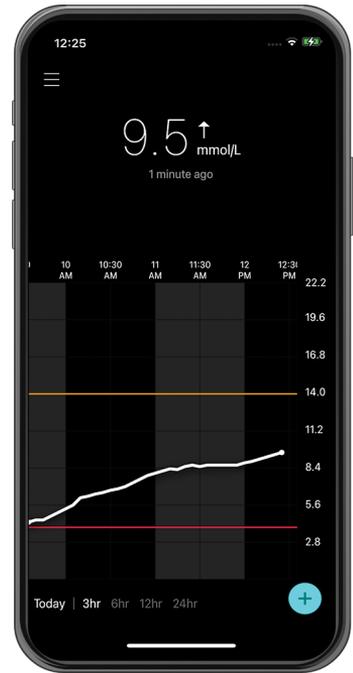


# GUARDIAN™

## APP USER GUIDE



Medtronic



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## Icon Table

	Catalogue number
	Manufacturer
	Consult instructions for use
	Bluetooth® wireless technology or Bluetooth® enabled
	Authorized representative in the European Community
	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union Acts.

# Guardian

## Introduction

The Guardian application (app) is a component of the Guardian 4 system that helps manage diabetes. The Guardian 4 system has the following features:

- Records glucose values throughout the day and night
- Displays glucose values in a convenient and discreet manner on a mobile device
- Sends alerts for glucose events on a mobile device
- Shows the effects that diet, exercise, and insulin can have on glucose levels

This user guide is designed to help understand the setup and operation of the Guardian app.

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

## System description

The Guardian 4 system includes the following components: Guardian iOS™ app (MMT-8200) or Guardian Android™ app (MMT-8201), Guardian 4 transmitter (MMT-7841Q), Guardian 4 sensor (MMT-7040Q), and compatible tester and charger.

Continuous glucose monitoring (CGM) is a technology that lets patients continuously view glucose values. The Guardian 4 system uses a glucose sensor, the Guardian 4 sensor, placed below the skin, to continuously measure the amount of glucose in the interstitial fluid. The Guardian 4 transmitter collects and processes these glucose measurements, which are then displayed on the Guardian app. The Guardian app can also provide alerts based on sensor glucose (SG) levels.

The Guardian app also provides a user interface for entering data such as exercise, insulin, meals, blood glucose (BG) values, and uploading information to the CareLink Personal website.

The Guardian app is available to download from the Apple™ App Store™ or the Google Play™ store and requires the Guardian 4 sensor and Guardian 4 transmitter to function.

**Note:** This product should only be used with supported mobile devices and operating systems. Refer to the local Medtronic website for information about supported devices and operating systems.

## **Diabetes treatment decisions**

Use a BG meter reading to make treatment decisions if no sensor data is available or if unsure that SG values are correct.

## **Indications for use**

The Guardian app is intended to be used with the Guardian 4 system.

The Guardian 4 system is a real-time, CGM system indicated for the management of diabetes in persons age 7 years and older.

The Guardian 4 system does not require calibration and is designed to replace finger stick BG testing for diabetes treatment decisions. 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 hyperglycemia and hypoglycemia and helping both current and long-term therapy decisions.

The system 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.

## **Contraindications**

Successful CGM use requires sufficient vision or hearing ability to allow recognition of the alerts generated by the Guardian app.

## **Clinical benefits**

The Guardian app is software that provides information that is used for diabetes management but does not provide any direct therapy. As a result, the app does not have direct therapeutic benefits but can support the management of diabetes by patients and caregivers.

## **User safety**

### **Warnings**

Follow the instructions and safety warnings in this user guide to receive alerts as intended. Missing alerts from the Guardian app may result in undetected low and high glucose levels.

- CGM is not recommended for people who are unwilling or unable to perform BG tests as required or for people who are unwilling or unable to maintain contact with their healthcare professional.
- Always allow notifications for the Guardian app. If notifications are turned off, the app will not send any alerts, including Urgent Low Alert.

