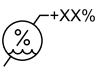
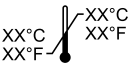
Medtronic

Simplera™

System User Guide

Icon Table

	Consult instructions for use
	Consult instructions for use or electronic instructions for use
	Caution: consult instructions for use for important warnings or precautions not found on the label
	Magnetic Resonance (MR) Unsafe
	Do not re-use
	Do not re-sterilize
	Do not use if package is damaged and consult instructions for use
	Importer
	Manufacturing site
	Recyclable, contains recycled content
	Bluetooth® wireless technology or Bluetooth® enabled
	Single sterile barrier system
	Contains biological material of human origin
	Contains human blood or plasma derivatives
	Manufacturer
	Country of manufacture (and Date of manufacture when a date appears beside)
	Date of manufacture (DoM)

	Non-pyrogenic
	Type BF applied part
	Use-by date
	Fragile, handle with care
	Keep dry
	RF Compliance Mark (RCM) Complies with ANZ radio communications requirement
	Humidity upper limit
	Temperature limits
MD	Medical device
SN	Serial number
UDI	Unique Device Identifier
REF	Catalogue number
LOT	Batch code
EC REP	Authorized representative in the European Community/European Union
CH REP	Authorized Representative in Switzerland
STERILE EO	Sterilized using ethylene oxide
$\mathrm{R_x}$ *Only*	Requires prescription in the USA
CE	Conformité Européenne (European Conformity). Device fully complies with applicable European Union Acts.
(1x)	One per container/package

(5x)	Five per container/package
CODE: XXX-XXX	Sensor pairing code
IP48	Protected against effects of continuous immersion in water at a depth of 8 feet (2.4 meters) for up to 30 minutes

Contents

Simplera system

Introduction

The Simplera system helps patients manage diabetes. The Simplera system has many key capabilities:

- It records glucose values throughout the day and night.
- It displays glucose values and sends alerts for glucose events in a convenient and discreet manner on a mobile device.
- It displays a history of diet, exercise, and medication events logged by the patient.
- It is compatible with the Apple Watch™* which can display glucose values and receive system and sensor glucose (SG) alerts.

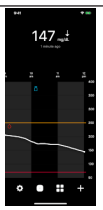
Note: The Simplera system should only be used with supported mobile devices and operating systems. Refer to the local Medtronic website or the local Medtronic support representative for information about compatible mobile devices and operating systems. The Simplera system may not be available in all regions.

Note: This user guide contains several instructions that are specific to the Android™* or iOS™* platform. Where applicable, follow the instructions specific to the platform in use. For more information on mobile device operating system settings go to https://medtronicdiabetes.com/simplera-app-settings.

CAUTION: U.S. law restricts the sale of the Simplera system to sale by or on the order of a physician.

System description

The Simplera system includes the following components:

Simplera system	
	Simplera app for iOS (MMT-8400) or Simplera app for Android (MMT-8401)
	Simplera sensor (MMT-5100J)

Continuous glucose monitoring (CGM) is a technology that lets patients continuously view glucose values. The Simplera system uses an inserted Simplera sensor with Bluetooth® wireless technology that converts small amounts of glucose from the interstitial fluid under the skin into

an electronic signal. The Simplera sensor uses that signal to provide SG values to the Simplera app on a compatible mobile device.

The Simplera app also provides alerts based on SG levels and contains a user interface for entering data such as insulin, meals, exercise, blood glucose (BG) values, and uploading information to the CareLink™ Personal website.

The Simplera app is available to download from the Apple™* App Store™* or the Google Play™* store and requires the Simplera sensor to function.

Diabetes treatment decisions

The Simplera system can be used to make diabetes treatment decisions, except during the first 12 hours of use.

Note: Use a blood glucose (BG) meter reading to make treatment decisions when you see the Check BG icon during the first 12 hours of wearing a sensor. Do not use sensor glucose (SG) readings to make treatment decisions during the first 12 hours of wearing a sensor.

SG readings can be used after the first 12 hours of wearing a sensor or when the Check BG icon no longer appears.

The following table shows the Check BG icon and its function.

Icon	Icon name	Description
	Check BG icon	Use your BG meter to check your BG and make treatment decisions during the first 12 hours of wearing a sensor.

For more information on when the user should not rely on the Simplera system for making treatment decisions, see *When to use BG meter readings, page 41*.

Intended use

The Simplera app in combination with the Simplera sensor is intended for use only by patients and caregivers using a compatible mobile device and operating system, and who have sufficient experience to adjust mobile device audio and notification settings. The system is intended to communicate with digitally connected devices for the purpose of managing diabetes.

Treatment decisions should be made based on the combination of SG readings and trend arrows. The system can track trends in glucose concentrations, and aid in detecting events of hypoglycemia and hyperglycemia and helping both current and long-term therapy decisions.

The Simplera system is intended for use in home environments.

Indications for use

The Simplera system is a real-time continuous glucose monitoring (CGM) system indicated for the management of diabetes in persons ages 18 years and older.

The Simplera system does not require calibration and is designed to replace fingerstick BG testing for diabetes treatment decisions, unless otherwise indicated.

Interpretation of the Simplera system results should be based on the glucose trends and several sequential sensor readings over time.

Intended target population

The intended target population for the Simplera system includes adults ages 18 years and older.

Intended users

The Simplera system is intended for personal use by individuals to assist in the management of their diabetes, or for use by caregivers who assist these individuals with diabetes management.

Contraindications

The Simplera system has no known contraindications.

Intended clinical benefits

The Simplera system provides information that is used for diabetes management but does not provide any direct therapy. Specifically, the low and high glucose alerts provided by the app when used in combination with the Simplera sensor may allow the user to take appropriate actions to prevent or minimize the severity of hypoglycemia and hyperglycemia.

User safety

Warnings

General

- CGM is not recommended for people who are unwilling or unable to perform blood glucose tests as required or for people who are unwilling or unable to maintain contact with their healthcare professional.
- Always consult a healthcare professional before using sensor glucose values to make treatment decisions if a medication that contains acetaminophen or paracetamol is taken while wearing the sensor. Medications that contain acetaminophen or paracetamol can falsely raise sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in the body and can differ for each person. Falsely elevated sensor readings can result in over-administration of insulin, which can cause hypoglycemia.
- Medications that contain acetaminophen or paracetamol include, but are not limited to, cold medicines and fever reducers. Check the label of any medications being taken to see if acetaminophen or paracetamol is an active ingredient. Use additional blood glucose meter readings to confirm blood glucose levels.
- Do not use continuous glucose monitoring if hydroxyurea, also known as hydroxycarbamide, is taken. Hydroxyurea is used to treat certain diseases, such as cancer and sickle cell anemia. Hydroxyurea use results in higher sensor glucose readings compared to blood glucose readings. Taking hydroxyurea while using continuous glucose monitoring can result in inaccurate or missed alerts, and substantially higher sensor glucose readings in reports than actual blood glucose readings.
- Always check the label of any medication being taken to confirm if hydroxyurea or hydroxycarbamide is an active ingredient. If hydroxyurea is taken, consult a healthcare professional. Use additional blood glucose meter readings to verify glucose levels.
- If a serious incident related to the device occurs, immediately report the incident to Medtronic and to the applicable competent authority having jurisdiction in their locale.
- Do not use the Simplera system if you are pregnant or critically ill. Since the system has not been studied in these populations, the impact of medications common to these conditions on system performance is unknown and the system may be inaccurate in these populations.

- Use a BG meter reading to make treatment decisions when you see the Check BG icon during the first 12 hours of wearing a sensor. Do not use SG readings to make treatment decisions during the first 12 hours of wearing a sensor.

App and mobile device

- Follow the instructions and safety warnings in this user guide to receive alerts. Missing alerts from the Simplera app can result in undetected low and high glucose levels.
- Always use a blood glucose meter reading to make treatment decisions if no sensor data are available or if symptoms do not match the sensor glucose value.
- Always allow notifications for the Simplera app. If notifications are turned off, the app will not send any alerts, including Urgent Low Alert.
- Do not use the Simplera app without sufficient vision and hearing, to allow recognition of the alerts sent by the app.
- Do not use the Simplera app without understanding how the mobile device settings work. If any settings are changed, the app display and notification features may not work as intended, including not receiving sensor glucose alerts or status alerts.
- Make sure Bluetooth is on, even if the mobile device is in airplane mode. If Bluetooth is off, the app will not send sensor glucose information or alerts.
- Do not use the Simplera app if the mobile device screen or speakers are damaged. If the mobile device is damaged, the app may not send sensor glucose alerts and sensor glucose information may not be shown correctly.
- Do not force close the Simplera app. If the app is closed, the app will not send sensor glucose information or alerts.
- Check the Simplera app occasionally to make sure it is running. The mobile device may close the Simplera app automatically when another app is in use, such as a game. If the Simplera app is closed, the app will not send sensor glucose alerts.
- Do not let the mobile device shut down due to low battery, or the app will not send sensor glucose alerts. Use of the app may deplete the mobile device battery more quickly. Have a charger available to charge the battery if needed.
- Always make sure to open the app after the mobile device restarts to ensure the app sends sensor glucose alerts.
- Make sure to set the snooze to a short enough time so that the app sends an alert again if glucose levels do not improve. When a sensor glucose alert is snoozed, the app will not send that alert again during the length of the set snooze time.
- Do not root or jailbreak the mobile device. Rooting the Android device or jailbreaking the iOS device means to change the software in a way the manufacturer did not intend. If the mobile device is changed in this way, the Simplera app will display an error message when launched and will not continue to operate.
- Confirm version compatibility of the Simplera app and mobile device operating system prior to updating the mobile device. Disable automatic operating system updates on the mobile device to avoid any unintentional updates that may prevent the app from operating.
- Always protect the mobile device with a passcode, face authentication, or fingerprint authentication. Sharing the passcode could compromise the security of the device.
- When power saving settings are enabled, the mobile device may delay the alerts and notifications from the Simplera app.
- Alerts for the Simplera app will sound through headphones when headphones are connected. If headphones are connected but they are not being used, sensor glucose alerts may not be heard.

Android users

- Allow **Do Not Disturb Permissions** and **Notifications** for the Simplera app. If **Do Not Disturb Permissions** or **Notifications** are turned off, the app will not send any alerts, including Urgent Low Alert.
- The **Digital Wellbeing** feature is intended to reduce alerts. If this feature is enabled, the Simplera app will not send alerts. If the app timer is set in the **Digital Wellbeing** feature for the Simplera app, the app will shut down and will not send any sensor glucose alerts when the timer expires.
- Do not lower the vibration level to the lowest setting in the Android **Vibration intensity** menu. If vibration is lowered to the lowest setting, the app will not send any vibrations with the alerts, including Urgent Low Alert.

iOS users

- Allow **Critical Alerts** and **Notifications** for the Simplera app. If **Critical Alerts** or **Notifications** are turned off, the app will not send any alerts, including Urgent Low Alert.
- The **Downtime** setting within the **Screen Time** feature is intended to prevent alerts during the **Downtime** period. If this setting is enabled, the Simplera app will be prevented from sending alerts.
- Do not modify settings in the **Accessibility** menu. Do not turn off vibration settings. If vibration is turned off, the app will not send any vibrations with the alerts, including Urgent Low Alert. Do not enable the **Assistive Access** feature. The **Assistive Access** feature may prevent the Simplera app from pairing with the sensor or displaying alerts.
- Vibrate on silent must be turned on in the iOS phone settings or the alerts, including Urgent Low, will not vibrate during Mute alerts.

Apple Watch users

- To receive sensor glucose information or alerts on the Apple Watch, ensure Bluetooth is enabled and the watch is within range of the mobile device.
- If the mobile device is damaged, the watch may not receive sensor glucose alerts. Do not use the watch if the screen or speakers are damaged.
- The Apple Watch will not vibrate for alerts from the Simplera app if **Haptic Alerts** are disabled.
- Do not disable the mirror feature for the Simplera app in the Apple Watch settings. If the mirror feature is disabled, the watch will not display any alerts, including Urgent Low Alert.
- When the watch enters Power Reserve mode or Low Battery mode, it no longer provides glucose alerts or sensor glucose information.
- If the mobile device is unlocked, sensor glucose alerts are not sent to the Apple Watch. Refer to the Simplera app on the mobile device for sensor glucose alerts.
- The Apple Watch may display connection requests. Do not accept connection requests from unknown devices.
- Always protect the Apple Watch with a passcode. Sharing the passcode could compromise the security of the device.

