

GETTING STARTED WITH CONTINUOUS GLUCOSE MONITORING

Guardian[™] Connect System

Medtronic

GETTING STARTED WITH CONTINUOUS GLUCOSE MONITORING Guardian[™] Connect System

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SECTION 1: WELCOME TO CONTINUOUS GLUCOSE MONITORING

The first step in using CGM is to understand the items included in your CGM system.





Your Continuous Glucose Monitoring (CGM) system includes 3 key items:		
A Glucose sensor	The Enlite sensor measures glucose levels in the body.	
B Transmitter*	The Guardian [™] Connect transmitter connects to the glucose sensor and sends glucose readings to your app.	
C Guardian [™] Connect app	The Guardian [™] Connect app displays glucose readings.	

Other items include: One-press Serter, overtape, transmitter charger and tester

Refer to the Guardian $^{\rm TM}$ Connect System User Guide for more information.

* The transmitter must be within 6.1 meters (20 feet) of the Guardian[™] Connect app in order to communicate sensor readings.

INTRODUCTION TO CONTINUOUS GLUCOSE MONITORING

Before we proceed, let's make sure that you have completed these important steps:

1 Charge your Guardian[™] Connect transmitter

Place the transmitter on the gray charger. The green light on the charger will flash. The transmitter is fully charged when the green light is off.

2 Download the Guardian[™] Connect app Download the app directly from your mobile device app store.

3 Turn on Bluetooth[®] wireless technology

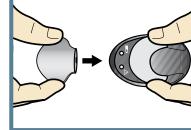
Make sure Bluetooth wireless technology is turned on in your mobile device. For Android devices, enable the Do Not Disturb permission for as long as you are using the Guardian[™] Connect App. You must also enable Location Services when you are pairing a new transmitter with the app for the first time. You can turn off Location Services once you have completed the initial pairing process.

4 Turn on internet connection

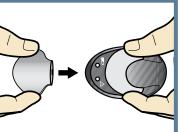
Internet must be available on your mobile device in order to access CareLink[™] Personal software.

5 Create a CareLink[™] Personal software account

If you do not have an existing account and need to enroll, or are unsure of your personal login, visit the following website: www.carelink.minimed.eu





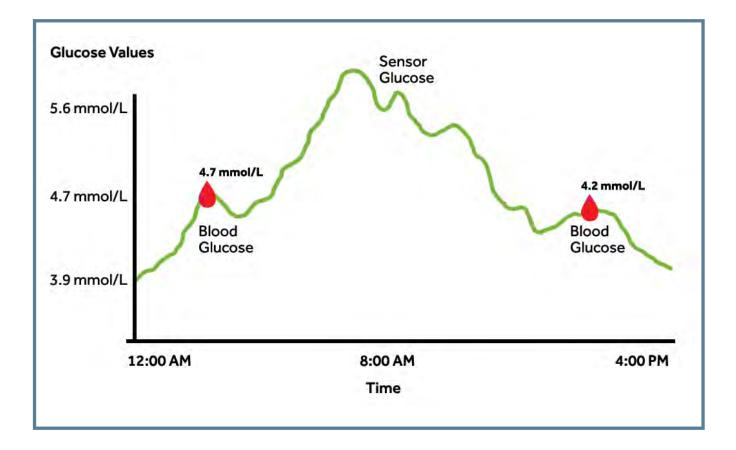




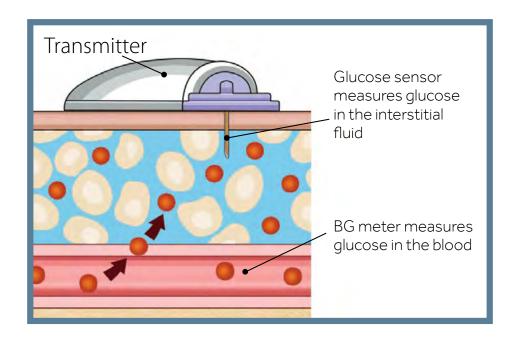
Guardian

SECTION 2: SENSOR GLUCOSE (SG) AND BLOOD GLUCOSE (BG)

Continuous Glucose Monitoring (CGM) allows you to see what your glucose values are when you are not testing. You will receive up to **288 sensor glucose readings every 24 hours,** filling the gaps between your blood glucose (BG) tests. CGM can alert you to your high and low glucose values and show you the speed and direction that your glucose levels are moving.



Your **BG meter** measures glucose levels in your **blood**. The **glucose sensor** measures glucose in the fluid surrounding the cells of your tissue called **interstitial fluid**.



Because your glucose moves between these two places, **your blood glucose meter readings (BG) and sensor glucose readings (SG) will be similar but will rarely match exactly**.

This difference is normal and should be expected.

You can expect to see a larger difference between your BG meter reading and the sensor glucose reading when your glucose levels are rising or falling quickly.

Examples of times when this larger difference may occur:

- After meals or taking a bolus of insulin
- During and after exercise
- When arrows appear on your GuardianTM Connect app screen as explained in the next section





IMPORTANT: Sensor glucose is not the same as blood glucose. Your SG and BG readings will be similar to one another but will rarely match exactly.

Sensor glucose values should not be used to make diabetes treatment decisions. Always confirm your glucose value with a BG meter first.

If you "feel" that your glucose is high or low, but your sensor glucose does not match your symptoms, always test your blood glucose using your BG meter.

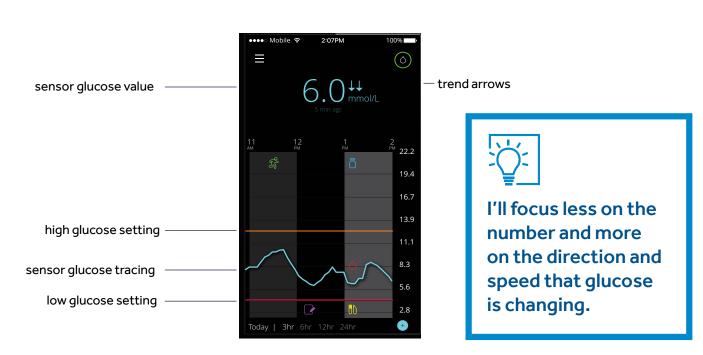
	KNOWLEDGE CHECK
Ê	Sometimes my SG and BG will not match exactly.
	A. True B. False
	Write either SG or BG next to each statement below.
	SG – Sensor Glucose BG – Blood Glucose
	readings are measured with your finger stick meter
	readings are measured using CGM
	is measured in interstitial fluid

SECTION 3: TRENDS

When using CGM, focus on sensor glucose trends. These trends give insight into the direction and the speed that your glucose is changing.

This allows you to:

- focus less on the individual sensor glucose numbers.
- focus more on how quickly your glucose may be rising or falling.