- Do not use the Guardian app without understanding how the mobile device settings work. If the mobile device settings are not set up correctly, the app may not send SG alerts.
- Make sure Bluetooth™\* is on, even if the mobile device is in airplane mode. If Bluetooth™\* is off, the app will not send SG information or alerts.
- Do not use the Guardian app if the mobile device screen or speakers are damaged. If the mobile device is damaged, the app may not send SG alerts and SG information may not be shown correctly.
- Do not force close the Guardian app. If the app is closed, the app will not send SG information or alerts.
- Check the Guardian app occasionally to make sure it is running. The mobile device may close the Guardian app automatically when another app is in use, such as a game. If the Guardian app is closed, the app will not send SG alerts.
- Do not let the mobile device shut down due to low battery, or the app will not send SG 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 SG 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 an SG alert is snoozed, the app will not send that alert again during the length of the set snooze time.
- 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.
- Taking medications that contain paracetamol or acetaminophen, such as fever reducers or cold medicine, while wearing the sensor may falsely raise SG readings. The level and duration of sensor inaccuracy depends on how much medication is working in the body and will be different for each person. If medication is taken with paracetamol or acetaminophen, use a BG meter reading for dosing decisions in order to avoid a possible hypoglycemic event. Consult a healthcare professional when determining insulin dosage.
- Turning off automatic updates on the mobile device may help to avoid unintentionally updating to an operating system that is not confirmed as compatible with the Guardian app.

- 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 Guardian app will display an error message when launched and will not continue to operate.

## Android™ Users

- Allow **Do Not Disturb Permissions** and **Notifications** for the Guardian app. If **Do Not Disturb Permissions** or **Notifications** are turned off, the app will not send any alerts, including Urgent Low Alert.
- The Android™ device may include battery saver settings. If these settings are active for the Guardian app, the mobile device will shut down the app and prevent it from sending alerts and notifications. Check the mobile device periodically to confirm that the Guardian app is active.
- The **Digital Wellbeing** feature is intended to prevent alerts. If this feature is enabled, the Guardian app will not send alerts. If the app timer is set in the **Digital Wellbeing** feature for the Guardian app, the app will shut down and will not send any SG 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.
- Alerts for the Guardian app will sound through headphones when headphones are connected. If headphones are connected when not in use, SG alerts may not be heard.

## iOS™ Users

- Allow **Critical Alerts** and **Notifications** for the Guardian app. If **Critical Alerts** or **Notifications** is 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 Guardian app will be prevented from sending alerts.
- Do not turn off vibration in the iOS™ Accessibility menu. If vibration is turned off, the app will not send any vibrations with the alerts, including Urgent Low Alert.
- If a serious incident related to the device occurs, immediately report the incident to the manufacturer and local competent authority.

## 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.

Refer to a healthcare professional for glucose target ranges.

## Risks and side effects

Software malfunction or failure to follow instructions of the Guardian app can lead to hypoglycemia, hyperglycemia, diabetic ketoacidosis, or possibly death.

## Assistance

Contact the local representative or refer to the local Medtronic website for assistance. Refer to the Medtronic Diabetes International Contacts list in this user guide for contact information.

## Guardian app setup

To set up the Guardian app, follow the instructions on the screen.

## Pairing the transmitter

The transmitter must be paired to the system before a sensor can be used. Follow the instructions on the screen to pair the transmitter to the mobile device.