Sensor

- Read this entire user guide before attempting to insert the Simplera sensor. The inserter portion of the sensor does not work the same way as other Medtronic insertion devices. The sensor is not inserted the same way as other Medtronic sensors. Failure to follow directions may result in improper insertion, pain, or injury.
- Do not use continuous glucose monitoring if hydroxyurea, also known as hydroxycarbamide, is taken. Hydroxyurea is used to treat certain diseases, such as cancer and sickle cell anemia.

Hydroxyurea use results in higher sensor glucose readings compared to blood glucose readings. Taking hydroxyurea while using continuous glucose monitoring can result in substantially higher sensor glucose readings in reports than actual blood glucose readings.

- Always check the label of any medication being taken to confirm if hydroxyurea or hydroxycarbamide is an active ingredient. If hydroxyurea is taken, consult a healthcare professional. Use additional blood glucose meter readings to verify glucose levels.
- Taking medications that contain acetaminophen or paracetamol, including, but not limited to fever reducers and cold medicine, while wearing the sensor, may falsely raise SG readings. The level of inaccuracy depends on the amount of acetaminophen or paracetamol active in the body and may be different for each person. Always check the label of any medications to confirm whether acetaminophen or paracetamol is an active ingredient.
- Always examine the Simplera sensor box for damage. If the sensor box is open or damaged, examine the sensor for damage. If the sensor is visibly damaged, discard the device to avoid possible contamination.
- Do not use the Simplera sensor if any part of the device is damaged. If the device is damaged, discard the device to avoid possible contamination.
- Do not use the Simplera sensor if the tamper band is broken, damaged, or is missing from the device. The sensor is sterile and non-pyrogenic unless the device is damaged. If the tamper band is broken, damaged, or is missing from the device, the sensor and needle can be exposed to contamination. A sensor and needle exposed to contamination can cause insertion site infection if inserted into the body.
- Do not use the Simplera sensor if the cap label is broken, damaged or missing from the device. The sensor is sterile and non-pyrogenic unless the device is damaged. If the cap label is broken, damaged, or missing from the device, the sensor and the needle can be exposed to contamination. A sensor and needle exposed to contamination can cause insertion site infection if inserted into the body.
- Do not unscrew or remove the Simplera sensor cap until the device is ready to be used. Do not remove the cap and store the device for future use. The sensor is sterile and non-pyrogenic unless the cap is removed from the device or the tamper band is broken. If the cap is not on the device or the tamper band is broken, the sensor and the needle can be exposed to contamination. A sensor and needle exposed to contamination can cause insertion site infection if inserted into the body.
- Do not remove the cap and place it back on the device. Placing the cap back on the device could cause damage to the needle, prevent a successful insertion, and cause injury.
- Do not change or modify the Simplera sensor. Changing or modifying the sensor can result in improper insertion, pain, or injury.
- Do not let children hold the Simplera sensor without adult supervision. Do not let children put any part of the Simplera sensor in their mouth. This product poses a choking hazard for young children that can result in serious injury or death.
- Watch for bleeding at the insertion site on top of the Simplera sensor. If bleeding occurs, apply steady pressure with a sterile gauze pad or clean cloth placed on top of the sensor for up to three minutes. If bleeding continues, is significantly visible on top of the sensor, or if there is excessive pain or discomfort after insertion, follow these steps:
    1. Remove the Simplera sensor and continue to apply steady pressure until the bleeding stops.
    2. Dispose of the Simplera sensor. See *Disposal, page 47*.
    3. Check the site for redness, bleeding, irritation, pain, tenderness, or inflammation. If there is redness, bleeding, irritation, pain, tenderness, or inflammation, contact a healthcare professional.
    4. Insert a new Simplera sensor in a different location.

- Report any adverse reactions associated with the Simplera sensor to 24-Hour Technical Support. Adverse reactions can cause serious injury.

Precautions

Diabetes treatment decisions should be made based on a combination of SG readings, trend arrows, glucose target ranges, active alerts, and recent events (such as insulin doses, exercise, meals, and medications).

Using CGM information to make treatment decisions

After becoming familiar with CGM, treatment decisions should be made based on all the information available, including the following:

- SG readings
- Trend arrows
- Active SG alerts
- Recent events such as insulin doses, medication, meals, exercise, etc.

Consult a healthcare professional to determine the right glucose target ranges.

Sensor

- Do not use the Simplera sensor adjacent to other electrical equipment that may cause interference with normal system operation. For more information on electrical equipment that may cause interference with normal system operation, see *Exposure to magnetic fields and radiation, page 17*.
- Some skin care products, such as sunscreens and insect repellents, can damage the Simplera sensor. Do not allow skin care products to touch the sensor. Wash hands after using skin care products before touching the sensor. If any skin care products touch the sensor, immediately wipe the sensor with a clean cloth.

Exposure to magnetic fields and radiation

- Do not expose the Simplera sensor to Magnetic Resonance Imaging (MRI) equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, CT scan, or other types of radiation). Exposure to strong magnetic fields can cause the sensor to malfunction, result in serious injury, or be unsafe.

IEC 60601-1-2; Special EMC Precautions for Medical Electrical Equipment

1. Special Precautions regarding Electromagnetic Compatibility (EMC): This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment where common levels of radiated "E" (V/m) or "H" fields (A/m) exist, such as cellular phones, Wi-Fi, Bluetooth wireless technology, electric can openers, microwave and induction ovens. This device generates, uses, and can radiate RF energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.
2. Portable and mobile RF communications equipment can affect medical electrical equipment. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that causes the interference.
3. Be careful when using the sensor closer than 12 in (30 cm) to portable RF equipment or electrical equipment. If the sensor must be used next to portable RF equipment or electrical equipment, observe the sensor to verify correct system operation. Degradation of the performance of the sensor could result.

Risks and side effects

General risks with the sensor include the following:

- Skin irritation or other reactions
- Bruising
- Discomfort
- Redness
- Bleeding
- Pain
- Rash
- Infection
- Raised bump
- Appearance of a small "freckle-like" dot where the sensor was inserted
- Allergic reaction
- Fainting secondary to anxiety or fear of needle insertion
- Soreness or tenderness
- Swelling at insertion site
- Sensor filament breakage or damage
- Minimal blood splatter associated with sensor needle removal
- Residual redness associated with adhesive or tapes or both
- Scarring

Failure to use the Simplera app according to the instructions for use may result in hypoglycemia or hyperglycemia. If your glucose alerts and sensor glucose readings do not match your symptoms, or if no sensor data are available, use a fingerstick blood glucose value from your blood glucose meter to make diabetes treatment decisions. Seek medical attention when appropriate. Consult a healthcare professional about how to use the information displayed on the app to help manage your diabetes.

Allergens

The Simplera sensor contains nickel in stainless steel.

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 the 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.

Assistance

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

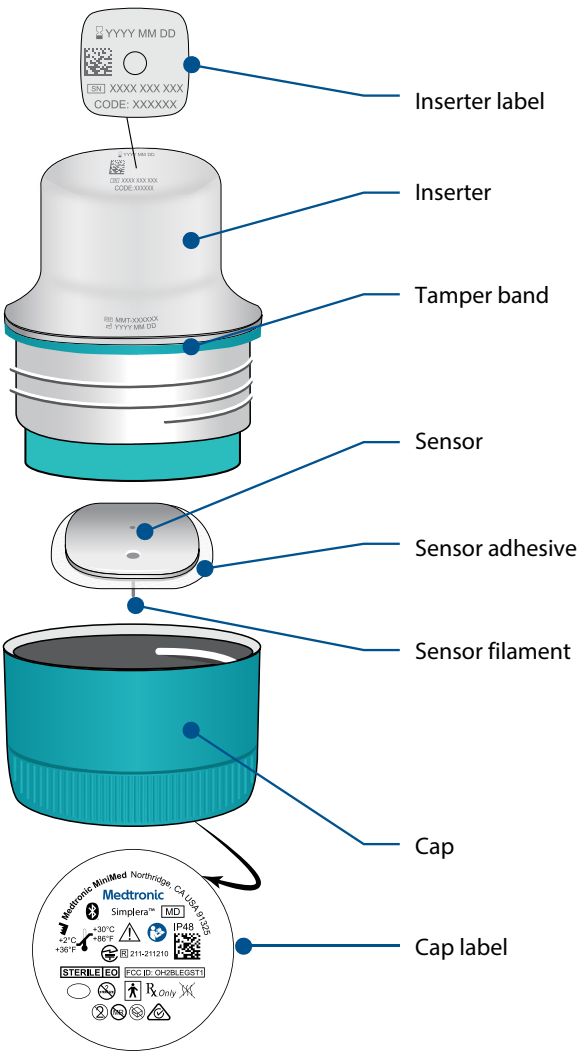
Department	Telephone number
24-Hour Technical Support (calls within the United States)	800 646 4633

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

Simplera app setup

Search for and download the Simplera app from the Apple App Store or Google Play store on the supported mobile device. To set up the Simplera app, follow the instructions on the screen.

Simplera sensor device components

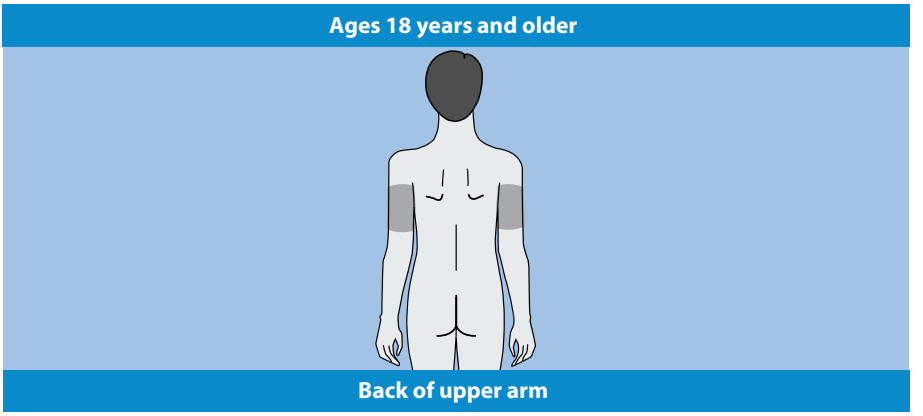


New sensor setup

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

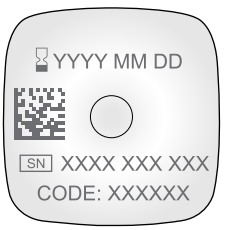
Where to insert the Simplera sensor

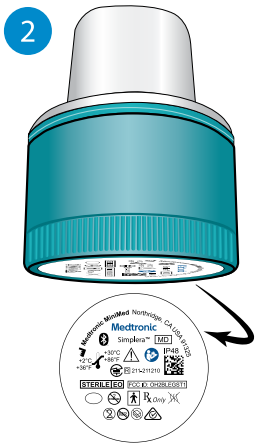
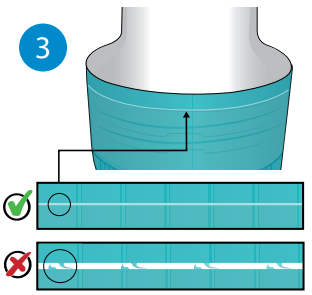
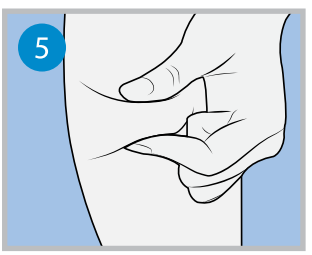
The image that follows shows the insertion site for ages 18 years and older. Target the shaded areas shown in the image, and make sure that the insertion site has a sufficient amount of fat.

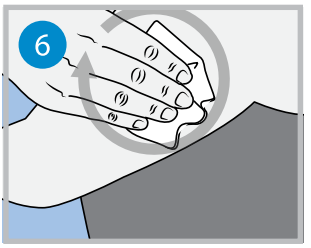


Insertion on abdomen and upper buttocks for ages 18 years and older has not been evaluated for accuracy.

