English

FreeStyle LibreLink

User's Manual

App Symbols

	App icon
	Direction your glucose is going. See Understanding Your Glucose Readings for more information.
	Scan button
	Caution
	Add/edit notes
	Food note
	Insulin note
	Food + insulin note
	Insulin pen error
	Exercise note
	Time change

	Alarms you have turned on are unavailable
	Sensor too cold
	Sensor too hot
	Multiple/Custom notes
	Share report
	Additional information
	Main menu
	Calendar

Important Information

Compatible Sensors

You can use FreeStyle LibreLink app with the below Sensors. The age range, wear duration and Performance Characteristics vary between Sensors. Please reference the labeling content that applies to your Sensor.

FreeStyle Libre or Libre 2 Sensor:

- 14-day wear duration
- Can be used by people age 4 and older

FreeStyle Libre 2 Plus Sensor:

- 15-day wear duration
- Can be used by people age 2 and older

Indications for Use

FreeStyle Libre or Libre 2 Sensor users:

FreeStyle LibreLink app ('App') when used with a FreeStyle Libre or FreeStyle Libre 2 Flash 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 carer who is at least 18 years of age. The carer 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.

FreeStyle Libre 2 Plus Sensor users:

FreeStyle LibreLink app ('App') when used with a FreeStyle Libre 2 Plus Flash Glucose Monitoring System Sensor ('Sensor') is indicated for measuring interstitial fluid glucose levels in people (age 2 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 2 – 12) is limited to those who are supervised by a carer who is at least 18 years of age. The carer 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.

Note: Not all products referenced in this User Manual are available in all countries.

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

CAUTION:

- FreeStyle LibreLink installed on a smartphone 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.
- If you are using a FreeStyle Libre Sensor with the FreeStyle LibreLink app or you started your FreeStyle Libre 2 or Libre 2 Plus Sensor with another device, you will not receive alarms from the FreeStyle LibreLink app.

  No Alarms from the App

You are using a FreeStyle Libre Sensor.

You started a FreeStyle Libre 2 or Libre 2 Plus Sensor with another device before using it with the App.

Alarms from the App

You started a FreeStyle Libre 2 or Libre 2 Plus Sensor with the App.

- You will only get alarms from the App if you use the App to start a FreeStyle Libre 2 or Libre 2 Plus Sensor. For you to receive alarms, make sure to:
  - Turn alarms ON and ensure that your smartphone is within 6 metres (20 ft) of you at all times. The transmission range is 6 metres (20 ft) unobstructed. If you are out of range, you may not receive glucose alarms.
  - Do not force close the App.
  - Check to make sure that you have the correct settings and permissions enabled on your phone to receive alarms.
    - Enable Bluetooth and allow the App to access Bluetooth.
    - Allow Notifications for the App. Turn on Lock Screen and Banner alerts, Notification sounds and general phone sounds or vibration. Make sure not to turn on any features or modify phone settings that may interrupt the presentation of notifications.
    - Turn off Do Not Disturb mode or select to turn on Override Do Not Disturb in your alarm settings. Do this 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 on.

      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.

  - Remember that alarm settings will follow your smartphone's sound and vibration settings so these should be at a level you can hear to prevent missed alarms.
  - You should disconnect headphones when you are not using them as you may not receive audio with alarms.
  - 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 smartphone well charged and turned on.

Additional Safety Information

- FreeStyle LibreLink does not share data with FreeStyle LibreLink special edition app, FreeStyle Libre Reader or FreeStyle Libre 2 Reader ('Readers').
- For complete information on a device, be sure to scan your Sensor every 8 hours with that device or when you see gaps in your graph; otherwise, your reports will not include all your data.

Security Information

- You are responsible for properly securing and managing your smartphone. If you suspect an adverse cybersecurity event related to FreeStyle LibreLink, 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.
- FreeStyle LibreLink is not intended for use on a smartphone 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 FreeStyle LibreLink.

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

WARNING:

- The Sensor contains small parts that may be dangerous if swallowed.
- 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.
- The FreeStyle Libre 2 Sensor can be used with the FreeStyle Libre Reader but the FreeStyle Libre Reader will NOT issue alarms.

CAUTION:

- 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.
- The Sensor uses all available glucose data to give you readings and can store up to 8 hours of data. If you are using a FreeStyle Libre Sensor or you started your FreeStyle Libre 2 or Libre 2 Plus Sensor with another device, you should scan your Sensor at least once every 8 hours for the most accurate performance. Scanning less frequently may result in decreased performance. If you are using two devices with the same Sensor, be sure to scan frequently with both devices.
- 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.
- The Sensor Pack and Sensor Applicator are packaged as a set and have the same Sensor code. Check that the Sensor codes match before using your Sensor Pack and Sensor Applicator. Sensor Packs and Sensor Applicators with the same Sensor code should be used together or your Sensor glucose readings may be incorrect.

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 4°C and 25°C. While you don’t need to keep your Sensor Kit in a refrigerator, you can as long as the refrigerator is between 4°C and 25°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 that 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.
- Do not use the System in people under the ages specified in the Indications for Use.
- The Sensor Pack is sterile unless opened or damaged.
- Your Sensor has been tested to withstand immersion into 1 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 LibreLink Overview

IMPORTANT: Read all of the information in this User’s Manual before using FreeStyle LibreLink with a Sensor. Refer to your iPhone instructions for use for how to use your iPhone. If you are using a Reader, refer to the User's Manual in the Reader kit.

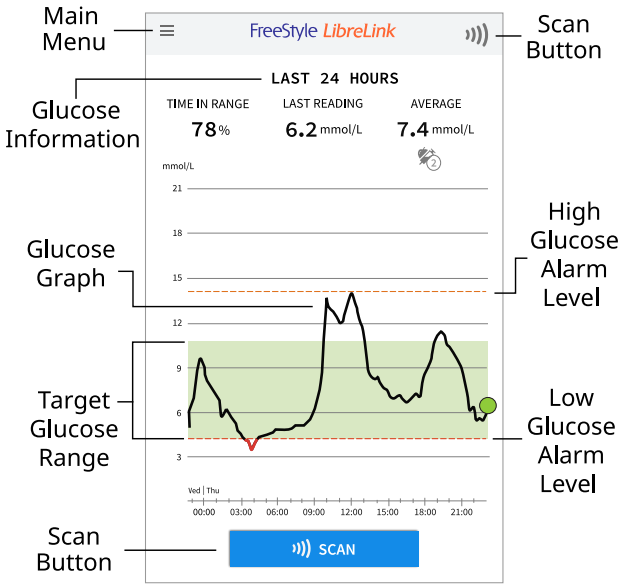
FreeStyle LibreLink is available for download from the App Store. When you're ready to start using FreeStyle LibreLink, you'll prepare and apply a Sensor to the back of your upper arm. You can then use the App to get glucose readings from the Sensor and store your glucose history and notes.

