FreeStyle Libre 2
Flash Glucose Monitoring System

App User's Manual

For use with

FreeStyle Libre 2 Sensor and FreeStyle Libre 2 Plus Sensor

FreeStyle Libre 2

App User's Manual

Welcome

You'll be on your way soon. This User's Manual will help you learn how to set up the App, apply your Sensor, and quickly check your glucose readings. You'll find troubleshooting information near the end, but don't hesitate to give our Customer Service team a call if you need assistance. We're here to help.

Features of the FreeStyle Libre 2 System

- Real-time glucose readings automatically sent every minute to your phone
- Optional alarms let you know the minute your glucose is too high or too low
- Bluetooth connection range between Sensor and App of 20 feet
- Small and discreet Sensor that's easy to apply and comfortable to wear

Choose Your Device

- Want to use your Reader instead of the App? Please refer to the Reader User's Manual that came with your Reader Kit. You can also access the latest version at www.FreeStyleLibre.com.
- Remember that once you start a Sensor, you can't switch between the Reader and App until your next Sensor.

Customer Service

Customer Service is available 7 days a week to answer any questions you may have. Call us at 1-855-632-8658 anytime between 8 a.m. to 8 p.m. Eastern Time (excluding holidays).

Peace of Mind

Using our System can increase your peace of mind[1] and improve your quality of life.[2] By sharing your glucose readings with the LibreLinkUp app, you can give your loved ones and caregivers peace of mind too.[1]

[1] Hilliard, M., et al. Diabetes Technology & Therapeutics. (2019): https:/doi.org/10.1089/dia.2019.0142

[2] Leelarathna, L. N Engl J Med. (2022): DOI: 10.1056/NEJMoa2205650

Important Safety Information

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Get Informed

- Before using the App, please review the complete product instructions and safety information in this User's Manual and take a look at the Interactive Tutorial on our website www.FreeStyleLibre.com. Tips for Kids are there too if you need.
- Be safe and follow the instructions properly. Using the System incorrectly could cause you to miss a severe low or high glucose event and/or make a harmful treatment decision.
- You'll always find the latest version of the User's Manual, including performance data at www.FreeStyleLibre.com. If you need a free printed copy, just call Customer Service: 1-855-632-8658, 7 days a week from 8 a.m. to 8 p.m. Eastern Time; excluding holidays.
- Talk to your health care professional about how to use your Sensor glucose information to help manage your diabetes.
- During the first 12 hours of Sensor wear the 🔍 symbol will display, and you cannot use Sensor values to make treatment decisions during this time. Confirm Sensor glucose readings with a blood glucose test before making treatment decisions during the first 12 hours of Sensor wear when you see the 🔍 symbol.

Compatible Sensors

You can use Libre app with the FreeStyle Libre 2 Sensor and the FreeStyle Libre 2 Plus Sensor (simply referred to as Libre 2 Sensor and Libre 2 Plus Sensor). Some of the information in this User's Manual and the performance characteristics vary between the Sensors. Please reference the labeling content that applies to your Sensor. Make sure you have a Libre 2 Plus Sensor if you plan to connect with a compatible automated insulin dosing (AID) system.

Libre 2 Sensor

- 14 day wear
- Can be used by people age 4 and older
- Do not use with automated insulin dosing (AID) systems
- Taking more than 500 mg of Vitamin C per day may affect Sensor readings. This could cause you to miss a severe low glucose event.

Libre 2 Plus Sensor

- 15 day wear
- Can be used by people age 2 and older
- Can be used with compatible automated insulin dosing (AID) systems
- Taking more than 1000 mg of Vitamin C per day may falsely raise Sensor readings. This could cause you to miss a severe low glucose event. You can take up to 1000 mg of Vitamin C per day and still use the Sensor readings to make treatment decisions.

Indications for Use

Libre 2 Sensor users:

The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.

The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time.

The System is also intended to autonomously communicate with digitally connected devices. The System can be used alone or in conjunction with these digitally connected devices where the user manually controls actions for therapy decisions.

Libre 2 Plus Sensor users:

The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 2 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.

The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time.

The System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The System can be used alone or in conjunction with these digitally connected devices for the purpose of managing

diabetes.

Check Compatibility

- Libre app is only compatible with certain phones and operating systems. Always check the Phone and OS Compatibility Guide before upgrading your phone or its operating system. This Guide is available in the App's Help Menu and at www.FreeStyleLibre.com.
- Authorized compatible products that you can use with your Sensor are also listed at www.FreeStyleLibre.com. Using your Sensor with products that are not on this list may cause inaccurate glucose readings. If you use a computer, you are responsible for keeping it secure and up to date, for example by using anti-virus software and installing system updates.

Contraindications

Diathermy: Remove all parts of your System before high-frequency electrical heat (diathermy) treatment. The effect of diathermy on the System hasn't been tested. The exposure may damage the Sensor, which could impact proper device function and cause inaccurate readings.

Automated Insulin Dosing (AID): The Libre 2 Sensor must not be used with AID systems, including closed loop and insulin suspend systems.

Warnings

- **Don't ignore low or high glucose symptoms.** Use your blood glucose meter to make treatment decisions when your Sensor readings don't match your symptoms or expectations. Get medical attention when appropriate.
- Use your blood glucose meter to make treatment decisions when your Sensor reading doesn't match how you feel, has no number, or you see the  symbol during the first 12 hours of Sensor wear. You cannot use Sensor values to make treatment decisions during the first 12 hours.
- **Choking hazard:** The System has small parts that may be dangerous if swallowed.
- You must have access to a blood glucose monitoring system. One is not provided when you use the App.

Cautions - Overall System

 **What to know before using the System:**

- Avoid infection by taking standard precautions for bloodborne pathogens.
- Don't share the App with another person to avoid confusing glucose information.
- The App doesn't share data with your System's Reader. Before you start a Sensor, you must choose whether to use the Reader or the App with the Sensor. Once you start a Sensor, you cannot switch your device.
- Make sure that your phone and Sensor Kits are kept in a safe place and under your control. This is important to help stop anyone from accessing or tampering with the System.

⚠ **Who should not use the System:**

- **Don't use in people under the age in the Indications for Use.** The System is not cleared for use under this age.
- **Don't use if you are on dialysis or critically ill.** The System hasn't been evaluated in these groups. Sensor readings may be inaccurate.
- The System hasn't been evaluated when used with other implanted medical devices, such as pacemakers.

⚠ **When is Sensor glucose different from blood glucose:**

- Glucose levels in interstitial fluid (what your Sensor measures) can be different from blood glucose levels (what your meter measures). You may notice this when your glucose is changing quickly. For example, after eating, taking insulin, or exercising.

Cautions - App Use

⚠ **What to know about the App:**

- Disable your phone's automatic operating system (OS) updates. Before updating your phone's OS or the App, check the Phone and OS Compatibility Guide to see if the App is compatible. This Guide is available in the App's Help menu and also at www.FreeStyleLibre.com. Check it regularly to make sure that your phone and OS remain compatible with the App.
- We may contact you if an App or OS update will make your previously compatible phone incompatible. Make sure that your LibreView account has your current email address to receive important information.
- After an OS update, open the App and check your device settings to make sure it's working properly. Some OS features may impact your ability to get alarms or glucose readings. For example, if you use the iPhone Screen Time feature, add Libre app to the

list of Always Allowed apps to ensure that you receive alarms. Or, if you use an Android phone, don’t use the Android Digital Wellbeing app.

- If you restart your phone, open the App to make sure it’s working properly.
- During set up, the App asks for phone permissions. Please allow these. If your phone is not set up properly, you will not be able to use the App and will not get alarms, including the Urgent Low Glucose Alarm. Confirm your settings are as follows:

  iPhone settings:

  - In the phone settings, keep Bluetooth ON
  - In the phone settings for the App, allow the App to access Bluetooth
  - In the phone settings for the App under Notifications, keep Critical Alerts ON

  Android phone settings:

  - In the phone settings, keep Bluetooth ON
  - In the phone settings for the App, keep Do Not Disturb access permission ON
  - In the phone settings for the App, keep Nearby Devices permission ON (for Android 12 and above)

  Follow the instructions in the App to turn on these settings and permissions. If your phone is not configured correctly, you will see **Alarms Unavailable** on your screen.

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

For you to receive alarms:

- Keep your phone charged and turned on.
- Don’t force close the App. The App must be running in the background to get alarms.
- Always keep your phone within 20 feet of you, with no obstacles between you. The Sensor itself will not issue alarms! If you’re out of range, you may not get alarms. If you want to use the App's optional alarms, keep these turned on.

- Disconnect headphones or speakers from your phone when not in use. You may miss alarm sounds if you don’t.
- Remember that if you have accessories connected to your phone (like wireless headphones or a smartwatch), you may get alarms on only one device, not all.

Go to the Alarms section to learn more about the App's alarms.

Cautions - Sensor Use

What to know before you apply the Sensor:

- Your Sensor Pack and Sensor Applicator come as a set with the same Sensor code. Check that the Sensor codes match! Don’t use Sensor Packs and Sensor Applicators with different Sensor codes together as you'll get incorrect glucose readings.
- The Sensor inserts just under your skin. You may have some bruising or bleeding.
- Clean your hands before handling the Sensor Kit contents. This will help prevent infection.
- Carefully follow the instructions to prepare the application site on the back of your upper arm. This will help your Sensor stay on for the full wear time and not fall off early. Wash the site using a plain soap. Then, dry and clean with an alcohol wipe. This removes any oily residue and helps the Sensor stick. Allow the site to air dry before applying the Sensor.
- Only apply the Sensor to the back of your upper arm. The Sensor may not work properly in other areas. Avoid scars, moles, stretch marks, and lumps. Choose an area that stays mostly flat (no bending or folding) during your day. Keep at least 1 inch away from insulin injection sites.
- Change sites between Sensors so your skin can recover.

What to know about wearing a Sensor:

- Your Sensor's product insert tells you how long you can wear your Sensor. Remember to always have your next Sensor on hand before your current one ends so you can keep getting your glucose readings.
- If your Sensor stops working and you don’t have another Sensor, use another method to check your glucose and make treatment decisions.
- The App can detect when the Sensor isn’t working properly. It will shut your Sensor off and tell you to replace it. This may happen if the Sensor gets knocked off your body, or if there’s a problem with it. Call us if you receive a Replace Sensor message before the end of your wear time. Customer Service: 1-855-632-8658. Available 7 days a week, 8 a.m. to

8 p.m. Eastern Time; excluding holidays.

- Some people 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. Contact your health care professional before continuing to use the System.
- Intense exercise may cause your Sensor to loosen due to sweat or Sensor movement. If the Sensor gets loose or its tip comes out of your skin, you may get no readings or unreliable low readings. Remove your Sensor and apply a new one. Don't attempt to reinsert the old one! Call us if any Sensor gets loose or falls off before the end of your wear time. Customer Service: 1-855-632-8658. Available 7 days a week, 8 a.m. to 8 p.m. Eastern Time; excluding holidays.
- Don't 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-sterilization. Further exposure to irradiation may cause unreliable low results.
- If a Sensor breaks in your body, call your health care professional.

How to store the Sensor Kit:

- Store between 36°F and 82°F. Storing outside this range may cause inaccurate Sensor glucose readings.
- If you think that the temperature may exceed 82°F (for example, in an un-airconditioned home in summer), you should refrigerate your Sensor Kit. Don't freeze your Sensor Kit.
- Store in a cool, dry place. Don't store in a parked car on a hot day.
- Store between 10-90% non-condensing humidity.

When to remove the Sensor:

- If the Sensor is becoming loose or if its tip is coming out of your skin, you may get no readings. Or, you may get unreliable readings that don't match how you feel. Check to make sure your Sensor is not loose. If it's loose, remove it and apply a new one. Please call Customer Service.
- If you think your glucose readings are incorrect or don't match how you feel, do a blood glucose test on your finger to check your glucose. If the problem continues, remove the Sensor and apply a new one. Call Customer Service: 1-855-632-8658. Available 7 days a week, 8 a.m. to 8 p.m. Eastern Time; excluding holidays.

When not to use the Sensor:

- Don't use if the Sensor Kit carton, Sensor Pack, or Sensor Applicator look damaged or opened. Infection may result.

- Don’t use if Sensor Kit contents have expired.

  Go to the Applying Your Sensor section to learn how to prepare and apply your Sensor.

MRI safety information:

- You can safely have a 1.5T or 3T MRI exam while wearing your Sensor, under the conditions listed below. Injury may result if the conditions are not followed. Leave your phone and Reader outside of the exam room. Sensor readings may be inaccurate during the MRI, but System function returns fully back to normal after 1 hour.

Parameter	Condition
Device Name	Libre 2 or Libre 2 Plus Sensor
Static Magnetic Field Strength (B0)	1.5T and 3T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	40 T/m (4,000 G/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating	

Mode	Normal Operating Mode
RF Conditions	Maximum Whole-body SAR: 2 W/kg
Scan Duration	1.5T scanners: Up to 1 hour of continuous scanning without cooling period.
	3T scanners: Up to 12 minutes of scanning between the pelvis and the sternum with a cooling period of 2 minutes between scans. Up to 1 hour of continuous scanning without cooling period when scanning elsewhere.
Scan Regions	All landmark locations are acceptable within the region-specific scan durations described above.
Image Artifact	The presence of a Libre 2 or Libre 2 Plus Sensor may produce an image artifact of 6.9 cm. Some manipulation of scan parameters may be needed to compensate for the artifact.
Device Functionality	Device readings may be inaccurate during active MRI scanning but device functionality fully returns to normal operation by 1 hour following MRI exposure.

Security Information

- You are responsible for properly securing and managing your phone. If you suspect an adverse cybersecurity event related to the App, contact Customer Service.
- The App is not intended for use on a phone that has been altered or customized to remove, replace or circumvent the manufacturer’s approved configuration or use restriction, or that otherwise violates the manufacturer’s warranty.
- Don't use the App on a jailbroken or rooted device. When used on a jailbroken or rooted device or in the case of a potential cybersecurity event, the App will stop without notification. This means you won't receive alarms and will need to use another method to check your glucose. Please contact Customer Service.
- Use of an unsupported mobile device or OS version may affect App security and functionality. You are responsible for the risks associated with the use of the App on an unsupported mobile device or OS version.
- The App should only be downloaded and/or updated through authorized distributors, including the App Store (iPhone) and Google Play Store (Android).

Interfering Substances

Libre 2 Sensor

Taking Vitamin C supplements while wearing the Sensor may falsely raise Sensor glucose readings. Taking more than 500 mg of Vitamin C per day may affect the Sensor readings. This could cause you to miss a severe low glucose event. Vitamin C can be found in supplements including multivitamins. Some supplements, including cold remedies such as Airborne® and Emergen-C®, may contain high doses of 1000 mg of Vitamin C. These should not be taken while using the Sensor. See your health care professional to understand how long Vitamin C is active in your body.

Libre 2 Plus Sensor

Taking more than 1000 mg of Vitamin C per day may falsely raise your Sensor readings. This could cause you to miss a severe low glucose event. Vitamin C can be found in supplements including multivitamins and cold remedies such as Airborne® and Emergen-C®. See your health care professional to understand how long Vitamin C is active in your body.

App Symbols

	App icon
	Scan button
	Alarms are unavailable
	Direction your glucose is going. See Glucose Trend Arrow for more information.
	Caution
	When you see this symbol during the first 12 hours of wearing a Sensor, confirm Sensor glucose readings with a blood glucose test before making treatment

	decisions
	Add/edit notes
	Food note
	Insulin note
	Exercise note
	Multiple notes
	Custom note
	Additional information
	Indicates your phone's time was changed
	Sensor too cold
	Sensor too hot

App Setup

1. First, check that your phone is connected to a network (WiFi or cellular). You can then download Libre app from the App Store (iPhone) or Google Play Store (Android). Tap the App icon to open the App.

   Note: You need to be connected to a network for setup, using LibreView, and sharing with other apps. You don't need to be connected to check your glucose or receive alarms.

2. Review and accept the App's Terms of Use and Privacy Notice.
3. Confirm your country and then review the information about compatibility. You will not be able to proceed if the App version is either not supported in your country or not compatible with your phone and/or operating system.
4. Follow the onscreen instructions to create a LibreView account or login to your existing account. You'll need a LibreView account to use the App and access your online reports and connected apps.
5. Confirm your glucose unit of measure and tap **Next**.
6. Select how you count carbohydrates (in grams or servings) and tap **Next**. The carbohydrate unit will be used in any food notes you enter in the App.
7. If you have an Android phone, select whether you want sound and vibration OR vibration only when you scan your Sensor. Tap **Next**.

   Note: This setting does not affect alarms.
8. Review the important information and accept the requested permissions to receive glucose readings and alarms. Tap **Next** after each screen.
9. App setup is complete, and it's time to apply your Sensor! Tap **Continue**.

Applying Your Sensor

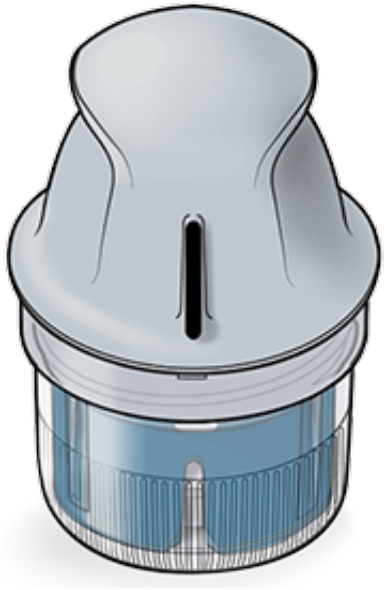
If you’re anxious about applying the Sensor for the first time, don’t be. We designed the process to be simple and easy.

Your Sensor initially comes in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. When you open your Sensor Kit, make sure you have both the parts and that they're undamaged. If there's an issue, please get in touch with us. Customer Service is available at 1-855-632-8658 7 days a week from 8 a.m. to 8 p.m. Eastern Time; excluding holidays.

Sensor Pack: Works with the Sensor Applicator to prepare the Sensor for use.

