User's Manual

FreeStyle Libre 3

CONTINUOUS GLUCOSE MONITORING SYSTEM

For use with
FreeStyle Libre 3 Sensor and
FreeStyle Libre 3 Plus Sensor

FreeStyle Libre 3 app

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

Abbott

Your Name _____

WARNING:

Before you use the FreeStyle Libre 3 System, review all the product instructions and the Interactive Tutorial. The Quick Reference Guide and Interactive Tutorial give you quick access to important aspects and limitations of the System. The User's Manual includes all safety information and instructions for use. Talk to your health care professional about how you should use your Sensor glucose information to help manage your diabetes.

Failure to use the System according to the instructions for use may result in you missing a severe low blood glucose or high blood glucose event and/or making a treatment decision that may result in injury. If your glucose alarms and readings from the System do not match symptoms or expectations, use a fingerstick blood glucose value from a blood glucose meter to make diabetes treatment decisions. Seek medical attention when appropriate.

Contents

Important Safety Information

You can use the FreeStyle Libre 3 System with either the FreeStyle Libre 3 Sensor or the FreeStyle Libre 3 Plus Sensor. The Indications for Use, Contraindications, Interfering Substance information, and Performance Characteristics are different between the two Sensors. Please reference the labeling content that applies to your Sensor. Make sure you have a FreeStyle Libre 3 Plus Sensor if you plan to connect with a compatible automated insulin dosing (AID) system.

FreeStyle Libre 3 Sensor

- 14 day wear duration
- Can be used by children age 4 and older
- Cannot be used with automated insulin dosing (AID) systems
- Taking more than 500 mg of Vitamin C per day may affect Sensor readings, which could cause you to miss a severe low glucose event

FreeStyle Libre 3 Plus Sensor

- 15 day wear duration
- Can be used by children 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, which could cause you to miss a severe low glucose event. You can take up to 1000 mg of Vitamin C per day and can still use the Sensor readings to make treatment decisions.

Online Labeling

The latest version of the User's Manual, including performance data, can always be accessed at www.FreeStyleLibre.us/support/overview.html
You can also order a free printed copy from Customer Service: 1-855-632-8658, 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

Indications For Use

FreeStyle Libre 3 Sensor users:

The FreeStyle Libre 3 Continuous Glucose Monitoring System is a real time continuous glucose monitoring (CGM) device with 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.

FreeStyle Libre 3 Plus Sensor users:

The FreeStyle Libre 3 Continuous Glucose Monitoring System is a real time continuous glucose monitoring (CGM) device with 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.

Compatible Devices, Apps, and Software

For a list of compatible devices, apps, and software that can be used with your Sensor, please go to: www.FreeStyleLibre.us/support/overview.html

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

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

If available, Abbott authorized Reader firmware updates will be made accessible through www.FreeStyleLibre.com.

Contraindications

MRI/CT/Diathermy: The System must be removed prior to Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The effect of MRI, CT scans, or diathermy on the performance of the System has not been evaluated. The exposure may damage the Sensor and may impact proper function of the device which could cause incorrect readings.

Automated Insulin Dosing: The FreeStyle Libre 3 Sensor must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems.

WARNINGS:

- **Do not ignore symptoms that may be due to low or high blood glucose:** If you are experiencing symptoms that are not consistent with your glucose readings, consult your health care professional.
- Use your blood glucose meter to make diabetes treatment decisions when you see the  symbol during the first 12 hours of wearing a Sensor, if your Sensor glucose reading does not match how you feel, or if the reading does not include a number.
- If you are using FreeStyle Libre 3 app, you must have access to a blood glucose monitoring system as the App does not provide one.
- **Choking hazard:** The System contains small parts that may be dangerous if swallowed.

Cautions and Limitations

The following are important cautions and limitations to keep in mind so you can use the System safely. They are grouped into categories for easy reference.

What to know about Reader Alarms:

- For you to receive alarms, they must be on and your Reader should be within 33 feet of you at all times. The transmission range is 33 feet unobstructed. If you are out of range, you may not receive glucose alarms.
- To prevent missed alarms, make sure the Reader has sufficient charge and that sound and/or vibration are turned on.

What to know about App Alarms:

- Disable your phone's automatic operating system (OS) updates. Prior to updating your phone's OS or updating the App, you should check the Mobile Device and OS Compatibility Guide to determine if the FreeStyle Libre 3 app is compatible with your OS and your phone. The OS Compatibility Guide is available in the Help Section of the App or on www.FreeStyleLibre.com. You should check the OS Compatibility Guide periodically to make sure that your OS and your phone continue to be compatible with the App.

- In the event that an App or OS update causes your previously compatible phone to become incompatible, you may be notified ahead of time via e-mail or through the App. Make sure that your LibreView account has your current e-mail address to receive important information.
- After an OS update, open your App and check your device settings to make sure it's working properly. Some OS features may impact your ability to receive alarms or glucose readings. For example, if you use an iPhone and the iOS Screen Time feature, add the FreeStyle Libre 3 app to the list of Always Allowed apps to ensure that you receive alarms or if you use an Android Phone do not use the Android Digital Wellbeing app.
- For you to receive alarms, your phone should be within 33 feet of you at all times. The transmission range is 33 feet unobstructed. If you are out of range, you may not receive alarms. If you want to receive the App's optional alarms, make sure these are turned on.
- For iPhone, do not force close the App. The App must be running in the background to receive alarms. If you force close the App you will not receive alarms. Re-open the App to ensure you will receive alarms.
- If you restart your phone, open your App to make sure it’s working properly.

- The App will ask for phone permissions which are needed to receive alarms. Allow these permissions when requested.
- Your phone must have a Bluetooth connection with your Sensor to receive glucose readings and glucose alarms. In the phone settings, keep Bluetooth **ON**. For iPhones, in the phone settings for the App, allow the App to access Bluetooth.
- Check to make sure that you have the correct phone settings and permissions enabled. If your phone is not configured properly, you will not be able to use the App, so you will not receive alarms or be able to check your glucose.
  - **iPhones:** In the phone settings for the App under Notifications, keep Allow Critical Alerts **ON**
  - **Android Phones:** In the phone settings for the App, keep Do Not Disturb Access permission **ON**
- If your phone is not configured correctly, the App will be in "Alarms Unavailable" state and you will not be able to check your glucose or receive any alarms, including the Urgent Low Glucose Alarm.
- To turn on Critical Alerts (iPhone) / Do Not Disturb Permission (Android Phone), follow the instructions in the App.
- For Android Phones, you may need to add the FreeStyle Libre 3 app to the list of apps that will not be restricted or put to sleep.

- If you adjust the phone ringer volume (iPhone) or Media volume (Android Phone) 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.
- You should disconnect headphones or speakers from your phone when you are not using them as you may not hear audio for alarms. If using headphones, keep them in your ears.
- If you are using peripheral devices connected to your phone, such as wireless headphones or a smartwatch, you may receive alarms on only one device or peripheral, not all.
- Keep your phone well charged and turned on.

What to know before using the System:

- Review all product information before use.
- Take standard precautions for transmission of blood borne pathogens to avoid contamination.
- Make sure that your devices and Sensor kits are kept in a safe place, and maintain your devices under your control during use. This is important to help prevent anyone from accessing or tampering with the System.

Who should not use the System:

- **Do not use the System in people under the age specified in the Indications for Use.** The System is not cleared for use in people under this age.
- **Do not use the System if you are on dialysis or critically ill.** The System is not cleared for use in these groups and it is not known how different conditions or medications common to these populations may affect performance of the System.
- Performance of the System when used with other implanted medical devices, such as pacemakers, has not been evaluated.

What should you know about wearing a Sensor:

- Wash application site on the back of your upper arm using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the Sensor from sticking properly. Allow site to air dry before proceeding. Carefully preparing the site according to these instructions will help the Sensor stay on your body for the full wear duration specified by your Sensor insert and help prevent it from falling off early.

- The Sensor can be worn for up to the wear duration specified by your Sensor insert. Remember to always have your next Sensor available before your current one ends so you can keep getting your glucose readings.
- In the event that your Sensor stops working and you do not have another Sensor readily available, you must use an alternate method to measure your glucose levels and inform your treatment decisions.
- The System is designed to detect certain conditions which may occur where the Sensor is not working as intended and shut it off, telling you to replace your Sensor. This may occur if the Sensor gets knocked off from the skin or if the System detects that the Sensor may not be performing as intended. Contact Customer Service if you receive a Replace Sensor message before the end of the wear duration specified by your Sensor insert. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

- Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If you notice significant skin irritation around or under your Sensor, remove the Sensor and stop using the System. Contact your health care professional before continuing to use the System.
- Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. If the Sensor is becoming loose or if the Sensor tip is coming out of your skin, you may get no readings or unreliable low readings. Remove and replace your Sensor if it starts to loosen and follow the instructions to select an appropriate application site. Do not attempt to reinsert the Sensor. Contact Customer Service if your Sensor becomes loose or falls off before the end of the wear period. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.
- Do not reuse Sensors. The Sensor and Sensor Applicator are designed for single use. Reuse may result in no glucose readings and infection. Not suitable for re-sterilization. Further exposure to irradiation may cause unreliable low results.
- If a Sensor breaks inside your body, call your health care professional.

How to Store the Sensor Kit:

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

How to Store the Reader:

- Store the Reader between -4°F and 140°F. Storage in temperatures outside of this range, such as in a parked car on a hot day, may cause the Reader to not function properly.

When not to use the System:

- Do NOT use if the Sensor Kit package or Sensor Applicator appear to be damaged or if tamper label indicates Sensor Applicator has already been opened due to risk of no results and/or infection.
- Do NOT use if Sensor Kit contents are past expiration date.
- Do NOT use if the Reader appears to be damaged due to risk of electric shock and/or no results.

What to know about the System:

- The FreeStyle Libre 3 System is intended for use by a single person. It must not be used by more than one person due to the risk of misinterpreting glucose information.
- FreeStyle Libre 3 app and FreeStyle Libre 3 Readers do not share data. 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.

What to know before you Apply the Sensor:

- Wash application site on the back of your upper arm using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the Sensor from sticking properly. Allow site to air dry before proceeding. Carefully preparing the site according to these instructions will help the Sensor stay on your body for the full wear duration specified by your Sensor insert and help prevent it from falling off early.
- Clean hands prior to Sensor handling/insertion to help prevent infection.
- Change the application site for the next Sensor application to prevent discomfort or skin irritation.

- Only apply the Sensor to the back of the upper arm. If placed in other areas, the Sensor may not function properly.
- Select an appropriate Sensor site to help the Sensor stay attached to the body and prevent discomfort or skin irritation. Avoid areas with scars, moles, stretch marks, or lumps. Select an area of skin that generally stays flat during normal daily activities (no bending or folding). Choose a site that is at least 1 inch away from an insulin injection site.

When is Sensor Glucose different from Blood Glucose:

- Physiological differences between the interstitial fluid and capillary blood may result in differences in glucose readings between the System and results from a fingerstick test using a blood glucose meter. Differences in glucose readings between interstitial fluid and capillary blood may be observed during times of rapid change in blood glucose, such as after eating, dosing insulin, or exercising.

What to know about X-Rays:

- The Sensor should be removed prior to exposing it to an X-ray machine. The effect of X-rays on the performance of the System has not been evaluated. The exposure may damage the Sensor and may impact proper function of the device to detect trends and track patterns in glucose values during the wear period.

When to remove the Sensor:

- If the Sensor is becoming loose or if the Sensor tip is coming out of your skin, you may get no readings or unreliable readings, which may not match how you feel. Check to make sure your Sensor has not come loose. If it has come loose, remove it, apply a new one, and contact Customer Service.
- If you believe your glucose readings are not correct or are inconsistent with how you feel, perform a blood glucose test on your finger to confirm your glucose. If the problem continues, remove the current Sensor, apply a new one, and contact Customer Service. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

What to know about the Reader:

- Do NOT place the Reader in water or other liquids as this may cause it to not function properly and may lead to **risk of fire or burns**.
- The FreeStyle Libre 3 Reader has a built-in blood glucose meter that is designed to be used only with FreeStyle Precision Neo blood glucose test strips and MediSense Glucose and Ketone Control Solution. Using other test strips with the Reader's built-in meter will produce an error or cause the Reader's built-in meter to not turn on or start a test. The Reader's built-in meter does not have ketone testing functionality.
- The Reader's built-in meter is not for use on people who are dehydrated,

hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.

- The Reader's built-in meter is not for use on neonates, in critically-ill patients, or for diagnosis or screening of diabetes.
- See *Using the Reader's Built-in Meter* section for additional important information on the use of the Reader's built-in meter.

What to know about charging your Reader:

- Always use the Abbott provided power adapter and yellow USB cable that came with your Reader to minimize the **risk of fire or burns**. Take care when plugging and unplugging your USB cable. Do not force or bend the end of the USB cable into the Reader's USB port.
- Choose a location for charging where you can easily access the power adapter and quickly disconnect to prevent the potential risk of electrical shock.
- The maximum surface temperature of the Reader could go as warm as 117°F. The maximum surface temperature of the power adapter when charging could go as warm as 129°F. Under these conditions, do not hold the Reader or the power adapter for five minutes or more. People with disorders of peripheral circulation or sensation should use caution at this temperature.
- Do NOT expose the USB cable or power adapter to water or other liquids as this may cause them to not function properly and may lead to **risk of fire or burns**.

Interfering Substances

FreeStyle Libre 3 Sensor users:

Taking ascorbic acid (Vitamin C) supplements while wearing the Sensor may falsely raise Sensor glucose readings. Taking more than 500 mg of ascorbic acid per day may affect the Sensor readings which could cause you to miss a severe low glucose event. Ascorbic acid 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 ascorbic acid and should not be taken while using the Sensor. See your health care professional to understand how long ascorbic acid is active in your body.

FreeStyle Libre 3 Plus Sensor users:

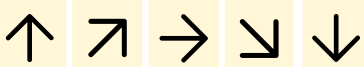
Taking more than 1000 mg of Vitamin C per day may falsely raise your Sensor readings, which could cause you to miss a severe low glucose event. Vitamin C can be found in supplements including multivitamins and cold remedies such as Airborne® and Emergen-C®. See your health care professional to understand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

Reader Symbols

Symbol	What It Means
	Active Sensor
	Direction your glucose is going. See *Understanding Your Glucose Readings* section for more information.
	Caution
	View previous/next screen
	Sound and Vibration **ON**
	Sound **ON**, Vibration **OFF**
	Sound **OFF**, Vibration **ON**
	Sound and Vibration **OFF**
	Sensor communicating with Reader
	Sensor not communicating with Reader

Symbol	What It Means
	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.
	Notes
	Add more information to notes
	Food note
	Insulin note
	Time changed on Reader
	Blood glucose test
	Settings
	Control solution test result
	Low battery
	Battery charging
	Sensor too cold
	Sensor too hot

App Symbols

Symbol	What It Means
	App icon
	Alarms are unavailable
	Scan New Sensor / Start New Sensor
	Direction your glucose is going. See *Understanding Your Glucose Readings* section 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

Symbol	What It Means
	Insulin (Rapid or Long-acting) note
	Alarm
	Exercise note
	Time change
	Main Menu
	Multiple/Custom notes
	Share report (Android Phone)
	Share report (iPhone)
	Additional information
	Calendar
	Sensor too cold
	Sensor too hot

Getting to Know Your System

The FreeStyle Libre 3 System ("System") has two main parts: a disposable Sensor and either a handheld Reader or mobile App to wirelessly receive and display your glucose readings from the Sensor. Before you start your Sensor, choose which device you want to use. The Reader and App only work with FreeStyle Libre 3 Sensor and FreeStyle Libre 3 Plus Sensor and cannot be used with other Sensors. When they're in range, the Sensor and your device automatically communicate to give you glucose alarms. These alarms are on by default.

Note: The FreeStyle Libre 3 Reader and App only work with the FreeStyle Libre 3 Sensor and FreeStyle Libre 3 Plus Sensor and cannot be used with other Sensors.

When the Sensor and your device are not in range or unable to communicate, the Sensor will store all glucose data up to the wear duration specified by your Sensor insert. This data is automatically sent from the Sensor to your device when the devices are back within range.

IMPORTANT:

- Before you use your System, review all the product instructions and the Interactive Tutorial. You can access the Interactive Tutorial at www.FreeStyleLibre.com. The Quick Reference Guide and Interactive Tutorial give you quick access to important aspects and limitations of the System. The User's Manual includes all safety information and instructions for use. Refer to your phone instructions for use for how to use your phone.
- Go to www.FreeStyleLibre.com to view the "Tips for Kids".
- Talk to your health care professional about how you should 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.

When opening your Sensor Kit and Reader Kit, check that the contents are undamaged and that you have all parts listed. If any parts are missing or damaged, contact Customer Service. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays. FreeStyle Libre 3 app is available for download from the App Store (iPhone) or Google Play Store (Android Phone).

Sensor Kit

The Sensor Kit includes:

- Sensor Applicator
- Product insert

Sensor Applicator
Applies the Sensor to your body.

The Sensor (only visible after applied) measures and stores glucose readings when worn on your body. By following the instructions, you use the Sensor Applicator to apply the Sensor on the back of your upper arm. The Sensor has a small, flexible tip that is inserted just under the skin. The Sensor can be worn for up to the wear duration specified by your Sensor insert.

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

Reader Kit

The Reader Kit includes:

- FreeStyle Libre 3 Reader
- Yellow USB Cable
- Interactive Tutorial on USB
- Power Adapter
- User's Manual
- Quick Start Guides for Reader & App
- Quick Reference Guide

Touchscreen

USB Port

Used to charge the Reader and connect it to a computer.

Home Button

Turns the Reader on/off and takes you to the Home Screen from any other screen.

Test Strip Port

Insert a test strip here to use the built-in meter.

Yellow USB Cable

Power Adapter

5V, 550mA or 0.55A

The Reader can be used to start a Sensor, receive glucose alarms, and get glucose readings from the Sensor. The Reader can store approximately 90-days of glucose history and notes you enter about activities, such as taking insulin, eating food, or exercising. This information can help you understand how these activities affect your glucose. The Reader also includes a built-in meter for blood glucose testing. To use the built-in meter, you need FreeStyle Precision Neo blood glucose test strips, control solution, a lancing device, and lancets. These items are not included in the Reader Kit and must be obtained separately from your FreeStyle Libre 3 System provider (pharmacy or mail order supplier). If you suspect an adverse cybersecurity event related to the FreeStyle Libre 3 System, contact Customer Service.

IMPORTANT:

- If the Reader is dropped or subjected to impact, do a Reader Test to check that it is still working properly. See *Perform a Reader Test* section for instructions.
- If the Reader becomes too hot to hold, do NOT use and contact Customer Service about replacing your Reader, yellow USB cable, and power adapter. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

FreeStyle Libre 3 app

You can use the App to start a Sensor, receive glucose alarms, get glucose readings from the Sensor, and store your glucose history and notes you enter.

FreeStyle Libre 3 iOS app is available for download from the App Store.

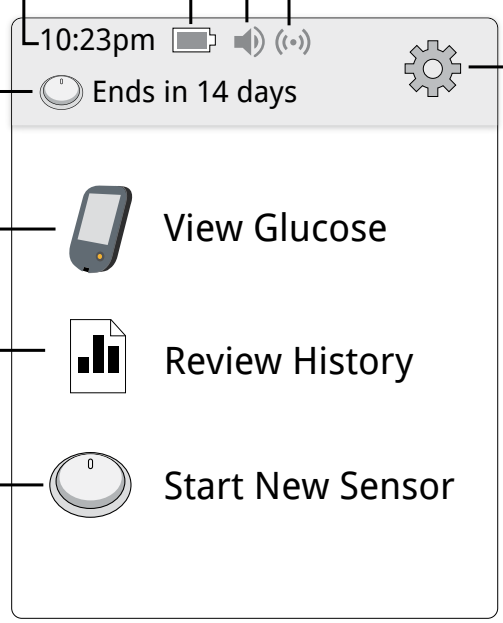
FreeStyle Libre 3 Android app is available for download from Google Play Store.

The App is not compatible with all phones. Before upgrading your phone or its operating system, check www.FreeStyleLibre.com.

- You must keep Critical Alerts (iPhone) / Do Not Disturb Permission (Android Phone) and Bluetooth on. If these settings are turned off, you will not be able to use the App, so you will not receive alarms or be able to check your glucose.
- You are responsible for properly securing and managing your phone. If you suspect an adverse cybersecurity event related to the FreeStyle Libre 3 System, contact Customer Service.
- FreeStyle Libre 3 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.

Reader Home Screen

The Reader Home Screen provides access to information about your glucose and the System. You can press the Home Button to get to the Home Screen.



Current time set on the Reader

Battery charge remaining

Sound/Vibration setting

Sensor Status

Information about your current Sensor.

Signal Status

Shows if Sensor is communicating with Reader.

View Glucose

Touch to view your Sensor glucose.

Settings

Touch to access Alarms, Reminders, and other Reader settings.

Review History

Touch to review information about your past glucose readings.

Start New Sensor

Touch to start a new Sensor.

App Home Screen

The App Home Screen displays your current glucose, glucose trend arrow, and glucose graph. It is automatically updated every minute with glucose data from the Sensor.

Main Menu

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

Alarms Unavailable

The symbol displays if alarms are not available. Tap the symbol for more information.

Current Glucose

Your most recent glucose value.