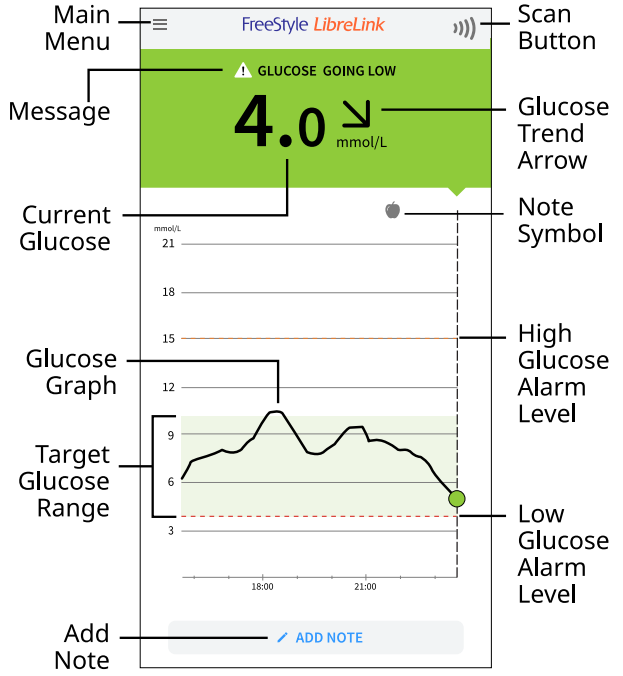
Note:

- Not all Sensors are available in all countries.
- Go to www.FreeStyleLibre.com for smartphone requirements and compatibility. Please keep in mind that the ease of scanning a Sensor may vary between devices.

Home Screen

Your Home Screen display will vary depending on what Sensor you're using and which device you started that Sensor with. Examples of both display types are below. 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.

Glucose Graph - Graph of your Sensor glucose readings.

Scan Button - Tap when you want to scan your Sensor.

Glucose Information - Your Time In Range, information about your last reading and average glucose for the last 24 hours.

Current Glucose - Your most recent glucose value.

Glucose Trend Arrow - Direction your glucose is going.

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

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

High Glucose Alarm Level – Your High Glucose Alarm level displays only when you have used the App to start a FreeStyle Libre 2 or Libre 2 Plus Sensor and have turned the alarm ON.

Low Glucose Alarm Level - Your Low Glucose Alarm level displays only when you have used the App to start a FreeStyle Libre 2 or Libre 2 Plus Sensor and have turned the alarm ON.

Add Note - Tap ✎ to add notes to the glucose reading.

Note Symbol - Tap to review notes you've entered.

Sensor Kit

The Sensor Kit includes:

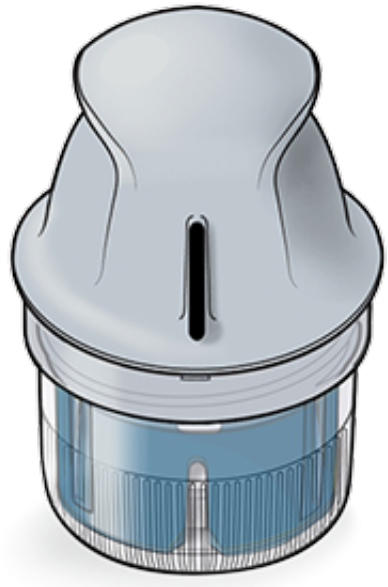
- Sensor Pack
- Sensor Applicator
- Product insert

When opening your kit, check that the contents are undamaged and that you have all parts

listed. If any parts are missing or damaged, contact Customer Service. The Sensor (only visible after applied) is initially in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. Once prepared and applied to your body, the Sensor measures your glucose using a small, flexible tip that inserts just under the skin.

Sensor Pack. Used with the Sensor Applicator to prepare the Sensor for use.

Sensor Applicator. Applies the Sensor to your body.



App Setup

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

1. Check that your iPhone is connected to a network (Wi-Fi or mobile). You can then install FreeStyle LibreLink from the App 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, add notes or review your history in the App.

2. Swipe to view some helpful tips or tap **GET STARTED NOW** at any point.
3. Confirm your country/region 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).

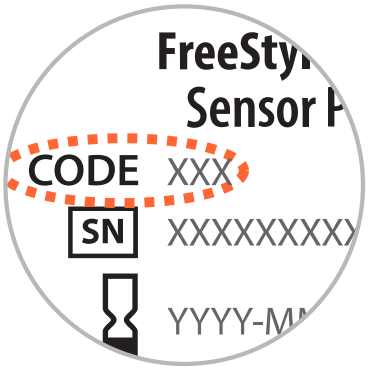
   Follow on-screen instructions to review legal information.
5. Confirm your glucose unit of measure and tap **NEXT**.
6. Select how you count carbohydrates (in grams or portions) and tap **NEXT**. The carbohydrate unit will be used in any food notes that you enter in the App.
7. The App now displays some useful information. Tap **NEXT** to review each screen.
8. Accept required 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:

- The Sensor Pack and Sensor Applicator are packaged together as a set and have the same Sensor code. Check that the Sensor codes match before using your Sensor Pack and Sensor Applicator. Sensor Packs and Sensor Applicators with the same Sensor code should be used together or your Sensor glucose readings may be incorrect.



- 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.

---

1. Apply Sensors 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 to remove any oily residue that may prevent the Sensor from sticking properly.

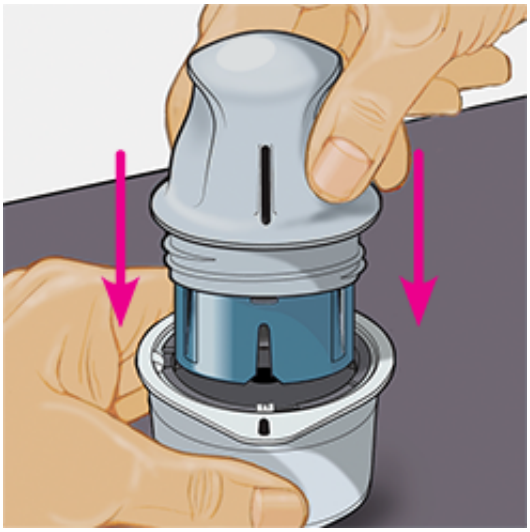
Allow site to air dry before proceeding.