## 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.

## Connecting the transmitter to the sensor

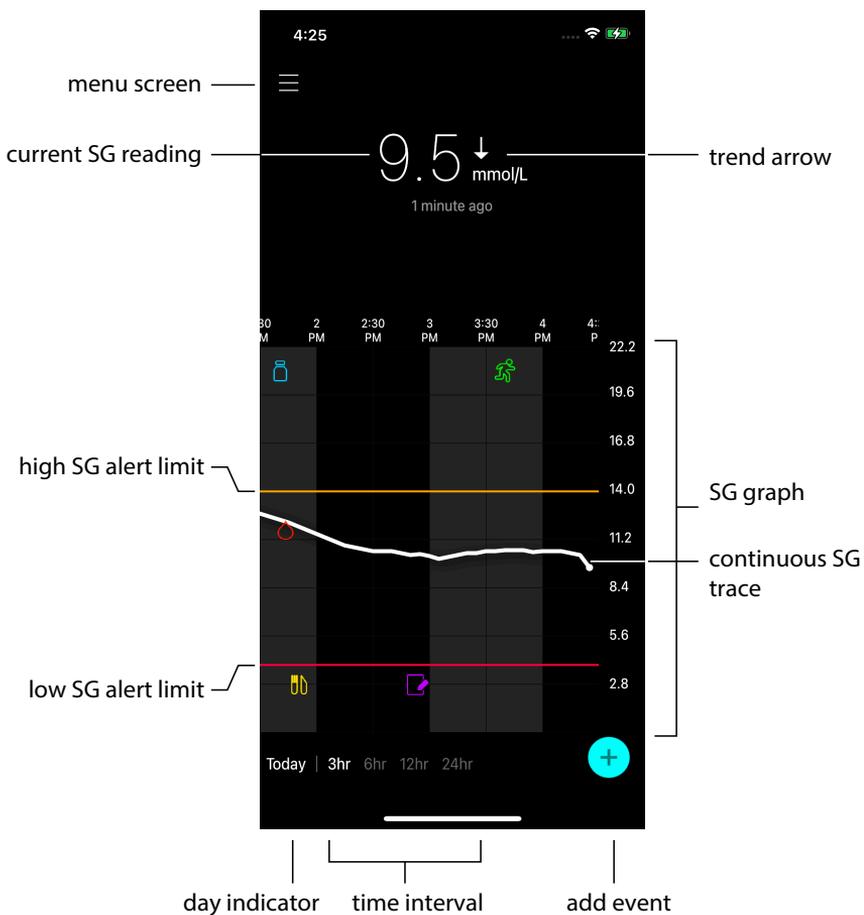
Refer to the *Guardian 4 Transmitter User Guide* for instructions on how to connect the transmitter to the sensor.

## Completing the app setup

Continue to follow the on-screen instructions to enable notifications. For more information, see *Alert settings, page 19*.

## Home screen

The following figure shows the Home screen of the app.



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

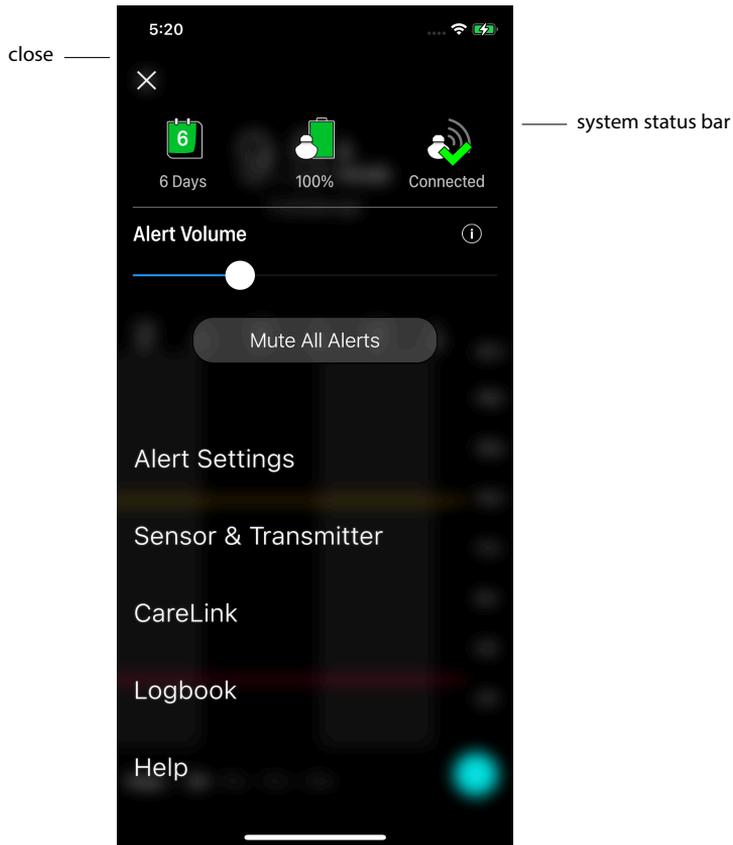
**Note:** The Home screen does not display sensor information the first time the app is opened. The first SG reading appears after the transmitter is successfully paired and the sensor warm-up is complete.