Note: The Sensor Pack is sterile and non-pyrogenic unless opened or damaged. Using a non-sterile or pyrogenic Sensor might cause infection.

Sensor Applicator: Applies the Sensor to your body. The Sensor has a small, flexible tip that inserts just under the skin to measure your glucose readings.

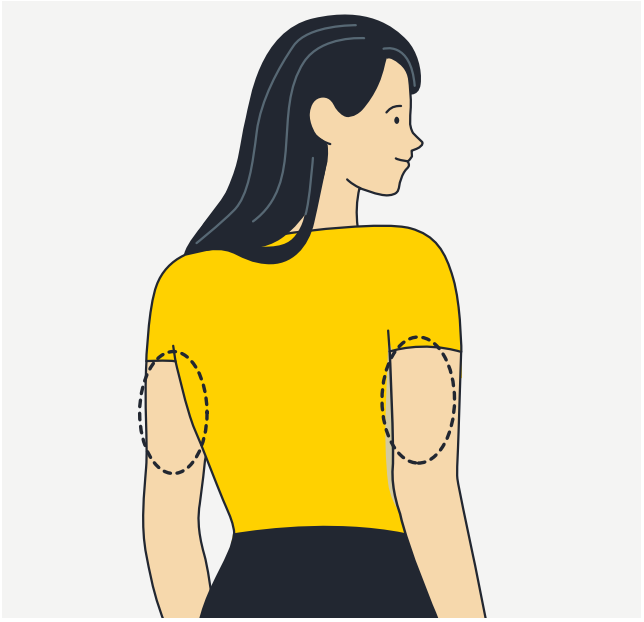


CAUTION: Review the safety information in Cautions - Sensor Use before you apply your Sensor.

IMPORTANT: Before using your Sensor Pack and Sensor Applicator, make sure you have an alcohol wipe (70% isopropyl alcohol) on hand to prepare the site. This is not included in the Sensor Kit.

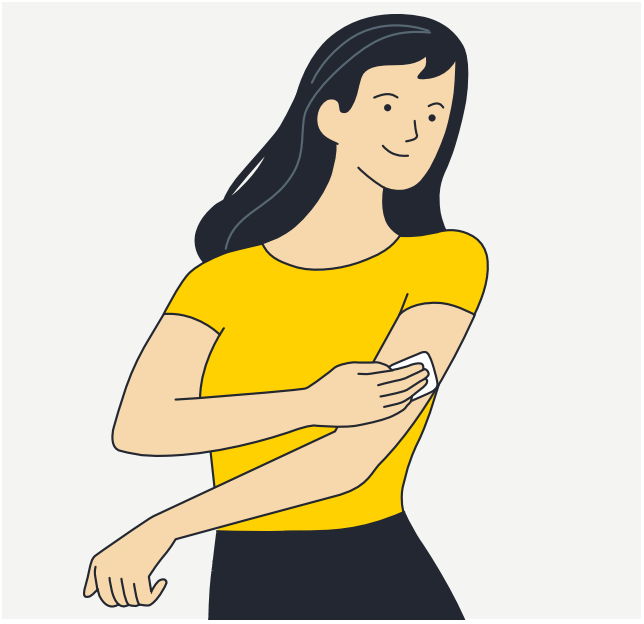
1. Apply the Sensor only on the back of your upper arm. Placing it in other areas may cause the Sensor to not function properly and could give inaccurate readings. When you choose your application site, select an area of skin that generally stays flat during your

normal daily activities (no bending or folding). Avoid scars, moles, stretch marks or lumps, and keep at least 1 inch away from insulin injection sites. You should also rotate sites between Sensors to help prevent any skin irritation.



2. Wash your application site with 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 the site to air dry before proceeding.

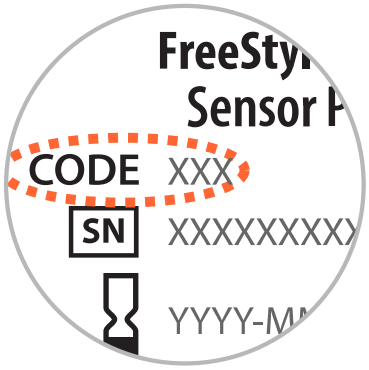
   Note: The area MUST be clean and dry following these instructions, or the Sensor may not stay on for the full wear duration.

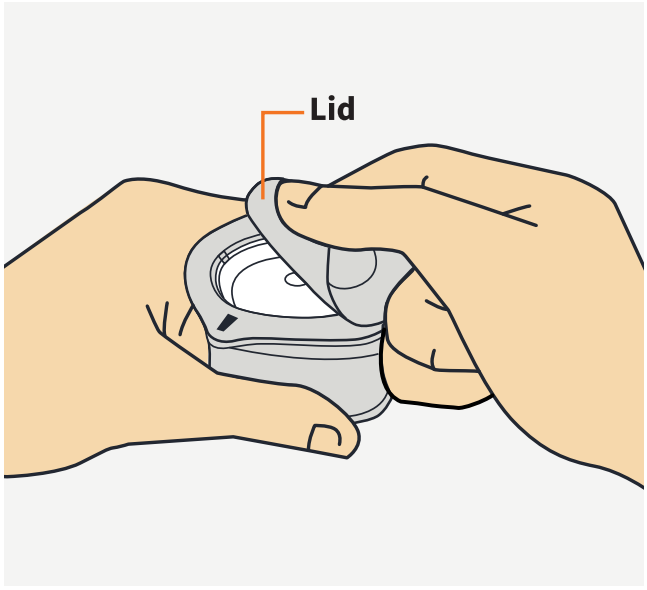


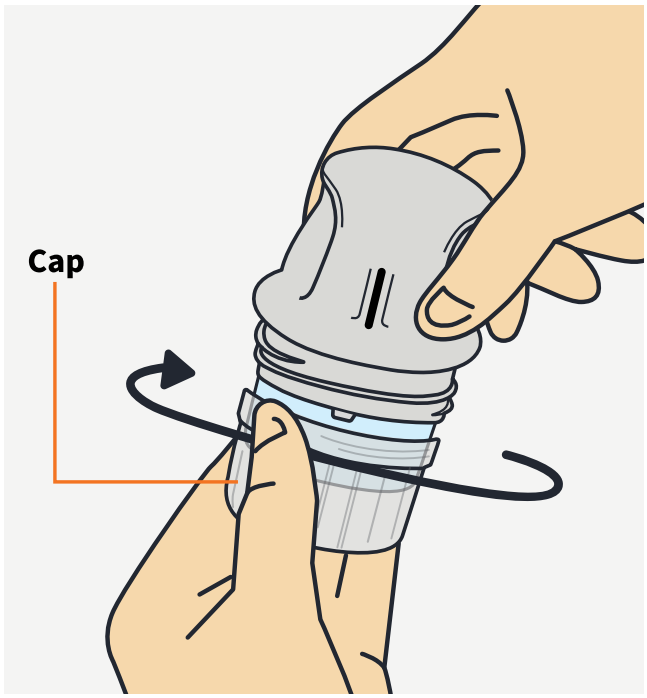
3. Open the Sensor Pack by peeling the lid off completely. Unscrew the cap from the Sensor Applicator and set the cap aside.

   CAUTION: Sensor codes must match on Sensor Pack and Sensor Applicator. Do NOT use

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

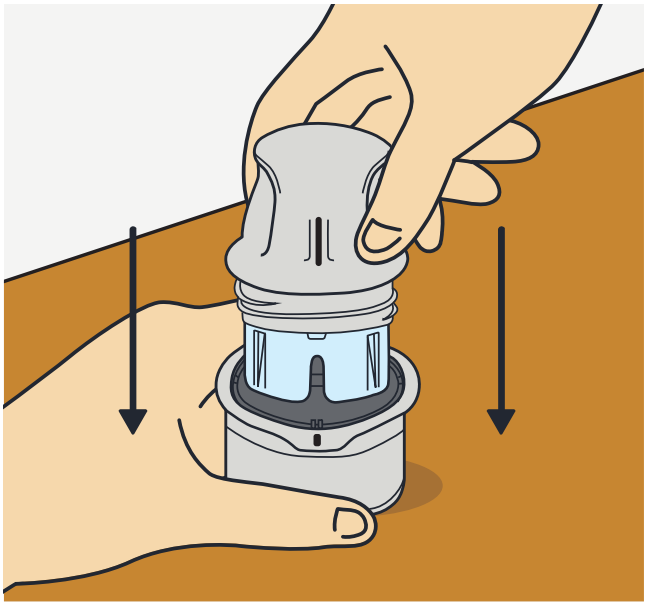




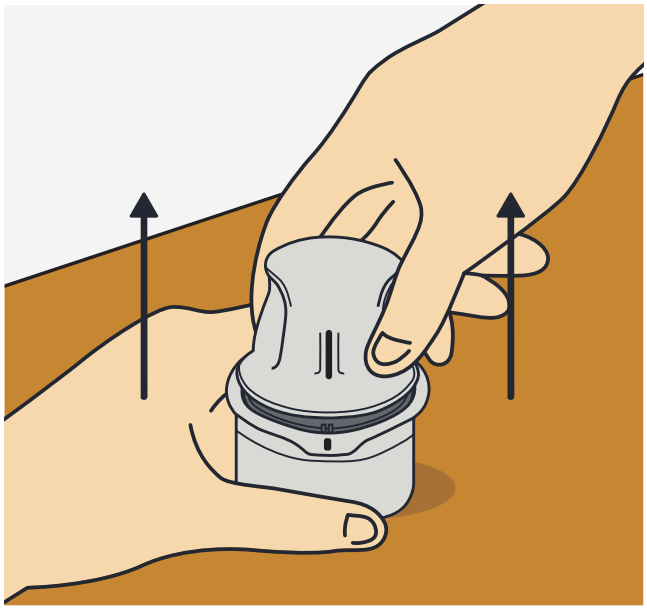


4. Line up the dark mark on the Sensor Applicator with the dark mark on the Sensor Pack.

On a hard surface, press down firmly on the Sensor Applicator until it comes to a stop.

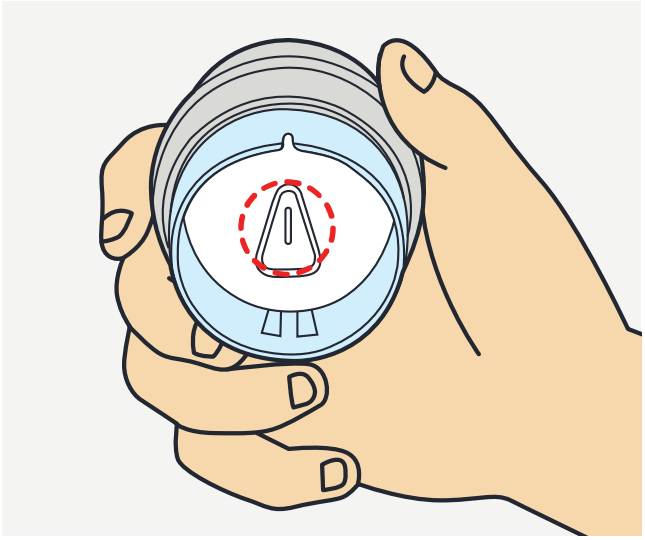


5. Lift the Sensor Applicator out of the Sensor Pack.



6. The Sensor Applicator is now ready.

   CAUTION: The Sensor Applicator has a tiny needle. Be careful NOT to touch inside the Sensor Applicator or put it back into the Sensor Pack.

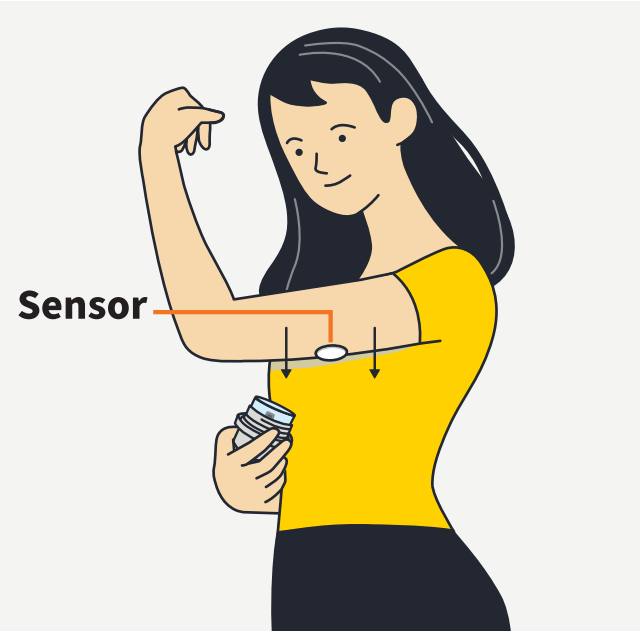


7. Place the Sensor Applicator over the area of your arm that you've cleaned and push down firmly to apply the Sensor to your body.

   CAUTION: Don't push down on the Sensor Applicator until it's placed over the 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 contact your health care professional.



9. Make sure your Sensor is secure after application. Put the cap back on the Sensor Applicator. Discard the used Sensor Applicator and Sensor Pack according to local regulations. You can now wear the Sensor for up to the wear duration specified by your Sensor insert.

Note: When it's time to remove your Sensor, pull the edge of the adhesive that keeps your Sensor attached to your skin. Slowly peel away from your skin in one motion. You can remove any adhesive residue on your skin with warm, soapy water or isopropyl alcohol. Discard the used Sensor according to the Disposal instructions.

Starting Your Sensor

Start your Sensor by scanning it with your phone's NFC antenna (this is the antenna that lets two devices talk when they're near each other, like Apple Pay or Google Pay). On iPhone, the NFC antenna is on the top edge. On Android phones, the location may vary between devices. Please check www.FreeStyleLibre.com for more information about device compatibility and the location of the NFC antenna on your phone.

IMPORTANT:

- When you scan your Sensor, 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.
- Remember that if you start the Sensor with the App, you won't be able to use the Reader with this Sensor to check your glucose or receive alarms. If you want to use the Reader instead, refer to the User's Manual in the Reader Kit.
- The App needs your phone to have date and time enabled to set automatically (e.g. when you travel across time zones). Making manual changes to your phone's time and date setting can lead to incorrect time records and inability to use the App.

1. Tap the scan button .
2. iPhone users, hold the top of your phone near the Sensor. Android phone users, hold the back of your phone near the Sensor. Keep your phone still until you hear a tone and/or feel a vibration. This completes the scan and activates NFC. If the scan dialog disappears, tap the scan button again.
3. You'll start getting glucose readings and alarms from your Sensor in 60 minutes. While the Sensor is starting up, feel free to navigate away from the App. If notifications for the App are on, you'll get a notification when your Sensor is ready.

Note:

- You may need to move your phone around slowly to find the right spot to scan.
- If your phone's volume is turned off, you won't hear a tone when you scan your Sensor.
- If your Sensor is not successfully scanned, you may get a scan error message. Follow the instructions in the message.

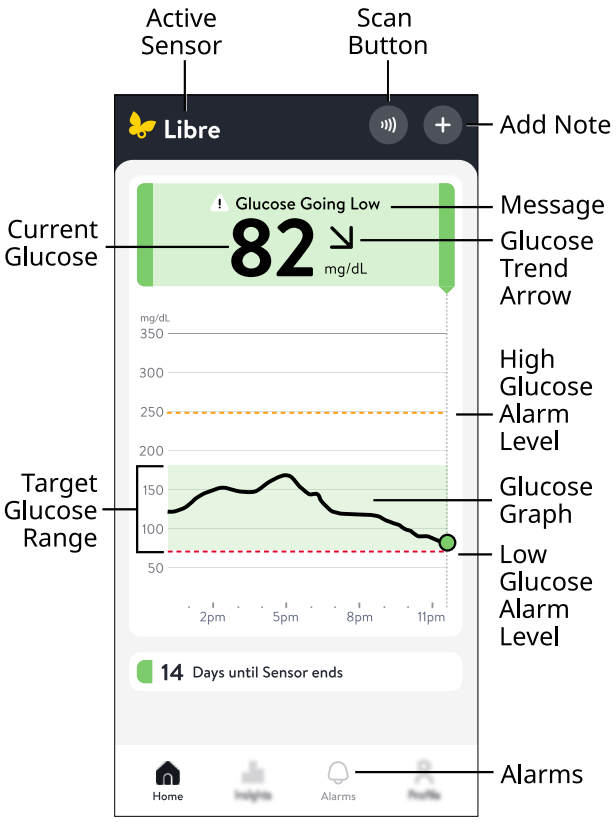
  See Troubleshooting for additional error messages.

Checking Your Glucose

1. Just open the App to see your glucose reading! It will automatically update every minute.

You can still scan your Sensor whenever you want though - for example, to fill in up to 8 hours of missing data or to get a glucose reading during signal loss. Just tap the scan button and hold the top (iPhone)/ back (Android) of your phone near the Sensor. Keep your phone still until you hear a tone and/or feel a vibration.

2. 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.

Message - Tap the message for more information.

Alarms - Tap to access your alarm settings.

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.

Low Glucose Alarm Level - Your Low Glucose Alarm level.

Add Note - Tap to add any notes you want to include. You can edit or review a note later by tapping on its symbol.

Active Sensor - Your Sensor type displays here.

Note:

- A Sensor can store up to 8 hours of glucose data. Scan it when you see gaps in your graph to capture all of your available glucose data.
- The graph line displays glucose readings above 350 mg/dL as 350 mg/dL. For consecutive readings above 350 mg/dL, a line is displayed at 350 mg/dL. The current glucose number can be as high as 400 mg/dL.
- 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.
- If you are not receiving automatic glucose readings you will not receive glucose alarms.
- Data is automatically sent from the Sensor to the App when the devices are within range. If you leave range and return, the Sensor should reconnect with the App in an average of 1 minute.

Understanding Your Glucose Readings

Glucose Trend Arrow

The Glucose Trend Arrow indicates the direction your glucose is going.