Example of sensor information on the Home Screen

When looking at the sensor information above, you can see that the current glucose reading is 6.0 mmol/L. But also notice:

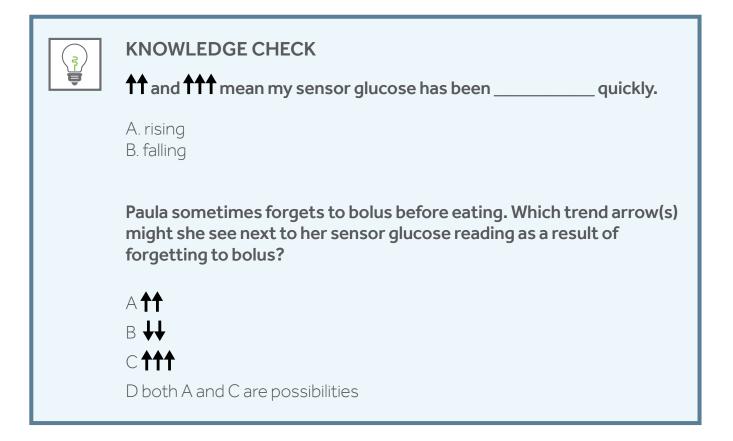
- the sensor glucose tracing shows the glucose has been trending downward.
- the two arrows next to the sensor glucose value tell you the glucose has been dropping.
- f or ↓ SG has been changing by 1-2 mmol/L over the last 20 minutes
- ↑↑ or ↓↓ SG has been changing quickly by 2-3 mmol/L over the last 20 minutes

↑↑↑ or ↓↓↓ - SG has been changing very quickly by more than 3 mmol/L over the last 20 minutes

TRENDS



Note: You can expect to see your glucose rising or falling quickly after eating, taking insulin, or when exercising.



SECTION 4: BEFORE I BEGIN USING MY GUARDIAN[™] CONNECT SYSTEM

Setting Up My Mobile Device to Use the Guardian[™] Connect App

The Guardian[™] Connect app can send you alerts when your glucose is trending above or below levels that you set. But because it is just like other apps on your mobile device, there are a few things you need to do so you will always get the alerts you want.

- 1 Make sure you know how these mobile device settings work: silent, vibrate, and Do Not Disturb.
- 2 Make sure that notifications are ON for your Guardian[™] Connect app. You will turn on notifications during your app setup. For Android devices, the Do Not Disturb permission is turned off by default and must be enabled in order for the Guardian[™] Connect App to sound alerts. Make sure the Do Not Disturb permission is enabled and remains enabled for the entire life of the app.
- 3 Make sure the Bluetooth[®] feature in your mobile device is always ON. With Android devices, you must have Location Services enabled when you are pairing a new transmitter with the app for the first time. You can turn off Location Services once you have completed the initial pairing process.
- 4 If you restart your mobile device (for example, after it's powered off or when the battery is empty and is recharged), always open your Guardian[™] Connect app. It will not reopen automatically.
- 5 The Guardian[™] Connect app runs in the background so it can send alerts. Don't force close your app unless you want to stop receiving the alerts.

6 Keep your mobile device charged.

- 7 Keep your mobile device and transmitter within 20 feet of each other. Otherwise, the system won't be able to send glucose information.
- 8 Set your mobile device's ringer to a level that you can hear or feel (vibrate).

Please check your mobile device's user manual for more information on adjusting your mobile device's settings.



WARNINGS: If you close the app you will not receive any sensor glucose information or

alerts. The app needs to be open or running in the background in order for you to get sensor glucose information.

Every now and then you should check that your app is still open and running. If you're running a few apps at once, it's possible that your Guardian[™] Connect app might close. You may see a "Lost Communication" notification if it closes.

If your mobile device shuts off and turns back on, your app will not reopen on its own. Open the app again after restarting your mobile device in order to avoid missing sensor glucose information and alerts.



Don't assume my app is always open and able to give alerts. Must check app is still running.



WARNINGS: You won't receive any sensor glucose alerts if Bluetooth is turned off in your mobile device. If you turn on Airplane mode, make sure to turn on Bluetooth.

You may also miss important sensor alerts if your mobile device's screen or speakers are damaged.

SECTION 5: SETTING UP MY GUARDIAN[™] CONNECT SYSTEM

Now that we have covered the basics of how CGM works let's set up your Guardian[™] Connect app on your mobile device.



Install the application:

To download your Guardian[™] Connect app:

 Search for "Guardian[™] Connect" in your mobile device's app store. Then follow the steps to install it.

To open the application:

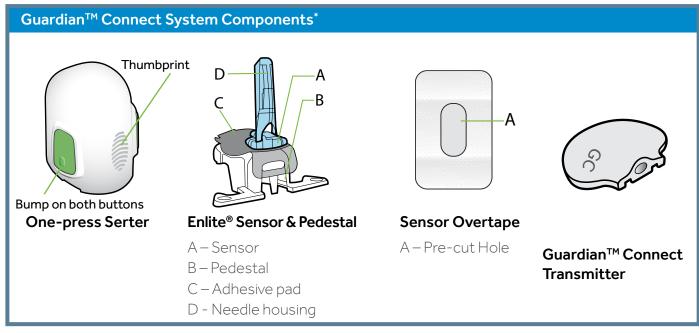
- 2. Tap 🧟 on your mobile device.
- Follow the steps on the screen to set up your Guardian[™] Connect app.
- 4. When you have reached the **Start Sensor** screen, go to the next page of this Getting Started Guide for **Inserting and Starting your Sensor**.





SECTION 6: INSERTING AND STARTING THE SENSOR

Before you insert your sensor, gather all of your supplies:



*For more details on the Enlite System Components, consult the User Guides

One-press Serter is required in order to insert the sensor properly and safely

Enlite sensor is individually packaged and comes attached to a plastic pedestal which is necessary for proper loading into the serter

Sensor overtape is required to keep the sensor securely in place

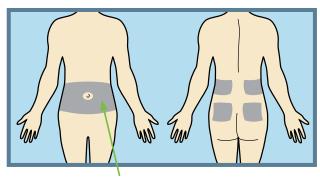
Guardian[™] Connect transmitter is connected after the sensor is inserted and covered with

the overtape

Selecting Your Site

Choose an insertion site that has an adequate amount of fat in the shaded areas shown to the right.^{**} The sensor insertion site should be at least:

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



Abdomen

^{**}Clinical trials for glucose sensors were performed on sensors inserted in the shaded area shown

For best sensor glucose performance, avoid sites:

- Where clothing may rub or constrict (for example, your beltline)
- Where your body naturally bends a great deal which may cause the sensor to pull out
- That are scarred or have hardened tissue or stretch marks
- Where there is a great deal of motion or friction

Preparing Your Site

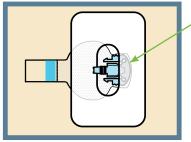
• Wash your hands with soap and water.

 Clean the selected site with an alcohol swab and allow the alcohol to dry. Do not use IV prep.





Example of Enlite sensor after insertion is complete

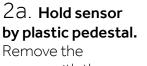


Overtape is covering both the sensor and the skin

Inserting Your Sensor



1. Open the sensor package. Pull the corner of the paper covering to open the sensor package.



sensor with the attached pedestal by holding the pedestal only. Place the sensor and pedestal on a clean, flat surface (a table).





Correct

Incorrect

2b. Tuck adhesive tab. Make sure that the sensor's adhesive tab is tucked under the sensor connector and snaps.





Correct

Incorrect



3. Load sensor into serter. Grip serter exactly as shown with thumb placed on thumbprint on serter. Do not hold green buttons.

Push serter down onto pedestal until base of serter sits flat on table.



Note: The thumbprint on the serter can be used for either left handed or right-handed insertion.

Inserting Your Sensor, continued

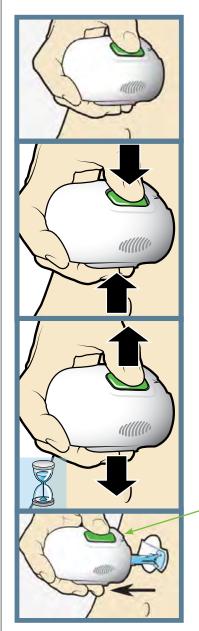
Fingers NOT holding green buttons



4. Detach serter from pedestal. To detach serter from pedestal, grip serter as shown, with thumb on thumbprint on serter. With the other hand, place two fingers on pedestal feet and slowly pull serter straight up. **NOTE:** Make sure that pedestal is firmly on the table before pulling serter away. Warning: Do not detach pedestal from serter in mid-air as this may damage sensor.