Glucose Graph

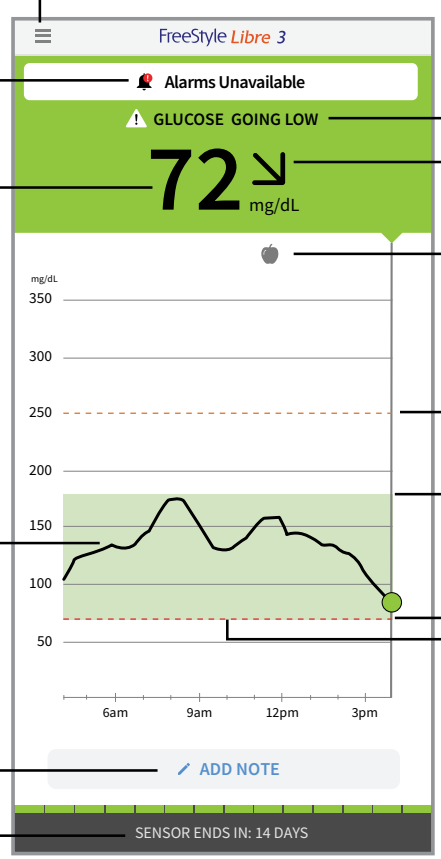
Graph of your current and stored glucose readings.

Add Note

Tap to add notes to the glucose reading.

Sensor Life

Remaining life time of Sensor.



Message

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

Glucose Trend Arrow

Direction your glucose is going.

Note Symbol

Tap to review notes you've entered.

High Glucose Alarm Level

Your High Glucose Alarm level.

Target Glucose Range

The graph shows your target glucose range. This is not related to glucose alarm levels.

Low Glucose Alarm Level

Your Low Glucose Alarm level.

(Example screen displayed for iPhone)

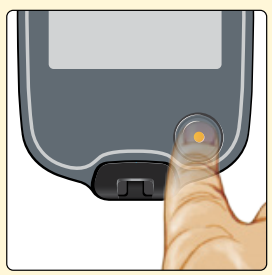
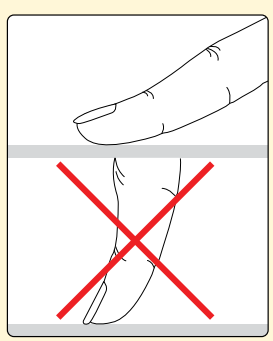
Reporting Software

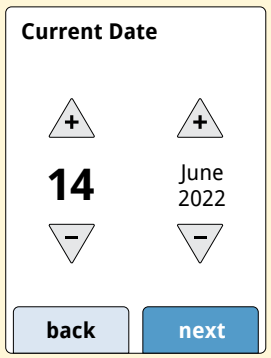
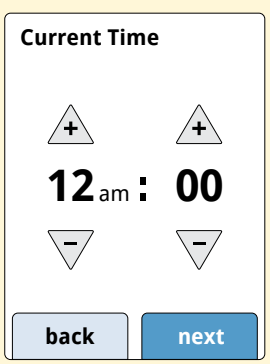
Software can be used to create reports based on glucose readings. Go to www.FreeStyleLibre.com and follow onscreen instructions to download and install the compatible software. You are responsible for keeping your computer secure and up to date, for example by using anti-virus software and installing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

Setting up Your System for the First Time

Reader Setup

Complete the setup if you want to use the Reader with the Sensor or use the Reader's built-in meter.

Step	Action
1	 Press the Home Button to turn on the Reader.
2	 If prompted, use the touchscreen to select your preferred language for the Reader. Touch **OK** to continue. **Note:** Use the pad of your finger. Do NOT use your fingernail or any other object on the screen.

Step	Action
3	 Set the **Current Date** using the arrows on the touchscreen. Touch **next** to continue.
4	 Set the **Current Time**. Touch **next** to continue. **CAUTION:** It is very important to set the time and date correctly. These values affect the Reader data and settings.

Step	Action
5	The Reader now displays important information about key topics to help you use the System. Touch **next** after reviewing each screen. Touch **done** to go to the Home Screen.

App Setup

Complete the setup if you want to use the App with the Sensor.

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

Step	Action
1	Check that your phone is connected to a network (WiFi or cellular). You can then install FreeStyle Libre 3 app from the App Store (iPhone) or Google Play Store (Android Phone). Tap the App icon to open the App. **Note:** You only need to be connected to a network for setup, using LibreView, and sharing with other authorized apps through the Connected Apps menu option within the FreeStyle Libre 3 app. You do not need to be connected to get glucose data from a Sensor, add notes, or review your history in the App.
2	Swipe left to view some helpful tips or tap **GET STARTED NOW** at any point.

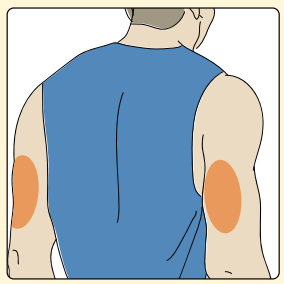
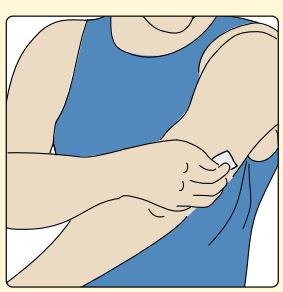
Step	Action
3	Confirm phone and OS compatibility and tap **NEXT**.
4	Confirm your country and tap **NEXT**.
5	You may need a LibreView account to use the App. Follow onscreen instructions to review legal information, phone warnings, and create a new account or login to your existing account. You can continue using an existing Sensor with the App on a compatible phone that is logged into the same LibreView account.

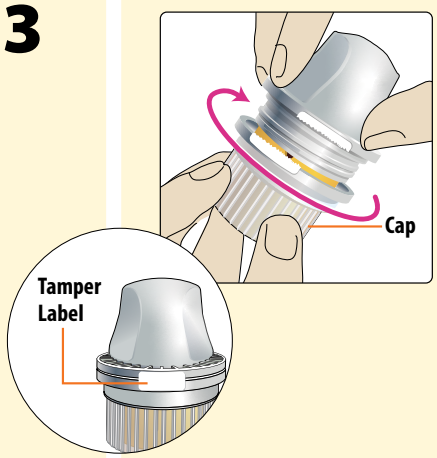
Step	Action
6	Confirm your glucose unit of measure and tap **NEXT**.
7	Select how you count carbohydrates (in grams or servings) and tap **NEXT**. The carbohydrate unit will be used in any food notes you enter in the App.
8	The App now displays some important information. Accept the requested permissions. Tap **NEXT** after reviewing each screen.
9	Apply a new Sensor and then tap **NEXT**. Go to *Starting Your Sensor* section. **Note:** If you need help applying your Sensor, tap **HOW TO APPLY A SENSOR** or go to *Applying Your Sensor* section.

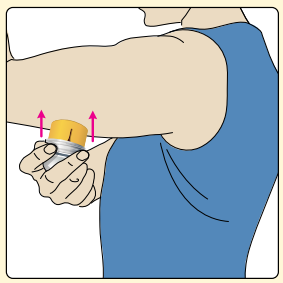
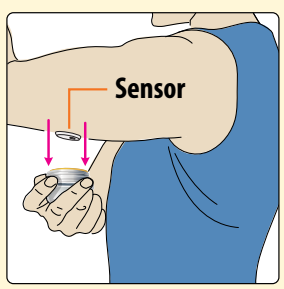
Applying Your Sensor

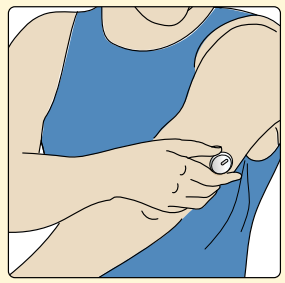
CAUTION: Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. If the Sensor is becoming loose or if the Sensor tip is coming out of your skin, you may get no readings or unreliable low readings. Remove and replace your Sensor if it starts to loosen and follow the instructions to select an appropriate application site. Do not attempt to reinsert the Sensor. Contact Customer Service if your Sensor becomes loose or falls off before the end of the wear period. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

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

Step	Action
1	 Apply Sensors only on the back of your upper arm. If placed in other areas, the Sensor may not function properly and could give you inaccurate readings. Avoid areas with scars, moles, stretch marks, or lumps. Select an area of skin that generally stays flat during your normal daily activities (no bending or folding). Choose a site that is at least 1 inch (2.5 cm) away from an insulin injection site. To prevent discomfort or skin irritation, you should select a different site other than the one most recently used.
2	 Wash application site using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the Sensor from sticking properly. Allow site to air dry before proceeding. **Note:** The area **MUST** be clean and dry following these instructions, or the Sensor may not stay on for the full wear duration specified by your Sensor insert.

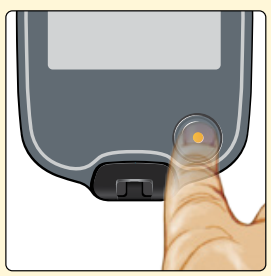
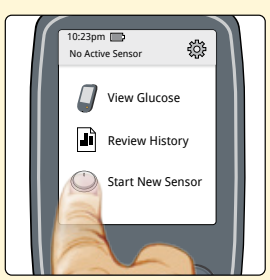
Step	Action
3	 Unscrew the cap from the Sensor Applicator and set the cap aside. **CAUTION:** • Do NOT use if the Sensor Kit package or Sensor Applicator appear to be damaged or tamper label indicates Sensor Applicator has already been opened. • Do NOT put cap back on as it may damage the Sensor. • Do NOT touch inside Sensor Applicator as it contains a needle.

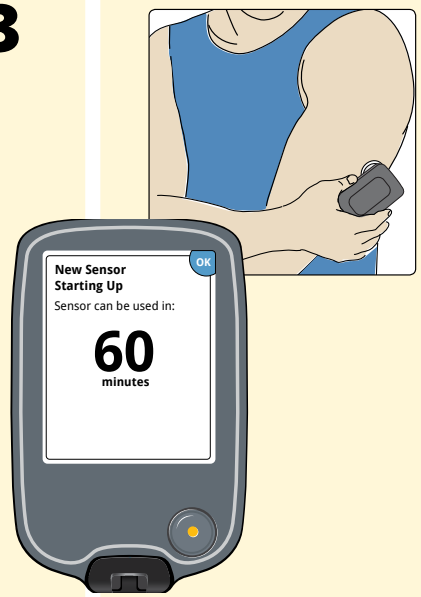
Step	Action
4	 Place the Sensor Applicator over the prepared site and push down firmly to apply the Sensor to your body. **CAUTION:** Do NOT push down on the Sensor Applicator until placed over prepared site to prevent unintended results or injury.
5	 Gently pull the Sensor Applicator away from your body. The Sensor should now be attached to your skin. **Note:** Applying the Sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the Sensor and contact your health care professional.

Step	Action
6	 Make sure the Sensor is secure after application. Put the cap back on the Sensor Applicator. Discard the used Sensor Applicator according to local regulations. **Note:** If using the App, you can tap **Help** in the Main Menu to access an in-app tutorial on applying a Sensor.

Starting Your Sensor with the Reader

Before you start your Sensor, choose which device you want to use. If you start the Sensor with the Reader, you will be unable to use the App to check your glucose or receive alarms.

Step	Action
1	 Press the Home Button to turn on the Reader.
2	 Touch **Start New Sensor**.

Step	Action
3	 Hold the Reader near the Sensor to scan it. This starts your Sensor. If sounds are turned on, the Reader beeps when the Sensor has been successfully activated. The Sensor can be used to check your glucose after 60 minutes. **Note:** If the Sensor is not successfully scanned within 15 seconds, the Reader displays a prompt to scan the Sensor again. Touch **OK** to return to the Home Screen and touch **Start New Sensor** to scan your Sensor.

Starting Your Sensor with the App

Before you start your Sensor, choose which device you want to use. If you start the Sensor with the App, you will be unable to use the Reader to check your glucose or receive alarms.

IMPORTANT:

- The App requires that your phone has date and time enabled to set automatically. You can check this in your phone settings. Manual changes to your phone's time and date setting can lead to incorrect time stamp or inability to use the App.
- When using the App, you should keep your phone well charged and be sure you have access to a blood glucose monitoring system.
- When you start your Sensor, you will receive a tone and vibration. If your phone's volume is turned off, you will not hear the tone.

- **iPhone Users:** The NFC (Near Field Communication) antenna is on the top edge of iPhone. Hold this area near your Sensor when you are scanning. You may need to adjust your scan distance based on what clothing you are wearing. In addition to proximity and orientation, other factors can affect NFC performance. For example, a bulky or metallic case can interfere with the NFC signal. Keep in mind that the ease of scanning a Sensor may vary between phone models.
- **Android Phone Users:** The NFC (Near Field Communication) antenna is located on the back side of most Android Phones. Move your phone around slowly and, if needed, gently touch the Sensor. 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 phone models.
- Please check www.FreeStyleLibre.com for more information about device compatibility and the location of the NFC antenna on your phone.

iPhone Users

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

Step	Action
3	The Sensor can be used to check your glucose after 60 minutes. While the Sensor is starting up, you can navigate away from the App. If notifications are enabled, you will see a notification when the Sensor is ready. **Note:** If you have an active Sensor and want to start a new Sensor, go to the Menu and tap **Start New Sensor** .

Android Phone Users

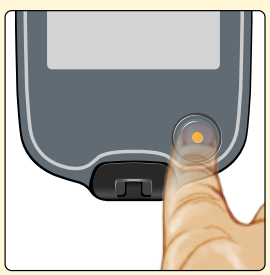
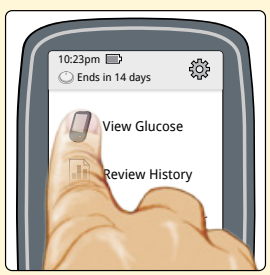
Step	Action
1	From the App Home Screen, scan the Sensor with the BACK of your phone to start it. You will receive a tone and vibration after you have successfully started the Sensor. If your phone's volume is turned off, you will not hear the tone. **Note:** Each phone model is different. Touch the Sensor with your phone or move your phone around slowly until you learn how to scan.

Step	Action
2	The Sensor can be used to check your glucose after 60 minutes. While the Sensor is starting up, you can navigate away from the App. You will see a notification when the Sensor is ready. **Note:** If you have an active Sensor and want to start a new Sensor, go to the Menu and tap **Start New Sensor** .

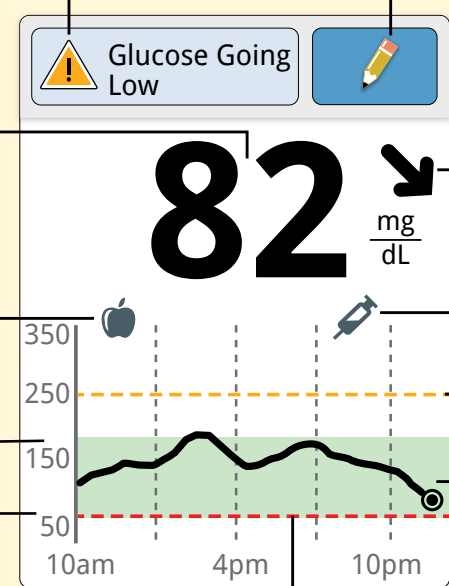
Note:

- If you need help, tap **HOW TO SCAN A SENSOR** to view an in-app tutorial. You can also access this later by going to the Main Menu and then tapping **Help**.
- If your Sensor is not successfully scanned, you may receive a Scan Error message. Follow the instructions in the message.
- See *Troubleshooting* section for additional error messages.

Checking Your Glucose with the Reader

Step	Action
1	 ***OR***  Turn the Reader on by pressing the Home Button or touch **View Glucose** from the Home Screen.
2	The Reader displays your current glucose reading. It includes your Current Glucose, a Glucose Trend Arrow indicating which way your glucose is going, and a graph of your current and stored glucose readings.

Step	Action
2 ***(cont.)***	



Message
Touch for more information.

Add Notes
Touch to add notes to the glucose reading.

Current Glucose
Your most recent glucose value.

Glucose Trend Arrow
Direction your glucose is going.

Food Note

Insulin Note

High Glucose Alarm Level

Target Glucose Range
Your Target Glucose Range is not related to your glucose alarm settings.

Glucose Graph
Graph of your current and stored glucose readings.

Low Glucose Alarm Level

Note:

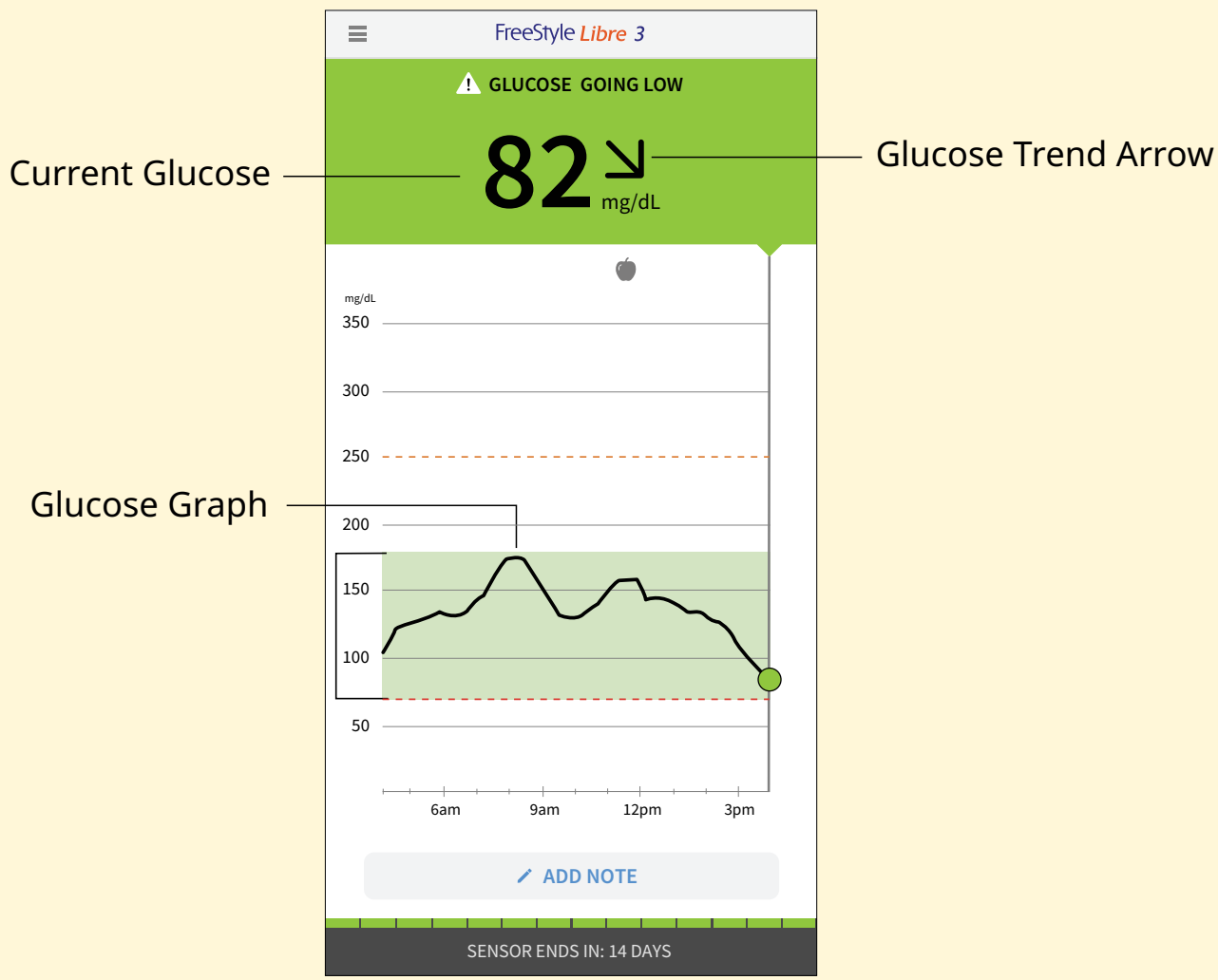
- The graph displays glucose readings above 350 mg/dL as 350 mg/dL. For sequential readings above 350 mg/dL, a line is displayed at 350 mg/dL. The Current Glucose number can be as high as 400 mg/dL.

Step	Action
2 ***(cont.)***	• The 🕒 symbol may appear, indicating the Reader time was changed. Gaps in the graph may result or glucose readings may be hidden. • All available glucose data is used to make your graph so you can expect to see some differences between the graph line and previous current glucose readings. • Results screen will not automatically update even if new data has arrived. Return to the Home Screen by pressing the Home Button and then touch **View Glucose** to update the results screen.

Checking Your Glucose with the App

Step	Action
1	Open the App.

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



(Example screen displayed for iPhone)

Step	Action
2 ***(cont.)***	**Current Glucose -** Your most recent glucose value. **Glucose Trend Arrow -** Direction your glucose is going. **Glucose Graph -** Graph of your current and stored glucose readings. **Note:** • The graph displays glucose readings above 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. • The  symbol may appear, indicating the phone's time was changed. • All available glucose data is used to make your graph so you can expect to see some differences between the graph line and previous current glucose readings.

