 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 **Cancel**.

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

Entering insulin injection information
If you have delivered insulin using an insulin pump, insulin pen, or a syringe, you can use the app to record the amount of insulin you injected.

To enter the type and amount of insulin you have delivered:

1 Make a note of the amount and type of injection you have taken.
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 have taken:
• Rapid acting
• Long acting
8 Tap **Done** at the top.
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 **Done** at the top.
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 **Duration** and set the time you have spent exercising.
The entered value appears above the number pad.

6 Tap **Intensity** and select Low, Medium, or High to indicate how intensely you have exercised.

7 Tap **Done** at the top.
The app returns to the Home screen, and appears on the graph at the selected time.

Entering other events

You can use the app to enter events other than blood glucose 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 other events:

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 **Done** at the top.
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 v 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** > **Home** to return to the Home screen. If you are on the main Logbook screen, tap **Home** to return to the Home 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 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 will no longer send 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.

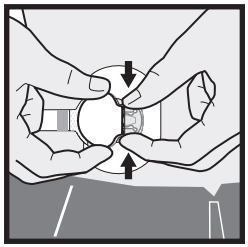
Note: *Your care partners will use the CareLink login information you create for them to access the CareLink Personal website.*

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

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 47*. 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 will go through another warm-up period before you can calibrate.

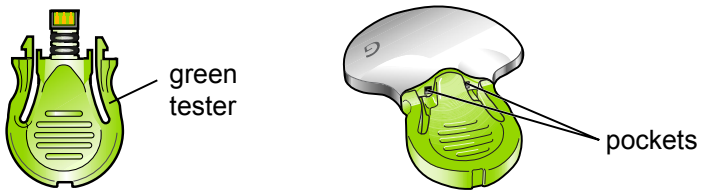
Tester

The tester is used to test the transmitter to make sure it is working. 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 will damage the transmitter.

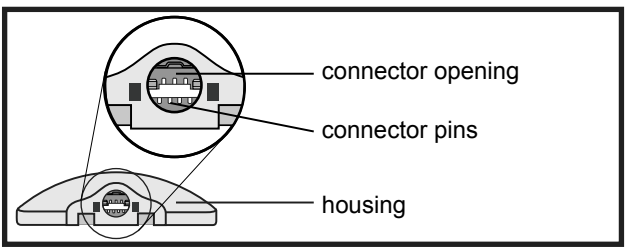
The tester can be used 61 times. If you continue to use the tester more than 61 times, the connector pins inside the transmitter could be damaged because the tester cannot continue to provide a waterproof seal. For instructions on how to check the connector pins, see *Inspecting the transmitter connector pins, on page 48*.

CAUTION: Only use the green colored 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.



Inspecting the transmitter connector pins

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

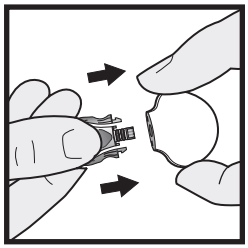


Look inside the connector opening of the transmitter to make sure that the connector pins are not damaged or corroded. If the connector pins are damaged or corroded, the transmitter cannot communicate with the charger or the app on your compatible mobile device. Contact the 24 Hour HelpLine. It may be 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

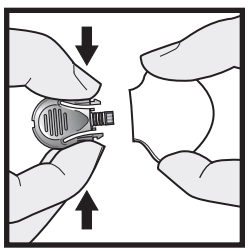
To connect the tester:



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 28*.
4 To clean the transmitter, see *Cleaning the transmitter, on page 49*.
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. For details, see Cleaning the transmitter, on page 49.*

Always clean the transmitter after each use.

To clean the transmitter, you need the following materials:

- mild liquid soap (for example, Ivory® liquid soap)
- soft-bristled toddler toothbrush
- container

- clean, lint-free dry cloths

You can find these supplies at Walmart, Target, or http://www.amazon.com/.

Use life

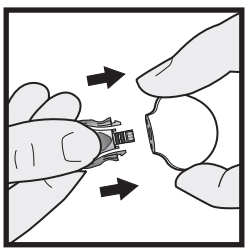
The transmitter can be cleaned up to 122 times or one year, whichever comes first. Discard the transmitter at this point. If you continue to use the transmitter beyond 122 times or one year, the cleaning process may damage the device. Contact Medtronic to order a new transmitter.

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 the 24 Hour HelpLine and discard the device according to local regulations for battery disposal (nonincineration), or contact your healthcare professional for disposal information.

To clean the transmitter:

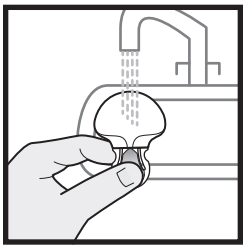
1 Wash your hands thoroughly.