 Glucose is rising quickly (more than 2 mg/dL per minute)

 Glucose is rising (between 1 and 2 mg/dL per minute)

 Glucose is changing slowly (less than 1 mg/dL per minute)

Glucose is falling (between 1 and 2 mg/dL per minute)

Glucose is falling quickly (more than 2 mg/dL per minute)

Messages

Below are messages you may see with your glucose readings. You can tap the ⚠ symbol next to the message for more information.

Low Glucose (Out of Glucose Reading Range): You will see **LO** on your screen if your reading is lower than 40 mg/dL. Check your blood glucose on your finger with a test strip. If you get a second **LO** result with a test strip, contact your health care professional IMMEDIATELY.

High Glucose (Out of Glucose Reading Range): You will see **HI** on your screen if your reading is higher than 400 mg/dL. Check your blood glucose on your finger with a test strip. If you get a second **HI** result with a test strip, contact your health care professional IMMEDIATELY.

Low Glucose: You will see a **Low Glucose** message if your glucose is lower than 70 mg/dL.

High Glucose: You will see a **High Glucose** message if your glucose is higher than 250 mg/dL.

Glucose Going Low: You will see a **Glucose Going Low** message if your glucose is projected to be lower than 70 mg/dL within 15 minutes.

Glucose Going High: You will see a **Glucose Going High** message if your glucose is projected to be higher than 250 mg/dL within 15 minutes.

Note:

- During the first 12 hours of Sensor wear the 🩸🔍 symbol will display, and you cannot use Sensor values to make treatment decisions during this time. Confirm Sensor glucose readings with a blood glucose test before making treatment decisions during the first 12 hours of Sensor wear when you see the 🩸🔍 symbol.
- If you are not sure what your glucose reading means, contact your health care professional for information.
- Messages you receive with glucose readings are not related to glucose alarm settings.

Background Color

Your current glucose value determines the background color on your glucose reading display:

Orange - High glucose (above 250 mg/dL)

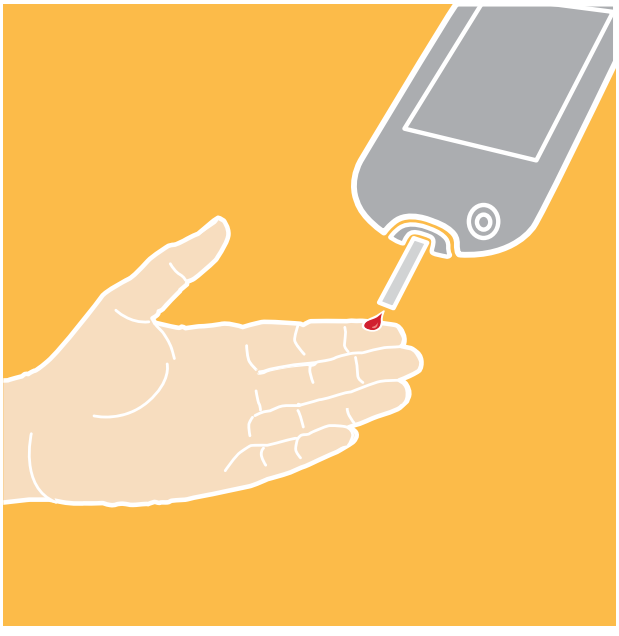
Yellow - Between the Target Glucose Range and high or low glucose level

Green - Within the Target Glucose Range

Red - Low glucose (below 70 mg/dL)

Making Treatment Decisions

Work with your health care professional to put together a plan for managing your diabetes that includes when to use the System information for making treatment decisions. **Continue to use your blood glucose meter for treatment decisions until you are comfortable with the information you receive from your System.** This includes understanding that Sensor performance can vary in between Sensors and within a Sensor wear period. Pay attention to how each newly inserted Sensor is working for you when deciding whether to make treatment decisions based on your Sensor readings.



When to Use Your Blood Glucose Meter

The System can replace blood glucose testing except in the below situations. These are the times when you need to do a blood glucose test before deciding what to do or what treatment decision to make:

No current glucose number

When there is no current glucose number, such as when you receive an error message or a LO or HI result, you don't have enough information to make a treatment decision. Do a blood glucose test and treat based on that result.

When you see the 🔍 symbol during the first 12 hours of wearing a Sensor

During the first 12 hours of Sensor wear the 🔍 symbol will display, and you cannot use Sensor values to make treatment decisions during this time. Confirm Sensor glucose readings with a blood glucose test before making treatment decisions during the first 12 hours of Sensor wear when you see the 🔍 symbol.

Symptoms don't match readings

There may be times when your symptoms don't match your Sensor glucose readings. For example, you are feeling shaky, sweaty, and dizzy – symptoms you generally get when you have low glucose, but your glucose reading is within your target range. When symptoms don't match readings, do a blood glucose test and treat based on that result. Don't ignore symptoms that may be due to low or high blood glucose.

When to do Nothing and Check Again Later

Your health care professional can help you understand when doing nothing and checking your glucose again later is the right treatment decision. For example, if your glucose is high and going up, your first instinct may be to take more insulin to lower your glucose, however depending on when you last took insulin or your recent activity, the right treatment decision may be to do nothing and check again later.

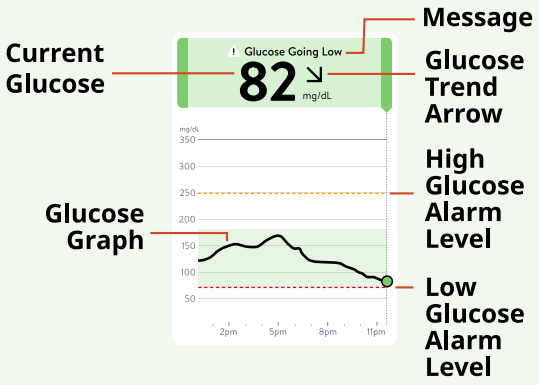
Don't take a correction dose within 2 hours of your meal dose. This may result in "insulin stacking" and low glucose.

Using Your Glucose Reading to Make a Treatment Decision

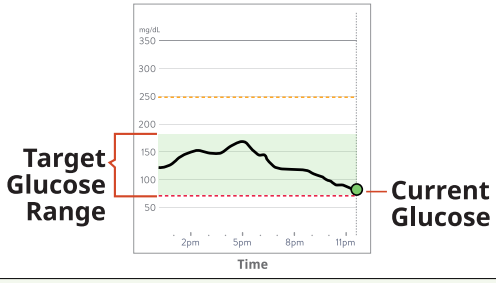
Use all of the information on the screen when deciding what to do or what treatment decision to make.

Glucose Trend Arrow
Direction your glucose is going

Arrow	What it means
↑	Glucose rising quickly
↗	Glucose rising
→	Glucose changing slowly
↘	Glucose falling
↓	Glucose falling quickly



Glucose Graph
Graph of your current and stored glucose readings



The below provides some information on how you can factor the Glucose Trend Arrow into your treatment decisions. Remember that you should never make a treatment decision based on the Glucose Trend Arrow alone.

Treatment decision considerations for Glucose Trend Arrow: ↑

Low Glucose (<70 mg/dL): Treat low glucose according to your health care professional's recommendation.

Glucose in Target Range: If you are about to eat, take insulin to cover your meal. Consider taking a little more since glucose is rising quickly.

If you have taken insulin recently, do nothing and check your glucose again later.

Avoid “insulin stacking”.

High Glucose (>250 mg/dL): If you are about to eat, take insulin to cover your meal. Consider taking a little more since glucose is high and rising quickly.

If this is between meals, consider taking an insulin correction dose, unless you have taken insulin recently. If you have taken insulin recently, do nothing and check your glucose again later.

Avoid “insulin stacking”.

Treatment decision considerations for Glucose Trend Arrow: ↗

Low Glucose (<70 mg/dL): Treat low glucose according to your health care professional’s recommendation.

Glucose in Target Range: If you are about to eat, take insulin to cover your meal. Consider taking a little more since glucose is rising.

If you have taken insulin recently, do nothing and check your glucose again later.

Avoid “insulin stacking”.

High Glucose (>250 mg/dL): If you are about to eat, take insulin to cover your meal. Consider taking a little more since glucose is high and rising.

If this is between meals, consider taking an insulin correction dose, unless you have taken insulin recently. If you have taken insulin recently, do nothing and check your glucose again later.

Avoid “insulin stacking”.

Treatment decision considerations for Glucose Trend Arrow: →

Low Glucose (<70 mg/dL): Treat low glucose according to your health care professional’s recommendation.

Glucose in Target Range: If you are about to eat, take insulin to cover your meal.

If this is between meals, do nothing and check your glucose again later.

High Glucose (>250 mg/dL): If you are about to eat, take insulin to cover your meal. Consider taking a little more since glucose is high.

If this is between meals, consider taking an insulin correction dose, unless you have taken insulin recently. If you have taken insulin recently, do nothing and check your glucose again

later.

Avoid “insulin stacking”.

Treatment decision considerations for Glucose Trend Arrow: ↘

Low Glucose (<70 mg/dL): Treat low glucose according to your health care professional’s recommendation.

Glucose in Target Range: If you are about to eat, take insulin to cover your meal. Consider taking a little less since glucose is falling.

If this is between meals, consider eating a snack or fast-acting carbohydrates to stay within target and check your glucose again later.

High Glucose (>250 mg/dL): If you are about to eat, take insulin to cover your meal. Consider taking a little less since glucose is falling.

If this is between meals, consider doing nothing and check your glucose again later.

Avoid “insulin stacking”.

Treatment decision considerations for Glucose Trend Arrow: ↓

Low Glucose (<70 mg/dL): Treat low glucose according to your health care professional’s recommendation.

Glucose in Target Range: If you are about to eat, take insulin to cover your meal. Consider taking a little less since glucose is falling quickly.

If this is between meals, consider eating a snack or fast-acting carbohydrates to stay within target and check your glucose again later.

High Glucose (>250 mg/dL): If you are about to eat, take insulin to cover your meal. Consider taking a little less since glucose is falling quickly.

If this is between meals, consider doing nothing and check your glucose again later.

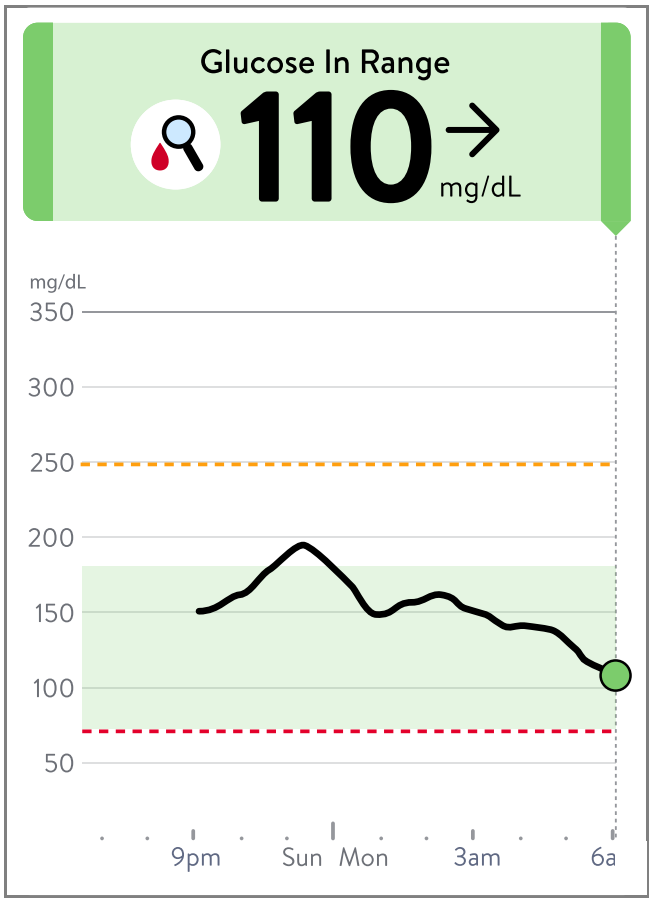
Avoid “insulin stacking”.

Example Scenarios

Here are some example scenarios to help you understand how to use the information on your screen. Always use all of the information on the screen before deciding what to do or treatment decision to make. If you are not sure about what to do, consult your health care

professional.

What you see - *When you wake-up*

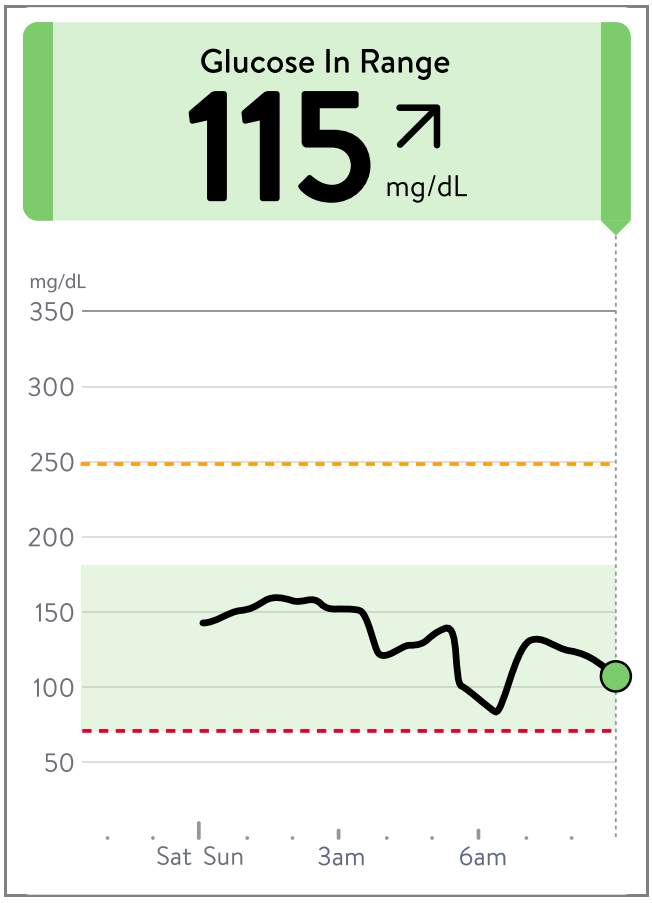


What it means

When you wake-up on your first day of wearing a Sensor, your current glucose is 110 mg/dL. There is also the symbol on the screen.

During the first 12 hours of Sensor wear the symbol will display, and you cannot use Sensor values to make treatment decisions during this time. Confirm Sensor glucose readings with a blood glucose test before making treatment decisions during the first 12 hours of Sensor wear when you see the symbol.

What you see - *Before breakfast*



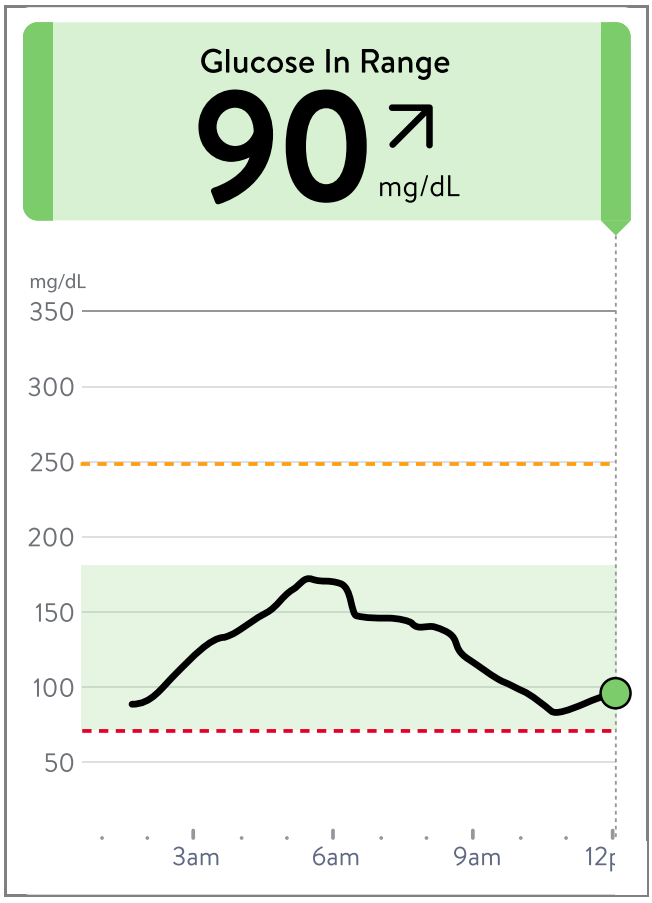
What it means

Before breakfast, your current glucose is 115 mg/dL. The graph shows that your glucose is going up and so does the trend arrow ↗.

Consider what might be causing your glucose to go up and what you might do to prevent a high glucose. For example:

- How much insulin should you take before your meal?
- Since you see ↗, should you consider taking a little more insulin?

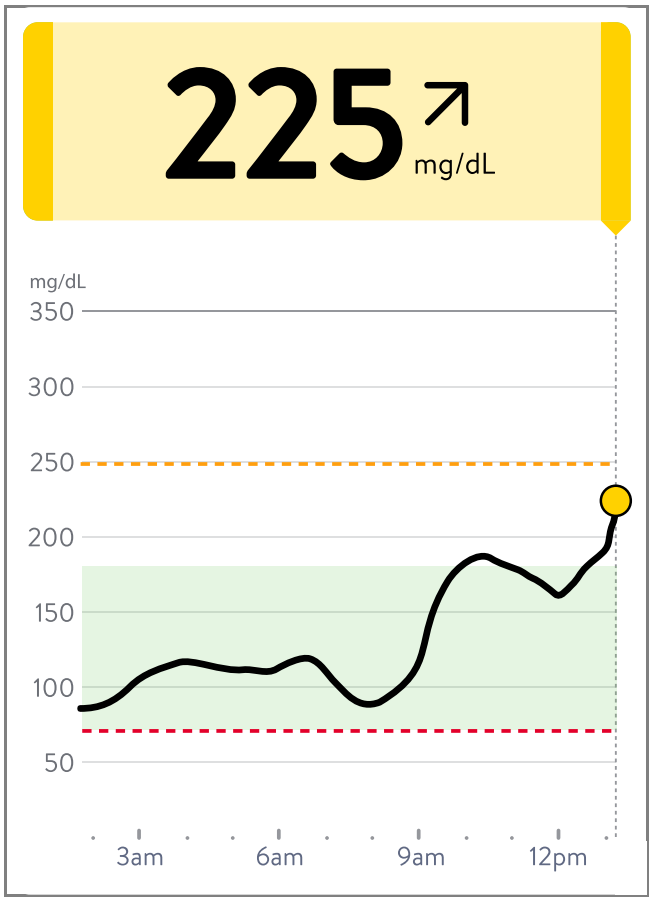
What you see - *Before lunch*



What it means

When you checked your glucose before lunch, it was 90 mg/dL and rising. Before eating lunch, you took enough insulin to cover the meal and a little more since your trend arrow was ↗.