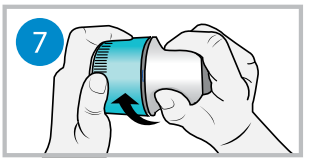
Inserting the Simplera sensor

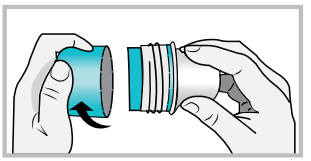
Preparing for insertion	
1 	The inserter label is on the top of the inserter. 1. Before insertion, perform the following steps: • Inspect the expiration date. Do not use an expired Simplera sensor. • Make note of the serial number (SN) and the CODE. Both numbers will be used later to pair the sensor with the Simplera app. **Note:** The SN and CODE label is also on the inside of the Simplera sensor box lid.

	2. Inspect the cap label for damage before insertion. **Note:** Do not use the Simplera sensor if the cap label is damaged or missing from the cap.
	3. Inspect the tamper band to make sure that it is not broken, damaged, or missing from the device. **Note:** Do not use the Simplera sensor if the tamper band is broken, damaged or missing.
	4. Wash hands thoroughly with soap and water. **Note:** Wear gloves when inserting the Simplera sensor into another person to avoid accidental contact with patient blood. Minimal bleeding can occur.
	5. Choose an insertion site that has a sufficient amount of fat. For the insertion site, see *Where to insert the Simplera sensor, page 20*. For the best sensor performance, and to avoid accidental sensor removal, do not insert the Simplera sensor into the following areas: • muscle, tough skin, or scar tissue • areas that are constrained by clothing or accessories • areas subjected to rigorous movement during exercise



6. Clean the insertion site with alcohol. Allow the insertion site to air dry.

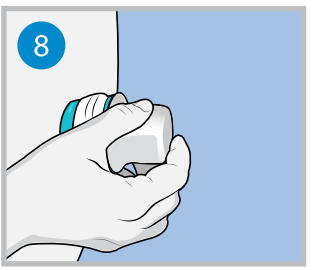




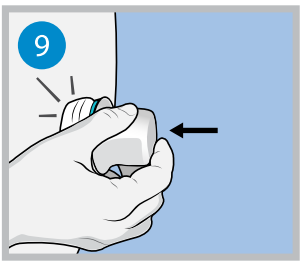
7. Unscrew the cap from the inserter, breaking the tamper band.

Note: Do not use the Simplera sensor if the tamper band is broken, damaged, or missing.

Insertion

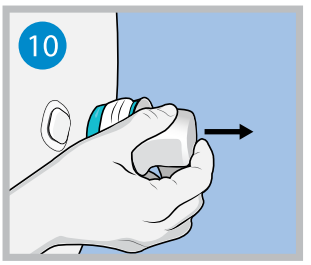


8. Place the inserter on top of the prepared insertion site.

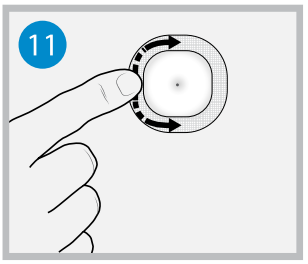
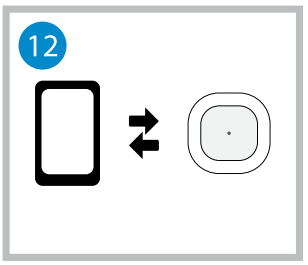


9. Press the inserter firmly against the body until there is a click.

After insertion



10. Gently pull the inserter straight from the body.

	11. Smooth down the sensor adhesive with a finger to ensure the sensor stays on the body for the entire duration of use. **Note:** Use over-the-counter tape if desired for additional adhesion.
	12. Pair the Simplera sensor with a compatible mobile device. **Note:** The SN and CODE are required to pair the sensor with a compatible mobile device. For details on how to pair the sensor with a compatible mobile device and the Simplera app, see *Pairing the Simplera sensor, page 23*.

Pairing the Simplera sensor

The Simplera sensor must be paired to the compatible mobile device before use. Follow the on-screen instructions to pair the sensor to the mobile device.

Completing the app setup

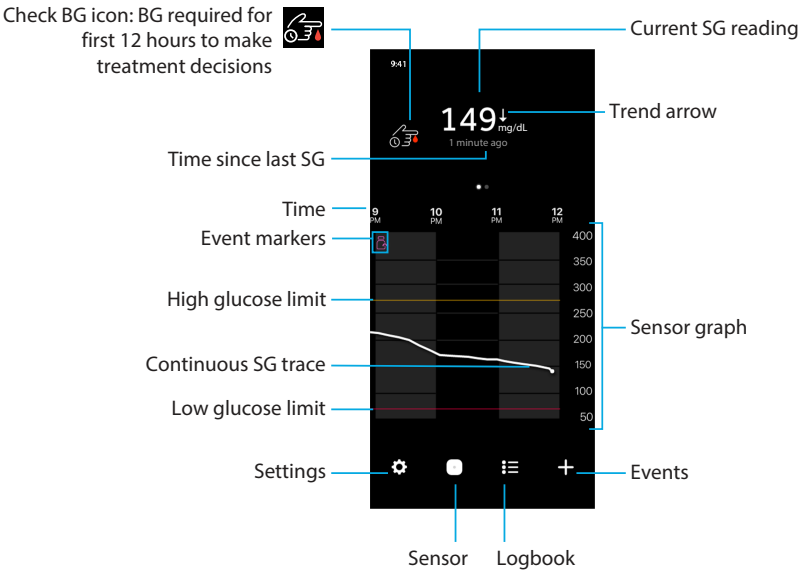
Continue to follow the on-screen instructions to enable notifications. For more information, see *Glucose alerts information, page 31*.

Note: Use a BG meter reading to make treatment decisions when you see the Check BG icon during the first 12 hours of wearing a sensor. Do not use SG readings to make treatment decisions during the first 12 hours of wearing a sensor.

Home screen

The following figure shows the Home screen of the app.

For more information on the icons involved when completing these steps, see *Table 1, page 24*.



Note: This screen may vary depending on the mobile device and platform.

Note: The Home screen does not display sensor information the first time the app is opened. The first SG reading appears after the sensor is successfully paired and warm-up is complete.

Table 1. Home screen icons

Icon	Item	Description
	Check BG icon: BG required for first 12 hours to make treatment decisions	This icon indicates that a blood glucose (BG) meter reading is needed to make treatment decisions. This icon will be displayed on the Home screen in the first 12 hours of use. When you see this icon, always use a BG meter reading when making treatment decisions. Do not use SG readings to make treatment decisions during the first 12 hours of wearing a sensor.
	Trend arrows	Display the glucose trend and the rate at which the most recent SG level has risen or fallen. For details on how to set the rate of change for falling and rising SG values, see *Glucose alerts, page 33*.
See *Table 3, page 38* for Event icons.	Event marker	Displays an icon for specific events, such as exercise, BG readings entered, carbs eaten, or insulin taken.
	Settings	Displays the Settings screen to customize additional features, such as Alert Volume, Mute alerts, Glucose Alerts, CareLink, Units, and provides access to the user guide, getting started guide, and Help.
	Sensor	Displays the Simplera system status information and allows the user to replace a sensor or unpair a sensor. For details, see *Sensor screen, page 28*.

Table 1. Home screen icons (continued)

Icon	Item	Description
	Logbook	Displays up to 30 days of logs, events, and alerts in chronological order.
	Events	Displays the Events screen to enter additional information for exercise, carbs, or insulin taken. For details, see *Sensor screen, page 28*.

Table 2. Home screen features

Item	Description
Current SG reading	Displays the current SG reading, which the sensor calculates and sends wirelessly to the app.
Time since last SG	Displays the time since the last SG reading that the sensor has sent wirelessly to the app.
Continuous SG trace	Displays current and previous SG readings. Tap any point on the graph to view the details of the selected SG reading or event. For more navigation tips, see *Sensor graph, page 37*.
Time	Displays preset time intervals of 3, 6, 12, and 24 hours.
High glucose limit and low glucose limit	Displays a line indicating the high and low SG limits on the sensor graph. The orange line indicates the high SG limit; the red line indicates the low SG limit.
Sensor graph	Displays a white line representing SG readings over a selected time interval. It also indicates high and low SG limits. For details on the sensor graph, see *Sensor graph, page 37*.

Time in range

The Time in range graph shows the percentage of time you spent in and out of a set SG range. This SG range is preset in the Simplera app and cannot be changed.

The preset SG range is 70 to 180 mg/dL.

The **orange** section shows the percent of time that you spent above 180 mg/dL during the past 24 hours.

The **green** section shows the percent of time that you spent between 70 and 180 mg/dL during the past 24 hours.

The **red** section shows the percent of time that you spent below 70 mg/dL during the past 24 hours.

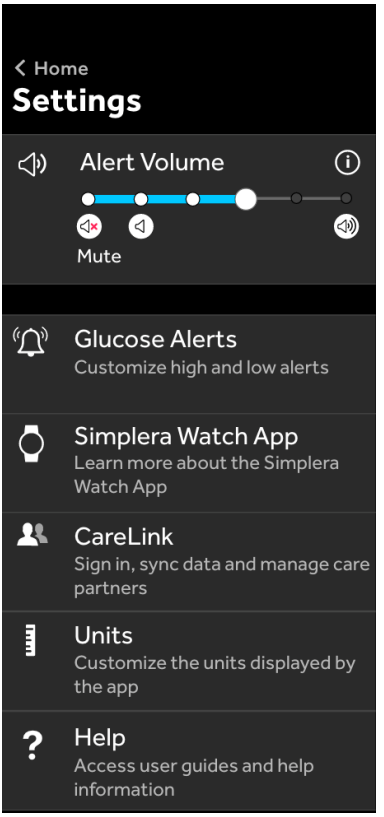
Your average SG reading is shown at the bottom of the screen.

A Not enough data message is shown if there is no sensor data for the past 24 hours.

Settings screen

Tap ⚙ to see the Settings screen.

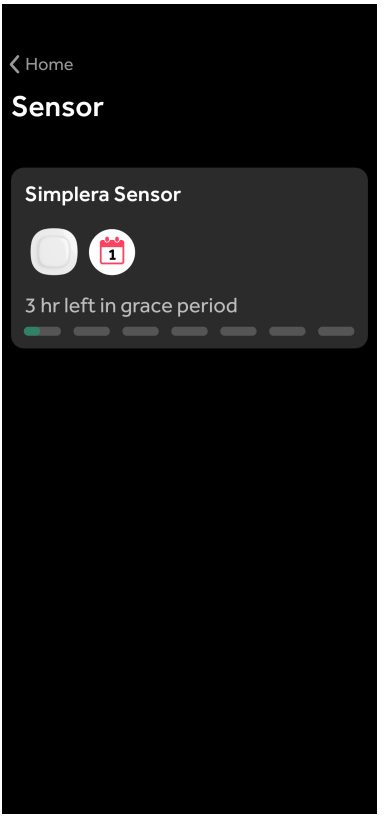
For more information on the icons involved when completing these steps, see *Table 1, page 24*.



Item	Description
Home	Closes the Settings screen and returns to the Home screen.
Alert Volume	Allows the option to adjust the volume of alerts. Alerts will sound louder and repeat if not acknowledged. For details, see *Glucose alerts information, page 31*.
Alert Volume information	Displays a description of Alert Volume slider and Mute alerts. For details, see *Glucose alerts information, page 31*.
Mute alerts	Allows the option to Mute alerts for a specified duration. Urgent Low Alert will vibrate. For details, see *Glucose alerts information, page 31*. **Note:** Urgent Low Alert will not vibrate if vibration is turned off in the iOS Accessibility menu or lowered to the lowest setting in the Android Vibration intensity menu.
Glucose Alerts	Display the options to set glucose monitoring alerts. For details, see *Glucose alerts information, page 31*.
CareLink	Provides access to a menu to change the CareLink user login information.
Units	Allows the option to display glucose in mg/dL or mmol/L. **Note:** This feature may not be available in all regions.
Help	Provides the user with software version information, access to the user guide, getting started guide, setup wizard, and the end user license agreement.

System status icons

The status icons appear on the Sensor screen. These icons provide a way to quickly check the status of the sensor. If any condition becomes critical and requires immediate attention, the corresponding status icon is also displayed on the Simplera app Home screen. The icons displayed on the Home screen are interactive and provide more information about the current status.