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

3. Open the Sensor Pack by peeling the lid off completely. Unscrew the cap from the Sensor Applicator and set the cap aside.

   CAUTION: Do NOT use if the Sensor Pack or Sensor Applicator seem to be damaged or already opened. Do NOT use if past expiry date.

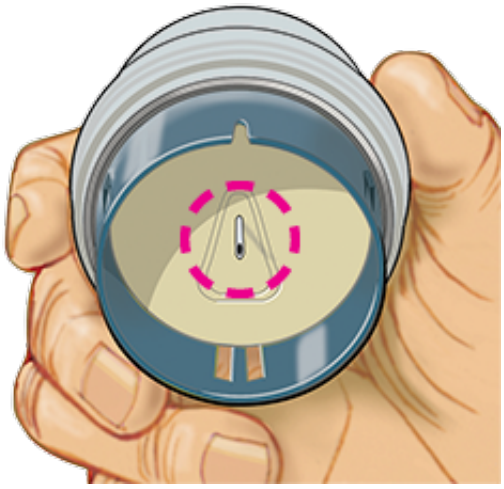
4. Line up the dark mark on the Sensor Applicator with the dark mark on the Sensor Pack. On a hard surface, press down firmly on the Sensor Applicator until it comes to a stop.



5. Lift the Sensor Applicator out of the Sensor Pack.

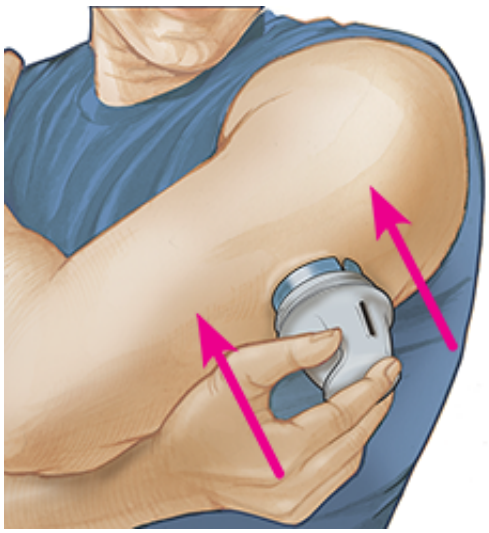
6. The Sensor Applicator is prepared and ready to apply the Sensor.

CAUTION: The Sensor Applicator now contains a needle. Do NOT touch inside the Sensor Applicator or put it back into the Sensor Pack.



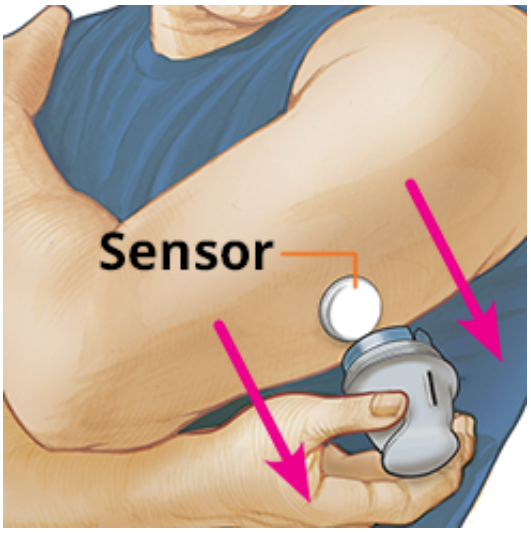
7. Place the Sensor Applicator over the prepared site and push down firmly to apply the Sensor to your body.

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



8. 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.



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

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

Starting Your Sensor

IMPORTANT:

- The NFC (Near Field Communication) antenna is on the top edge of iPhone. Hold this area near your Sensor when you are scanning. You may need to adjust your scan distance based on what clothing you are wearing. In addition to proximity and orientation, 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 devices.
- The App requires that your iPhone has date and time enabled to set automatically. You can check this in your iPhone settings.

- When using the App, you should keep your iPhone well charged and make sure that you have access to a blood glucose meter.
- When you scan your Sensor, you will receive a tone and vibration. If your iPhone's volume is turned off, you will not hear the tone.

---

1. Tap the scan button at the top of the screen. NFC is now activated and your iPhone is ready to scan the Sensor.

   Note: If the scan dialogue disappears, tap the scan button again.

2. Hold the top of your iPhone near the Sensor (this can be done over clothing). Do not move your iPhone until you hear a tone and/or feel a vibration. This completes the scan.

   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.

   See Troubleshooting for additional error messages.

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:

   - You can connect both the FreeStyle LibreLink app and another device (FreeStyle LibreLink special edition app, FreeStyle Libre Reader or FreeStyle Libre 2 Reader) with the Sensor at the same time. If you want to use both the FreeStyle LibreLink app and another device, you must start the Sensor with the other device first and then scan with the FreeStyle LibreLink app. If you start a FreeStyle Libre 2 or Libre 2 Plus Sensor with another device, remember that you will only get alarms from that device. The FreeStyle LibreLink app will only issue alarms if you use it to start a FreeStyle Libre 2 or Libre 2 Plus Sensor.
   - Performance between the Reader and App may vary depending on your Reader's software version. Please refer to the performance data insert that's included in the Reader Kit for Reader performance information.
   - FreeStyle LibreLink does not share data with FreeStyle LibreLink special edition app, FreeStyle Libre Reader or FreeStyle Libre 2 Reader.
   - For complete information on a device, make sure that you scan your Sensor every

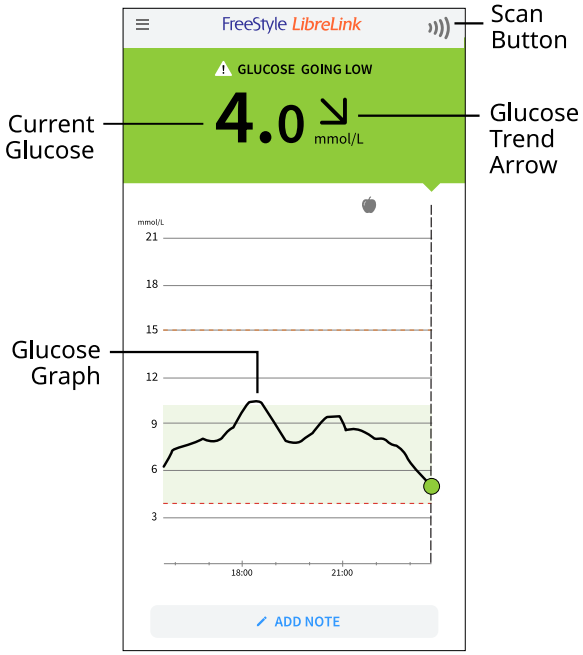
8 hours with that device or when you see gaps in your graph; otherwise, your reports will not include all your data.