What you see - *After lunch*



What it means

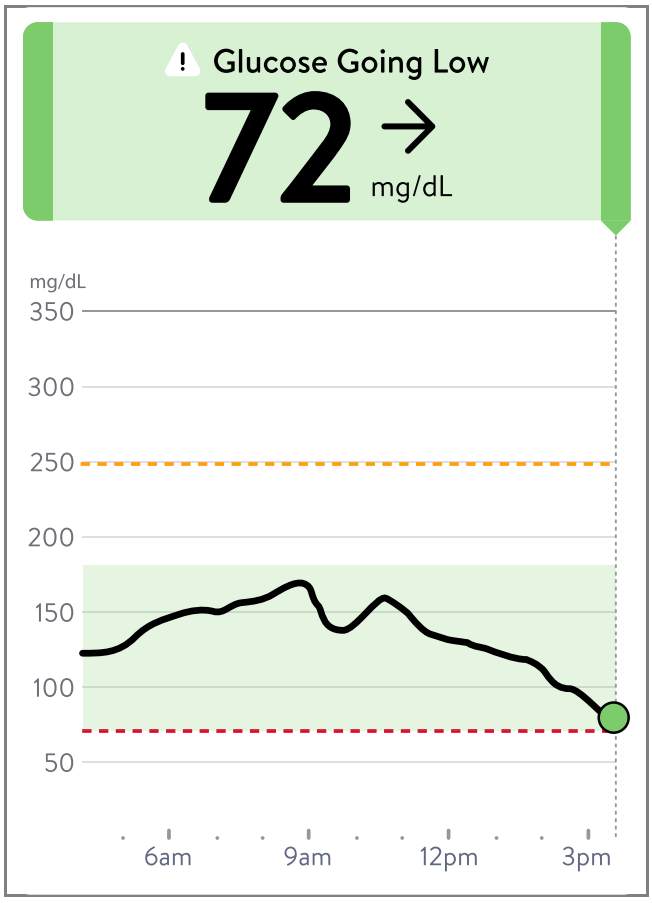
90 minutes later, your current glucose is 225 mg/dL. The graph shows that your glucose is still going up, and so does the trend arrow ↗.

Don’t take a correction dose within 2 hours of your meal dose. This may result in “insulin stacking” and low glucose.

Consider what might be causing your glucose to go up and what you might do to prevent a high glucose. For example:

- Has the insulin you took for your meal reached its full effect?
- Check your glucose again later.

What you see - *In the afternoon*

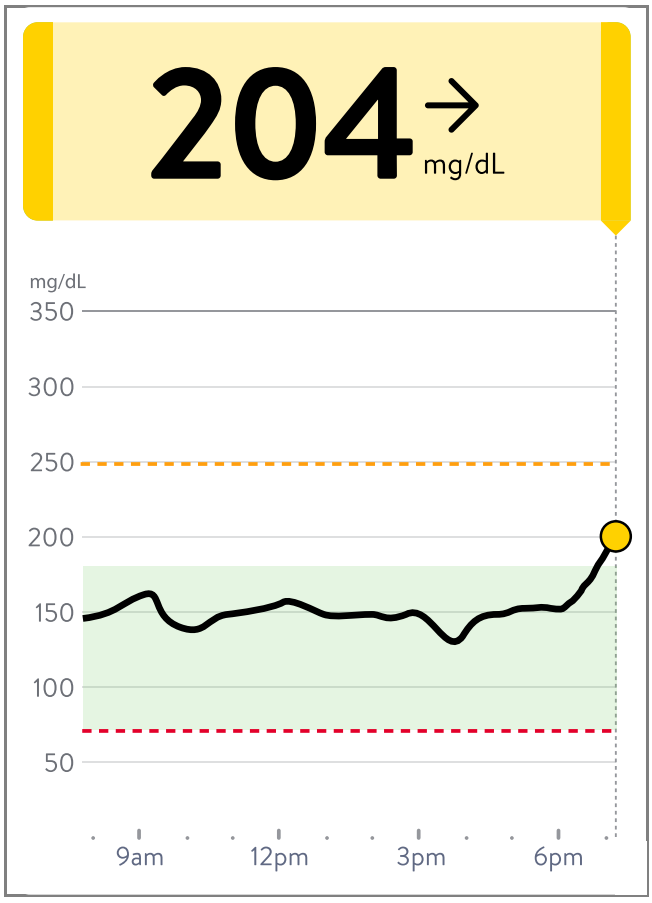


What it means

Between meals, your current glucose is 72 mg/dL. The Glucose Going Low message tells you that your glucose is projected to be low within 15 minutes.

Think about what might be causing your glucose to go low. Consider eating a snack to stay within target. **Avoid taking insulin as this can cause low glucose.**

What you see - *After exercising*

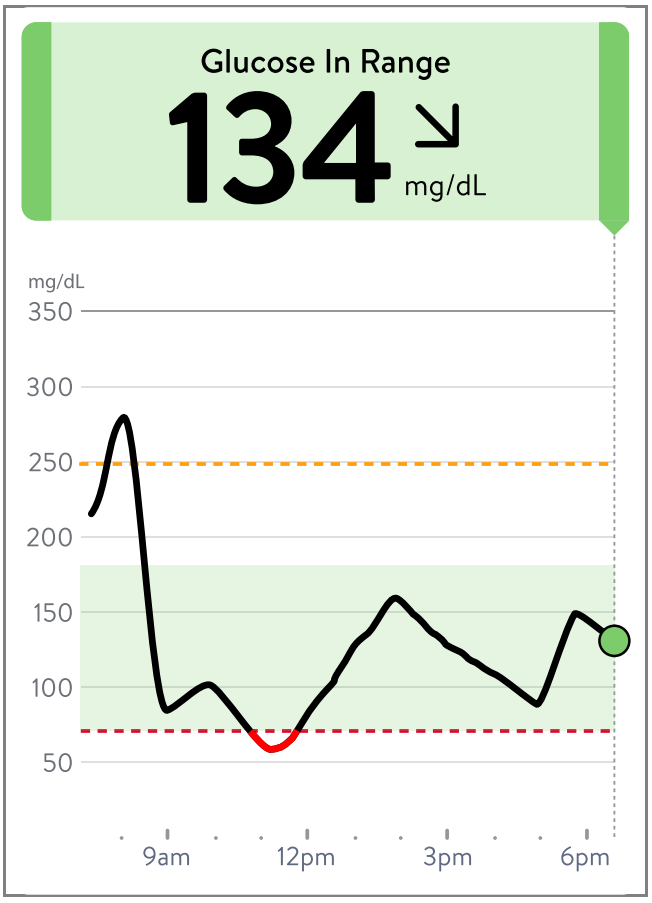


What it means

After exercising, you are feeling shaky, sweaty, and dizzy – symptoms you generally get when you have low glucose. But, your current glucose is 204 mg/dL.

Anytime you get a reading that doesn't match how you feel, do a blood glucose test.

What you see - *Before dinner*



What it means

Before dinner, your current glucose is 134 mg/dL. The graph shows that your glucose is going down and so does the trend arrow ↘.

Consider what might be causing your glucose to go down and what you might do to prevent a low glucose. For example:

- How much insulin should you take to cover your meal?
- Since you see ↘, should you think about taking a little less insulin?

Alarms

The App includes several types of alarms to help you manage your glucose levels and let you know about times when you're not getting Sensor readings. These are all turned on by default and initially set to sound regardless of your phone's sound or Do Not Disturb settings. If there's a time where you need quiet, you have a couple of options:

- You can choose to silence all your glucose and signal loss alarms for a set period by turning on the App's **Silent Mode**.
- You can individually select to turn off the **Override Do Not Disturb** setting for the Low

Glucose, High Glucose, or Signal Loss Alarm if you want the alarm to follow your phone's volume setting and be silent when you have Do Not Disturb enabled.

Note: The Urgent Low Glucose Alarm can only be silenced by turning on Silent Mode.

When you get an alarm, acknowledge it by opening the App or tapping the **Dismiss** button. Then, use the information on your Sensor reading screen to take action as needed.

If you ignore a glucose or signal loss alarm, you'll get it again in 5 minutes if the condition still exists. Only your most recent alarm notifications will show on your screen.

CAUTION: Review all the information in this section and the alarm safety information in Cautions - App Use before setting and using alarms.

IMPORTANT:

- Glucose alarms are an important safety feature. Please talk to your health care professional to determine your settings.
- The Urgent Low, Low, and High Glucose Alarms should not be used exclusively to detect low or high glucose conditions. 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 Range.
- **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 enable **Silent Mode** in your alarm settings, you won't receive audible glucose and signal loss alarms even if the Override Do Not Disturb setting is on.
- If you see the symbol, you may not be receiving alarms. You can tap the symbol for more information. Confirm your settings are as follows:

  iPhone settings:

  - 'Allow Notifications' for the App is ON
  - Lock Screen and Banner notifications for the App are ON
  - Notification sounds for the App are ON

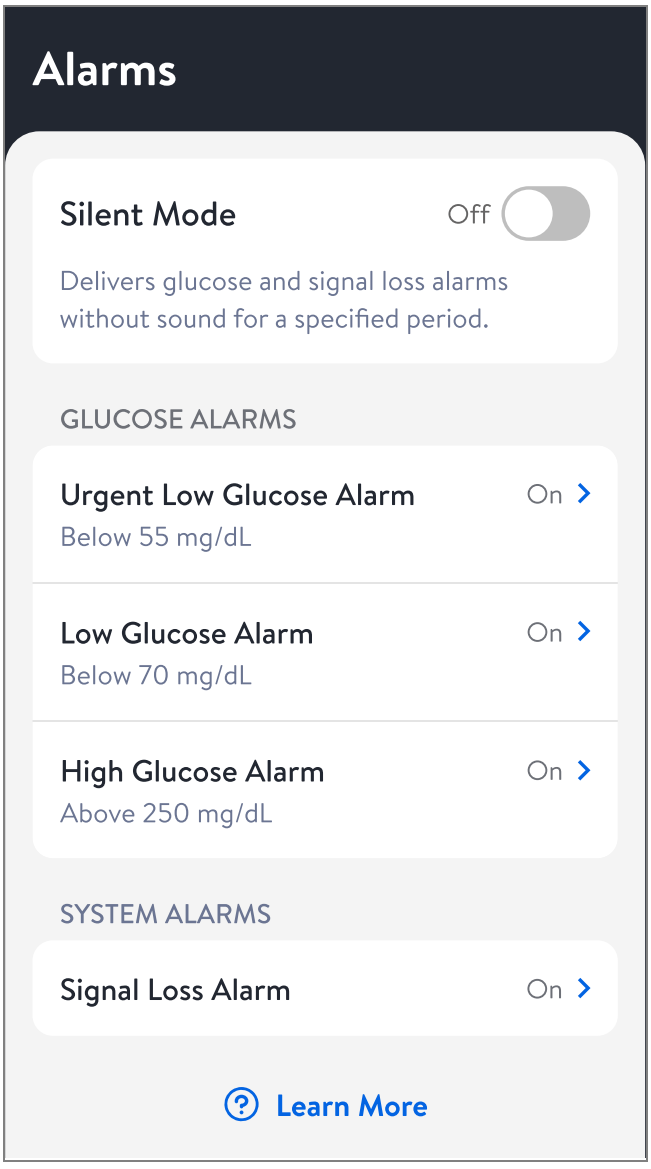
Android phone settings:

- Channel notifications for the App are ON
- Lock Screen or Pop-up notifications for the App are ON
- Battery optimization is OFF
- Phone Media volume is ON

If alarms are unavailable because of any of these settings, you will still be able to check your glucose.

Glucose and Signal Loss Alarms

At the bottom of your screen, you'll see the **Alarms** button. Tap it to access your glucose and signal loss alarm settings.



Silent Mode

1. Silent Mode is off by default. If you want to turn it on, tap the slider.
2. Tap the time field to set the duration. Tap **Save**.
3. Tap **Turn On** to confirm.

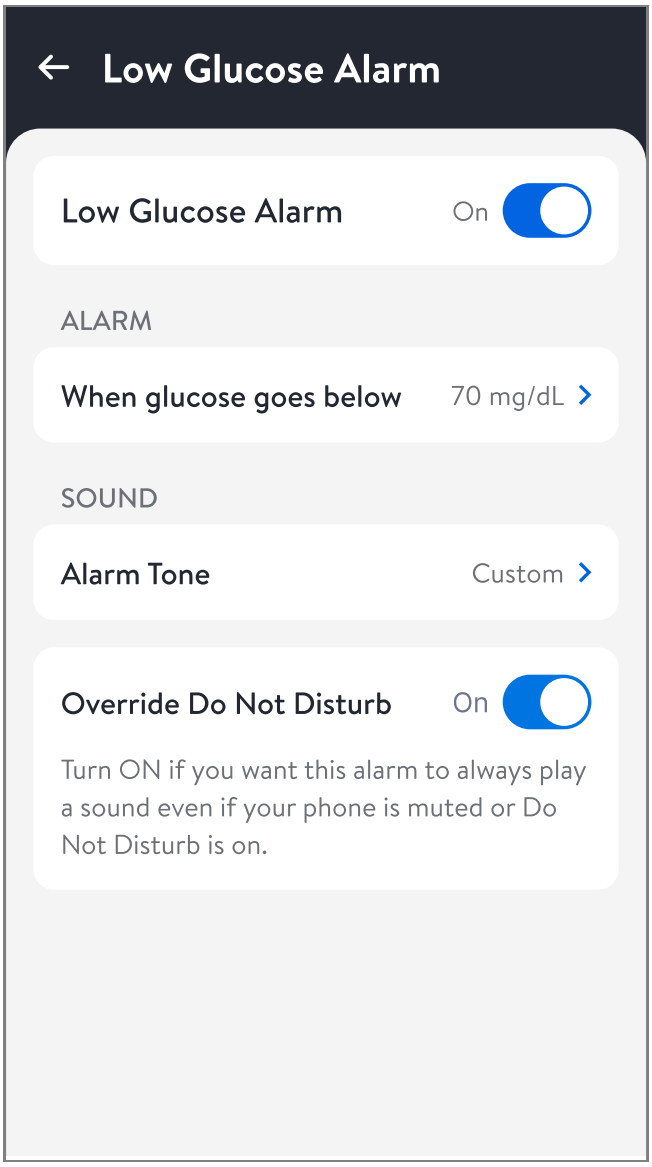
   Note: You can turn Silent Mode off at any time before the end of the set duration.

   IMPORTANT: When Silent Mode is enabled, you will not hear your glucose and signal loss alarms even if you've turned on 'Override Do Not Disturb'. You may still get the visual and vibratory notifications based on your phone's settings.

Urgent Low Glucose Alarm: You'll get an **Urgent Low Glucose Alarm** app notification if your glucose drops below 55 mg/dL. It will include your current glucose level and direction your glucose is going. You'll get a notification every 30 minutes until your glucose reading is at or above 55 mg/dL. This alarm cannot be turned off but can be silenced with your other glucose alarms for a set period.

Low Glucose Alarm:

1. The alarm is on by default and the alarm level is initially set to 70 mg/dL. Tap to change this value between 60 mg/dL and 100 mg/dL. Tap **Save**. If the alarm is on, you will be notified when your glucose falls below the level you set. Tap the slider to turn the alarm off.
2. iPhone users can choose the alarm sound. Tap **Save**.
3. **Override Do Not Disturb** for the alarm is on by default. Keep Override Do Not Disturb on if you want the alarm to play a sound and appear on the lock screen even if your phone is muted or Do Not Disturb is on. The alarm vibration will match your phone setting. You won't hear a sound if you have turned on Silent Mode.
4. Tap the back button to return to the main alarm settings screen.



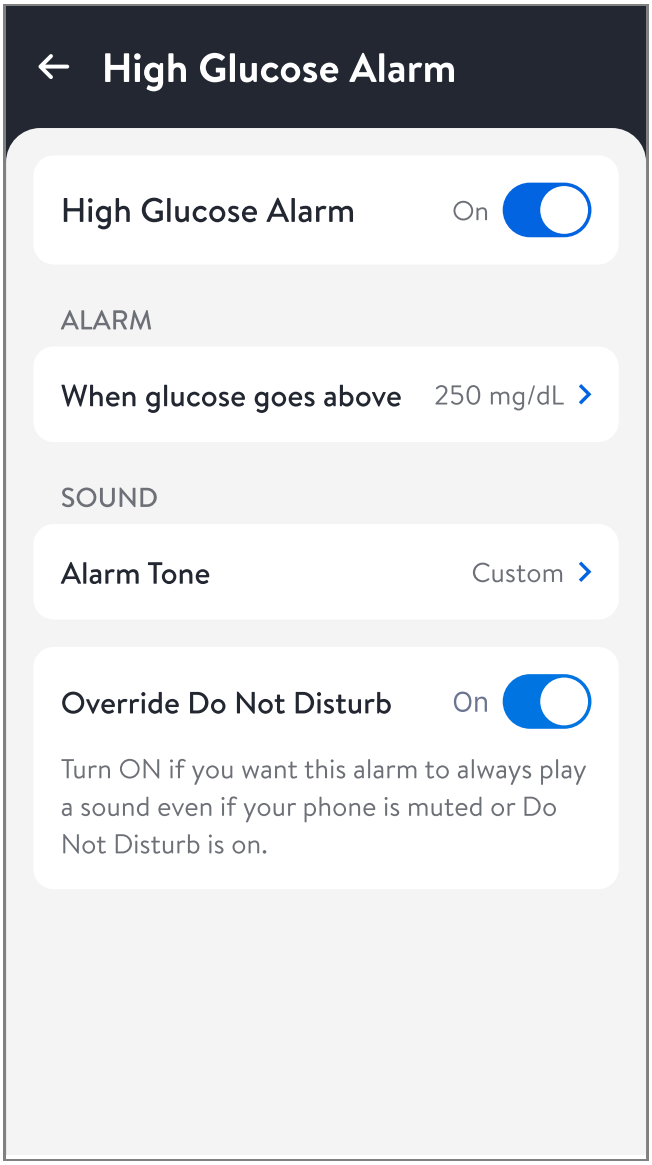
5. You'll get a **Low Glucose Alarm** app notification if your glucose drops below the level you set. It will include your current glucose level and direction your glucose is going. You will only receive one alarm per low glucose episode so if you dismiss it, you won't get one again until the next episode.

