

Medtronic

Simplera™ System

Getting Started with Continuous Glucose Monitoring



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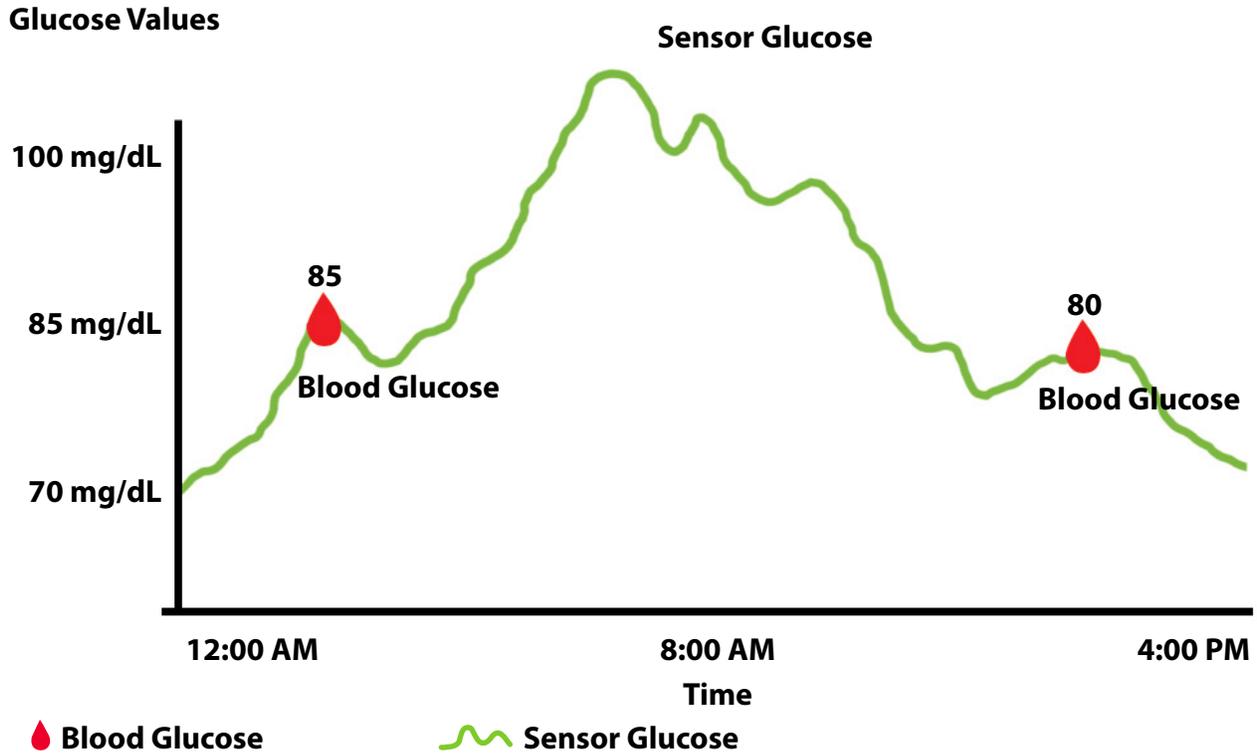
Simplera System

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Welcome to Continuous Glucose Monitoring

Section 1: Welcome to Continuous Glucose Monitoring

Continuous glucose monitoring (CGM) lets you see more glucose values than when you check with your blood glucose (BG) meter. You will get up to **288 sensor glucose (SG) readings every 24 hours** to fill the gaps between your BG checks. CGM can also alert you when your glucose levels are high or low.



WARNING: Do not use continuous glucose monitoring if you are taking hydroxyurea, also known as hydroxycarbamide. Hydroxyurea is used to treat certain diseases, such as cancer and sickle cell anemia. Using hydroxyurea results in much higher sensor glucose readings compared to blood glucose readings. Taking hydroxyurea while using continuous glucose monitoring can result in inaccurate or missed CGM alerts. Always check the package label of any medication you are taking to confirm if hydroxyurea or hydroxycarbamide is an active ingredient. If you are taking hydroxyurea, consult a healthcare professional. Use additional blood glucose meter readings to verify your glucose levels.

Welcome to Continuous Glucose Monitoring



WARNING: Always consult a healthcare professional before using sensor glucose values to make treatment decisions if you are taking a medication that contains acetaminophen or paracetamol while wearing the sensor. Medications that contain acetaminophen or paracetamol can falsely raise sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen or paracetamol that is active in the body and can differ for each person. Falsely elevated sensor readings can result in over-administering insulin, which can cause hypoglycemia. Medications that contain acetaminophen or paracetamol include, but are not limited to, cold medicines and fever reducers. Check the package label of any medications you are taking to see if acetaminophen or paracetamol is an active ingredient. Use additional blood glucose meter readings to verify your glucose levels.



WARNING: If you “feel” that your glucose is high or low, but your sensor glucose doesn’t match what you’re feeling, always check your blood glucose using your BG meter.

Setting Up Your Simplera System

Section 2: Setting Up Your Simplera System

To get started with the Simplera system you will need to download the Simplera app. When you first open the app it will walk you through the complete set up process.

1. Search for “Simplera” in your mobile device app store and install the app.

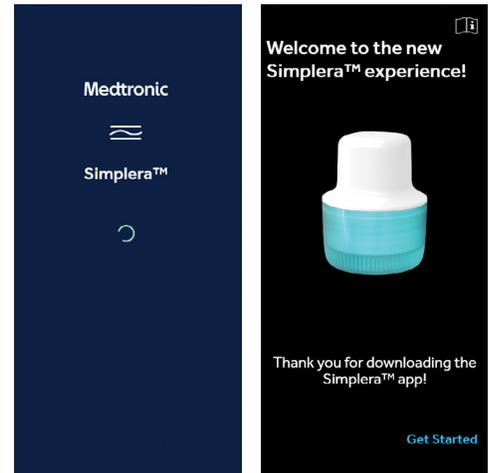


NOTE: The Simplera app should be used with a compatible mobile device and operating system. To view a list of compatible devices, please visit your local Medtronic website or contact the Medtronic representative listed in the Simplera System User Guide. Confirm version compatibility of the Simplera app and mobile device operating system prior to updating the mobile device. Disable automatic updates on the mobile device to avoid any unintentional updates that may prevent the app from operating.



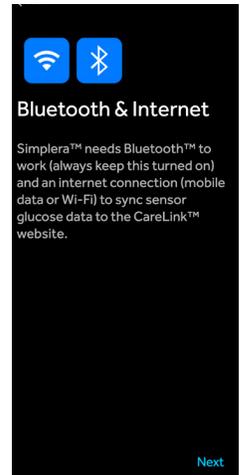
WARNING: Do not use your Simplera app if your mobile device screen or speakers are damaged. Otherwise, you may miss important alerts and sensor information.

2. Open the Simplera app. Tap **Get Started**.



Setting Up Your Simplera System

- 3. Turn on Bluetooth® in your mobile device so that the app is connected to the sensor. To sync your data into CareLink™, make sure that your mobile device has an internet connection, either through a mobile data plan or Wi-Fi™*.



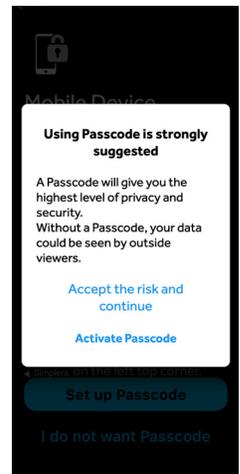
WARNING: You won't receive any sensor glucose alerts if Bluetooth is turned off in your mobile device. If you turn on airplane mode, make sure to turn on Bluetooth.

- 4. To protect your privacy, it is strongly recommended that you lock your mobile device when you are not using it. If you have not set up a passcode, fingerprint, or face ID set up, your Simplera app will ask you to set one up.

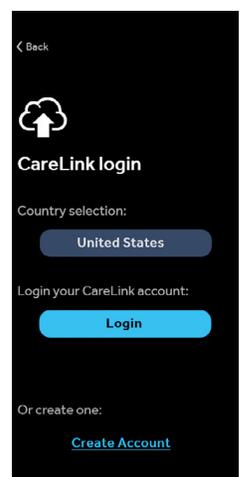
Apple®



Android™*

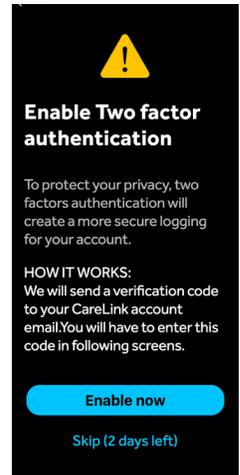


- 5. Sign into your CareLink account. Be sure to select the appropriate country for your account. If you do not have an account, tap **Create Account**.



Setting Up Your Simplera System

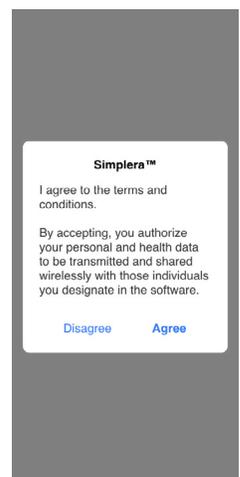
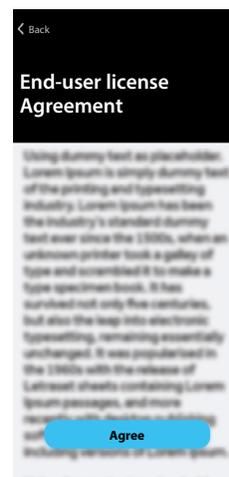
6. In certain countries it is recommended that you turn on Two factor authentication. Tap **Enable now**. You will receive a code in your email that you use for your CareLink account. A screen will display where you can enter that code.