Checking Your Glucose

1. Open the App.
2. To get your glucose reading with a scan, tap the scan button . Hold the top of your phone near the Sensor until you hear a tone and/or feel a vibration. If the scan dialogue disappears, tap the scan button again.

   Your reading will automatically display on the Home Screen if you are using a FreeStyle Libre 2 or Libre 2 Plus Sensor that you started with the App. If your glucose reading does not automatically display, update the App, and continue to scan your current Sensor to get glucose readings. When you start your next FreeStyle Libre 2 or Libre 2 Plus Sensor with the updated App, you should see your readings display and automatically update every minute.

3. Your glucose reading 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.



Scan Button - Tap to scan your Sensor.

Current Glucose - Your most recent glucose value.

Glucose Trend Arrow - Direction your glucose is going.

Glucose Graph - Graph of your Sensor glucose readings.

Note:

- A Sensor can store up to 8 hours of glucose data, so scan it at least once every 8 hours or when you see gaps in your graph to capture all of your available glucose data.
- The graph will scale to 27.8 mmol/L to accommodate glucose readings above 21 mmol/L.
- The symbol may appear, indicating the smartphone's time was changed. Gaps in the graph may result or glucose readings may be hidden.
- All available glucose data is used to make your graph so you can expect to see some differences between the graph line and previous current glucose readings.
- Your current glucose value determines the background colour on your glucose reading display:

Orange	- High glucose (above 13.3 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)

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)

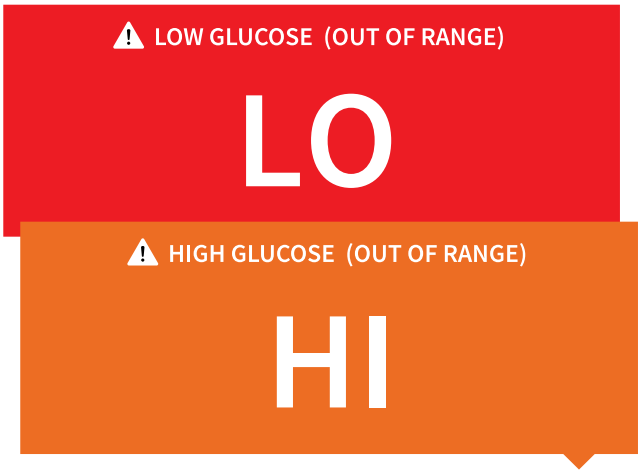
Glucose is falling (between 0.06 and 0.1 mmol/L per minute)

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

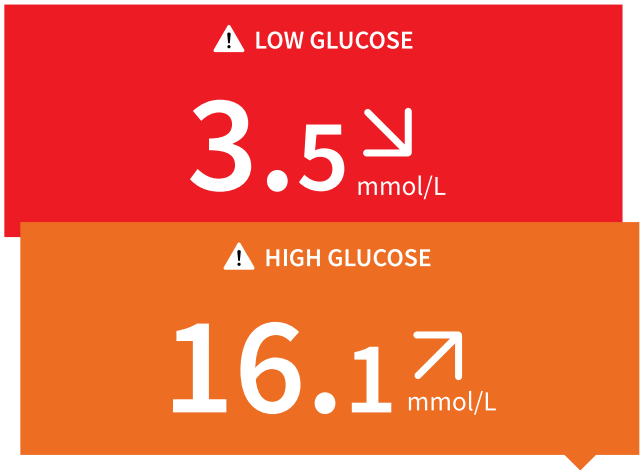
Messages

Below are messages you may see with your glucose readings.

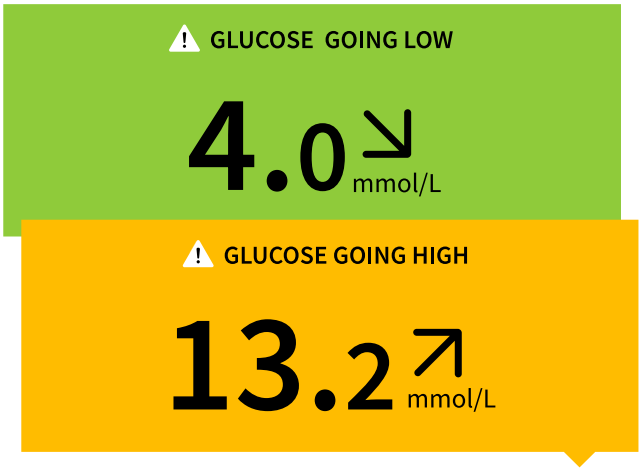
LO | HI: If **LO** appears, your reading is lower than 2.2 mmol/L. If **HI** appears, your reading is higher than 27.8 mmol/L. You can tap the ⚠ symbol for more information. Check your blood glucose on your finger with a test strip. If you get a second **LO** or **HI** result, contact your healthcare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



Low Glucose | High Glucose: If your glucose is higher than 13.3 mmol/L or lower than 3.9 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 higher than 13.3 mmol/L or lower than 3.9 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 glucose readings are not related to glucose alarm settings.

Alarms with a FreeStyle Libre 2 or Libre 2 Plus Sensor

If you use the App to start a FreeStyle Libre 2 or Libre 2 Plus Sensor, you can get Low and High Glucose Alarms from the Sensor if you turn them ON. These alarms are turned OFF by default.

This section explains how to turn on and set alarms as well as how to use them. Please read all the information in this section before setting and using alarms.

CAUTION:

- If you are using a FreeStyle Libre Sensor with the FreeStyle LibreLink app or you started your FreeStyle Libre 2 or Libre 2 Plus Sensor with another device, you will not receive alarms from the FreeStyle LibreLink app.

  No Alarms from the App

   You are using a FreeStyle Libre Sensor.

   You started a FreeStyle Libre 2 or Libre 2 Plus Sensor with another device before using it with the App.