High Glucose Alarm:

1. The alarm is on by default and the alarm level is initially set to 250 mg/dL. Tap to change this value between 120 mg/dL and 400 mg/dL. Tap **Save**. If the alarm is on, you will be notified when your glucose rises above the level you set. Tap the slider to turn the alarm off.
2. iPhone users can choose the alarm sound. Tap **Save**.
3. **Override Do Not Disturb** for the alarm is on by default. Keep Override Do Not Disturb on if you want the alarm to play a sound and appear on the lock screen even if your phone is muted or Do Not Disturb is on. The alarm vibration will match your phone

setting. You won't hear a sound if you have turned on Silent Mode.

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

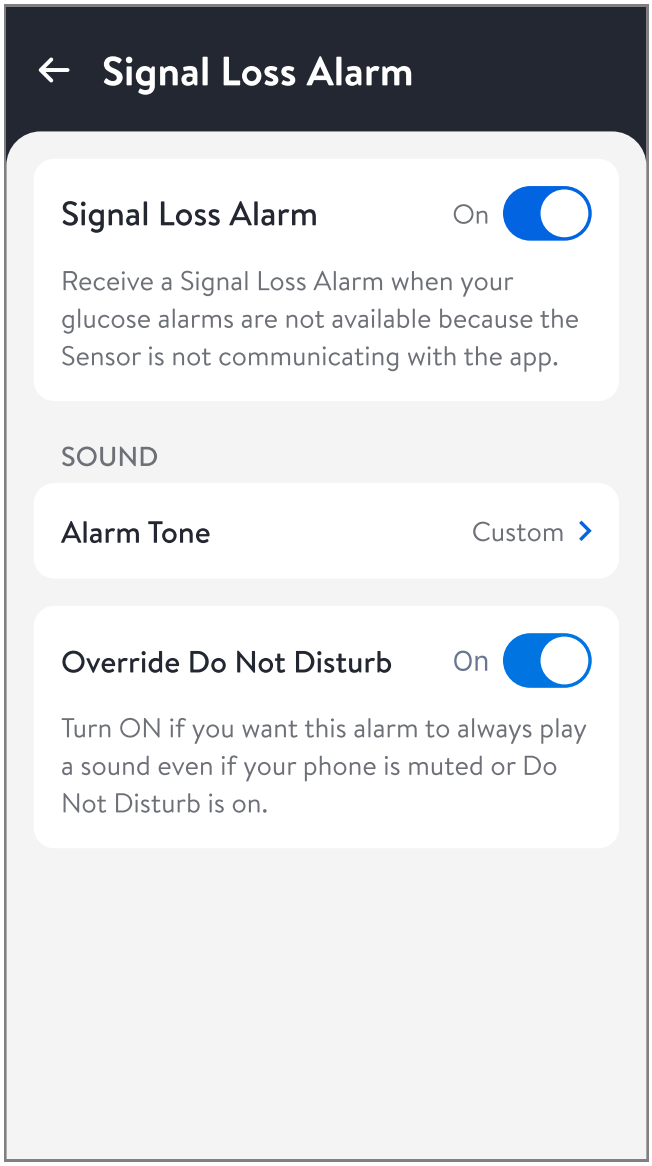


5. You'll get a **High Glucose Alarm** app notification if your glucose rises above the level you set. It will include your current glucose level and direction your glucose is going. You will only receive one alarm per high glucose episode so if you dismiss it, you won't get one again until the next episode.

Signal Loss Alarm:

1. 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 any of your glucose alarms. Tap the slider to turn the alarm off.
2. iPhone users can choose the alarm sound. Tap **Save**.

3. **Override Do Not Disturb** for the alarm is on by default. Keep Override Do Not Disturb on if you want the alarm to play a sound and appear on the lock screen even if your phone is muted or Do Not Disturb is on. The alarm vibration will match your phone setting. You won't hear a sound if you have turned on Silent Mode.
4. Tap the back button to return to the main alarm settings screen.



5. You'll get a **Signal Loss Alarm** app notification if your Sensor has not communicated with the App for 20 minutes and you are not receiving any glucose alarms. Signal loss could be caused by the Sensor being too far away from your phone (over 20 ft) or another issue such as an error or problem with your Sensor.

Other Alarms

The App has some alarms to let you know you are no longer receiving glucose readings or glucose alarms. These alarms are a little different and will always sound regardless of your

phone's sound, Do Not Disturb, or Silent Mode settings. These alarms cannot be modified or turned off and indicate you are no longer receiving glucose readings or glucose alarms.

Replace Sensor; Sensor Ended: Notifies you that your Sensor needs to be replaced.

App Stopped: Notifies you that the App has been closed. The App must always be running in the background for you to get alarms. Tap the alarm to re-open the App.

Looking After 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 3 feet (1 meter) or immerse it longer than 30 minutes in water. Note that Bluetooth performance may be impacted if using the System while underwater.

Sleeping: The Sensor can store up to 8 hours of data so we suggest that you review your glucose graph before you go to sleep and when you wake up to check for gaps. Scan your Sensor if needed to capture all your data. If you have glucose alarms set, place your phone near your bed so you can hear them.

Traveling by Air: You can use your System while on a plane, following any requests from the flight crew.

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

- Some airport full-body scanners include 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.

Disposal

This product should be disposed of in accordance with all applicable local regulations related to the disposal of electronic equipment, batteries, sharps, and materials potentially exposed to body fluids.

Contact Customer Service for further information on the appropriate disposal of system

components. Customer Service is available at 1-855-632-8658 7 days a week from 8 a.m. to 8 p.m. Eastern Time; excluding holidays.

Troubleshooting

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 then clean with an alcohol wipe.
3. Follow the instructions in Applying Your Sensor and Starting Your Sensor. Consider shaving the site, avoiding use of lotions prior to insertion, and applying the Sensor to your non-dominant arm.

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 health care professional to identify the best solution.

Troubleshooting Display Messages

Display: **Sensor Starting Up**

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

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

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. You will not be able to use the App to receive glucose readings or start a new Sensor until the setting is turned on.

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 20 feet of the Sensor. 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 Alarm** shows again, contact Customer Service.

Display: **Signal Loss**

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

What to do: Make sure your phone is within 20 feet 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: **Allow Access to Critical Alerts (iPhone)**

What it may mean: The App's access to Critical Alerts was disabled.

What to do: Follow the instructions on the screen to allow the permission. You won't be able to use the App to receive glucose readings or start a new Sensor until the permission is allowed.

Display: **Allow Access to Do Not Disturb (Android)**

What it may mean: The App's access to Do Not Disturb was disabled.

What to do: Follow the instructions on the screen to allow the permission. You won't be able to use the App to receive glucose readings or start a new Sensor until the permission is allowed.

Display: **App Permission Required**

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

What to do: Follow the instructions on the screen to turn the permission on. You won't be able to use the App to receive glucose readings or start a new Sensor until the permission is turned on.

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 phone 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: **Scan Error**

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

What to do: Try scanning the Sensor again. Make sure to follow the scanning directions in Starting Your Sensor.

Display: **Sensor Error**

What it may mean: Your Sensor runs continuous quality checks, and glucose readings have been paused. Once it passes these checks, your Sensor will resume providing readings.

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

Note: If you receive this error during your first 12 hours of wearing a Sensor, it may mean that your body is still adjusting to the Sensor. Use a blood glucose meter to check your glucose while you wait. You don't need to remove your Sensor.

Display: **Sensor Already in Use**

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

What to do: The App can only be used with a Sensor that it started. Use the device that started the Sensor. Or, apply and start a new Sensor.

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, your Sensor was not applied properly. Apply and start a new Sensor.

Display: **Replace Sensor**

What it may mean: Your Sensor runs continuous quality checks, and it has shut itself down for your safety.

What to do: Apply and start a new Sensor to continue monitoring your glucose.

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: **Incompatible Sensor**

What it may mean: Libre app can only be used with a compatible Sensor.

What to do: If you still have questions about compatibility, tap **Learn more** or call Customer Service.

Problems Receiving Alarms

What it may mean: You have turned alarms off.

What to do: Tap the **Alarms** button at the bottom of the screen. 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 your Sensor. You will see the symbol at the top of the screen 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.

What to do: The Sensor must be within range (20 feet) of your phone for you to receive alarms. Make sure that you are within this range. 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 you still see the symbol, 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. Go to the Alarms section for more information.

What it may mean: You have enabled Silent Mode in the App.

What to do: Check your alarm settings to confirm Silent Mode is turned off.

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'll receive another alarm when a new low or high glucose episode starts.

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

What to do: Disconnect accessories when you are not using them.

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 (Android only): The App was put to sleep by the phone operating system.

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

Sensor Specifications

Sensor glucose assay method: Amperometric electrochemical sensor

Sensor glucose reading range: 40 to 400 mg/dL

Sensor size: 5 mm height and 35 mm diameter

Sensor weight: 5 grams

Sensor power source: One silver oxide battery

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

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

Sensor transmission range: 20 ft (6 meters) unobstructed

Operating temperature: 50°F to 113°F

Sensor Applicator and Sensor Pack storage temperature: 36°F to 82°F

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

Sensor water resistance and ingress protection: IP27: Can withstand immersion into 3 ft (1 meter) of water for up to 30 minutes. Protected against insertion of objects >12 mm diameter.

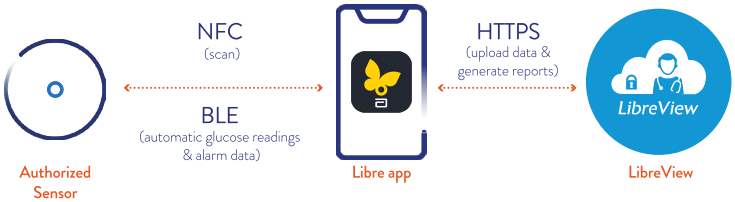
Operating and storage altitude: -1,250 ft (-381 meters) to 10,000 ft (3,048 meters)

Radio frequency: 2.402-2.480 GHz BLE; GFSK; 0 dBm EIRP

Security Measures and Quality of Service

Security Measures

The communication between the App and Sensor during a scan is a short range Near Field Communication (NFC) method which makes it difficult to interfere with or intercept during transmission. The communication between the App and Sensor for automatic glucose readings and alarm data is a standard Bluetooth Low Energy (BLE) connection. The pairing of the Sensor to the App is accomplished during activation with an authenticated login procedure using NFC. This prevents unauthorized devices from connecting to the Sensor. The transmitted data is protected by a proprietary data format and encryption. This prevents unauthorized devices from accessing the data if they are within range and intercept the transmission. Under normal operation, the industry standard BLE protocols allow for many users to be in the same vicinity. In the case where the connection is lost due to out-of-range or interference, reconnection is only possible when logged in to the same LibreView account that activated the Sensor. Authenticated login through LibreView is used to ensure secure transfer of data. All data transferred to/from LibreView is encrypted using industry-standard HTTPS to ensure that it remains private.



The Software Bill of Materials (SBOM) is available on request from Customer Service.

Quality of Service (QoS)

QoS for the App and Sensor wireless communication using NFC is assured within the effective range of 1 cm between the Sensor and phone.

QoS for the App and Sensor wireless communication using BLE is assured at regular 1 minute intervals. If connection is lost between the App and Sensor for 5 minutes, the App will display an indication of "Signal Loss" on the screen. If connection is lost for 20 minutes, the App notifies the user if the Signal Loss alarm is turned on. If connection is lost between the Sensor and the App, up to 8 hours of glucose results can be retrieved by performing a scan with the App. The App is designed to only accept radio frequency (RF) communications from recognized and paired Sensors. The transmission range for BLE communication is 20 feet unobstructed. If the phone and Sensor are seeing frequent signal loss at longer distances, bring them closer together.

Performance Characteristics

Different clinical studies were conducted to evaluate the performance of the Libre 2 Sensor and the Libre 2 Plus Sensor. Please reference the section that applies to the Sensor you are using.

Libre 2 Sensor Performance Characteristics

Overview of Clinical Studies

Two studies were conducted in the United States (US) to evaluate the performance, safety, effectiveness, and precision of the FreeStyle Libre 2 System (System) with the Libre 2 Sensor. One study included adults (Adult study) and the other study included children (Pediatric study). All subjects in both studies required insulin to manage their diabetes. To measure the precision of the System, each subject wore two Sensors, one on the back of each upper arm, for a period of up to 14 days. While in the clinic, subjects had their venous blood glucose analyzed using a laboratory reference method, the Yellow Springs Instrument Life Sciences 2300 STAT Plus™ Glucose & Lactate Analyzer (YSI). Sensor glucose readings were then compared to the YSI glucose results in subjects 6 years and older to evaluate the System's performance. In the pediatric study, System performance was compared against a self-monitoring blood glucose meter for subjects 4-5 years old.

Adult study: The Adult study was conducted at 5 centers with 146 subjects in total (91.1% Type 1, 8.9% Type 2), all aged eighteen and older. Subjects had their venous blood glucose analyzed over three separate visits to the clinical center. Each visit lasted up to ten hours. 144 subjects were analyzed during the beginning of the Sensor wear period (day 1, 2, or 3),

91 subjects were analyzed during the early middle period (day 7 or 8), 55 subjects were analyzed during the late middle period (day 9 or 12), and 76 subjects were analyzed during the end period (day 13 or 14). During each visit, adult subjects had their glucose levels deliberately manipulated per the study protocol to raise or lower glucose. This was done to assess performance of the System over the range that the System measures glucose (40-400 mg/dL).

Pediatric study: The Pediatric study was conducted at 4 centers with 139 subjects in total (98.6% Type 1, 1.4% Type 2), all aged four to seventeen. Subjects age six and older had their venous blood glucose analyzed for up to 16 hours over one or two separate visits to the clinical center. Each visit lasted up to eight hours. During each visit, subjects age 11 and older had their glucose levels deliberately manipulated per the study protocol to raise or lower glucose. This was done to assess performance of the System over the range that the System measures glucose (40-400 mg/dL). 48 subjects were analyzed during the beginning of the Sensor wear period (day 1 or 2), 50 subjects were analyzed during the early middle period (day 7 or 8), 51 subjects were analyzed during the late middle period (day 9 or 12), and 51 subjects were analyzed during the end period (day 13 or 14). All subjects tested their blood glucose using fingerstick capillary samples at least four times during each day of the study.

Accuracy

Accuracy of the System was measured by comparing paired Sensor glucose readings (CGM) to YSI blood glucose values. For blood glucose values <70 mg/dL, the difference in mg/dL between the CGM and YSI blood glucose values was calculated. For values >70 mg/dL, the relative difference (%) to the YSI blood glucose values was calculated. The percentage of total CGM readings that were within 20 mg/dL or 20% of YSI blood glucose values is displayed in Table 1. The Mean Absolute Relative Difference (MARD) gives an indication of the average percent disagreement between the CGM and the reference. For example, in the Adult study, 92.4% of the readings fell within ±20 mg/dL of YSI blood glucose values <70 mg/dL and within ±20% of YSI blood glucose values ≥70 mg/dL. The total number of data pairs considered in the analysis was 18,735. In the Adult study, the Mean Absolute Relative Difference was 9.2% for the comparison with YSI reference. In the Pediatric study, the Mean Absolute Relative Difference was 9.7% for the comparison with YSI reference.

Table 1. Overall Accuracy to YSI Reference

Subject Group	Number of CGM-Reference Pairs	Number of Subjects	Percent Within ±20% / ±20 mg/dL	Percent Within ±20% / ±20 mg/dL on Day 1	Percent Within ±20% / ±20 mg/dL in first 12 hours	MARD (%)
Adults	18735	144	92.4	87.5	81.7	9.2
Children (age 6-17)	6546	129	91.6	84.1	80.3	9.7

Children (age 4-5)*	341	8	85.9	87.9	90.9	11.8

* No YSI measurements were obtained for children ages 4-5; results displayed are from CGM-SMBG matched paired measurements.

The following tables give you further accuracy information within CGM glucose ranges (Table 2 and Table 3) and within YSI glucose ranges (Table 4 and Table 5). This information tells you how likely it is that your Sensor glucose reading matches your blood glucose level.

Table 2. Accuracy to YSI within CGM Glucose Ranges (Adult; n=144)

CGM Glucose Level † (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean Bias (mg/dL)	MARD (%)
<54	518	85.9	93.8	99.4				-6.4	13.8
54-69	3012	89.5	94.2	99.1				-3.3	10.8
70-180	7785				76.5	86.6	99.2	-4.8	10.6
181-250	3037				89.1	95.0	99.9	-10.1	7.8
>250	4383				94.0	97.9	100.0	-6.3	6.1

† System range is 40-400 mg/dL.