7. To keep your information safe, the app will automatically log you out if you have not used it for more than 7 days.



8. Review the End-user license Agreement and tap **Agree**.



Setting Up Your Simplera System

- 9. Make sure you have set aside enough time to complete the setup of your system.



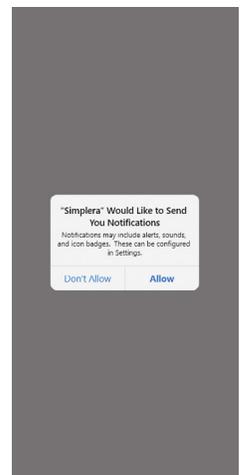
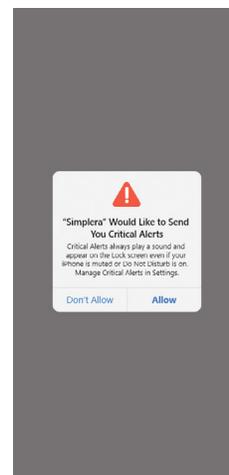
For Android users: Read all important warnings for your mobile device settings. If your mobile device includes battery saver settings, you will see a message asking you to turn these settings off. If these settings are active while using the Simplera app, the mobile device will shut down the app and prevent it from sending alerts and notifications. To make sure that you receive your glucose alerts, please follow the directions on the screen to correctly configure your settings.

If the battery saver settings are not disabled you will continue to see a message reminding you to adjust the settings every time you use the Simplera app.



WARNING: The mobile device may include battery saver settings. If these settings are active for the Simplera 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 Simplera app is active.

- 10. For Apple® users (iPhone®): Read all the important warnings on your mobile device screen. If you use an Apple device (iPhone), it is important that you always keep notifications and critical alerts turned ON in your mobile device settings to ensure that you receive your Simplera notifications.



Setting Up Your Simplera System



WARNING for Apple users: Do NOT turn off notifications or critical alerts in your mobile device settings or you will not receive any Simplera alerts including the Urgent Low Alert.

For Android users: Your mobile device settings allow you to turn on the Do Not Disturb setting to avoid being bothered by text messages, app alerts, phone calls, and other notifications.

However, to continue getting SG alerts from your Simplera app, it is important that you allow the Do Not Disturb Permission setting when asked on your screen.

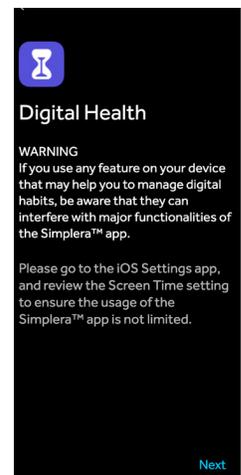


WARNING for Android users: Do NOT turn off notifications or do not disturb permission in your mobile device settings or you will not receive any Simplera alerts including the Urgent Low Alert.



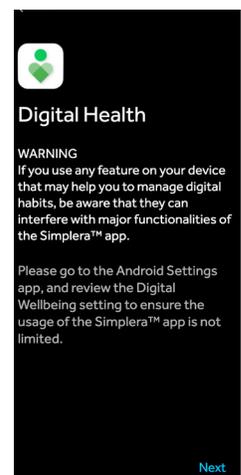
11. For Apple users (iPhone): Your mobile device settings menu has a feature called Screen Time that allows you to block apps during a Downtime period that you set. If you choose to use this feature, it is very important that you add the Simplera app to the "Always Allowed" apps. Otherwise, you will not get any alerts during Downtime.

Apple



For Android users: Your mobile device settings menu has a Digital Wellbeing feature that allows you to limit the amount of time the app can be used per day. It is very important not to set the app timer for your Simplera app or you will lose access to your SG and alerts.

Android



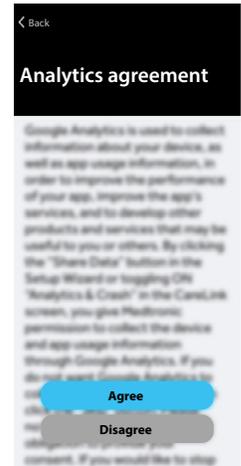
Setting Up Your Simplera System



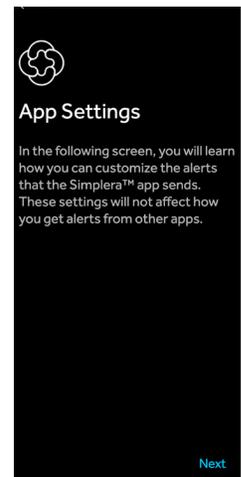
WARNING: Do not use any mobile device settings such as Screen Time (in Apple) or Digital Wellbeing (in Android) that may prevent your Simplera app from sending you alerts.

If you set the app timer in Digital Wellbeing for your Simplera app and let it expire, your Simplera app will shut down and you will not get any sensor glucose alerts.

12. Help Medtronic improve the app by sharing your anonymous usage data. Tap **Share data**, then **Agree**.



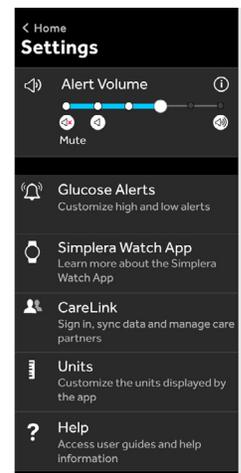
13. Tap **Next** to continue to your Simplera app settings.



14. You can control the volume of your alerts by going to  on the bottom left corner of your home screen and then selecting **Alert Volume**. Slide the volume bar to decrease or increase the volume of your alerts. You will be able to adjust the volume after you complete the set up process.



NOTE: If you do not respond to an alert, then the alert will sound louder and repeat every few minutes until you respond to it. **Alert Volume** only controls the sound of your alerts. You can still see the alerts as muting the volume does not affect visual alerts.

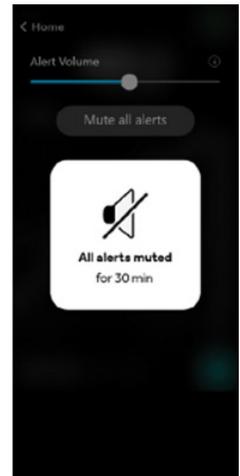
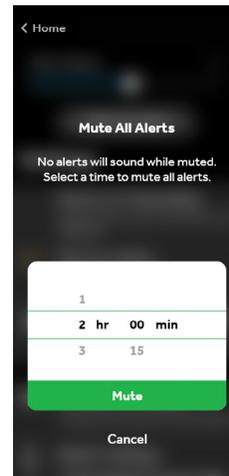
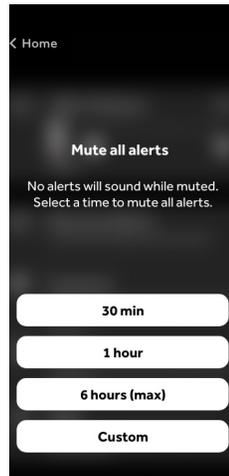


Setting Up Your Simplera System

15. You can silence all of your Simplera alerts for up to 6 hours by going to the  on the bottom left corner of your home screen and tapping **Mute** under alert volume. None of your alerts will make a sound for the entire time that you choose.



NOTE: When Mute alerts is set, the Urgent Low Alert will still vibrate but will not sound. The other alerts will also vibrate if your mobile device vibration setting is turned on. Mute alerts only controls the sound of your alerts. You can still see the alerts because muting the volume does not affect visual alerts.

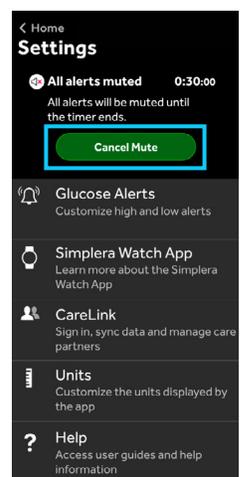


An icon will appear at the top of your home screen showing that all your alerts are muted. You can tap the icon to check the time remaining until the mute time ends.

Icon showing that all alerts are muted



You can tap **Cancel Mute** on your **Settings** menu at any time.



Setting Up Your Simplera System



WARNING for Apple users: Do not modify settings in the iOS Accessibility menu. Do not turn off vibration settings. If vibration is turned off, the app will not send any vibrations with the alerts, including Urgent Low Alert. Vibrate on silent must be turned on in your mobile device settings or your alerts, including Urgent Low Alert, will not vibrate while all alerts are muted. Do not enable the Assistive Access feature. The Assistive Access feature may prevent the Simplera app from pairing with the sensor or displaying alerts.

WARNING for Android users: Do not lower the vibration feedback to the lowest level in your mobile device vibration intensity menu. Otherwise, you will not get any vibrations with your alerts, including Urgent Low Alert.



KNOWLEDGE CHECK 1

What's the difference between sliding the Alert Volume to zero volume versus selecting Mute alerts?

Tap for the answer



KNOWLEDGE CHECK 2

Why is it important to not reduce the vibration setting on your mobile device to minimum or turn off vibrations?