  Alarms from the App

   You started a FreeStyle Libre 2 or Libre 2 Plus Sensor with the App.

- You will only get alarms from the App if you use the App to start a FreeStyle Libre 2 or Libre 2 Plus Sensor. For you to receive alarms, make sure to:
  - Turn alarms ON and ensure that your smartphone is within 6 metres (20 ft) of you at all times. The transmission range is 6 metres (20 ft) unobstructed. If you are out of range, you may not receive glucose alarms.
  - Do not force close the App.
  - Check to make sure that you have the correct settings and permissions enabled on your phone to receive alarms.
    - Enable Bluetooth and allow the App to access Bluetooth.
    - Allow Notifications for the App. Turn on Lock Screen and Banner alerts, Notification sounds and general phone sounds or vibration. Make sure not to turn on any features or modify phone settings that may interrupt the presentation of notifications.
    - Turn off Do Not Disturb mode or select to turn on Override Do Not Disturb in your alarm settings. Do this 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 on.

      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.

- Remember that alarm settings will follow your smartphone's sounds and vibration settings, so these should be at a level that you can hear to prevent missed alarms.
- You should disconnect headphones when you are not using them as you may not receive audio with alarms.
- 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 smartphone well charged and turned on.

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 that you set in the alarm. Your Target Glucose Range is displayed on glucose graphs in the App and used to calculate your Time In Range.
- Make sure that your smartphone 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 or symbol on the screen when the Sensor is not communicating with the App. Make sure that the **Signal Loss Alarm** is on so that you will be notified if your Sensor has not communicated with the App for 20 minutes.
- If you see the or symbol, this means that you are not getting glucose alarms because of one or more of the following:
  - Bluetooth is OFF
  - Bluetooth access for the App is OFF
  - App notifications are OFF
  - Sensor is not communicating with the App
  - Lock Screen and Banner alerts, or Notification sounds are OFF
  - Override Do Not Disturb is turned on for an alarm but you have not allowed Critical Alerts.

Setting Alarms

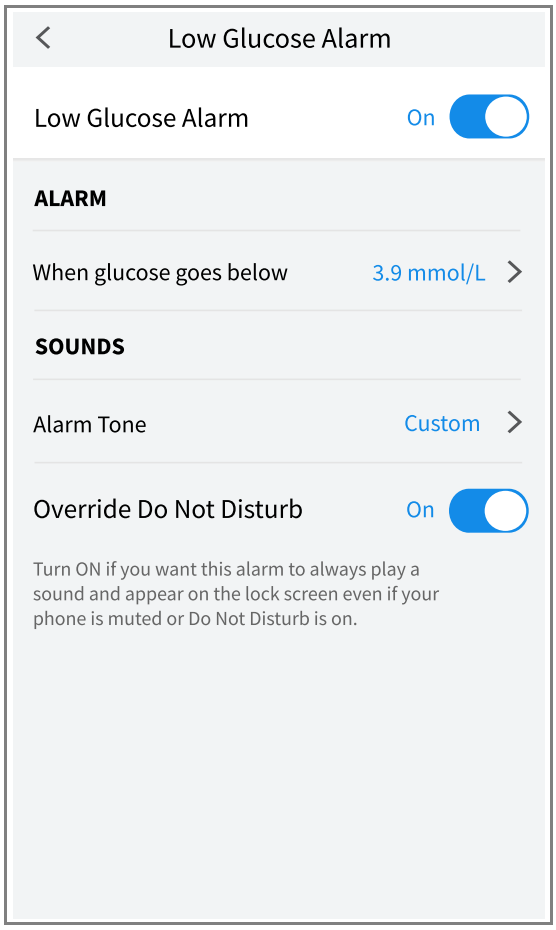
To set or turn on alarms, go to the Main menu and tap **Alarms**. Select the alarm you want to turn on and set.

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 smartphone settings. Tap **SAVE**.
4. 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 on.

   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.

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

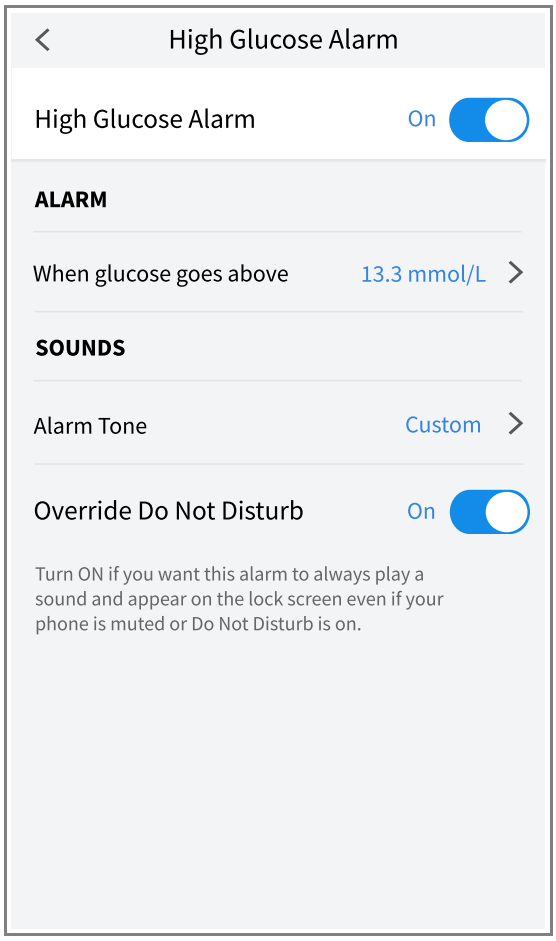


High Glucose Alarm

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 13.3 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 smartphone settings. Tap **SAVE**.
4. 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 on.

   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.