- Your current glucose value determines the background color on the Home Screen:

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)

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

Understanding Your Glucose Readings

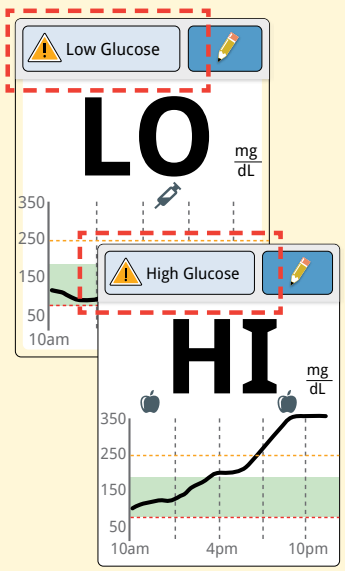
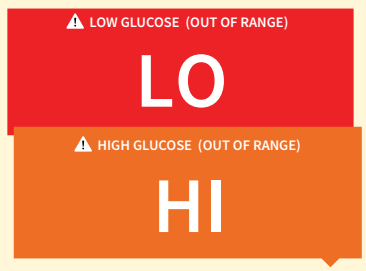
Glucose Trend Arrow

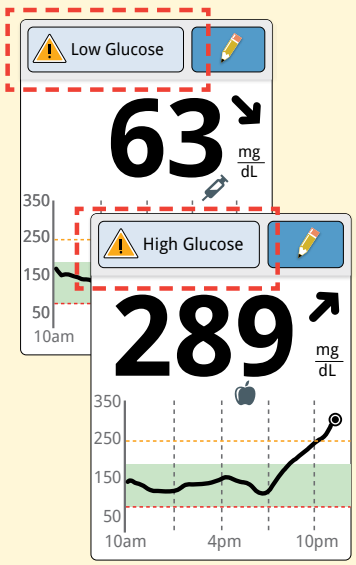
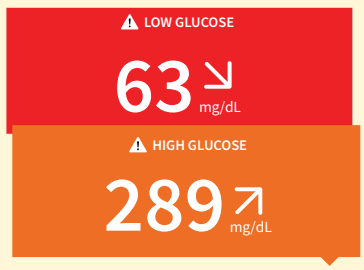
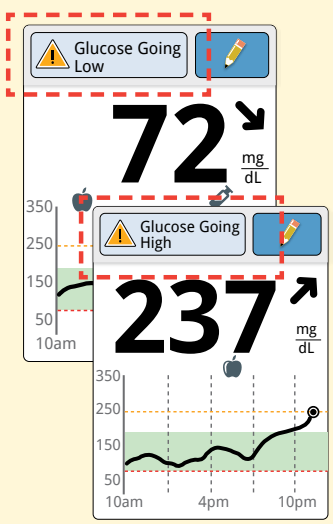
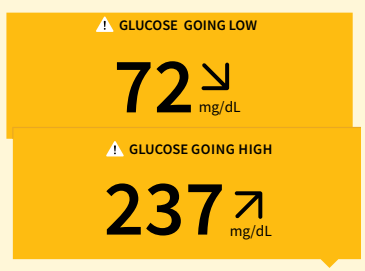
The Glucose Trend Arrow gives you an indication of the direction your glucose is going.

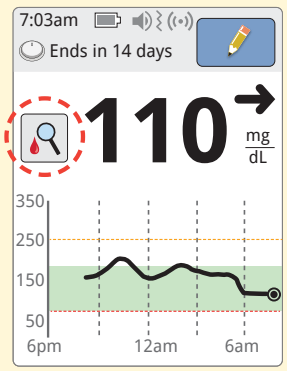
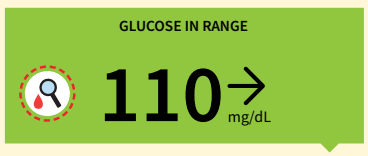
	**Glucose is rising quickly** (more than 2 mg/dL per minute)
	**Glucose is rising** (between 1 and 2 mg/dL per minute)
	**Glucose is changing slowly** (less than 1 mg/dL per minute)
	**Glucose is falling** (between 1 and 2 mg/dL per minute)
	**Glucose is falling quickly** (more than 2 mg/dL per minute)

Messages

Below are messages you may see with your glucose readings.

Reader Display	App Display	What To Do
		If **LO** appears, your reading is lower than 40 mg/dL. If **HI** appears, your reading is higher than 400 mg/dL. You can tap the ⚠ symbol for more information. Check your blood glucose on your finger with a test strip. If you get a second **LO** or **HI** result after doing a blood glucose test, contact your health care professional **immediately**. **Note:** In the App, the background color corresponds to your current glucose value.

Reader Display	App Display	What To Do
		If your glucose is higher than 250 mg/dL or lower than 70 mg/dL, you will see a message on the screen. You can tap the ⚠ symbol for more information and set a reminder to check your glucose.
		If your glucose is projected to be higher than 250 mg/dL or lower than 70 mg/dL within 15 minutes, you will see a message on the screen. You can tap the ⚠ symbol for more information and set a reminder to check your glucose.

Reader Display	App Display	What To Do
		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.

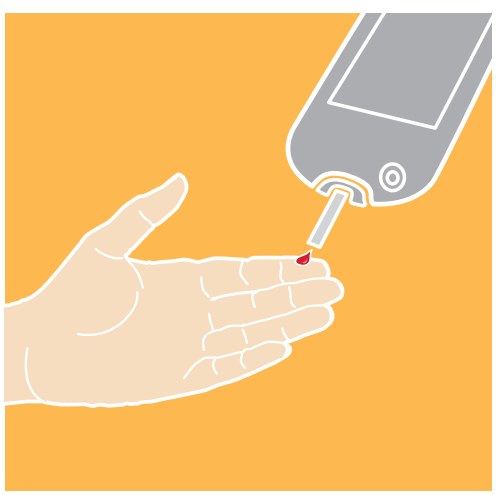
Note:

- If you are not sure about a message or reading, contact your health care professional before you do anything.
- Messages you receive with your glucose readings are not related to your glucose alarm settings.

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. You should also talk to your health care professional about the best times to check your glucose. Consider checking your glucose before a period when you will not be monitoring your glucose, such as before driving, exercising or sleeping.

WARNING: 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 as Sensor readings may not accurately reflect blood glucose levels:



Do a blood glucose test if you think your glucose readings are not correct or do not match how you feel. Do not ignore symptoms that may be due to low or high glucose.

Do a blood glucose test when you see the  symbol during the first 12 hours of wearing a Sensor or the Sensor glucose reading does not include a Current Glucose number.

Making Treatment Decisions – Getting Started

Before you start using the System for treatment decisions, make sure you have a good understanding of how the System works for your body. **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, within a Sensor wear period (duration specified by your Sensor insert), and in different situations. There may be variations between Sensors during the first 12 hours after insertion, so pay attention to how each newly inserted Sensor is working for you when deciding whether to make treatment decisions based on your Sensor readings.

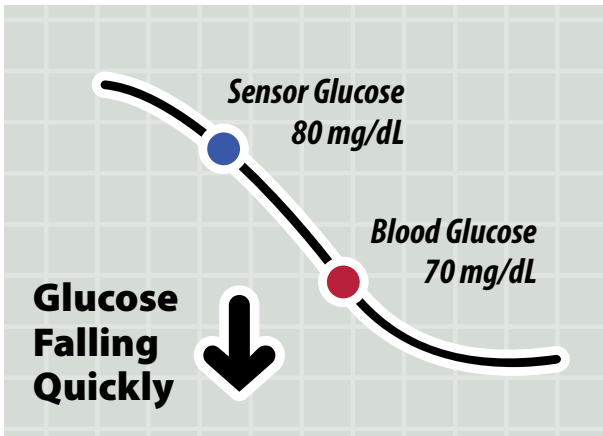
Getting familiar with the System could take days, weeks, or even months. The more you check readings from the System with a blood glucose meter, the better you will understand how the System works for you.

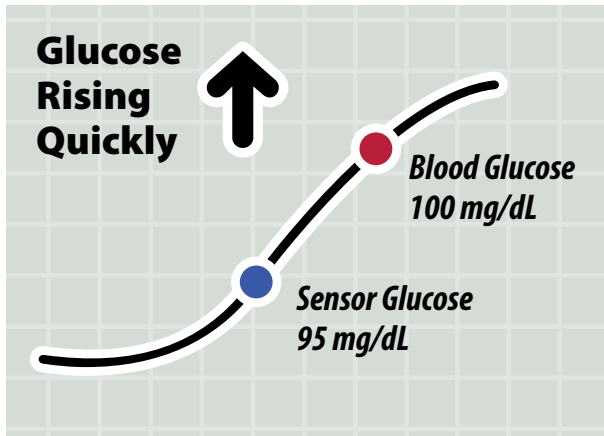
Work with your health care professional to put together a plan for managing your diabetes that includes when to use the System information for making treatment decisions.

Helpful Tips

- Confirm your Sensor glucose readings with a blood glucose meter until you understand:
  - **Sensor accuracy may vary between Sensors.**
  - **Sensor accuracy may vary during a Sensor wear session.**
  - **Sensor accuracy may vary in different situations (meals, exercise, first day of use, etc.).**
- Check your glucose often to see how carbs, medication, exercise, illness, or stress levels impact your Sensor glucose readings. The information you get can help you figure out why your glucose sometimes goes too high or too low, and how to prevent it from doing so in the future.
- Talk to your health care professional about how your insulin works. The more you understand about your insulin, including how long it takes to start working and how long it lasts in your body, the more likely you will be to make better treatment decisions.
- Making a treatment decision doesn't just mean taking insulin. Treatment decisions can also include things like taking fast-acting carbs, eating, or even doing nothing and checking again later.

- Your health care professional can also help you to understand when doing nothing and checking 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. Avoid "insulin stacking".
- Sensor glucose values, which are based on interstitial fluid glucose levels, can be different from blood glucose levels (fingersticks), particularly during times when your blood glucose is changing quickly. If your glucose readings and alarms from the System do not match your symptoms or expectations, use a fingerstick blood glucose value from a blood glucose meter to make diabetes treatment decisions.





When <u>not</u> to use Sensor Glucose readings for treatment decisions

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.

Think Your Readings are Incorrect?

Don't trust Sensor glucose readings that you think may be incorrect or that don't match what you would expect based on your recent activity. For example, if you ate dinner but forgot to take insulin before eating, you would expect your glucose to be high. If your glucose reading is low, then it doesn't match your recent activity, so don't use it to make treatment decisions. Don't make treatment decisions if you think your Sensor glucose readings are incorrect. Do a blood glucose test and treat based on that result.

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.

If you're the caregiver, pay attention to times when the symptoms of the one you're caring for don't match their Sensor glucose readings. When symptoms don't match readings, do a blood glucose test and treat based on that result.

When to do Nothing and Check Again Later

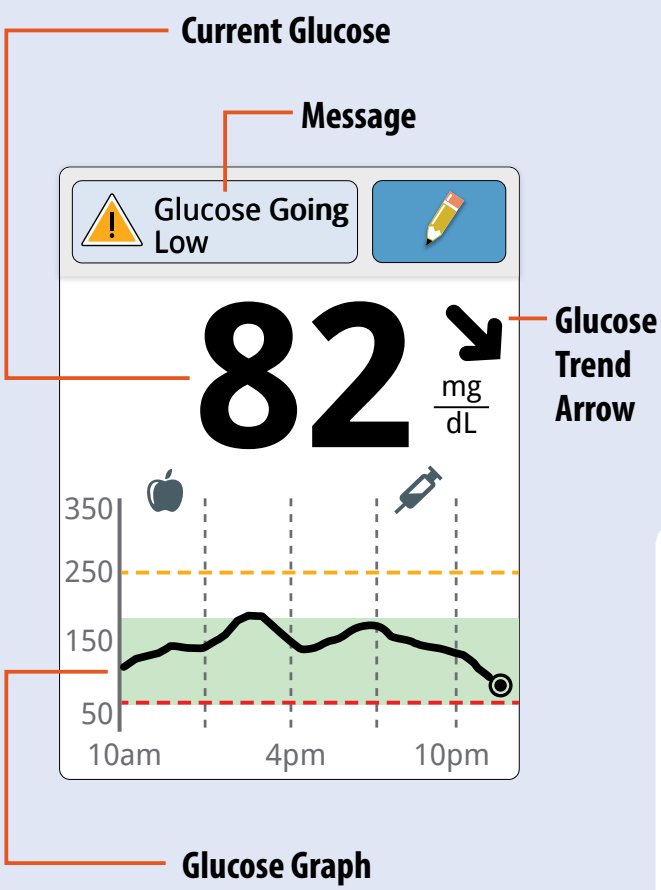
Your health care professional can help you understand when doing nothing and checking again later is the right treatment decision. For example, if your glucose is high and going up, your first instinct may be to take more insulin to lower your glucose, however depending on when you last took insulin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

After you check your glucose, use all of the information on the screen when deciding what to do or what treatment decision to make.

Reader



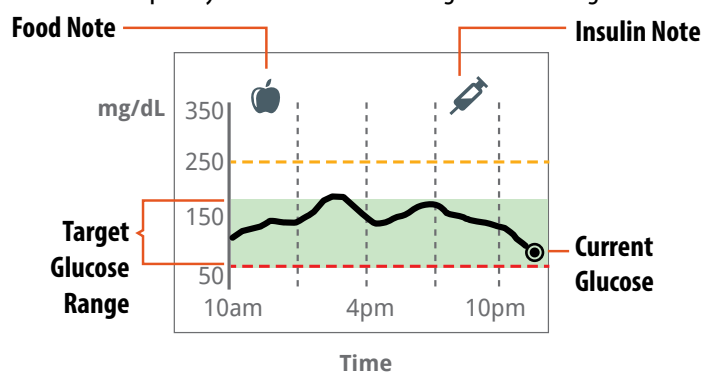
Glucose Trend Arrow

Direction your glucose is going

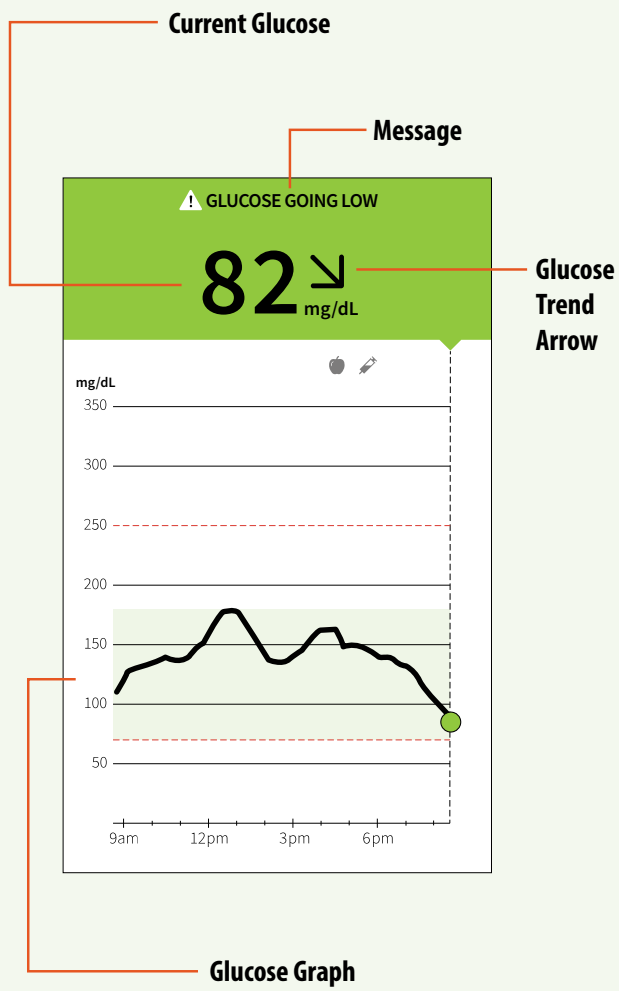
Arrow	What it means
↑	Glucose rising quickly
↗	Glucose rising
→	Glucose changing slowly
↘	Glucose falling
↓	Glucose falling quickly

Glucose Graph

Graph of your current and stored glucose readings



App



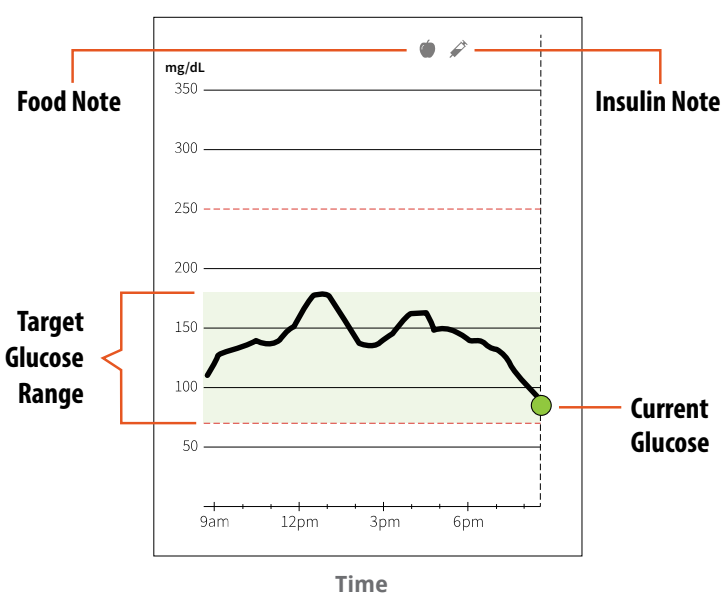
Glucose Trend Arrow

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



This table 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.

Glucose Trend Arrow	Treatment Decision Considerations		
	Low Glucose (< 70 mg/dL)	**Glucose in Target Range**	**High Glucose (> 250 mg/dL)**
↑	Treat low glucose according to your health care professional's recommendation.	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 again later. Avoid "insulin stacking".	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 again later. Avoid "insulin stacking".

Glucose Trend Arrow	Treatment Decision Considerations		
	Low Glucose (< 70 mg/dL)	**Glucose in Target Range**	**High Glucose (> 250 mg/dL)**
↗	Treat low glucose according to your health care professional's recommendation.	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 again later. Avoid "insulin stacking".	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 again later. Avoid "insulin stacking".

Glucose Trend Arrow	Treatment Decision Considerations		
	Low Glucose (< 70 mg/dL)	**Glucose in Target Range**	**High Glucose (> 250 mg/dL)**
→	Treat low glucose according to your health care professional's recommendation.	If you are about to eat, take insulin to cover your meal. If this is between meals, do nothing and check again later.	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 again later. Avoid "insulin stacking".

Glucose Trend Arrow	Treatment Decision Considerations		
	Low Glucose (< 70 mg/dL)	**Glucose in Target Range**	**High Glucose (> 250 mg/dL)**
↘	Treat low glucose according to your health care professional's recommendation.	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 again later.	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 again later. Avoid "insulin stacking".

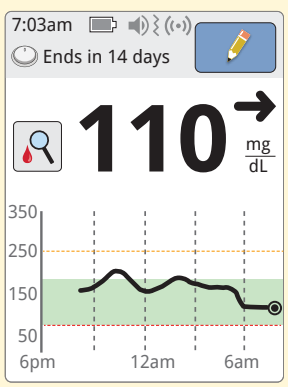
Glucose Trend Arrow	Treatment Decision Considerations		
	Low Glucose (< 70 mg/dL)	**Glucose in Target Range**	**High Glucose (> 250 mg/dL)**
↓	Treat low glucose according to your health care professional's recommendation.	If you are about to eat, take insulin to cover your meal. Consider taking a little 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 again later.	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 again later. Avoid "insulin stacking".

Example Scenarios

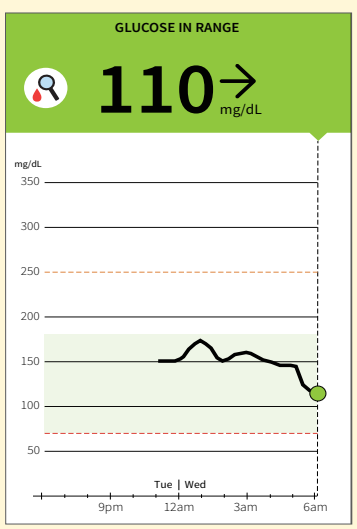
Here are some example scenarios to help you understand how to use the information on your screen. Always use all of the information on the screen before deciding what to do or what treatment decision to make. If you are not sure about what to do, consult your health care professional.

What you see	What it means
When you wake-up:	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.

Reader



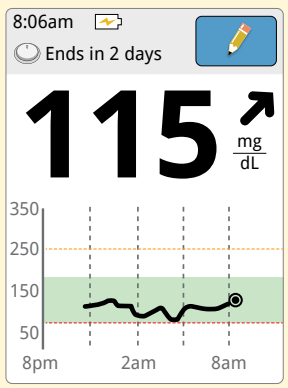
App



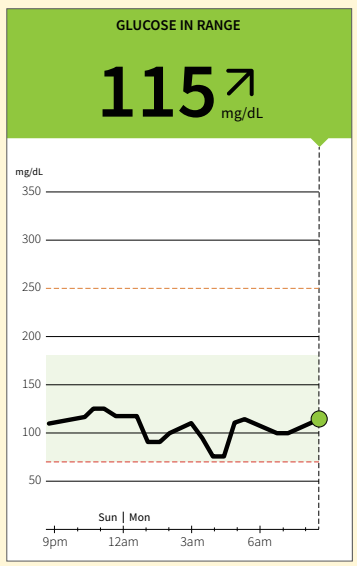
What you see

Before breakfast:

Reader



App



What it means

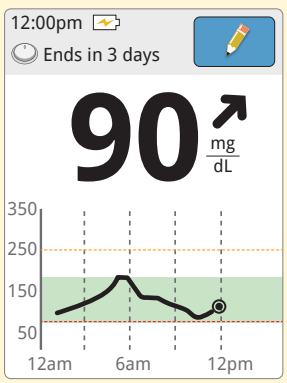
Before breakfast, your current glucose is 115 mg/dL. The graph shows that your glucose is going up and so does the trend arrow ↗.

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

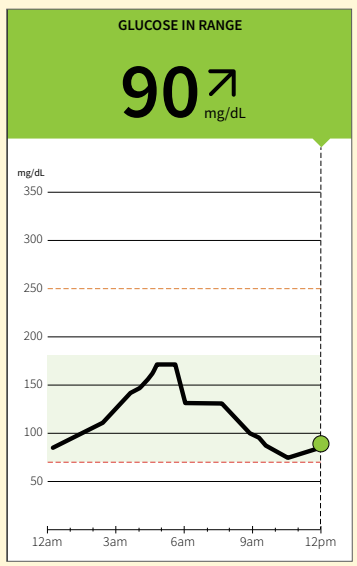
- How much insulin should you take before your meal?
- Since you see ↗, should you consider taking a little more insulin?