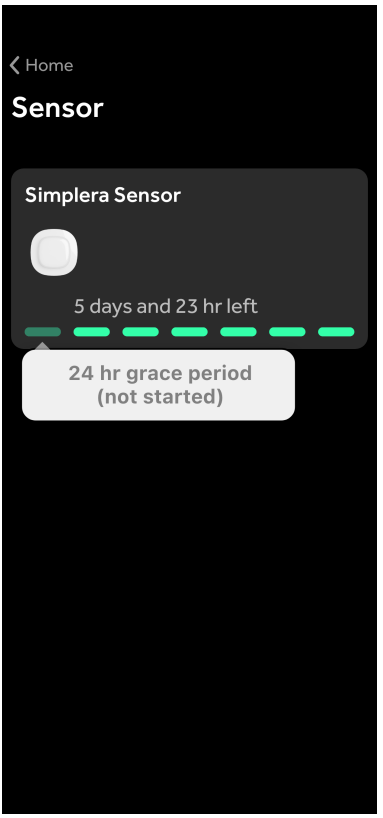


Icon	Icon name	Description
	Sensor life	Indicates there is fewer than one day left of overall sensor life. Overall sensor life includes up to six-days sensor wear followed by a grace period of 24 hours.
	Sensor expired	The sensor has expired and must be replaced.
	Communication error	Indicates there is a communication error, the sensor is not paired to the mobile device, or Bluetooth is off.
	General error	Indicates a general error.

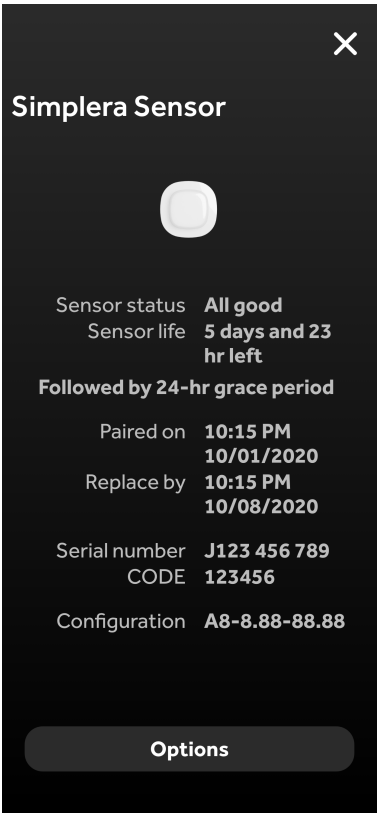
Sensor screen

Tap ▢ at the bottom of the Home screen to see the Sensor screen. This screen displays the sensor status as well as status icons.

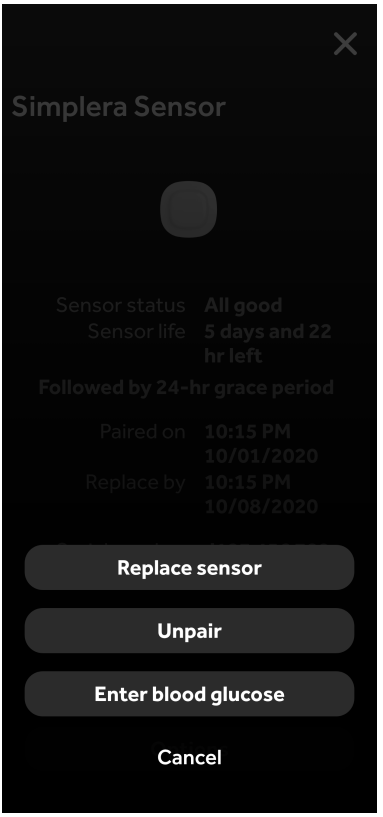
For more information on the icons involved when completing these steps, see *Table 1, page 24*.



Tap ▢ to see sensor information.



Tap **Options** to show the menu.



Item	Description
Sensor status	Sensor events or error messages are displayed.
Sensor life	The time remaining until the sensor must be replaced is displayed.
Grace period	An extra period of 24 hours after your six days of sensor wear. This grace period allows you more time to change your sensor. During this time, your sensor will work like normal.
Paired on	The time and date the sensor was last paired is displayed.
Replace on	The estimated time and date when the sensor must be replaced is displayed.
Replace sensor	Allows the addition of a new sensor.
Unpair	Provides directions to unpair a sensor from the mobile device settings.
Enter blood glucose	Shows the screen that allows entry of blood glucose values.
Cancel	Returns to the previous screen.

Note: The Bluetooth devices list in the mobile device will grow as new sensors are paired. Periodically review the list and remove old sensors. Avoid removing the currently paired sensor from the list, or it will need to be paired again in the app. The current sensor will appear in the paired devices list, or it will show that it is connected.

Enter blood glucose as an optional calibration

While the Simplera system does not require calibration, the Simplera app gives the option to enter BG meter readings as an optional calibration. Enter the BG meter reading into the app immediately after checking BG. Review the BG meter instructions for guidance on how to check the BG.

- Always make sure hands are clean before testing BG.
- Avoid use of an old BG reading or reuse of BG readings from previous calibrations.
- If for some reason calibration is unsuccessful, wait at least 15 minutes before attempting another calibration.
- If glucose levels are rising or falling rapidly, avoid use of BG readings for calibrations.

For more information on the icons involved when completing these steps, see *Table 1, page 24* and *Table 3, page 38*.

To enter an optional calibration into the Sensor screen:

1. Measure the BG with a BG meter.
2. Tap ⦾ in the lower center of the Home screen to see the Sensor screen.
3. Tap on the sensor card to see the sensor details.
4. Tap **Options** to show the menu.
5. Tap **Enter blood glucose**.
6. Use the number pad to enter the BG meter reading.
7. 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.
8. To calibrate the sensor with the entered BG meter reading, tap **Calibrate**. The app returns to the Home screen, and ◆ appears on the graph at the selected time.

To enter an optional calibration into the BG Event screen:

1. See *Entering BG meter readings, page 39* and follow the steps to log the most recent BG meter reading into the app.
2. Tap **Yes** to calibrate your sensor on the displayed pop up.

Alerts

The Simplera app provides **glucose alerts** and **system status alerts**. These alerts provide information about glucose levels and the status of the Simplera system.

Glucose alerts information

Set **glucose alerts** for the following situations:

- SG values are rising or falling faster than the set limits
- SG values have gone above or below the set limits
- SG values are predicted to go above or below the set limits

The **glucose alerts** in the Simplera system are listed in the following table:

Alert type	Description
High Alert	SG values have gone above the set high limit.
High predicted	The SG value is predicted to go above the set high limit, within a set period of time (up to 60 minutes ahead).
Rise Alert	The SG value is rising faster than the set rate (corresponding to the rising arrows displayed next to the SG level).

Alert type	Description
Low Alert	The SG value has gone below the set low limit.
Low predicted	The SG value is predicted to go below the set low limit, within a set period of time (up to 60 minutes ahead).
Fall Alert	The SG value is falling faster than the set rate (corresponding to the falling arrows displayed next to the SG level).
Urgent Low Alert	The SG level is at 63 mg/dL or below.

Note: If the Simplera app detects that alerts are disabled, the app will not send any alerts, including the Urgent Low Alert.

Glucose alerts can be customized and are set up as described in *Glucose alerts, page 33*.

System status alerts

The Simplera system also has system **status alerts** that provide information 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, page 44*.

The **status alerts** in the Simplera system are listed below:

Make sure to act on these alerts to continue to receive SG information in the future.

Alert type	Description
Mobile device battery low	The mobile device battery has reached or fallen below 20% of its power.
Sensor warmup	The sensor is warming up. This will take 2 hours.
Calibration not accepted	The BG meter value could not be used to calibrate.
Change sensor	The sensor is not working properly and needs to be replaced.
Lost communication	The app and sensor have not been communicating for 30 minutes. The app may have closed if there are too many apps running at the same time or if there is radio frequency interference.
Insufficient battery	The sensor has insufficient battery. Change the sensor.
Sensor end of life	The sensor has reached its maximum life of 6 days + 24 hours grace period. The Simplera app is no longer receiving sensor information. Insert a new sensor.
Sensor updating	The sensor is updating. Updating can take up to 2 hours. SG readings will not be available during this time. Measure the BG value with the meter.
Connection error	The sensor is trying to reconnect. Wait at least 30 minutes.
Jailbroken device detected	The software on the iOS mobile device has been changed such that it no longer works in the way the manufacturer intended. The app cannot be used with a jailbroken device. Changing the mobile device operating software causes the app to stop working.
Rooted device detected	The software on the Android mobile device has been changed such that it no longer works in the way the manufacturer intended. The app cannot be used with a rooted device. Changing the mobile device operating software causes the app to stop working.

Glucose alerts

Setting low alerts

Low alert settings include the following:

Low alert setting	Description
Day Starts at	Set when the day begins, what the low limit is during the day, and when the app should send alerts at this setting.
Night Starts at	Set when the night begins, what the low limit is during the night, and when the app should send alerts at this setting.
Low Limit	The Low Limit is the SG value on which the other low settings are based. The low limit can be set from 65 to 90 mg/dL. On the SG graph, the low limit appears as a red horizontal line at the set value.
Don't alert me	When Don't alert me is selected, the app will not send any alerts for low glucose. The app still sends an Urgent Low Alert since this alert is always on.
At Low Limit	When At Low Limit is selected, the system displays a Low Sensor Glucose alert when the SG value reaches or falls below the low limit.
Before Low Limit	When Before Low Limit is selected, the app sends a Low predicted alert any time the SG is predicted to reach the low limit. This alert notifies of potential low glucose levels before they occur.
Before and at Low Limit	When Before and at Low Limit is selected, the app sends a Low predicted alert any time the SG is predicted to reach the low limit and when the SG value reaches or falls below the low limit.
Time Before Low	Time Before Low is available only when Before Low Limit or Before and at Low Limit is selected. Time Before Low determines when the app will send a Low predicted alert, if the SG values continue to decrease at the current rate of change. The option is available to set a time between ten minutes and one hour.
Max Volume at Night	Max Volume at Night is available only in the Night Time section and when Alert Me is selected. Toggle **Max Volume at Night** on for low alerts to make all low alerts sound at max volume at night.

For more information on the icons involved when completing these steps, see *Table 1, page 24* and *Table 3, page 38*.

To set low alerts:

1. On the Home screen, tap ⚙ and select **Glucose Alerts** > **Low Alerts**.
2. Tap **Day starts at** and set the desired start time. Tap **Save**.
3. Tap **Low Limit** and set the desired limit between 65 and 90 mg/dL. Tap **Save**.
4. To receive alerts when the SG value approaches the low limit, tap **Alert Me** and choose one of the following:
    a. At Low Limit
    b. Before Low Limit
    c. Before and at Low Limit
5. If **Before Low Limit** or **Before and at Low Limit** is selected, the **Time Before Low** appears. Set the desired duration of time to receive a Low predicted alert and tap **Save**.
6. Return to the Low Alerts screen and tap **Night starts at**. Set the desired start time and tap **Save**. Repeat steps 3 through 5 to set night time alerts.

7. Toggle **Max Volume At Night** on or off. When **Max Volume At Night** is toggled on, the low alerts sound at max volume at night.
8. When the alerts are set up, tap ◀ to return to the Glucose Alerts screen.
9. Tap ◀ to return to the Settings screen.
10. Tap ◀ to close the menu and return to the Home screen.

Setting high alerts

High alert settings include the following:

High alert setting	Description
Day Starts at	Set when the day begins, what the high limit is during the day, and when the app should send alerts at this setting.
Night Starts at	Set when the night begins, what the high limit is during the night, and when the app should send alerts at this setting.
High Limit	The high limit is the SG value on which the other high settings are based. The high limit can be set from 100 to 400 mg/dL. On the SG graph, the high limit appears as an orange horizontal line at the set value.
Don't alert me	When Don't alert me is selected, the app does not send any alerts for high glucose.
At High Limit	When At High Limit is selected, the system displays a High Sensor Glucose alert when the SG value reaches or exceeds the high limit.
Before High Limit	When Before High Limit is selected, the app sends a High predicted alert any time the SG value is predicted to reach the high limit. This notifies of potential high glucose levels before they occur.
Before and at High Limit	When Before and at High Limit is selected, the app sends a High predicted alert any time the SG is predicted to reach the high limit and when the SG value reaches or rises above the high limit.
Time Before High	The Time Before High option is available only when Before High Limit or Before and At High Limit is selected. This option determines when the app sends a High predicted alert if the SG values continue to increase at the current rate of change. Set a time between ten minutes and one hour.
Max Volume at Night	Max Volume at Night is available only in the Night time section and when Alert Me is selected. Toggle **Max Volume at Night** on for high alerts to make all high alerts sound at max volume at night.