Tap for the answer

Setting Up Your Simplera System



KNOWLEDGE CHECK 3

Let's say you're going to a movie and you tap Mute alerts and set it for 3 hours. What would happen if you get a Low SG alert during the 3 hours?

Choose the correct answer:

When I first get the Low SG alert it would not make a sound, but it would get louder after a few minutes if I don't respond to the alert.

The Low SG alert would not make any sound for the entire 3 hours.

The Low SG alert would show on my mobile device.



KNOWLEDGE CHECK 4

You're going to a meeting and you slide the Alert Volume to zero. What would happen if you get a Low SG alert?

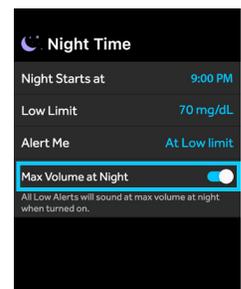
Choose the correct answer:

When I first get the Low SG alert it would not make a sound, but it would get louder after a few minutes if I don't do anything about the alert.

The Low SG alert would not make any sound whether I respond to the alert or not.

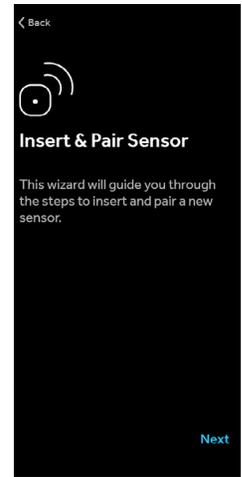
The Low SG alert would show on my mobile device.

16. The setting called **Max Volume at Night** will play your low and/or high alerts at the loudest volume at night to help you hear them while you are sleeping. You can change this setting in alert settings.



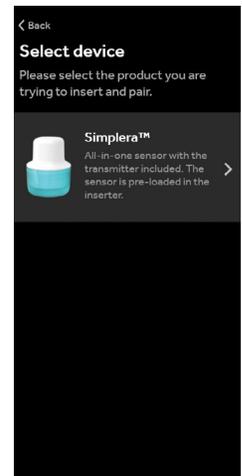
Setting Up Your Simplera System

17. Follow the screens to set up and insert your sensor.

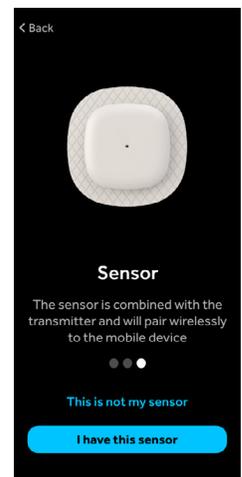


Inserting and Pairing the Sensor

18. Tap the Simplera option on the next screen.



19. The Simplera sensor and transmitter are combined and are inside the inserter. After insertion, you will pair your sensor to your mobile device in order to send SG information to the Simplera app. Tap **I have this sensor.**



Setting Up Your Simplera System

20. Do not throw away the inserter after you insert the sensor. You will need the serial number (SN) and CODE that are printed on top of the inserter to pair the sensor with your mobile device. Tap **Next**.



21. Read the Simplera Sensor User Guide first. Then, watch the training video to help you insert the sensor. You may review the printed instructions on the following pages of this Getting Started Guide instead to learn how to insert your sensor.



WARNING: Check your sensor site for bleeding after you insert the sensor. If there is bleeding, put pressure on the sensor site using a sterile gauze for up to three minutes. If the bleeding doesn't stop, or there is a lot of blood, or you have pain, then remove and discard the used sensor and insert a new one in a different spot.



Inserting the Simplera Sensor

22. The inserter label is on the top of the inserter.

Do the following steps before inserting the sensor:

- a.** Check the expiration date. Do not use an expired Simplera sensor.
- b.** Keep the SN and CODE to pair the Simplera sensor with your app in a later step.

Note: The SN and CODE label are also on the inside of the Simplera sensor box lid.



23. Inspect the cap label for damage before insertion.

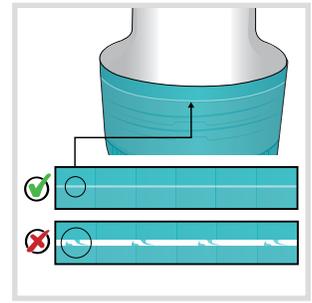
Note: Do not use the Simplera sensor if the cap label is damaged, or missing from the cap.



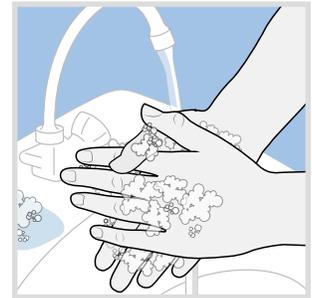
Setting Up Your Simplera System

24. Inspect the tamper band to make sure that it is not damaged, broken, or missing.

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



25. Wash your hands thoroughly with soap and water.



PRECAUTION: Some skin care products, such as sunscreens and insect repellents, can damage the Simplera sensor. Do not allow skin care products to touch the sensor. Wash your hands after using skin care products before touching the sensor. If any skin care products touch the sensor, immediately wipe the sensor with a clean cloth.

Setting Up Your Simplera System

Selecting Your Insertion Site

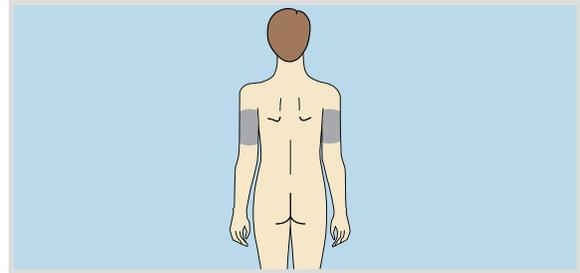
26. Choose the following site to insert the sensor:

- The back of your upper arm (ages 18 and older)



NOTE: Assistance from another person may be needed for sensor insertion into the back of the upper arm. If assistance is not needed, a mirror may be helpful for self-insertion.

Ages 18 years and older



Back of upper arm

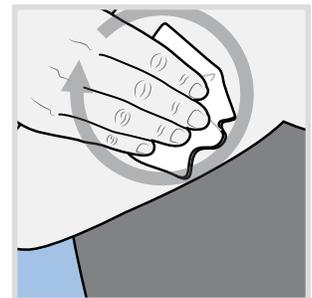


Insertion on abdomen and upper buttocks for ages 18 years and older has not been evaluated for accuracy.

For best sensor performance, avoid sites:

- Where your clothing may rub or be too tight
- Where your body naturally bends a lot as this may cause the sensor to pull out
- Where there is a lot of movement or rubbing (such as the inside of your arm)
- That are scarred or have hardened tissue or stretch marks

27. Clean the site you have chosen with alcohol. Let it air dry.

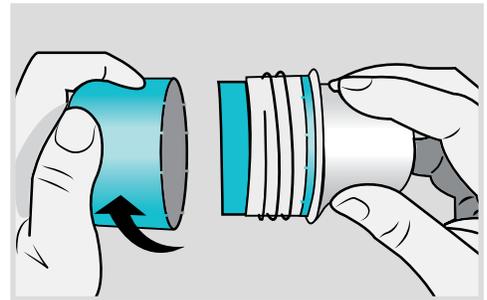


Setting Up Your Simplera System

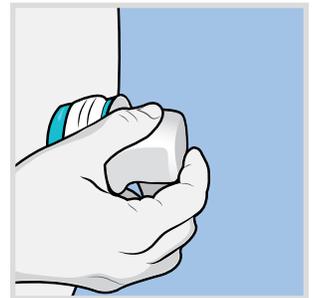
- 28.** Unscrew the cap from the inserter, breaking the tamper band.



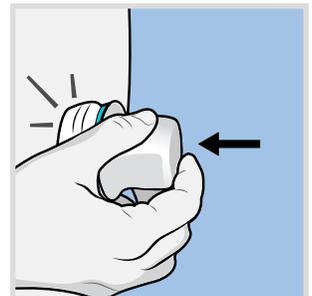
NOTE: Do not use the Simplera sensor if the tamper band is damaged, broken, or missing.



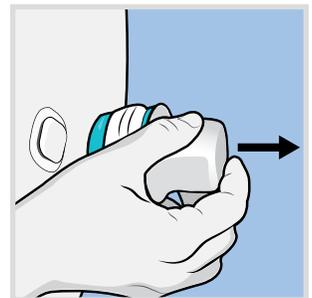
- 29.** Place the inserter on top of the prepared insertion site.



- 30.** Press the inserter firmly against your body until you hear a click.



- 31.** Gently pull the inserter straight from your body.

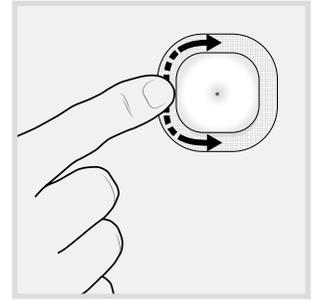


Setting Up Your Simplera System

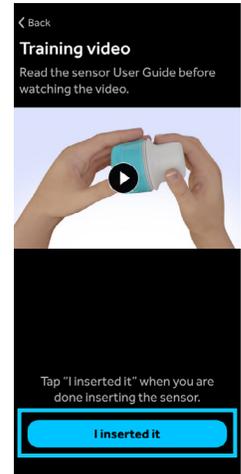
- 32.** Smooth down the sensor adhesive with your finger to ensure the sensor stays on your body for the entire time of use.