Item	Description
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 <i>Setting rate alerts</i> , page 22.
Menu screen	Provides access to the menu screen, which displays the Guardian 4 system status information and allows the user to define alert settings, set up the sensor, calibrate, pair the transmitter, access CareLink Personal settings, view the logbook, and access help documentation. For details, see <i>Menu screen</i> , page 15.
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 navigating tips, see <i>Navigating through the SG graph</i> , page 24.
System status icons	Display the corresponding status icon if the transmitter battery is empty, the sensor life has expired, the connection with the transmitter is lost, notifications are silenced, or the status of these features is unknown. For details, see <i>System status icons</i> , page 16.
Time interval	Displays preset time intervals of 3, 6, 12, and 24 hours. Tap this icon to switch between time intervals.
Current SG reading	Displays the current SG reading, which the transmitter calculates and sends wirelessly to the app.
High and low SG limits	Display a line showing 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 status message	Displays the latest active status notification. If a current SG reading is not available, the sensor status message will appear where the SG information would be displayed.
SG 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 <i>Sensor graph</i> , page 24.

Item	Description
Day indicator	Displays the date of the data shown in the graph. Scroll further back into historical data to see Today, Yesterday, and days of the previous week.
Add event	Displays the events screen to enter additional information, such as exercise, BG readings, meals, or insulin taken. Certain BG readings entered here may be also used for sensor calibration. For details, see <i>Events</i> , page 25.

## Menu screen

Tap  in the upper left hand corner of the Home screen to see the menu screen.



Item	Description
Close (X)	Closes the menu screen and returns to the Home screen.
System status bar	Displays icons that show a quick status of the Guardian 4 system, including sensor life, transmitter battery, and transmitter communication. For details on the individual icons and their status, see <i>System status icons</i> , page 16.
Alert Volume	Allows the option to adjust the volume of alerts. Alerts will sound louder and repeat if not acknowledged. For details, see <i>Alert settings</i> , page 19.
Alert Volume Information	Displays a description of Alert Volume slider and Mute All Alerts button. For details, see <i>Alert settings</i> , page 19.
Mute All Alerts	Allows the option to mute all alerts for a specified duration. Urgent Low Alert will always vibrate. For details, see <i>Alert settings</i> , page 19.  <b>Note:</b> 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.
Alert Settings	Display the options to set glucose monitoring alerts. For details, see <i>Alert settings</i> , page 19.
Sensor & Transmitter	Displays the instructions to start a new sensor, calibrate, and pair a transmitter. For details, see <i>New sensor setup</i> , page 12.
CareLink	Provides access to a menu to change the CareLink user login information. For details, see <i>Syncing data to the CareLink Personal website</i> , page 32.
Logbook	Displays a history of alerts and events that have occurred in the Guardian 4 system. For details, see <i>Logbook</i> , page 29.
Help	Provides the user with software version information, access to the app user guide, getting started guide, setup wizard and the end user license agreement.

## System status icons

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

Icon name	Description
Transmitter battery	As the battery life is used, the icon changes in the following order:  

Icon name	Description
	<p> indicates that approximately 100% of the battery capacity remains, which means at least 7 days of use remain</p> <p> indicates that approximately 50% of the battery capacity remains</p> <p> indicates that up to one day of use remains</p> <p> indicates that the battery is empty</p> <p> indicates that the battery status is unknown</p>
Sensor life	<p>As the sensor life is used, the number on the icon indicates the number of days left before the sensor needs to be replaced, and the color of the icon changes as shown:</p> <div data-bbox="287 439 761 486" style="text-align: center;">  </div> <p>When a new sensor is inserted, the icon is solid green. When there is less than one day left, the 1-day icon remains red, and the text below it indicates the number of hours that remain. The question mark indicates that the sensor life is unknown. When the sensor is expired, an "X" is displayed.</p>
Transmitter communication	<p>Displays the communication status between the transmitter and the app:</p> <p> indicates the transmitter is active and connected</p> <p> indicates there is a communication error, the transmitter is not paired to the mobile device, or Bluetooth™ is off</p>

## Alerts

The Guardian app provides **glucose alerts** and **system status alerts**. These alerts provide information about glucose levels and the status of the Guardian 4 system.

### Glucose alerts

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 Guardian 4 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).
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 has gone below 3.0 mmol/L (54 mg/dL).

**Note:** If the Guardian app is in “Alerts 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 *Alert settings, page 19*.

## System status alerts

The Guardian 4 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 33*.

The **status alerts** in the Guardian 4 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.
Calibrate now	Measure the BG value with the meter and calibrate the sensor to get SG readings.
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 Guardian app and transmitter 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.