Note: The sensor remains inside the serter after removing the pedestal. The arrow on each side of the serter indicates location of the sensor needle. NOTE: Failing to hold serter securely flat against the body may allow serter to spring back after pressing the buttons and result in improper insertion of the sensor.



5a. Place serter on body. Hold serter steadily against your cleaned insertion site, without pushing serter too deeply into skin.

5b. Insert sensor. Press and release the **bump** on both buttons at same time. Do not pull the serter away from your body just yet.

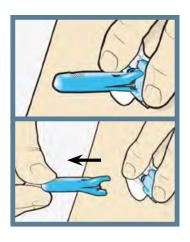
5C. Hold serter against body.

Continue holding serter against your body to allow adhesive time to stick to skin.

Do not press buttons

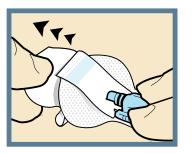
5d. Remove serter from body. Slowly pull serter away from skin, making sure buttons are not pressed.

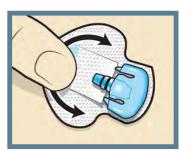
Inserting Your Sensor, continued



6. Remove needle

housing. Gently hold sensor base against skin at sensor connector and opposite end of sensor base. With the other hand, hold needle housing **at the top** and slowly pull straight out, away from sensor. Dispose needle housing in sharps container.







7a. Remove adhesive pad liner. Hold sensor in place and gently remove liner from under adhesive pad. Do not remove liner on rectangular adhesive tab yet.

7b. Press entire adhesive pad to skin.

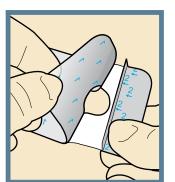
Firmly press adhesive pad against skin and smooth entire adhesive pad so it sticks to skin.

8a. Untuck adhesive tab. Untuck adhesive tab from under sensor connector.

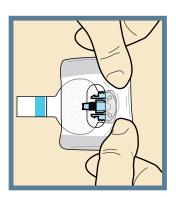
8b. Straighten adhesive tab. Straighten adhesive tab so it lies flat against your skin, but do not remove adhesive liner yet.

Taping Your Sensor

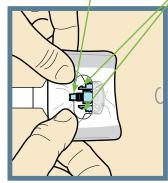
Before you connect the Guardian[™] Connect transmitter to your Enlite sensor it is very important that you properly secure the sensor against your skin using the sensor overtape.



1. Remove adhesive liner 1. Remove liner 1 from the overtape. Do not remove the two smaller liners marked 2 on the sides of the overtape.



Sensor connector is uncovered



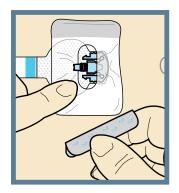
2. Apply overtape on sensor and skin. Important: Attach the overtape to both the rounded part of the sensor and the skin next to the sensor.

Sensor snaps are uncovered.

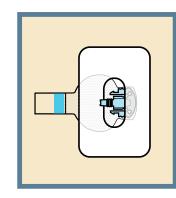
3. Apply remainder of overtape on adhesive pad. Stretch the remaining part of the overtape around the sensor connector so that the tape sticks to the curved adhesive pad and does not block the sensor connector and snaps. **Continue to press** the overtape to your skin to help ensure

that it sticks se-

curely.



4. **Remove liners marked 2.** Remove the liners marked 2 from both sides of the overtape and press the adhesive against the skin.



5. This image is an example of the overtape applied correctly. The sensor base and skin next to it are covered, but the sensor connector and snaps are uncovered and appear in the opening in the center of the overtape.

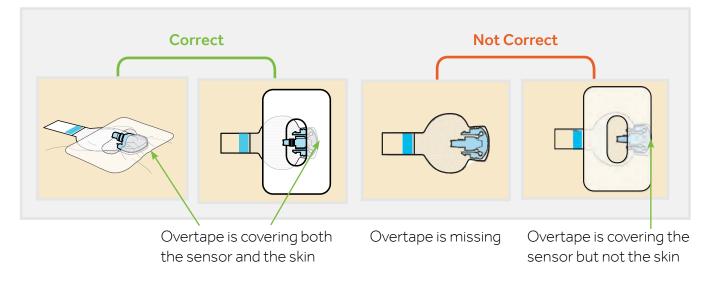


IMPORTANT: All sensor tapes and adhesives stick best when you continue to apply pressure after putting them on your skin. Doing so helps the Enlite sensor stay securely placed and fully inserted.

Checking Proper Tape Application

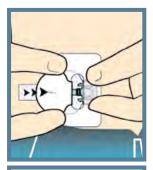
It is important to check your sensor site periodically to make sure the sensor is still secure and has not been pulled out. If the sensor has been pulled out, do not try to push it back into place. A new sensor may need to be inserted.

Check Proper Tape Application



Connecting Your Transmitter

After the glucose sensor is inserted and taped securely, connect the transmitter to the glucose sensor immediately.



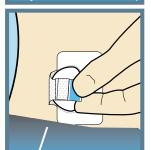
1. Connect transmitter to sensor. With one hand, hold the sensor in place. With the other hand, connect the transmitter to the sensor.

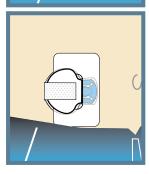
2. Cl light. "click" two pa Check

2. Check for green light. You will hear a faint "click" indicating that the two parts are connected. Check for a green light to flash on the transmitter.

3. **Remove liner on tab.** Remove the paper

on the adhesive tab.





4. Apply tab. Fold the adhesive tab over and onto the transmitter. Important: Be careful not to pull the adhesive tab too tightly or it may cause the transmitter to bend or pull from the sensor connection.

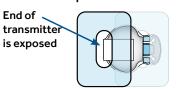
5. **Press tab.** Press the adhesive onto the transmitter.

Applying Optional Second Overtape

After connecting your transmitter to your sensor, apply a second piece of overtape, if needed, use Option 1 or 2.

If you have skin irritation due to moisture buildup, follow Option 1. If transmitter catches on your clothes, follow Option 2.

Option 1



Tape is over end of transmitter



Option 2

Starting the Sensor

Now that you have inserted and taped your sensor return to your Guardian[™] Connect app on your mobile device to complete the sensor start up. Tap **Start New Sensor.**

Removing Sensor in Six Days

- 1. Peel off tape.
- 2. Disconnect transmitter by pinching side arms of sensor. Then pull transmitter away.
- 3. Place transmitter on charger.
- 4. Peel off and discard sensor.



IMPORTANT If you do not see a green light flashing on the transmitter after it is connected to the sensor, then disconnect the transmitter and place it back on the charger to ensure that it is fully charged. Then reconnect the transmitter to the sensor.



Note: When your transmitter is connected to your sensor they are water-tight at 2.4 meters (8 feet) for up to 30 minutes. You can shower and swim without removing them.



Properly applying the overtape is key to ensuring your success with the Enlite sensor. Due to the sensor's small size and flexible nature, the overtape helps to secure it from body motion or physical activity that can cause it to be pulled out.



KNOWLEDGE CHECK

Placing your thumb on the thumbprint marking on the serter is necessary in order to:

- A. Avoid accidentally pressing the green buttons before you are ready to insert the sensor.
- B. To insert the sensor into the skin.
- C. I don't know.