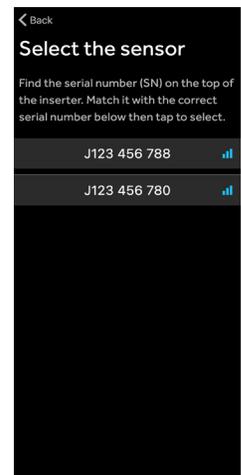
NOTE: Use commercially available or over-the-counter tape if needed to help the sensor stick better.



- 33.** When you are done, return to the app and tap **I inserted it.**



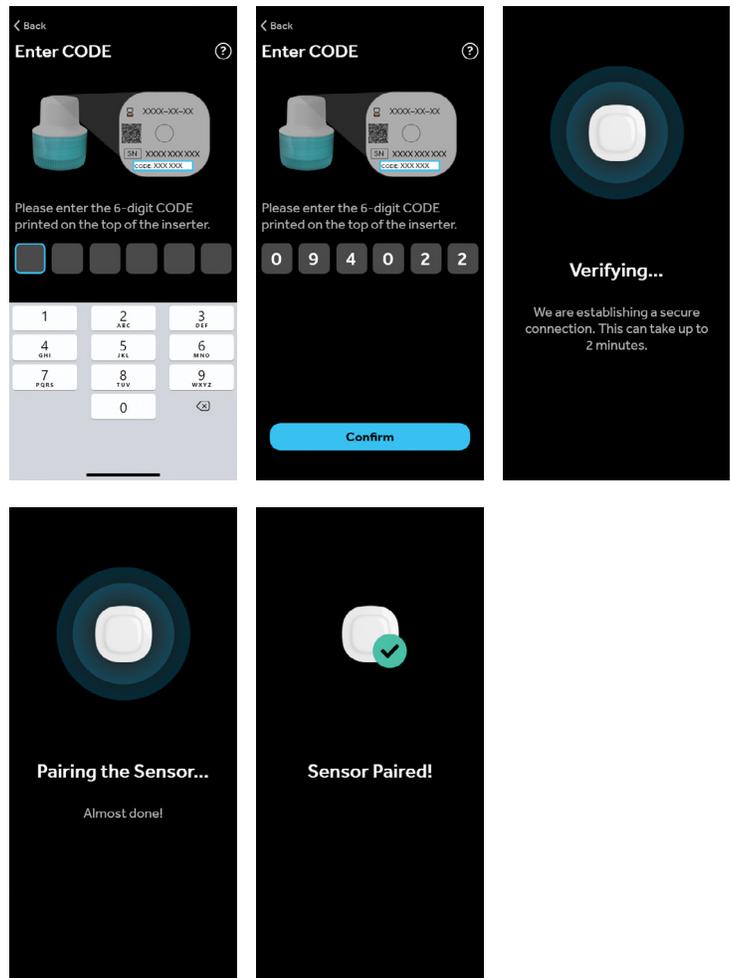
- 34.** Your app is searching for your sensor. Match the SN from the top of your inserter with the correct SN on the app screen. Tap the matching serial number.



Setting Up Your Simplera System

- 35.** Look for the 6-digit CODE on the top of the inserter. Enter the CODE into the app. Tap **Confirm**. Keep this CODE for reference until you dispose of the sensor. You may need to re-enter this CODE if you have to troubleshoot the sensor.

The CODE can also be found on the inside of the lid of the sensor box.

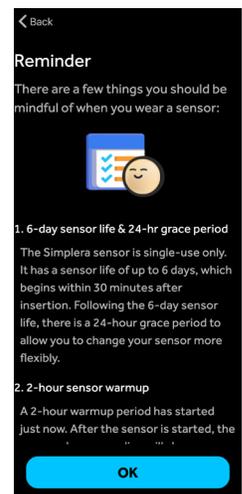


- 36.** It will take up to 2 hours for your sensor to warm up before you start to see SG values on your home screen. The sensor will continue to work for up to 6 days, followed by a 24-hour grace period. Then you will have to insert a new sensor.



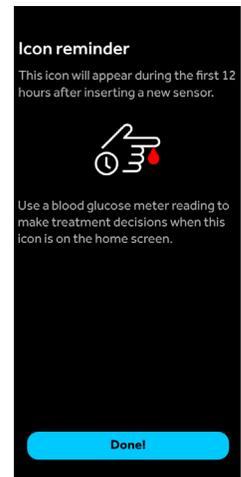
NOTE: After 6 days, followed by a 24-hour grace period, do the following to remove the Simplera sensor:

1. Gently peel the sensor adhesive away from your body.
2. Dispose of the sensor in accordance with all local laws and regulations. For additional information, see “Disposal” in the Simplera Sensor User Guide.



Setting Up Your Simplera System

- 37.** Use your BG meter to check your BG and make treatment decisions during the first 12 hours of wearing a sensor when you see this icon on the home screen. Please see *Section 4: Using Your SG to Make Treatment Decisions*, page 33 for more information. Tap **Done**.



WARNING: 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. Open the app again after force closing your mobile device in order to avoid missing sensor glucose information and alerts.

You should regularly check that your app is still open and running. If you're running a few apps at once, it's possible that your Simplera 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.



PRECAUTION: Do not expose your sensor to Magnetic Resonance Imaging (MRI) equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, x-ray and CT scan devices or devices emitting other types of radiation). Always remove your sensor before entering a room that has x-ray, MRI, diathermy, or CT scan equipment. Exposing your sensor to a strong magnetic field has not been evaluated and can cause the sensor to malfunction, result in serious injury, or be unsafe.



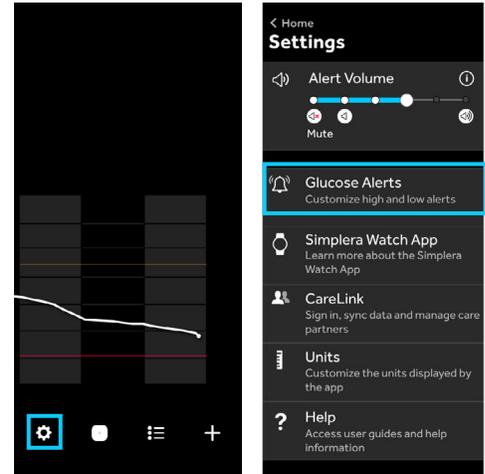
Using Your Simplera System

Section 3: Using Your Simplera System

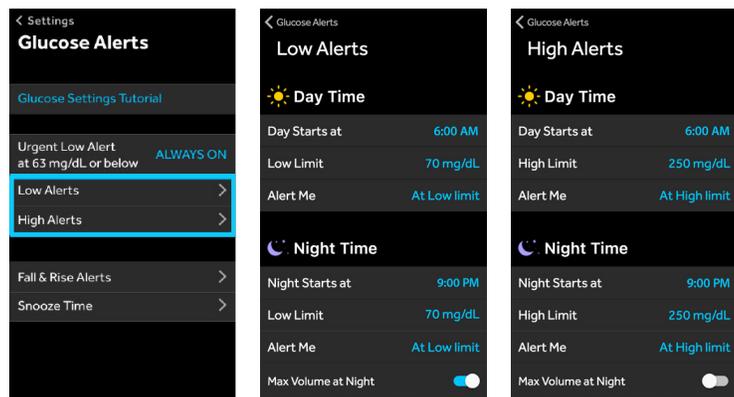
Adjusting Alerts

Follow up with your healthcare professional, as your settings may need to be changed.

1. Tap  on the bottom left of your home screen. Then, tap **Glucose Alerts**.

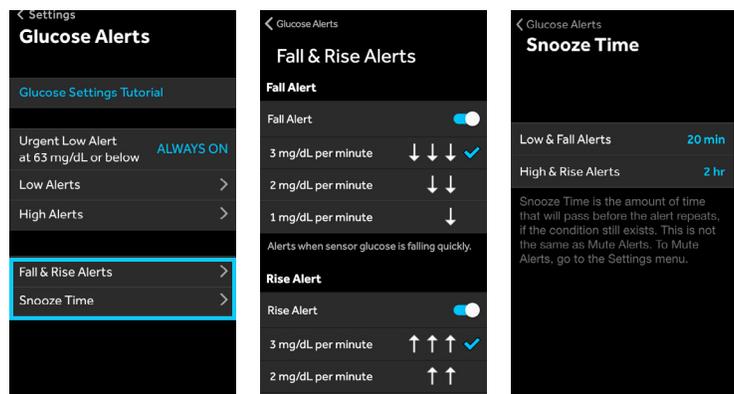


2. To change low alert settings, tap **Low Alerts**.
3. To change high alert settings, tap **High Alerts**.



WARNING: Be mindful of muting alerts or turning off vibration. If you mute alerts, the Urgent Low Alert will not sound but will vibrate, only. If you mute alerts and turn off vibration in your mobile device settings, the Urgent Low Alert will neither sound nor vibrate.

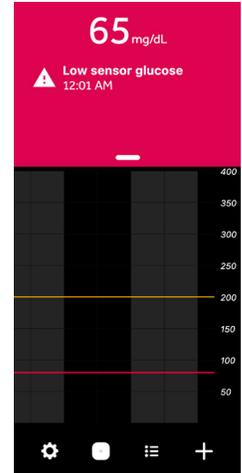
4. To change fall and rise alert settings, tap **Fall & Rise Alerts**.
5. To change snooze settings, tap **Snooze Time**.