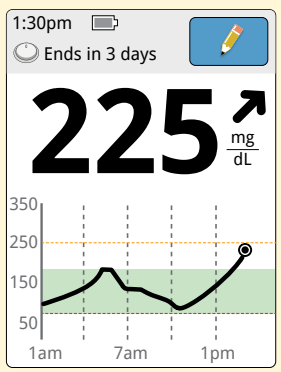
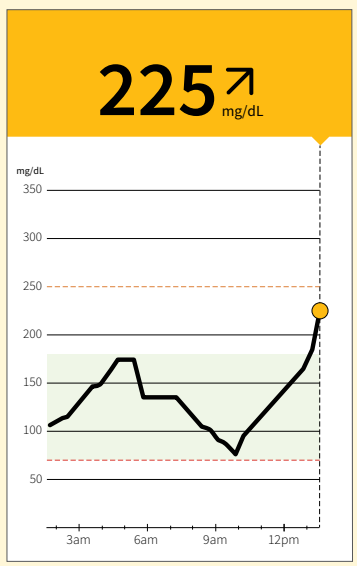
What you see	What it means
Before lunch:	When you checked your glucose before lunch, it was 90 mg/dL and rising. Before eating lunch, you took enough insulin to cover the meal and a little more since your trend arrow was ↗.

Reader



App

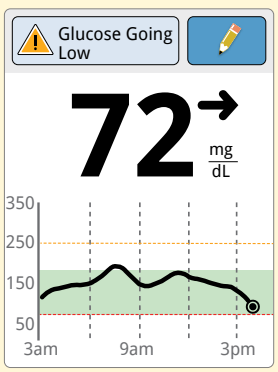


What you see	What it means
After lunch: **Reader**  **App**  	90 minutes later, your current glucose is 225 mg/dL. The graph shows that your glucose is still going up, and so does the trend arrow ↗. **Don't take a correction dose within 2 hours of your meal dose.** This may result in "insulin stacking" 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.

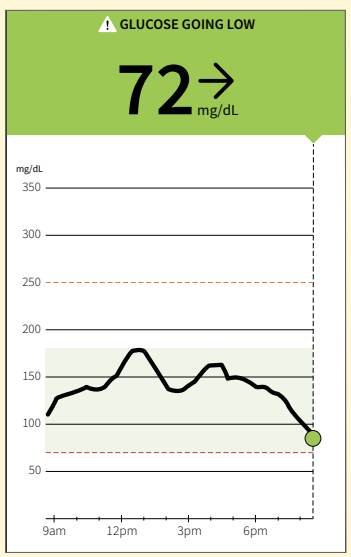
What you see

In the afternoon:

Reader



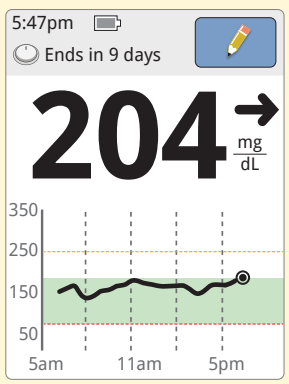
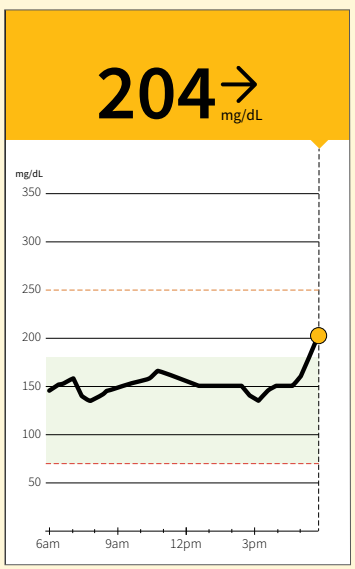
App



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.

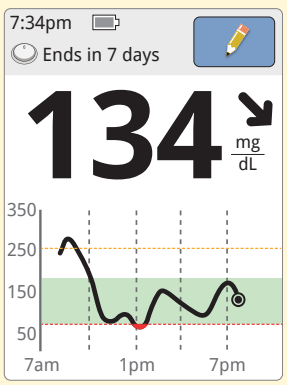
Think about what might be causing your glucose to go low. Consider eating a snack to stay within target. **Avoid taking insulin as this can cause low glucose**.

What you see	What it means
After exercising: **Reader**  **App**  	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.

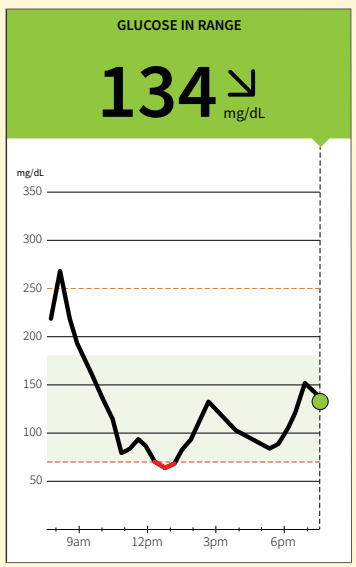
What you see

Before dinner:

Reader



App



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?

Other considerations

Deciding how much rapid-acting insulin to take for different meals and situations can be difficult. Work with your health care professional to discuss different situations and what might work best for you. Here are some questions to consider:

Meal dosing

- What do you do if your before meal glucose is high?
- What do you do if your before meal glucose is low?
- How much time do you wait to eat after taking your meal insulin?
- Do you adjust the amount of meal insulin based on the number of carbs or how much you are planning to eat?
- Do you adjust your meal insulin dose for high fat foods such as pizza?
- Do you know how to adjust your insulin doses when drinking alcoholic beverages?

High glucose corrections

- Do you take extra insulin if your glucose is high?
- How do you decide how much insulin to take for a high glucose?
- How long do you wait between insulin doses to avoid insulin stacking?

Bedtime

- How often do you check your glucose before bed?
- What do you consider a safe bedtime glucose?
- What do you do if your bedtime glucose is high?
- What do you do if your bedtime glucose is low?
- When should you eat a bedtime snack?
- What do you do if your before meal glucose is high?
- What do you do if your before meal glucose is low?

Other factors

- How do you adjust your insulin dose based on the Glucose Trend Arrow?
- How do you adjust your insulin dose for different types of exercise or activities?
- How do you adjust your insulin doses for stress?
- How do you adjust your insulin doses for illness?

Reader Alarms

When in range of the Reader, your Sensor automatically communicates with the Reader to give you Low and High Glucose Alarms. These alarms are on by default.

Please read all the information in this section before setting and using alarms.

IMPORTANT: Glucose alarms are an important safety feature for some people. For example, those that have impaired awareness of hypoglycemia or a history of severe hypoglycemia. Before you turn alarms off or change their settings, please consult your health care professional.

CAUTION:

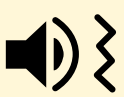
- For you to receive alarms, they must be on and your Reader should be within 33 feet of you at all times. The transmission range is 33 feet unobstructed. If you are out of range, you may not receive glucose alarms.
- To prevent missed alarms, make sure the Reader has sufficient charge and that sound and/or vibration are turned on.

IMPORTANT: What to know about glucose alarms

- Check your glucose often. If you get a Low or High Glucose Alarm, you must obtain a glucose result to determine what to do next.
- The Low and High Glucose Alarms should not be used exclusively to detect low or high glucose conditions. The glucose alarms should always be used along with your current glucose, glucose trend arrow, and glucose graph.
- Low and High Glucose Alarm levels are different from your Target Glucose Range values. Low and High Glucose Alarms tell you when your glucose has passed the level you set in the alarm. Your Target Glucose Range is displayed on glucose graphs on the Reader and used to calculate your Time In Target.

IMPORTANT: How to prevent missed alarms

- Alarms must be kept on for you to receive them and you should ensure that your Reader is within 33 feet of you at all times. The Sensor itself will not issue alarms.
- **If the Sensor is not communicating with the Reader, you will not receive glucose alarms, and you may miss detecting low glucose or high glucose episodes**. You will see the  symbol on the Home Screen when the Sensor is not communicating with the Reader. Make sure the Signal Loss Alarm is on so you will be notified if your Sensor has not communicated with the Reader for 20 minutes.
- Make sure the Reader's sound and/or vibration settings are on and your Reader is near you. The Home Screen indicates the sound/vibration setting when any alarm is on:

 Sound and Vibration **ON**

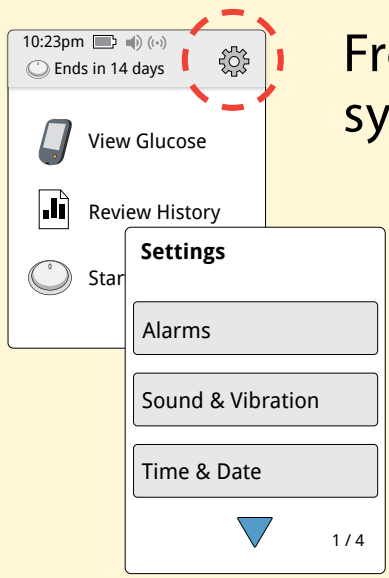
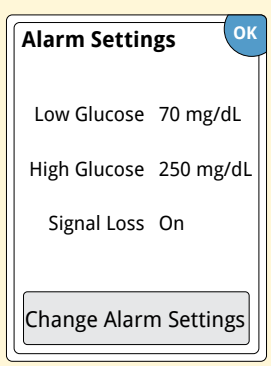
 Sound **ON**, Vibration **OFF**

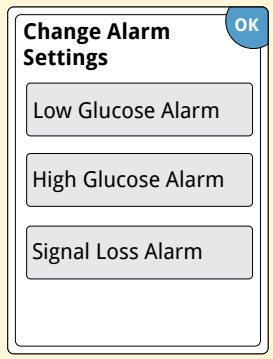
 Sound **OFF**, Vibration **ON**

 Sound and Vibration **OFF**

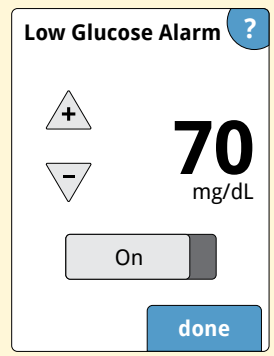
Setting Reader Alarms

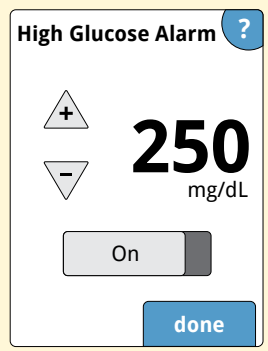
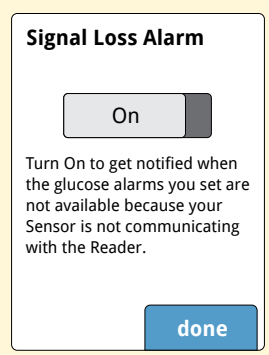
Work with your health care professional to determine your alarm settings.

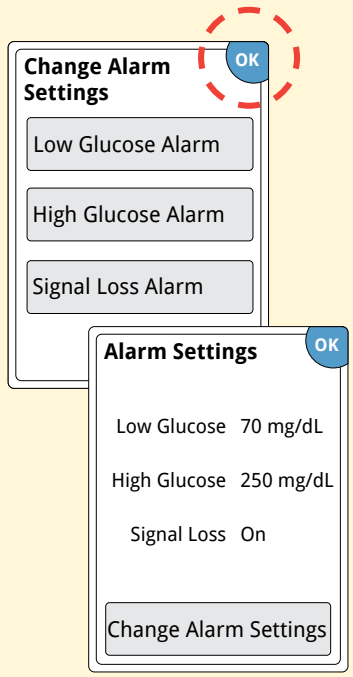
Step	Action
1	 From the Home Screen, touch the Settings symbol ⚙. Touch **Alarms**.
2	 Touch **Change Alarm Settings**.

Step	Action
3	 Select the alarm you want to set or turn off. **CAUTION:** If alarms are turned off, you will not get a notification when you have low glucose or high glucose. Low Glucose Alarm: Notifies you when your glucose is below the level you set. High Glucose Alarm: Notifies you when your glucose is above the level you set. Signal Loss Alarm: Notifies you when your Sensor is not communicating with the Reader and that you will not receive Low or High Glucose Alarms.

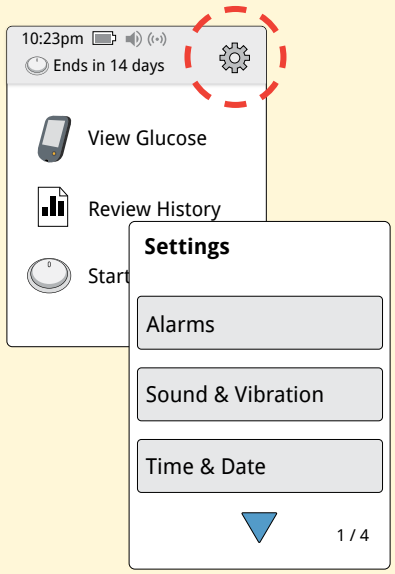
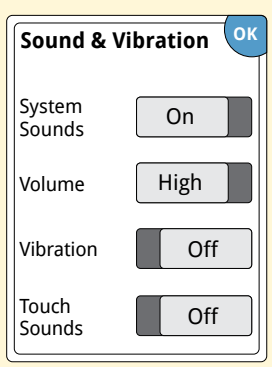
Alarm	How to Set
Low Glucose Alarm	The Low Glucose Alarm is on by default. The alarm level is initially set to 70 mg/dL. You can use the arrows to change this value between 60 mg/dL and 100 mg/dL. If the alarm is on, you will be notified when your glucose falls below the level you set. Touch the slider to turn the alarm off. Touch **done** to save.



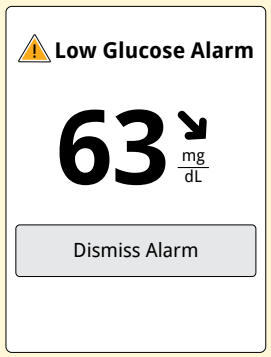
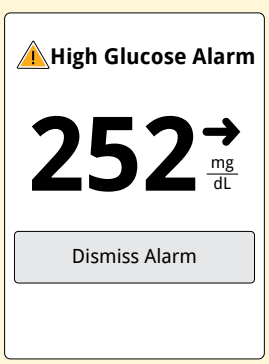
Alarm	How to Set
High Glucose Alarm	The High Glucose Alarm is on by default. The alarm level is initially set to 250 mg/dL. You can use the arrows to change this value between 120 mg/dL and 400 mg/dL. If the alarm is on, you will be notified when your glucose rises above the level you set. Touch the slider to turn the alarm off. Touch **done** to save. 
Signal Loss Alarm	If the alarm is on, you will be notified when your Sensor has not communicated with your Reader for 20 minutes and you are not receiving Low or High Glucose Alarms. Touch the slider to turn the alarm off. Touch **done** to save. 

Step	Action
4	 When you are finished setting your alarms, touch **OK**. The Alarms Settings screen now shows your current alarm settings. Touch **OK** to return to the main Settings menu, or touch **Change Alarm Settings** to make additional updates.

Setting Reader Alarm Sounds

Step	Action
1	 From the Home Screen, touch the Settings symbol ⚙. Touch **Sound & Vibration** to change the alarm sounds.
2	 Touch the sound or vibration setting you would like to change. **Note:** These settings apply to the alarms as well as other Reader functions. Touch **OK** to save.

Using Reader Alarms

What you See	What it Means
	The Low Glucose Alarm notifies you if your glucose drops below the level you set. Touch **Dismiss Alarm** or press the Home Button to dismiss the alarm. You will only receive one alarm per low glucose episode.
	The High Glucose Alarm notifies you if your glucose rises above the level you set. Touch **Dismiss Alarm** or press the Home Button to dismiss the alarm. You will only receive one alarm per high glucose episode.

What you See	What it Means
	The Signal Loss Alarm notifies you if your Sensor has not communicated with the Reader for 20 minutes and you are not receiving Low or High Glucose Alarms. Signal loss could be caused by the Sensor being too far away from the Reader (over 33 feet) or another issue such as an error or problem with your Sensor or Reader. Touch **Dismiss Alarm** or press the Home Button to dismiss the alarm. You will only receive one alarm per signal loss episode.

Note: If you ignore an alarm, you will receive it again in 5 minutes if the condition still exists.

App Alarms

FreeStyle Libre 3 app includes several types of alarms. 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 **Silent Mode** (if available).
- You can individually select to turn off the **Override Do Not Disturb** setting for the High Glucose, Low 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.

Optional Glucose Alarms: Low Glucose and High Glucose Alarms are turned on by default, but can be turned off or customized to alarm at different glucose levels.

Urgent Low Glucose: Urgent Low Glucose Alarm will be delivered when your glucose goes below 55 mg/dL. This alarm cannot be turned off or customized but can be silenced with your other glucose alarms for a set period.

Optional Signal Loss Alarm: Signal Loss Alarm will be delivered when your Sensor isn't communicating with the App. This alarm is turned on by default, but can be turned off or customized.

Fixed System Alarms: Replace Sensor and Sensor Ended Alarms will be delivered when your Sensor needs to be replaced, and the Check Sensor Alarm will be delivered when the Sensor tip may not have been inserted under the skin. 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.

Note: The iPhone app includes an App Stopped Alarm to indicate you have force closed the App.

Please read all the information in this section before setting and using alarms.

CAUTION:

- Disable your phone's automatic operating system (OS) updates. Prior to updating your phone's OS or updating the App, you should check the Mobile Device and OS Compatibility Guide to determine if the FreeStyle Libre 3 app is compatible with your OS and your phone. The OS Compatibility Guide is available in the Help Section of the App or on www.FreeStyleLibre.com. You should check the OS Compatibility Guide periodically to make sure that your OS and your phone continue to be compatible with the App.
- In the event that an App or OS update causes your previously compatible phone to become incompatible, you may be notified ahead of time via e-mail or through the App. Make sure that your LibreView account has your current e-mail address to receive important information.
- After an OS update, open your App and check your device settings to make sure it's working properly. Some OS features may impact your ability to receive alarms or glucose readings. For example, if you use an iPhone and the iOS Screen Time feature, add the FreeStyle Libre 3 app to the list of Always Allowed apps to ensure that you receive alarms or if you use an Android Phone do not use the Android Digital Wellbeing app.

- For you to receive alarms, your phone should be within 33 feet of you at all times. The transmission range is 33 feet unobstructed. If you are out of range, you may not receive alarms. If you want to receive the App's optional alarms, make sure these are turned on.
- For iPhone, do not force close the App. The App must be running in the background to receive alarms. If you force close the App you will not receive alarms. Re-open the App to ensure you will receive alarms.
- If you restart your phone, open your App to make sure it’s working properly.
- The App will ask for phone permissions which are needed to receive alarms. Allow these permissions when requested.
- Your phone must have a Bluetooth connection with your Sensor to receive glucose readings and glucose alarms. In the phone settings, keep Bluetooth ON. For iPhones, in the phone settings for the App, allow the App to access Bluetooth.
- Check to make sure that you have the correct phone settings and permissions enabled. If your phone is not configured properly, you will not be able to use the App, so you will not receive alarms or be able to check your glucose.

- **iPhones** are to be configured as follows:
  - In the phone settings for the App under Notifications, keep Allow Critical Alerts **ON**.
- **Android Phones** are to be configured as follows:
  - In the phone settings for the App, keep Do Not Disturb Access permission **ON**.

- If your phone is not configured correctly, the App will be in "Alarms Unavailable" state and you will not be able to check your glucose or receive any alarms, including the Urgent Low Glucose Alarm.
- To turn on Critical Alerts (iPhone) / Do Not Disturb Permission (Android Phone), follow the instructions in the App.
- If you adjust the phone ringer volume (iPhone) or Media volume (Android Phone) 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.
- You should disconnect headphones or speakers from your phone when you are not using them as you may not hear audio for alarms. If using headphones, keep them in your ears.
- If you are using peripheral devices connected to your phone, such as wireless headphones or a smartwatch, you may receive alarms on only one device or peripheral, not all.
- Keep your phone well charged and turned on.

IMPORTANT:

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

- If you see the symbol, this means you are not getting alarms. Confirm your settings are as follows:

  iPhone settings:

  - Allow Notifications is **ON**
  - Lock screen and Banners alerts are **ON**
  - Notifications sounds are **ON**

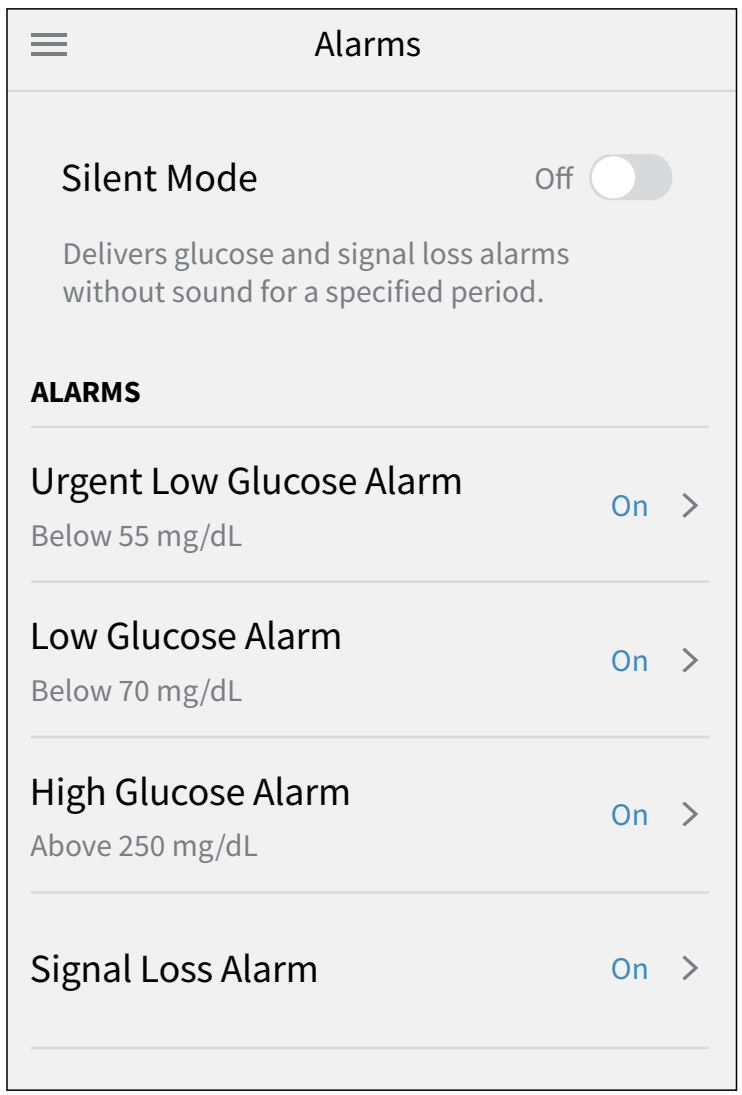
  Android Phone settings:

  - Lock screen notifications are **ON**
  - Channel notifications or Pop-up notifications are **ON**
  - Battery optimization is **OFF**
  - Phone Media volume is **ON**
  - In the phone settings for the App, keep Nearby Devices permission **ON** (For Android 12 and above)
  - In the phone settings for the App, keep Alarms and Reminders permission **ON** (For Android 12 and above)

If alarms are unavailable because of any of these settings you will still be able to check your glucose. Touch the symbol for more information.

