Abbott

FreeStyle Libre 3

CONTINUOUS GLUCOSE MONITORING SYSTEM

APP

User's Manual

English

FreeStyle Libre 3

User's Manual

App Symbols

	App icon
	Alarms you have turned on are unavailable
	Scan New Sensor/Start New Sensor
	Direction your glucose is going. See Understanding Your Glucose Readings for more information.
	Caution
	Add/edit notes
	Food note
	Insulin (Rapid or Long-acting) note
	Alarm
	Exercise note
	Time change
	Main menu
	Multiple/Custom notes

 Share report (iOS)

 Share report (Android)

 Additional information

 Calendar

 Sensor too cold

 Sensor too hot

Important Information

Indications for Use

FreeStyle Libre 3 app (‘App’) when used with a FreeStyle Libre 3 Continuous Glucose Monitoring System Sensor (‘Sensor’) is indicated for measuring interstitial fluid glucose levels in people (age 4 and older) with diabetes mellitus, including pregnant women. The App and Sensor are designed to replace blood glucose testing in the self-management of diabetes, including dosing of insulin.

The indication for children (age 4–12) is limited to those who are supervised by a caregiver who is at least 18 years of age. The caregiver is responsible for managing or assisting the child to manage the App and Sensor and also for interpreting or assisting the child to interpret Sensor glucose readings.

Compatible Devices, Apps and Software

For a list of compatible devices, apps and software that can be used with the FreeStyle Libre 3 Sensor, please go to:

www.FreeStyleLibre.com

Use of the Sensor with devices, apps and software that are not listed may cause inaccurate glucose readings.

WARNINGS

If you are using the FreeStyle Libre 3 app, you must also have access to a blood glucose monitoring system as the App does not provide one.

CAUTION:

- The FreeStyle Libre 3 app installed on a phone is intended for use by a single person. It must not be used by more than one person due to the risk of misinterpreting glucose information.
- For you to receive alarms, make sure to:
  - Turn alarms **ON** and ensure that your phone is within 10 metres (33 ft) of you at all times. The transmission range is 10 metres (33 ft) unobstructed. If you are out of range, you may not receive alarms. If you want to receive the App's optional alarms, make sure these are turned on.
  - Do not force close the App. The App must be running in the background to receive alarms. If you force close the App you will not receive alarms. Re-open the App to ensure you will receive alarms.
  - If you restart your phone, open your App to make sure it’s working properly.
  - The App will ask for phone permissions which are needed to receive alarms. Allow these permissions when requested.
  - Check to make sure that you have the correct phone settings and permissions enabled. If your phone is not configured properly, you will not receive alarms.
    - **iPhones** are to be configured as follows:
      - In the phone settings, ensure Bluetooth is **ON**
      - In the phone settings for the App, allow the App to access Bluetooth
      - In the phone settings for the App under notifications
        - Keep Allow Critical Alerts **ON**
        - Keep Allow Notifications **ON**
        - Keep Lock Screen and Banner alerts **ON**
        - Keep sounds **ON**

- If you adjust the phone ringer volume to silent or use the phone do not disturb setting, turn 'Override Do Not Disturb' setting in the App **ON** for Low Glucose, High Glucose, and Signal Loss Alarms to ensure you receive audible alarms.

Note: You must accept the App's permission request for Critical Alerts to use the Override Do Not Disturb feature. You can also enable the Critical Alerts setting directly from the App's notification settings.

- **Android phones** are to be configured as follows:
  - In the phone settings
    - Keep Bluetooth **ON**
    - Keep phone Media volume **ON**
    - Keep Battery Saver mode **OFF**
  - In the phone settings for the App
    - Keep Show Notifications **ON**
    - Keep Do Not Disturb access permission **ON**
    - Keep Battery Optimisation **OFF**
  - Do **NOT** modify channel notification settings for the App
    - Keep Lock Screen notifications **ON**
    - Keep Pop-up notifications **ON**
  - You may need to add the FreeStyle Libre 3 app to the list of apps that will not be restricted or put to sleep.
  - If you adjust the phone Media volume to silent or use the phone do not disturb setting, turn 'Override Do Not Disturb' setting in the App **ON** for Low Glucose, High Glucose, and Signal Loss Alarms to ensure you receive audible alarms.

Note: You must accept the App's permission request for Do Not Disturb access to use the Override Do Not Disturb feature. You can also enable the

Do Not Disturb access setting directly from the App's notification settings.

- You should disconnect headphones or speakers from your phone when you are not using them as you may not hear audio for alarms. If using headphones, keep them in your ears.
- If you are using peripheral devices connected to your phone, such as wireless headphones or a smartwatch, you may receive alarms on only one device or peripheral, not all.
- Keep your phone well charged and turned on.
- Disable your phone's automatic operating system updates. After an operating system update, open your App and check your device settings to make sure it's working properly.
- Some operating system features may impact your ability to receive alarms. For example, if you use an iPhone and the iOS Screen Time feature, add FreeStyle Libre 3 to the list of always allowed apps to ensure that you receive alarms or if you use an Android phone do not use the Android Digital Wellbeing app.

Security Information

- You are responsible for properly securing and managing your phone. If you suspect an adverse cybersecurity event related to the FreeStyle Libre 3 app, contact Customer Service.
- Make sure that your phone and Sensor kit are kept in a safe place, under your control. This is important to help prevent anyone from accessing or tampering with the System.
- The FreeStyle Libre 3 app is not intended for use on a phone that has been altered or customised to remove, replace or circumvent the manufacturer's approved configuration or use restriction, or that otherwise violates the manufacturer's warranty.

The following Contraindication, Warnings and other safety information apply to the Sensor, when used with the FreeStyle Libre 3 app.

CONTRAINDICATION: The Sensor must be removed prior to Magnetic Resonance Imaging (MRI).

WARNING: Do not ignore symptoms that may be due to low or high blood glucose. If you have symptoms that do not match the Sensor glucose reading, or suspect your reading may be inaccurate, check the reading by conducting a fingerstick test using a blood glucose meter. If you are experiencing symptoms that are not consistent with your glucose readings, consult your healthcare professional.

CAUTION:

- The Sensor contains small parts that may be dangerous if swallowed.
- On rare occasions, you may get inaccurate Sensor glucose readings. If you believe your readings are not correct or are inconsistent with how you feel, perform a blood glucose test on your finger to confirm your glucose and check to make sure your Sensor has not come loose. If the problem continues or if your Sensor is coming loose, remove the current Sensor and apply a new one.
- Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. If your Sensor comes loose, you may get no readings or unreliable readings, which may not match how you feel. Follow the instructions to select an appropriate application site.
- Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If you notice significant skin irritation around or under your Sensor, remove the Sensor and stop using the Sensor. Contact your healthcare professional before continuing to use the Sensor.
- Performance of the Sensor when used with other implanted medical devices, such as pacemakers, has not been evaluated.
- Do not reuse Sensors. The Sensor and Sensor Applicator are designed for single use. Reuse may result in no glucose readings and infection. Not suitable for re-sterilisation. Further exposure to irradiation may cause inaccurate results.

Additional Safety Information

- Physiological differences between the interstitial fluid and capillary blood may

result in differences in glucose readings. Differences in Sensor glucose readings between interstitial fluid and capillary blood may be observed during times of rapid change in blood glucose, such as after eating, dosing insulin or exercising.

- Store the Sensor Kit between 2°C and 28°C. While you don't need to keep your Sensor Kit in a refrigerator, you can as long as the refrigerator is between 2°C and 28°C.
- If you have a medical appointment that includes strong magnetic or electromagnetic radiation – for example an X-ray, MRI (Magnetic Resonance Imaging) or CT (Computed Tomography) scan – remove the Sensor you are wearing and apply a new one after the appointment. The effect of these types of procedures on the performance of the Sensor has not been evaluated.
- The Sensor has not been evaluated for use in persons on dialysis or people less than 4 years of age.
- The Sensor Applicator is sterile unless opened or damaged.
- Your Sensor has been tested to withstand immersion into one metre (3 ft) of water for up to 30 minutes. It is also protected against insertion of objects > 12 mm diameter. (IP27)
- Do not freeze the Sensor. Do not use if expiry date has passed.

FreeStyle Libre 3 app Overview

IMPORTANT: Read all of the information in this User's Manual before using the FreeStyle Libre 3 app with a Sensor. Refer to your phone's instructions for use for how to use your phone.

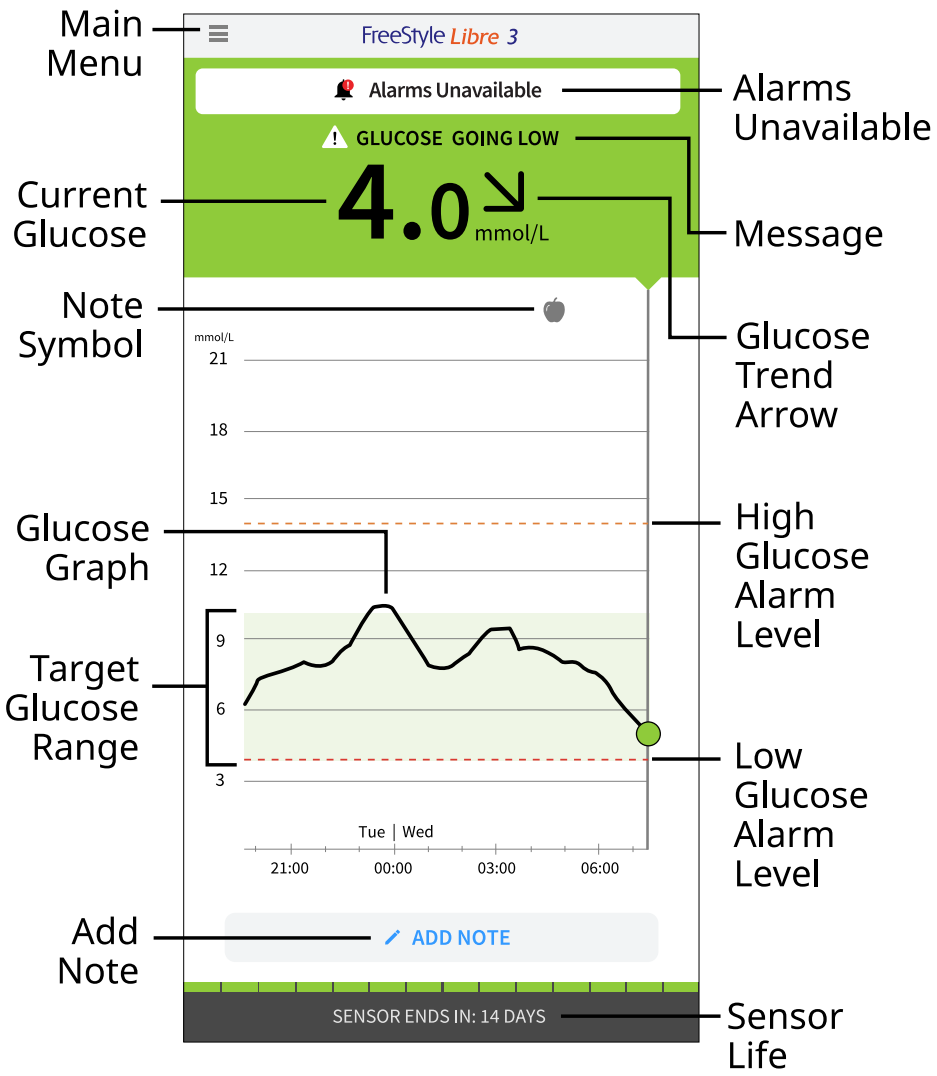
The FreeStyle Libre 3 app is available for download from the App Store or Google Play Store. When you're ready to start using the FreeStyle Libre 3 system, you'll prepare and apply a Sensor to the back of your upper arm. You can then use the App to get glucose readings from the Sensor and store your glucose history and notes. The Sensor comes in a Sensor Kit and can be worn on your body for up to 14 days.

Note: The FreeStyle Libre 3 app is only compatible with certain mobile devices and operating systems. Please check www.FreeStyleLibre.com for more information

about device compatibility before upgrading your phone or its operating system.

Home Screen

The Home Screen displays your current glucose, glucose trend arrow and glucose graph. It is automatically updated every minute with glucose data from the Sensor. To return to the Home Screen from another screen, go to the Main Menu and tap **Home**.



Main Menu – Tap to access the Home Screen, Alarms, Logbook, other history options and Connected Apps. You can also access Settings, Help and other information

Message – You may be able to tap the message for more information

Alarms Unavailable – The 🔔 displays if alarms you have turned on are not available

Current Glucose – Your most recent glucose value

Glucose Trend Arrow – Direction your glucose is going

Glucose Graph – Graph of your current and stored glucose readings

Target Glucose Range – The graph shows your target glucose range. This is not related to glucose alarm levels

High Glucose Alarm Level – The graph shows your High Glucose Alarm level. This displays only when you have turned the alarm **ON**

Low Glucose Alarm Level – The graph shows your Low Glucose Alarm level. This displays only when you have turned the alarm **ON**

Sensor Life – The number of days of life remaining on the Sensor

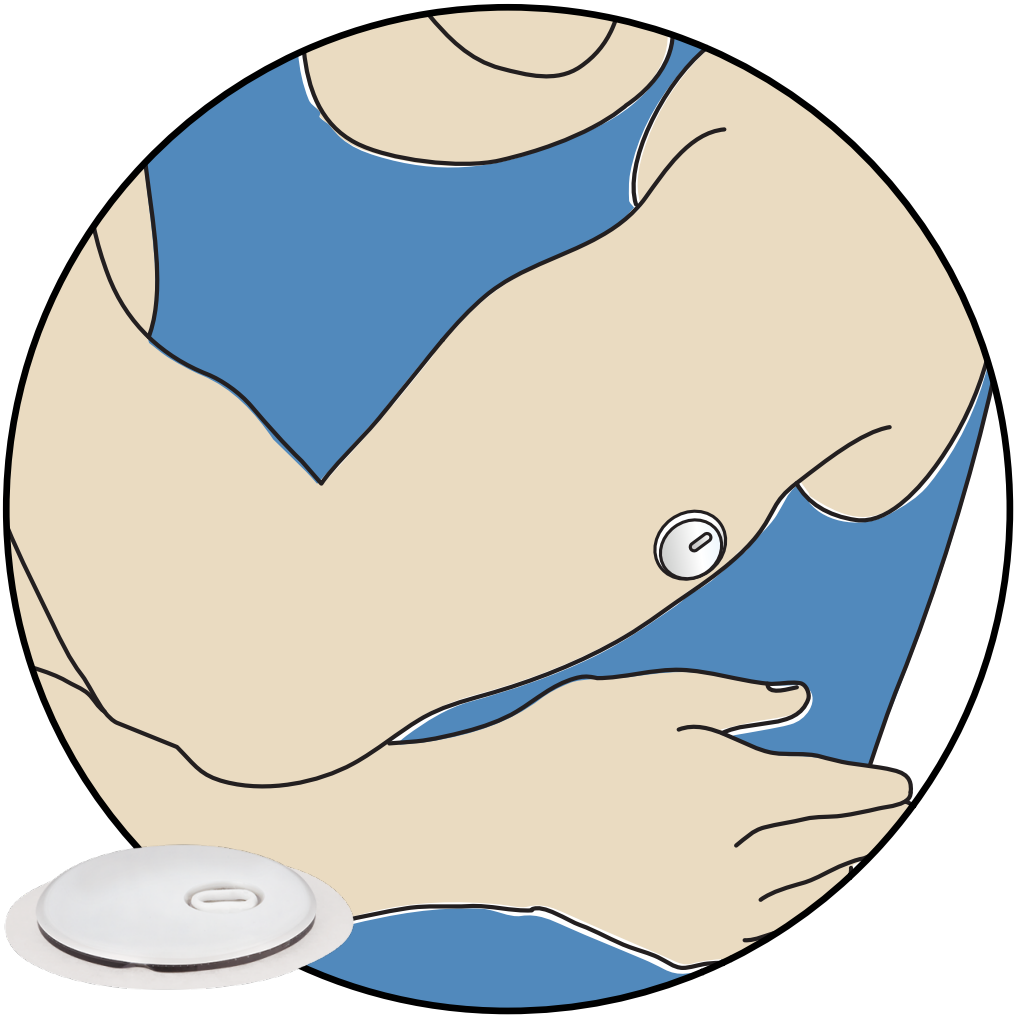
Add Note – Tap to add notes to the glucose reading

Note Symbol – Tap to review notes you've entered

Reporting Software

Software can be used to create reports based on glucose readings from FreeStyle Libre 3 Sensors. Go to www.FreeStyleLibre.com and follow onscreen instructions to access the compatible software. You are responsible for keeping your computer secure and up to date; for example, by using anti-virus software and installing system updates.