Using Your Simplera System

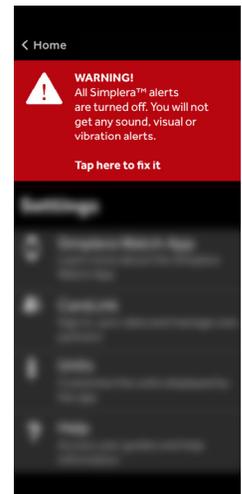
Responding to Alerts

1. An example of an alert that you may receive is a Low sensor glucose alert when your SG reaches or falls below your low limit. To **snooze the alert** using your programmed snooze time, swipe the alert up.

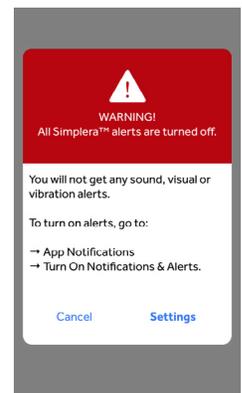
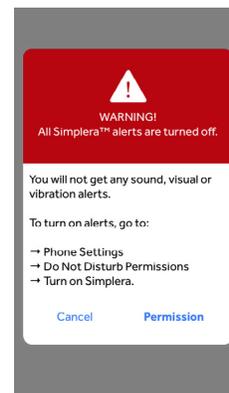


Alerts Turned Off

1. If you see a red **WARNING!** on your screen that says **All Simplera™ alerts are turned off**, you will not get any sound, visual, or vibration alerts. To correct this issue, tap on the warning or go to your mobile device settings.

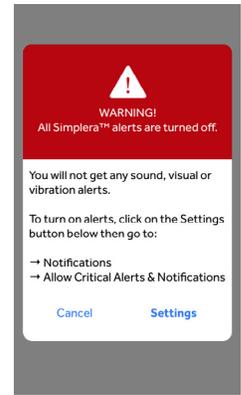


2. If you are using an Android device, turn on notifications and do not disturb permission.



Using Your Simplera System

3. If you are using an Apple device (iPhone), turn on **Critical Alerts** and **Notifications**.



WARNING for Apple users: Do NOT turn off notifications or critical alerts in your mobile device settings or you will not receive any Simplera alerts including the Urgent Low Alert.

WARNING for Android users: Do NOT turn off notifications or do not disturb permission in your mobile device settings or you will not receive any Simplera alerts including the Urgent Low Alert.

Using Your Simplera System

Alerts You May Receive

- Low alerts will show as **red**.
- High alerts will show as **orange**.
- Status alerts will show as **blue**.

To **snooze the alert**, swipe the alert up. You can change the Snooze Time for future alerts in your app's alert settings.

Alert setting	Alert shown on screen	What it means	What you should do
Urgent Low Alert (cannot be changed)	Urgent low sensor glucose	Your SG falls to 63 mg/dL or below. If you select Mute alerts in the app, then Urgent Low Alert will vibrate only.	Follow your healthcare professional's instructions for treating high or low glucose levels.
At Low Limit	Low sensor glucose	Your SG value is equal to or lower than your low limit that you have set. This is an additional alert to the Urgent Low Alert.	
Before Low Limit	Low predicted	Your SG is expected to reach your low limit in the amount of time you have set.	
Fall Alert	Fall alert	Your SG has been falling at a rate that is equal to or faster than the fall rate you have set: ↓, ↓↓, ↓↓↓.	
At High Limit	High sensor glucose	Your SG value is equal to or greater than your high limit that you have set.	
Before High Limit	High predicted	Your SG is expected to reach your high limit in the amount of time you have set.	
Rise Alert	Rise alert	Your SG has been increasing at a rate that is equal to or faster than the rise rate that you have set: ↑, ↑↑, ↑↑↑.	



WARNING: Do not turn off vibration in your mobile device settings. For Apple, the vibration setting may be through the Accessibility menu. For Android, it may be by setting vibration feedback to the lowest setting.



WARNING: Do not root or jailbreak the mobile device. Rooting the Android device or jailbreaking the Apple device means to change the software in a way the manufacturer did not intend. If the mobile device is changed in this way, the Simplera app will display an error message when launched and will not function.

Using Your Simplera System



WARNING: Keep your device near you and regularly check that your app is still open and running. If you are away from your device for too long, you will miss important alerts from the app.

These sensor alerts come pre-programmed in your app. You cannot change these alerts. The app requires them.

Alert	What it means	What you should do
Sensor end of life	Sensor has reached its maximum life of 6 days and 24-hour grace period.	Remove your sensor. Follow the instructions in this Getting Started Guide or the video in your app for inserting and starting a new sensor.
Change sensor	The current sensor does not work properly and needs to be changed.	To continue to receive SG values, a new sensor must be used. See the Simplera Sensor User Guide for instructions on how to change the sensor.
Lost communication	Your Simplera app and sensor haven't been communicating for 30 minutes. This may be because your mobile device is too far away, or because the Simplera app has been stopped by your mobile operating system due to other apps running. Other equipment may be causing radio frequency interference. Another cause is that your sensor pulled out of your skin.	Open the app to make sure it is running properly. Move your mobile device closer to your sensor. Move away from equipment that can cause radio frequency interference. Insert a new sensor if you see that it has pulled out. If still not working, call 24-Hour Technical Support.
Sensor updating	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.	The sensor is updating and the update may take up to 2 hours. No SG information will be available. You should check your BG with your meter.
Calibration not accepted	Your BG meter value could not be used to calibrate.	Wait at least 15 minutes before attempting another calibration. The Simplera system will request another calibration, if needed, after 15 minutes from when the Calibration not accepted alert was received. Wash your hands and check your BG again. Enter this BG value into app.

Using Your Simplera System

Alert	What it means	What you should do
Calibrate now	Your Simplera system needs you to complete a calibration.	Review the BG meter instructions for use on how to test BG. Enter this new value in the app for calibration.
Mobile device battery low	Your mobile device's battery has reached or fallen below 20% of its power.	Charge your mobile device.



WARNING: If your device shuts down due to low battery and restarts after charging, the Simplera app will not restart automatically and you won't receive any alerts. Carry a charger for your mobile device so you can charge the battery as needed and check that the app is running after any restart.

For a complete list of alerts, check the Simplera System User Guide.



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.

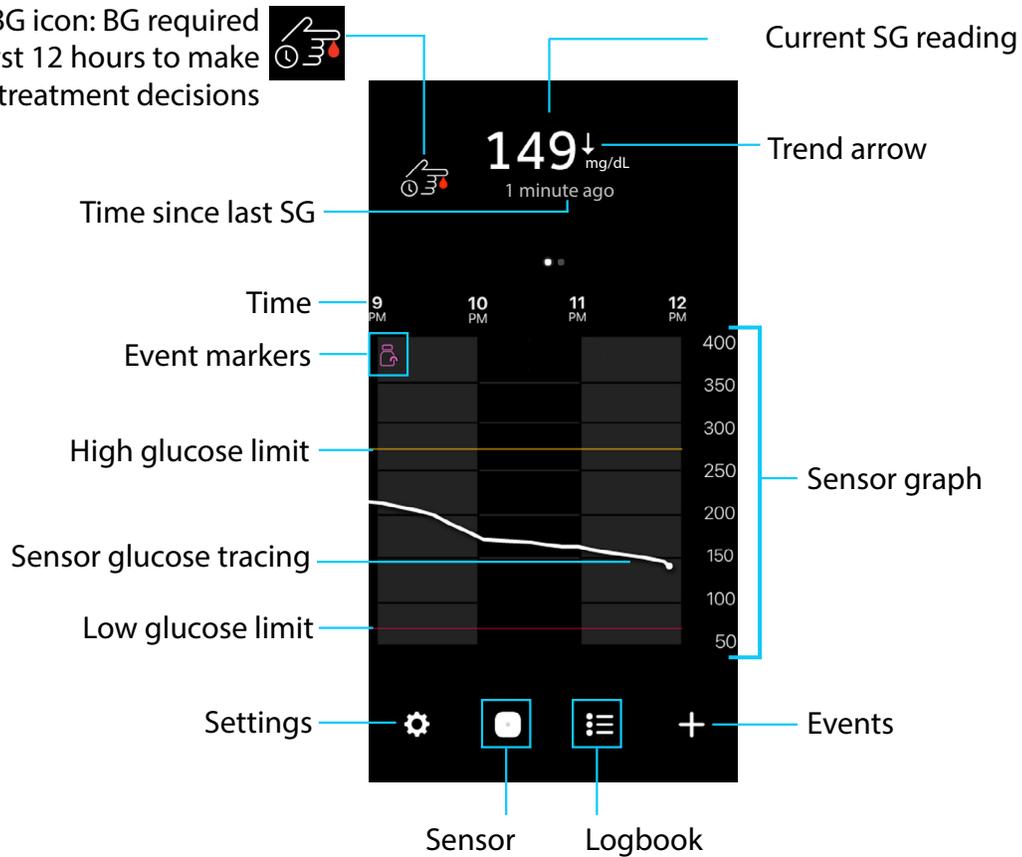


WARNING: Do not use your Simplera app if your mobile device screen or speakers are damaged. Otherwise, you may miss important alerts and sensor information.