For more information on the icons involved when completing these steps, see *Table 1, page 24* and *Table 3, page 38*.

To set high alerts:

1. On the Home screen, tap ⚙ and select **Glucose Alerts** > **High Alerts**.
2. Tap **Day starts at** and set the desired start time. Tap **Save**.
3. Tap **High Limit** and set the desired limit between 100 and 400 mg/dL. Tap **Save**.
4. To receive alerts when the SG value approaches the high limit, tap **Alert Me** and choose one of the following:
    a. At High Limit
    b. Before High Limit
    c. Before and at High Limit

5. If **Before High Limit** or **Before and at High Limit** is selected, the **Time Before High** appears. Set the desired time to receive a High predicted alert and tap **Save**.
6. Return to the High Alerts screen and tap **Night starts at**. Set the desired start time and tap **Save**. Repeat steps 3 through 5 to set night time alerts.
7. Toggle **Max Volume At Night** on or off. When **Max Volume At Night** is toggled on, high alerts sound at max volume at night.
8. When the alerts are set up, tap ◀ to return to Glucose Alerts screen.
9. Tap ◀ to return to the Settings screen.
10. Tap ◀ to close the menu and return to the Home screen.

Setting rate alerts

Rate alerts notify when the SG value is rising (Rise Alert) or falling (Fall Alert) equal to or faster than the set rate. These alerts help to understand how glucose levels are affected, for example, by carbs or exercise.

On the Home screen, these fall or rise rates are indicated by arrows, as shown in *Home screen, page 23*. The more arrows, the faster the rate of change.

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

For more information on the icons involved when completing these steps, see *Table 1, page 24* and *Table 3, page 38*.

To set rate alerts:

1. On the Home screen, tap ⚙ and select **Glucose Alerts** > **Fall & Rise Alerts**.
2. Toggle **Fall Alert** on.
3. Tap the arrow option with the desired fall rate.
4. Toggle **Rise Alert** on.
5. Tap the arrow option with the desired rise rate.
6. When fall and rise alerts are set up, tap ◀ to return to Glucose Alerts screen.

Setting alert snooze time

The snooze feature gives the option to set a snooze time to delay the repeating of alert notifications. If an acknowledged alert condition still persists after the set snooze time, the app will send another notification of the alert. The set snooze time for high and rise alerts may be different from the set snooze time for low and fall alerts.

For more information on the icons involved when completing these steps, see *Table 1, page 24* and *Table 3, page 38*.

To set the alert snooze time:

1. On the Home screen, tap ⚙, and select **Glucose Alerts** > **Snooze Time**.
2. Tap **Low & Fall Alerts** and set the desired snooze time for low and fall alerts. Tap **Save**.
3. Tap **High & Rise Alerts** and set the desired snooze time for high and rise alerts. Tap **Save**.

Adjusting alert volume

All Simplera app alerts sound at the volume set in the app. Alerts sound louder and repeat if not acknowledged.

For more information on the icons involved when completing these steps, see *Table 1, page 24* and *Table 3, page 38*.

To adjust alert volume:

1. On the Home screen, tap ⚙.
2. At the top, there is a slider. Swipe left and right to adjust the volume.

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

Muting alerts

All Simplera app alerts will be muted for the selected time. Urgent Low Alert will vibrate.

For more information on the icons involved when completing these steps, see *Table 1, page 24* and *Table 3, page 38*.

To mute alerts:

1. On the Home screen, tap ⚙.
2. Tap **Mute** under alert volume and 4 options will appear.
    a. 30 min
    b. 1 hour
    c. 6 hours (max)
    d. Custom

    If Custom is selected, adjust the mute time to the desired length and tap **Mute**.
3. A popup message appears to confirm the alerts are muted. To cancel the mute, tap **Cancel Mute**.

Acting on Simplera app alerts

The Simplera app sends alerts, similar to notifications sent from other apps on the mobile device. All alerts vibrate according to the mobile device vibration settings.

Open the Simplera app to address an alert. Dismissing the notification only removes it from the list of notifications on the mobile device. If the notification is dismissed from the mobile device, but isn't acted on it in the Simplera app, the alert may repeat.

The alert is displayed on the screen when the app is opened. Select **OK** to clear system status alerts. For SG alerts, swipe the alert up, which will snooze the alert for the set snooze period.

Sensor graph

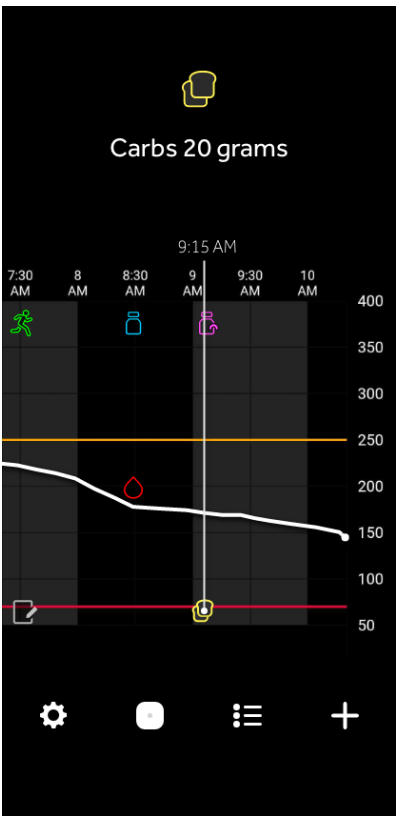
The sensor graph displays the current SG reading. It also gives the option to view a history of SG readings and entered events.

Navigating through the SG 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 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 gives the option to view the details of the selected SG reading or event in an information box that appears above the graph. For details, see *Graph information boxes, page 37*.
- Double tap the vertical SG values axis to the right of the graph to return to the current SG reading displayed on the graph.

Graph information boxes

Tap on the graph to view information about an event or SG reading. The tapped time is marked by a vertical cursor on the graph, and a box with the information about the tapped event or SG reading appears above the graph. The following figure provides an example:



For SG readings, information boxes display the SG value, its date and time, and trend arrows, similar to the current SG value information displayed on the Home screen. If there is no SG value for the selected time point, the information box displays the sensor status message for that point.

For event markers, information boxes display the details specific to each event type. For details, see *Events screen, page 38*.

Drag the cursor across the graph, to skip at five-minute intervals, to pinpoint a specific SG value on the graph.

Information boxes appear for a few seconds and then close.

Logbook screen

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.

For more information on the icons involved when completing these steps, see *Table 1, page 24*.

To view Logbook entries:

1. On the Home screen, tap to 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. To view the entire list, select **all**.
   - Swipe down and up on the list to view the entries.
   - To delete an event entry, swipe it left and tap **Delete**.

     Note: Alerts or calibration events cannot be deleted.
   - Tap the desired entry to expand it and view the details.

Events screen

Events help capture information that may affect glucose levels. Use the Events screen on the app to enter and save certain types of events.

Table 3. Events screen

Event icon	Event name	Description
	Blood Glucose	The Blood Glucose marker represents the BG meter readings.
	Rapid acting insulin	The Rapid acting insulin marker represents the type and amount of insulin delivered.
	Long acting insulin	The Long acting insulin marker represents the type and amount of insulin delivered.
	Carbs	The Carbs marker represents the amount of carbohydrates consumed, either with food or drink.

Table 3. Events screen (continued)

Event icon	Event name	Description
	Exercise	The Exercise marker represents the intensity and duration of exercise routine.
	Note	The Note marker represents other information relevant to diabetes management. For example, a record of other medications taken, illness, or stress.

Note: Make it a practice to enter events when they happen. Events can be deleted and entered again.

Entering BG meter readings

The app gives the option to enter BG meter readings. For example, if measuring BG when eating or when the SG value is rising or falling rapidly, enter the BG meter reading into the app.

Note: Enter a BG value between 10 mg/dL and 600 mg/dL into the Events screen.

For more information on the icons involved when completing these steps, see *Table 1, page 24* and *Table 3, page 38*.

To enter a BG meter reading:

1. Measure the BG with a BG meter.
2. At the bottom of the Home screen, tap +.
3. Tap on the Events screen.
4. Use the number pad to enter the BG meter reading.
5. 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.
6. Tap **Log** at the bottom of the screen. The app returns to the Home screen, and appears on the graph at the selected time.

Note: A pop up to optionally calibrate your sensor with the BG meter reading may appear. Tap **Yes** to calibrate your sensor or **No** to dismiss the pop up. See *Enter blood glucose as an optional calibration, page 31*.

Entering insulin injection information

If delivering insulin using an insulin pump, insulin pen, or a syringe, use the app to record the amount of insulin injected.

For more information on the icons involved when completing these steps, see *Table 1, page 24* and *Table 3, page 38*.

To enter the amount of rapid acting insulin injected:

1. Make a note of the amount of insulin taken.
2. At the bottom of the Home screen, tap +.

3. Tap on the Events screen.
4. To change the date or time for the entry, tap **now** and make the appropriate changes.
5. Use the number pad to 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 **Log** at the bottom of the screen. The app returns to the Home screen, and appears on the graph at the selected time.

To enter the amount of long acting insulin injected:

1. Make a note of the amount of insulin taken.
2. At the bottom of the Home screen, tap .
3. Tap on the Events screen.
4. To change the date or time for the entry, tap **now** and make the appropriate changes.
5. Use the number pad to 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 **Log** at the bottom of the screen. The app returns to the Home screen, and appears on the graph at the selected time.

Entering carbohydrate information

Use the app to record information about the carbohydrates consumed.

For more information on the icons involved when completing these steps, see *Table 1, page 24* and *Table 3, page 38*.

To enter carbohydrate information:

1. Determine the total amount, in grams, of carbohydrates in the planned meal, snack, or drink.
2. At the bottom of the Home screen, tap .
3. On the Events screen, tap .
4. To change the date or time for the entry, tap **now** and make the appropriate changes.
5. Use the number pad to enter the amount of carbohydrates 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 **Log** at the bottom of the screen. The app returns to the Home screen, and appears on the graph at the selected time.

Entering exercise information

Use the app to enter information about exercise regimen. Make sure to be consistent and enter the marker either before or after each period of exercise.

For more information on the icons involved when completing these steps, see *Table 1, page 24* and *Table 3, page 38*.

To enter exercise information:

1. Make a note about the length of time 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. To change the date or time, tap **now** and set the desired day and time for this exercise entry. After tapping **OK**, set the exercise duration and tap **OK** to save the changes.
5. Tap **High**, **Medium**, or **Low** to indicate the intensity of exercise.
6. Tap **Log** at the bottom of the screen. The app returns to the Home screen, and appears on the graph at the selected time.

Entering notes

Use the app to enter events other than BG measurements, insulin injections, carbohydrates consumed, and exercise information. For example, record information such as when medications are taken, illness, or stress.

For more information on the icons involved when completing these steps, see *Table 1, page 24* and *Table 3, page 38*.

To enter notes:

1. At the bottom of the Home screen, tap .
2. On the Events screen, tap .
3. Use the text field to enter the relevant information.
4. To change the date or time, tap **now**. Tap **OK** to save the changes.
5. Tap **Save** at the top of the screen. The app returns to the Home screen, and appears on the graph at the selected time.

Before using SG readings to make treatment decisions

Before using SG readings to make treatment decisions, consult with the healthcare professional to do the following:

- Develop a diabetes management plan
- Determine personal glucose target ranges

If the SG readings do not match symptoms, use a BG meter reading to confirm the SG value. If SG readings continue to be different than symptoms, consult the healthcare professional about how to use SG readings to help manage diabetes.

In the first 12 hours, this system requires the use of a BG meter reading. Check your home screen to make sure that the Check BG icon is no longer present before using SG to make treatment decisions.