Table 3. Accuracy to YSI within CGM Glucose Ranges (Pediatric*; n=129)

CGM Glucose Level † (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean Bias (mg/dL)	MARD (%)
<54	139	71.9	79.1	97.1				-9.9	17.1
54-69	863	86.4	90.5	97.1				-4.9	12.0
70-180	2690				77.4	87.6	98.7	-3.4	10.6
181-250	1236				86.0	94.7	99.7	-8.9	8.3
>250	1618				92.2	97.7	99.8	-2.2	7.2

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

† System range is 40-400 mg/dL.

Table 4. Accuracy to YSI within YSI Glucose Ranges (Adult; n=144)

YSI Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean Bias (mg/dL)	MARD (%)
<54	440	91.1	97.5	100.0				7.4	15.5
54-69	3028	94.7	98.6	100.0				1.5	10.2
70-180	7504				77.5	86.9	99.4	-4.8	10.4

181-250	2937				87.9	93.7	99.7	-8.0	8.0
>250	4826				90.9	95.9	99.7	-11.8	6.9

Table 5. Accuracy to YSI within YSI Glucose Ranges (Pediatric*; n=129)

YSI Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean Bias (mg/dL)	MARD (%)
<54	131	93.9	98.5	100.0				6.6	14.2
54-69	751	96.5	98.8	100.0				1.0	9.3
70-180	2743				74.3	84.8	98.0	-3.0	11.4
181-250	1104				86.6	92.9	99.0	-3.9	8.4
>250	1817				90.2	97.5	99.9	-10.2	7.6

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

Agreement of 'LO' and 'HI' CGM Reading with YSI Reference

The System reports glucose concentrations between 40 and 400 mg/dL. When the System determines that glucose level is below 40 mg/dL, it will report as 'LO'. When the System determines that glucose level is above 400 mg/dL, it will report as 'HI'. Table 6 and Table 7 show the comparison of a CGM 'LO' reading to the reference YSI glucose. For example, in the Adult study, when CGM reading was 'LO', YSI glucose values were less than 50 mg/dL 20.0% of the time, less than 60 mg/dL 40.0% of the time, less than 70 mg/dL 40.0% of the time, less than 80 mg/dL 80.0% of the time, and equal to or above 80 mg/dL 20.0% of the time.

Table 6. Distribution of YSI Values when CGM Reading is 'LO' (Adult; n=144)

CGM-Reference Pairs	YSI (mg/dL)					N
	<50	**<60**	**<70**	**<80**	**≥80**	
n	1	2	2	4	1	5
Cumulative %	20.0	40.0	40.0	80.0	20.0	

Table 7. Distribution of YSI Values when CGM Reading is 'LO' (Pediatric*; n=129)

CGM-Reference Pairs	YSI (mg/dL)					N
	<50	**<60**	**<70**	**<80**	**≥80**	
n	0	1	2	2	0	2
Cumulative %	0.0	50.0	100.0	100.0	0.0	

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

Table 8 and Table 9 show the comparison of a CGM 'HI' reading to the reference YSI

glucose. In the Adult study, when CGM reading was 'HI', YSI glucose values were above 350 mg/dL 97.5% of the time, above 300 mg/dL 100.0% of the time, above 250 mg/dL 100.0% of the time, and less than or equal to 250 mg/dL 0.0% of the time.

Table 8. Distribution of YSI Values when CGM Reading is 'HI' (Adult; n=144)

CGM-Reference Pairs	YSI (mg/dL)				N
	>350	>300	>250	≤250	
n	118	121	121	0	121
Cumulative %	97.5	100.0	100.0	0.0	

Table 9. Distribution of YSI Values when CGM Reading is 'HI' (Pediatric*; n=129)

CGM-Reference Pairs	YSI (mg/dL)				N
	>350	>300	>250	≤250	
n	40	43	45	0	45
Cumulative %	88.9	95.6	100.0	0.0	

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

Concurrence of System and Reference (CGM vs. YSI)

The following tables show the concurrence of the CGM readings to YSI values. Table 10 and Table 11 tell you for each CGM range what percentage of YSI values were in the same glucose range as the CGM (shaded) or in glucose ranges above or below the CGM. For example, in the Adult study, when the System glucose readings were within the 81 to 120 mg/dL range, actual blood glucose values were between 40 and 60 mg/dL 0.2% of the time, between 61 and 80 mg/dL 11.0% of the time, between 81 and 120 mg/dL 70.1% of the time, between 121 and 160 mg/dL 17.8% of the time, between 161 and 200 mg/dL 0.8% of the time, and between 201 and 250 mg/dL 0.1% of the time. Table 12 and Table 13 tell you for each YSI range what percentage of CGM readings were in the same glucose range (shaded) as the YSI or in glucose ranges above or below the YSI.

Table 10. Concurrence Analysis by CGM Glucose Level (Adult; n=144)

CGM Glucose Level (mg/dL)	YSI Glucose Level (mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40†	20.0	20.0	40.0	20.0	-	-	-	-	-	-	-	5
40-60	0.4	52.9	43.3	3.3	-	0.1	-	-	-	-	-	1889
61-80	-	18.9	62.7	18.1	0.4	0.0	-	-	-	-	-	3090
81-120	-	0.2	11.0	70.1	17.8	0.8	0.1	-	-	-	-	3040
121-160	-	-	0.1	9.1	69.9	18.9	1.6	0.3	0.2	-	-	2407

161-200	-	-	-	-	10.6	60.6	26.9	1.6	0.3	-	-	1745
201-250	-	-	-	-	-	7.0	65.5	25.6	1.9	0.1	-	2181
251-300	-	-	-	-	-	0.1	8.4	66.9	22.7	1.8	0.1	2327
301-350	-	-	-	-	-	-	0.4	13.6	68.8	16.0	1.2	1522
351-400	-	-	-	-	-	-	-	0.6	27.5	63.3	8.6	534
>400†	-	-	-	-	-	-	-	-	2.5	62.8	34.7	121

† Levels out of System dynamic range.

Table 11. Concurrence Analysis by CGM Glucose Level (Pediatric*; n=129)

CGM Glucose Level (mg/dL)	YSI Glucose Level (mg/dL)											N
	<40	**40-60**	**61-80**	**81-120**	**121-160**	**161-200**	**201-250**	**251-300**	**301-350**	**351-400**	**>400**	
<40†	-	50.0	50.0	-	-	-	-	-	-	-	-	2
40-60	0.6	48.6	42.5	7.8	0.6	-	-	-	-	-	-	527
61-80	-	12.1	61.9	24.3	1.7	-	-	-	-	-	-	915
81-120	-	0.2	11.2	69.0	18.2	1.3	0.1	-	-	-	-	1006
121-160	-	-	-	11.4	71.0	15.8	1.8	-	-	-	-	868
161-200	-	-	-	0.1	18.2	61.3	20.1	0.3	-	-	-	703
201-250	-	-	-	-	0.2	9.6	55.3	33.6	1.2	0.1	-	909
251-300	-	-	-	-	-	0.1	14.1	60.8	23.7	1.3	-	818
301-350	-	-	-	-	-	-	0.3	24.8	58.2	16.5	0.2	593
351-400	-	-	-	-	-	1.0	-	0.5	33.8	59.4	5.3	207
>400†	-	-	-	-	-	-	-	4.4	6.7	33.3	55.6	45

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

† Levels out of System dynamic range.

Table 12. Concurrence Analysis by YSI Glucose Level (Adult; n=144)

YSI Glucose Level (mg/dL)	CGM Glucose Level (mg/dL)											N
	<40†	**40-60**	**61-80**	**81-120**	**121-160**	**161-200**	**201-250**	**251-300**	**301-350**	**351-400**	**>400†**	
<40	12.5	87.5	-	-	-	-	-	-	-	-	-	8
40-60	0.1	62.9	36.6	0.4	-	-	-	-	-	-	-	1591
61-80	0.1	26.4	62.6	10.8	0.1	-	-	-	-	-	-	3093
81-120	0.0	2.1	18.8	71.1	7.3	-	-	-	-	-	-	2971
121-160	-	-	0.5	22.3	69.6	7.7	-	-	-	-	-	2418
161-200	-	0.1	0.1	1.5	26.9	62.5	9.0	0.1	-	-	-	1694
201-250	-	-	-	0.1	1.8	21.9	66.8	9.1	0.3	-	-	2139
251-300	-	-	-	-	0.3	1.2	23.7	66.0	8.8	0.1	-	2359

301-350	-	-	-	-	0.3	0.3	2.3	29.8	58.9	8.3	0.2	1777
351-400	-	-	-	-	-	-	0.3	6.1	34.7	48.1	10.8	703
>400	-	-	-	-	-	-	-	1.9	16.7	42.6	38.9	108

† Levels out of System dynamic range.

Table 13. Concurrence Analysis by YSI Glucose Level (Pediatric*; n=129)

YSI Glucose Level (mg/dL)	CGM Glucose Level (mg/dL)											N
	<40†	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400†	
<40	-	100.0	-	-	-	-	-	-	-	-	-	3
40-60	0.3	69.2	30.0	0.5	-	-	-	-	-	-	-	370
61-80	0.1	24.8	62.6	12.5	-	-	-	-	-	-	-	904
81-120	-	3.9	21.0	65.7	9.4	0.1	-	-	-	-	-	1057
121-160	-	0.3	1.7	19.3	65.0	13.5	0.2	-	-	-	-	948
161-200	-	-	-	1.9	20.4	64.2	13.0	0.1	-	0.3	-	671
201-250	-	-	-	0.1	2.1	18.1	64.7	14.8	0.3	-	-	778
251-300	-	-	-	-	-	0.2	32.0	52.1	15.4	0.1	0.2	954
301-350	-	-	-	-	-	-	1.8	31.1	55.4	11.2	0.5	623
351-400	-	-	-	-	-	-	0.4	4.4	39.5	49.6	6.0	248
>400	-	-	-	-	-	-	-	-	2.7	29.7	67.6	37

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

† Levels out of System dynamic range.

Glucose Trend Arrow Accuracy

The System's ability to detect glucose rate of change (displayed by the Glucose Trend Arrow) was assessed against the YSI reference rate of change. The analysis is presented in Table 14 and Table 15. The following example shows how to use the information in the tables. For adult participants, when the Glucose Trend Arrow indicated that glucose was changing slowly downward (-1 to 0 mg/dL/min (→)), actual glucose levels in the body were falling quickly (<-2 mg/dL/min) 1.2% of the time, falling (-2 to -1 mg/dL/min) 8.3% of the time, changing slowly downward (-1 to 0 mg/dL/min) 67.1% of the time, changing slowly upward (0 to 1 mg/dL/min) 19.7% of the time, rising (1 to 2 mg/dL/min) 2.6% of the time, and were rising quickly (>2 mg/dL/min) 1.2% of the time. Note that digitally connected systems which don't use the System's trend arrow calculations may see different glucose rate of change accuracy.

Table 14. Trend Arrow Accuracy versus YSI (Adult; n=144)

CGM Rate Change	YSI Rate Change (mg/dL/min)						N

(mg/dL/min)	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2 (↓)	34.4	44.9	18.3	2.2	0.3	-	323
-2 to -1 (↘)	6.8	46.5	41.2	4.0	0.9	0.6	1090
-1 to 0 (→)	1.2	8.3	67.1	19.7	2.6	1.2	9389
0 to 1 (→)	0.9	3.4	26.0	46.9	15.5	7.3	5420
1 to 2 (↗)	0.1	1.7	7.7	31.6	38.4	20.5	1151
>2 (↑)	0.1	0.2	3.1	14.6	32.9	49.0	881

Table 15. Trend Arrow Accuracy versus YSI (Pediatric*; n=129)

CGM Rate Change (mg/dL/min)	YSI Rate Change (mg/dL/min)						N
	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2 (↓)	44.1	44.7	8.8	2.4	-	-	170
-2 to -1 (↘)	11.4	49.5	32.8	5.2	0.4	0.6	463
-1 to 0 (→)	2.1	11.2	60.0	20.8	3.9	1.9	2587
0 to 1 (→)	1.4	5.6	25.2	43.2	14.8	9.7	2095
1 to 2 (↗)	0.2	2.6	10.4	29.7	35.5	21.5	498
>2 (↑)	-	0.9	4.2	15.0	29.7	50.2	448

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

Alarm Performance

The tables in this section show the accuracy of the System's Low and High Glucose Alarms. The Alarm Rate tells you how often the alarm is right or wrong. The Detection Rate tells you how often the System is able to recognize and notify you about a low or high glucose event.

Low Glucose Alarm Performance

Table 16 and Table 17 display the percentages for these parameters:

True Alarm Rate

Tells you: When you got a low glucose alarm, were you actually low?

Definition: Percentage of time the alarm issued and blood glucose was below the alarm level within 15 minutes before or after the alarm.

False Alarm Rate

Tells you: Did you get a low glucose alarm that you shouldn't have?

Definition: Percentage of time the alarm issued and blood glucose was not below the alarm level within 15 minutes before or after the alarm.

Detection Rate

Tells you: When you were low, did you get a low glucose alarm?

Definition: Percentage of time blood glucose was below the alarm level and the alarm issued within 15 minutes before or after the glucose event.

Missed Detection Rate

Tells you: When you were low, did you miss a low glucose alarm?

Definition: Percentage of time blood glucose was below the alarm level and the alarm didn't issue within 15 minutes before or after the glucose event.

For example, the Adult study found that for a Low Glucose alarm level set to 70 mg/dL:

86.0% of the time a low glucose alarm was received when blood glucose was indeed below the alarm level but 14.0% of the time a low glucose alarm was received when blood glucose wasn't actually below the alarm level.

89.3% of the time blood glucose was below the alarm level and a low glucose alarm was appropriately issued but 10.7% of the time the glucose event was missed and no alarm was issued.

Table 16. Low Glucose Alarm Performance (Adult; n=144)

Low Glucose Alarm Level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
60	9861	72.6	27.4	1527	75.7	24.3
70	21504	86.0	14.0	3652	89.3	10.7
80	32784	91.3	8.7	4753	97.3	2.7
90	41299	93.6	6.4	5591	98.5	1.5

Table 17. Low Glucose Alarm Performance (Pediatric*; n=129)

Low Glucose Alarm Level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
60	2780	62.9	37.1	373	87.4	12.6
70	6363	80.3	19.7	963	93.5	6.5
80	9747	85.6	14.4	1318	96.4	3.6
90	12550	92.2	7.8	1656	97.3	2.7

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

High Glucose Alarm Performance

Table 18 and Table 19 display the percentages for these parameters:

True Alarm Rate

Tells you: When you got a high glucose alarm, were you actually high?

Definition: Percentage of time the alarm issued and blood glucose was above the alarm level within 15 minutes before or after the alarm.

False Alarm Rate

Tells you: Did you get a high glucose alarm that you shouldn't have?

Definition: Percentage of time the alarm issued and blood glucose was not above the alarm level within 15 minutes before or after the alarm.

Detection Rate

Tells you: When you were high, did you get a high glucose alarm?

Definition: Percentage of time blood glucose was above the alarm level and the alarm issued within 15 minutes before or after the glucose event.

Missed Detection Rate

Tells you: When you were high, did you miss a high glucose alarm?

Definition: Amount of time blood glucose was above the alarm level and the alarm didn't issue within 15 minutes before or after the glucose event.

For example, the Adult study found that for a High Glucose alarm level set to 200 mg/dL:

99.2% of the time a high glucose alarm was received when blood glucose was indeed above the alarm level but 0.8% of the time a high glucose alarm was received when blood glucose wasn't actually above the alarm level.

97.1% of the time blood glucose was above the alarm level and a high glucose alarm was appropriately issued but 2.9% of the time the glucose event was missed and no alarm was issued.

Table 18. High Glucose Alarm Performance (Adult; n=144)

	Alarm Rate	Detection Rate

High Glucose Alarm Level (mg/dL)	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
120	105544	99.1	0.9	11417	98.2	1.8
140	93574	99.1	0.9	10152	98.1	1.9
180	74290	99.2	0.8	8080	97.8	2.2
200	66039	99.2	0.8	7269	97.1	2.9
220	57549	99.0	1.0	6390	96.9	3.1
240	48733	98.4	1.6	5550	95.6	4.4
300	21512	96.3	3.7	2672	90.0	10.0

Table 19. High Glucose Alarm Performance (Pediatric*; n=129)

High Glucose Alarm Level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
120	34176	98.8	1.2	4441	98.2	1.8
140	30107	98.0	2.0	3945	98.4	1.6
180	22430	98.4	1.6	3125	98.0	2.0
200	19425	98.0	2.0	2791	98.0	2.0
220	16371	98.2	1.8	2492	96.9	3.1
240	13559	98.0	2.0	2172	95.7	4.3
300	6064	90.8	9.2	962	91.0	9.0

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

Sensor Accuracy Over Time

The Libre 2 Sensor can be worn for up to 14 days. The percentage of System readings within YSI values and the Mean Absolute Relative Difference (MARD) is presented for the following different wear periods in Table 20 and Table 21: Beginning (Adult: 144 subjects, Day 1, 2 or 3; Pediatric: 48 subjects, Day 1 or 2) Early Middle (Adult: 91 subjects, Day 7 or 8; Pediatric: 50 subjects, Day 7 or 8), Late Middle (Adult: 55 subjects, Day 9 or 12; Pediatric: 51 subjects, Day 9 or 12), and End (Adult: 76 subjects, Day 13 or 14; Pediatric: 51 subjects, Day 13 or 14). For values 70 mg/dL and above, the percentage of readings within 15%, 20%, and 40% of the YSI value was calculated. For values below 70 mg/dL, the percentage of readings within 15 mg/dL, 20 mg/dL, and 40 mg/dL of the YSI value was calculated.