Sensor Kit

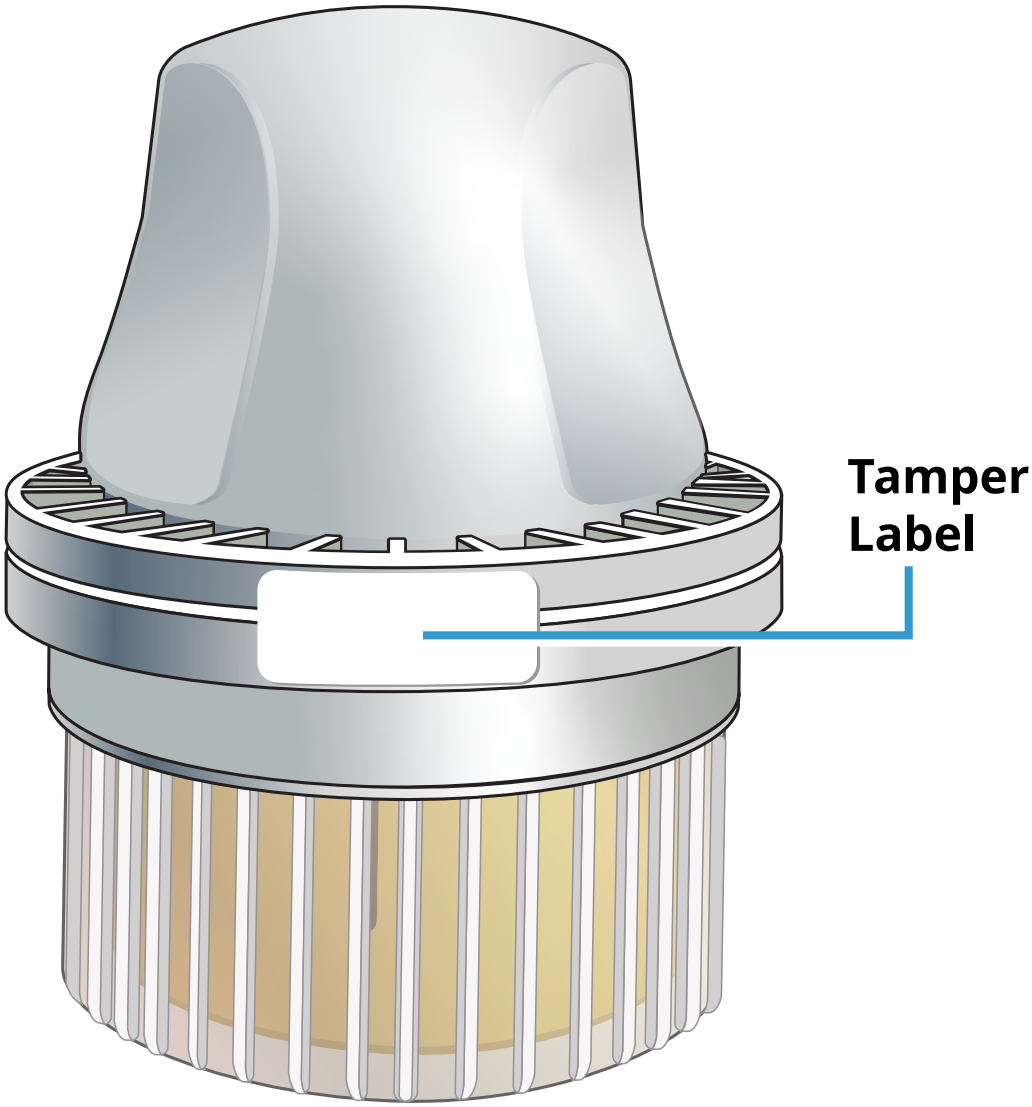


A FreeStyle Libre 3 Sensor Kit includes:

- Sensor Applicator
- Product insert

When opening your kit, check that the contents are undamaged and that you have all parts listed. If any parts are missing or damaged, or if the tamper label indicates the Sensor Applicator has already been opened, contact Customer Service. The Sensor (only visible after applied) measures and stores glucose readings when worn on your body. By following the instructions, you use the Sensor Applicator to apply the Sensor on the back of your upper arm. The Sensor has a small, flexible tip that is inserted just under the skin.

Sensor Applicator. Applies the Sensor to your body.



App Setup

The FreeStyle Libre 3 app is only compatible with certain mobile devices and operating systems. Please check www.FreeStyleLibre.com for more information about device compatibility before upgrading your phone or its operating system.

Before using the App for the first time, you must complete the setup.

1. Check that your phone is connected to a network (Wi-Fi or mobile). You can then install the FreeStyle Libre 3 app from the App Store or Google Play Store. Tap the App icon to open the App.

   Note: You only need to be connected to a network for setup, using LibreView and sharing with other apps. You do not need to be connected to check your glucose, receive alarms, add notes or review your history in the App.

2. Swipe left to view some helpful tips or tap **GET STARTED NOW** at any point. If you already have a LibreView account, tap **Sign In**.
3. Confirm your country and tap **NEXT**.
4. You have the option to create a LibreView account so that you can:
   - View your data and reports online at www.LibreView.com
   - Share your data with your care team through Connected Apps
   - Connect your Sensor to your account, allowing you to transfer it to a different phone (for instance, if you lose your phone)

   Follow onscreen instructions to review legal information.
5. Confirm your glucose unit of measure and tap **NEXT**.
6. Select how you count carbohydrates (in grams or portions) and tap **NEXT**. The carbohydrate unit will be used in any food notes you enter in the App.
7. The App now displays some useful information. Tap **GET STARTED NOW** then tap **NEXT** to review each screen.
8. Accept required notification permissions.
9. Apply a new Sensor and then tap **NEXT**. Go to Starting Your Sensor.

   Note: If you need help applying your Sensor, tap **HOW TO APPLY A SENSOR** or go to Applying Your Sensor.

Applying Your Sensor

CAUTION:

Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. If your Sensor comes loose, you may get no readings or unreliable readings, which may not match how you feel. Follow the instructions to select an appropriate application site.

Note: Tap Help in the Main Menu to access an in-app tutorial on applying a Sensor.

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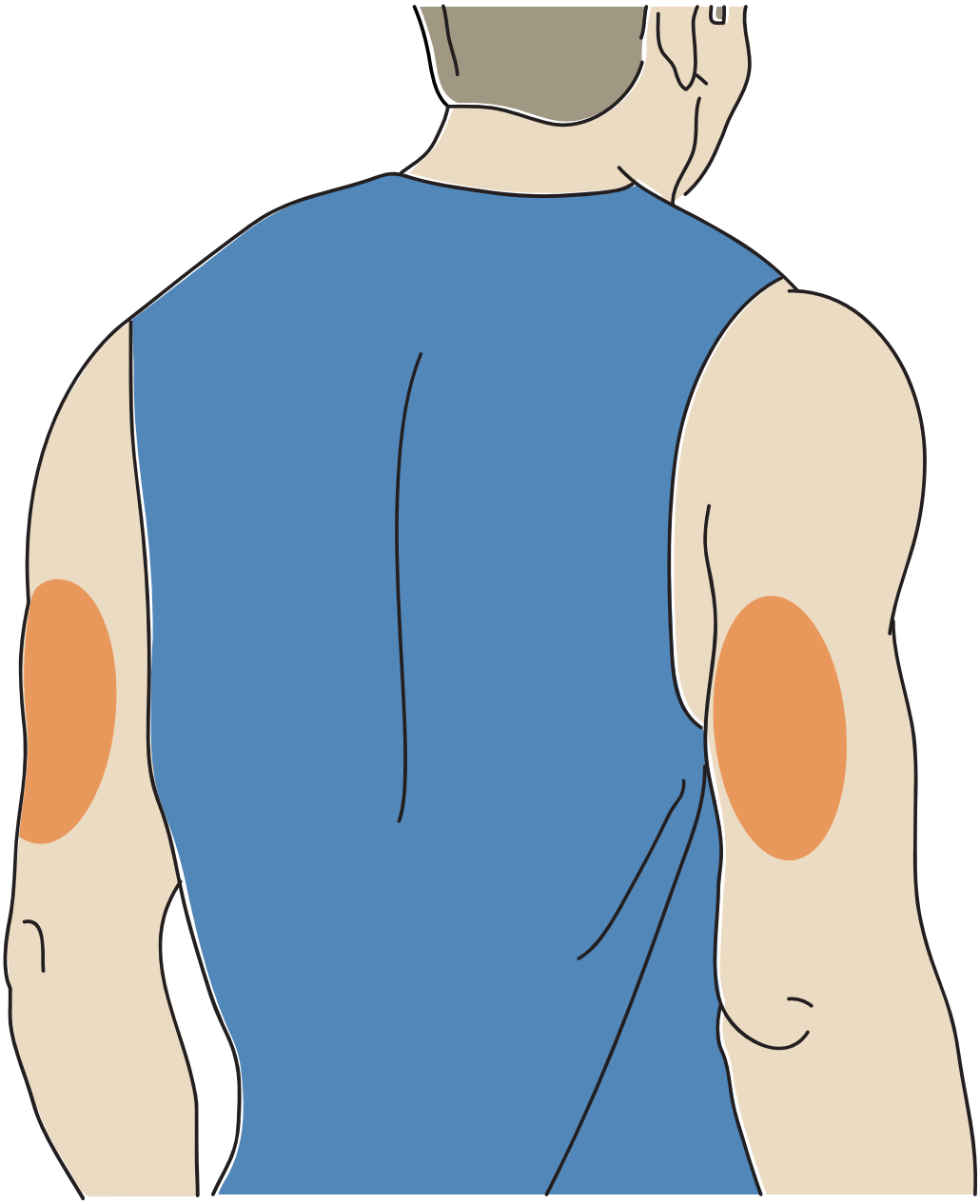
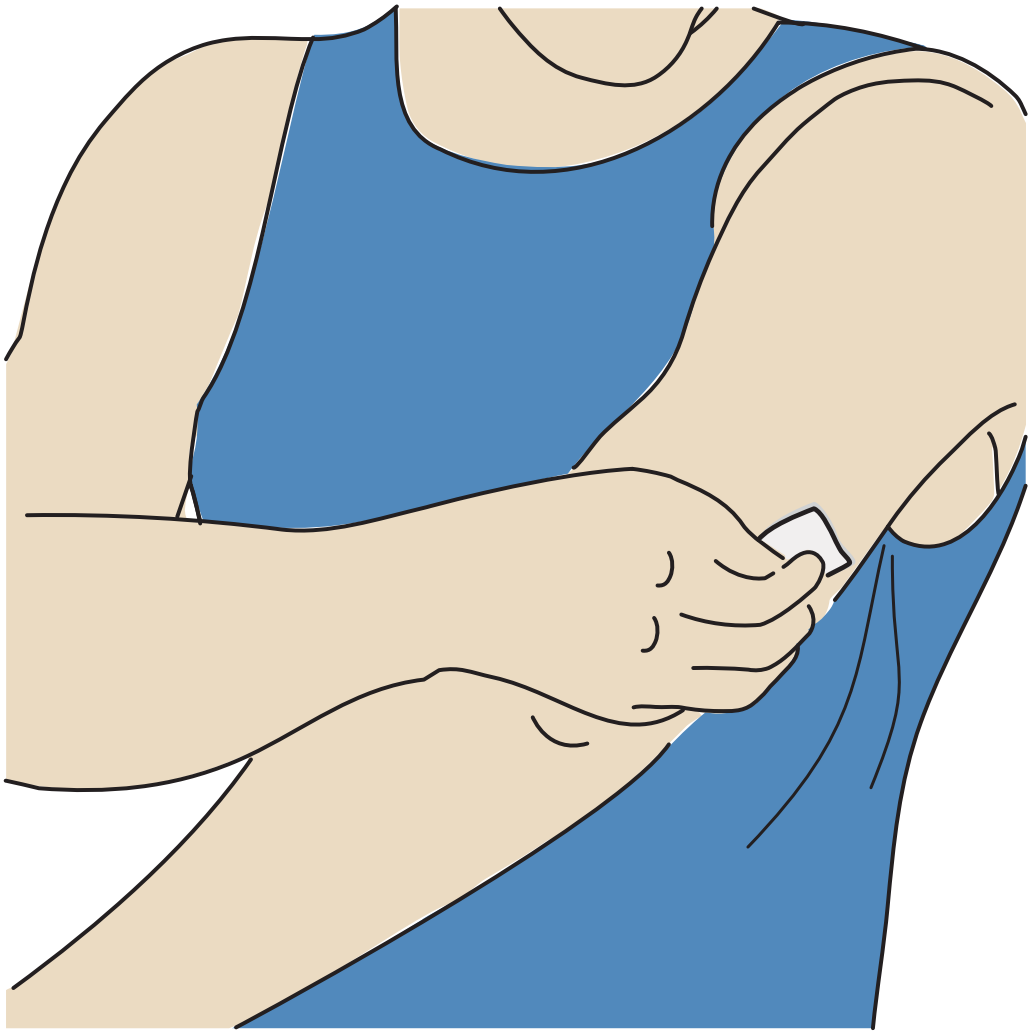
1. Apply the Sensor only on the back of your upper arm. Avoid areas with scars, moles, stretch marks or lumps. Select an area of skin that generally stays flat

during your normal daily activities (no bending or folding). Choose a site that is at least 2.5 cm (1 inch) away from an insulin injection site. To prevent discomfort or skin irritation, you should select a different site other than the one most recently used.

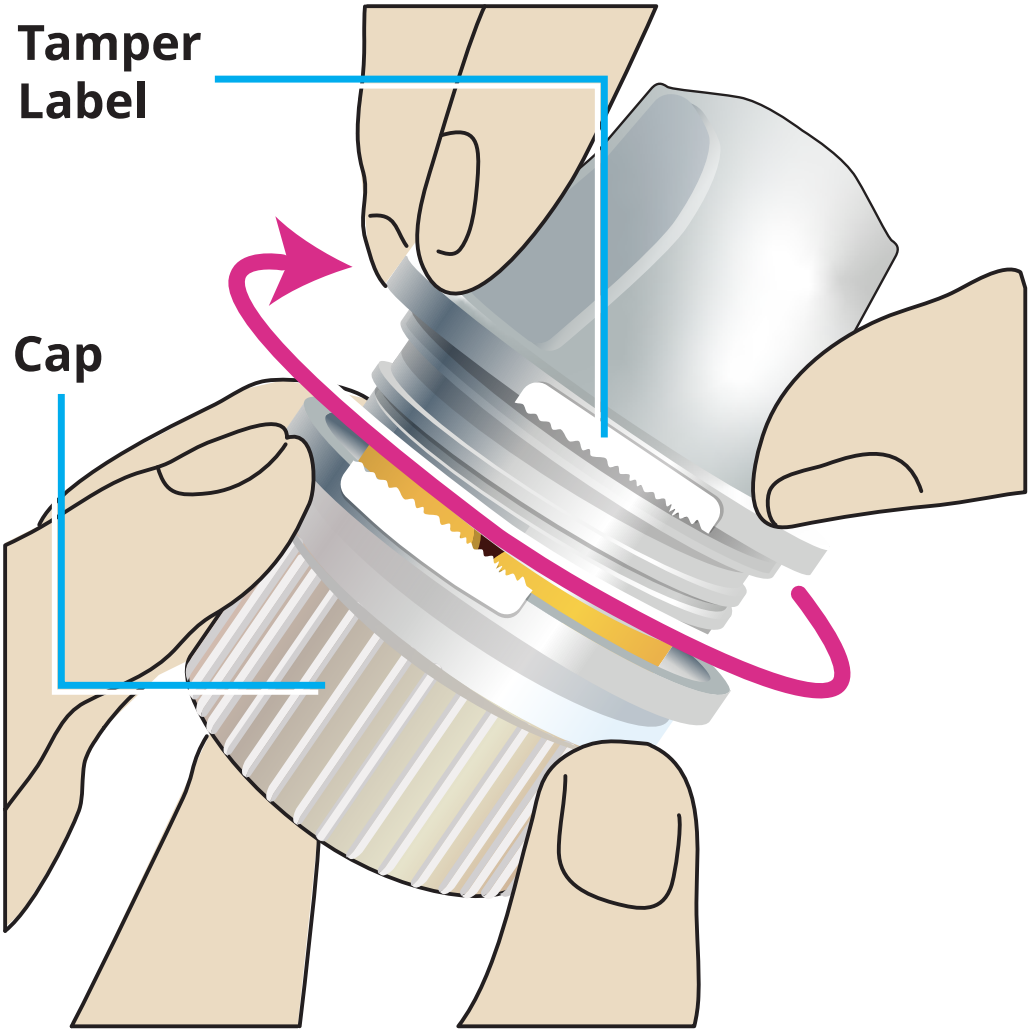


2. Wash application site using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the Sensor from sticking properly. Allow site to air-dry before proceeding.