When to use BG meter readings

In the following conditions, use the BG meter readings to make treatment decisions.

- **When you see this icon**.

  In the first 12 hours of sensor use, a BG meter reading is needed when making treatment decisions. When you see the Check BG icon, do not use SG to make treatment decisions during the first 12 hours of wearing a sensor.
- **The medication taken contains paracetamol or acetaminophen**.

  Wait to use the SG reading to make treatment decisions until no longer taking medication. Medication that contains paracetamol or acetaminophen used to reduce fevers or treat cold and flu symptoms, can falsely raise SG readings.
- **The most recent SG reading is unavailable**.

If a new sensor is inserted or the Sensor updating message is displayed the SG reading will be unavailable. Check the BG value with a BG meter reading, and use the BG reading to make treatment decisions until sensor readings are available.

- **Symptoms do not match the SG value**.

  Check the BG value with a BG meter reading before using the SG value to make treatment decisions.

  CAUTION: Only use blood from fingertips to check BG levels. Do not use any other part of the body to obtain blood to test BG.

  – Always make sure hands are clean before testing BG.
  – Avoid use of an old BG reading or reuse of BG readings.

Note: The Simplera app contains a feature which provides alerts prior to SG levels reaching a set high or low limit. SG readings can vary from actual BG readings, therefore there may be situations when alerts are displayed and BG levels have not reached the set high or low limit. Consult the healthcare professional for actions and adjustments to alerts. There may also be situations when BG levels have reached the set high or low limit without any alerts displayed on the Simplera app. If there are symptoms of high or low BG levels, check the BG value immediately. Consult the healthcare professional for actions and adjustments for high or low BG levels.

Using SG readings to make treatment decisions

When using CGM, there are several things to consider to help make treatment decisions.

Look at the most recent SG value along with the SG graph, trend arrows, and alerts. The SG graph helps to understand how SG values may have recently changed. The trend arrows indicate what the SG level may be soon.

- If the SG reading is lower than the SG target, and CGM shows ↑↑, this indicates the SG value is increasing. As a result, consider waiting to treat or adjust treatment for the low SG value. Consider symptoms before making treatment decisions based on the SG value.
- If the SG reading is higher than the SG target, and CGM shows ↓↓, this indicates the SG value is decreasing. As a result, consider waiting to treat or adjust treatment for the high SG value. Consider symptoms before making treatment decisions based on the SG value.

WARNING: When you see the Check BG icon, always use a BG meter reading when making treatment decisions.

Before taking an insulin dose based on the current SG, consider whether insulin from a previous dose is still lowering glucose levels. Stacking insulin is the process of taking an additional dose of insulin while there is still active insulin. Insulin stacking may cause low BG levels.

Note: Use a BG meter reading to make treatment decisions when you see the Check BG icon during the first 12 hours of wearing a sensor. Do not use SG readings to make treatment decisions during the first 12 hours of wearing a sensor.

The following table can help to make treatment decisions.

Arrows Displayed	Low glucose	High glucose	Target glucose
None	May need to take a fast-acting sugar.	May adjust insulin to correct a high glucose to reach the glucose target range. Do not stack insulin.	Consider last insulin dose and carbs taken. Watch for any changes to glucose levels. Do not stack insulin.
1 UP Arrow ↑	Watch for any changes to glucose levels, consider symptoms, and wait to see if SG returns to target range. Make sure to not overtreat for a low SG level.	May adjust insulin to correct a high glucose to reach the glucose target range. Do not stack insulin.	Consider last insulin dose and carbs taken. May need to take insulin to stay within the glucose target range. Do not stack insulin.
2 UP Arrows ↑↑	Watch for any changes to glucose levels, consider symptoms, and wait to see if SG returns to target range. Make sure to not overtreat for a low SG level.	May adjust insulin to correct a high glucose to reach the glucose target range. Do not stack insulin.	May need to take insulin to stay within the glucose target range if insulin was not already taken with a recent meal or snack. Do not stack insulin.
3 UP arrows ↑↑↑	Watch for any changes to glucose levels, consider symptoms, and wait to see if SG returns to target range. Make sure to not overtreat for a low SG level.	May adjust insulin to correct a high glucose to reach the glucose target range. Do not stack insulin.	May need to take insulin to stay within target range. Do not stack insulin.
1 DOWN arrow ↓	May need to take a fast-acting sugar or eat a snack.	Consider last insulin dose and activity taken. May need to watch and wait to reach target range. Do not stack insulin.	May need to take a fast-acting sugar and eat a snack.
2 DOWN arrows ↓↓	May need to take a fast-acting sugar.	Consider last insulin dose and activity taken. May need to watch and wait to reach target range. Do not stack insulin.	May need to take a fast-acting sugar and eat a snack.
3 DOWN arrows ↓↓↓	May need to take a fast-acting sugar.	Consider last insulin dose and activity taken. May need to watch and wait to reach target range. Do not stack insulin.	May need to take a fast-acting sugar and eat a snack.

Syncing data to the CareLink Personal website

The Simplera system allows 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 sensor history information used to create CareLink Personal reports. This information can be viewed by a patient on the CareLink Personal website at carelink.minimed.com. Please note that the mobile device must be connected to the Internet to send data to the website. If using a cellular connection, the mobile device provider's data rates may apply.

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

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

Sharing CareLink Personal data with care partners

Now that the app is synced with the CareLink Personal website, users can share their data with a care partner, such as a family member or friend. Care partners can visit carelink.minimed.com on a personal computer to create an account. Use the Manage Care Partners feature to give another person access to your information.

For more information, refer to the *CareLink Personal User Guide* that can be found on the CareLink Personal website.

Removing the Simplera sensor

To remove the Simplera sensor:

1. Gently peel the sensor adhesive away from the body.
2. Dispose of the Simplera sensor in accordance with all local laws and regulations. For additional information, see *Disposal, page 47*.

Bathing and swimming

While on the body, the sensor is protected against continuous immersion in water at a depth of 8 feet (2.4 meters) for up to 30 minutes. Shower and swim without removing the sensor.

Troubleshooting

The following table contains troubleshooting information for the alerts.

Alerts

Problem	Likely Cause(s)	Resolution
Lost communication alert	Another app is in use, such as a game, that takes up a lot of the memory on the mobile device. This means that the Simplera app stops running and can't communicate with the sensor.	Open the app to ensure it is running properly. Check periodically to see if the app is still running in the background in order to receive alerts and SG values.
	The app has been closed. The Simplera app has stopped running and can't communicate with the sensor. Potential causes include using other apps and features (for example task manager apps), or selecting Force Stop for the Simplera app from an Android device Settings menu.	
Lost communication alert	The mobile device is out of range.	Make sure the mobile device and the sensor are located within 20 feet (6 meters). It is helpful to keep the devices on the same side of the body to minimize any radio frequency (RF) interference.
Lost communication alert	There is RF interference from other devices.	Move away from any equipment that can cause RF interference, such as cordless phones or routers.
Lost communication alert	The sensor pulled out from the skin.	Make sure that the sensor is still inserted. If the sensor has been pulled out from the skin, a new sensor must be used.
Mobile device battery low alert	The mobile device battery level is at 20% or lower. The battery needs to be recharged soon.	Recharge the mobile device battery to ensure that the Simplera system can function and send alerts. Remember to always carry a charger for the mobile device to ensure continuous use of the Simplera system.
Change sensor alert	The current sensor does not work properly and needs to be replaced.	To continue to receive SG values, a new sensor must be used. See *Inserting the Simplera sensor, page 20* for instructions on how to insert the sensor.
Sensor end of life alert	The current sensor has reached the end of its life and will no longer display SG values on the Simplera app.	To continue to receive SG values, a new sensor must be used. See *Inserting the Simplera sensor, page 20* for instructions on how to insert the sensor.

Problem	Likely Cause(s)	Resolution
Calibration not accepted alert	The last calibration value entered was not accepted by the Simplera system.	Wait at least 15 minutes before attempting another calibration. The Simplera system will request another calibration, if needed, after 15 minutes from when the Calibration not accepted alert was received. Review the BG meter instructions for use on how to test BG. Enter this new value in the app for calibration.
Connection error alert	There is an error with the sensor.	No action is required. The sensor is updating and this may take 30 minutes. During this time, do not rely on alerts from the app as SG information will not be available. Monitor BG levels with the meter.
Sensor updating alert	There is an error with the sensor.	No action is required. The sensor is updating and this may take up to 2 hours. During this time, do not rely on alerts from the system as SG information will not be available. Monitor BG levels with the meter.
Jailbroken device detected alert	The software on the iOS mobile device has been changed so that it no longer works in the way that the manufacturer intended.	The app cannot be used on a jailbroken device. To use the Simplera app the device software must remain as the manufacturer has designed. Changing the mobile device operating software causes the app to stop working.
Rooted device detected alert	The software on the Android mobile device has been changed so that it no longer works in the way that the manufacturer intended.	The app cannot be used on a rooted device. To use the Simplera app the device software must remain as the manufacturer has designed. Changing the mobile device operating software causes the app to stop working.

CareLink

Problem	Likely Cause(s)	Resolution
Unable to upload data to the CareLink Personal website.	The phone has lost connection to the internet. The password has been changed through the CareLink website. CareLink servers are temporarily not responding.	1. Check that the phone is connected to a Wi-Fi or mobile network data. Go to a web browser and try to access any web page to see if the internet connection is working through Wi-Fi or through mobile network data. 2. If the internet can be accessed, go to Menu > CareLink screen and re-log into CareLink again with latest CareLink credentials. 3. If credentials are updated, there is internet connection, and upload is still failing, CareLink servers may be temporarily not responding. Please try again later.

Specifications

Biocompatibility	Sensor: Complies with EN ISO 10993-1
Applied parts	Sensor
Operating conditions	Sensor temperature: 36 °F to 104 °F (2 °C to 40 °C) Sensor relative humidity: 15% to 95% with no condensation Sensor pressure: 10.2 psi to 15.4 psi (70.33 kPa to 106.17 kPa)
Storage conditions	Sensor temperature: 36 °F to 86 °F (2 °C to 30 °C) Sensor relative humidity: up to 95% with no condensation Sensor pressure: 10.2 psi to 15.4 psi (70.33 kPa to 106.17 kPa) **CAUTION:** Do not freeze the Simplera sensor, or store it in direct sunlight, extreme temperatures, or high humidity. These conditions may damage the device.
Sensor glucose measurement range	50 to 400 mg/dL
Duration of use	Up to six days of CGM followed by a grace period of 24 hours
Operating frequency	2.4 GHz band, Bluetooth wireless technology (version 4.2)
Effective radiated power (ERP)	1.53 mW (1.85 dBm)
Effective isotropic radiated power (EIRP)	2.51 mW (4.00 dBm)
Operating range	Minimum of 20 ft (6.09 m) line of sight in free-air
Sensor device approximate dimensions	2.366 x 2.366 x 2.919 in (6.009 x 6.009 x 7.414 cm)
Sensor device approximate weight	2.56 ounces (72.5 g)
Sensor approximate dimensions	1.128 x 1.128 x 0.188 in (2.865 x 2.865 x 0.477 cm)
Sensor approximate weight	0.16 ounces (4.6 g)

Maintenance

Cleaning

Not applicable.

Disinfecting

Not applicable.

Disposal

Disposal requirements for electronic equipment, batteries, sharps and potential biohazardous materials differ based on location. Confirm disposal requirements for electronic equipment, batteries, sharps, and potential biohazardous materials with local laws and regulations.

The used inserter contains a needle which has been in contact with blood or other bodily fluids.

The used sensor contains a battery and has been in contact with blood or other bodily fluids. Disposal of the battery in any receptacle that could be exposed to extreme heat may cause the battery to ignite and result in serious injury.

Do not dispose of any component of this product with household waste or recyclables.

Dispose of the inserter and sensor in accordance with local laws and regulations.

Essential performance

The Simplera system displays patient sensor glucose data and interprets alerts through the Simplera app. The essential performance of the Simplera sensor includes accurate sensor measurements and communication of that data to the Simplera app.

Life of use

The Simplera sensor can be used one time and has a life of up to six days, followed by a grace period of 24 hours. During the grace period, the sensor will continue to work like normal, which allows the patient more time to change their sensor.