Using Your Simplera System

Viewing the Home Screen

Check BG icon: BG required for first 12 hours to make treatment decisions



NOTE: When you see this icon during the first 12 hours after you insert a new sensor, use a BG meter reading to make treatment decisions. Please see *Section 4: Using Your SG to Make Treatment Decisions*, page 33 for more information.



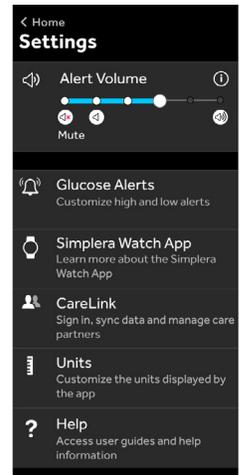
NOTE: This icon will show at the top of your home screen when your sensor has one day or less before it expires.



Using Your Simplera System

Viewing Your Settings Menu

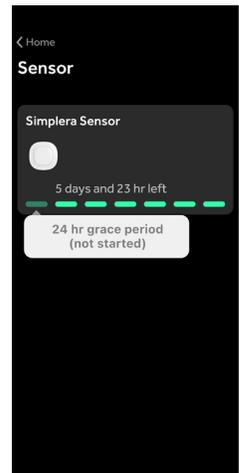
Tap  on the bottom left corner of your app's home screen.



Device Management

Sensor Life

Tap  on the bottom of your home screen after you insert a new sensor. You will see how many days your sensor has left. The sensor timer will count down with each day that passes.



Using Your Simplera System

Sensor Information and Options

When you tap the Simplera sensor icon, information about the sensor will be displayed.

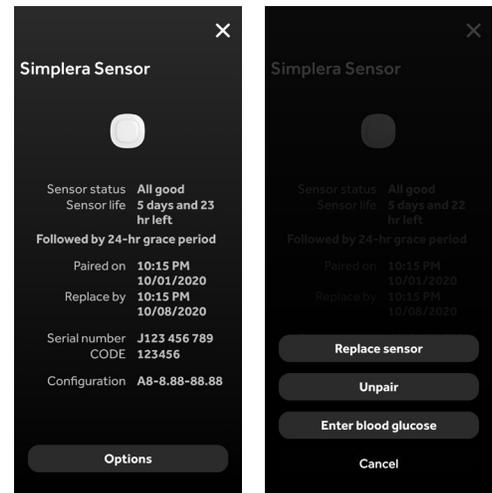
Tap Options:

- **Replace sensor** - when you are ready to insert and pair a new sensor.
- **Unpair** - when you want to disconnect your sensor from your mobile device. Before unpairing your sensor, save the CODE by taking a screenshot or writing it down. You must have this CODE in order to pair it again.
- **Enter blood glucose** - when you want to **calibrate** your sensor. Although it is not required that you calibrate your sensor, you may optionally calibrate it using your BG meter value if you want your sensor value to be similar. You may also choose to optionally calibrate if your symptoms do not match your SG values.
- If glucose levels are rising or falling rapidly, avoid use of BG readings for calibrations.

Option to Calibrate Sensor To calibrate:

1. Check your BG with your BG meter.
2. Tap  at the bottom of your home screen.
3. Tap the Simplera sensor icon.
4. Tap **Options**.
5. Tap **Enter blood glucose** and complete the steps.

You may also optionally calibrate the sensor when logging a blood glucose event, see *Entering Event Markers*, page 31.



Using Your Simplera System

Current SG Value

The sensor reading is updated every 5 minutes. The sensor measures glucose values from 50 mg/dL to 400 mg/dL.

You can see that the SG value on the screen in *Viewing the Home Screen*, page 26 is 149 mg/dL. You can also notice the following:

- **the SG tracing** shows the glucose has been trending downward.
- **the one arrow next to the SG value** also tells you the glucose has been dropping.

If you see:

↑ or ↓ This means your **SG has been changing** by 1-2 mg/dL per minute.

↑↑ or ↓↓ This means your **SG has been changing quickly** by 2-3 mg/dL per minute.

↑↑↑ or ↓↓↓ This means your **SG has been changing very quickly** by greater than 3 mg/dL per minute.

Viewing My Sensor Graph

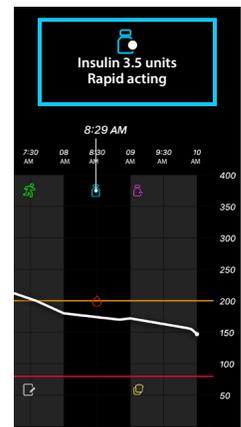
Swipe center of graph, right and left: to view past sensor information and return to the current SG value.

Double tap vertical glucose line on right: to return to current glucose.

Touch SG tracing: to view more details, SG reading, time, date.

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

Pinch and stretch the center of the graph: to zoom in and out on the graph.

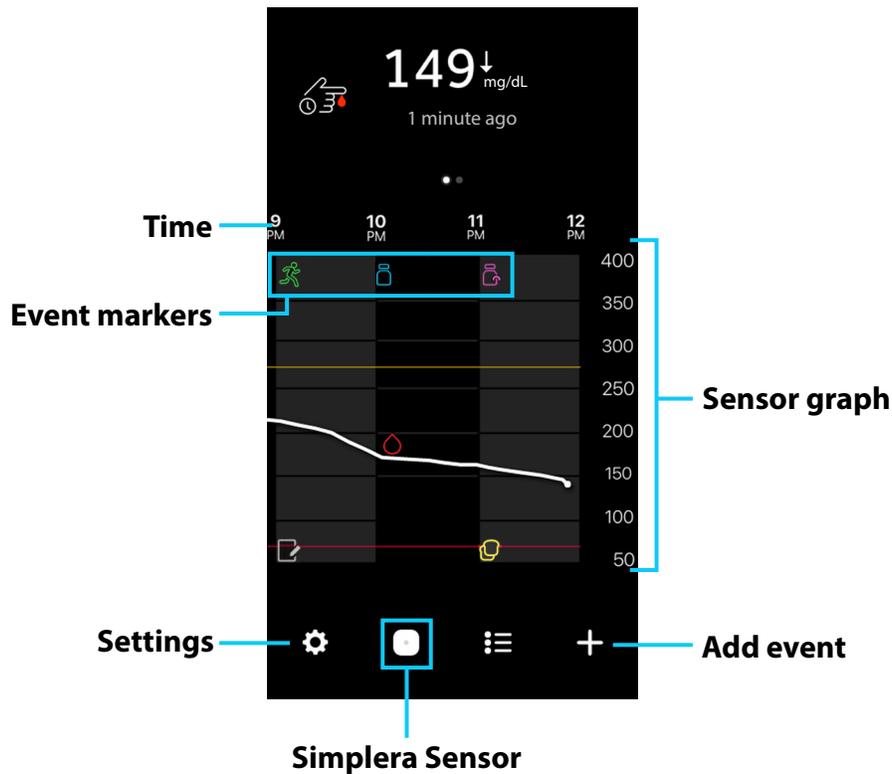


Example of an info box for insulin

Using Your Simplera System

Additional Sensor Graphs

To view 3-hour, 6-hour, 12-hour, and 24-hour glucose graph, tap the sensor graph twice.



Time in range

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

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

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

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

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

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

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

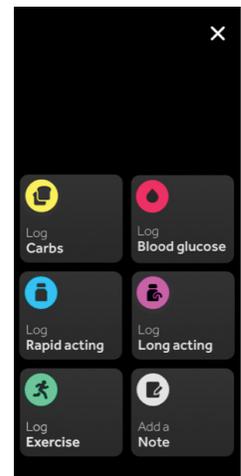
Using Your Simplera System

Entering Event Markers

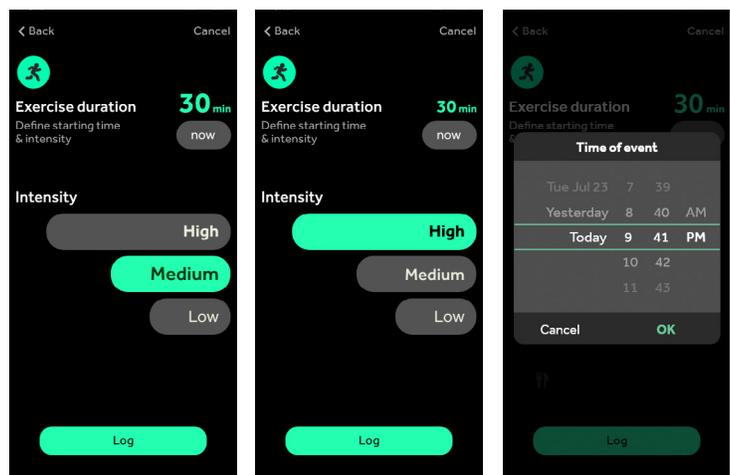
You can capture events or other information right on your app:

-  **Blood glucose:** To log your BG meter values. You can use your most recent BG meter value to optionally calibrate your sensor.
-  **Long acting insulin:** The type and amount of insulin you use
-  **Rapid acting insulin:** The type and amount of insulin you use
-  **Carbs:** The amount of carbohydrates you eat or drink
-  **Exercise:** The intensity and duration of exercise you do
-  **Note:** This event can be used to enter any other information about your diabetes management. For example, you can record when you take other medications, when you feel ill, or when you are under stress.