   Note: The area **MUST** be clean and dry, or the Sensor may not stick to the site.

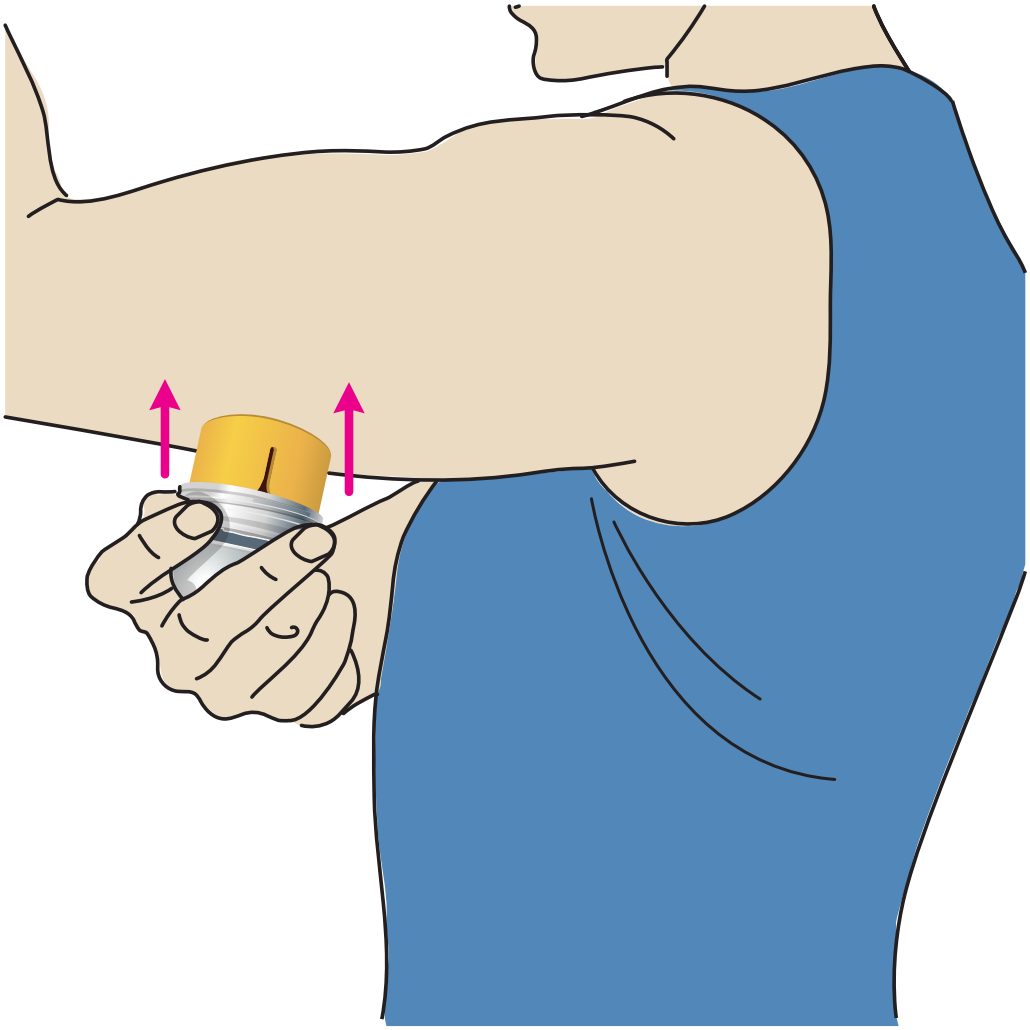


3. Unscrew the cap from the Sensor Applicator and set the cap aside.
   CAUTION:
   - Do NOT use if damaged or if tamper label indicates Sensor Applicator has already been opened.
   - Do NOT put cap back on as it may damage the Sensor.
   - Do NOT touch inside Sensor Applicator as it contains a needle.
   - Do NOT use if past expiry date.



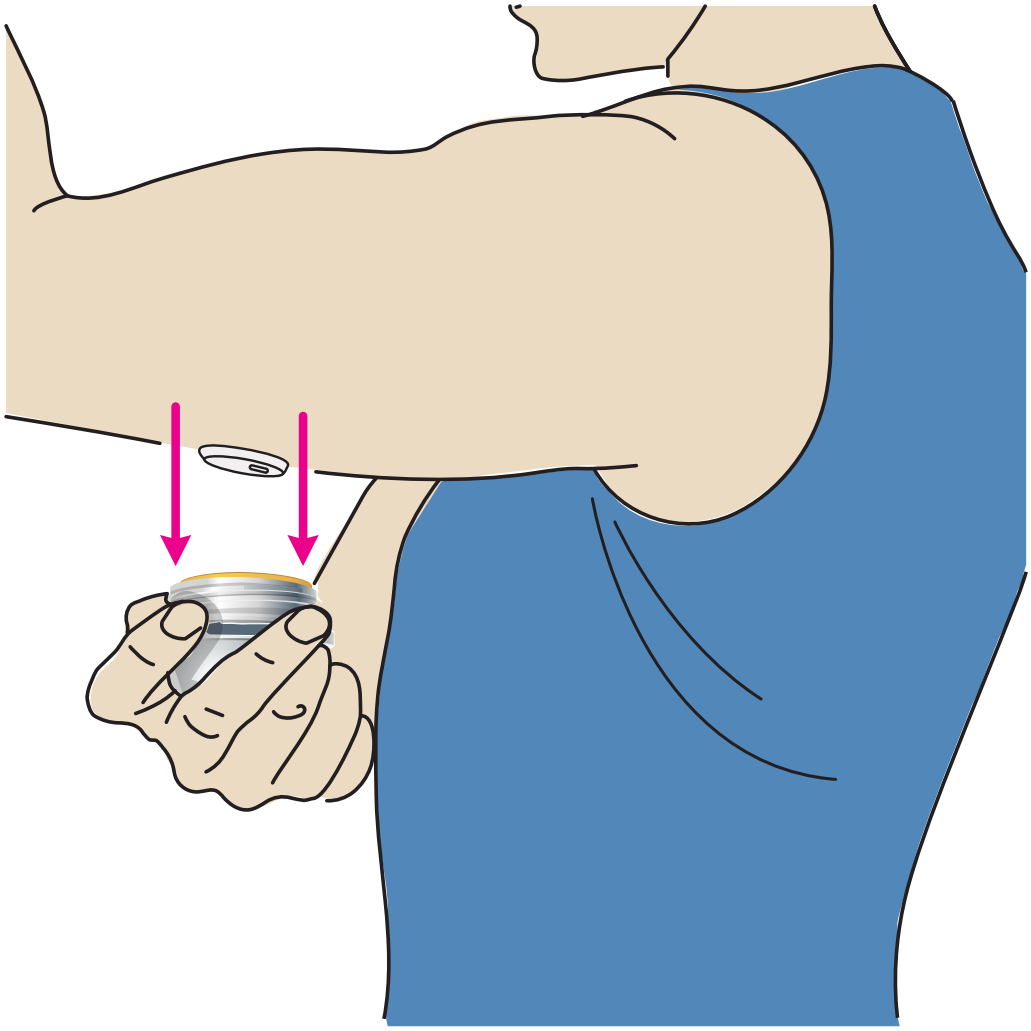
4. Place the Sensor Applicator over the prepared site and push down firmly to apply the Sensor to your body.

   CAUTION: Do NOT push down on Sensor Applicator until placed over prepared site to prevent unintended results or injury.

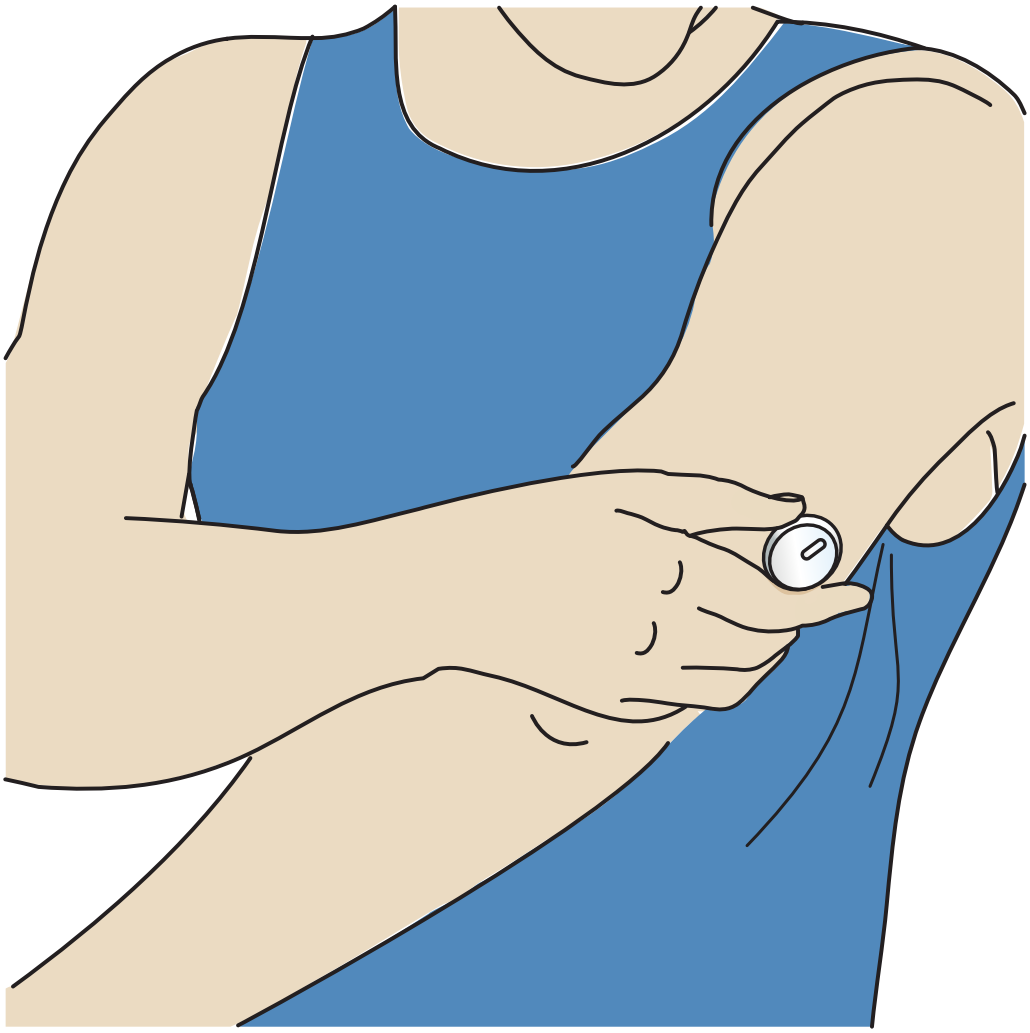


5. Gently pull the Sensor Applicator away from your body. The Sensor should now be attached to your skin.

   Note: Applying the Sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the Sensor, and apply a new one at a different site.



6. Make sure Sensor is secure after application. Put the cap back on the Sensor Applicator. Discard used Sensor Applicator. See Disposal.



Starting Your Sensor

Start a new Sensor by scanning it with your phone.

IMPORTANT:

- The App requires that your phone has the correct date and time for recording your health information. Your phone's date and time should be set to update automatically. You can check this in your phone settings.
- When using the App, you should keep your phone well charged and be sure you have access to a blood glucose monitoring system.
- **iPhone:** The NFC (Near Field Communication) antenna is on the top edge of the phone. Scan your Sensor by touching the Sensor with the TOP of your phone. Move your phone around slowly if needed. Proximity, orientation, and other factors can affect NFC performance. For example, a bulky or metallic case can interfere with the NFC signal. Keep in mind that the ease of scanning a Sensor

may vary between phone models.

- **Android:** The NFC (Near Field Communication) antenna is located on the back side of most Android phones. Scan your Sensor by touching the Sensor with the BACK of your phone. Move your phone around slowly if needed. Proximity, orientation, and other factors can affect NFC performance. For example, a bulky or metallic case can interfere with the NFC signal. Keep in mind that the ease of scanning a Sensor may vary between phone models.
- For more information on device compatibility, access the Mobile Device & OS Compatibility guide at www.FreeStyleLibre.com

iPhone:

1. From the App Home Screen, tap the Scan New Sensor button. Your phone is now ready to scan the Sensor to start it.
2. Touch the Sensor with the TOP of your phone. You will receive a tone and vibration after you have successfully started the Sensor. If your phone's volume is turned off, you will not hear the tone.

3. The Sensor can be used to check your glucose after 60 minutes. While the Sensor is starting up, you can navigate away from the App. If notifications are

enabled, you will see a notification when the Sensor is ready.

Note: If you have an active Sensor and want to start a new Sensor, go to the Menu and tap Start New Sensor))).

Android:

1. From the App Home Screen, scan the Sensor with the BACK of your phone to start it. You will receive a tone and vibration after you have successfully started the Sensor. If your phone's volume is turned off, you will not hear the tone.

   Note: Each phone model is different. Touch the Sensor with your phone or move your phone around slowly until you learn how to scan.

2. The Sensor can be used to check your glucose after 60 minutes. While the Sensor is starting up, you can navigate away from the App. If notifications are enabled, you will see a notification when the Sensor is ready.

   Note: If you have an active Sensor and want to start a new Sensor, go to the Menu and tap Start New Sensor))).