Setting App Alarms

To access your alarm settings, go to the Main Menu and tap **Alarms**. Work with your health care professional to determine your alarm settings.



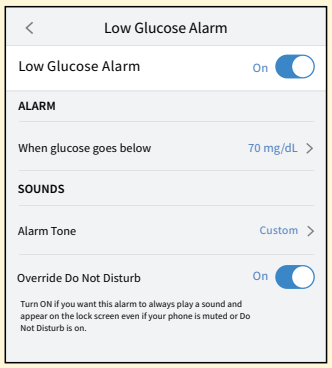
Silent Mode (if available)

Step	Action
1	Silent Mode is off by default. If you want to turn it on, touch 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.

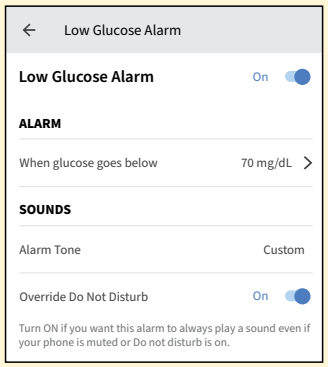
Low Glucose Alarm

Step	Action
1	The Low Glucose Alarm is on by default. The alarm level is initially set to 70 mg/dL. Tap to change this value between 60 mg/dL and 100 mg/dL. 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. Tap **SAVE**.
2	Choose the sound for this alarm. 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.

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



(Example screen displayed for iPhone)

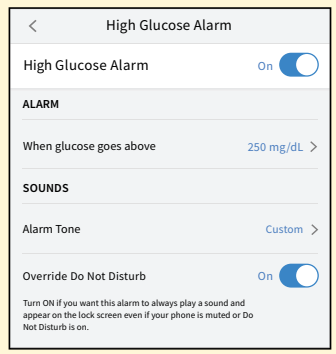


(Example screen displayed for Android Phone)

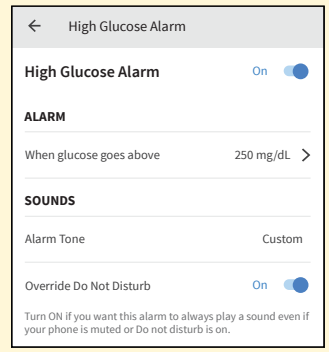
High Glucose Alarm

Step	Action
1	The High Glucose Alarm is on by default. The alarm level is initially set to 250 mg/dL. Tap to change this value between 120 mg/dL and 400 mg/dL. 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. Tap **SAVE**.
2	Choose the sound for this alarm. 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.

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



(Example screen displayed for iPhone)

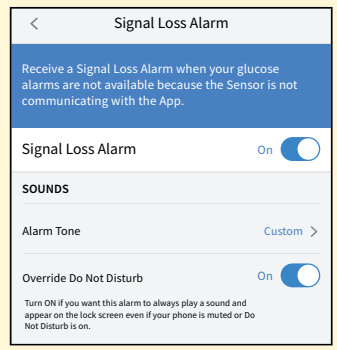


(Example screen displayed for Android Phone)

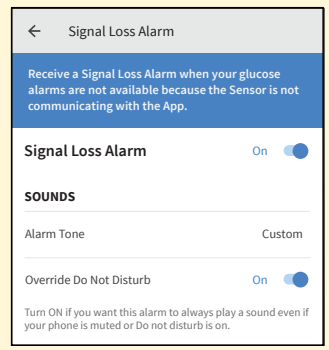
Signal Loss Alarm

Step	Action
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 glucose readings, Urgent Low, Low, or High Glucose Alarms. Tap the slider to turn the alarm off.
2	Choose the sound for this alarm. 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.

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

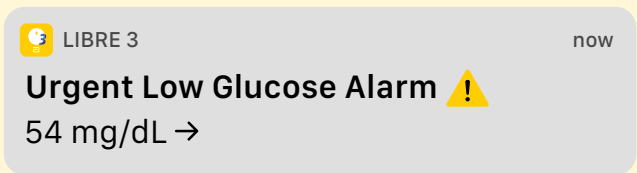
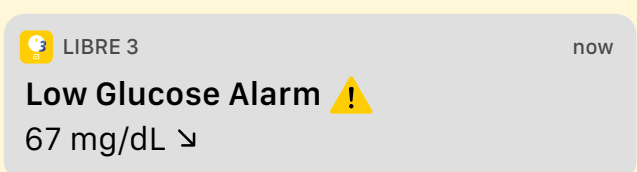


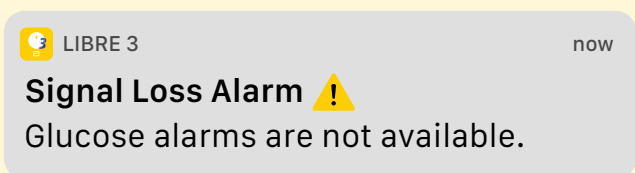
(Example screen displayed for iPhone)

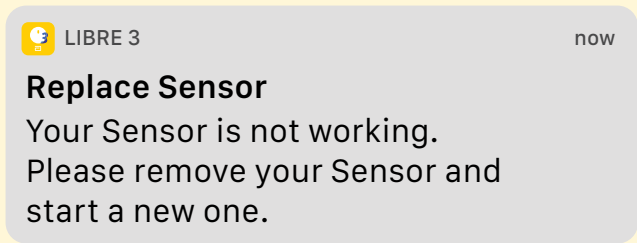
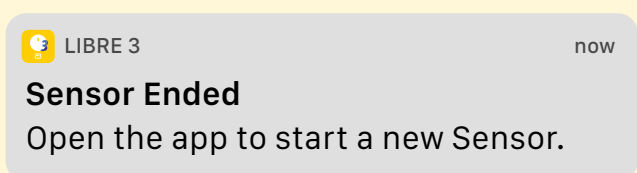


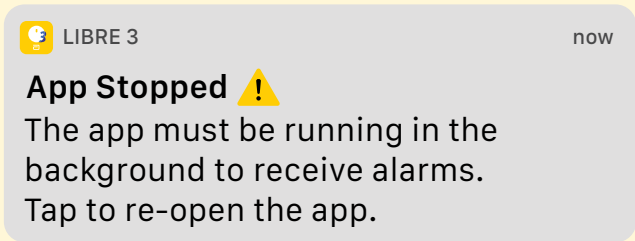
(Example screen displayed for Android Phone)

Using App Alarms

What you see	What it means
	Notifies you if your glucose drops below 55 mg/dL. Open the App or tap the Dismiss button to dismiss the alarm. You will receive the Urgent Low Glucose Alarm every 30 minutes until your glucose reading is at or above 55 mg/dL.
	Notifies you if your glucose drops below the level you set. Open the App or tap the Dismiss button to dismiss the alarm. You will only receive one alarm per low glucose episode.

What you see	What it means
	Notifies you if your glucose rises above the level you set. Open the App or tap the Dismiss button to dismiss the alarm. You will only receive one alarm per high glucose episode.
	Notifies you if your Sensor has not communicated with the App for 20 minutes and you are not receiving glucose readings or Urgent Low, Low, or High Glucose Alarms. Signal loss could be caused by the Sensor being too far away from your phone (over 33 feet) or another issue such as an error or problem with your Sensor. Open the App or tap the Dismiss button to dismiss the alarm.

What you see	What it means
	Notifies you if your Sensor has ended. You will not receive glucose alarms after this time unless you start a new Sensor. Remove your Sensor and start a new Sensor to check your glucose. Open the App or tap the Dismiss button to dismiss the alarm.
	Notifies you if your Sensor has ended. You will not receive glucose alarms after this time unless you start a new Sensor. Remove your Sensor and start a new Sensor to check your glucose. Open the App or tap the Dismiss button to dismiss the alarm.

What you see	What it means
 *(iPhone only)*	Notifies you if the App has been closed. The App must be running in the background to receive alarms. Tap the alarm to re-open the App.

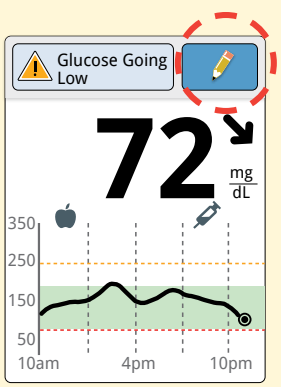
Note: For all alarms except the Sensor Ended Alarm and App Stopped Alarm: If you ignore an alarm, you will receive it again in 5 minutes if the condition still exists. Only your most recent alarms will display on your screen.

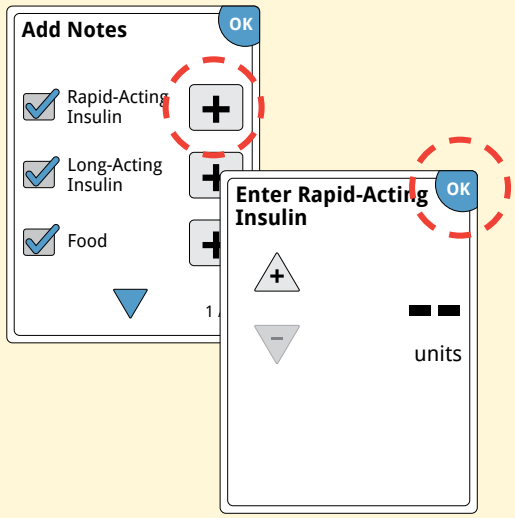
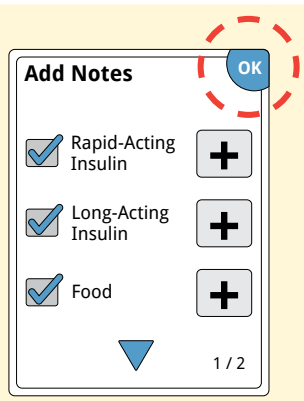
Adding Notes to Glucose Readings

Notes can be saved with your glucose readings to help you track things like food, insulin, and exercise.

Adding Notes in the Reader

You can add a note at the time of your glucose reading or within 15 minutes after your reading was obtained.

Step	Action
1	 From the Glucose Reading screen, add notes by touching the symbol in the upper right corner of the touchscreen. If you do not want to add notes, you can press the Home Button to go to the Home Screen or hold the Home Button to turn the Reader off.

Step	Action
2	 Select the checkbox next to the notes you would like to add. Touch the down arrow to view other note options. After you check the box for food and insulin notes, the + symbol appears to the right of the note. You can touch it to add more specific information to your note. Then touch **OK**. • Insulin notes: Enter the number of units taken. • Food notes: Enter grams or serving information. **Note:** Food and insulin notes are shown on your glucose graphs and in your Logbook as symbols.
3	 Touch **OK** to save your notes.

You can review your notes from the Logbook. See *Reviewing Your History* section for more information.

Adding Notes in the App

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

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

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


Food


Exercise


Insulin (Rapid or Long-acting)


Food + Insulin

Multiple/Custom notes – indicates different types of notes entered together or notes entered within a short period of time. A numbered badge next to the symbol indicates the number of notes.

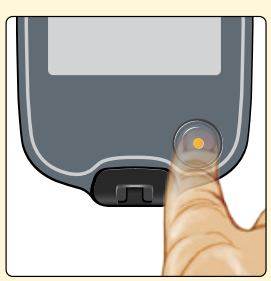
Reviewing Your History

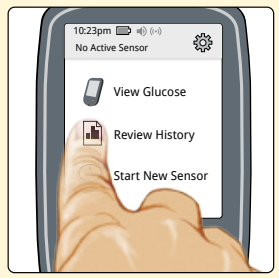
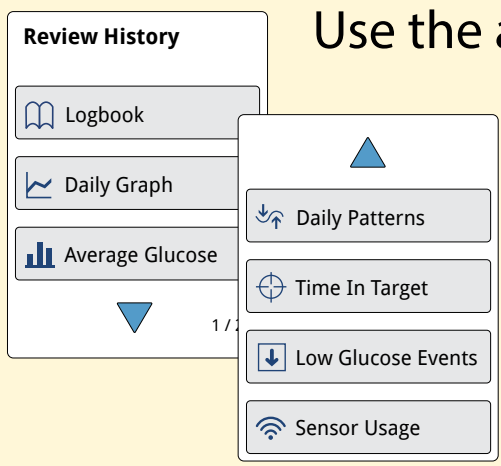
Reviewing and understanding your glucose history can be an important tool for improving your glucose control. The Reader and App store about 90 days of information and have several ways to review your past glucose readings, notes, past alarm data, and other information.

IMPORTANT:

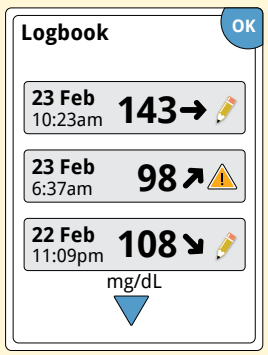
- Work with your health care professional to understand your glucose history.
- Remember that FreeStyle Libre 3 app and FreeStyle Libre 3 Readers do not share data.

Reviewing Your History in the Reader

Step	Action
1	 Press the Home Button to turn on the Reader.

Step	Action
2	 Touch the **Review History** icon.
3	 Use the arrows to view the available options.

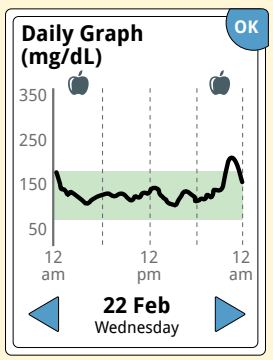
Logbook



The Logbook contains entries for notes you added as well as each time you received an Urgent Low, Low, or High Glucose Alarm. If you entered Notes with a glucose reading, the symbol appears in that row. For more information about the symbols, see *Reader Symbols* section.

Touch the entry to review the detailed information, including any Notes you entered.

Daily Graph



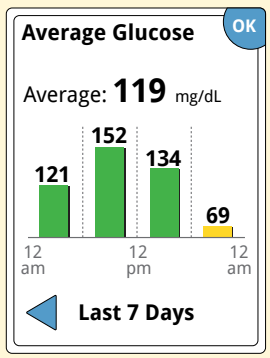
A graph of your Sensor glucose readings by day. The graph shows your Target Glucose Range and symbols for notes you have entered.

Note:

- While Sensor glucose readings are gathered in the System range of 40-400 mg/dL, the Daily Graph display range is 0-350 mg/dL for ease of review on screen. Glucose readings above 350 mg/dL are displayed as 350 mg/dL. For sequential readings above 350 mg/dL, a line is displayed at 350 mg/dL.
- The symbol may appear indicating the Reader time was changed. Gaps in the graph may result or glucose readings may be hidden.

Other History Options

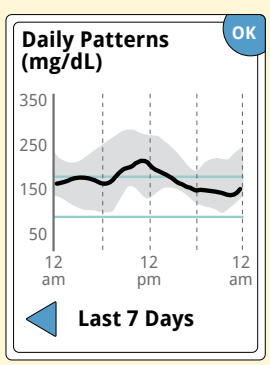
Use the arrows to view information about your last 7, 14, 30, or 90 days.



Average Glucose

Information about the average of your Sensor glucose readings. The overall average for the time is displayed above the graph. The average is also shown for four different 6-hour periods of the day.

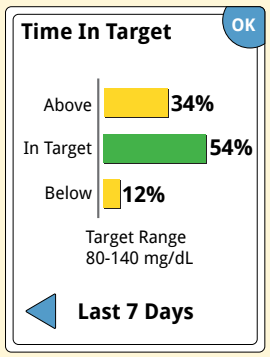
Readings above or below your Target Glucose Range are yellow, while readings in range are green.



Daily Patterns

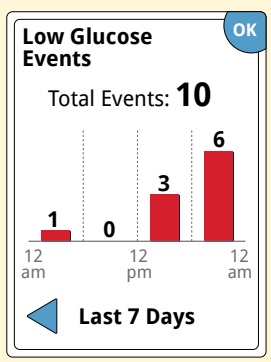
A graph showing the pattern and variability of your Sensor glucose over a typical day. The thick black line shows the median (midpoint) of your glucose readings. The gray shading represents a range (5-95 percentiles) of your Sensor readings.

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



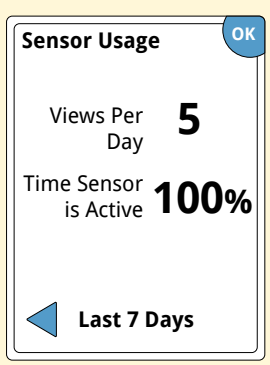
Time In Target

A graph showing the percentage of time your Sensor glucose readings were above, below, or within certain glucose ranges. The graph is based on your Target Glucose Range.



Low Glucose Events

Information about the number of low glucose events measured by your Sensor. A low glucose event is recorded when your Sensor glucose reading is lower than 70 mg/dL for 15 minutes or longer. The total number of events is displayed above the graph. The bar graph displays the low glucose events in four different periods of the day.



Sensor Usage

Information about how often you viewed your Sensor glucose readings and how much information has been captured from your Sensor.

Reviewing Your History in the App

From the Main Menu, tap **Logbook** to view the Logbook or tap on one of the other history options under **Reports**.

Logbook

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

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

Other History Options

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

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

Time In Ranges: A graph showing the percentage of time your Sensor glucose readings were above, below, or within certain glucose ranges. The Custom graph is based on your Target Glucose Range, and the Standard graph is based on a Target Range of 70 to 180 mg/dL.

Low Glucose Events: Information about the number of low glucose events measured by your Sensor. A low glucose event is recorded when your Sensor glucose reading is lower than 70 mg/dL for longer than 15 minutes. The total number of events is displayed below the graph. The bar graph displays the low glucose events in different periods of the day.

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

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

- Glucose readings above 350 mg/dL are displayed as 350 mg/dL. For sequential readings above 350 mg/dL, a line is displayed at 350 mg/dL.
- The  symbol may appear indicating a time change. Gaps in the graph may result or glucose readings may be hidden.

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

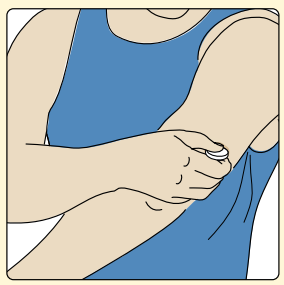
Glucose Management Indicator (GMI): Glucose Management Indicator uses average Sensor glucose data. GMI* can be used as an indicator of how well your glucose levels have been controlled.

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

Note:

- Tap the symbol (iPhone) or symbol (Android Phone) on any report to share a screenshot of the report.
- Tap the symbol to view a description of the report.
- To view a different report, tap the dropdown menu above the report, or go to the Main Menu.
- On all reports except the Daily Graph, you can select to show information about your last 7, 14, 30, or 90 days.

Removing Your Sensor

Step	Action
1	 Pull up the edge of the adhesive that keeps your Sensor attached to your skin. Slowly peel away from your skin in one motion. **Note:** Any remaining adhesive residue on the skin can be removed with warm soapy water or isopropyl alcohol.
2	Discard the used Sensor following directions from your health care professional. See *Maintenance and Disposal* section. When you are ready to apply a new Sensor, follow the instructions in *Applying Your Sensor* and *Starting Your Sensor* sections. If you removed your last Sensor before it ended, go to **Start New Sensor** in the menu to start the new one. You will be prompted to confirm that you would like to start a new Sensor. **Note:** After removing your Sensor you may observe a slight bump at the insertion site. This goes away quickly, usually in a day or two.