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



Signal Loss Alarm

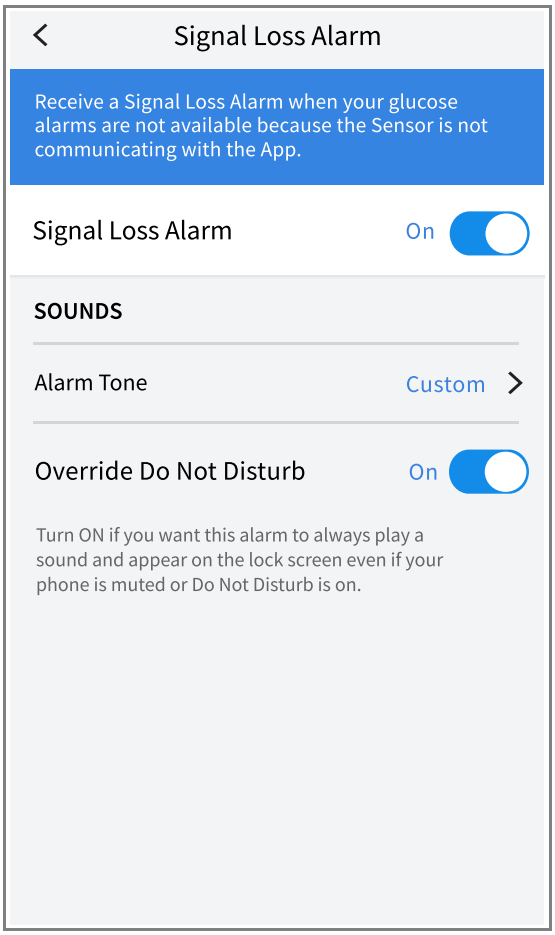
1. Tap the slider to turn the alarm on. If the alarm is on, you will be notified when your Sensor has not communicated with the App for 20 minutes and you are not receiving Low or High Glucose Alarms.

   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 smartphone settings. Tap **SAVE**.
3. 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 on.

   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.

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

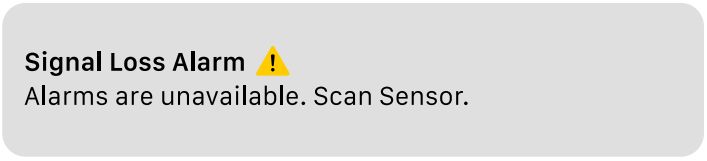


Using Alarms

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 Low or High Glucose Alarms. Signal loss could be caused by the Sensor being too far away from your smartphone (over 6 metres (20 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 ignore an alarm, you will receive it again in 5 minutes if the condition still exists.
- 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 your glucose reading 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. 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 on the information you would like to change. Tap **DONE** when you are finished.

 Food

	Insulin
	Exercise
	Food + insulin
	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 your past glucose readings and notes. 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.
- FreeStyle LibreLink does not share data with FreeStyle LibreLink special edition app, FreeStyle Libre Reader or FreeStyle Libre 2 Reader.
- For complete information on a device, make sure that you scan your Sensor every 8 hours with that device or when you see gaps in your graph; otherwise, your reports will not include all your data.

Logbook

The **Logbook** contains entries for each time that you scanned your Sensor as well as notes that you added. 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 . Select your note information and tap **DONE**.

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

Insulin Pens

The **Insulin Pens** option in the Main Menu allows you to connect compatible insulin pens to the App. Once you have connected your insulin pen, you can transfer insulin doses from your insulin pen to the App. Insulin doses can be reviewed in the Logbook. For more information, refer to the Insulin Pen User Guide in the Help section. Review all instructions provided by your insulin pen manufacturer prior to insulin pen use.

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 10th – 90th percentile range of your glucose readings. Dark blue shading represents the 25th – 75th percentile range.

Note: This report needs at least 5 days of glucose data.

Time In Range: A graph showing the percentage of time your Sensor glucose readings were above, below or within your Target Glucose Range.

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 15 minutes or longer. 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 graph will scale to 27.8 mmol/L to accommodate glucose readings above 21 mmol/L.
- You might see gaps in the graph during times when you have not scanned at least once in 8 hours or if you lost Bluetooth connection (may apply to FreeStyle Libre 2 or Libre 2 Plus Sensors).
- The symbol may appear indicating a time change. Gaps in the graph may result or glucose readings may be hidden.

Estimated A1c: Your estimated A1c level (also called HbA1c) is based on available Sensor glucose data from the last 90 days. The more data available, the better your estimation will

be. However, the estimated level may not match your A1c measured in a laboratory*. A1c can be used as an indicator of how well your glucose levels have been controlled and may be used to monitor your diabetes treatment regimen.

* The formula is based on the published reference, which compared average Sensor glucose and laboratory-measured A1c:

$A1c_{\%} = (Avg\ SG_{mg/dL} + 46.7)/28.7$

$A1c_{\%} = (Avg\ SG_{mmol/L} + 2.59)/1.59$

Reference: Nathan DM, Kuenen J, Borg R, Zheng H, Schoenfeld D, Heine RJ for the A1c-Derived Average Glucose (ADAG). Study Group: Translating the hemoglobin A1c assay into estimated average glucose values. Diabetes Care 2008, 31:1473-8.

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

Note:

- Tap the symbol 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, tap the drop-down menu above the report, or go to the Main Menu.
- On all reports except the **Daily Graph** and **Estimated A1c**, 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.

Replacing Your Sensor

Your Sensor automatically stops working after the wear duration 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. There is one default reminder to help you remember to check your glucose. This 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 smartphone is turned on, sound is set at a level you can hear and your smartphone'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.
4. Tap **DONE**. You will now see your reminder on the list along with the time you will receive it.

   Note:

   - To delete a reminder, swipe the reminder and tap the 🗑 symbol. The reminder to check your glucose 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

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 your Time In Range. 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.

Text to Speech – Turn on to have the glucose reading read aloud when you scan the Sensor. You will hear only your current glucose value and trend arrow direction. Additional information, such as the glucose graph and any message, are available on your glucose reading screen. Always review your glucose reading to get complete information. Remember that this feature inherits the volume settings on your phone. If your phone volume is turned off, you will not hear the glucose reading read aloud. Tap **SAVE** when you are done.

Note: If you are using a FreeStyle Libre 2 or Libre 2 Plus Sensor that you started with the App, you can tap your glucose reading to have it read aloud if this feature is turned on.

Account Settings:

Note: A LibreView account is required to manage Account Settings.

Account Details – View/change your LibreView account information.

Account Password – Change your LibreView account password.

Account Options – Sign out or delete your LibreView account.

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

- Use the account with the FreeStyle LibreLink 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 LibreLink app.
- Use the Connected Apps or Account Settings features.

Connected Apps

The **Connected Apps** option in the Main menu opens a web browser within the App. It lists different apps you can connect with to share your data. The available apps may vary based on your country/region. To connect your data with apps listed in this option, select them from the list of apps and follow the onscreen instructions.

Note: A LibreView account is required to use this feature.

Help

View in-app tutorials, access this User's Manual and review the App's legal information. You can also view a list of events recorded by the App, which 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 smartphone nearby. The Sensor can store up to 8 hours of data, therefore it is suggested that you review your glucose graph before you go to sleep and when you wake up to check for gaps and scan your Sensor if needed to capture all your data.