CAUTION: Do not use the sensor if there is a sudden rise in sensor temperature. When operating the sensor in air temperatures of 104 °F (40 °C), under certain fault conditions, the temperature of the sensor may briefly rise up to 121 °F (50 °C). If there is a sudden rise in temperature or the sensor becomes hot or uncomfortable, remove and discard the sensor.

Simplera system quality of service

The Simplera system can use either Wi-Fi or cellular data to send data to the CareLink Connect app for remote monitoring, and to upload history to the CareLink Personal website. The Simplera system 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 the Simplera system is encrypted, a secured Wi-Fi network is recommended.

The Simplera sensor connects to a compatible mobile device via a Bluetooth low energy technology network. The sensor sends glucose data and system-related alerts to the compatible mobile device, which verifies the integrity of received data after wireless transmission. The quality of the connection is in accordance with the Bluetooth Specification v4.2.

Data security

The Simplera sensor is designed to only accept radio frequency (RF) communications from a recognized and linked compatible mobile device. The sensor must be paired with the mobile device before the mobile device accepts information from the sensor.

The compatible mobile device ensures data security via encryption of all transmitted data and data integrity via cryptographic message authentication checks.

The Simplera app has been designed with security features to help keep its data secure. However, there are important recommended steps to take to ensure the compatible mobile device used with the Simplera app is also secure:

- Do not leave the compatible mobile device unattended.
- Use caution when viewing or sharing data with others.
- Enable a security lock on the compatible mobile device. When the compatible mobile device is not in use, lock it in a way that requires the password to be entered in order to use it.

- Do not remove or interfere with the security features on the compatible mobile device.
- Do not attempt to modify the operating system, jailbreak, or root the device.
- Use only the official application store, such as the Apple App Store or the Google Play store to get all mobile applications used with the compatible mobile device.
- Do not click on links from email messages, web pages, or text messages received from an unknown or untrusted source.
- Avoid the use of unknown Wi-Fi networks or public Wi-Fi hotspots.
- Enable security protection on a home Wi-Fi network, such as the use of a password and encryption.

The app may send anonymous analytic data to Medtronic if permission has been granted in the setup of the app. This data is used to analyze crash logs and app performance. This access can be revoked or reinstated at any time in the CareLink screen of the app.

Traveling by air

The Simplera sensor is safe for use on commercial airlines.

FCC notice

The Simplera sensor complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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

Open Source Software (OSS) disclosure

This document identifies the Open Source Software that may be separately called, executed, linked, affiliated, or otherwise utilized by this product.

Such Open Source Software is licensed to users subject to the terms and conditions of the separate software license agreement for such Open Source Software.

Use of the Open Source Software by you shall be governed entirely by the terms and conditions of such license.

The source/object code and applicable license for the Open Source Software can be obtained at the following site: www.medtronicdiabetes.com/ossnotices.

Guidance and manufacturer's declaration

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	CISPR 11 Group 1, Class B	The transmitter uses RF energy only for system communications. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2 Test Level**	**IEC 60601-1-2 Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	For use in a typical domestic, commercial, or hospital environment.
Power frequency magnetic field IEC 61000-4-8	30 A/m	30 A/m	For use in a typical domestic, commercial, or hospital environment.
Proximity magnetic fields IEC 61000-4-39, Table 11	IEC 60601-1-2, Table 11	IEC 60601-1-2, Table 11	For use in a typical domestic, commercial, or hospital environment.
Proximity fields from RF wireless communications equipment	IEC 60601-1-2, Table 9	IEC 60601-1-2, Table 9	For use in a typical domestic, commercial, or hospital environment. Portable and mobile RF communications equipment should be used no closer to any part of the transmitter than the recommended separation distance of 12 in (30 cm). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF electromagnetic fields IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.			

Simplera system performance

Note: A patient should review the information in this section with a healthcare professional to understand the performance of the Simplera system.

Clinical study overview

The performance of the Simplera system was evaluated using data collected during a multi-center prospective clinical study. The study enrolled a total of 123 subjects ages 18-80 years previously diagnosed with type 1 or 2 diabetes, and 118 of these subjects completed the study. Subjects ages 18-80 years were instructed to wear a total of two sensors, in the arm. For all subjects, the sensors were used to record raw sensor signals during the study and there was no real-time calculation of sensor glucose value[1].

Frequent sample testing (FST) was performed on four occasions for subjects 18 and older.

During FST, reference blood (plasma) glucose values were obtained with a Yellow Springs Instrument (YSI™*) Glucose Analyzer every 5-15 minutes for subjects 18 and older. During each FST, subjects 18 and older with an established insulin sensitivity ratio and insulin carbohydrate ratio underwent a hypoglycemic challenge or a hyperglycemic challenge.

Data collected during the study was post-processed after the study using the Simplera system sensor algorithm to convert the raw sensor information to sensor glucose values every five minutes. For the accuracy information presented in the following section, YSI reference values were paired with the closest sensor glucose reading within five minutes of the time of the reference value measurement.

Sensor accuracy

Sensor accuracy was calculated for sensors compared to a YSI reference for subjects ages 18 and older.

Table 4. Overall Accuracy Compared to YSI

Patient Population	Insertion Site	Number of Subjects	Number of paired SG-YSI	Percent of SG within 20/20% of YSI % (95% lower bound)	Mean Absolute Relative Difference (%)
Adults (18+)	Arm	116	15405	90.7 (90.3)	10.2

CGM readings are within 50-400 mg/dL, inclusive.

**For 20% agreement, 20 mg/dL used when YSI <70 mg/dL.

In *Table 5*, the agreement of the SG values to paired YSI values was assessed by calculating the percentage of SG values that were within 15%, 20%, and 40% of the paired YSI values. For SG readings less than 70 mg/dL, the absolute difference in mg/dL between the SG and paired YSI values was calculated.

Table 5. Overall accuracy of SG-YSI paired points within SG ranges; Adults, Arm

CGM Glucose Range (mg/dL)	Number of Subjects	Number of paired CGM- YSI	Percent of SG within 15 mg/dL YSI	Percent of SG within 20 mg/dL YSI	Percent of SG within 40 mg/dL YSI	Percent of SG within 15% YSI	Percent of SG within 20% YSI	Percent of SG within 40% YSI	Bias (mg/dL)	MARD (%)
A) < 54	29	164	84.1	90.9	98.2				-7.8	14.6
B) 54-69	72	1609	90.1	94.7	98.2				-2.3	10.6
C) 70-180	116	9655				74.3	85.7	98.6	-1.6	11.0
D) 181-250	101	2593				85.6	94.8	99.6	-8.5	8.6
E) > 250	79	1384				89.8	96.7	100.0	-14.1	7.4

For reference range < 70 mg/dL, agreement was based on 15/20/40 mg/dL.

CGM readings are within 50-400 mg/dL, inclusive.

[1] https://clinicaltrials.gov/study/NCT04436822. Evaluation of Updated Continuous Monitoring (CGM) Form Factor in adults, Adolescents and Pediatrics. Updated June 2, 2023. Accessed August 16, 2024.

Agreement when CGM reads "Below 50 mg/dL" or "Above 400 mg/dL"

The real-time CGM systems display glucose values between 50 mg/dL and 400 mg/dL. It displays "Below 50 mg/dL" when the SG value detected is below 50 mg/dL. It displays "Above 400 mg/dL" when the SG value detected is above 400 mg/dL. *Table 6* and *Table 7* illustrate the number and percentage of the paired YSI values in different BG levels when the CGM system displays "Below 50 mg/dL" (LOW) or "Above 400 mg/dL" (HIGH).

Table 6. The number and percentage of YSI values collected when CGM displays "Below 50 mg/dL" (LOW)

				YSI (mg/dL)					
CGM Display	**Population**	**Insertion Site**	**CGM-YSI pairs**	**<55**	**<60**	**<70**	**<80**	**≥80**	**Total**
LOW	Adult	Arm	Cumulative, n	67	119	169	197	10	207
			Cumulative %	32%	57%	82%	95%	5%	

Table 7. The number and percentage of YSI values collected when CGM displays "Above 400 mg/dL" (HIGH)

				YSI (mg/dL)					
CGM Display	**Population**	**Insertion Site**	**CGM-YSI pairs**	**>340**	**>320**	**>280**	**>240**	**≤240**	**Total**
HIGH	Adult	Arm	Cumulative, n	14	14	14	14	0	14
			Cumulative %	100%	100%	100%	100%	0%	

Concurrence of SG and YSI values

Table 8 shows, for each SG range, the percentage of concurring data points where the paired YSI values were in different blood glucose ranges.

Table 8. Overall concurrence of YSI values and SG readings using SG ranges; Adults, 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 ranges mg/dL**										
		< 50	**≥ 50-60**	**> 60-80**	**>80-120**	**> 120-160**	**>160-200**	**> 200-250**	**> 250-300**	**> 300-350**	**> 350-400**	**> 400**
A) < 50	207	15.0% (31/207)	42.5% (88/207)	37.7% (78/207)	4.3% (9/207)	0.5% (1/207)	0.0% (0/207)	0.0% (0/207)	0.0% (0/207)	0.0% (0/207)	0.0% (0/207)	0.0% (0/207)
B) ≥ 50-60	684	5.8% (40/684)	43.4% (297/684)	47.1% (322/684)	2.3% (16/684)	1.3% (9/684)	0.0% (0/684)	0.0% (0/684)	0.0% (0/684)	0.0% (0/684)	0.0% (0/684)	0.0% (0/684)
C) > 60-80	2285	1.9% (44/2285)	15.6% (356/2285)	68.5% (1566/2285)	12.6% (288/2285)	1.3% (29/2285)	0.1% (2/2285)	0.0% (0/2285)	0.0% (0/2285)	0.0% (0/2285)	0.0% (0/2285)	0.0% (0/2285)
D) > 80-120	3693	0.1% (2/3693)	0.9% (34/3693)	12.6% (465/3693)	68.8% (2542/3693)	16.9% (625/3693)	0.5% (19/3693)	0.1% (4/3693)	0.1% (2/3693)	0.0% (0/3693)	0.0% (0/3693)	0.0% (0/3693)
E) > 120-160	3532	0.0% (0/3532)	0.0% (0/3532)	0.1% (2/3532)	17.6% (622/3532)	66.3% (2342/3532)	15.3% (539/3532)	0.6% (22/3532)	0.1% (5/3532)	0.0% (0/3532)	0.0% (0/3532)	0.0% (0/3532)
F) > 160-200	2149	0.0% (0/2149)	0.0% (0/2149)	0.0% (0/2149)	0.3% (6/2149)	15.0% (323/2149)	59.7% (1282/2149)	24.2% (521/2149)	0.7% (14/2149)	0.1% (3/2149)	0.0% (0/2149)	0.0% (0/2149)
G) > 200-250	1678	0.0% (0/1678)	0.0% (0/1678)	0.0% (0/1678)	0.0% (0/1678)	0.7% (11/1678)	12.5% (210/1678)	63.6% (1068/1678)	21.8% (366/1678)	1.1% (19/1678)	0.2% (4/1678)	0.0% (0/1678)
H) > 250-300	879	0.0% (0/879)	0.0% (0/879)	0.0% (0/879)	0.0% (0/879)	0.0% (0/879)	0.1% (1/879)	11.1% (98/879)	53.8% (473/879)	31.6% (278/879)	3.0% (26/879)	0.3% (3/879)
I) > 300-350	404	0.0% (0/404)	0.0% (0/404)	0.0% (0/404)	0.0% (0/404)	0.0% (0/404)	0.0% (0/404)	0.2% (1/404)	7.4% (30/404)	66.3% (268/404)	25.5% (103/404)	0.5% (2/404)
J) > 350-400	101	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	0.0% (0/101)	13.9% (14/101)	78.2% (79/101)	7.9% (8/101)
K) > 400	14	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	71.4% (10/14)	28.6% (4/14)

Trend Accuracy

Table 9. Trend accuracy compared to YSI over time; Adults, Arm

SG Rate Ranges (mg/dL/min)	**YSI (mg/dL/min)**						
	No. of Paired SG - YSI	**< -2**	**[−2 , −1)**	**[−1 , 0)**	**[0 , 1]**	**(1 , 2]**	**> 2**
< -2	201	58.2% (117/201)	33.8% (68/201)	6.5% (13/201)	1.5% (3/201)	0.0% (0/201)	0.0% (0/201)
[−2 , −1)	838	7.9% (66/838)	48.8% (409/838)	40.9% (343/838)	2.3% (19/838)	0.0% (0/838)	0.1% (1/838)

Table 9. Trend accuracy compared to YSI over time; Adults, Arm (continued)

SG Rate Ranges (mg/dL/min)	YSI (mg/dL/min)						
	No. of Paired SG - YSI	< -2	[–2 , –1)	[–1 , 0)	[0 , 1]	(1 , 2]	> 2
[–1 , 0)	7350	0.2% (18/7350)	4.1% (301/7350)	75.9% (5581/7350)	19.1% (1407/7350)	0.5% (35/7350)	0.1% (8/7350)
[0 , 1]	5484	0.1% (3/5484)	0.6% (33/5484)	22.9% (1257/5484)	68.5% (3757/5484)	7.6% (416/5484)	0.3% (18/5484)
(1 , 2]	1156	0.0% (0/1156)	0.1% (1/1156)	2.5% (29/1156)	31.5% (364/1156)	56.5% (653/1156)	9.4% (109/1156)
> 2	350	0.0% (0/350)	0.0% (0/350)	0.6% (2/350)	4.6% (16/350)	36.0% (126/350)	58.9% (206/350)

CGM readings are within 50-400 mg/dL, inclusive.