Replacing Your Sensor

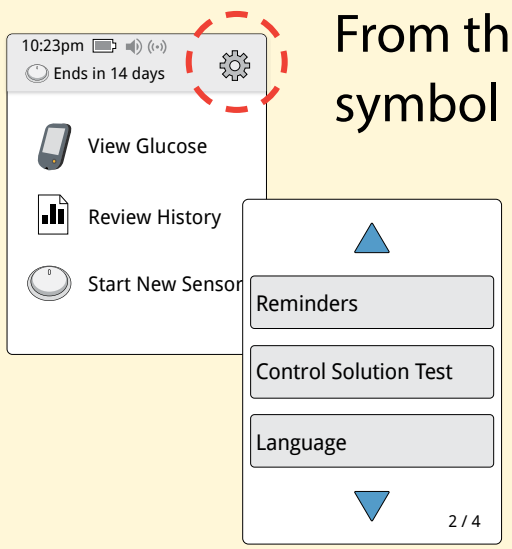
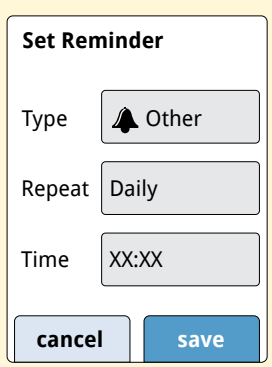
Your Sensor automatically stops working after the wear duration and must be replaced. You should also replace your Sensor if you notice any irritation or discomfort at the application site or if your device reports a problem with the Sensor currently in use. Taking action early can keep small problems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

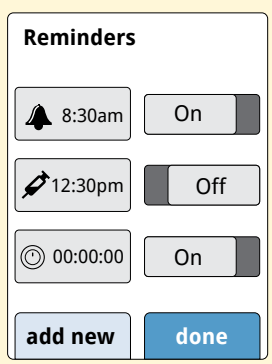
CAUTION: If the Sensor is becoming loose or if the Sensor tip is coming out of your skin, you may get no readings or unreliable readings, which may not match how you feel. Check to make sure your Sensor has not come loose. If it has come loose, remove it, apply a new one, and contact Customer Service. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

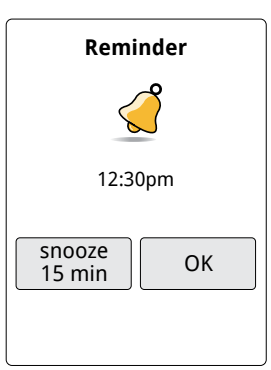
Using Reminders

You can create single or repeating reminders to help you remember things like checking your glucose or taking insulin. You can also set a reminder to remind you to check your alarm settings if you have turned off any of your alarms temporarily.

Using Reminders in the Reader

Step	Action
1	 From the Home Screen, touch the Settings symbol ⚙. Scroll down using the arrow and touch **Reminders**.
2	 Touch to select which **Type** of reminder you want to set: Check Glucose, Take Insulin, or Other, which is a general reminder to help you remember something.

Step	Action
3	Touch to select how often you want the reminder to **Repeat**: Once, Daily, or Timer. **Note:** You can set the reminders for a specific time (e.g. 8:30am) or as a timer (e.g. 3 hours from the current time).
4	Set the reminder **Time** using the arrows on the touchscreen. Touch **save**.
5	 From the Reminders screen, you can turn the reminder **On/Off** or **add new** reminders. Touch **done** to return to the Home Screen.

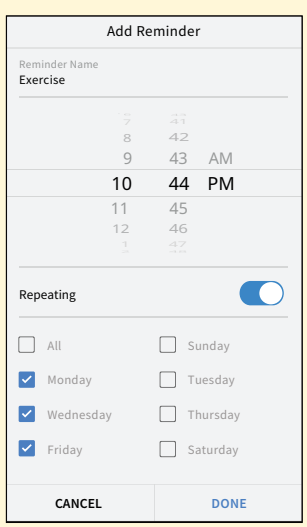


You will get your reminder even if the Reader is turned off. Touch **OK** to dismiss your reminder or **snooze** to be reminded again in 15 minutes.

Note: Reminders will not appear if the Reader is connected to a computer.

Using Reminders in the App

Note: To receive reminders, make sure notifications for the App are enabled. If you want to receive a sound/vibration with your reminder, ensure that sound/vibration on your phone is turned on, sound is set at a level you can hear, and your phone's Do Not Disturb feature is turned off. If Do Not Disturb is on, you will only see your reminder on the screen. For Android phones, ensure Alarms and Reminders permission for the App is **ON** (For Android 12 and above).

Step	Action
1	To add a new reminder, go to the Main Menu and tap **Reminders**. Tap **ADD REMINDER**.
2	Name your reminder.
3	 Tap the time fields to set the time for the reminder. **Note:** If you would like the reminder to repeat, tap the slider to the right. You can also select which days you would like to receive the reminder. *(Example screen displayed for iPhone)*

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

Note:

- There is one default reminder to help you remember to check your glucose. This Check Glucose reminder can be changed or disabled but cannot be deleted.
- To turn off a reminder, tap the slider to the left.
- To delete a reminder, swipe the reminder (swipe left for iPhones, swipe right for Android Phones) and tap the symbol. The Check Glucose reminder cannot be deleted.
- Your reminders will be received as notifications that you can swipe or tap to dismiss.

Using the Reader's Built-in Meter

The Reader has a built-in meter that can be used to test your blood glucose, or to test the meter and strips with control solution.

> **WARNING:** Do NOT use the built-in meter while the Reader is connected to an electrical outlet or a computer due to the potential risk of electrical shock.

Intended Use

The FreeStyle Libre 3 Reader's built-in meter is for use outside the body only (*in vitro* diagnostic use) in the quantitative measurement of glucose in fresh whole blood for self testing by lay users from the fingers. It is not intended to be used for testing neonatal blood samples or for the diagnosis or screening of diabetes.

The FreeStyle Libre 3 Reader's built-in meter is indicated for the home (lay) user in the management of patients with diabetes. It is intended to be used by a single person and should not be shared.

The FreeStyle Precision Neo Blood Glucose Test Strips are for use with the FreeStyle Libre 3 Reader's built-in meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

IMPORTANT:

- Use only FreeStyle Precision Neo test strips. Other test strips may produce inaccurate results.
- Read all the instructions in this section. Failure to follow instructions may cause incorrect blood glucose results. Practice the testing procedures before using the Reader's built-in meter.
- Read the test strip instructions for use before performing your first blood glucose test as they contain important information. They also let you know how to store and handle the test strips and give you information about sample types.
- The Reader's built-in meter is not for use on people who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.
- The Reader's built-in meter is not for use on neonates, in critically-ill patients, or for diagnosis or screening of diabetes.
- Follow your health care professional's advice when testing blood glucose levels.
- Severe dehydration (excessive water loss) may cause false low test strip results. If you believe you are suffering from dehydration, consult your health care professional right away.

IMPORTANT: ***(cont.)***

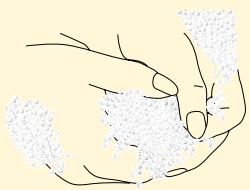
- Inaccurate test strip results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate test strip results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Observe caution when using around children. Small parts may constitute a choking hazard.
- You should clean and disinfect the Reader once per week. The Reader should also be cleaned and disinfected prior to being handled by any person providing testing assistance to the user.
- The Reader is for use by a single person. It must not be used on more than one person including other family members due to the risk of spreading infection. All parts of the Reader are considered biohazardous and can potentially transmit infectious diseases, even after performing the cleaning and disinfection procedure.[1, 2]
- Use the Reader's built-in meter within the test strip operating temperature range (59˚F – 104˚F) or you will see Error Message E-1.
- Use a test strip immediately after removing from its foil packet.
- Only use a test strip once.

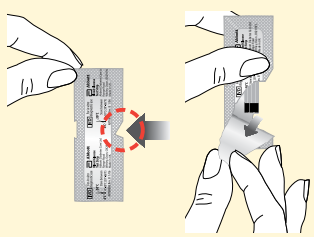
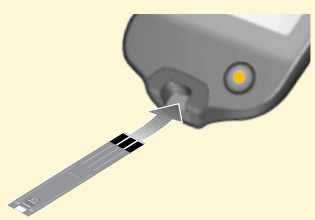
IMPORTANT: ***(cont.)***

- Do not put urine on the test strip.
- Do not use expired test strips as they may cause inaccurate results.
- Do not use at altitudes higher than 10,000 feet above sea level.
- Do not use a wet, bent, scratched, or damaged test strip.
- Do not use the test strip if the foil packet has a hole or is torn.
- Results from the built-in meter are shown only in your Logbook and not in other history options.
- Refer to your lancing device instructions for use for how to use your lancing device.
- This device is not intended for use with multiple patients in health care or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

Blood Glucose Testing

You can use the built-in meter to check your blood glucose, whether you are wearing a Sensor or not. Be sure to read the test strip instructions for use prior to using the built-in meter.

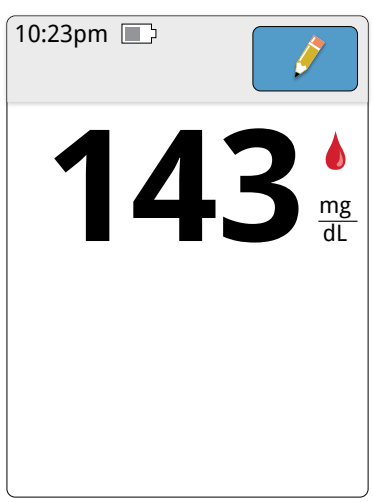
Step	Action
1	 **CAUTION:** Test on your fingers in accordance with the Intended Use in this section. Wash your hands with warm soapy water for accurate results. Thoroughly dry your hands. To warm the site, apply a warm dry pad or rub vigorously for a few seconds. **Note:** Do not use lotion or cream on the test site. Avoid moles, veins, bones, and tendons. Bruising may occur at the test site. If you get a bruise, consider selecting another site.

Step	Action
2	Check the test strip expiration date. Do not use expired test strips as they may give inaccurate results.
3	 Open the foil test strip packet at the notch and tear down to remove the test strip. Use the test strip immediately after removing from the foil packet.
4	 Insert the test strip with the three black lines at the end facing up. Push the strip in until it stops. **Note:** The Reader's built-in meter turns off after 2 minutes of inactivity.

Step	Action
5	 Use your lancing device to obtain a blood drop and apply blood to the white area at the end of the test strip. Refer to your lancing device instructions for use if you need help using your lancing device. If sounds are turned on, the Reader beeps once to let you know you have applied enough blood.  You will see a butterfly on the screen while you wait for your result. Do not remove the test strip while the butterfly is on the screen. If sounds are turned on, the Reader beeps once when your result is ready. If the butterfly does not appear, you may not have applied enough blood to the test strip. Apply a second drop of blood to the test strip within 5 seconds of the first drop. If the butterfly still does not appear or if more than 5 seconds have passed, discard the test strip. Turn off the Reader and repeat the steps in this section with a new test strip.

Step	Action
5 ***(cont.)***	**Note:** • **E-3** means the blood drop is too small, or incorrect test procedure, or there may be a problem with the test strip. • **E-4** means the blood glucose level may be too high to be read by the system or there may be a problem with the test strip. See *Troubleshooting* section for more information.
6	After reviewing your result, remove and discard the used test strip according to local regulations.

IMPORTANT: After performing a blood glucose test, wash your hands with soap and water and thoroughly dry them.



Example Screen Only

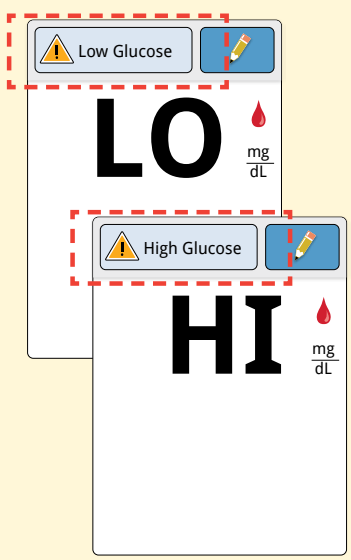
Your Blood Glucose Results

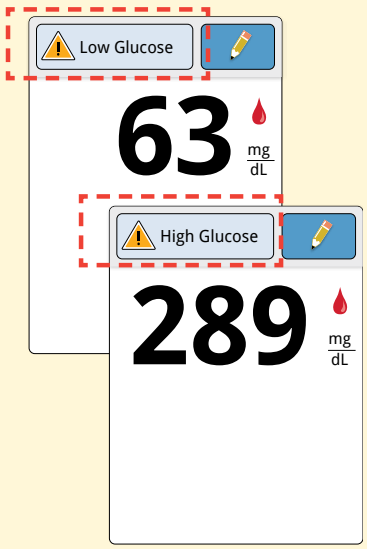
Blood glucose results are marked on the results screen and in the Logbook with the symbol.

Note: Contact your health care professional if you have symptoms that do not match your test results.

IMPORTANT: The built-in meter displays results from 20 - 500 mg/dL. Low or high blood glucose results can indicate a potentially serious medical condition.

The normal glucose level for a non-diabetic adult is below 100 mg/dL when fasting, and less than 140 mg/dL within two hours of a meal.[3] Consult your health care professional to determine the range that is appropriate for you.

Display	What To Do
	If **LO** appears on the Reader, your result is lower than 20 mg/dL. If **HI** appears on the Reader, your result is higher than 500 mg/dL. You can touch the message button for more information. Check your blood glucose again with a test strip. If you get a second **LO** or **HI** result, contact your health care professional **immediately**.

Display	What To Do
	If your glucose is higher than 250 mg/dL or lower than 70 mg/dL, you will see a message on the screen. You can touch the message button for more information and set a reminder to check your glucose.

After you get your blood glucose result, you can add Notes by touching the symbol. If you do not want to add a Note, press the Home Button to go to the Home Screen or hold the Home Button to turn the Reader off.

IMPORTANT: You should clean and disinfect your Reader once per week. Refer to the *Maintenance and Disposal* section for instructions.

Accuracy of the Reader's built-in meter

Results from the Reader's built-in meter may vary slightly from your actual blood glucose value. This may be due to slight differences in technique and natural variation in test technology. The table below shows the results of a study where 119 typical users used the built-in meter to check their blood glucose level. For example, in the study, the built-in meter gave results within 15% of true blood glucose level 115 out of 119 times.

Accuracy results for all glucose concentrations

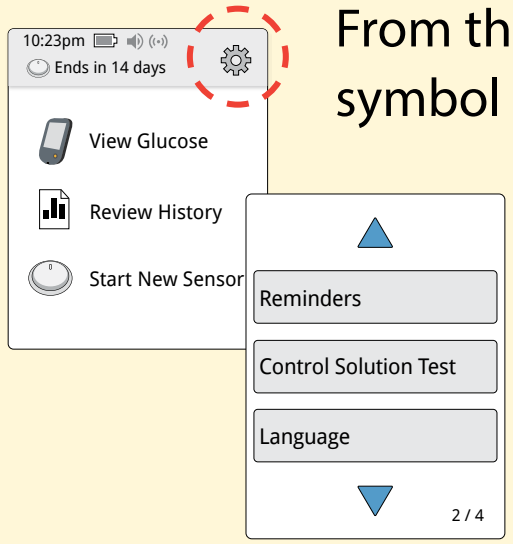
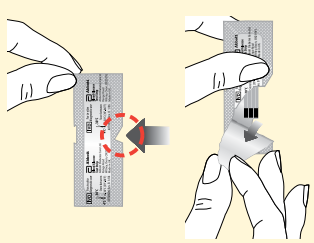
Difference range between the true blood glucose level and the built-in meter result	Within ± 5 mg/dL and 5%	Within ± 10 mg/dL and 10%	Within ± 15 mg/dL and 15%	Within ± 15 mg/dL and 20%
The number and percent that match true blood glucose level within X%	68/119 (57.1%)	105/119 (88.2%)	115/119 (96.6%)	116/119 (97.5%)

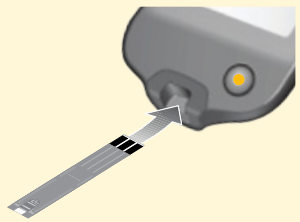
Control Solution Testing

You should do a control solution test when you are not sure of your test strip results and want to check that your Reader's built-in meter and test strips are working properly.

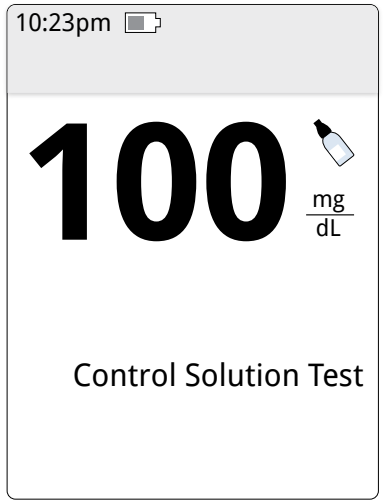
IMPORTANT:

- Control solution results should fall within the control solution range printed on the test strip instructions for use.
- Do NOT use control solution past the expiration date. Discard control solution 3 months after opening or on the expiration date printed on the bottle, whichever comes first. (Example: open April 15, discard July 15; write the discard date on the side of the bottle.).
- The control solution range is a target range for control solution only, not for your blood glucose results.
- The control solution test does not reflect your blood glucose level.
- Use only MediSense (low, medium or high) Glucose and Ketone Control Solution with the Reader's built-in meter.
- Check that the LOT number printed on the test strip foil packet and instructions for use match.
- Replace the cap securely on the bottle immediately after use.
- Do NOT add water or other liquid to the control solution.
- Contact your FreeStyle Libre 3 System provider (pharmacy or mail order supplier) for how to obtain control solution.

Step	Action
1	 From the Home Screen, touch the Settings symbol ⚙ . Scroll down using the arrow and touch **Control Solution Test**.
2	Check the test strip expiration date.
3	 Open the foil test strip packet at the notch and tear down to remove the test strip.

Step	Action
4	 Insert the test strip with the three black lines facing up. Push the strip until it stops. **Note:** The Reader's built-in meter turns off after 2 minutes of inactivity.
5	 Shake the control solution bottle to mix the solution. Apply a drop of control solution to the white area at the end of the test strip. If sounds are turned on, the Reader beeps once to let you know that you have applied enough control solution.

Step	Action
5 ***(cont.)***	 You will see a butterfly on the screen while you wait for the result. Do not remove the test strip while the butterfly is on the screen. If sounds are turned on, the Reader beeps once when the result is ready. If the butterfly does not appear, you may not have applied enough control solution to the test strip. Apply a second drop of control solution to the test strip within 5 seconds of the first drop. If the butterfly still does not appear or if more than 5 seconds have passed, discard the test strip. Turn off the Reader and repeat the steps in this section with a new test strip.



Example Screen Only

Control Solution Results

Compare the control solution result to the range printed on the test strip instructions for use. The result on your screen should be in this range.

Control solution results are marked on the results screen and in the Logbook with a symbol.

Note: Repeat the control solution test if the results are outside of the range printed on the test strip instructions for use. Stop using the built-in meter if the control solution results are repeatedly outside of the printed range. Contact Customer Service. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

Activities

Activity	What You Need To Know
Bathing, Showering, and Swimming	**CAUTION:** Do NOT place the Reader in water or other liquids as this may cause it to not function properly and may lead to **risk of fire or burns**. Your Sensor is water-resistant and can be worn while bathing, showering, or swimming. **Note:** Do NOT take your Sensor deeper than 3 feet (1 meter) or immerse it longer than 30 minutes in water. Bluetooth performance may be impacted if using the system while underwater.

Activity	What You Need To Know
Sleeping	Your Sensor should not interfere with your sleep. Place your device nearby so you will receive alarms and any reminders you have set.
Traveling by Air	You may use your System while on an aircraft, following any requests from the flight crew. **IMPORTANT:** You will not receive alarms or glucose readings while your phone is in airplane mode unless you enable Bluetooth. • The Reader is classed as a Medical-Portable Electronic Device (M-PED) that meets all required M-PED emission standards for safe use onboard an aircraft: RTCA/DO160, Section 21, Category M.

Activity	What You Need To Know
Traveling by Air ***(cont.)***	• Some airport full-body scanners include x-ray or millimeter radio-wave, which you cannot expose your Sensor to. The effect of these scanners has not been evaluated and the exposure may damage the Sensor or cause inaccurate results. To avoid removing your Sensor, you may request another type of screening. If you do choose to go through a full-body scanner, you must remove your Sensor. • The Sensor can be exposed to common electrostatic (ESD) and electromagnetic interference (EMI), including airport metal detectors. You can also keep your Reader on while going through these.

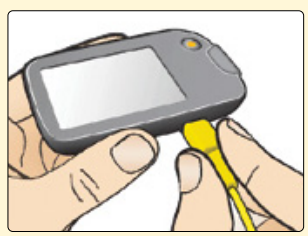
Activity	What You Need To Know
Traveling by Air ***(cont.)***	**Note:** Changing the time and date affects the graphs and statistics. The  symbol may appear on your glucose graph indicating a time change. Gaps in the graph may result or glucose readings may be hidden. If you are changing time zones, you can change the time and date settings on the Reader by touching the Settings symbol  from the Home Screen, then **Time & Date**.

Charging the Reader

A fully charged Reader battery should last up to 4 days. Your battery life may vary depending on your usage. A **Low Battery** message accompanies your result when you have enough charge remaining for about one day of use.

CAUTION:

- Always use the Abbott provided power adapter and yellow USB cable that came with your Reader to minimize the **risk of fire or burns**. Take care when plugging and unplugging your USB cable. Do not force or bend the end of the USB cable into the Reader's USB port.
- Choose a location for charging where you can easily access the power adapter and quickly disconnect to prevent the potential risk of electrical shock.
- The maximum surface temperature of the Reader could go as warm as 117°F. The maximum surface temperature of the power adapter when charging could go as warm as 129°F. Under these conditions, do not hold the Reader or the power adapter for five minutes or more. People with disorders of peripheral circulation or sensation should use caution at this temperature.
- Do NOT expose the USB cable or power adapter to water or other liquids as this may cause them to not function properly and may lead to **risk of fire or burns**.

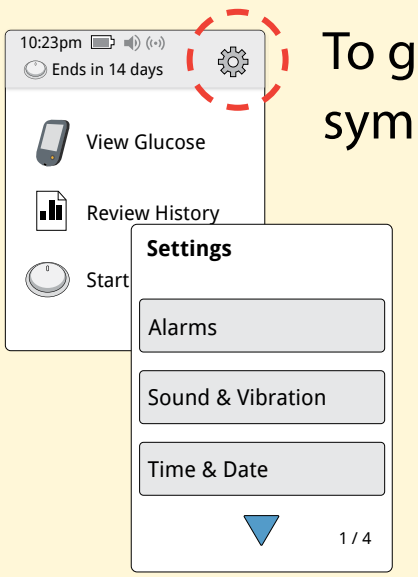
Step	Action
1	Before charging, to minimize the **risk of fire or burns**: • Check the provided power adapter and yellow USB cable to make sure they are not damaged. • Check the Reader's USB port and make sure it is dry and free of debris.
2	 Plug the yellow USB cable into an electrical outlet using the power adapter. Then, plug the other end of the USB cable into the USB port on the Reader.