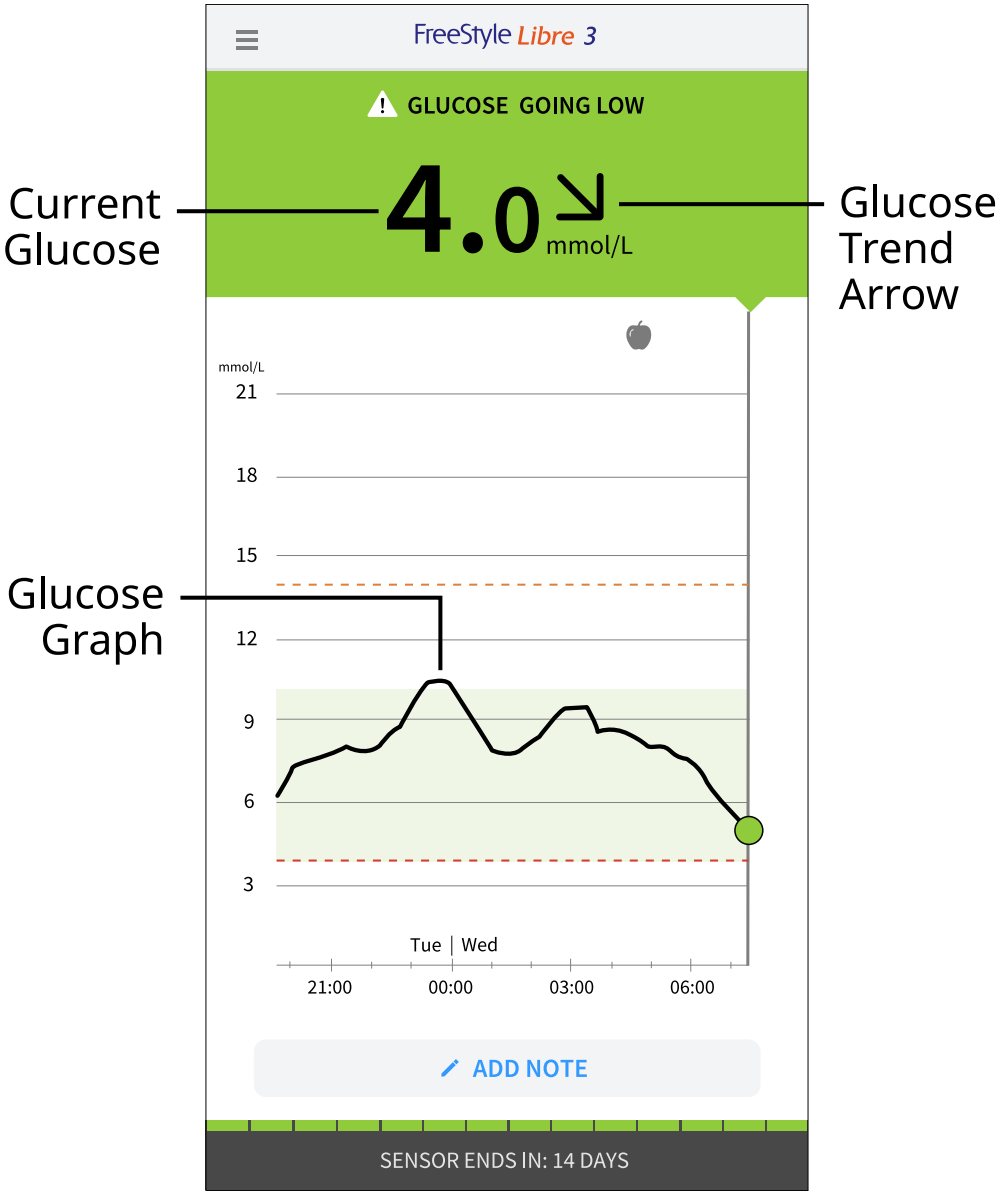
Note:

- If you need help, tap **HOW TO SCAN A SENSOR** to view an in-app tutorial. You can also access this later by going to the Main Menu and then tapping **Help**.

- If your Sensor is not successfully scanned, you may receive a Scan Error message. Follow the instructions in the message.
- See Troubleshooting for additional error messages.

Checking Your Glucose

1. Open the App.
2. If you have an active Sensor, the Home Screen displays your glucose reading. It includes your Current Glucose, a Glucose Trend Arrow indicating which way your glucose is going, and a graph of your current and stored glucose readings.



Current Glucose – Your most recent glucose value

Glucose Trend Arrow – Direction your glucose is going

Glucose Graph – Graph of your current and stored glucose readings

Note:

- The graph displays glucose readings above 21 mmol/L as 21 mmol/L. For consecutive readings above 21 mmol/L, a line is displayed at 21 mmol/L. The Current Glucose number can be as high as 27.8 mmol/L.
- The symbol may appear, indicating the phone's time was changed.
- Your current glucose value determines the background colour on the Home Screen:

  Orange - High glucose (above 13.9 mmol/L)

  Yellow - Between the Target Glucose Range and high or low glucose level

  Green - Within the Target Glucose Range

  Red - Low glucose (below 3.9 mmol/L)

- If you are not receiving glucose readings you will not receive Low or High Glucose Alarms.
- In order for the FreeStyle Libre 3 app to share data with other connected apps, please do the following:
  - Enable Wi-Fi or mobile service.
  - Disable Low Data mode.

Understanding Your Glucose Readings

Glucose Trend Arrow

The Glucose Trend Arrow gives you an indication of the direction your glucose is going.


Glucose is rising quickly (more than 0.1 mmol/L per minute)


Glucose is rising (between 0.06 and 0.1 mmol/L per minute)


Glucose is changing slowly (less than 0.06 mmol/L per minute)

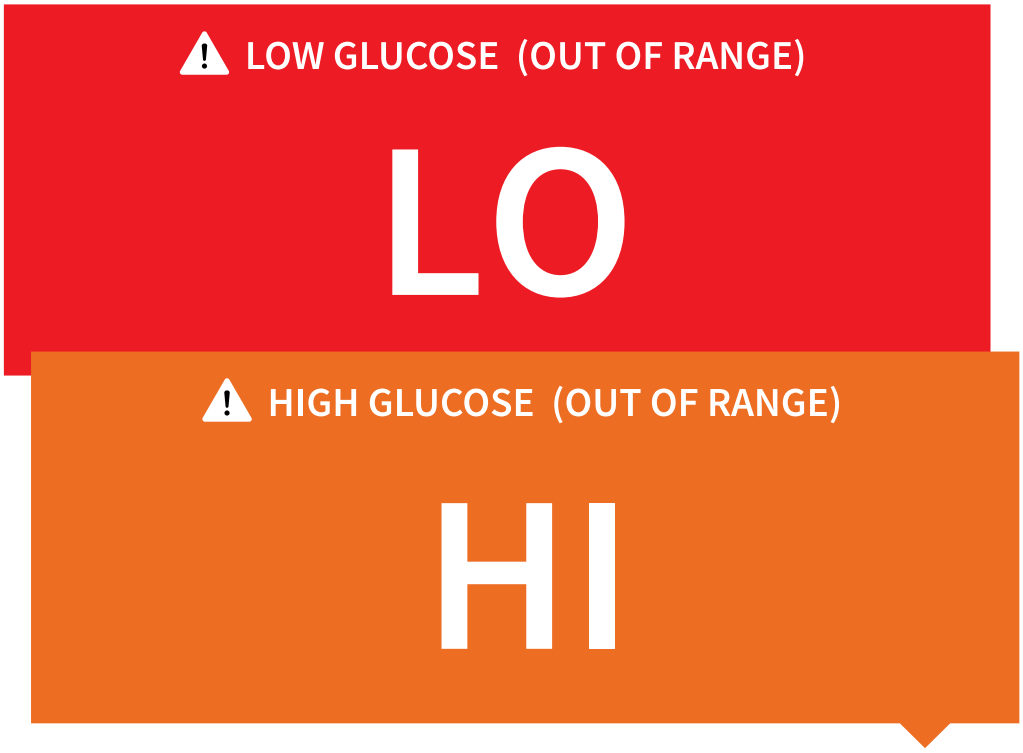

Glucose is falling (between 0.06 and 0.1 mmol/L per minute)


Glucose is falling quickly (more than 0.1 mmol/L per minute)

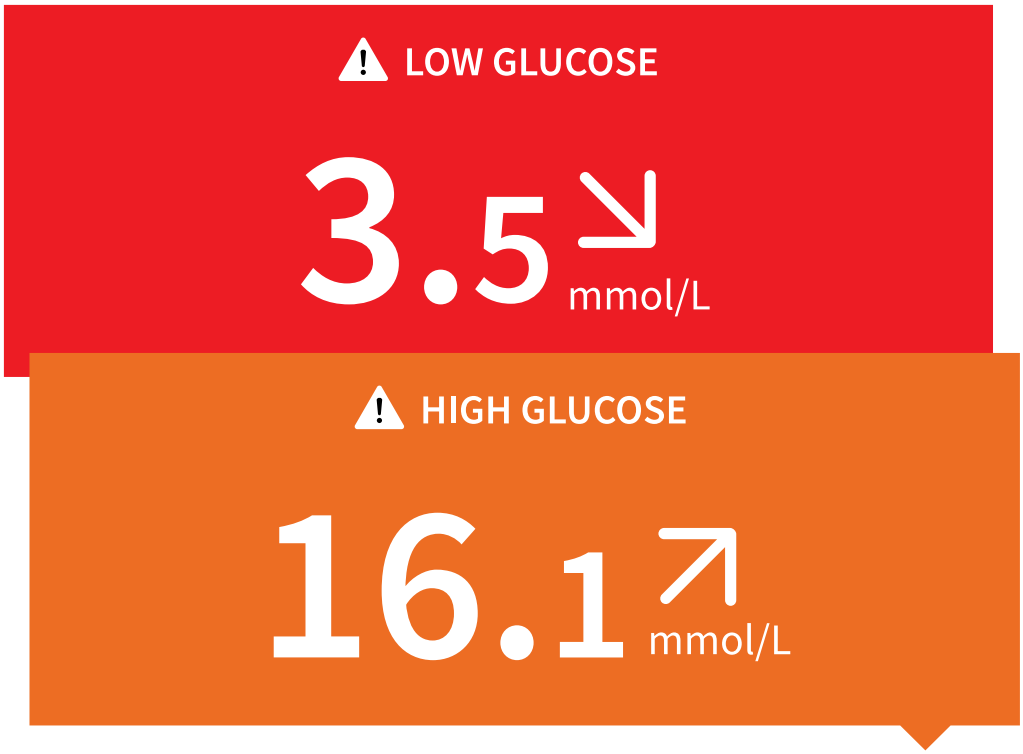
Messages

Below are messages you may see with your glucose readings.

LO | HI: If **LO** appears, your reading is lower than 2.2 mmol/L. If **HI** appears, your reading is higher than 27.8 mmol/L. You can tap the ⚠ symbol for more information. Check your blood glucose on your finger with a test strip. If you get a second **LO** or **HI** result, contact your healthcare professional **immediately**.

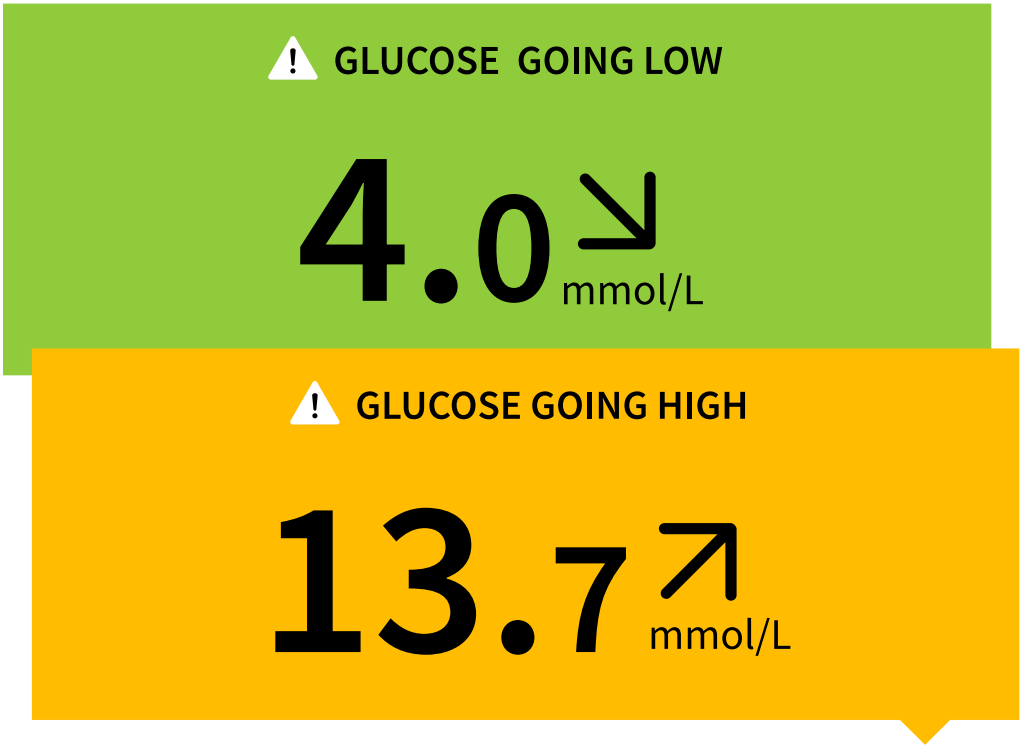


Low Glucose | High Glucose: If your glucose is lower than 3.9 mmol/L or higher than 13.9 mmol/L, you will see a message on the screen. You can tap the ⚠ symbol for more information and set a reminder to check your glucose.



Glucose Going Low | Glucose Going High: If your glucose is projected to be lower than 3.9 mmol/L or higher than 13.9 mmol/L within 15 minutes, you will see a message on the screen. The background colour corresponds to your current

glucose value. You can tap the ⚠ symbol for more information and set a reminder to check your glucose.



Note:

- If you are not sure about a message or reading, contact your healthcare professional for information.
- Messages you receive with your glucose readings are not related to your glucose alarm settings.

Alarms

This section explains how to set and use alarms. Please read all the information in this section so that you may ensure that you receive glucose alarms when they are enabled.

CAUTION:

- For you to receive alarms, make sure to:
  - Turn alarms **ON** and ensure that your phone is within 10 metres (33 ft) of you at all times. The transmission range is 10 metres (33 ft) unobstructed. If you are out of range, you may not receive alarms. If you want to receive the App's

optional alarms, make sure these are turned on.

- Do not force close the App. The App must be running in the background to receive alarms. If you force close the App you will not receive alarms. Re-open the App to ensure you will receive alarms.
- If you restart your phone, open your App to make sure it's working properly.
- The App will ask for phone permissions which are needed to receive alarms. Allow these permissions when requested.
- Check to make sure that you have the correct phone settings and permissions enabled. If your phone is not configured properly, you will not receive alarms.
  - **iPhones** are to be configured as follows:
    - In the phone settings, ensure Bluetooth is **ON**
    - In the phone settings for the App, allow the App to access Bluetooth
    - In the phone settings for the App under notifications
      - Keep Allow Critical Alerts **ON**
      - Keep Allow Notifications **ON**
      - Keep Lock Screen and Banner alerts **ON**
      - Keep sounds **ON**
    - If you adjust the phone ringer volume to silent or use the phone do not disturb setting, turn 'Override Do Not Disturb' setting in the App **ON** for Low Glucose, High Glucose, and Signal Loss Alarms to ensure you receive audible alarms.

    Note: You must accept the App's permission request for Critical Alerts to use the Override Do Not Disturb feature. You can also enable the Critical Alerts setting directly from the App's notification settings.

  - **Android phones** are to be configured as follows:
    - In the phone settings
      - Keep Bluetooth **ON**
      - Keep phone Media volume **ON**

- Keep Battery Saver mode **OFF**

- In the phone settings for the App
  - Keep Show Notifications **ON**
  - Keep Do Not Disturb access permission **ON**
  - Keep Battery Optimisation **OFF**

- Do **NOT** modify channel notification settings for the App
  - Keep Lock Screen notifications **ON**
  - Keep Pop-up notifications **ON**

- You may need to add the FreeStyle Libre 3 app to the list of apps that will not be restricted or put to sleep.
- If you adjust the phone Media volume to silent or use the phone do not disturb setting, turn 'Override Do Not Disturb' setting in the App **ON** for Low Glucose, High Glucose, and Signal Loss Alarms to ensure you receive audible alarms.

Note: You must accept the App's permission request for Do Not Disturb access to use the Override Do Not Disturb feature. You can also enable the Do Not Disturb access setting directly from the App's notification settings.

- You should disconnect headphones or speakers from your phone when you are not using them as you may not hear audio for alarms. If using headphones, keep them in your ears.
- If you are using peripheral devices connected to your phone, such as wireless headphones or a smartwatch, you may receive alarms on only one device or peripheral, not all.
- Keep your phone well charged and turned on.
- Disable your phone's automatic operating system updates. After an operating system update, open your App and check your device settings to make sure it's working properly.

- Some operating system features may impact your ability to receive alarms. For example, if you use an iPhone and the iOS Screen Time feature, add FreeStyle Libre 3 to the list of always allowed apps to ensure that you receive alarms or if you use an Android phone do not use the Android Digital Wellbeing app.

Note: To receive alarms, make sure notifications for the App are enabled. If you want to receive a sound/vibration with your alarm, ensure that sound/vibration on your phone is turned on, sound is set at a level you can hear and your phone's Do Not Disturb feature is turned off. If Do Not Disturb is on, you will only see your alarm on the screen.