2 Attach the tester to the transmitter.



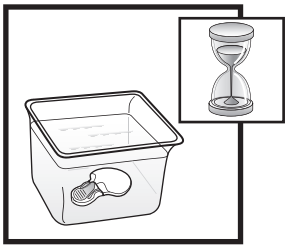
3 If there is adhesive residue on the transmitter, see *Removing adhesive residue, on page 52*.

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.



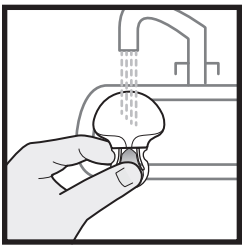
5 Prepare a mild liquid soap solution using 1 teaspoon (5 milliliters) of mild liquid soap per 1 gallon (3.8 liters) of room temperature tap water.

6 With the tester still attached, submerge the transmitter in the mild liquid soap solution and soak for one minute.

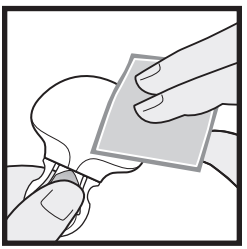


7 Holding the tester, brush the entire surface of the transmitter using a soft-bristled toddler toothbrush. Make sure to brush all hard-to-reach areas until visibly clean.

8 Rinse the transmitter under running room temperature tap water for at least one minute, and until all visible liquid soap is gone.

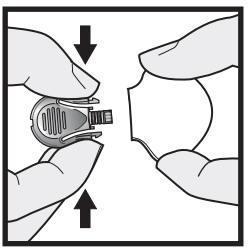


9 Dry the transmitter and tester with a clean, dry cloth.



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 Detachol® medical adhesive remover, and cotton swabs. You can buy Detachol at http://www.amazon.com/, http://www.medtronicdiabetes.com, or by calling 800 646 4633.

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

To remove adhesive residue:

1 Make sure the tester is attached to the transmitter.

2 Holding the tester, saturate a cotton swab in the Detachol solution and gently rub the adhesive residue on the transmitter until it is fully removed.

3 Continue with the cleaning procedure. See *Cleaning the transmitter, on page 49* 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 will need the following materials: mild liquid soap (for example, Ivory® 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. Continue rinsing 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 48*. If the pins are damaged or corroded, contact the 24 Hour HelpLine. 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 12*.
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 12*.
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 the 24 Hour HelpLine. It may be time to replace your transmitter.
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 12*. 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 the 24 Hour HelpLine. It may be time to replace your transmitter.

Problem	Likely Cause(s)	Resolution
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 the 24 Hour HelpLine. It may be time to replace your transmitter.
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 10*. 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 the 24 Hour HelpLine. It may be time to replace your transmitter.

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 sensor glucose values.
	Your mobile device is out of range.	Make sure your mobile device and your transmitter are located within 20 feet. 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. For more information on Radio Frequency (RF) interference, see *Radio Frequency (RF) communication, on page 10*.
	Your sensor disconnected from your transmitter.	Reconnect your sensor to your transmitter. Be careful not to pull the sensor out. Note: Upon reconnecting your transmitter to your sensor, your sensor will go through a warm-up period which may last up to 2 hours.
	Your sensor pulled out from your skin.	You cannot continue using this sensor. You must insert a new sensor to continue receiving sensor glucose values. See *Disconnecting the transmitter from the sensor and Removing the sensor*, on page 42 of this user guide for instructions on how to change your sensor. Review the *New sensor setup* instructions on page 12 of this user guide for directions on how to insert a new sensor. For best results, recharge your transmitter between each use to ensure full transmitter battery life. If your transmitter is still not communicating with the app, call the 24 Hour HelpLine for assistance.

Problem	Likely Cause(s)	Resolution
Transmitter Battery Empty alert	Your transmitter battery is empty and needs to be recharged.	See *Disconnecting the transmitter from the sensor*, on page 42 of this user guide for instructions on how to disconnect your transmitter from your sensor. Review instructions from *Charging the transmitter* on page 12. For best results, recharge your transmitter between each use to ensure full transmitter battery life. Note: Upon 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 is at or below the 20 % battery threshold and 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 sensor glucose values, a new sensor must be used. See *Disconnecting the transmitter from the sensor and Removing the sensor*, on page 42 of this user guide for instructions on how to change your sensor. Review the *New sensor setup* instructions on page 12 of this user guide to insert a new 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 will no longer display sensor glucose values on the Guardian Connect app.	To continue receiving sensor glucose values, a new sensor must be used. See *Disconnecting the transmitter from the sensor and Removing the sensor*, on page 42 of this user guide for instructions on how to change your sensor. Review the *New sensor setup* instructions on page 12 of this user guide to insert a new sensor. For best results, recharge your transmitter between each use to ensure full transmitter battery life.