Taping the sensor for extra security is optional.

A. True B. False

SECTION 7: PERSONALISED ALERTS

Completing Setup of the Guardian[™] Connect System

When you have reached the **Sensor Alerts** screen refer to the descriptions of the alert settings below.

Then write in your alert settings prescribed by your healthcare professional on the **CGM Settings Form** on page 20. These are the alert settings you will use to complete the setup of your Guardian[™] Connect system.

• Your CGM alert settings are most beneficial if they are personalised for your needs.

Your healthcare professional will work with you to determine your

initial settings and help you with adjustments that need to be made. **Personalising My Alerts High Limit** 250 ert on Hiał Alert Before High (🔶 Low Snooze) Rise Rate Fall Rate (Ĥigh Snooze) Alert Before Low Sensor Glucose Readings Alert on Low 70 Low Limit Urgent Low 3.0 mmol/L CGM Alert Setting

WARNING: The Guardian[™] Connect app will ask to send you notifications. Please allow notifications so that you will not miss important alerts.

Notifications

Notifications for your app must be turned ON in order for you to receive any alerts. When you are setting up your app for the first time, it will ask you to allow the notifications. You must NOT turn off the Notifications in your mobile device settings. If you turn off Notifications by mistake, will appear on the app's home screen. Tap will and then, tap the message.

Audio Override

The app has an override feature that allows your app alerts to sound at maximum volume even if your mobile device's ringer volume is set to Do Not Disturb, low volume, or silent (vibrate). The audio override feature is already turned On for all app alerts when you first start using your app. But you can choose which alerts (Low Glucose, High Glucose, and/or System Status Alerts) will override the ringer volume. You can change this setting in the app menu if you prefer not to override your mobile device's ringer volume.



Turned On

To Change Your Audio Override Setting:

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

WARNING: If you turn off your audio override, the volume for your app alerts will be the same as your mobile device's ringer volume. You might miss important app alerts when your mobile device's volume is set to Do Not Disturb, silent (vibrate), or low volume. Make sure to set your mobile device's volume high enough so that you can hear the alerts.

ecco Mobile 9	11:30 AM	* 69% 🔳
K Back	Audio	Save
	ger setting to alwa	
Override		0
Note: the Urgent ringer, regardless	Low Alert wik always o of this setting.	werride your
		wirride your
ringer, regardless		werride your
ringer, regardless OPTIONS		werride your

HOW DOES THE AUDIO OVERRIDE WORK?		
Your app settings	Your mobile device's volume	App alerts you will get
Audio Override ON	Ringer is ON Ringer is OFF (silent or vibrate) Do Not Disturb is ON	Sound at maximum volume
Audio Override OFF	Ringer is ON	Same sound as mobile device's ringer volume
\bigcirc	Ringer is OFF (silent or vibrate) Do Not Disturb is ON	No sound (and will vibrate if on) No sound or vibrate

Using the Audio Override...



Marley is getting ready to sleep. She sets her phone to Do Not Disturb because she doesn't want to hear any calls or text messages until the next morning. But she wants to wake up if she gets a **low sensor glucose alert.**

Which alert should she set to override her phone's Do Not Disturb?

Answer: Audio Override on for Low Alerts

ocoo Mobile 🕈	11:30 AM	\$ 69%
Back	Audio	Save
Overrides ringer tone, even when		
Override		
Note: the Urgani Le ringer, regardless of		overtide your
OPTIONS		
Low Alerts		
High Alerts		101
Status Alerts		61

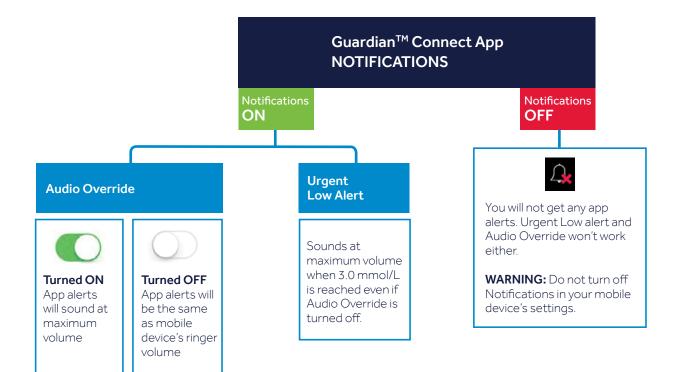
Urgent Low Alert

There is one exception. You will still get an **Urgent Low Sensor Glucose Alert** that sounds when your sensor glucose value reaches or falls below **3.0 mmol/L** even if the audio override is turned off. But remember, notifications must be on.

PERSONALISED ALERTS

WARNING: Notifications must be turned on for the Guardian[™] Connect app in order for the Audio Override to work and to hear the Urgent Low alert.

This graphic shows whether you will get your app alerts when Notifications are turned On or Off:



ALERT SETTING	ALERT SHOWN ON SCREEN	WHAT DOES IT MEAN
HIGH SETTINGS		
High Limit	No alert is shown. The high limit is the value that the other high settings are based on.	The sensor glucose value that your healthcare provider determines is above the sensor glucose range appropriate for you.
Alert on High	High Sensor Glucose	Your sensor glucose value has reached or risen above your high limit.
Alert Before High	High Predicted	Your sensor glucose value is predicted to reach your programmed high limit.
Time Before High	N/A	You can be notified from 10 minutes up to 1 hour before your sensor glucose value is expected to reach your high limit.
Rise Alert	Rise Alert	Your sensor glucose has been rising rapidly. Indicated by \uparrow , $\uparrow\uparrow$, or $\uparrow\uparrow\uparrow$
Snooze Time	N/A	You can be reminded when any of the high alert situations still exist after 5 minutes up to 1 hour has passed. Applies to all high settings.

Snooze...

Stephen's doctor instructed him to turn on **Alert on High** with a **Snooze** of 2 hours. If his sensor glucose reaches his high limit, he checks his BG and takes insulin if he needs it. His Guardian[™] Connect system will check again in 2 hours and alert him if he is still at or above his high limit.





Don't turn off notifications for my app or I won't get any app alerts.

PERSONALISED ALERTS

ALERT SETTING	ALERT SHOWN ON SCREEN	WHAT DOES IT MEAN
LOW SETTINGS		
Low Limit	No alert is shown. The low limit is the value that the other low settings are based on.	The sensor glucose value that your healthcare provider determines is below the sensor glucose range appropriate for you.
Alert on Low	Low Sensor Glucose	Your sensor glucose value has reached or fallen below your low limit.
Alert Before Low	Low Predicted	Your sensor glucose value is predicted to reach your programmed low limit.
Time Before Low	N/A	You can be notified from 10 minutes up to 1 hour before your sensor glucose value is predicted to reach your programmed low limit.
Fall Alert	Fall Alert	Your sensor glucose has been falling rapidly. Indicated by ♦, ♦♦, or ♦♦♦.
Snooze Time	N/A	You can be reminded when any of the low alert situations still exist after 5 minutes up to 1 hour has passed. Applies to all low settings.

 \bigwedge

WARNING: If you turn OFF notifications for your app, the Audio Override feature will not work. You will not get the Urgent Low alert either.



Marley is getting ready to go to sleep. She sets her phone to silent because she doesn't want to hear phone calls or texts, but she does want to hear her Guardian[™] Connect app alerts. What should she do?

A. Check that the Audio Override is ON.

B. Check that the Audio Override is OFF.

C. l'm not sure.



KNOWLEDGE CHECK

Stephen is going to a class. He doesn't want to hear any phone calls, texts, or Guardian[™] Connect app alerts. He wants all his phone calls, texts, and app alerts to be silent. What should he do?