IMPORTANT:

- The Low and High Glucose Alarms should not be used exclusively to detect low or high glucose conditions. The glucose alarms should always be used along with your current glucose, glucose trend arrow and glucose graph.
- Low and High Glucose Alarm levels are different from your Target Glucose Range values. Low and High Glucose Alarms tell you when your glucose has passed the level you set in the alarm. Your Target Glucose Range is displayed on glucose graphs in the App and used to calculate your Time In Ranges.
- Make sure your phone is near you. The Sensor itself will not issue alarms.
- **If the Sensor is not communicating with the App, you will not receive glucose alarms, and you may miss detecting low glucose or high glucose episodes.** You will see the 🔔 symbol on the screen when the Sensor is not communicating with the App. If the Signal Loss Alarm is on, you will be notified if your Sensor has not communicated with the App for 20 minutes.
- If you see the 🔔 symbol, this means you are not getting glucose alarms because the Sensor is not communicating with the App, or the phone settings are incorrect. Confirm your settings are as follows:
  - **iPhone settings:**
    - Bluetooth is **ON**
    - Allow Critical Alerts is **ON**

- Allow Notifications is **ON**
- Lock Screen and Banner alerts are **ON**
- Notification sounds are **ON**

- **Android phone settings:**
  - Bluetooth is **ON**
  - Lock Screen notifications are **ON**
  - Channel notifications or Pop-up notifications are **ON**
  - Battery Optimisation is **OFF**
  - Do Not Disturb Access permission is **ON**
  - Phone Media volume is **ON**

Touch the 🔔 symbol for more information.

Setting Alarms

To set or turn on alarms, go to the Main Menu and tap **Alarms**. Select the alarm you want to turn on and set.

Low Glucose Alarm

1. The Low Glucose Alarm is off by default. Tap the slider to turn the alarm on.
2. If the alarm is on, you will be notified when your glucose falls below the alarm level, which is initially set to 3.9 mmol/L. Tap to change this value between 3.3 mmol/L and 5.6 mmol/L. Tap **SAVE**.
3. Choose the sound for this alarm. Volume and vibration will match your phone settings. Tap **SAVE**.
4. To override your phone's sound and vibration settings:
   - **iPhone:** Select whether to turn on Override Do Not Disturb for this alarm. Turn ON if you want the alarm to always play a sound and appear on the lock screen even if your phone is muted or Do Not Disturb is enabled on your

phone.

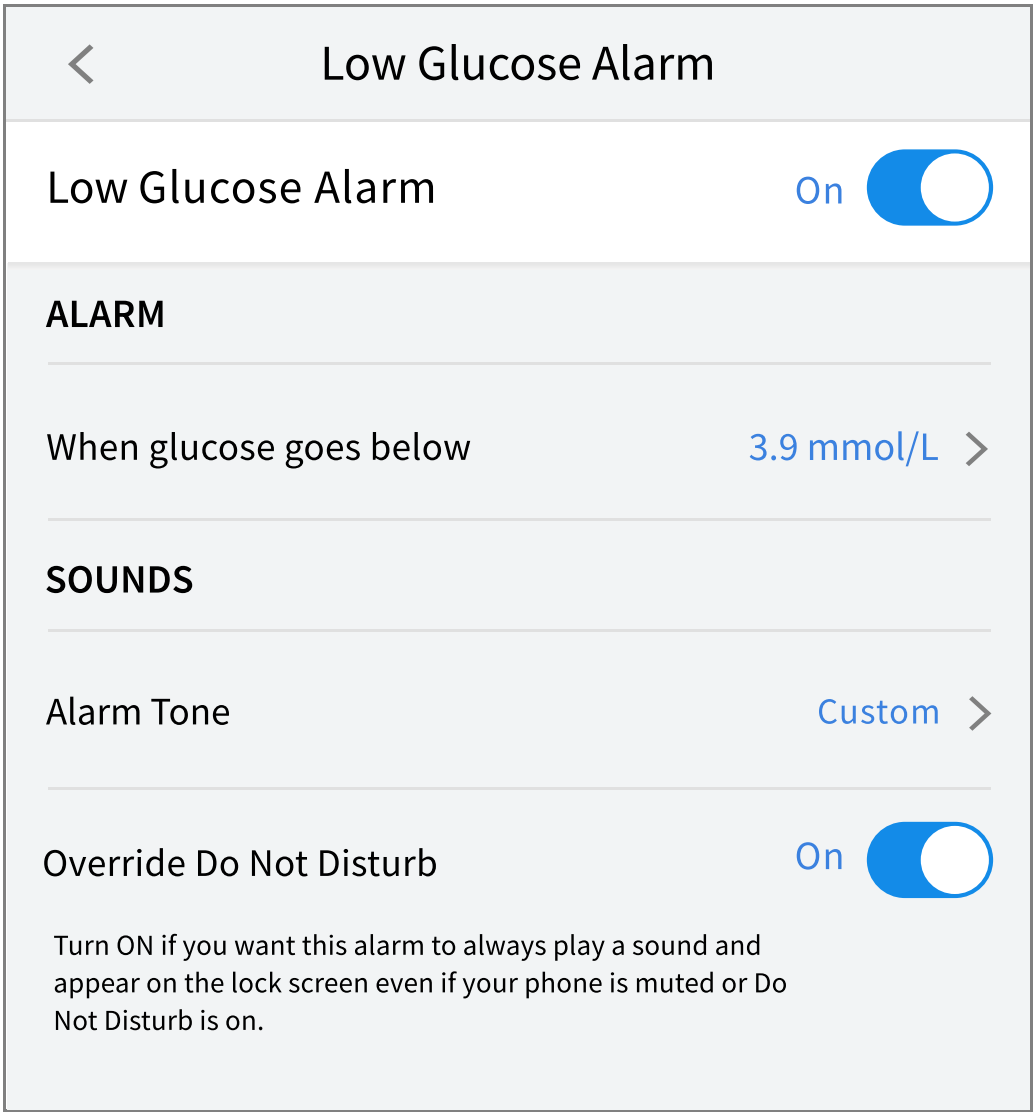
Note: You must accept the App's permission request for Critical Alerts to use this feature. You can also enable the Critical Alerts setting directly from the App's notification settings.

- **Android:** Select whether to turn on Override Do Not Disturb for this alarm. Turn ON if you want the alarm to always play a sound and appear on the lock screen, even if your phone's Media volume is muted.

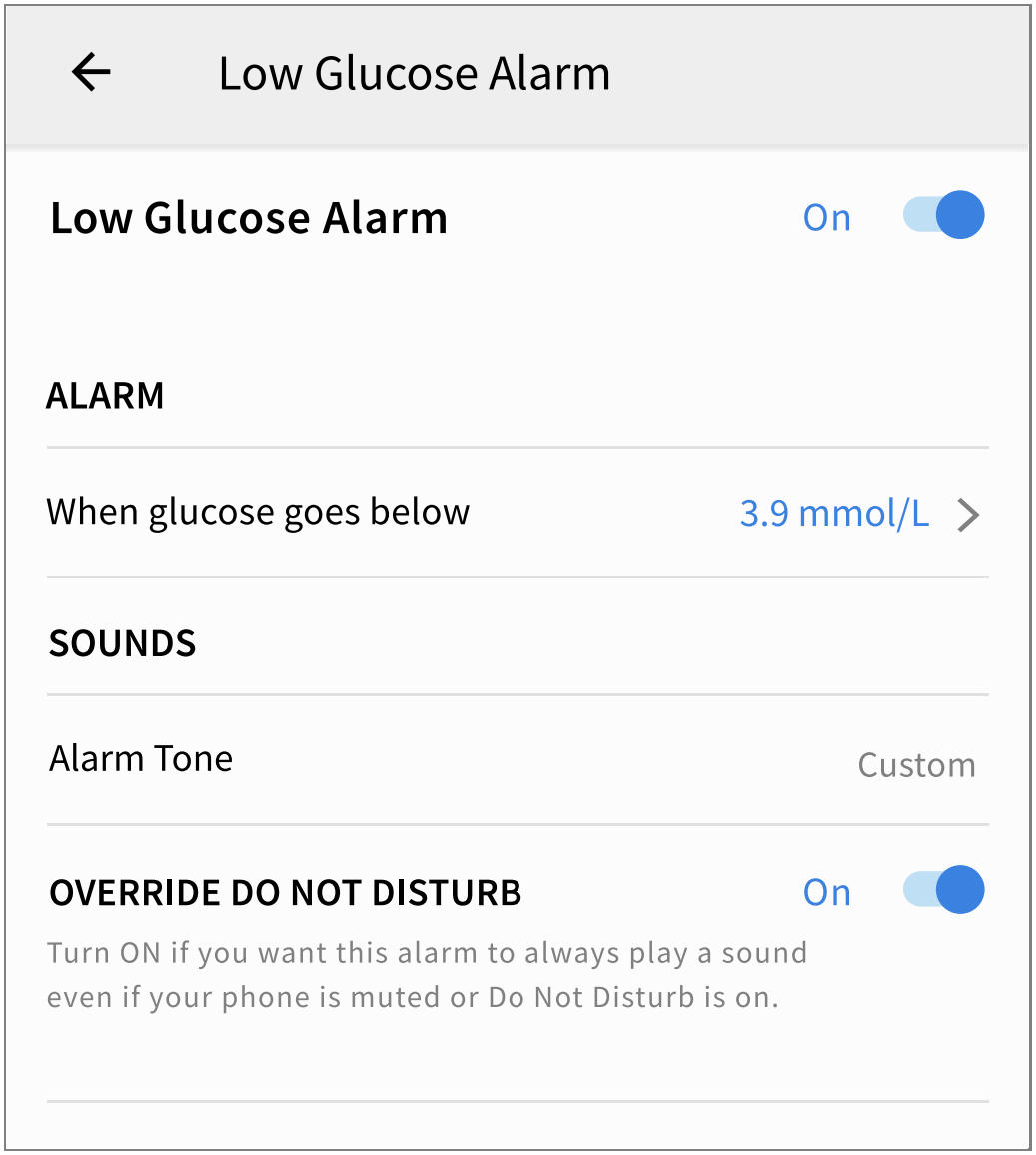
  Note: You must accept the App's permission request for Do Not Disturb access permission to use this feature. You can also enable the Do Not Disturb access setting directly from the App's notification settings.

5. Tap the back button to return to the main alarm settings screen.

iPhone


Low Glucose Alarm
Low Glucose Alarm
On
ALARM
When glucose goes below
3.9 mmol/L
SOUNDS
Alarm Tone
Custom
Override Do Not Disturb
On
Turn ON if you want this alarm to always play a sound and appear on the lock screen even if your phone is muted or Do Not Disturb is on.

Android



High Glucose Alarm

1. The High Glucose Alarm is off by default. Tap the slider to turn the alarm on.
2. If the alarm is on, you will be notified when your glucose rises above the alarm level, which is initially set to 13.9 mmol/L. Tap to change this value between 6.7 mmol/L and 22.2 mmol/L. Tap **SAVE**.
3. Choose the sound for this alarm. Volume and vibration will match your phone settings. Tap **SAVE**.
4. To override your phone's sound and vibration settings:
   - **iPhone:** Select whether to turn on Override Do Not Disturb for this alarm. Turn ON if you want the alarm to always play a sound and appear on the lock screen even if your phone is muted or Do Not Disturb is enabled on your phone.

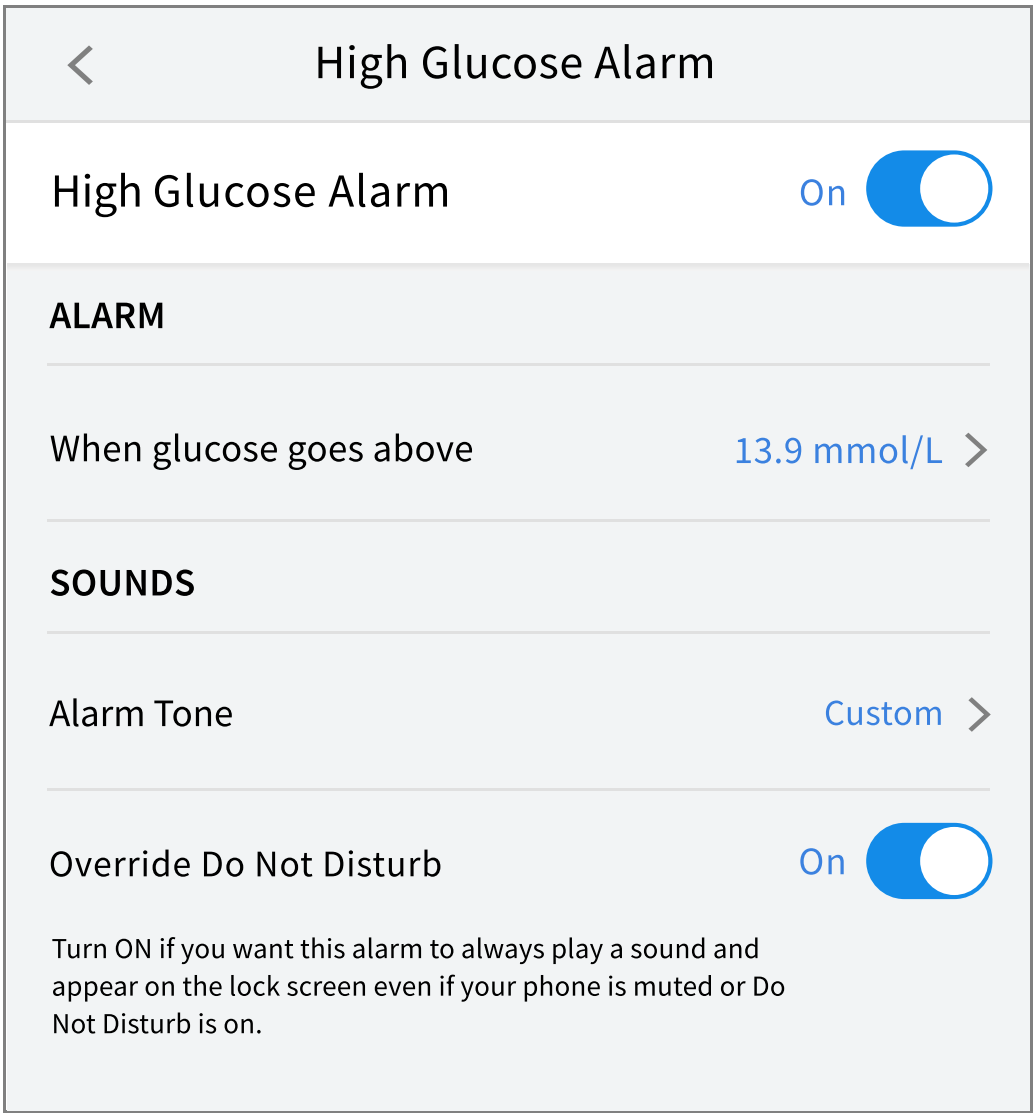
Note: You must accept the App's permission request for Critical Alerts to use this feature. You can also enable the Critical Alerts setting directly from the App's notification settings.

- **Android:** Select whether to turn on Override Do Not Disturb for this alarm. Turn ON if you want the alarm to always play a sound and appear on the lock screen, even if your phone's Media volume is muted.