Travelling by Air: You may use your Sensor while on an aircraft, following any requests from the flight crew.

IMPORTANT: Sensor glucose readings and alarms will not be issued while your phone is in aeroplane mode unless Bluetooth is enabled.

- You can continue to scan your Sensor to get glucose readings after you put your phone in aeroplane mode.
- Some airport full-body scanners include X-ray or millimetre 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

Reader and Sensor: These devices 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, and per Regulations 2013 (No. 3113) in the UK is required. Contact the manufacturer for details.

As Readers and 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 one part household bleach

and nine parts water.

Note: Readers and 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 of Sensor Applicators at a designated sharps collection site. Ensure the cap is on the Sensor Applicator as it contains a needle.

Sensor Pack: Used Sensor Packs may be disposed of via municipal waste collection.

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. Clean the site with a plain soap and water and consider shaving. 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 or Receiving Sensor Readings

Display: **Sensor Starting Up**

What it may mean: Sensor is not ready to read glucose.

What to do: Wait until the 60 minute Sensor start-up period has completed.

Display: **Signal Loss Alarm**

What it may mean: Sensor has not automatically communicated with the App in the last 20 minutes.

What to do: Make sure your phone is within 6 metres (20 ft) of the Sensor. Try scanning the Sensor to get a glucose reading. Then try turning Bluetooth OFF then ON again. If that doesn't work, try turning your phone OFF then ON again. If **Signal Loss Alarm** shows again, contact Customer Service.

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 6 metres (20 ft) of the Sensor and you have not force closed the App. First try scanning your Sensor. Then try turning Bluetooth OFF then ON again. If that doesn't work, try turning your phone OFF then ON again. If **Signal Loss** shows again, contact Customer Service.

Display: **Sensor Ended**

What it may mean: The Sensor life has ended.

What to do: Apply and start a new Sensor.

Display: **New Sensor Found**

What it may mean: You scanned a new Sensor before your previous Sensor ended.

What to do: Your smartphone can only be used with one Sensor at a time. If you start a new Sensor, you will no longer be able to use your old Sensor. If you would like to begin using the new Sensor, select **Yes**.

Display: **Sensor Error**

What it may mean: The Sensor is unable to provide a glucose reading.

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

Display: **Glucose Reading Is Unavailable**

What it may mean: The Sensor is unable to provide a glucose reading.

What to do: 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.

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.

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

Display: **Check Sensor**

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

What to do: Try to start your Sensor again. If you see **Check Sensor** again on the screen, your Sensor was not applied properly. Apply and start a new Sensor.

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: **Unexpected Application Error**

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

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

Display: **Incompatible Sensor**

What it may mean: The Sensor cannot be used with the App.

What to do: Call Customer Service.

Display: **Scan Error**

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

What to do: Your scan was unsuccessful. Tap the scan button and scan again.

Display: **Bluetooth Off**

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: **App Permission Required**

What it may mean: A required App permission is turned off.

What to do: Follow the instructions on the screen to turn the permission on.

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: You are using a FreeStyle Libre Sensor or you started a FreeStyle Libre 2 or Libre 2 Plus Sensor with another device before using it with the FreeStyle LibreLink app.

What to do: Start a new FreeStyle Libre 2 or Libre 2 Plus Sensor with the FreeStyle LibreLink app.

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 (6 metres (20 ft)) of your smartphone for you to receive alarms. Make sure that you are within this range. You will see the or 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. First try scanning your Sensor. Then 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 following is turned off: Bluetooth, Bluetooth access for the App, App notifications, Lock Screen and Banner alerts, Notification sounds or general phone sounds or vibration. Or, you have set the App notifications to 'Deliver Quietly' or turned on Do Not Disturb mode without enabling Override Do Not Disturb.

What to do: Check to make sure that you have the correct settings and permissions enabled on your phone to receive alarms. Go to Alarms with a FreeStyle Libre 2 or Libre 2 Plus Sensor 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 that 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: 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: You have closed the App.

What to do: Make sure that 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.

Customer Service

Customer service is available to answer any questions you may have about FreeStyle LibreLink. 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/region. 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 person's 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: 5 mm height and 35 mm diameter

Sensor weight: 5 grams

Sensor power source: One silver oxide battery

Sensor life: FreeStyle Libre or Libre 2 Sensor: Up to 14 days; FreeStyle Libre 2 Plus Sensor: Up to 15 days

Sensor memory: 8 hours (glucose readings stored every 15 minutes)

Operating temperature: 10°C to 45°C

Sensor Applicator and Sensor Pack storage temperature: 4°C to 25°C

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

Sensor water resistance and ingress protection: IP27: Can withstand immersion into 1 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 (FreeStyle Libre 2 or Libre 2 Plus Sensor): 2.402-2.480 GHz BLE; GFSK; 0dBm EIRP

Sensor transmission range (FreeStyle Libre 2 or Libre 2 Plus Sensor): 6 metres (20 ft) unobstructed

Labelling Symbols and Definitions

Consult instructions for use

	Temperature limit
	Manufacturer
	Date of Manufacture
	CE Mark
	Authorised Representative in the European Community
	UKCA Marking
	Importer
	Single sterile barrier system
LOT	Batch code
UDI	Unique Device Identifier
	Type BF applied part
CODE	Sensor code
	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, and per Regulations 2013 (No. 3113) in the UK 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 the System 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 ensure 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 ensure that it is used in such an environment.

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

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

Compliance level: ±8 kV contact; ±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

Compliance level: 30 A/m

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

Compliance level: 10 V/m

If you are using FreeStyle Libre Sensor, follow the guidance below.

Electromagnetic environment – guidance:

Recommended separation distance

$d = 1.2 \sqrt{P}$

80 MHz to 800 MHz

$d = 2.3 \sqrt{P}$

800 MHz to 2.5 GHz

P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).

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

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

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] 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.

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

Recommended separation distances between portable and mobile RF communications equipment and the Sensor

The Sensor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sensor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sensor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power	**Separation distance according to frequency of transmitter** m		

of transmitter W	**150 kHz to 80 MHz** $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

If you are using a FreeStyle Libre 2 or Libre 2 Plus Sensor, refer to the additional immunity test information and follow the guidance below.

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

Test Level: See the 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 the Sensor. 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 shall be 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.

Performance Characteristics

The performance characteristics differ between Sensors. Please reference the section that applies to the Sensor that you are using.