<b>Alert type</b>	<b>Description</b>
Sensor end of life	Sensor has reached its maximum life of 7 full days.
Sensor updating	The sensor is updating and no SG information will be available. Measure the BG value with the meter.
Transmitter battery empty	The transmitter battery is empty and needs to be recharged. The app is no longer receiving sensor information.
Transmitter error	The transmitter is trying to fix a problem.
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.

## Alert settings

### Setting low alerts

Low alert settings include the following:

<b>Low alert setting</b>	<b>Description</b>
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 3.3 to 5.0 mmol/L (60 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.

Low alert setting	Description
Before and at Low Limit	When Before and at Low Limit is selected, the app sends a Low predicted alert anytime 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 <b>Max Volume at Night</b> on for low alerts to make all low alerts sound at max volume at night.

### To set low alerts:

1. On the Home screen, tap  and select **Alert Settings > Low Alerts**.
2. Tap **Day starts at** and set the desired start time. Tap **Save**.
3. Tap **Low Limit** and set the desired limit between 3.3 to 5.0 mmol/L (60 to 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 Alert Settings screen.
9. Tap  to return to the menu 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 5.5 to 22.2 mmol/L (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 <b>Max Volume at Night</b> on for high alerts to make all high alerts sound at max volume at night.

### To set high alerts:

1. On the Home screen, tap  and select **Alert Settings > High Alerts**.
2. Tap **Day starts at** and set the desired start time. Tap **Save**.
3. Tap **High Limit** and set the desired limit between 5.5 to 22.2 mmol/L (100 to 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

- 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**.
- 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.
- Toggle **Max Volume At Night** on or off. When **Max Volume At Night** is toggled on, high alerts sound at max volume at night.
- When the alerts are set up, tap  to return to Alert Settings screen.
- Tap  to return to the Menu screen.
- 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 meals or exercise.

On the Home screen, these fall or rise rates are indicated by arrows, as shown in *Home screen, page 13*. The more arrows, the faster the rate of change.

↑	SG has been rising at a rate of 0.06 mmol/L (1 mg/dL) or more per minute, but less than 0.11 mmol/L (2 mg/dL) per minute.
↓	SG has been falling at a rate of 0.06 mmol/L (1 mg/dL) or more per minute, but less than 0.11 mmol/L (2 mg/dL) per minute.
↑↑	SG has been rising at a rate of 0.11 mmol/L (2 mg/dL) or more per minute, but less than 0.17 mmol/L (3 mg/dL) per minute.
↓↓	SG has been falling at a rate of 0.11 mmol/L (2 mg/dL) or more per minute, but less than 0.17 mmol/L (3 mg/dL) per minute.
↑↑↑	SG has been rising at a rate of 0.17 mmol/L (3 mg/dL) or more per minute.
↓↓↓	SG has been falling at a rate of 0.17 mmol/L (3 mg/dL) or more per minute.

## To set rate alerts:

- On the Home screen, tap  and select **Alert Settings > Fall & Rise Alerts**.
- Toggle **Fall Alert** on.
- Tap the arrow option with the desired fall rate.
- Toggle **Rise Alert** on.
- Tap the arrow option with the desired rise rate.
- When fall and rise alerts are set up, tap  to return to Alert Settings screen.

## Setting alert snooze time

The snooze feature gives the option to set a snooze time for alerts. If the alert condition still persists after the set snooze time, the app sends a 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.

### To set the alert snooze time:

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

## Adjusting alert volume

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

### To adjust alert volume:

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

**Note:** If 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, tap **Mute All Alerts**."

## Muting alerts

All Guardian alerts will be muted for the selected time. Urgent Low Alert will always vibrate.

### To mute alerts:

1. On the Home screen, tap .
2. Tap **Mute All Alerts** and 4 options appear.
  - a. 30 min
  - b. 1 hour
  - c. 4 hours (max)
  - d. Custom

If 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 Guardian app alerts

The Guardian 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 Guardian 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 Guardian app, the alert may repeat.

The alert is displayed on the screen when the app is opened. Click **OK** to clear system status alerts. For SG alerts, either swipe the alert up, which will snooze the alert for the set snooze period, or swipe the alert down to set a new 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 24*.
- 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, page 25*.

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.