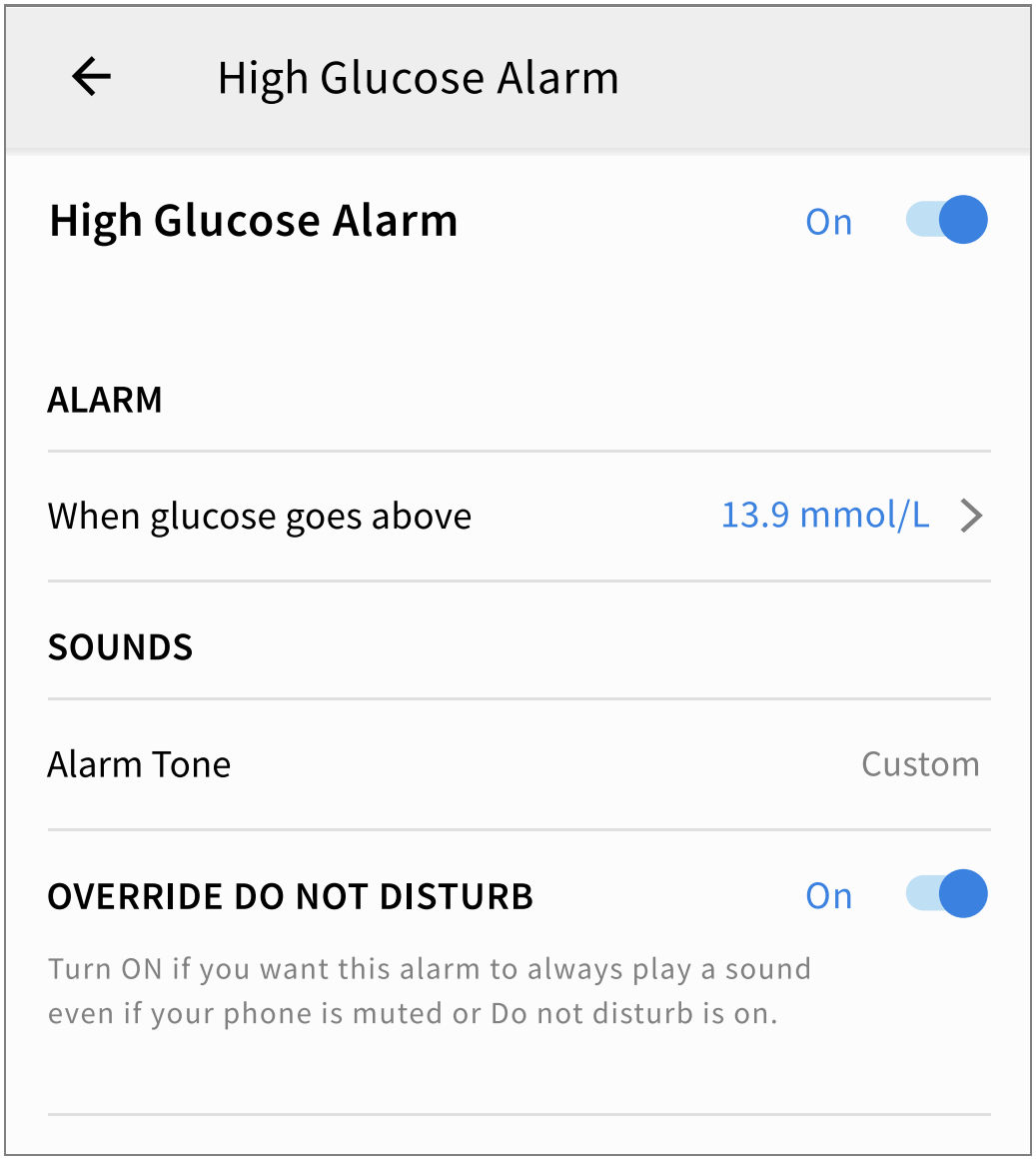
  Note: You must accept the App's permission request for Do Not Disturb access permission to use this feature. You can also enable the Do Not Disturb access setting directly from the App's notification settings.

5. Tap the back button to return to the main alarm settings screen.

iPhone



Android



Signal Loss Alarm

1. The Signal Loss Alarm is off by default. Tap the slider to turn the alarm on. If the alarm is on, you will be notified when your Sensor has not communicated with the App for 20 minutes and you are not receiving glucose readings or Low or High Glucose Alarms.

   Note: The Signal Loss Alarm automatically turns on the first time you turn the Low or High Glucose Alarm on.

2. Choose the sound for this alarm. Volume and vibration will match your phone settings. Tap **SAVE**.
3. To override your phone's sound and vibration settings:

- **iPhone:** Select whether to turn on Override Do Not Disturb for this alarm. Turn ON if you want the alarm to always play a sound and appear on the lock screen even if your phone is muted or Do Not Disturb is enabled on your phone.

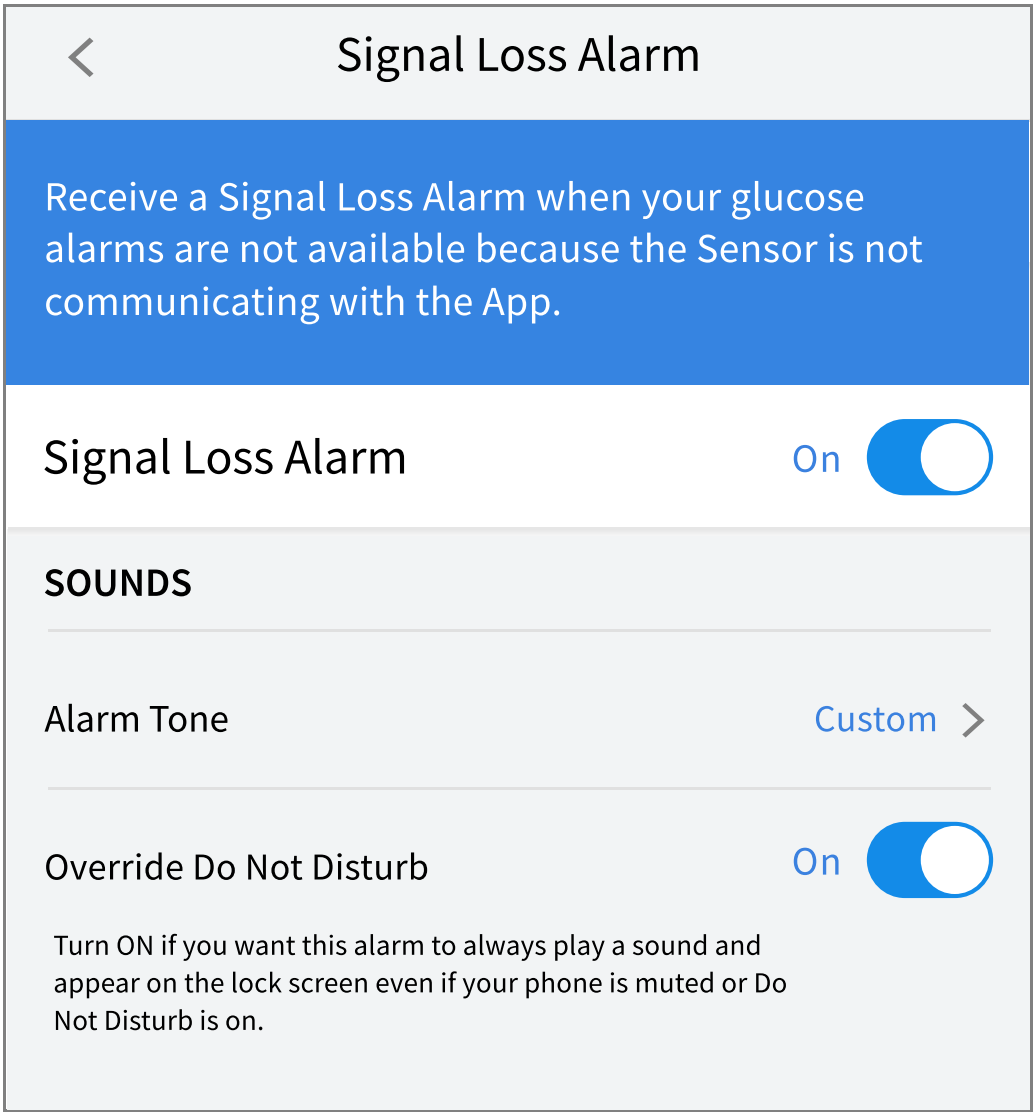
  Note: You must accept the App's permission request for Critical Alerts to use this feature. You can also enable the Critical Alerts setting directly from the App's notification settings.

- **Android:** Select whether to turn on Override Do Not Disturb for this alarm. Turn ON if you want the alarm to always play a sound and appear on the lock screen, even if your phone's Media volume is muted.

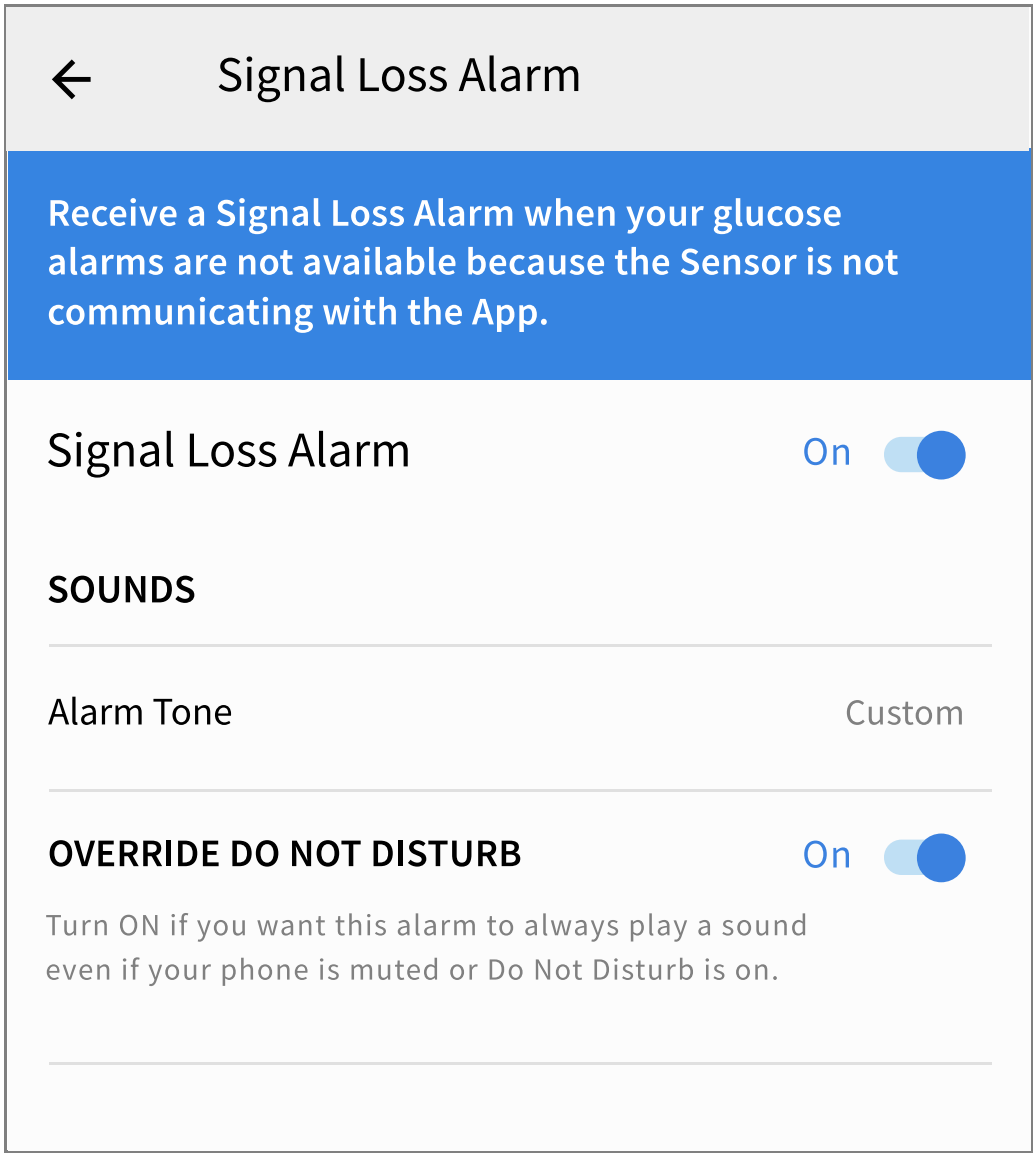
  Note: You must accept the App's permission request for Do Not Disturb access permission to use this feature. You can also enable the Do Not Disturb access setting directly from the App's notification settings.

4. Tap the back button to return to the main alarm settings screen.

iPhone

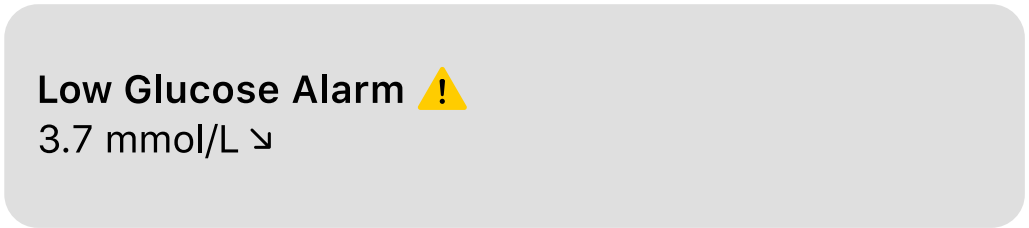

Signal Loss Alarm
Receive a Signal Loss Alarm when your glucose alarms are not available because the Sensor is not communicating with the App.
Signal Loss Alarm
On
SOUNDS
Alarm Tone
Custom
Override Do Not Disturb
On
Turn ON if you want this alarm to always play a sound and appear on the lock screen even if your phone is muted or Do Not Disturb is on.

Android

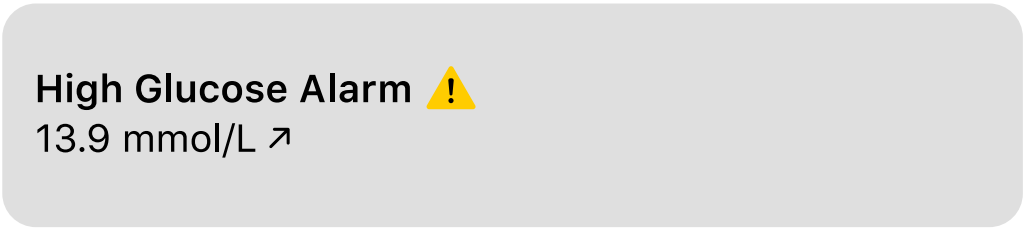


Using Alarms

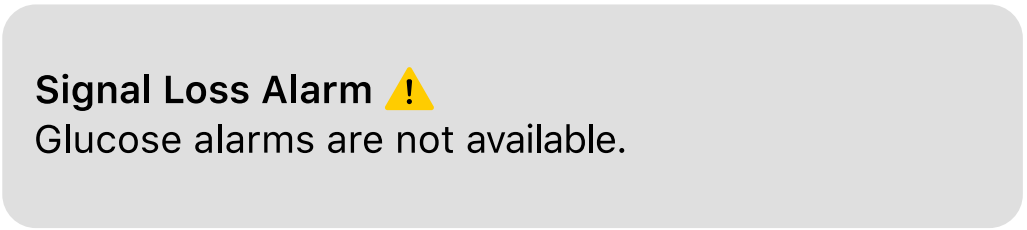
Low Glucose Alarm notifies you if your glucose drops below the level you set. Open the App or tap the Dismiss button to dismiss the alarm. You will only receive one alarm per low glucose episode.



High Glucose Alarm notifies you if your glucose rises above the level you set. Open the App or tap the Dismiss button to dismiss the alarm. You will only receive one alarm per high glucose episode.



Signal Loss Alarm notifies you if your Sensor has not communicated with the App for 20 minutes and you are not receiving glucose readings or Low or High Glucose Alarms. Signal loss could be caused by the Sensor being too far away from your phone (over 10 metres (33 ft)) or another issue such as an error or problem with your Sensor. Open the App or tap the Dismiss button to dismiss the alarm.



Note:

- If you do not dismiss a glucose alarm notification, you will receive it every 5 minutes while your glucose remains high or low. Once you dismiss the alarm notification, the alarm will not present again until your next high or low glucose episode.
- Only your most recent alarms will display on your screen.

Adding Notes

Notes can be saved with your glucose readings to help you track food, insulin and exercise. You can also add your own comment.

1. Tap ✎ on the Home Screen.
2. Select the tick box next to the notes you would like to add. After you tick the box, you can add more specific information to your note.
   - Food notes: Enter meal type and grams or portion information
   - Insulin notes: Enter the number of units taken
   - Exercise notes: Enter intensity and duration

3. Tap **DONE** to save your note.

Notes you add are shown on your glucose graph and in your Logbook as symbols. Low or high glucose alarms you receive will also be shown in the Logbook. You can review a note by tapping its symbol on your glucose graph or by going to the Logbook. See Reviewing Your History for more information about the Logbook. To edit a note from the glucose graph, tap the symbol and then tap the ✎. Tap **DONE** when you are finished.

Food
Insulin (Rapid or Long-acting)
Exercise
Food + insulin
Alarm
Multiple/Custom notes – indicates different types of notes entered together or notes entered within a short period of time. A numbered badge next to the symbol indicates the number of notes.