Problem	Likely Cause(s)	Resolution
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 guidance on how to test your blood glucose. Enter this new value in the app for calibration. For details on how to calibrate your sensor, see *Calibrating guidelines, on page 30*.
Calibrate Now alert	A calibration is required by the system.	Review your BG meter instructions for guidance on how to test your blood glucose. Enter this new value in the app for calibration. For details on how to calibrate your sensor, see *Calibrating guidelines*, on page 28.
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 will go through a warm-up period which may last up to 2 hours. If you are still experiencing issues, you may need to replace your transmitter. Contact the 24 Hour HelpLine for more assistance.

Storing the devices

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

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)
Maximum output power (EIRP)	0.1 mW (-9.9 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)

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 using a Wi-Fi connection, it is recommended to connect to a secure Wi-Fi network (such as WPA2 or other newer wireless security protocols).

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		
The transmitter is intended for use in the electromagnetic environment specified below. The customer or the user of the transmitter should make sure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The transmitter must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The transmitter is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The transmitter is intended for use in the electromagnetic environment specified below. The customer or the user of the transmitter should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2 kV, ±4 kV, ±8 kV, ±15 kV Air ±2 kV, ±4 kV, ±6 kV, ±8 kV Contact	±2 kV, ±4 kV, ±8 kV, ±15 kV Air ±2 kV, ±4 kV, ±6 kV, ±8 kV Contact	For use in a typical domestic, commercial, or hospital environment.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Requirement does not apply to this battery powered device.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Requirement does not apply to this battery powered device.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	Not applicable	Requirement does not apply to this battery powered device.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial, or hospital environment.
Note: *U_T is the a.c. mains voltage prior to application of the test level.*			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The transmitter is intended for use in the electromagnetic environment specified below. The customer or user of the transmitter should assure that it is used in such an electromagnetic environment.			
Immunity Test	**IEC 60601 Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Conducted RF IEC 61000-4-6	3 V/m 150 kHz to 80 MHz	Not applicable	Not applicable

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The transmitter is intended for use in the electromagnetic environment specified below. The customer or user of the transmitter should assure that it is used in such an electromagnetic environment.			
Immunity Test	**IEC 60601 Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 6 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the transmitter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Refer to the recommended separation distance table for more information. $d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.70\sqrt{P}$ 800 MHz to 6 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The transmitter is intended for use in the electromagnetic environment specified below. The customer or user of the transmitter should assure that it is used in such an electromagnetic environment.

Immunity Test	IEC 60601 Level	Compliance Level	Electromagnetic Environment Guidance

Note: *At 80 MHz and 800 MHz, the higher frequency range applies.*

Note: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.*

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the transmitter is used exceeds the applicable RF compliance level above, the transmitter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the transmitter.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the transmitter

The transmitter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the transmitter users can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the transmitter as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)		
	150 kHz to 80 MHz Not applicable	80MHz to 800MHz $d = 0.35\sqrt{P}$	800MHz to 6.0GHz $d = 0.70\sqrt{P}$
0.01	Not applicable	0.035	0.07
0.1	Not applicable	0.11	0.22
1	Not applicable	0.35	0.7
10	Not applicable	1.1	2.2
100	Not applicable	3.5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Recommended separation distances between portable and mobile RF communications equipment and the transmitter			
The transmitter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the transmitter users can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the transmitter as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to the frequency of transmitter (m)**		
	150 kHz to 80 MHz Not applicable	**80MHz to 800MHz** $d = 0.35\sqrt{P}$	**800MHz to 6.0GHz** $d = 0.70\sqrt{P}$
Note: *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*			
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 transmitter enables CGM (Continuous Glucose Monitoring) technology. The transmitter transmits sensor glucose values calculated by the real-time algorithm to a primary display device, allowing you to monitor your sensor glucose values.

Clinical study description

The performance of the Guardian Sensor (3) was evaluated in a clinical study[1]. 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.

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.

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.

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 sensor glucose 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.

The CONTOUR®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 blood glucose meters may differ from the performance with the CONTOUR 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®) 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 sensor glucose (SG) values and the paired blood glucose 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 or 4 times a day		Calibration every 12 hours		Calibration 3 or 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:** 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 15/20/30/4 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.

				YSI (mg/dL)				
CGM Display	**Insertion Site**	**CGM-YSI pairs**	**<55**	**<60**	**<70**	**<80**	**>80**	**Total**
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.