## Events

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

Event icon	Event name	Description
	BG	The BG marker represents the BG meter readings. These can be used either to calibrate the system or simply to manage diabetes without calibrating the system.
	Insulin	The Insulin marker represents the type and amount of insulin delivered.
	Meal	The Meal marker represents the amount of carbohydrates consumed, food or drink.
	Exercise	The Exercise marker represents the intensity and duration of exercise routine.
	Notes	The Notes 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.

The app also gives the option to use the entered BG meter reading for calibration purposes, if calibration is allowed at the time when the event is entered. To use the BG meter reading for calibration, the value must be between 2.8 mmol/L and 22.2 mmol/L (50 mg/dL and 400 mg/dL.) When calibrating the sensor from the Blood Glucose screen, enter the current BG value, or a value that is up to ten minutes old.

**Note:** Enter a BG value between 1.1 mmol/L and 33.3 mmol/L (20 mg/dL and 600 mg/dL) into the Events screen. However, for sensor calibration, a BG value between 2.8 mmol/L and 22.2 mmol/L (50 mg/dL and 400 mg/dL) must be entered.

## To enter a BG meter reading into the Events screen:

1. Measure the BG with a BG meter.
2. Tap  at the bottom of the Home screen.
3. Tap  on the Events screen.
4. To change the date or time for the entry, tap **Time** and make the appropriate changes.
5. Use the number pad to enter the BG meter reading.
6. Make sure the value displayed above the number pad is correct. If the value is incorrect, tap  to clear it and enter the correct value.
7. To avoid calibrating the sensor with this reading, tap **Save** at the bottom of the screen.
8. To calibrate the sensor with the entered BG meter reading when calibration is available, tap **Calibrate** at the bottom of the screen.

The app returns to the Home screen after selecting **Save** or **Calibrate**, and  appears on the graph at the selected time.

The following icons may appear during calibration. Select the icon to see more information about the calibration status.

 indicates that the calibration status is unknown

 indicates that calibration is currently not permitted

## 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.

### To enter the type and amount of insulin injected:

1. Make a note of the amount and type of injection taken.
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 **Time** 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 **Type** and select the type of insulin taken:
  - Rapid-acting
  - Long-acting
  - Unspecified
8. Tap  to return to the Insulin Event screen.

9. Tap **Save** at the bottom of the screen. The app returns to the Home screen, and  appears on the graph at the selected time.

## Entering meal information

Use the app to record information about the carbohydrates consumed with meals or snacks.

### To enter meal information:

1. Determine the total amount, in grams or exchanges, 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 **Time** 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 **Save** at the bottom.  
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.

### 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 **Time** and set the desired day and time for this exercise entry.
5. Tap **Intensity** and select **Low**, **Medium**, or **High** to indicate the intensity of exercise.
6. Tap **Duration**.
7. Tap **Save** at the bottom.  
The app returns to the Home screen, and  appears on the graph at the selected time.

## Entering notes

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.

### 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. Tap **Save** at the bottom.

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

## Logbook

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

### To view Logbook entries:

1. On the Home screen, tap  and select **Logbook**.
2. Do any of the following to view the desired information:
  - Tap **Alerts** or **Events** to filter the list by the specific type. 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. Use  and  at the top of the expanded view to scroll through the list entries.

## 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

Until becoming comfortable using SG readings to make treatment decisions, continue to use BG meter readings to make treatment decisions and confirm SG readings.

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.

## When to use BG meter readings

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

- **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.

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.

**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 from previous calibrations.
- If for some reason calibration is unsuccessful, wait at least 15 minutes before attempting another calibration.

**Note:** The Guardian 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 Guardian app. If there are symptoms of high or low BG levels, check the BG value immediately. Refer to 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 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.

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.

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 meal 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 meal 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	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.

Arrows Displayed	Low glucose	High glucose	Target glucose
	SG returns to target range. Make sure to not overtreat for a low SG level.		Do not stack insulin.
<b>3 UP arrows</b> ↑↑↑	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.
<b>1 DOWN arrow</b> ↓	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.
<b>2 DOWN arrows</b> ↓↓	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.
<b>3 DOWN arrows</b> ↓↓↓	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

Guardian 4 offers remote monitoring by Care Partners and daily uploads to the CareLink Personal website. This is done using an automatic feature called Sync to CareLink.