Reviewing Your History

Reviewing and understanding your glucose history can be an important tool for improving your glucose control. The App stores about 90 days of information and has several ways to review notes and past alarm data. From the Main Menu, tap **Logbook** to view the Logbook or tap on one of the other history options under **Reports**.

IMPORTANT: Work with your healthcare professional to understand your glucose history.

Logbook

The Logbook contains entries for notes you added as well as each time you received a low or high glucose alarm. If you would like to view a different day, tap the symbol or use the arrows. To add a note to a Logbook entry, tap on the entry and then tap the symbol. Select your note information and tap **DONE.**

To add a note that is independent of a Logbook entry, tap the symbol on the main Logbook screen. Tap the symbol if you want to add a note on a different date.

Other History Options

Daily Patterns: A graph showing the pattern and variability of your Sensor glucose readings over a typical day. The thick black line shows the median (midpoint) of your glucose readings. The light blue shading represents the 5th–95th percentile range of your glucose readings. Dark blue shading represents the 25th–75th percentile range.

Note: Daily Patterns needs at least 5 days of glucose data.

Time In Ranges: A graph showing the percentage of time your Sensor glucose readings were above, below or within certain glucose ranges. The Custom graph is based on your Target Glucose Range, and the Standard graph is based on a Target Range of 3.9 to 10.0 mmol/L.

Low Glucose Events: Information about the number of low glucose events measured by your Sensor. A low glucose event is recorded when your Sensor glucose reading is lower than 3.9 mmol/L for longer than 15 minutes. The total number of events is displayed below the graph. The bar graph displays the low glucose events in different periods of the day.

Average Glucose: Information about the average of your Sensor glucose readings. The overall average for the selected time period is displayed below the graph. The average is also shown for different periods of the day. Readings above or below your Target Glucose Range are yellow, orange or red. Readings in range are green.

Daily Graph: A graph of your Sensor glucose readings by day. The graph shows your Target Glucose Range and symbols for notes you have entered.

- The symbol may appear indicating a time change. Gaps in the graph may result or glucose readings may be hidden.

Sensor Usage: Information about how often you viewed your Sensor glucose readings in the App and how much information has been captured from your Sensor.

Glucose Management Indicator (GMI): Glucose Management Indicator uses average Sensor glucose data. GMI* can be used as an indicator of how well your glucose levels have been controlled.

*The formula is based on the published reference:
GMI (%) = 3.31 + 0.02392 x (mean glucose mg/dL)
GMI (mmol/mol) = 12.71 + 4.70587 x (mean glucose mmol/L)
Reference: Bergenstal, Richard M. et al. 'Glucose Management Indicator (GMI): A New Term for Estimating A1C From Continuous Glucose Monitoring.' Diabetes Care, ADA, November 2018.

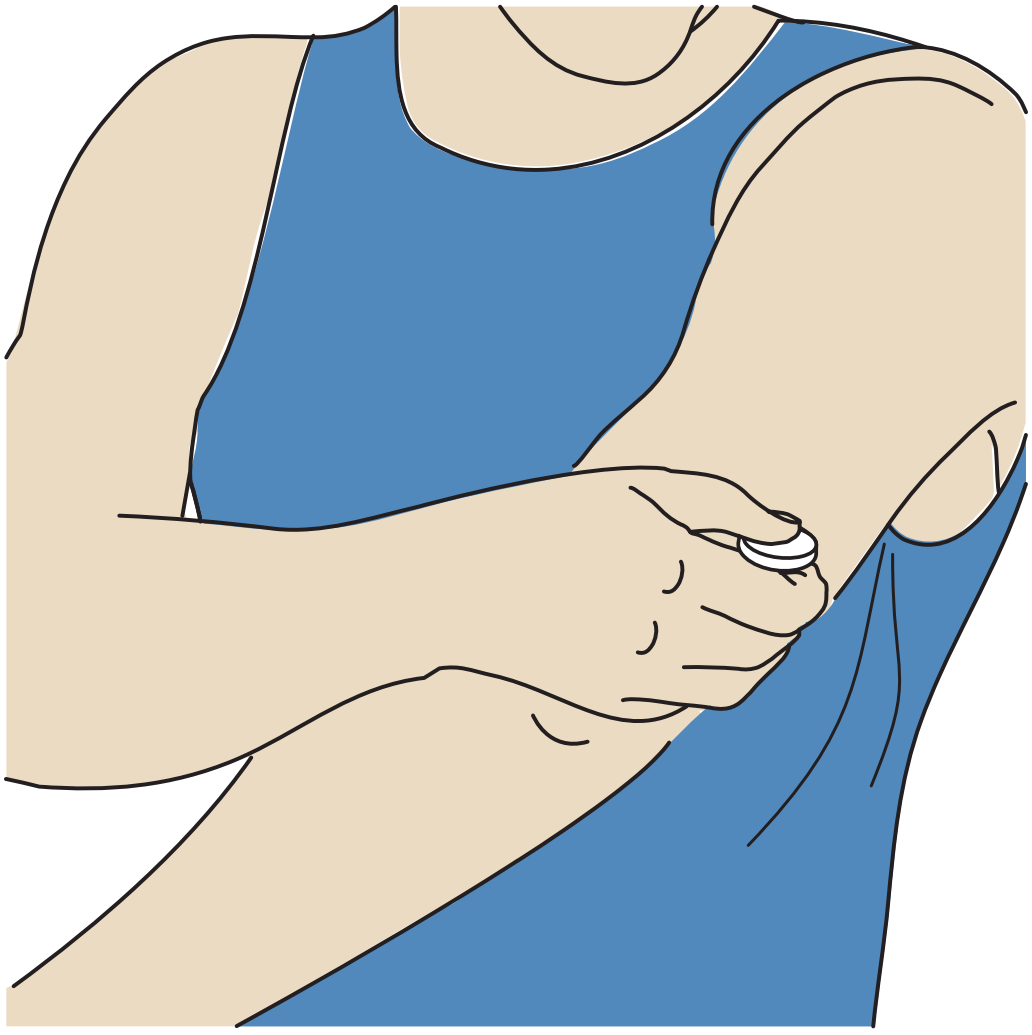
Note:

- Tap the symbol (iOS) or symbol (Android) on any report to share a screenshot of the report.
- Tap the symbol to view a description of the report.
- To view a different report:
  - **iOS:** Tap the dropdown menu above the report.
  - **Android:** From any report screen, swipe left or right to view the next or previous report.
- On all reports except the Daily Graph, you can select to show information about your last 7, 14, 30 or 90 days.

Removing Your Sensor

1. Pull up the edge of the adhesive that keeps your Sensor attached to your skin. Slowly peel away from your skin in one motion.

   Note: Any remaining adhesive residue on the skin can be removed with warm soapy water or isopropyl alcohol.



2. Discard the used Sensor. See Disposal. When you are ready to apply a new Sensor, follow the instructions in Applying Your Sensor and Starting Your Sensor. If you removed your last Sensor before it ended, go to 'Start New Sensor' in the menu to start the new one. You will be prompted to confirm that you would like to start a new Sensor.

   Note: After removing your Sensor you may observe a slight bump at the insertion site. This goes away quickly, usually in a day or two.

Replacing Your Sensor

Your Sensor automatically stops working after 14 days of wear and must be replaced. You should also replace your Sensor if you notice any irritation or discomfort at the application site or if the App reports a problem with the Sensor currently in use. Taking action early can keep small problems from turning into larger ones.

CAUTION: If the glucose readings from the Sensor do NOT seem to match with how you feel, check to make sure that your Sensor has not come loose. If the Sensor tip has come out of your skin, or your Sensor is coming loose, remove the Sensor and apply a new one.

Setting Reminders

You can create single or repeating reminders to help you remember things like checking your glucose or taking insulin. You can also set a reminder to remind you to check your alarm settings if you have disabled your alarms temporarily. There is one default reminder to help you remember to check your glucose. This Check Glucose reminder can be changed or disabled but cannot be deleted.

Note: To receive reminders, make sure notifications for the App are enabled. If you want to receive a sound/vibration with your reminder, ensure that sound/vibration on your phone is turned on, sound is set at a level you can hear and your phone's Do Not Disturb feature is turned off. If Do Not Disturb is on, you will only see your reminder on the screen.

1. To add a new reminder, go to the Main Menu and tap **Reminders**. Tap **ADD REMINDER**.
2. Name your reminder.
3. Tap the time fields to set the time for the reminder.

   Note: If you would like the reminder to repeat, tap the slider to the right. You can also select which days you would like to receive the reminder.

4. Tap **DONE**. You will now see your reminder on the list along with the time you

will receive it.

Note:

- To turn off a reminder, tap the slider to the left.
- To delete a reminder, swipe the reminder to the left and tap the 🗑 symbol. The Check Glucose reminder cannot be deleted.
- Your reminders will be received as notifications that you can swipe or tap to dismiss.

Settings and Other Options in the Main Menu

You can go to the Main Menu to manage LibreView account settings.

Settings

App Settings:

Unit of Measurement – View the glucose unit of measure used in the App.

Report Settings – Work with your healthcare professional to set your Target Glucose Range, which is displayed on glucose graphs in the App and used to calculate the Time in Ranges Custom report. The Target Glucose Range setting will not set glucose alarm levels. Tap **SAVE** when you are done.

Carbohydrate Units – Choose grams or portions for food notes that you enter. Tap **SAVE** when you are done.

Account Settings:

Note: You must have a LibreView account and be signed in to manage Account Settings. To sign into an existing account or create a new account choose Sign In from the Main Menu.

Account Settings – View/change your LibreView account information.

Account Password – Change your LibreView account password.

Sign Out (Android) – Sign out of your LibreView Account.

Account Options (iOS)- Sign out or delete your LibreView account.

Signing out of your account means you will no longer be able to:

- Use the account with the FreeStyle Libre 3 app unless you sign back in.
- Use the Connected Apps or Account Settings features.

Deleting your account means you will no longer be able to:

- Use your current sensor.
- Access your account and all related data. Data will be deleted and cannot be recovered for future use.
- Use the account with the FreeStyle Libre 3 app.
- Use the Connected Apps or Account Settings features.

Connected Apps

Note: A LibreView Account is required to manage Connected Apps.

The Connected Apps option in the Main menu opens a web browser within the App. It may list different apps you can connect with to share your data. To connect your data with apps listed in the Connected Apps option, select them from the list of apps, and follow the onscreen instructions. If there is an issue with Connected Apps, you may see this icon ⚠.

Help

View in-app tutorials, access the App's User Manual and review the App’s legal information. You can also view the Event Log, which is a list of events recorded by the App. This may be used by Customer Service to help troubleshoot.

About

View App software version and other information.

Living with your Sensor

Activities

Bathing, Showering and Swimming: Your Sensor is water-resistant and can be worn while bathing, showering or swimming. Do NOT take your Sensor deeper than 1 metre (3 ft) or immerse it longer than 30 minutes in water. Note that bluetooth performance may be impacted if using the system while underwater.

Sleeping: Your Sensor should not interfere with your sleep. If you have reminders set to go off while you are sleeping or have glucose alarms set, place your phone nearby.

Travelling by Air: You may use your System while on an aircraft, following any requests from the flight crew. You can continue to get Sensor glucose readings and alarms after you put your phone in aeroplane mode, as long as Bluetooth is enabled.

IMPORTANT: Glucose alarms will not be issued while your phone is in aeroplane mode unless you enable Bluetooth.

- Some airport full-body scanners include X-ray or millimeter radio-wave, which you cannot expose your Sensor to. The effect of these scanners has not been evaluated and the exposure may damage the Sensor or cause inaccurate results. To avoid removing your Sensor, you may request another type of screening. If you do choose to go through a full-body scanner, you must remove your Sensor.
- The Sensor can be exposed to common electrostatic (ESD) and electromagnetic interference (EMI), including airport metal detectors.

Note: Changing the time affects the graphs and statistics. The symbol may appear on your glucose graph indicating a time change. Gaps in the graph may result or glucose readings may be hidden.

Maintenance

The Sensor has no serviceable parts.

Disposal

Sensor:

Sensors must not be disposed of via municipal waste collection. Separate collection for electrical and electronic equipment waste per Directive 2012/19/EU in the European Union is required. Contact the manufacturer for details. As Sensors may have been exposed to bodily fluids, you may wipe prior to disposing, such as by using a cloth dampened with a mixture of 1 part household bleach to 9 parts water.

Note: Sensors contain non-removable batteries and must not be incinerated. Batteries may explode upon incineration.

Sensor Applicator:

Please consult your local waste management authority for instructions on how to dispose Sensor Applicators at a designated sharps collection site. Ensure the cap is on the Sensor Applicator as it contains a needle.

Troubleshooting

This section lists problems that you may experience, the possible cause(s) and recommended actions. If there is an error, a message will appear on the screen with directions to resolve the error.

IMPORTANT: If you are having issues with the App, please keep in mind that uninstalling the App will cause you to lose all historical data and end the Sensor currently in use. Please call Customer Service if you have any questions.

Problems at the Sensor Application Site

Problem: **The Sensor is not sticking to your skin.**

What it may mean: The site is not free of dirt, oil, hair or sweat.

What to do: 1. Remove the Sensor. 2. Consider shaving and/or cleaning the site with soap and water. 3. Follow the instructions in Applying Your Sensor and

Starting Your Sensor.

Problem: **Skin irritation at the Sensor application site.**

What it may mean: Seams or other constrictive clothing or accessories causing friction at the site **OR** you may be sensitive to the adhesive material.

What to do: Ensure that nothing rubs on the site. If the irritation is where the adhesive touches skin, contact your healthcare professional to identify the best solution.

Problems Starting Your Sensor

Display: **Scan Error**

What it may mean: The phone was unable to scan the Sensor.

What to do:

- **iPhone:** Tap the scan button and try scanning the Sensor again. The NFC antenna is on the top edge of the phone. Scan your Sensor by touching the Sensor with the TOP of your phone. Move your phone around slowly if needed. Proximity, orientation, and other factors can affect NFC performance. For example, a bulky or metallic case can interfere with the NFC signal.
- **Android:** Try scanning the Sensor again. The NFC antenna is located on the back side of most Android phones. Scan your Sensor by touching the Sensor with the BACK of your phone. Move your phone around slowly if needed. Proximity, orientation, and other factors can affect NFC performance. For example, a bulky or metallic case can interfere with the NFC signal. Make sure you are not touching any buttons on the phone or the screen.

Display: **Sensor Already in Use**

What it may mean: The Sensor was started by another device.

What to do: Your App can only be used with a Sensor started with the same

LibreView account. If you're unable to use the Sensor with your App, check your glucose with the device that started it. Or, apply and start a new Sensor.

Display: **Enable Bluetooth**

What it may mean: The Bluetooth setting on your phone is turned off.

What to do: Go to your phone settings and enable Bluetooth.

Display: **Incompatible Sensor**

What it may mean: The Sensor cannot be used with the App. Check that you have installed the app that is compatible with your Sensor. You may need to download a different app if your Sensor is not compatible.

What to do: Tap **Learn More** to find out what Sensors can be used. If you still have questions, call Customer Service.

Display: **Replace Sensor**

What it may mean: The App has detected a problem with your Sensor.

What to do: Apply and start a new Sensor.

Problems Receiving Sensor Readings

Display: **Sensor ready in X minutes**

What it may mean: The Sensor is unable to provide a glucose reading during the start-up period.

What do to: Check again after the duration specified on the screen.

Display: **Replace Sensor**

What it may mean: The App has detected a problem with your Sensor.

What to do: Apply and start a new Sensor.

Display: **Check Sensor**

What it may mean: The Sensor tip may not be under your skin.

What do to: Try to start your Sensor again. If you see ‘Check Sensor’ again on the screen, your Sensor was not applied properly. Remove this Sensor and apply and start a new Sensor.

Display: **Sensor Ended**

What it may mean: Your Sensor has ended.

What to do: Apply and start a new Sensor.

Display: **Signal Loss**

What it may mean: Sensor has not automatically communicated with the App in the last 5 minutes.

What to do: Make sure your phone is within 10 metres (33 ft) of the Sensor and you have not force-closed the App. Tap the ⓘ symbol for more information. Try turning Bluetooth OFF then ON again. If that doesn't work, try turning your phone OFF then ON again.