				YSI (mg/dL)				
CGM Display	**Insertion Site**	**CGM-YSI pairs**	**<55**	**<60**	**<70**	**<80**	**>80**	**Total**
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)
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)

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	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 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	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)

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	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)
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)

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	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 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% (0/0)	0.1% (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)

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
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)	29.6% (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	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)
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)
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% (35/427)	62.5% (267/427)	27.6% (118/427)	1.4% (6/427)	0.0% (0/0)	0.0% (0/0)
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

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

** 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.*

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						
	YSI Rate-of-Change Range (mg/dL/min)						
SG Rate-of-Change Range (mg/dL/min)	**Number of Paired SG-YSI**	**<-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)	0.0% (0/162)
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						
	YSI Rate-of-Change Range (mg/dL/min)						
SG Rate-of-Change Range (mg/dL/min)	**Number of Paired SG-YSI**	**<-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)

	Percent of Matched Pairs-in Each YSI Rate-of-Change Range for Each SG Rate-of-Change Range						
	YSI Rate-of-Change Range (mg/dL/min)						
SG Rate-of-Change Range (mg/dL/min)	**Number of Paired SG-YSI**	**<-2**	**[-2, -1]**	**[-1, 0]**	**[0, 1]**	**[1, 2]**	**>2**
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 worn 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 through seven days of use.

Alert performance

CGM enables your device to display sensor glucose readings, glucose trend arrows, glucose trend graphs, and sensor glucose 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 sensor glucose alerts (**Threshold alerts**) let the user know when the sensor glucose 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 sensor glucose level may soon reach a high or low limit setting. Users may select how early they would like to be notified before their sensor glucose 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 will receive a Predictive alert when their sensor glucose 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 will have 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 sensor glucose level compared to the high or low limit setting. If the predicted future sensor glucose value is above the high limit or below the low limit, then a predictive alert is sounded even though the current sensor glucose level has not crossed the high or low limit. The predicted sensor glucose level is calculated using the current sensor glucose level, the derivative of current and previous sensor glucose readings (the trend or slope of the sensor glucose readings) and the Time Before High or Time Before Low duration the user selects.

The device will always alert 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 blood glucose 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 blood glucose 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 blood glucose 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 blood glucose 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 blood glucose 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) blood glucose. 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 blood glucose 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 blood glucose 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 blood glucose 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 users blood glucose 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 blood glucose 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 blood glucose 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 blood glucose 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 blood glucose is low (or high) so that they can correct the low (or high) blood glucose. 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 blood glucose 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 blood glucose 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 blood glucose 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 blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A high glucose correct detection rate indicates that users can have confidence that they will be notified by the device if their blood glucose 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 blood glucose 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 blood glucose is low (or high), so that they can correct the low (or high) blood glucose. A low missed detection rate indicates that users can have confidence that they will be notified by the device if their blood glucose 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 blood glucose 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.

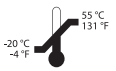
This warranty shall be personal to the original purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original purchaser shall cause this warranty to immediately terminate. This warranty does not apply to Glucose Sensors and other 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

SN	Serial number
REF	Catalogue or model number
(1x)	One transmitter, charger, and serter per container/package
(2x)	Two testers per container/package
	Date of manufacture (YYYY-MM-DD)
	Manufacturer
	Must refer to instruction manual before every use (appears blue on label).
	Temperature limit
	Non-ionizing electromagnetic radiation (RF communication).
CONF	Configuration or unique version identifier
	Degree of protection against electric shock: Type BF applied part
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].
	Humidity limitation
R_{x} *Only*	Prescription only
	Fragile, handle with care
	Keep dry

	Recycle cardboard, paper, plastic packaging supplies and unwanted written material.
	Recycle: Electronic Equipment
	Magnetic Resonance (MR) unsafe: keep away from magnetic resonance imaging (MRI) equipment.
	*Bluetooth*® wireless technology or *Bluetooth*® enabled

Guardian™ is a trademark of Medtronic MiniMed, Inc.

Enlite® are CareLink® are registered trademarks of Medtronic MiniMed, Inc.

Bluetooth® is a registered trademark of Bluetooth SIG, Inc.

Ivory® is a registered trademark of The Procter & Gamble Company.

Detachol® is a registered trademark of Ferndale Laboratories Inc.

Tylenol® is a registered trademark of Johnson & Johnson consumer Inc.

Skin Tac™ is a trademark of Torbot Group, Inc.

CONTOUR® is a registered trademark of Ascensia Diabetes Care.

YSI® is a registered trademark of YSI Inc.

Glucagon™ is a trademark of Eli Lilly and Company.

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℞ *Only*

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