A. Turn the phone's ringer to silent. Turn ON the Audio Override.

B. Turn the phone's ringer to silent. Turn OFF the Audio Override.

C. I don't know.

Stephen is going home now that the class has ended. He wants to hear his Guardian[™] Connect app alerts even if his phone calls and texts stay silent. What should he do?

A. Keep the phone's ringer to silent. Turn ON Audio Override.

B. Turn ON phone's ringer. Turn OFF Audio Override.

C. I have no idea.

Marley has High Alerts set up. But she turns OFF Notifications for her Guardian[™] Connect app in her phone's Settings. Now what would happen if she has a high glucose?

- A. She would get the high glucose alert.
- B. She would NOT get the high glucose alert.
- C. I'm not sure.

Marley glances at her Guardian[™] Connect app and sees that her sensor glucose is high, but she didn't get an alert. What should she do?

A. Check that Notifications are ON for her app in the phone's Settings.

- B. Turn OFF Audio Override
- C. I don't know.

Stephen is going to a loud music festival. What should he do to stay on top of his diabetes?

A. Do nothing different.

B. Check his GuardianTM Connect app more often as he won't be able to hear the alerts. C I'm not sure

C. I'm not sure.

Marley is on a flight to New York. The flight attendant instructs everyone to put their phones in Airplane Mode. What should she do to stay on top of her diabetes?

- A. Turn on Airplane Mode and then turn on Bluetooth.
- B. Don't turn on Bluetooth while in Airplane Mode, but know that she won't get any glucose alerts. Check with a blood glucose meter instead.
- C. Either A or B

Guardian[™] Connect - Continuous Glucose Monitoring Settings Form

Record your CGM settings here for future reference.

HIGH SETTING	LOW SETTING
High Limit	Low Limit
mmol/L	mmol/L
Alert Before High	Alert Before Low
ONOFF	ONOFF
Time Before High	Time Before Low
MinutesHour	MinutesHour
Alert on High	Alert on Low
ONOFF	ONOFF
Rise Alert	Fall Alert
fff +f +f	
Snooze Time	Snooze Time
MinutesHour	MinutesHour
Audio Override	Audio Override
ONOFF	ONOFF



My settings may need to be adjusted after I start using CGM

SECTION 8: CALIBRATION

Calibration is necessary to receive sensor glucose readings and for optimal CGM performance. To calibrate, you must use a fingerstick blood sample to test your BG on your meter and then enter that value into your GuardianTM Connect app. CGM does not eliminate the need for BG meter tests.

If the system is not calibrated regularly, then you will not receive sensor glucose readings until there is a calibration.

You will need to calibrate your sensor after it is inserted:

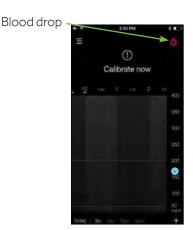
- About 2 hours after you connect your transmitter to your sensor and start the **Warm up** period. You will receive a **Calibrate now** alert when it is ready for its first calibration.
- Again within 6 hours from the first calibration. You will only need to do this on the day you insert the sensor.
- Again every 12 hours from your last calibration
- Again if the system asks you to calibrate more often to improve the sensor's performance.

Calibration Checklist:

- Wash your hands before checking your BG
- Calibrate at least 2 times a day or when you get a **Calibrate now** alert. 3 4 times a day is best.
- Calibrate before meals and when there are no arrows showing on your app
- Enter the BG into the app right away if it is a good time to calibrate
- Don't use an old BG reading
- Don't reuse BG readings from earlier calibrations
- Wait at least 15 minutes in between calibrations

Tap the blood drop on the app to calibrate.

Calibration Schedule Day 1
Enlite sensor inserted:h
l will calibrate:
2 hours after sensor inserted:h
Within the next 6 hours:h
At bedtime:h
Day 2 to Day 6
l will calibrate:
When I wake up:h
Again within 12 hours:h
Again during the day: h
At bedtime:h



Calibrating the Sensor

Calibration timer

On the Home screen the calibration icon tells you the amount of time left until your next calibration is due:

12 hours left before the next calibration is due

6 hours left before you need to calibrate again



 (\circ)

3 hours are remaining



1 hour is remaining

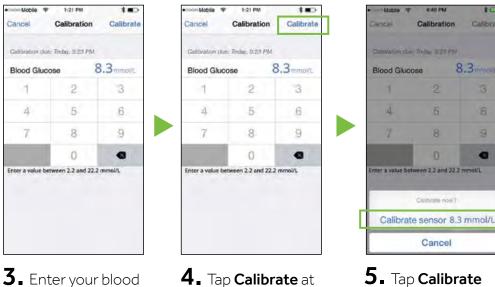
Calibration is due now. Calibrate using your blood glucose meter

Calibration is not permitted yet



To calibrate:

- **1.** Test your blood glucose on your meter.
- **2.** Tap the **blood drop** on the top right corner of the Home Screen.



3. Enter your blood glucose reading (2.2 mmol/L to 22.2 mmol/L) using the keypad.

4. Tap **Calibrate** at the top right corner of the screen.

5. Tap Calibrate sensor -- mmol/L.

The application returns to the home screen. A gappears on the graph at the time it was entered. Your sensor glucose reading will appear in about 5 minutes after the calibration is entered.



IMPORTANT If you notice a large difference between your BG meter reading and sensor glucose readings, wash your hands and do another BG fingerstick test to make sure it is an accurate reading. Check the sensor site to ensure that the sensor overtape is still holding the sensor in place. If there is still a large difference in glucose readings, another calibration may be needed to bring the readings closer together again.

Calibration Reminder

You can use the Calibration Reminder to give you notice before the next calibration is necessary. The Calibration Reminder can be set from 5 minutes to 1 hour from the Alert Settings menu option.

Using a Calibration Reminder

Lina calibrates at 7:00 when she wakes up. Her next calibration would be due 12 hours later at 19:00. Her calibration reminder is set to 1 hour so she would be reminded at 18:00 that a calibration will be needed.



KNOWLEDGE CHECK

What might happen if a calibration is required and it's not entered into your app?

- A SG readings will not display
- B I will continue to get the SG data on my app
- C I may not get important alerts such as Low Sensor Glucose
- D Both A and C

SECTION 9: READING THE SENSOR DISPLAY

Viewing the Main Menu

Press on the top left corner of the Home Screen. You will now see these 3 icons in the system status bar.

A Sensor Life Icon

After you insert a new sensor you will see how many days of sensor use are left. The sensor icon will change with each day that passes.

B Transmitter Battery Icon

When the transmitter is fully charged, the battery icon will appear as solid green. The icon will change as the battery life is used.



C Transmitter Communication Icon





A communication error, the transmitter is not paired, or Bluetooth is off on your mobile device.

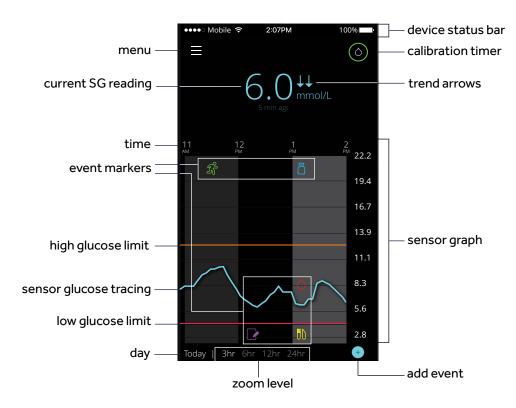
Note: When the Transmitter Battery is depleted, Transmitter is not paired, or the sensor has one day or less before it expires, then these icons will appear in both the Main Menu and at the top of the Home Screen.