Table 20. Sensor Accuracy Relative to YSI Over Wear Duration (Adult; n=144)

Wear Period	Number of CGM-Reference Pairs	MARD (%)	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±40% / ±40 mg/dL
Beginning	6955	9.9	83.4	90.4	99.3
Early Middle	4522	8.5	87.7	94.5	99.8

Late Middle	3503	8.8	86.8	93.4	99.7
End	3755	9.1	86.4	92.9	100.0

Table 21. Sensor Accuracy Relative to YSI Over Wear Duration (Pediatric*; n=129)

Wear Period	Number of CGM-Reference Pairs	MARD (%)	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±40% / ±40 mg/dL
Beginning	1828	10.7	79.6	88.5	98.6
Early Middle	1642	8.0	89.5	94.2	98.5
Late Middle	1534	9.7	83.6	92.9	99.5
End	1542	10.2	82.6	91.1	99.3

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

Sensor Wear Duration

The Libre 2 Sensor can be worn for up to 14 days. To estimate how long a Sensor will work over the wear duration, 146 Sensors were evaluated in the Adult study and 139 Sensors were evaluated in the Pediatric study to determine how many days of readings each Sensor provided. Subjects did not wash the insertion site with soap and water before applying the Sensors and wore two Sensors simultaneously. Of the 146 Sensors in the Adult study, 71.1% lasted until the final day of use. 6 Sensors (4.1%) had “early sensor shut-off” where the Sensor algorithm detected that the Sensors did not function as intended and presented the user with a Replace Sensor message. In the Pediatric study, 78.1% of the Sensors lasted until the final day of use. 3 Sensors (2.2%) had “early sensor shut-off” where the Sensor algorithm detected that the Sensors did not function as intended and presented the user with a Replace Sensor message. Table 22 and Table 23 display the data for each day in the wear duration for the Adult & Pediatric studies.

A third clinical study was also conducted to further evaluate wear duration in subjects who first washed the insertion site with a plain soap and water, according to the full instructions in the labeling and wore only a single Sensor. Of the 39 Sensors evaluated in this study, 97% lasted until the final day of use.

Table 22. Sensor Survival Rate Over Wear Duration (Adult; n=146)

Day of Wear	Number of Sensors	Survival Rate (%)
1	145	99.3
2	142	97.3
3	140	95.9
4	137	93.8
5	134	91.8

6	133	91.1
7	132	90.4
8	127	87.0
9	123	84.9
10	119	82.2
11	112	77.3
12	111	76.6
13	104	71.8
14	100	71.1

Table 23. Sensor Survival Rate Over Wear Duration (Pediatric; n=139)

Day of Wear	Number of Sensors	Survival Rate (%)
1	137	98.6
2	136	97.8
3	134	97.1
4	133	96.4
5	133	96.4
6	133	96.4
7	133	96.4
8	131	94.9
9	126	91.3
10	124	89.9
11	122	88.4
12	120	87.0
13	114	83.4
14	104	78.1

Glucose Reading Availability

The System is designed to show a Sensor glucose reading after each scan that is performed throughout the wear period after the start-up time. Table 24 and Table 25 show the expected glucose reading capture rate for each day of the wear duration.

Table 24. Glucose Reading Capture Rate Over Wear Duration (Adult; n=146)

Day of Wear	Number of Sensors	Capture Rate (%)
1	146	98.3
2	145	98.1
3	143	98.3

4	140	98.3
5	138	98.4
6	135	98.3
7	134	98.4
8	131	98.4
9	128	98.4
10	123	98.4
11	120	98.4
12	113	98.5
13	112	98.5
14	104	98.6

Table 25. Glucose Reading Capture Rate Over Wear Duration (Pediatric; n=139)

Day of Wear	Number of Sensors	Capture Rate (%)
1	139	94.6
2	137	94.9
3	136	95.2
4	133	95.3
5	134	95.5
6	133	95.6
7	133	96.0
8	133	95.9
9	130	95.7
10	125	95.6
11	125	95.6
12	122	95.8
13	119	95.9
14	116	95.8

Precision

Precision of the System was evaluated by comparing the glucose readings from two separate Sensors worn on the same subject at the same time. Table 26 provides data from 146 subjects in the Adult study; Table 27 provides data from 137 subjects in the Pediatric study. For adults, the paired absolute relative difference (PARD) between the two Sensors was 8.1% with coefficient of variation (CV) of 5.7%. For children ages 4-5, PARD was 6.7% with CV of 4.8%. For children ages 6-17, PARD was 8.2% with CV of 5.8%. Paired absolute difference (PAD) is a measurement of absolute difference (in mg/dL) between paired CGM readings, while PARD is the absolute relative difference (in %) between paired CGM

readings.

Table 26. Overall between Sensor Precision (Adult; n=146)

	Coefficient of Variation (%)	Paired Absolute Difference (mg/dL)	Paired Absolute Relative Difference (%)	Number of Paired Readings
Adults ages 18+	5.7	12.4	8.1	26791

Table 27. Overall between Sensor Precision (Pediatric; n=137)

	Coefficient of Variation (%)	Paired Absolute Difference (mg/dL)	Paired Absolute Relative Difference (%)	Number of Paired Readings
Children ages 4-5	4.8	10.7	6.7	248
Children ages 6-17	5.8	13.0	8.2	10623

Adverse Events

No device related serious adverse events occurred during the studies. In the Adult study, mild skin irritations, such as erythema, bruising, bleeding, and scabbing were reported around the insertion site and adhesive area by a small number of subjects (10 out of 146 or 6.8%). Pain was mostly reported as none with only one instance of mild pain. In the Pediatric study, there were 8 instances of erythema (4 “well-defined redness”, and 4 “slight pink”), 5 instances of edema (3 slight edema, 2 slight edema with defined edges), 2 instances of mild bleeding, one instance of mild induration and one instance of mild rash.

Vitamin C Interference (Libre 2 Sensor)

Taking Vitamin C supplements while wearing the Sensor may falsely raise Sensor glucose readings. Taking more than 500 mg of Vitamin C per day may affect the Sensor readings which could cause you to miss a severe low glucose event. Vitamin C can be found in supplements including multivitamins. Some supplements, including cold remedies such as Airborne® and Emergen-C®, may contain high doses of 1000 mg of Vitamin C and should not be taken while using the Sensor. See your health care professional to understand how long Vitamin C is active in your body.

Additional Notes for Health Care Professionals

A clinical study was conducted to evaluate the effect of ascorbic acid (Vitamin C) on the Libre 2 Sensor performance. Data from 57 adult subjects with diabetes was collected over a 13-hour period. Each subject had a one-hour baseline phase where venous blood was collected every 10 minutes. After this first hour, a dose of 1000 mg ascorbic acid was given with a meal and venous samples were collected every 20 minutes for the next four hours. A maximum average Sensor bias of 9.3 mg/dL was observed around 3 hours after the

1000 mg ascorbic acid dose. Subjects then received a second dose of 1000 mg ascorbic acid with a meal and the same process was continued for another 4 hours. A third dose of 1000 mg ascorbic acid was then given and study subjects were followed for 4 more hours. After the second dose of ascorbic acid the maximum average Sensor bias increased, with minimal change in Sensor bias after the third dose, suggesting that saturation had occurred by the second 1000 mg dose of ascorbic acid. The maximum average Sensor bias after the three 1000 mg doses of ascorbic acid was less than 20 mg/dL.

Libre 2 Plus Sensor Performance Characteristics

Overview of Clinical Study

A clinical study was conducted in the United States (US) to evaluate the performance, safety, effectiveness, and precision of the FreeStyle Libre 2 System (System) with the Libre 2 Plus Sensor. The study enrolled a total of 285 evaluable participants in 7 centers across the United States and included adult (18 years and older) and pediatric (2 to 17 years) participants. There were 149 adult participants, 124 pediatric participants ages 6-17, and 12 pediatric participants ages 2-5. 264 participants had Type 1 diabetes mellitus and 21 participants had Type 2 diabetes mellitus. All subjects required insulin to manage their diabetes.

To measure the precision of the System, each subject wore two Sensors, one on the back of each upper arm, for a period of up to 15 days. Participants ages 6 and older had their venous blood glucose analyzed using a laboratory reference method, the Yellow Springs Instrument Life Sciences 2300 STAT Plus™ Glucose & Lactate Analyzer (YSI) over up to three separate visits to the clinical center. Sensor glucose readings were then compared to the YSI glucose results to evaluate the System's performance.

Clinic sessions took place at the beginning (days 1, 2, and 3), early middle (days 5, 6, and 7), late middle (days 9, 10 and 11) and end (days 13, 14, and 15) of Sensor wear. Each visit lasted up to ten hours. During each visit, subjects age 11 and older had their glucose levels deliberately manipulated per the study protocol to raise or lower glucose. This was done to assess System performance over the range that the System measures glucose (40–400 mg/dL). Glucose was not manipulated for participants 10 years and younger. For participants ages 2-5, System performance was compared against a self-monitoring blood glucose meter during a 4-hour clinic visit. All participants tested their blood glucose using fingerstick capillary samples at least four times during each day of the study.

Accuracy

Accuracy of the System was measured by comparing paired Sensor glucose readings (CGM) to YSI blood glucose values. For blood glucose values <70 mg/dL, the difference in mg/dL between the CGM and YSI blood glucose values was calculated. For values ≥70 mg/dL, the

relative difference (%) to the YSI blood glucose values was calculated. The percentage of total CGM readings that were within 20 mg/dL or 20% of YSI blood glucose values is displayed in Table 1. The Mean Absolute Relative Difference (MARD) gives an indication of the average percent disagreement between the CGM and the reference. For example, for adult participants, 93.7% of the readings fell within ±20 mg/dL of YSI blood glucose values <70 mg/dL and within ±20% of YSI blood glucose values ≥70 mg/dL. For both adult and pediatric participants, the Mean Absolute Relative Difference was 8.2% for the comparison with YSI reference.

Table 1. Overall Accuracy to YSI Reference

Subject Group	Number of CGM-Reference Pairs	Number of Subjects	Percent Within ±20% / ±20 mg/dL	Percent Within ±20% / ±20 mg/dL on Day 1	Percent Within ±20% / ±20 mg/dL in first 12 hours	MARD (%)
Adults	20497	149	93.7	82.9	79.2	8.2
Children (age 6-17)	7025	124	93.5	89.8	90.5	8.2
Children (age 2-5)*	135	10	86.7	78.9	88.9	9.7

* No YSI measurements were obtained for children ages 2-5; results displayed are from CGM-SMBG matched paired measurements obtained during clinic visits from 10 of the 12 subjects. 2 of the 12 subjects did not have CGM-SMBG matched paired measurements obtained from clinic visits.

The following tables give you further accuracy information within CGM glucose ranges (Table 2 and Table 3) and within YSI glucose ranges (Table 4 and Table 5). This information tells you how likely it is that your Sensor glucose reading matches your blood glucose level.

Table 2. Accuracy to YSI within CGM Glucose Ranges (Adult; n=149)

CGM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean Bias (mg/dL)	MARD (%)
<54	555	84.3	91.0	98.4				-5.9	14.1
54-69	3157	91.5	95.2	99.1				-3.8	10.0
70-180	8258				82.3	90.2	99.1	-6.0	9.5
181-250	2976				89.9	94.5	99.9	-9.1	7.4
>250	5551				96.5	98.7	100.0	-3.1	5.1

Table 3. Accuracy to YSI within CGM Glucose Ranges (Pediatric*; n=124)

CGM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean Bias (mg/dL)	MARD (%)
<54	175	75.4	86.3	97.7				-8.9	15.7

54-69	755	84.5	88.6	97.5				-6.9	11.2
70-180	3074				82.6	90.9	99.6	-8.1	9.2
181-250	1176				92.0	97.4	100.0	-11.2	7.5
>250	1845				98.3	99.8	100.0	-3.5	4.8

* Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

Table 4. Accuracy to YSI within YSI Glucose Ranges (Adult; n=149)

YSI Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean Bias (mg/dL)	MARD (%)
<54	460	93.9	98.3	100.0				6.7	14.4
54-69	2799	97.6	99.0	99.6				-0.1	8.4
70-180	8386				80.6	89.2	98.9	-5.8	9.8
181-250	2792				89.9	94.6	99.7	-6.3	7.3
>250	6060				94.2	96.8	99.9	-7.5	5.8

Table 5. Accuracy to YSI within YSI Glucose Ranges (Pediatric*; n=124)

YSI Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean Bias (mg/dL)	MARD (%)
<54	94	100.0	100.0	100.0				4.1	9.7
54-69	599	97.7	99.8	100.0				-2.1	7.6
70-180	3178				79.4	87.9	99.0	-7.8	10.1
181-250	1080				89.8	96.2	99.8	-8.7	7.6
>250	2074				96.5	98.7	99.9	-8.0	5.6

* Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

Agreement of ‘LO’ and ‘HI’ CGM Reading with YSI Reference

The System reports glucose concentrations between 40 and 400 mg/dL. When the System determines that glucose level is below 40 mg/dL, it will report as ‘LO’. When the System determines that glucose level is above 400 mg/dL, it will report as ‘HI’. Table 6 and Table 7 show the comparison of a CGM 'LO' reading to the reference YSI glucose. For example, for adult participants, when CGM reading was ‘LO’, YSI glucose values were less than 50 mg/dL 100.0% of the time.

Table 6. Distribution of YSI Values when CGM Reading is 'LO' (Adult; n=149)

CGM-Reference Pairs	YSI (mg/dL)					N
	<50	<60	<70	<80	≥80	

n	1	1	1	1	0	1
Cumulative %	100.0	100.0	100.0	100.0	0.0	

Table 7. Distribution of YSI Values when CGM Reading is 'LO' (Pediatric*; n=124)

CGM-Reference Pairs	YSI (mg/dL)					N
	<50	<60	<70	<80	≥80	
n	0	3	4	4	0	4
Cumulative %	0.0	75.0	100.0	100.0	0.0	

* Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

Table 8 and Table 9 show the comparison of a CGM 'HI' reading to the reference YSI glucose. For example, for adult participants, when CGM reading was `HI', YSI glucose values were above 350 mg/dL 98.3% of the time and above 300 mg/dL 100.0% of the time.

Table 8. Distribution of YSI Values when CGM Reading is 'HI' (Adult; n=149)

CGM-Reference Pairs	YSI (mg/dL)				N
	>350	>300	>250	≤250	
n	119	121	121	0	121
Cumulative %	98.3	100.0	100.0	0.0	

Table 9. Distribution of YSI Values when CGM Reading is 'HI' (Pediatric*; n=124)

CGM-Reference Pairs	YSI (mg/dL)				N
	>350	>300	>250	≤250	
n	49	49	49	0	49
Cumulative %	100.0	100.0	100.0	0.0	

* Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

Concurrence of System and Reference (CGM vs. YSI)

The following tables show the concurrence of the CGM readings to YSI values. Table 10 and Table 11 tell you for each CGM range what percentage of YSI values were in the same glucose range as the CGM (shaded) or in glucose ranges above or below the CGM. For example, for adult participants, when the System glucose readings were within the 81 to 120 mg/dL range, actual blood glucose values were between 40 and 60 mg/dL 0.2% of the time, between 61 and 80 mg/dL 6.6% of the time, between 81 and 120 mg/dL 71.5% of the time, between 121 and 160 mg/dL 20.4% of the time, between 161 and 200 mg/dL 1.2% of the time, and between 201 and 250 mg/dL 0.1% of the time. Table 12 and Table 13 tell you for each YSI range what percentage of CGM readings were in the same glucose range (shaded) as the YSI or in glucose ranges above or below the YSI.

Table 10. Concurrence Analysis by CGM Glucose Level (Adult; n=149)

CGM Glucose Level (mg/dL)	YSI Glucose Level (mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40†	-	100.0	-	-	-	-	-	-	-	-	-	1
40-60	0.7	53.1	42.1	4.0	0.1	0.1	-	-	-	-	-	1929
61-80	0.0	12.2	68.0	19.0	0.7	-	-	-	-	-	-	3112
81-120	-	0.2	6.6	71.5	20.4	1.2	0.1	-	-	-	-	3338
121-160	-	-	0.1	6.8	72.5	19.2	1.2	0.2	-	-	-	2568
161-200	-	-	-	0.1	9.7	68.2	18.9	3.0	0.1	-	-	1897
201-250	-	-	-	-	0.2	8.6	61.7	27.2	2.4	-	-	2102
251-300	-	-	-	-	-	0.0	6.1	71.5	21.5	0.8	0.1	2818
301-350	-	-	-	-	-	-	0.1	16.4	74.6	8.7	0.3	2100
351-400	-	-	-	-	-	-	0.2	1.3	22.7	70.6	5.2	633
>400†	-	-	-	-	-	-	-	-	1.7	60.3	38.0	121

† Levels out of System dynamic range.

Table 11. Concurrence Analysis by CGM Glucose Level (Pediatric*; n=124)

CGM Glucose Level (mg/dL)	YSI Glucose Level (mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40†	-	75.0	25.0	-	-	-	-	-	-	-	-	4
40-60	-	46.5	44.5	8.0	1.0	-	-	-	-	-	-	499
61-80	-	6.2	62.4	30.5	1.0	-	-	-	-	-	-	840
81-120	-	0.1	4.1	71.0	24.1	0.7	-	-	-	-	-	1321
121-160	-	-	-	7.2	71.6	21.0	0.2	-	-	-	-	975
161-200	-	-	-	-	9.0	65.1	25.0	0.7	0.1	-	-	680
201-250	-	-	-	-	-	6.1	61.0	31.3	0.6	0.9	-	865
251-300	-	-	-	-	-	-	6.1	75.7	18.1	0.1	-	995
301-350	-	-	-	-	-	-	-	11.2	79.4	9.4	-	607
351-400	-	-	-	-	-	-	-	0.4	24.3	67.1	8.2	243
>400†	-	-	-	-	-	-	-	-	-	34.7	65.3	49

* Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

† Levels out of System dynamic range.

Table 12. Concurrence Analysis by YSI Glucose Level (Adult; n=149)

YSI	CGM Glucose Level (mg/dL)										

Glucose Level (mg/dL)	<40†	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400†	N
<40	-	92.9	7.1	-	-	-	-	-	-	-	-	14
40-60	0.1	72.5	26.9	0.5	-	-	-	-	-	-	-	1412
61-80	-	25.8	67.2	7.0	0.1	-	-	-	-	-	-	3151
81-120	-	2.4	18.3	73.8	5.4	0.1	-	-	-	-	-	3233
121-160	-	0.0	0.8	24.7	67.6	6.7	0.1	-	-	-	-	2754
161-200	-	0.0	-	2.0	24.6	64.3	9.0	0.0	-	-	-	2011
201-250	-	-	-	0.1	1.7	19.3	69.6	9.2	0.1	0.1	-	1863
251-300	-	-	-	-	0.2	1.9	19.0	67.1	11.5	0.3	-	3001
301-350	-	-	-	-	-	0.0	2.1	25.5	66.1	6.1	0.1	2368
351-400	-	-	-	-	-	-	-	3.2	25.1	61.7	10.1	725
>400	-	-	-	-	-	-	-	2.3	6.9	37.9	52.9	87

† Levels out of System dynamic range.