This automatic Sync to CareLink feature sends data displayed in the app to the CareLink Connect tab of the CareLink Personal website. This data is sent approximately every five minutes when an Internet connection to the website is available. This feature also automatically sends sensor history information used to create CareLink Personal reports roughly every 24 hours. This information can be viewed by a patient or a care partner on the CareLink Personal website at [carelink.minimed.eu](http://carelink.minimed.eu). 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.eu](http://carelink.minimed.eu) on a personal computer to create an account and send a follow request.

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

## Disconnecting the transmitter from the sensor

Always refer to the *Guardian 4 Transmitter User Guide* for instructions on how to disconnect the transmitter from the sensor.

## Reconnecting the existing sensor

If necessary, a transmitter can be reconnected to an existing sensor. When the app detects the connection, confirm that the sensor is an existing sensor. It may take a few seconds to establish a connection when connecting an existing sensor. If an existing sensor is reconnected, the sensor will go through another warm-up period.

## 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 Guardian app stops running and can't communicate with the transmitter.	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 Guardian app has stopped running and can't communicate with the transmitter. Potential causes include using other apps and features (for example task manager apps), or selecting Force Stop for Guardian from an Android™* device Settings menu.	
Lost communication alert	The mobile device is out of range.	Make sure the mobile device and the transmitter are located within 6 meters (20 feet). 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 disconnected from the transmitter.	Reconnect the sensor to the transmitter. Be careful not to pull the sensor out. Note: When the transmitter is reconnected to the sensor, the sensor will go through a warm-up period which may last up to 2 hours.

Problem	Likely Cause(s)	Resolution
Lost communication alert	The sensor pulled out from the skin.	Do not continue to use this sensor. Insert a new sensor to continue to receive SG values. For best results, recharge the transmitter before starting use of a new sensor to ensure full transmitter battery life. If the transmitter is still not communicating with the app, contact the local Medtronic representative for assistance.
Transmitter battery empty alert	The transmitter battery is empty and needs to be recharged.	See the <i>Guardian 4 Transmitter User Guide</i> for instructions on how to disconnect the transmitter from the sensor. For best results, recharge the transmitter between each use to ensure full transmitter battery life. <b>Note:</b> When the transmitter is reconnected to the sensor, the sensor will go through a warm-up period which may last up to 2 hours.
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 Guardian 4 system can function and send alerts. Remember to always carry a charger for the mobile device to ensure continuous use of the Guardian 4 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 the <i>Guardian 4 Transmitter User Guide</i> for instructions on how to change the sensor. For best results, recharge the transmitter between each use to ensure full transmitter battery life.
Sensor end of life alert	The current sensor has reached the end of its life and will no longer display SG values on the Guardian app.	To continue to receive SG values, a new sensor must be used. See the <i>Guardian 4 Transmitter User Guide</i> for instructions on how to change the sensor. For best results, recharge the transmitter between each use to ensure full transmitter battery life.
Calibration not accepted alert	The last calibration value entered was not accepted by the Guardian system.	Wait at least 15 minutes before attempting another calibration. The Guardian system will request another calibration, if needed, after 15 minutes from when the Calibration not accepted alert was received. Review the BG meter

<b>Problem</b>	<b>Likely Cause(s)</b>	<b>Resolution</b>
		instructions for use on how to test BG. Enter this new value in the app for calibration.
Calibrate now alert	A calibration is required by the system.	Review the BG meter instructions for use on how to test BG. Enter this new value in the app for calibration.
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.
Transmitter error alert	There is an error with the transmitter.	Disconnect the transmitter from the sensor and reconnect it. Upon reconnecting the transmitter to the sensor, the sensor will go through a warm-up period which may last up to 2 hours. The transmitter may need to be replaced if issues are still being experienced. Contact 24-Hour Technical Support or the local Medtronic representative for more assistance.
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 Guardian 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 Guardian app the device software must remain as the manufacturer has designed. Changing the mobile device operating software causes the app to stop working.

## **Maintenance**

### **Cleaning**

Not applicable.

## **Storage**

Not applicable.

## **Disposal**

Not applicable.

## **Technical specifications**

### **Data security**

The Guardian 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 Guardian 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<sup>™</sup> App Store<sup>™</sup> or the Google Play<sup>™</sup> 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<sup>™</sup> networks or public Wi-Fi<sup>™</sup> hotspots.
- Enable security protection on your home Wi-Fi<sup>™</sup> 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 Help screen of the app.





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