1. Tap  on the bottom right corner of your home screen.
2. Tap the event icon you want.

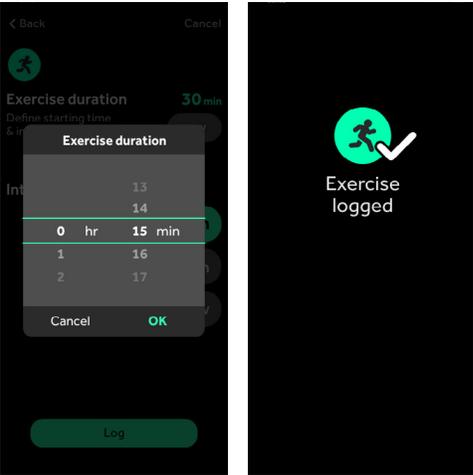


3. Enter the information for your event.



Using Your Simplera System

4. Tap **Log** when finished.



Your app returns to the home screen and the event icon shows on the graph.

Using Your SG to Make Treatment Decisions

Section 4: Using Your SG to Make Treatment Decisions

You can use your SG information instead of your BG when deciding to treat a low glucose or correct a high glucose. However, some situations will require you to use your BG meter, such as when you see this icon .

When To Use Your Fingerstick BG Values

Always use your BG meter in the following situations:

- when you see this icon 
- when calibrating your sensor
- when you aren't sure if your SG value is correct
- when your symptoms don't match your SG value
- when a SG value isn't available
- when you have taken medications that contain acetaminophen (such as Tylenol®) or paracetamol as they may cause your SG readings to become falsely raised



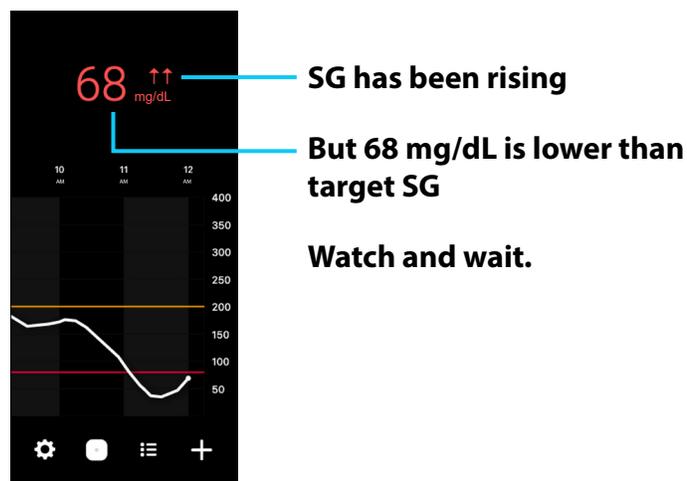
NOTE: You may still need to carry a BG meter with you.

How to Use Your SG Information to Make Treatment Decisions

Look at your **current SG** value along with your **trend arrows** and **graph** to help you decide what to do next.

EXAMPLE 1:

If you see \uparrow , $\uparrow\uparrow$, $\uparrow\uparrow\uparrow$, this means your SG has been rising and may continue to rise. But if **your SG value is lower than your target SG value**, you might want to wait before you make a treatment decision.

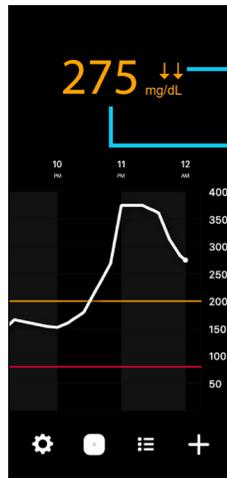


Sample screen only.

Using Your SG to Make Treatment Decisions

EXAMPLE 2:

If you see ↓, ↓↓, ↓↓↓, this means your SG has been falling and may continue to fall. But if your **SG value is higher than your target SG value**, you might want to wait before taking insulin.



SG has been falling

But 275 mg/dL is higher than target SG

Watch and wait.

Sample screen only.

With either example, make sure to also **pay attention to your symptoms** for high or low glucose to help you decide what to do.



NOTE: Keep track of when you took your last insulin injection or log your insulin each time in the events in your app. Taking more insulin when you already have insulin working in your body might cause your glucose to fall lower.



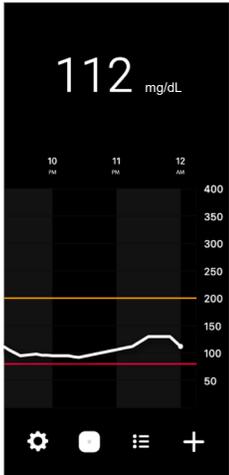
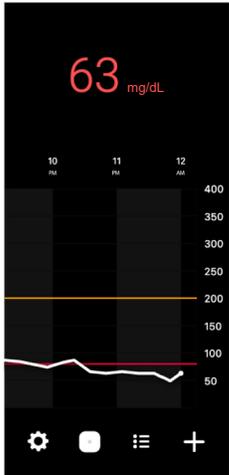
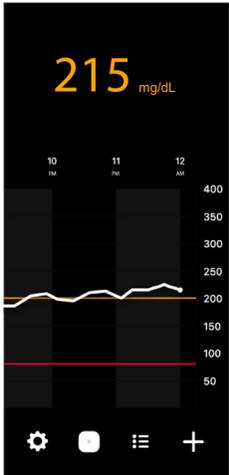
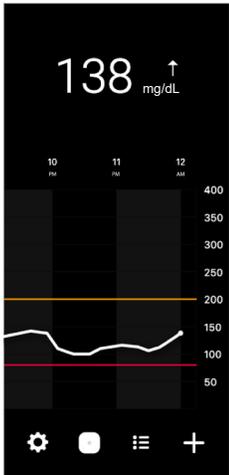
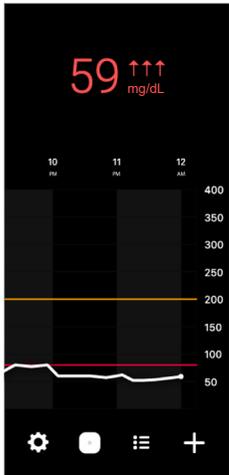
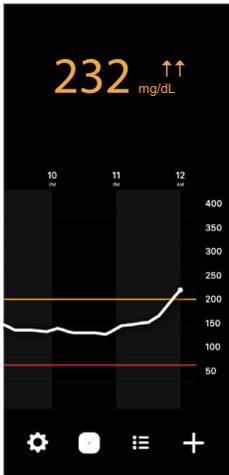
WARNING: When you see this icon , always use a blood glucose meter reading when making treatment decisions.

Using Your SG to Make Treatment Decisions

Here's a cheat sheet to help you:

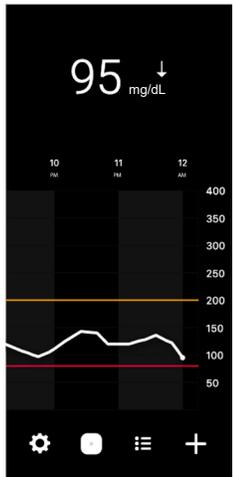
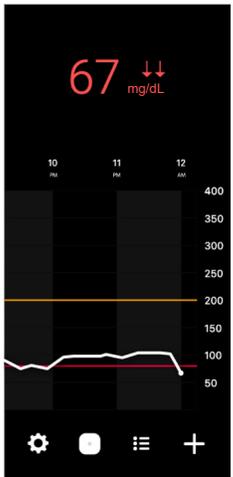
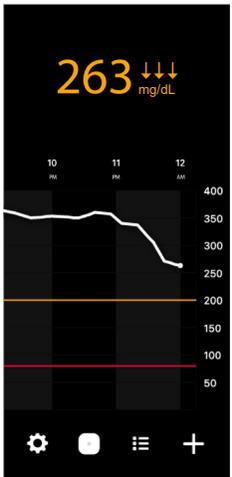
How Do I Use My SG Information to Make Treatment Decisions?

NOTE: When you see this icon , always use a BG meter reading to make treatment decisions.

	If your SG is within Target	If your SG is Lower	If your SG is Higher
SG readings but no trend arrows	 <p>When did you last eat or take insulin?</p> <p>Watch for any changes to your glucose levels.</p>	 <p>You may need to take a fast-acting sugar.</p>	 <p>You may need to take insulin. Don't take too much insulin if you took it recently.</p>
SG readings and trend arrows ↑ or ↑↑ or ↑↑↑	 <p>When did you last eat or take insulin?</p> <p>You may need to take insulin to stay within your target SG.</p> <p>Be careful not to take too much insulin if you took it recently.</p>	 <p>Watch and wait to give your SG a chance to return to your target.</p> <p>You may have over treated your low glucose.</p>	 <p>You may need to take insulin. Don't take too much insulin if you took it recently.</p>

Using Your SG to Make Treatment Decisions

Here's a cheat sheet to help you:

How Do I Use My SG Information to Make Treatment Decisions?			
<p>NOTE: When you see this icon , always use a BG meter reading to make treatment decisions.</p>			
	If your SG is within Target	If your SG is Lower	If your SG is Higher
<p>SG readings and ↓ or ↓↓ or ↓↓↓</p>	 <p>You may need to eat a snack or take a fast-acting sugar.</p>	 <p>You may need to take a fast-acting sugar.</p>	 <p>When did you last eat or take insulin?</p> <p>Watch and wait to give your SG a chance to return to your target.</p>
<p>No SG reading and no trend arrows</p>	<p>Use only your BG meter to make treatment decisions</p>		

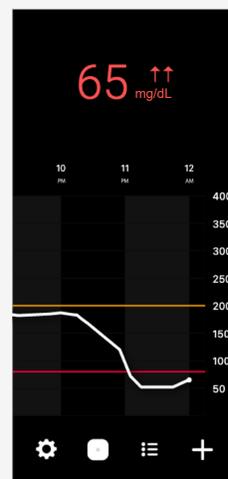


USING CGM FOR A LOW SG

Lina gets a CGM alert that her SG is 65 mg/dL. She also sees ↑↑ on her screen because she just ate. Her SG target range is 70-180 mg/dL.