Once the sensor has started giving you sensor glucose readings, the Home screen will display:



Current Sensor Glucose Value

The most current sensor reading is updated every 5 minutes. The sensor reads glucose values from 2.2 mmol/L to 22.2 mmol/L.

Viewing the Sensor Graph

Swipe center of graph, right and left: to view past sensor information

Double tap screen: to return to current glucose.

Slide your finger on SG tracing: to view more details, SG reading, time, date.

Touch anywhere on graph: to view more details, event information.

Example of an "info box" for Insulin

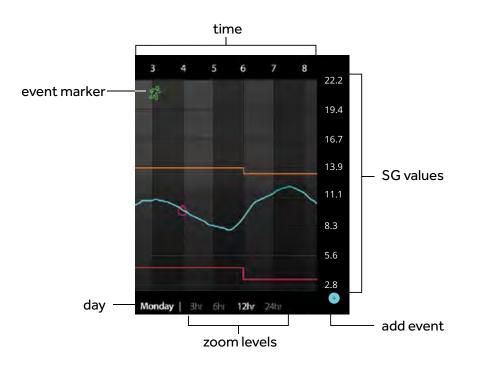


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Additional Sensor Graphs

To view 3-hour, 6-hour, 12-hour, and 24-hour glucose graphs:

- tap graph twice or
- select graph hours at bottom of Home screen.



Entering Event Markers

Capture other information right on your app:



Blood Glucose: BG meter readings. These can be used both to calibrate the sensor and simply to manage your diabetes without calibrating the system.



Insulin: The type and amount of insulin you use.



Meal: The amount of carbohydrates you eat or drink.



Exercise: The intensity and duration of exercise you do.



Other: This event can be used to enter any other information relevant to your diabetes management. For example, you can record when you take medications, when you feel ill, or when you are under stress.



To enter an event marker

1. Tap 💽 on the bottom right corner of the home screen.







2. Tap the desired event icon.

- **3.** Enter the information for the selected event.
- **4.** Tap **Done** at the top of the screen when finished.

The application returns to the home screen and the event icon appears on the graph at the selected time.



Note: A BG reading entered as an event can be used to calibrate the sensor.

1. Enter BG reading

2. Select Done

3. When Calibrate now? appears, select Calibrate Sensor -- mmol/L if you are sure you want to calibrate.



SECTION 10: SENSOR ALERTS

Receiving alerts is a part of wearing CGM. We discussed some of these alerts earlier in Section 3: Personalised Alerts. There are other alerts that you will receive as well.

When a sensor alert occurs:

- High alerts will appear as orange,
- Low alerts will be red,
- and all **other alerts** (such as Calibrate now) will be **blue**.

Follow the instructions on the screen to address the alert.

Clear alert: Drag bottom of alert screen upwards.

Snooze alert: Drag bottom of alert screen downwards. Then tap or adjust the snooze time.



WARNING: If you snooze a sensor glucose alert, you won't get the alert again during the length of the snooze time that you have set, even if your sensor glucose level doesn't improve. Check your glucose with your BG meter while you're in the snooze period.

Sensor Alerts

Example of the **Low Sensor Glucose** alert message:

Note: If your mobile device has returned to the locked screen, alerts will also appear on this screen. **Do not turn off notifications or enable the Do Not Disturb setting on your mobile device. Doing so may result in missing important alerts requiring your immediate attention.**



WARNING: If your headphones are plugged into your mobile device and you are not using them, you may not hear important alerts that require you to take action.



WARNING: Notifications must be turned ON for your app in order to get any app alerts. Otherwise, you won't get the Urgent Low alert and Audio Override feature.

See Quick Reference Guides section on page 45-46 of this guide for other alerts.



What if I get a Lost Communication Alert?

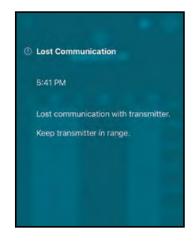
Lost Communication means your app isn't communicating with your transmitter.

The causes include:

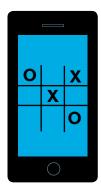
- Your app isn't running
- An issue communicating to your mobile device
- An issue with your sensor

Because you may not know what is causing the problem, it is best to follow these steps:

- 1 Open your app to make sure it's still running properly. It may take a few minutes to communicate again.
- 2 Bring your mobile device closer to your transmitter and sensor
- 3 Move away from other equipment (for example, cordless phone or WIFI router) that can cause radio frequency interference
- 4 If that doesn't work, then inspect your transmitter and sensor:
 - Reconnect your transmitter to your sensor ONLY if you see that they have disconnected. Note: Doing this will start the warm-up time again which may last up to two hours.
 - Insert a new sensor in a different spot on your body if you see that your current sensor has pulled out from your skin.



Lost Communication Alert



Hanna has a few different apps running on her phone including a game she is playing. Then she sees a **Lost Communication** alert from her Guardian[™] Connect app. This means her app isn't giving her any sensor information.

What should she do?

- Open her app to make sure it's running properly. It may take a few minutes to start working again.
 - She should also check periodically to see if the app is still running in the background.
- If her transmitter is still not communicating with her app, then she should follow the other steps above. If that still doesn't work, then she should call the Helpline to assist her.

Note: If your mobile device has returned to the locked screen, alerts will also appear on this screen.

Your app must be OPEN or running in the background at all times in order for you to get sensor glucose information and alerts.



KEY REMINDERS:

l will:



check my BG with my meter to confirm my SG before making treatment decisions (for example, dosing insulin before a meal or taking carbohydrates to treat a low glucose).



calibrate my sensor at least twice a day or more often if the system asks me to. 3 - 4 calibrations a day is best.



avoid closing my Guardian[™] Connect app so that I can continue getting sensor glucose alerts.



check my Guardian[™] Connect app regularly to make sure it is still running.



keep Bluetooth on so that my transmitter communicates with my app.



avoid turning off notifications for my app. Otherwise, I won't get any app alerts.



keep Audio Override turned on to hear my app alerts.



keep my mobile device charged so that I can always get sensor alerts.



select New Sensor (not Reconnect Sensor) each time l insert a new sensor.



charge my transmitter after seven days of wearing it.

SECTION 11: CARELINK[™] PERSONAL SOFTWARE

Creating a Care Partner Account and Sharing Your Information

Guardian[™] Connect allows you to sync your data to CareLink[™] Personal software automatically. This automated sync sends data displayed in your Guardian[™] Connect app to the CareLink[™] Connect tab of the CareLink[™] Personal website approximately every five minutes. This feature also automatically sends pump and sensor history information to create your CareLink[™] Personal report every 24 hours.



Reminder: Have your healthcare professional (HCP) view your information at the office or bring a report with you to your next visit.

You can invite a family member, friend, or other care partner to view your CGM information on the CareLink[™] Personal website by selecting **Manage Care Partners**.



2) Be sure Sync to Carelink is toggled ON. Tap on Manage Care Partners.

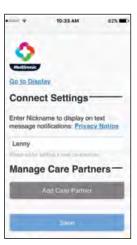


 Set a nickname for yourself so when text message notifications are sent, this is the name that will appear in the message. Then tap Save.

4) Tap on Add Care Partner. In the next screen fill the mandatory fields for your care partner (First and Last name). You can add up to 5 Care Partners to your CareLink[™] Personal account.