Table 13. Concurrence Analysis by YSI Glucose Level (Pediatric*; n=124)

YSI Glucose Level (mg/dL)	CGM Glucose Level (mg/dL)											N
	<40†	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400†	
<40	-	-	-	-	-	-	-	-	-	-	-	0
40-60	1.0	80.6	18.1	0.3	-	-	-	-	-	-	-	288
61-80	0.1	27.7	65.4	6.7	-	-	-	-	-	-	-	801
81-120	-	3.1	19.6	71.9	5.4	-	-	-	-	-	-	1304
121-160	-	0.5	0.7	29.2	64.0	5.6	-	-	-	-	-	1091
161-200	-	-	-	1.3	28.9	62.4	7.5	-	-	-	-	710
201-250	-	-	-	-	0.3	22.3	69.4	8.0	-	-	-	761
251-300	-	-	-	-	-	0.5	24.7	68.6	6.2	0.1	-	1098
301-350	-	-	-	-	-	0.1	0.7	24.8	66.3	8.1	-	727
351-400	-	-	-	-	-	-	3.3	0.4	23.2	66.3	6.9	246
>400	-	-	-	-	-	-	-	-	-	38.5	61.5	52

* Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

† Levels out of System dynamic range.

Glucose Trend Arrow Accuracy

The System's ability to detect glucose rate of change (displayed by the Glucose Trend Arrow) was assessed against the YSI reference rate of change. The analysis is presented in Table 14 and Table 15. The following example shows how to use the information in the tables. For adult participants, when the Glucose Trend Arrow indicated that glucose was

changing slowly downward (-1 to 0 mg/dL/min), actual glucose levels in the body were falling quickly (<-2 mg/dL/min) 1.5% of the time, falling (-2 to -1 mg/dL/min) 7.8% of the time, changing slowly downward (-1 to 0 mg/dL/min) 65.8% of the time, changing slowly upward (0 to 1 mg/dL/min) 21.1% of the time, rising (1 to 2 mg/dL/min) 2.6% of the time, and were rising quickly (>2 mg/dL/min) 1.2% of the time. Note that digitally connected systems which don't use the System's trend arrow calculations may see different glucose rate of change accuracy.

Table 14. Trend Arrow Accuracy versus YSI (Adult; n=149)

CGM Rate Change (mg/dL/min)	YSI Rate Change (mg/dL/min)						N
	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2 (↓)	31.5	43.1	20.0	3.4	1.0	1.0	295
-2 to -1 (↘)	11.1	44.5	37.8	5.5	0.8	0.4	841
-1 to 0 (→)	1.5	7.8	65.8	21.1	2.6	1.2	9254
0 to 1 (→)	1.1	4.2	25.5	47.2	15.2	6.7	6905
1 to 2 (↗)	0.1	2.9	9.9	29.9	36.7	20.6	1577
>2 (↑)	-	1.2	4.8	17.5	32.2	44.3	1038

Table 15. Trend Arrow Accuracy versus YSI (Pediatric*; n=124)

CGM Rate Change (mg/dL/min)	YSI Rate Change (mg/dL/min)						N
	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2 (↓)	27.7	53.5	16.8	1.0	1.0	-	101
-2 to -1 (↘)	8.2	46.8	39.9	3.5	1.1	0.5	376
-1 to 0 (→)	1.1	8.8	66.5	20.5	2.0	1.1	2969
0 to 1 (→)	1.2	3.3	24.6	51.7	13.1	6.2	2344
1 to 2 (↗)	-	3.2	8.8	30.8	39.9	17.3	571
>2 (↑)	-	2.0	5.4	15.2	32.4	45.1	408

* Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

Alarm Performance

The tables in this section show the accuracy of the System's Low and High Glucose Alarms. The Alarm Rate tells you how often the alarm is right or wrong. The Detection Rate tells you how often the System is able to recognize and notify you about a low or high glucose event.

Low Glucose Alarm Performance

Table 16 and Table 17 display the percentages for these parameters:

True Alarm Rate

Tells you: When you got a low glucose alarm, were you actually low?

Definition: Percentage of time the alarm issued and blood glucose was below the alarm level within 15 minutes before or after the alarm.

False Alarm Rate

Tells you: Did you get a low glucose alarm that you shouldn't have?

Definition: Percentage of time the alarm issued and blood glucose was not below the alarm level within 15 minutes before or after the alarm.

Detection Rate

Tells you: When you were low, did you get a low glucose alarm?

Definition: Percentage of time blood glucose was below the alarm level and the alarm issued within 15 minutes before or after the glucose event.

Missed Detection Rate

Tells you: When you were low, did you miss a low glucose alarm?

Definition: Percentage of time blood glucose was below the alarm level and the alarm didn't issue within 15 minutes before or after the glucose event.

For example, for a Low Glucose alarm level set to 70 mg/dL in the adult population:

84.6% of the time a low glucose alarm was received when blood glucose was indeed below the alarm level but 15.4% of the time a low glucose alarm was received when blood glucose wasn't actually below the alarm level.

95.5% of the time blood glucose was below the alarm level and a low glucose alarm was appropriately issued but 4.5% of the time the glucose event was missed and no alarm was issued.

Table 16. Low Glucose Alarm Performance (Adult; n=149)

Low Glucose Alarm Level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
60	9756	71.1	28.9	1376	84.5	15.5
70	23078	84.6	15.4	3451	95.5	4.5
80	33676	90.8	9.2	4655	98.0	2.0
90	42322	92.2	7.8	5525	98.8	1.2

Table 17. Low Glucose Alarm Performance (Pediatric*; n=124)

Low Glucose Alarm Level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
60	2760	58.9	41.1	275	87.6	12.4
70	6138	74.2	25.8	735	98.6	1.4
80	9664	82.8	17.2	1104	98.6	1.4
90	13113	88.3	11.7	1434	99.7	0.3

* Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

High Glucose Alarm Performance

Table 18 and Table 19 display the percentages for these parameters:

True Alarm Rate

Tells you: When you got a high glucose alarm, were you actually high?

Definition: Percentage of time the alarm issued and blood glucose was above the alarm level within 15 minutes before or after the alarm.

False Alarm Rate

Tells you: Did you get a high glucose alarm that you shouldn't have?

Definition: Percentage of time the alarm issued and blood glucose was not above the alarm level within 15 minutes before or after the alarm.

Detection Rate

Tells you: When you were high, did you get a high glucose alarm?

Definition: Percentage of time blood glucose was above the alarm level and the alarm issued within 15 minutes before or after the glucose event.

Missed Detection Rate

Tells you: When you were high, did you miss a high glucose alarm?

Definition: Amount of time blood glucose was above the alarm level and the alarm didn't issue within 15 minutes before or after the glucose event.

For example, for a High Glucose alarm level set to 200 mg/dL in the adult population:

98.5% of the time a high glucose alarm was received when blood glucose was indeed above the alarm level but 1.5% of the time a high glucose alarm was received when blood glucose wasn't actually above the alarm level.

98.0% of the time blood glucose was above the alarm level and a high glucose alarm was appropriately issued but 2.0% of the time the glucose event was missed and no alarm was issued.

Table 18. High Glucose Alarm Performance (Adult; n=149)

High Glucose Alarm Level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
120	96119	99.3	0.7	13212	97.8	2.2
140	83016	99.2	0.8	11728	98.0	2.0
180	61513	98.8	1.2	9337	98.0	2.0
200	53287	98.5	1.5	8388	98.0	2.0
220	45745	98.4	1.6	7615	97.8	2.2
240	38393	98.9	1.1	6902	97.2	2.8
300	16594	94.8	5.2	3369	91.2	8.8

Table 19. High Glucose Alarm Performance (Pediatric*; n=124)

High Glucose Alarm Level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
120	34730	99.4	0.6	4845	97.2	2.8
140	29844	99.2	0.8	4268	97.2	2.8
180	21855	99.0	1.0	3352	97.9	2.1
200	18820	99.2	0.8	3030	97.9	2.1
220	15886	98.8	1.2	2753	96.9	3.1
240	12743	98.4	1.6	2449	96.0	4.0
300	5140	97.5	2.5	1098	92.2	7.8

* Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

Sensor Accuracy Over Time

The Libre 2 Plus Sensor can be worn for up to 15 days. The percentage of System readings within YSI values and the Mean Absolute Relative Difference (MARD) is presented for the following different wear periods in Table 20 and Table 21: Beginning (Adult: 105 subjects, Day 1, 2, or 3; Pediatric: 57 subjects, Day 1, 2, or 3) Early Middle (Adult: 94 subjects, Day 5, 6,

or 7; Pediatric: 51 subjects, Day 5, 6, or 7), Late Middle (Adult: 90 subjects, Day 9, 10, or 11; Pediatric: 35 subjects, Day 9, 10, or 11), and End (Adult: 95 subjects, Day 13, 14, or 15; Pediatric: 33 subjects, Day 13, 14, or 15). For values 70 mg/dL and above, the percentage of readings within 15%, 20%, and 40% of the YSI value was calculated. For values below 70 mg/dL, the percentage of readings within 15 mg/dL, 20 mg/dL, and 40 mg/dL of the YSI value was calculated.

Table 20. Sensor Accuracy Relative to YSI Over Wear Duration (Adult; n=149)

Wear Period	Number of CGM-Reference Pairs	MARD (%)	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±40% / ±40 mg/dL
Beginning (days 1-3)	5410	10.0	83.0	89.7	99.1
Early Middle (days 5-7)	5043	7.2	91.6	96.1	99.8
Late Middle (days 9-11)	5142	7.7	89.9	94.8	99.3
End (days 13-15)	4902	7.8	90.0	94.5	99.6

Table 21. Sensor Accuracy Relative to YSI Over Wear Duration (Pediatric*; n=124)

Wear Period	Number of CGM-Reference Pairs	MARD (%)	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±40% / ±40 mg/dL
Beginning (days 1-3)	2634	9.0	84.0	91.0	99.5
Early Middle (days 5-7)	2277	6.9	92.3	97.3	99.9
Late Middle (days 9-11)	1209	6.9	92.3	96.9	99.8
End (days 13-15)	905	10.4	82.1	87.0	97.9

* Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

Sensor Wear Duration

The Libre 2 Plus Sensor can be worn for up to 15 days. To estimate how long a Sensor will work over the wear duration, 151 Sensors were evaluated in the adult population and 142 Sensors were evaluated in the pediatric population to determine how many days of readings each Sensor provided. Subjects wore two Sensors simultaneously. Some Sensors were excluded from the survival analysis due to reasons not related to the device (e.g., subject dropped out of study or physical factors such as accidental knocking off the Sensor etc.). Of the 151 Sensors in the adult population, 83.1% lasted until the final day of use. 4 Sensors (2.6%) had “early sensor shut-off” where the Sensor algorithm detected that the Sensors did not function as intended and presented the user with a Replace Sensor message. In the pediatric population, 76.8% of the Sensors lasted until the final day of use. 3 Sensors (2.1%) had “early sensor shut-off” where the Sensor algorithm detected that the Sensors did not function as intended and presented the user with a Replace Sensor

message. Table 22 and Table 23 display the data for each day in the wear duration for the adult and pediatric populations.

Another clinical study was also conducted to further evaluate wear duration in subjects who wore only a single Sensor. Of the 39 Sensors evaluated in this study, 94.9% lasted until the final day of use.

Table 22. Sensor Survival Rate Over Wear Duration (Adult; n=151)

Day of Wear	Number of Sensors	Survival Rate (%)
1	150	100.0
2	150	100.0
3	149	99.3
4	147	98.7
5	142	96.0
6	139	95.3
7	138	95.3
8	131	92.5
9	129	91.1
10	127	90.4
11	125	88.9
12	122	87.5
13	118	85.3
14	111	83.1
15	105	83.1

Table 23. Sensor Survival Rate Over Wear Duration (Pediatric; n=142)

Day of Wear	Number of Sensors	Survival Rate (%)
1	141	100.0
2	140	99.3
3	140	99.3
4	136	96.5
5	134	95.0
6	131	93.6
7	129	92.9
8	126	90.7
9	123	90.0
10	119	89.3

11	115	87.7
12	111	85.4
13	102	79.3
14	97	77.7
15	85	76.8

Glucose Reading Availability

The System is designed to show a Sensor glucose reading after each scan that is performed throughout the wear period after the start-up time. Table 24 and Table 25 show the expected glucose reading capture rate for each day of the wear duration.

Table 24. Glucose Reading Capture Rate Over Wear Duration (Adult; n=150)

Day of Wear	Number of Sensors	Capture Rate (%)
1	146	96.4
2	146	97.4
3	146	97.7
4	142	97.8
5	143	97.9
6	141	97.9
7	136	98.1
8	135	98.1
9	130	98.2
10	127	98.3
11	125	98.2
12	123	98.2
13	118	98.2
14	116	98.2
15	111	98.3

Table 25. Glucose Reading Capture Rate Over Wear Duration (Pediatric; n=142)

Day of Wear	Number of Sensors	Capture Rate (%)
1	141	96.9
2	138	96.5
3	135	97.1
4	137	96.6
5	137	96.9
6	129	96.9

7	127	97.0
8	122	96.8
9	118	96.6
10	118	96.6
11	112	96.5
12	111	96.4
13	109	96.3
14	101	96.3
15	101	96.1

Precision

Precision of the System was evaluated by comparing the glucose readings from two separate Sensors worn on the same subject at the same time. Table 26 provides data from 148 adult participants and 136 pediatric participants. For adults, the paired absolute relative difference (PARD) between the two Sensors was 8.0% with coefficient of variation (CV) of 5.6%. For children ages 6-17, PARD was 8.6% with CV of 6.1%. For children ages 2-5, PARD was 6.5% with CV of 4.6%. Paired absolute difference (PAD) is a measurement of absolute difference (in mg/dL) between paired CGM readings, while PARD is the absolute relative difference (in %) between paired CGM readings.

Table 26. Overall between Sensor Precision

	Coefficient of Variation (%)	Paired Absolute Difference (mg/dL)	Paired Absolute Relative Difference (%)	Number of Paired Readings
Adults ages 18+	5.6	12.3	8.0	25029
Children ages 6-17	6.1	13.8	8.6	10945
Children ages 2-5	4.6	10.5	6.5	428

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%).

Vitamin C Interference (Libre 2 Plus Sensor)

Taking more than 1000 mg of Vitamin C per day may falsely raise your Sensor readings, which could cause you to miss a severe low glucose event. Vitamin C can be found in supplements including multivitamins and cold remedies such as Airborne® and Emergen-C®. See your health care professional to understand how long Vitamin C is active

in your body.

Additional Notes for Health Care Professionals

While using the Libre 2 Sensor, ascorbic acid (Vitamin C) doses of larger than 500 mg per day can affect the Sensor readings, making them look higher than they really are. While using the Libre 2 Plus Sensor, users can take up to 1000 mg of ascorbic acid per day and can still use the Sensor readings to make treatment decisions.

A clinical study was conducted to evaluate the effect of ascorbic acid on the performance of the Libre 2 Plus Sensor. Data from 60 adult subjects with diabetes was collected over a 13-hour period. Each subject had a one-hour baseline phase where venous blood was collected every 10 minutes. After this first hour, a dose of 1000 mg ascorbic acid was given with a meal and venous samples were collected every 15 minutes for the next 12 hours. A maximum average Sensor bias of +5.1 mg/dL was observed around 2 hours after the 1000 mg ascorbic acid dose. Subjects then received a second dose of 1000 mg ascorbic acid with a meal and the same process was continued for another 4 hours. A third dose of 1000 mg ascorbic acid was then given, and study subjects were followed for 4 more hours. After the second dose of ascorbic acid the maximum average Sensor bias increased, with minimal change in Sensor bias after the third dose, suggesting that saturation had occurred by the second 1000 mg dose of ascorbic acid. The maximum average Sensor bias after the three 1000 mg doses of ascorbic acid was +9.2 mg/dL.

Sensor Insertion Experience

Clinical study subjects were asked to complete a survey about their experience inserting the Sensor. Survey results were as follows:

- 98.3% said their Sensor insertions were easy (strongly agree or agree). (n=293)
- 99.2% said their Sensor insertions were painless (no, slight, or mild pain). (n=242)

Electromagnetic Compatibility (EMC)

Libre 2 Sensor and Libre 2 Plus Sensor - FCC ID: QXS-LIB02S or QXS-LIB02S2

Please see the Sensor kit carton for the assigned FCC ID for your product.

- 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 Sensor 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.
- The Sensor complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) The Sensor may not cause harmful interference, and (2) the Sensor must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not approved by Abbott could void the user's authority to operate the equipment.

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

Compliance level: ±8 kV 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

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

IEC 60601 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 any part of the Sensor. Otherwise, degradation of the performance of the Sensor could result.

The table below lists the immunity 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 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.

Labeling Symbols


Consult instructions for use


Temperature limit


Humidity limitation


Manufacturer

Batch code


Type BF applied part

CODE	Sensor code
	Do not re-use
	MR conditional
	Use-by date
REF	Catalog number
SN	Serial number
STERILE R	Sterilized by irradiation
	Do not use if package is damaged
$R_{X\ Only}$	**CAUTION:** Federal law restricts this device to sale by or on the order of a physician.

This product contains electronic equipment, batteries, sharps and materials that may contact bodily fluids during use.

Dispose of product in accordance with all applicable local regulations.

Patent: www.abbott.com/patents

Manufacturer:

Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502 USA

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Abbott