What should she do?

Tap for the answer



Using Your SG to Make Treatment Decisions

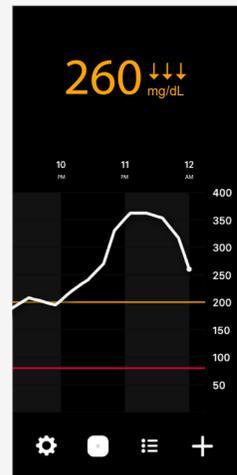


USING CGM FOR A HIGH SG

Dave sees that his SG is 260 mg/dL with ↓↓↓. He ate a big breakfast and took insulin about an hour ago. His target is 80 - 200 mg/dL.

What should he do?

Tap for the answer

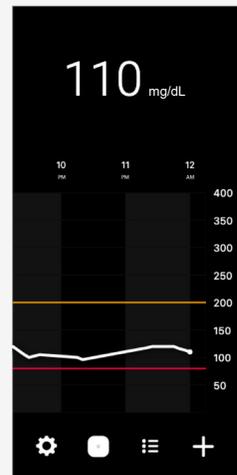


USING CGM WITHIN TARGET SG RANGE

Maria sees that her SG has been stable at about 110 mg/dL for the last hour with no trend arrows.

What should she do?

Tap for the answer



For more information, please refer to your Simpler System User Guide.

Sharing Data with Your Care Partner

Section 5: Sharing Data with Your Care Partner

The Simplera app lets you share your SG information with a care partner through the CareLink Connect app. You can invite a family member, friend, or other care partner to view your sensor data. Real time data, updated every 5 minutes, is shown on the **CareLink Connect app**.



NOTE: Ask your healthcare professional (HCP) to look at your CareLink reports at the office or bring your reports with you to your next visit.

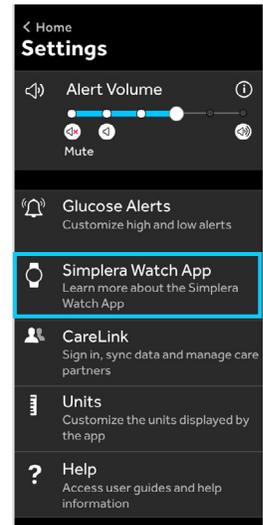
From the Simplera App

From the Simplera app home screen:

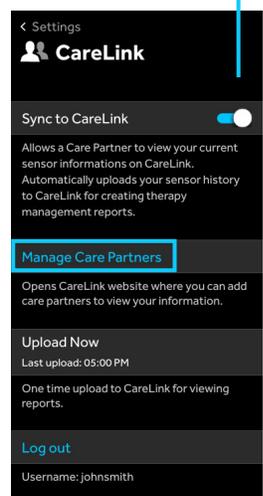
1. Tap  on the bottom left corner of the home screen. Tap **CareLink**.

2. Be sure the Sync to CareLink feature is turned ON.

Tap **Manage Care Partners**.



The Sync to CareLink feature is turned On.



Sharing Data with Your Care Partner

3. Once your care partner has registered and sent the request to view your data, accept the invitation in your CareLink Personal account to start sharing.

Your Care Partner

Once your care partner has been set up they will have access to your sensor data. In their CareLink account care partners can decide which alerts they would like to receive. Care partners will be able to decide which alerts they would like to receive in the app. They can also choose to receive a text for any alert, not just status messages, in their CareLink account.

Sensor Care and Travel

Section 6: Care and Travel

Traveling by Air

The Simplera sensor is safe for use on commercial airlines.

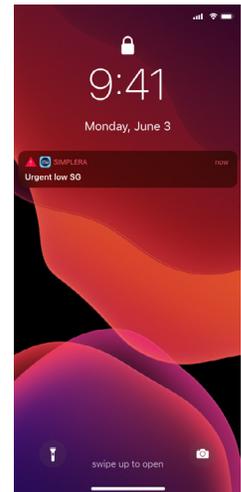


WARNING: Turning on airplane mode will disconnect Bluetooth on mobile devices. You must manually turn Bluetooth back on in order to receive alerts and notifications while in airplane mode.



NOTE: If your mobile device has returned to the locked screen, notifications from your app 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 alerts and SG information.

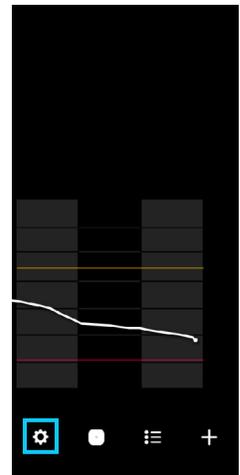


Using the Simplera App On Your Apple Watch

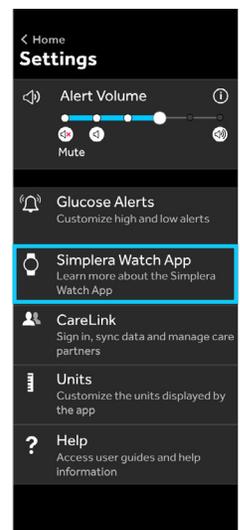
Section 7: Using the Simplera App On Your Apple Watch

You can use the Simplera app on your Apple Watch if you have a compatible Apple Watch connected to your Apple mobile device. To view a list of compatible devices, please visit your local Medtronic website or contact the Medtronic representative listed in the Simplera System User Guide. Using the Simplera app with your Apple Watch allows you to view your glucose data discreetly and receive system and SG alerts.

1. Open the Apple Watch app on your compatible iPhone, scroll down to **INSTALLED ON APPLE WATCH** and confirm that the Simplera app is installed. If it is not there, scroll further to **AVAILABLE APPS**, and tap **INSTALL** next to Simplera.
 - For optimal viewing of different displays (called “Complications”), it is recommended to use multi-color setting in your Apple Watch app.
 - You must have notifications turned on in both the Apple Watch app and phone app to receive system and SG alerts.
2. Open the Simplera app.
3. Tap .



4. Tap **Simplera Watch App**.



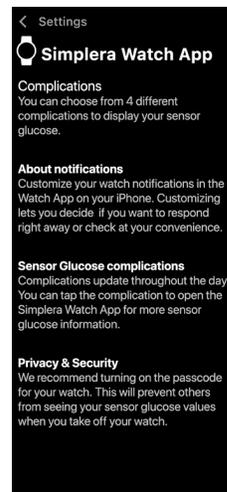
Using the Simplera App On Your Apple Watch

Complications

Your Apple Watch offers 4 different displays that you can choose from to view your SG information. These are known as Complications. Below are the 4 options available to choose from:



SG and Trend arrows



Sensor Glucose Complications allow you to see your SG and trend arrows from your Apple Watch and will update throughout the day. You can tap the Complication to get the latest SG value.



NOTE for Apple Watch users: Do not use the Do Not Disturb feature, otherwise, you will not get any vibrations with your alerts, including Urgent Low Alert. Theater mode will provide vibrations but you will not get any visible notifications on screen unless you tap the screen.

Viewing the Sensor Graph on Your Apple Watch

To view the sensor graph on your Apple Watch, open the Simplera app from your Apple Watch menu and tap the Complication. The graph will display the last 3 hours of sensor data. To see all of the details for the events that occurred in the last 3 hours, scroll down.



BG checks required for first 12 hours to make treatment decisions



NOTE: When you see this icon during the first 12 hours after you insert a new sensor, use a BG meter reading to make treatment decisions. Please see *Section 4: Using Your SG to Make Treatment Decisions*, page 33 for more information.



Using the Simplera App On Your Apple Watch

See *Section 4: Using Your SG to Make Treatment Decisions*, page 33. Refer to the sensor data on your mobile device app when you see the following screen on your Apple Watch:



Viewing Notifications on Your Apple Watch

To view a list of the most recent notifications swipe down from the top of your Apple Watch.



Using the Simplera App On Your Apple Watch



WARNINGS: If the mobile device is damaged, the Apple Watch may not receive sensor glucose alerts. Do not use the Apple Watch for the Simplera app if the Apple Watch screen or speakers are damaged.

Your Apple Watch will not vibrate for alerts from the Simplera app if Haptic Alerts are disabled.

To receive sensor glucose information or alerts on the Apple Watch, ensure Bluetooth is enabled and the Apple Watch is within range of the mobile device.

Do not disable mirror feature for the Simplera app in the Apple Watch settings. If mirror feature is disabled, the app will not send any alerts, including Urgent Low Alert.

When the Apple Watch enters power reserve mode or low battery mode, it will no longer provide glucose alerts.

If the mobile device is unlocked, all glucose alerts will only go to the mobile device and will not go to the Apple Watch.

Always protect the Apple Watch with a passcode. Sharing your passcode could compromise the security of your device.

The Apple Watch may display connection requests. Do not accept connection requests from unknown devices.

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