Note:

- You must charge the Reader when the battery is low  to keep using the Reader.
- To fully charge the battery, charge the Reader for at least 3 hours.
- If the Reader does not turn on after being charged or you notice a significant deterioration in battery life, contact Customer Service about replacing your Reader, yellow USB cable, and power adapter. Customer Service is available at 1-855-632- 8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.
- Fully charge your Reader before storing it for more than 3 months.

Reader Settings and Information

You can go to the Settings menu to change many settings on the Reader, like alarm settings, sound & vibration, time & date, and target range. The Settings menu is also where you go to do a Control Solution Test or to check the System Status.

Step	Action
1	 To get to the Settings menu, touch the Settings symbol ⚙ on the Home Screen.
2	Touch the setting you want to change: **Alarms** – See *Reader Alarms* section for information on setting alarms **Sound & Vibration** – Set Reader sound and vibration. These also apply to alarms

Step	Action
2 ***(cont.)***	**Time & Date** – Change the Time or Date **Reminders** – See *Using Reminders* section for information on setting reminders **Control Solution Test** – Perform a control solution test **Language** – Change the language on the Reader **System Status** – Check Reader information and performance • View System Information: The Reader will display information about your System including: o Current Sensor end date and time o Reader serial number and version number o Serial numbers and status codes of most recent Sensors (up to three) o Sensor version for most recent Sensor o Number of Sensors that have been used with Reader o Number of tests that have been performed using test strips

Step	Action
2 ***(cont.)***	• View Event Logs: A list of events recorded by the Reader, which may be used by Customer Service to help troubleshoot your System • Perform a Reader Test: The Reader Test will perform internal diagnostics and allow you to check that the Display is showing all pixels, sounds and vibrations are working, and the Touchscreen is responding when touched **Report Settings** – Work with your health care professional to set your Target Glucose Range, which is displayed on glucose graphs on the Reader and used to calculate your Time In Target. Your Target Glucose Range is not related to your alarm settings **Reader Basics** – Review the information screens shown during the Reader setup **Dose Increment** – You can set the insulin dose increment to either 1.0 or 0.5 units for use with insulin notes

App Settings and Other Menu Options

You can go to the Main Menu to change settings like your LibreView password. You can also access the Connected Apps option, Help, and information about the App.

App Settings:

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

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

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

Account Settings:

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

Account Settings – View/change your LibreView account information.

Account Password – Change your LibreView account password.

Sign Out – Sign out of your LibreView Account.

Account Options – Sign out or delete your LibreView account.

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

- Use the account with the FreeStyle Libre 3 app unless you sign back in.

- Use the Connected Apps or Account Settings features.

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

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

Connected Apps:

The Connected Apps option in the Main Menu opens a web browser within the App. It lists different apps you can connect with to share your data. To connect your data with apps listed in the Connected Apps option, select them from the list of apps, and follow the onscreen instructions.

Help:

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

About:

View App software version and other information.

Maintenance and Disposal

Cleaning and Disinfecting the Reader

Cleaning and disinfecting your Reader is important to prevent the spread of infectious diseases. The Reader has a mean use life of 3 years and has been validated for 156 cleaning and disinfection cycles (the equivalent of 1 cycle per week for 3 years).

You should clean and disinfect the Reader once a week. The Reader should also be cleaned and disinfected prior to being handled by any person providing testing assistance to the user.

Cleaning is the physical removal of organic soil from the Reader surfaces. Keeping the Reader clean helps ensure that it is working properly and that no dirt gets in the device. Cleaning allows for successful, subsequent disinfection.

Disinfection is a process that destroys pathogens, such as viruses and other microorganisms, on the Reader surfaces. Disinfecting the Reader helps ensure that no infection is passed on when you or others come in contact with the Reader.

This device is not intended for use with multiple patients in health care or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures.

Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

To clean and disinfect your Reader, you will need Clorox Healthcare Bleach Germicidal Wipes, EPA Reg. #67619-12.

These disinfectant wipes contain a 0.55% Sodium Hypochlorite (NaOCl) solution and have been shown to be safe for use with the Reader. They may be purchased at major online retailers, such as Walmart.com, Amazon.com, and OfficeDepot.com.

Note: Additional information about the risks for transmitting bloodborne pathogens to persons undergoing fingerstick procedures for blood sampling can be found. See *References* section for more information.

Step	Action
1	Turn off the Reader before you clean and disinfect it.
2	Clean the outside surfaces of the Reader with a bleach wipe until visibly clean. Make sure liquid does not get into the test strip and USB ports.
3	For disinfection, use a second bleach wipe to wipe all outside surfaces of the Reader until they are wet. Make sure liquid does not get into the test strip and USB ports. Allow the Reader surfaces to remain wet for 60 seconds.
4	Dry with clean paper towel to remove any residual moisture.

Step	Action
5	When finished, thoroughly wash your hands with soap and water.

IMPORTANT: Do NOT use the Reader if you notice any signs of deterioration on the Reader (such as clouding or crazing on the display of the Reader, corroding, eroding or swelling of the plastic housing, or cracking of plastic housing or display) or if the Reader does not turn on. Contact Customer Service about replacing your Reader. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

CAUTION: Do NOT place the Reader in water or other liquids. Avoid getting dust, dirt, blood, control solution, water, bleach, or any other substance in the test strip or USB port as this may cause the Reader to not function properly and may lead to **risk of fire or burns**.

Maintenance

The System has no serviceable parts.

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 8AM to 8PM Eastern Time; excluding holidays.

Troubleshooting

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

IMPORTANT: If you are having issues with the App, please keep in mind that uninstalling the App will cause you to lose all historical data on the App, and may end the Sensor currently in use. Please call Customer Service if you have any questions. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

Reader Does Not Power On

Problem	What It May Mean	What To Do
Reader does not power on after you press the Home Button or insert a test strip.	Reader battery is too low.	Charge the Reader.
	Reader is outside of its operating temperature range.	Move the Reader to a temperature between 50°F and 113°F and then try to power it on.

If the Reader still does not power on after trying these steps, contact Customer Service. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

Problems at the Sensor Application Site

Problem	What It May Mean	What To Do
The Sensor is not sticking to your skin.	The site is not free of dirt, oil, hair, or sweat.	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 and Starting Your Sensor* sections. Consider shaving the site, avoiding use of lotions prior to insertion, and applying the Sensor to your non-dominant arm.

Customer Service: 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

Problem	What It May Mean	What To Do
Skin irritation at the Sensor application site.	Seams or other constrictive clothing or accessories causing friction at the site.	Ensure that nothing rubs on the site.
	You may be sensitive to the adhesive material.	If the irritation is where the adhesive touches skin, contact your health care professional to identify the best solution.

Problems Starting Your Sensor or Receiving Sensor Readings

Display	What It May Mean	What To Do
Scan Error	The device was unable to scan the Sensor.	• **iPhone:** Tap the scan button and try scanning the Sensor again. The NFC antenna is on the top edge of the phone. Scan your Sensor by touching the Sensor with the TOP of your phone. Move your phone around slowly if needed. Proximity, orientation, and other factors can affect NFC performance. For example, a bulky or metallic case can interfere with the NFC signal. Contact Customer Service if the error persists after repeated attempts of scanning. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

Customer Service: 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

Display	What It May Mean	What To Do
Scan Error *(cont.)*		• **Android Phone:** Try scanning the Sensor again. The NFC antenna is located on the back side of most Android phones. Scan your Sensor by touching the Sensor with the BACK of your phone. Move your phone around slowly if needed. Proximity, orientation, and other factors can affect NFC performance. For example, a bulky or metallic case can interfere with the NFC signal. Make sure you are not touching any buttons on the phone or the screen. • **Reader:** Try scanning again. You may need to move away from potential sources of electromagnetic interference.

Display	What It May Mean	What To Do
Sensor Already in Use	The Sensor was started by another device.	Both the Reader and App can only be used with a Sensor that it started. Check your glucose with the device that started it. Or, apply and start a new Sensor.
Enable Bluetooth	The Bluetooth setting on your phone is turned off.	Go to your phone settings and enable Bluetooth.

Display	What It May Mean	What To Do
Incompatible Sensor	The FreeStyle Libre 3 Reader and FreeStyle Libre 3 app can only be used with the FreeStyle Libre 3 Sensor and FreeStyle Libre 3 Plus Sensor. Check that you are using the App or Reader that is compatible with your Sensor. You may need to download a different app if your Sensor is not compatible.	If you still have questions about compatibility, tap **Learn more** or call Customer Service.
Replace Sensor	The System has detected a problem with your Sensor.	Apply and start a new Sensor.

Display	What It May Mean	What To Do
Allow Access to Critical Alerts (iPhone) / Allow Access to Do Not Disturb (Android Phone)	Access to Critical Alerts / Do Not Disturb was disabled.	Follow the instructions on the screen to allow permission for Critical Alerts (iPhone) / Do Not Disturb (Android Phone). You will not be able to receive Sensor readings or start a new Sensor until these permissions are allowed.
Sensor ready in X minutes	The Sensor is unable to provide a glucose reading during the start-up period.	Check again after the duration specified on the screen.

Display	What It May Mean	What To Do
Scan Timeout (Reader only)	The Reader is not held close enough to the Sensor.	Bring the screen of the Reader close to the Sensor.
Check Sensor	The Sensor tip may not be under your skin.	Try to start your Sensor again. If you see **Check Sensor** again on the screen, your Sensor was not applied properly. Remove this Sensor and apply and start a new Sensor.
Sensor Ended	The Sensor has ended.	Apply and start a new Sensor.

Display	What It May Mean	What To Do
Signal Loss	Sensor has not automatically communicated with your device in the last 5 minutes.	Make sure your device is within 33 feet of the Sensor. If using the App, make sure you have not force closed the App. Tap the ⓘ symbol for more information. Try turning Bluetooth OFF then ON again. If that doesn't work, try turning your phone OFF then ON again.
Signal Loss Alarm	Sensor has not automatically communicated with your device in the last 20 minutes.	Make sure your device is within 33 feet of the Sensor. If the Signal Loss Alarm continues to show, contact Customer Service.
Bluetooth Off	Bluetooth is turned off.	Go to your phone settings and enable Bluetooth.

Customer Service: 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

Display	What It May Mean	What To Do
Sensor Error	The Sensor is unable to provide a glucose reading. Tap the ⓘ symbol for more information.	Check again after the duration specified in the message.
Sensor Too Hot	Your Sensor is too hot to provide a glucose reading. Tap the ⓘ symbol for more information.	Move to a location where the temperature is appropriate and check again in a few minutes.
Sensor Too Cold	Your Sensor is too cold to provide a glucose reading. Tap the ⓘ symbol for more information.	Move to a location where the temperature is appropriate and check again in a few minutes.

Display	What It May Mean	What To Do
Unexpected Application Error	The App has detected an unexpected error.	Shut down the App completely and restart.
New Sensor Starting Up (Reader) or New Sensor Starting Up (App)	Sensor is not ready to read glucose.	Wait until the Sensor start-up period has completed.
New Sensor Found	You scanned a new Sensor before your previous Sensor ended.	Your device 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** and scan again.
Glucose Reading Unavailable	Your Sensor is too hot or too cold.	Move to a location where the temperature is appropriate and check your glucose again.

Customer Service: 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

Problems Receiving Alarms

Problem	What It May Mean	What To Do
You are not receiving alarms.	You have turned alarms off.	If using the Reader, touch the Settings symbol  and then select **Alarms**. If using the App, go to the Main Menu and then select **Alarms**. Choose the alarm you want to turn on and set.

Problem	What It May Mean	What To Do
You are not receiving alarms. *(cont.)*	The Sensor is not communicating with your device. or There may be a problem with your Sensor or device.	The Sensor must be within range (33 feet) of your device for you to receive alarms. Make sure that you are within this range. You will see the  symbol at the top of the Home Screen (if using the Reader) and the  symbol at the top of the screen (if using the App) when your Sensor has not communicated with your device in 5 minutes. If the Signal Loss Alarm is on, you will be notified if there has been no communication for 20 minutes. If the Signal Loss Alarm is on and continues to show even when your Sensor is in range of your device, contact Customer Service.

Problem	What It May Mean	What To Do
You are not receiving alarms. *(cont.)*	Sound/vibration are turned off in your Reader settings.	Check the Reader's sound and vibration settings to confirm sound/vibration are on.
	One or more of the phone settings or permissions is incorrect.	Check to make sure that you have the correct settings and permissions enabled on your phone to receive alarms.

iPhone settings:

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

Android Phone settings:

- Bluetooth is **ON**
- Lock Screen notifications are **ON**
- Channel notifications or Pop-up notifications are **ON**
- Battery Optimization is **OFF**
- Do Not Disturb access permission is **ON**
- Phone Media volume is **ON**
- Nearby Devices permission for the App is **ON** (For Android 12 and above)
- Alarms and Reminders permission for the App is **ON** (For Android 12 and above)

Go to *Setting App Alarms* section for more information.

Problem	What It May Mean	What To Do
You are not receiving alarms. *(cont.)*	You have enabled Silent Mode in the App.	Check your alarm settings to confirm Silent Mode is turned off.
	You may have set an alarm level that is higher or lower than you intended.	Confirm your alarm settings are appropriate.
	You have already dismissed this type of alarm.	You will receive another alarm when a new low or high glucose episode starts.
	Your Sensor has ended.	Replace your Sensor with a new one.

Problem	What It May Mean	What To Do
You are not receiving alarms. *(cont.)*	If you are using peripherals such as wireless headphones or a smartwatch, you may receive alarms on only one device or peripheral, not all.	Disconnect headphones or peripherals when you are not using them.
	You have closed the App.	Make sure the App is always open in the background.
	Your device's battery is dead.	Charge your device. If using the Reader, use the included USB cable.

Blood Glucose Error Messages

Error Message	What It May Mean	What To Do
E-1	The temperature is too hot or too cold for the Reader to work correctly.	1. Move the Reader and test strips to a location where the temperature is within the test strip operating range. (See test strip instructions for use for the appropriate range). 2. Wait for the Reader and test strips to adjust to the new temperature. 3. Repeat the test using a new test strip. 4. If the error reappears, contact Customer Service.
E-2	Reader error.	1. Turn off the Reader. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Service.

Customer Service: 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

Error Message	What It May Mean	What To Do
E-3	Blood drop is too small. or Incorrect test procedure. or There may be a problem with the test strip.	1. Review the testing instructions. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Service.
E-4	The blood glucose level may be too high to be read by the system. or There may be a problem with the test strip.	1. Repeat the test using a new test strip. 2. If the error reappears, contact your health care professional **immediately**.

Customer Service: 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

Error Message	What It May Mean	What To Do
E-5	Blood was applied to the test strip too soon.	1. Review the testing instructions. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Service.
E-6	The test strip may not be compatible with the Reader.	1. Check that you are using the correct test strip for the Reader. (See test strip instructions for use to verify your strip is compatible with the Reader). 2. Repeat the test using a test strip for use with your Reader. 3. If the error reappears, contact Customer Service.

Customer Service: 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

Error Message	What It May Mean	What To Do
E-7	Test strip may be damaged, used, or the Reader does not recognize it.	1. Check that you are using the correct test strip for the Reader. (See test strip instructions for use to verify your strip is compatible with the Reader). 2. Repeat the test using a test strip for use with your Reader. 3. If the error reappears, contact Customer Service.
E-9	Reader error.	1. Turn off the Reader. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Service.

Customer Service: 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

Problems Checking Your Blood Glucose

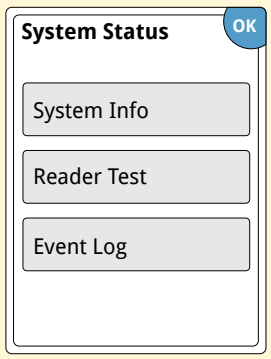
Problem	What It May Mean	What To Do
The Reader does not start a test after inserting a test strip.	Test strip is not inserted correctly or not inserted fully into the strip port.	1. With the 3 black lines facing up, insert the test strip into the strip port until it stops. 2. If the Reader still does not start a test, contact Customer Service.
	Reader battery is too low.	Charge the Reader.
	The test strip is damaged, used, or unrecognizable by the Reader.	Insert a new FreeStyle Precision Neo test strip.
	Reader is outside of its operating temperature range.	Move the Reader to a temperature between 50°F and 113°F and then try to power it on.

Customer Service: 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

Problem	What It May Mean	What To Do
The test does not start after applying the blood sample.	Blood sample is too small.	1. See test strip instructions for use for re-application instructions. 2. Repeat the test using a new test strip. 3. If the test still does not start, contact Customer Service.
	Sample applied after the Reader turned off.	1. Review the testing instructions. 2. Repeat the test using a new test strip. 3. If the test still does not start, contact Customer Service.
	Problem with Reader or test strip.	1. Repeat the test using a new test strip. 2. If the test still does not start, contact Customer Service.

Customer Service: 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

Perform a Reader Test



If you think the Reader is not working properly, you can check the Reader by performing a Reader Test.

Touch the Settings symbol from the Home Screen, select **System Status** and then select **Reader Test**.

Note: The Reader Test will perform internal diagnostics and will allow you to check that the display, sounds, and touchscreen are working properly.

Customer Service

Customer Service is available to answer any questions you may have about your FreeStyle Libre 3 System. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays. A printed copy of the User's Manual is available upon request. The latest version of the User's Manual is available at www.FreeStyleLibre.us/support/overview.html

System Specifications

See test strip and control solution instructions for use for additional specifications.

Sensor Specifications

Sensor glucose assay method	Amperometric electrochemical sensor
Sensor glucose reading range	40 to 400 mg/dL
Sensor size	2.9 mm height and 21 mm diameter
Sensor weight	1 gram
Sensor power source	One silver oxide battery
Sensor data	FreeStyle Libre 3 Sensor: Up to 14 days FreeStyle Libre 3 Plus Sensor: Up to 15 days

Sensor memory	FreeStyle Libre 3 Sensor: Up to 14 days (glucose readings stored every 5 minutes); FreeStyle Libre 3 Plus Sensor: Up to 15 days (glucose readings stored every 5 minutes)
Sensor transmission range	33 feet (10 meters) unobstructed
Operating temperature	50°F to 113°F
Sensor Applicator 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 feet (one 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; 4.6 dBm EIRP

Reader Specifications

Blood glucose assay range	20 to 500 mg/dL
Reader size	95 mm x 60 mm x 16 mm
Reader weight	65 grams
Reader power source	One lithium-ion rechargeable battery
Reader battery life	4 days of typical use
Reader memory	90 days of typical use
Reader operating temperature	50°F to 113°F
Reader storage temperature	-4°F to 140°F

Operating and storage relative humidity	10-90%, non-condensing
Reader moisture protection	Keep dry
Operating and storage altitude	-1,250 ft (-381 meters) to 10,000 ft (3,048 meters)
Reader display timeout	60 seconds (120 seconds when test strip is inserted)
Radio Frequency	Near Field Communication (13.56 MHz RFID); ASK Modulation; 124 dBuV/m; 2.402-2.480 GHz BLE; GFSK; 2dBm EIRP
Data port	Micro USB
Minimum Computer Requirements	System must only be used with EN60950-1 rated computers
Mean use life	3 years of typical use

Reader cleaning and disinfection	The Reader has a mean use life of 3 years, which is 156 cleaning and disinfection cycles (1 cycle per week for 3 years).
Power Adapter	Abbott Diabetes Care PRT31887 (Phihong Model PSM03A-050Q-3A-R, Luxshare Model LACA175) Output: 5V, 550mA or 0.55A Operating temperature: 50°F to 104°F
USB Cable	Abbott Diabetes Care PRT21373 Length: 37 inches (94 cm) Color: Yellow

Security Measures and Quality of Service

Security Measures:
The communication between the Receiver (App or Reader) and Sensor during an activation 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 Receiver and Sensor for glucose data is a standard Bluetooth Low Energy (BLE) connection. Mutual authentication is performed between the Receiver and Sensor during the pairing process using application certificates, preventing unauthorized devices from connecting to the Sensor. The transmitted data is protected

by 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, only the authenticated Receiver that is paired with the Sensor will be able to reconnect and receive glucose data. For apps, only apps logged into the same LibreView account that activated the Sensor are able to complete pairing with the Sensor. For Readers, only the Reader that activated the Sensor is able to complete pairing with the Sensor.

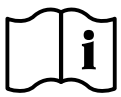
Quality of Service (QoS):
QoS for the FreeStyle Libre 3 Reader and Sensor wireless communications using NFC (for Sensor activation) is assured when the Reader is brought near the Sensor. The communication for activation is specified to occur within 15 seconds.

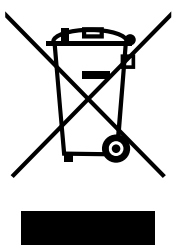
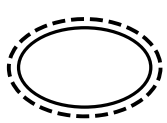
QoS for the Reader and Sensor wireless communications using BLE for normal operation (receiving glucose readings and alarms) is assured at regular 1-minute intervals. If connection is lost between the Reader and Sensor for 5-minutes, the Reader will display an indication of "Signal Loss" on the results screen. If connection is lost for 20 minutes, the Reader alarms the user if the alarm is turned on. If connection is lost between the Reader and the Sensor, all lost glucose data will be automatically retrieved when the connection is restored. The Reader is designed to only accept BLE data from recognized and paired Sensors. The transmission range for BLE communication is 33 feet unobstructed. If the Reader and Sensor are seeing frequent signal loss at longer distances, bring them closer together.

QoS for the FreeStyle Libre 3 app and Sensor wireless communication using NFC (for Sensor activation) is assured when the phone is touched to the Sensor. The communication for activation takes place within 1 second. If the expected response is not received, the phone will continue to retry.