Accuracy over time

The wear period was defined as: beginning (Elapsed day 1, 2), middle (Elapsed day 3, 4, 5), and end (Elapsed day 6, 7).

Table 10. Sensor Accuracy Compared to YSI Over Time; Adults, Arm

Wear Period	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 40/40% of YSI (%)	Mean Absolute Relative Difference (%)
Beginning	4377	75.1	86.7	98.6	12
Middle	8207	82.4	92.5	99.7	9.5
End	2821	82.9	91.7	99	9.6

For reference range < 70 mg/dL, agreement was based on 15/20/40 mg/dL.

CGM readings are within 50-400 mg/dL, inclusive.

Reading capture rate

Table 11. Reading Capture Rate by Functional Wear Day; Adults, Arm.

Functional Wear Day	Number of Sensors	Capture Rate* (%)
1	118	98.5
2	114	99.8
3	110	99.9
4	110	99.8
5	104	99.1
6	99	97.7
7	88	96.7
*The capture rate is based on the sensor's functional end time.		

Precision

Precision of the system was evaluated by comparing the results from two separate sensors worn in the location on the same subject at the same time.

	Number of paired points	Percent Absolute Relative Difference (PARD)	Coefficient of variation (%CV)
18+ YO Arm	36459	9	6.2

Alert performance

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

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

Predicted alerts notify users that their SG level may soon reach a high or low limit setting. Users may select how early they would like to be notified before their SG level reaches a high or low limit. The earliest warning is 60 minutes before reaching a high or low limit, but users can reduce the amount of warning down to 10 minutes. Users receive a Predictive alert when their SG level is

predicted to reach their high or low limit in Time Before High or Time Before Low setting they select. In general, the earlier the warning, the more time a user has to react to a potential high or low, but this also increases the potential for false alerts.

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

The device always alerts the user with an Urgent Low glucose alert when the CGM reads that the user is at or below 63 mg/dL, regardless of the high/low threshold and/or predictive alerts that the user sets.

Glucose true alert rate

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

- True Threshold Hypoglycemic alert rate is a measure of how often the CGM read that the user was at or below the low threshold and the user's BG was actually at or below that low threshold.
- True Threshold Hyperglycemic alert rate is a measure of how often the CGM read that the user was at or above the high threshold and the user's BG was actually at or above that high threshold.
- True Predictive Hypoglycemic alert rate is a measure of how often the CGM predicted that the user would reach or go below the low threshold and the user's BG was actually at or below that low threshold within 15 or 30 minutes.
- True Predictive Hyperglycemic alert rate is a measure of how often the CGM predicted that the user would reach or go above the high threshold and the user's BG was actually at or 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 BG is low or high so that they can correct the low or high BG. A high true alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's BG is likely to be at or approaching that threshold. For example, per the following table, the low glucose alerts would have correctly indicated that the user was at or below (i.e., threshold only), or predicted to reach or go below the threshold (i.e., predictive only) or both (predictive and threshold) 81.0%, 42.5%, or 53.3% of the time within 30 minutes (or 80.4%, 41.0% or 52.0% of the time within 15 minutes) when the user had BG values at or lower than 70 mg/dL for a sensor inserted in the arm.

Table 12. Glucose True Alert Rate, Adults

Glucose True Alert Rate							
		Threshold Only		Predictive Only		Threshold & Predictive	
Glucose (mg/dL)	Insertion Site	30 min	15 min	30 min	15 min	30 min	15 min
63	Arm	73.7%	72.9%	40.2%	36.0%	48.6%	45.2%
65	Arm	75.4%	75.4%	43.4%	39.6%	52.0%	49.2%
70	Arm	81.0%	80.4%	42.5%	41.0%	53.3%	52.0%
80	Arm	79.4%	78.0%	44.9%	41.8%	55.4%	52.8%
90	Arm	75.9%	75.9%	49.2%	46.1%	58.5%	56.4%
180	Arm	88.5%	88.3%	63.0%	60.5%	72.5%	70.8%
220	Arm	89.8%	89.1%	60.8%	58.5%	71.2%	69.5%
250	Arm	90.1%	89.5%	57.7%	55.2%	68.5%	66.7%
300	Arm	95.7%	95.7%	62.0%	57.2%	72.5%	69.2%

Glucose false alert rate

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

- False Threshold Hypoglycemic alert rate is a measure of how often the CGM read that the user was at or below the low threshold, but the user's BG was actually above that low threshold.
- False Threshold Hyperglycemic alert rate is a measure of how often the CGM read that the user was at or above the high threshold, but the user's BG was actually below that high threshold.
- False Predictive Hypoglycemic alert rate is a measure of how often the CGM predicted that the user would be at or below the low threshold, but the user's BG was actually above that low threshold within 15 or 30 minutes.
- False Predictive Hyperglycemic alert rate is a measure of how often the CGM predicted that the user would be at or above the high threshold, but the user's BG was actually below the high threshold within 15 or 30 minutes.

The false alert rate is important because it is necessary that users be correctly notified when their BG is low or high so that they can correct the low or high BG. A low false alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's BG is likely to be at or approaching that threshold. For example, per the following table, the high glucose threshold alerts would have incorrectly indicated that the user was at or above (i.e., threshold only), or predicted to reach or go above the threshold (i.e., predictive only), or both (threshold and predictive) for adult 11.5%, 37.0% or 27.5% of the time within 30 minutes (or 11.8%, 39.5%, or 29.2% of the time within 15 minutes) when the user had BG at or greater than 180 mg/dL for a sensor inserted in the arm.

Table 13. Glucose False Alert Rate, Adults

Glucose False Alert Rate							
		Threshold Only		Predictive Only		Threshold & Predictive	
Glucose (mg/dL)	Insertion Site	30 min	15 min	30 min	15 min	30 min	15 min
63	Arm	26.3%	27.1%	59.8%	64.0%	51.4%	54.8%
65	Arm	24.6%	24.6%	56.6%	60.4%	48.0%	50.8%
70	Arm	19.0%	19.6%	57.5%	59.0%	46.7%	48.0%
80	Arm	20.6%	22.0%	55.1%	58.2%	44.6%	47.2%
90	Arm	24.1%	24.1%	50.8%	53.9%	41.5%	43.6%
180	Arm	11.5%	11.8%	37.0%	39.5%	27.5%	29.2%
220	Arm	10.2%	10.9%	39.2%	41.5%	28.8%	30.5%
250	Arm	9.9%	10.5%	42.3%	44.8%	31.5%	33.3%
300	Arm	4.3%	4.3%	38.0%	42.8%	27.5%	30.8%

Glucose correct detection alert rate

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

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

For example, per the following table, the threshold alert, the predictive alert, or both (threshold and predictive) for adults notified the user 90.2%, 98.4% or 98.6% of the time within 30 minutes (or 88.3%, 95.1% or 95.8% within 15 minutes) when the user had BG at or greater than 180 mg/dL in a sensor inserted in the arm.

Table 14. Glucose Correct Detection Alert Rate, Adults

Glucose Correct Detection Alert Rate							
		Threshold Only		Predictive Only		Threshold & Predictive	
Glucose (mg/dL)	Insertion Site	30 min	15 min	30 min	15 min	30 min	15 min
63	Arm	65.9%	65.9%	94.1%	90.4%	94.1%	91.1%
65	Arm	72.0%	70.6%	95.8%	93.0%	95.8%	93.7%
70	Arm	82.2%	82.2%	94.7%	92.1%	94.7%	92.8%
80	Arm	86.8%	84.9%	96.2%	93.4%	96.2%	93.9%
90	Arm	84.9%	84.6%	94.4%	90.2%	94.4%	91.9%
180	Arm	90.2%	88.3%	98.4%	95.1%	98.6%	95.8%
220	Arm	85.9%	85.6%	95.8%	93.3%	96.1%	94.0%
250	Arm	80.3%	80.3%	93.6%	90.6%	93.6%	91.6%
300	Arm	74.6%	73.7%	94.9%	89.0%	94.9%	89.8%

Glucose missed detection alert rate

Glucose missed detection alert rate is the rate that the device did not alert when it should have alerted. For example, the BG was at or below the hypoglycemic threshold, or at or above the hyperglycemic threshold, and the device did not sound a threshold or predictive alert

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

For example, per the following table, the threshold alert, predictive alert, or both alerts (threshold and predictive) for adults did not sound 17.8%, 5.3% or 5.3% of the time within 30 minutes (or 17.8%, 7.9% or 7.2% within 15 minutes) when the user had BG at or less than 70 mg/dL in a sensor inserted in the arm.

Table 15. Glucose Missed Detection Alert Rate, Adults

Glucose Missed Detection Alert Rate							
		Threshold Only		Predictive Only		Threshold & Predictive	
Glucose (mg/dL)	Insertion Site	30 min	15 min	30 min	15 min	30 min	15 min
63	Arm	34.1%	34.1%	5.9%	9.6%	5.9%	8.9%
65	Arm	28.0%	29.4%	4.2%	7.0%	4.2%	6.3%
70	Arm	17.8%	17.8%	5.3%	7.9%	5.3%	7.2%
80	Arm	13.2%	15.1%	3.8%	6.6%	3.8%	6.1%
90	Arm	15.1%	15.4%	5.6%	9.8%	5.6%	8.1%
180	Arm	9.8%	11.7%	1.6%	4.9%	1.4%	4.2%
220	Arm	14.1%	14.4%	4.2%	6.7%	3.9%	6.0%
250	Arm	19.7%	19.7%	6.4%	9.4%	6.4%	8.4%
300	Arm	25.4%	26.3%	5.1%	11.0%	5.1%	10.2%

Sensor life

Adults

Sensors are designed to be worn for up to six days, followed by a grace period of 24 hours. Combining the six-day wear period with the 24-hour grace period allows for up to seven days of sensor usage. However, some sensors may not survive the full wear period for a variety of reasons. Please be prepared to replace the sensor during the grace period to ensure sensor glucose values continue to be monitored. To estimate how long a sensor will work, sensors were evaluated in a clinical study to determine how many days and hours of readings each sensor provided.

Among the 128 sensors evaluated, 11 sensors (8.6%) were censored from the survival analysis due to various reasons not related to the commercial device (e.g., subject dropped out of the study, subject accidentally removed sensors at the incorrect time, or software anomalies that are only applicable to the investigational device but resolved for the commercial device). 75.2% of the sensors lasted through the end of the entire six-day wear period, and 66.7% lasted through the end of the six-day wear period followed by a grace period of 24 hours.

Safety

Device related adverse events were limited to pain or bruising at the sensor insertion site.

Medtronic

Medtronic MiniMed
18000 Devonshire Street
Northridge, CA 91325
USA
1 800 646 4633
+1 818 576 5555
www.medtronicdiabetes.com

REF MMT-8400 MMT-8401 MMT-5100J

℞ *Only*

M052531C001_3
2024-09-27

M052531C001