> Create a unique username for your care partner and temporary password, then tap Save. This temporary password is valid for 24 hours. Give this username and password to your care partner.





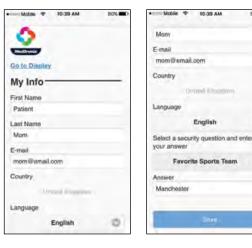
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Back to Car	e Partner Manag	Ineme
Add Ca	re Partner	
Enter the ca name	re partner's first	and last
Patient		
Mom		
this care pa	ername and pas rtner will use to ur information	
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Set Up and Access to the Care Partner Account

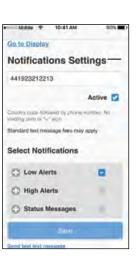
- 1) Next, your care partner will need to:
 - go to the CareLinkTM Personal website **(www.carelink.minimed.eu)** using a web browser on his/her own mobile device or computer.
 - login with the username and temporary password that you created.
 - check all boxes in Terms of Use. Tap Accept
 - change the temporary password to a new one. Tap **Next**.

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 The care partner will fill out their remaining information on the My Info screen. Then tap Save.



3) The care partner must enter their mobile number and have the **Active** box checked in order to receive text message alert notifications. Tap Save when complete.



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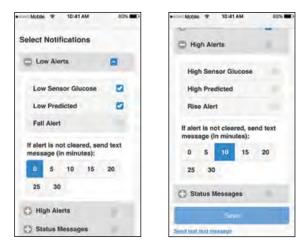
Notifications Settings Screen

Selecting Low Alerts and High Alerts

Your care partner can select and choose what alerts and alarms from Guardian[™] Connect they want to receive. If the alert has not been cleared in the Guardian[™] Connect app, a text message will be sent to the care partner based on the 0-30 minute delay set in Select Notifications. If your care partner does not want a delay in alerts, select 0. Once all desired notifications have been made, tap Save.

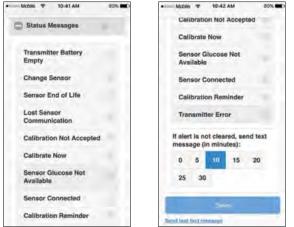


Note: The care partner may only receive alerts and alarms that have been set by the patient in the GuardianTM Connect app regardless of the Notification selected. For example, if the patient does not set High Alerts in the GuardianTM Connect app, the care partner will not receive High Alert messages even if they select it in Select Notifications on the CareLinkTM Personal website.



Status Messages

The care partner can also select to receive text messaging on sensor alarms from the GuardianTM Connect app. If the alarm has not been cleared in the GuardianTM Connect app, a text message will be sent to the care partner based on the 0-30 minute delay set in Select Notifications. If your care partner does not want a delay in alerts, select 0. Once all desired notifications have been selected, tap Save.



SECTION 12: APPENDIX

Charging and Storing the Transmitter

Charge the transmitter before each use. When the transmitter is charging, a green light will flash on the charger. This green light will turn off when the transmitter is completely charged. You will need to charge the transmitter after each sensor use. A fully charged transmitter can be used for a maximum of six days without recharging. It can take up to 2 hours to fully recharge.

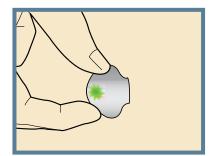
When you remove the transmitter from the charger, a green light should flash on the transmitter. This indicates that it has enough battery power to be connected to the sensor. If you do not see the green flashing light on the transmitter place it back on the charger until it is fully charged.

Store the transmitter, charger, and tester in a clean, dry location at room temperature. Do not store the transmitter on the charger for more than 60 days. Otherwise, the transmitter battery will be permanently damaged. If the transmitter is not in use, you must charge the transmitter at least once every 60 days.

If you connect transmitter to charger and you see no lights on the charger: replace the battery in the charger.

While charging your transmitter you see a flashing red light on the charger: replace the battery in the charger.

While charging your transmitter you see a mix of short and long flashing red lights on the charger: replace the battery in the charger and fully charge the transmitter. +





Tester

Refer to your transmitter and charger User Guides for more information.

X-rays, MRI, or CT Scan

If you are going to have an X-ray, MRI, CT scan, or other type of diagnostic imaging involving radiation exposure or strong magnetic field, remove your mobile device (where your Guardian[™] Connect app is installed), transmitter, and glucose sensor and place them outside of the testing area.

Going through Airport Security

The full body scanner may be a form of x-ray. If you choose to go through the full body scanner, you will need to remove your sensor and transmitter prior to the scan. To avoid removing your devices, you should request an alternative screening process that does not use x-ray. Your CGM system can withstand exposure to metal detectors and wands used at airport security checkpoints.

Traveling by Air

If you wear a CGM device, it is safe for use on commercial airlines. If airline personnel request that you turn off your CGM device, you must comply.

Note: It is important that you test your blood glucose (BG) more frequently while you are traveling. The routine hassle of travel, including stress, changes in time zones, schedules and activity levels, meal times and types of food, can all affect your diabetes control. Be extra attentive to monitoring your BG frequently, and be prepared to respond if needed.



Page 6: 1) A 2) BG, SG, SG Page 8: 1) A 2) D

Page 19: 1) A 2) B Page 24-25: 1) A 2) B 3) A 4) B 5) A 6) B 7) C





What Do My Sensor Alerts Mean?

See your healthcare professional regularly to check your CGM settings. Your settings may need to be changed at times. Follow the instructions on the screen to address the alert.

To **clear the alert**, drag the bottom of the alert screen up.

To **snooze the alert**, drag the bottom of the alert screen down. Then tap the snooze time. You can change the snooze time using the **-** and **+**.

Alert setting	Alert shown on screen	What it means	What I should do
High Limit	High Sensor Glucose	Your sensor glucose value is equal to or greater than your high limit that you have set.	 Check your blood glucose using your BG meter. Make sure to use a blood sample from
Low Limit	Low Sensor Glucose	Your sensor glucose value is equal to or lower than your low limit that you have set. This setting is in addition to Urgent Low alert.	 your finger. Don't use your sensor glucose values to make treatment decisions (for example, dosing insulin before a meal or
Urgent Low (cannot be changed)	Urgent Low Sensor Glucose	Your sensor glucose has gone below 3.1 mmol/L. You will still hear a sound with this alert regardless of your mobile device's volume or Audio Override. But remember, notifications must be kept on.	 Follow your healthcare professional's instructions for treating your glucose.
Alert Before High Time Before High	High Predicted	Your sensor glucose is expected to reach your high glucose limit in the length of time you have set.	
Alert Before Low Time Before Low	Low Predicted	Your sensor glucose is expected to reach your low glucose limit in the amount of time you have set.	
Rise Alert	Rise Alert	Your sensor glucose has been increasing at a rate that is equal to or faster than the Rise Rate that you have set: ↑, ↑↑, ↑↑↑.	
Fall Alert	Fall Alert	Your sensor glucose has been falling at a rate that is equal to or faster than the Fall rate you have set \downarrow , $\downarrow \downarrow$, $\downarrow \downarrow \downarrow$.	

These sensor alerts come pre-programmed in the Guardian[™] Connect application with the exception of the last alert, "Calibrate by" (alert setting is called "Calibration Reminder"). These alerts cannot be modified and are required by the app.