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

Performance Characteristics: FreeStyle Libre Sensors | FreeStyle Libre 2 Sensors

Performance of the Sensor was evaluated in a controlled clinical study. The study was conducted in 5 centres and a total of 146 subjects 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 analysed over 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.

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

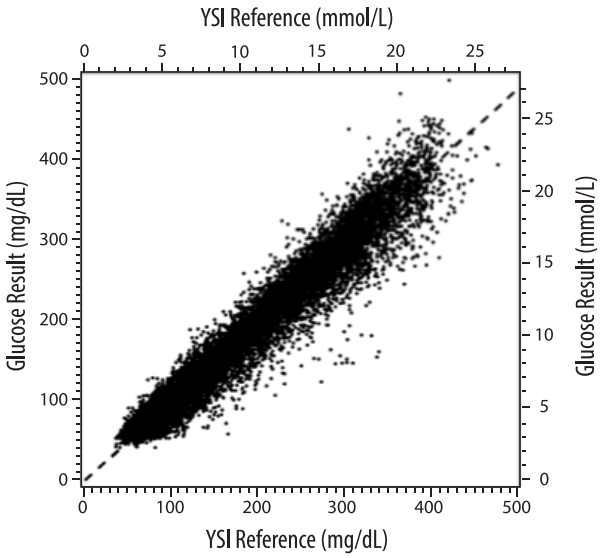


Table 1. Regression analysis of the Sensors vs. YSI reference

Slope	0.97
Intercept	-1.3 mg/dL (-0.1 mmol/L)
Correlation	0.98
N	18926
Range	37 - 479 mg/dL (2.0 - 26.6 mmol/L)
Overall mean bias	-5.6 mg/dL (-0.3 mmol/L)
Mean Absolute Relative Difference (MARD)	9.2%

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

Sensor accuracy results for glucose concentrations <80 mg/dL (4.4 mmol/L)	**Within ±15 mg/dL (within ±0.83 mmol/L)**	**Within ±20 mg/dL (within ±1.11 mmol/L)**	**Within ±30 mg/dL (within ±1.67 mmol/L)**
	4199 / 4595 (91.4%)	4482 / 4595 (97.5%)	4583 / 4595 (99.7%)
Sensor accuracy results for glucose concentrations ≥80 mg/dL (4.4 mmol/L)	**Within ±15%**	**Within ±20%**	**Within ±30%**
	12143 / 14331 (84.7%)	13153 / 14331 (91.8%)	14012 / 14331 (97.8%)
Sensor accuracy for all results	**Within ±20 mg/dL (±1.11 mmol/L) and within ±20% of reference**		
	17635 / 18926 (93.2%)		

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

Glucose	**Mean Absolute Relative Difference**
≤50 mg/dL	9.1 mg/dL

(2.8 mmol/L)	(0.5 mmol/L)*
51-80 mg/dL (2.8-4.4 mmol/L)	7.0 mg/dL (0.4 mmol/L)*
81-180 mg/dL (4.5-10.0 mmol/L)	10.1%
181-300 mg/dL (10.0-16.7 mmol/L)	7.5%
301-400 mg/dL (16.7-22.2 mmol/L)	7.1%
>400 mg/dL (22.2 mmol/L)	10.2%

* For glucose ≤80 mg/dL (4.4 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 (±1.11 mmol/L) and within ±20% of reference	91.2%	95.1%	94.2%	93.7%
Mean Absolute Relative Difference (%)	10.0	8.5	8.8	9.1

Skin Interaction

Based on the examination of 146 study participants, the following incidence of skin issues were observed. Four occurrences of erythema were reported to be moderate in intensity. All other skin issues were reported to be mild in intensity.

Bleeding – 0.7% of the time

Bruising – 0.7% of the time

Erythema – 2.7% of the time

Pain – 0.7% of the time

Scabbing – 2.7% of the time

Performance Characteristics: FreeStyle Libre 2 Plus Sensors

Performance of the Sensor was evaluated in a controlled clinical study. The study was conducted in 7 centres and a total of 285 subjects with diabetes were included in the effectiveness analysis. Each subject wore up to two Sensors on the back of the upper arm.

During the study, subjects ages 6 and older had their venous blood glucose analysed over up to three separate visits to the clinical centre using the Yellow Springs Instrument (YSI) Life Sciences 2300 STAT Plus™. For subjects ages 2–5, Sensor results were compared to self-monitoring of blood glucose (SMBG) results.

Table 5. Overall accuracy vs. YSI reference

Subject group	Number of CGM-Reference Pairs	Number of Subjects	Percent Within ±20% / ±20 mg/dL (±1.1 mmol/L)	MARD (%) (Mean Absolute Relative Difference)
Overall*	27694	273	94.2%	8.2%
Adults	20619	149	94.2%	8.2%
Children (age 6 – 17)	7075	124	94.0%	8.1%
Children (age 2–5)†	477	12	86.6%	11.2%

* Includes only YSI reference data.

† No YSI measurements were obtained for children ages 2–5; results displayed are compared to SMBG reference data.

Table 6. Accuracy of results vs. YSI reference

Subject group	Glucose concentrations <80 mg/dL (4.4 mmol/L) Within ±20 mg/dL (±1.1 mmol/L)	Glucose concentrations ≥80 mg/dL (4.4 mmol/L) Within ±20 %
Overall	97.9%	93.2%
Adults	97.9%	93.2%
Children (age 6 – 17)	97.6%	93.3%

Table 7. Accuracy over wear duration vs. YSI reference

Subject group	MARD (%) (Mean Absolute Relative Difference)			
	Beginning (days 1–3)	Early Middle (days 5–7)	Late Middle (days 9–11)	End (days 13–15)
Overall	9.7%	7.1%	7.5%	8.2%
Adults	10.0%	7.2%	7.7%	7.8%
Children (age 6 – 17)	9.0%	6.8%	6.9%	10.4%

Adverse Events

No device-related serious adverse events occurred during the study. Mild skin irritations, such as erythema (16 instances), bruising (3 instances) and rash (3 instances) were reported around the insertion site and adhesive area by a small number of subjects (14 out of 293 or 4.8%).

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 glycaemic 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.

[1] Textbook of Diabetes, Volumes 1 & 2; Pickup and Williams, 1999.
[2] ADA Position Statement. Test of glycemia 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

UK CA 0086

CE 2797

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

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

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

ART47661-001 Rev. A 02/24


Abbott