Display: **Bluetooth Off**

What it may mean: Bluetooth is turned off.

What to do: Go to your phone settings and enable Bluetooth.

Display: **Sensor Error**

What it may mean: The Sensor is unable to provide a glucose reading. Tap the ⓘ symbol for more information.

What do to: Check again after the duration specified in the message.

Display: **Sensor Too Hot**

What it may mean: Your Sensor is too hot to provide a glucose reading. Tap the ⓘ symbol for more information.

What to do: Move to a location where the temperature is appropriate and check again in a few minutes.

Display: **Sensor Too Cold**

What it may mean: Your Sensor is too cold to provide a glucose reading. Tap the ⓘ symbol for more information.

What to do: Move to a location where the temperature is appropriate and check again in a few minutes.

Display: **Unexpected Application Error**

What it may mean: The App has detected an unexpected error.

What to do: Shut down the App completely and restart.

Problems Receiving Glucose Alarms

What it may mean: You have not turned glucose alarms on.

What to do: Go to the main menu and then select **Alarms**. Choose the alarm you want to turn on and set.

What it may mean: The Sensor is not communicating with the App or there may be a problem with the Sensor.

What to do: The Sensor must be within range (10 metres (33 ft)) of your phone for you to receive alarms. Make sure that you are within this range. You will see the 🔔 symbol when your Sensor has not communicated with the App in 5 minutes. If the Signal Loss Alarm is on, you will be notified if there has been no communication for 20 minutes. Try turning Bluetooth OFF then ON again. If that doesn't work, try turning your phone OFF then ON again. If the Signal Loss Alarm persists, contact Customer Service.

What it may mean: One or more of the phone settings or permissions is incorrect.

What to do: Check to make sure that you have the correct settings and permissions enabled on your phone to receive alarms.

iPhone settings:

- Bluetooth is **ON**
- Allow Critical Alerts is **ON**
- Allow Notifications is **ON**
- Lock Screen and Banner alerts are **ON**
- Notification sounds are **ON**

Android phone settings:

- Bluetooth is **ON**
- Lock Screen notifications are **ON**
- Channel notifications or Pop-up notifications are **ON**
- Battery Optimisation is **OFF**
- Do Not Disturb Access permission is **ON**
- Phone Media volume is **ON**

Go to Setting Alarms for more information.

What it may mean: You may have set an alarm level that is higher or lower than you intended.

What to do: Confirm your alarm settings are appropriate.

What it may mean: You have already dismissed this type of alarm.

What to do: You will receive another alarm when a new low or high glucose episode starts.

What it may mean: You have closed the App.

What to do: Make sure the App is always open in the background.

What it may mean: Your Sensor has ended.

What to do: Replace your Sensor with a new one.

What it may mean: If you are using peripherals such as wireless headphones or a smartwatch, you may receive alarms on only one device or peripheral, not all.

What to do: Disconnect headphones or peripherals when you are not using them.

What it may mean **(Android only):** The FreeStyle Libre 3 app was put to sleep by the phone operating system.

What to do: Put the FreeStyle Libre 3 app on the list of apps that will not be put to sleep.

Customer Service

Customer Service is available to answer any questions you may have about the FreeStyle Libre 3 system. Please go to www.FreeStyleLibre.com or refer to the product insert in your Sensor Kit for your Customer Service phone number. A printed copy of this User's Manual is available upon request.

Reporting of Serious Incidents

If a serious incident has occurred in relation to this device, it should be reported to Abbott Diabetes Care. Please go to www.FreeStyleLibre.com or refer to the product insert in your Sensor Kit for your Customer Service phone number.

In European Union Member States, serious incidents should also be reported to the competent authority (the government department responsible for medical devices) in your country. Please refer to your government website for details of how to contact your competent authority.

A 'serious incident' means any incident that directly or indirectly led, might have led or might lead to:

- The death of a patient, user or other person,

- The temporary or permanent serious deterioration of a patient's, user's or other persons' state of health.

Sensor Specifications

Sensor glucose assay method: Amperometric electrochemical sensor

Sensor glucose reading range: 2.2 to 27.8 mmol/L

Sensor size: 2.9 mm height and 21 mm diameter

Sensor weight: 1 gram

Sensor power source: One silver oxide battery

Sensor life: Up to 14 days

Sensor memory: Up to 14 days (glucose readings stored every 5 minutes)

Operating temperature: 10°C to 45°C

Sensor Applicator storage temperature: 2°C and 28°C

Operating and storage relative humidity: 10–90%, non-condensing

Sensor water resistance and ingress protection: IP27: Can withstand immersion into one metre (3 ft) of water for up to 30 minutes. Protected against insertion of objects > 12 mm diameter.

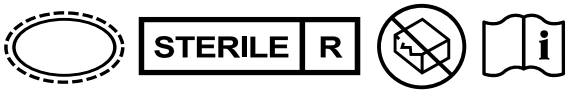
Operating and storage altitude: -381 metres (-1,250 ft) to 3,048 metres (10,000 ft)

Radio Frequency: 2.402–2.480 GHz BLE; GFSK; 4.6 dBm EIRP

Sensor transmission range: 10 metres (33 ft) unobstructed

Labelling Symbols and Definitions

	Consult instructions for use
	Temperature limit
	Manufacturer
	Date of manufacture
	CE Mark
	Authorised Representative in the European Community
	Importer
	Single sterile barrier system with protective packaging outside

LOT	Batch code
	Type BF applied part
	Do not re-use
	Use-by date
REF	Catalogue number
SN	Serial number
	Caution
STERILE R	Sterilised by irradiation
	Sterile Barrier. Refer to Instructions for Use if opened or damaged.
	Humidity limitation
	Do not use if package is damaged.
	**For Sterile Barrier:** Do not use if the product sterile barrier system or its packaging is compromised.
	This product must not be disposed of via municipal waste collection. Separate collection for electrical and electronic

equipment waste per Directive 2012/19/EU in the European Union is required. Contact the manufacturer for details.

Electromagnetic Compatibility

- The Sensor needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect the Sensor.
- Use of accessories, transducers and cables other than those specified or provided by Abbott Diabetes Care could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- The Sensor should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Sensor should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions test: RF emissions; CISPR 11

Compliance: Group 1

Electromagnetic environment – guidance: The Sensor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Emissions test: RF emissions; CISPR 11

Compliance: Class B

Electromagnetic environment – guidance: The Sensor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test: Electrostatic discharge (ESD); IEC 61000-4-2

IEC 60601 test level: ± 8kV contact; ± 2 kV, 4 kV, 8 kV, 15 kV air

Compliance level: ± 8kV contact; ± 2 kV, 4 kV, 8 kV, 15 kV air

Electromagnetic environment – guidance: Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Immunity test: Power frequency (50/60 Hz); magnetic field; IEC 61000-4-8

IEC 60601 test level: 30 A/m 50 Hz or 60 Hz

Compliance level: 30 A/m 50 Hz or 60 Hz

Electromagnetic environment – guidance: Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.

Immunity test: Radiated RF; IEC 61000-4-3

IEC 60601 test level: 10 V/m; 80 MHz to 2.7 GHz; 80% AM at 1 KHz

Compliance level: 10 V/m; 80 MHz to 2.7 GHz; 80% AM at 1 KHz

Electromagnetic environment – guidance:

Immunity test: Proximity fields from RF wireless communications equipment; IEC 61000-4-3

IEC 60601 test level: See table below

Compliance level: Compliance to the tested levels

Electromagnetic environment – guidance: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the System, including cables specified by Abbott Diabetes Care. Otherwise, degradation of the performance of the System could result.

The table below lists the immunity test levels at specific test frequencies for testing the effects of some wireless communications equipment. The frequencies and services listed in the table are representative examples in healthcare and in various locations where the System may be used.

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
385	380–390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430–470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704–787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100–5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

[a] For some services, only the uplink frequencies are included.

[b] The carrier is modulated using a 50% duty cycle square wave signal.

[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because, while it does not represent actual modulation, it would be worst case.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[d] should be less than the compliance level in each frequency range.[e]

Interference may occur in the vicinity of equipment marked with the following symbol:

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

[e] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Performance Characteristics

Note: Please consult your healthcare team on how to use the information in this section.

Performance Characteristics

Performance of the Sensor was evaluated in a controlled clinical study. The study was conducted in 4 centers and a total of 100 subjects ages 4 years and older with diabetes were included in the effectiveness analysis. Each subject wore up to two Sensors for up to 14 days on the back of the upper arm. During the study, subjects had their venous blood glucose analyzed over up to three separate visits to the clinical centre using the Yellow Springs Instrument Life Sciences 2300 STAT Plus™. Three lots of Sensors were evaluated in the study.

Fig 1. Comparison of the Sensors vs. YSI reference.

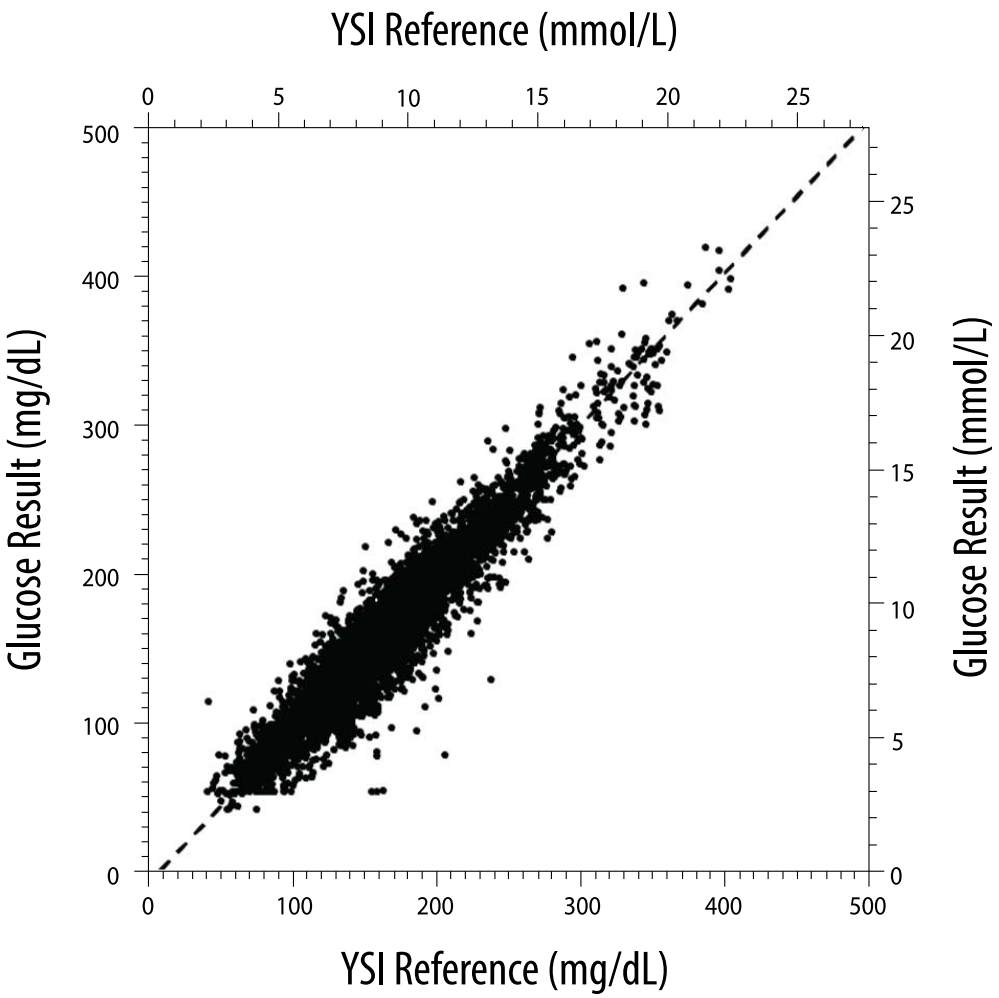


Table 1. Regression analysis of the Sensors vs. YSI reference

Slope	1.03
Intercept	-8.1 mg/dL (-0.45 mmol/L)
Correlation	0.96
N	6845
Range	40 – 405 mg/dL (2.2 – 22.5 mmol/L)
Overall mean bias	-3.7 mg/dL (-0.2 mmol/L)
Mean Absolute Relative Difference (MARD)	7.8%

Table 2. Sensor accuracy for all results vs. YSI reference

Sensor accuracy results for glucose concentrations <70 mg/dL (3.9 mmol/L)	**Within ±15 mg/dL (within ±0.8 mmol/L)**	**Within ±20 mg/dL (within ±1.1 mmol/L)**	**Within ±40 mg/dL (within ±2.2 mmol/L)**
	103 / 120 (85.8%)	112 / 120 (93.3%)	119 / 120 (99.2%)
Sensor accuracy results for glucose concentrations ≥70 mg/dL (3.9 mmol/L)	**Within ±15%**	**Within ±20%**	**Within ±40%**
	5902 / 6725 (87.8%)	6278 / 6725 (93.4%)	6692 / 6725 (99.5%)
Sensor accuracy for all results	**Within ±20 mg/dL (±1.1 mmol/L) and within ±20% of reference**		
	6390 / 6845 (93.4%)		

Table 3. Sensor performance relative to YSI reference at different glucose levels

Glucose	Mean Absolute Relative Difference
<54 mg/dL (3.0 mmol/L)	16.5 mg/dL (0.9 mmol/L)*
54-69 mg/dL (3.0-3.8 mmol/L)	8.0 mg/dL (0.4 mmol/L)*
70-180 mg/dL (3.9-10.0 mmol/L)	8.4%
181-250 mg/dL (10.0-13.9 mmol/L)	6.3%
251-350 mg/dL (13.9-19.4 mmol/L)	4.9%
>350 mg/dL (19.4 mmol/L)	4.1%

* For glucose ≤69 mg/dL (3.8 mmol/L), the differences in mg/dL (mmol/L) are presented instead of relative differences (%).

Table 4. Sensor accuracy over wear duration vs. YSI reference

	Beginning	Early Middle	Late Middle	End
Within ±20 mg/dL (±1.1 mmol/L) and within ±20% of reference	92.1%	91.3%	96.0%	95.0%
Mean Absolute Relative Difference (%)	8.6	8.7	6.4	7.0

Skin Interaction

Based on the examination of 101 study participants, the following incidence of skin issues were observed. All skin issues were reported to be mild or moderate in severity.

Bleeding – 3.0% of participants

Edema – 1.0% of participants

Erythema – 5.0% of participants

Induration – 2.0% of participants

Itching – 1.0% of participants

Expected Clinical Benefits

Complications as a result of diabetes mellitus (including, but not limited to: diabetic retinopathy, diabetic nephropathy) are well documented.[1] Self-monitoring of blood glucose (SMBG) by patients has revolutionised management of diabetes.[2] Using glucose monitoring devices patients with diabetes can work to achieve and maintain specific glycaemia goals. Given the results of the Diabetes Control and Complications Trial (DCCT)[3] and other studies, there is broad consensus on the health benefits of normal or near-normal blood glucose levels and on the importance, especially in insulin-treated patients, of glucose monitoring devices in treatment efforts designed to achieve these glycaemic goals. Based principally on the DCCT results, experts recommend that most individuals with diabetes should attempt to achieve and maintain blood glucose levels as close to normal as is

safely possible. Most patients with diabetes, especially insulin treated patients, can achieve this goal only by using glucose monitoring devices.

References

1. Textbook of Diabetes, Volumes 1 & 2; Pickup and Williams, 1999.

2. ADA Position Statement. Test of glycaemia in diabetes. Diabetes Care 2003; 26(Suppl.1) S106-108.

3. Diabetes Control and Complications Trial Research Group (DCCT): The effect of intensive treatment of diabetes on the development and progression of long term complications in insulin dependent diabetes mellitus. New Engl J Med, 329: 977-86; 1993.

Customer Service: www.FreeStyleLibre.com

Patent: www.Abbott.com/patents

Abbott B.V.,
Wegalaan 9, 2132 JD Hoofddorp,
The Netherlands

EC REP Abbott B.V.
Wegalaan 9, 2132 JD Hoofddorp,
The Netherlands

CE 2797

Abbott Diabetes Care Ltd.
Range Road
Witney, Oxon
OX29 0YL, UK

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Abbott