Alert	What it means	What I should do
Calibrate now	You need to calibrate your sensor in order to get sensor glucose readings.	Wash hands and check blood glucose using a fingerstick sample and blood glucose meter. Enter blood glucose value into your Guardian™ Connect app.
Lost communication	Your Guardian [™] Connect app and transmitter haven't been communicating for 30 minutes. Your app may have closed if there are too many apps running at the same time. Other equipment may be causing radio frequency interference. Another cause is that your transmitter disconnected from your sensor or your sensor pulled out of your skin.	Move your mobile device closer to your transmitter and sensor. Move away from equipment that can cause radio frequency interference. Open app to make sure it is running properly. If it's still not working check that transmitter is still connected to sensor. If not, then reconnect it. Insert a new sensor if you see that it has pulled out. If still not working, call the 24-hour help line.
Calibration not accepted	Your BG meter value could not be used to calibrate; it was too different from the SG value.	Wait 15 minutes. Wash your hands and check your blood glucose again. Enter this blood glucose value into app.
Sensor end of life	Sensor has reached it's maximum life of 6 full days.	Remove your sensor. Recharge your transmitter. Follow the instructions in the User Guide for inserting and starting a new sensor.
Change sensor	You may have received a second Calibration not accepted alert or the sensor is not working properly.	Remove your sensor and follow the instructions in the User Guide for inserting and starting a new sensor.
Sensor glucose not available	There is no sensor information due to several possible causes. Some causes include the sensor pulling out of your skin or your sensor not working properly.	Don't calibrate unless the app tells you to. The system is trying to correct the problem. This could take up to 3 hours. You don't need to do anything at this time.
Calibrate by	You programmed the Calibration Reminder setting to alert you when a calibration will be due.	Do a calibration by the time that the alert shows you.
Mobile device battery low	Your mobile device's battery has reached or fallen below 20% of its power.	Charge your mobile device. WARNING: Don't let your mobile device shut down due to low battery, or you won't get any alerts. Carry a charger for your mobile device so that you can charge the battery.
		For a complete list of Alerts and

If phone battery is empty & recharges, my app will not restart automatically

Part 1. Removing Sensor in Six Days

- 1. Peel off tape.
- 2. Disconnect transmitter by pinching side arms of sensor. Then pull transmitter away from sensor.
- 3. Place transmitter on charger.
- 4. Peel off and discard sensor.

Part 2. Inserting a New Sensor

Wash your hands and clean insertion site with alcohol.

1. Open sensor package.



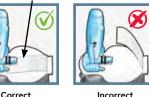
2a. Hold sensor by plastic

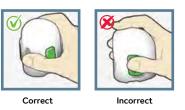
pedestal. Remove sensor with attached pedestal by holding pedestal only. Place sensor and pedestal on a clean, flat surface (a table).

2b.Tuck adhesive tab.

Make sure that sensor's adhesive tab is tucked under sensor connector and snaps.





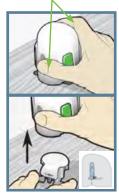


3. Load sensor into serter. Grip serter exactly as shown with thumb placed on thumbprint on serter. Do not hold side buttons. Push serter down on to pedestal until base of serter sits flat on table.



4. Detach serter from pedestal. To detach serter from pedestal, arip serter as shown, with thumb on thumbprint on serter. With other hand, place two fingers on pedestal feet and slowly pull serter straight up. NOTE: Make sure that pedestal is firmly on table before pulling serter away. Warning: Do not detach pedestal from serter in mid-air as this may damage sensor.

Fingers NOT holding green buttons



5a. Place serter on body.

Hold serter steadily against your cleaned insertion site, without pushing serter too deeply into skin. **Note:** Failing to hold serter securely flat against body may allow serter to spring back after pressing buttons and result in improper insertion of sensor.



5b. Insert sensor.

Press and release the **bump** on both buttons at same time.

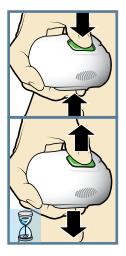
5c. Hold serter against body.

Continue holding serter against your body to allow adhesive time to stick to skin.

5d. Remove serter from body. Slowly pull serter away from skin, making sure buttons are not pressed.

6. Remove needle housing. Gently hold sensor base against skin at sensor connector and opposite end of sensor base. With the other hand, hold needle housing at the top and slowly pull straight out, away from sensor. Dispose needle housing in sharps container.

7a. Remove adhesive pad liner. Hold sensor in place and gently remove liner from under adhesive pad. Do not remove liner on rectangular adhesive tab yet.







Part 2. Inserting a New Sensor, cont'd

7b. Press entire adhesive pad to skin. Firmly press adhesive pad against skin and smooth entire adhesive pad so it sticks to skin.

8a. Untuck adhesive tab. Untuck adhesive tab from under sensor connector.

8b. Straighten adhesive tab.

Straighten adhesive tab so it lies flat against your skin, but do not remove adhesive liner yet.

Part 3. Taping Sensor

Before you connect the transmitter to your Enlite sensor it is very important that you properly secure the sensor against your skin using the sensor overtape.

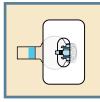
 Remove adhesive liner 1. Remove liner 1 from overtape. Do not remove two smaller liners marked 2 from the sides of overtape.



- 2. Apply overtape on sensor and skin. Important: Attach overtape to both rounded part of sensor and skin next to sensor.
- 3. Apply remainder of overtape on adhesive pad. Stretch remaining part of overtape around sensor connector so that tape sticks to curved adhesive pad and does not block sensor connector. Continue to press overtape to your skin to help ensure that it sticks securely.
- 4. **Remove liners marked 2.** Remove two paper tabs from sides of overtape and press adhesive against skin.



5. This image is an example of overtape applied correctly.

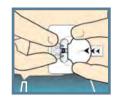


IMPORTANT: All sensor tapes and adhesives stick best when you continue to apply pressure after putting them on your skin. Doing so helps the Enlite sensor stay securely placed and fully inserted.

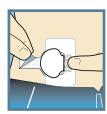
Part 4. Connecting the Transmitter

After glucose sensor is inserted and taped securely, connect transmitter to glucose sensor immediately.

1. **Connect transmitter to sensor.** With one hand, hold sensor in place. With other hand, connect transmitter to sensor.



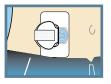
- 2. **Check for green light.** You will hear a faint "click" indicating that the two parts are connected. Check for a green light to flash on the transmitter.
- 3. **Remove liner on tab.** Remove the paper on the adhesive tab.



- Apply tab. Fold the adhesive tab over and onto the transmitter. Important: Be careful not to pull the adhesive tab too tightly or it may cause the transmitter to bend or pull from the sensor connection.
- 5. **Press tab.** Press the adhesive onto the transmitter.

IMPORTANT If you do not see a green light flashing on transmitter after it is connected to sensor, then disconnect transmitter and place it back on charger to ensure that it is fully charged. Then reconnect transmitter to sensor.

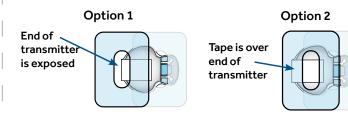




Part 5. Applying Optional Second Overtape

After connecting your transmitter to your sensor, apply a second piece of overtape, if needed, use Option 1 or 2.

If you have skin irritation due to moisture buildup, follow Option 1. If transmitter catches on your clothes, follow Option 2.



Part 6. Starting the Sensor

 When Sensor connected screen appears automatically, tap New Sensor. Then tap OK.



Part 7. Calibrating

- 1. Check your blood glucose using a blood sample from your finger.
- 2. Tap on top right corner of Home Screen.



 Enter your blood glucose reading (2.2 mmol/L to 22.2 mmol/L) using keypad.



- 4. Tap **Calibrate** at top right corner of screen.
- 5. Tap, Calibrate sensor -- mmol/L.





Notes

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