QoS for the FreeStyle Libre 3 app and Sensor wireless communications using BLE for normal operation (receiving glucose reading and alarms) 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 Home Screen. If connection is lost for 20 minutes, the App alarms the user if the alarm is turned on. If connection is lost between the Sensor and the App, all lost glucose data will be automatically retrieved when the connection is restored. The App is designed to only accept BLE data from recognized and paired Sensors. The transmission range for BLE communication is 33 feet unobstructed. If the phone and Sensor are seeing frequent signal loss at longer distances, bring them closer together.

Labeling Symbols

	Consult instructions for use		Catalog number
	Temperature limit		Serial number
	Manufacturer		Keep dry
	Batch code		Non-ionizing radiation
	Type BF applied part		Caution
	Do not re-use		Sterilized using irradiation
	MR unsafe		Humidity limitation
	Use-by date		FCC Declaration of Conformity mark

	Do not use if package is damaged. **For Sterile Barrier**: Do not use if the product sterile barrier system or its packaging is compromised.
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.
	Sterile Barrier. Refer to Instructions for Use if opened or damaged.
	Single sterile barrier system with protective packaging outside

Performance Characteristics

The FreeStyle Libre 3 System can be used with either the FreeStyle Libre 3 Sensor or the FreeStyle Libre 3 Plus Sensor. Different clinical studies were conducted to evaluate the performance of each Sensor. Please reference the section that applies to the Sensor you are using.

A. Performance Characteristics of FreeStyle Libre 3 Continuous Glucose Monitoring System with FreeStyle Libre 3 Sensor:

Overview of Clinical Studies

Three studies were conducted in the United States (US) to evaluate the performance, safety, effectiveness, and precision of the FreeStyle Libre 3 Continuous Glucose Monitoring System (System). One study included adults (Study 1), one study included pediatrics (Study 2) and one study included both adults and pediatrics (Study 3).

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 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. For subjects 4-5 years old, System performance was compared against a self-monitoring blood glucose meter.

Study 1: Study 1 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).

Study 2: Study 2 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.

Study 3: Study 3 was conducted at 4 centers with 100 adult and pediatric subjects in total (83.0 % Type 1, 17.0% Type 2). 56 adult subjects were aged 18 and older, 39 pediatric subjects were aged six to seventeen and 5 pediatric subjects were aged four to five. Subjects aged 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. 81 subjects were analyzed during the beginning of the Sensor wear period (day 1, 2 or 3), 46 subjects were analyzed during the early middle period (day 7 or 8), 47 subjects were analyzed during the late middle period (day 9 or 12), and 34 subjects were analyzed during the end period (day 13 or 14).

Accuracy

Accuracy of the System was measured by comparing paired System Glucose Measurement (CGM) and YSI blood glucose values. The percentage of total System readings that were within 20 mg/dL for YSI blood glucose values < 70 mg/dL or 20% of YSI for blood glucose values ≥ 70 mg/dL is displayed in **Table 1a**. 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 subject group, 92.9% 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 23,503. In the Adult subject group, the Mean Absolute Relative Difference was 8.9% for the comparison with YSI reference. In the Pediatric subject group, the Mean Absolute Relative Difference was 9.4% for the comparison with YSI reference.

Table 1a: Overall Accuracy to YSI

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	23503	200	92.9	87.5	81.4	8.9
Children (age 6-17)	8614	168	91.1	85.4	81.6	9.4
Children (age 4-5)*	413	13	86.4	87.5	89.2	11.5

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

The accuracy of different CGM glucose ranges versus YSI reference was assessed by calculating the percentage of System readings that were within 15%, 20%, and 40% for reference values ≥ 70 mg/dL, and within 15 mg/dL, 20 mg/dL, and 40 mg/dL for values < 70 mg/dL. 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 results categorized within CGM glucose ranges are presented in **Tables 1b and 1c**. The results categorized within YSI glucose ranges are presented in **Tables 1d and 1e**.

Table 1b: Accuracy to YSI within CGM Glucose Ranges (Adult; n=200)

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	543	84.7	92.6	99.4				-6.7	14.2
54-69	3124	88.7	93.7	99.0				-3.6	11.0
70-180	11128				79.8	88.8	99.3	-4.9	9.8
181-250	4112				90.9	96.0	99.9	-7.7	7.2
>250	4596				94.1	98.0	100.0	-5.9	6.0

† System range is 40-400 mg/dL.

Table 1c: Accuracy to YSI within CGM Glucose Ranges (Pediatric*; n=168)

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	153	68.6	75.8	95.4				-12.1	18.8
54-69	915	84.6	88.9	96.7				-5.6	12.6
70-180	4149				78.8	87.8	98.9	-4.9	10.1
181-250	1640				87.9	95.4	99.7	-7.1	7.7
>250	1757				92.7	97.8	99.8	-2.1	6.9

* 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 1d: Accuracy to YSI within YSI Glucose Ranges (Adult; n=200)

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	446	91.0	97.5	100.0				7.4	15.5
54-69	3111	94.5	98.5	100.0				1.4	10.3
70-180	10748				80.2	88.7	99.5	-4.5	9.7
181-250	4122				89.7	95.1	99.8	-7.3	7.5
>250	5076				91.3	96.1	99.7	-11.5	6.9

Table 1e: Accuracy to YSI within YSI Glucose Ranges (Pediatric*; n=168)

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	140	91.4	96.4	99.3				7.6	16.4
54-69	773	96.4	98.7	100.0				1.0	9.4
70-180	4168				76.7	85.7	98.3	-4.2	10.7
181-250	1559				86.8	92.9	99.1	-5.0	8.1
>250	1974				90.8	97.7	99.9	-9.9	7.4

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

Agreement with 'LO' and 'HI' CGM Reading against 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'. **Tables 2a and 2b** display the concurrence between the CGM and YSI reference glucose when CGM reads 'LO'. For example, in the Adult subject group, 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 2a: Concurrence Analysis with 'LO' CGM Reading (Adult; n=200)

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 2b: Concurrence Analysis with 'LO' CGM Reading (Pediatric*; n=168)

CGM-Reference Pairs	YSI (mg/dL)					N
	<50	<60	<70	<80	≥80	
n	0	1	3	3	0	3
Cumulative %	0.0	33.3	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.

Tables 2c and 2d display the concurrence between the CGM and YSI reference glucose when CGM reads 'HI'. In the Adult subject group, when CGM reading was 'HI', YSI glucose values were above 350 mg/dL 97.6% 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 2c: Concurrence Analysis with 'HI' CGM Reading (Adult; n=200)

CGM-Reference Pairs	YSI (mg/dL)				N
	>350	>300	>250	≤250	
n	120	123	123	0	123
Cumulative %	97.6	100.0	100.0	0.0	

Table 2d: Concurrence Analysis with 'HI' CGM Reading (Pediatric*; n=168)

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 percentage of concurring glucose values (CGM vs. YSI) in each glucose reference range is presented for each CGM range in **Tables 3a and 3b** and for each YSI range in **Tables 3c and 3d**. For example, in the Adult subject group, 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 9.2% of the time, between 81 and 120 mg/dL 70.5% of the time, between 121 and 160 mg/dL 19.4% of the time, between 161 and 200 mg/dL 0.7% of the time, and between 201 and 250 mg/dL 0.1% of the time.

Table 3a: Concurrence Analysis by CGM Glucose Level (Adult; n=200)

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	52.0	43.7	3.8	.	0.1	.	.	.	.	.	1950
61-80	.	17.8	62.2	19.6	0.4	0.0	.	.	.	.	.	3317
81-120	.	0.2	9.2	70.5	19.4	0.7	0.1	.	.	.	.	4147
121-160	.	.	0.1	8.4	71.1	19.1	1.0	0.2	0.1	.	.	3883
161-200	.	.	.	.	10.4	66.4	22.1	1.0	0.2	.	.	2806
201-250	.	.	.	.	.	8.6	67.8	22.0	1.5	0.1	.	2804
251-300	.	.	.	.	.	0.1	8.8	67.6	21.7	1.7	0.1	2469
301-350	.	.	.	.	.	.	0.4	13.9	68.9	15.8	1.1	1580
351-400	.	.	.	.	.	.	.	0.5	27.8	62.9	8.8	547
>400[†]	.	.	.	.	.	.	.	.	2.4	63.4	34.1	123

[†] Levels out of System dynamic range.

Table 3b: Concurrence Analysis by CGM Glucose Level (Pediatric*; n=168)

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†	.	33.3	66.7	.	.	.	.	.	.	.	.	3
40-60	0.5	47.5	41.3	9.6	0.9	0.2	.	.	.	.	.	554
61-80	.	11.4	59.7	26.8	2.0	.	.	.	.	.	.	1025
81-120	.	0.2	8.2	67.4	22.8	1.3	0.1	.	.	.	.	1590
121-160	.	.	.	9.1	71.1	18.4	1.3	.	.	.	.	1437
161-200	.	.	.	0.1	15.5	66.0	18.2	0.2	.	.	.	1094
201-250	.	.	.	.	0.3	10.6	59.1	29.0	1.0	0.1	.	1157
251-300	.	.	.	.	.	0.1	13.6	63.8	21.3	1.2	.	933
301-350	.	.	.	.	.	.	0.3	24.4	58.4	16.7	0.2	616
351-400	.	.	.	.	.	1.0	.	0.5	34.1	59.1	5.3	208
>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 3c: Concurrence Analysis by YSI Glucose Level (Adult; n=200)

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	.	.	.	.	.	.	.	1612
61-80	0.1	25.8	62.5	11.5	0.1	.	.	.	.	.	.	3301
81-120	0.0	1.9	16.3	73.5	8.2	.	.	.	.	.	.	3977
121-160	.	.	0.3	20.8	71.4	7.5	.	.	.	.	.	3871
161-200	.	0.0	0.0	0.9	25.7	64.8	8.4	0.1	.	.	.	2876
201-250	.	.	.	0.1	1.4	22.2	68.2	7.8	0.2	.	.	2787
251-300	.	.	.	.	0.3	1.1	24.3	65.6	8.6	0.1	.	2543
301-350	.	.	.	.	0.3	0.3	2.2	29.3	59.5	8.3	0.2	1830
351-400	.	.	.	.	.	.	0.3	6.0	34.8	48.0	10.9	716
>400	.	.	.	.	.	.	.	1.8	16.4	43.6	38.2	110

[†] Levels out of System dynamic range.

Table 3d: Concurrence Analysis by YSI Glucose Level (Pediatric*; n=168)

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	68.5	30.5	0.8	.	.	.	.	.	.	.	384
61-80	0.2	23.5	62.8	13.4	.	.	.	.	.	.	.	974
81-120	.	3.5	18.0	70.0	8.6	0.1	.	.	.	.	.	1532
121-160	.	0.3	1.3	22.9	64.6	10.7	0.2	.	.	.	.	1583
161-200	.	0.1.	.	1.8	23.4	63.7	10.8	0.1	.	0.2	.	1134
201-250	.	.	.	0.2	1.8	19.3	66.2	12.3	0.2	.	.	1033
251-300	.	.	.	.	.	0.2	30.9	54.8	13.8	0.1	0.2	1085
301-350	.	.	.	.	.	.	1.7	30.9	55.9	11.0	0.5	644
351-400	.	.	.	.	.	.	0.4	4.3	40.7	48.6	5.9	253
>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 Rate of Change Accuracy

The System's glucose rate of change (ROC) accuracy, as assessed by concurrence analysis, is presented in **Tables 4a and 4b**. For example, in the Adult subject group, when the Sensor glucose ROC 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) 1.0% of the time, falling (-2 to -1 mg/dL/min) 7.7% of the time, changing slowly downward (-1 to 0 mg/dL/min) 68.0% of the time, changing slowly upward (0 to 1 mg/dL/min) 19.9% of the time, rising (1 to 2 mg/dL/min) 2.3% of the time, and were rising quickly (>2 mg/dL/min) 1.0% of the time.

Table 4a: Concurrence Analysis by Glucose Rate of Change (Adult; n=200)

CGM (mg/dL/min)	YSI (mg/dL/min)						N
	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2 (↓)	34.5	44.9	18.0	2.3	0.3	.	345
-2 to -1 (↘)	6.9	46.6	41.2	4.0	0.8	0.5	1210
-1 to 0 (→)	1.0	7.7	68.0	19.9	2.3	1.0	11735
0 to 1 (→)	0.7	2.8	26.0	50.3	14.3	5.8	7270
1 to 2 (↗)	0.2	1.7	7.7	32.7	38.0	19.8	1322
>2 (↑)	0.1	0.4	3.1	14.9	33.2	48.4	941

Table 4b: Concurrence Analysis by Glucose Rate of Change (Pediatric*; n=168)

CGM (mg/dL/min)	YSI (mg/dL/min)						N
	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2 (↓)	41.7	44.3	10.9	3.1	.	.	192
-2 to -1 (↘)	10.5	50.3	33.1	5.0	0.4	0.7	543
-1 to 0 (→)	1.7	10.1	62.7	20.5	3.4	1.5	3481
0 to 1 (→)	1.1	4.5	24.6	49.0	13.4	7.5	2923
1 to 2 (↗)	0.2	2.5	9.5	29.0	38.1	20.7	603
>2 (↑)	.	1.0	3.9	14.8	29.9	50.4	488

* 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

Tables 5a and 5b 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:
84.3% of the time a low glucose alarm was received when blood glucose was indeed below the alarm level but 15.7% of the time a low glucose alarm was received when blood glucose wasn't actually below the alarm level.
89.0% of the time blood glucose was below the alarm level and a low glucose alarm was appropriately issued but 11.0% of the time the glucose event was missed and no alarm was issued.

Table 5a: Low Glucose Alarm Performance (Adult; n=200)

Low Glucose Alarm level (mg/dL)	Alarm Rate		Detection Rate	
	True Alarm Rate (%)	False Alarm Rate (%)	Correct Detection Rate (%)	Missed Detection Rate (%)
60	70.9	29.1	75.8	24.2
70	84.3	15.7	89.0	11.0
80	90.3	9.7	97.0	3.0
90	92.3	7.7	98.4	1.6

Table 5b: Low Glucose Alarm Performance (Pediatric*; n=168)

Low Glucose Alarm level (mg/dL)	Alarm Rate		Detection Rate	
	True Alarm Rate (%)	False Alarm Rate(%)	Correct Detection Rate (%)	Missed Detection Rate (%)
60	60.5	39.5	86.8	13.2
70	77.1	22.9	92.8	7.2
80	82.3	17.7	96.2	3.8
90	90.0	10.0	97.5	2.5

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

High Glucose Alarm Performance

Tables 5c and 5d 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:
98.7% of the time a high glucose alarm was received when blood glucose was indeed above the alarm level but 1.3% of the time a high glucose alarm was received when blood glucose wasn't actually above the alarm level.
96.7% of the time blood glucose was above the alarm level and a high glucose alarm was appropriately issued but 3.3% of the time the glucose event was missed and no alarm was issued.

Table 5c: High Glucose Alarm Performance (Adult; n=200)

High Glucose Alarm level (mg/dL)	Alarm Rate		Detection Rate	
	True Alarm Rate (%)	False Alarm Rate (%)	Correct Detection Rate (%)	Missed Detection Rate (%)
120	99.0	1.0	98.0	2.0
140	98.7	1.3	97.5	2.5
180	98.7	1.3	96.8	3.2
200	98.7	1.3	96.7	3.3
220	98.3	1.7	96.7	3.3
240	98.0	2.0	95.5	4.5
300	96.2	3.8	90.2	9.8

Table 5d: High Glucose Alarm Performance (Pediatric*; n=168)

High Glucose Alarm level (mg/dL)	Alarm Rate		Detection Rate	
	True Alarm Rate (%)	False Alarm Rate (%)	Correct Detection Rate (%)	Missed Detection Rate (%)
120	98.9	1.1	97.2	2.8
140	97.8	2.2	97.0	3.0
180	98.1	1.9	97.0	3.0
200	97.4	2.6	97.6	2.4
220	97.7	2.3	96.8	3.2
240	97.6	2.4	95.2	4.8
300	90.9	9.1	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 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 **Tables 6a and 6b**: Beginning (Adult: 198 Subjects, Day 1, 2 or 3; Pediatric: 75 Subjects, Day 1, 2 or 3) Early Middle (Adult: 124 Subjects, Day 7 or 8; Pediatric: 63 Subjects, Day 7 or 8), Late Middle (Adult: 86 Subjects, Day 9 or 12; Pediatric: 67 Subjects, Day 9 or 12), and End (Adult: 97 Subjects, Day 13 or 14; Pediatric: 64 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 6a: Sensor Accuracy Relative to YSI over the wear duration (Adult; n=200)

Wear Period	Number of CGM-reference pairs	MARD (%)	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±40% / ±40 mg/dL
Beginning	8753	9.6	84.2	91.1	99.4
Early Middle	5540	8.4	88.2	94.7	99.8
Late Middle	4753	8.3	87.9	93.8	99.7
End	4457	8.8	86.8	93.2	99.9

Table 6b: Sensor Accuracy Relative to YSI over the wear duration (Pediatric*; n=168)

Wear Period	Number of CGM-reference pairs	MARD (%)	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±40% / ±40 mg/dL
Beginning	2695	10.2	80.3	88.6	98.6
Early Middle	2031	9.0	85.5	90.9	98.4
Late Middle	1947	8.9	86.4	94.1	99.6
End	1941	9.5	84.1	91.7	99.4

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

Sensor Wear Duration

The Sensor can be worn for up to 14 days. To estimate how long a Sensor will work over the wear duration, 101 Sensors were evaluated to determine how many days of readings each Sensor provided. Of the 101 Sensors, 68.3% lasted until the final day of use. 15 Sensors (14.9%) 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 7** displays the data for each day in the wear duration for Study 3.

Because Study 3 was negatively affected by a software configuration unique to the investigational device, a subsequent study was conducted in adults to assess the impact of the final software configuration on "early Sensor shut-off" as well as to determine the survival rate after eliminating for physical factors (for example, getting caught in car seat belt, accidental knocking off the Sensor, etc.). A total of 34 of the 39 (87.2%) Sensors gave glucose results over the entire intended wear period of 14 days. After accounting for these factors, the actual survival rate was 94.4%.

Table 7: Sensor Survival Rate Over Wear Duration (n=101)

Day of Wear	Number of Sensors	Survival Rate (%)
1	99	98.0
2	99	98.0
3	99	98.0
4	98	97.0
5	96	95.0
6	96	95.0
7	93	92.1
8	92	91.1
9	90	89.1
10	85	84.2
11	79	78.2
12	73	72.3
13	70	69.3
14	69	68.3

Glucose Reading Availability

The System is designed to log a glucose reading every minute throughout the wear period after the start-up time. **Table 8** shows the glucose reading capture rate for each day of the wear duration for Study 3.

Table 8: Glucose Reading Capture Rate Over Wear Duration (n=101)

Day of Wear	Number of Sensors	Capture Rate (%)
1	101	99.8
2	99	99.9
3	99	99.8
4	99	99.8
5	98	99.9
6	96	99.7
7	96	100.0
8	93	99.9
9	92	99.9
10	90	99.9
11	85	99.5
12	80	99.8
13	73	99.7
14	70	100.0

Precision

Precision of the System was evaluated by comparing the results from two separate Sensors worn on the same subject at the same time. **Table 9** provides data from 100 subjects in Study 3. For adults, the paired absolute relative difference (PARD) between the two Sensors was 5.9% with coefficient of variation (CV) of 4.2%. For children ages 4-5, PARD was 4.7% with CV of 3.3%. For children ages 6-17, PARD was 8.1% with CV of 5.7%. 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 9: Overall between Sensor Precision (n=100)

Subject Group	Coefficient of Variation (%)	Paired Absolute Difference (mg/dL)	Paired Absolute Relative Difference (%)	Number of Paired Readings
Adults ages 18+	4.2	9.1	5.9	156942
Children ages 4-5	3.3	9.3	4.7	14190
Children ages 6-17	5.7	12.8	8.1	103741

Study 3

The purpose of Study 3 was to assess the performance of the system with a smaller form factor Sensor, which is the final FreeStyle Libre 3 configuration. Accuracy of the System was measured by comparing paired System Glucose Measurement (CGM) and YSI blood glucose values. The percentage of total system readings that were within 20 mg/dL for YSI blood glucose value < 70 mg/dL or 20% of YSI for blood glucose values ≥ 70 mg/dL is displayed in **Table 10**. The Mean Absolute Relative Difference (MARD) gives an indication of the average percent disagreement between the CGM and the reference. For example, 93.2% 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 6836. In this study the Mean Absolute Relative Difference was 7.9% for the comparison with the YSI reference.

Table 10: Overall Accuracy to YSI

Subject Group	Number of Subjects	Number of CGM-Reference Pairs	Percent Within ±20% / ±20 mg/dL	MARD (%)
Overall	95	6836	93.2	7.9
Adults	56	4768	94.7	7.6
Children ages 6-17	39	2068	89.7	8.7
Children ages 4-5*	5	72	88.9	10.1

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

Adverse Events

No device related serious adverse events occurred during the studies. In Study 1, 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 Study 2, 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. In Study 3, there were 5 instances of erythema (3 "well-defined redness", and 2 "slight pink"), 4 instances of mild or moderate bleeding, 2 instances of mild induration, one instance of edema ("slight") and one instance of mild itching.

Vitamin C Interference (FreeStyle Libre 3 Sensor)

Taking ascorbic acid (Vitamin C) supplements while wearing the Sensor may falsely raise Sensor glucose readings. Taking more than 500 mg of ascorbic acid per day may affect the Sensor readings which could cause you to miss a severe low glucose event. Ascorbic acid 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 ascorbic acid and should not be taken while using the Sensor. See your health care professional to understand how long ascorbic acid is active in your body.

Additional notes for Health Care Professionals

A clinical study was conducted to evaluate the effect of ascorbic acid on 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.

B. Performance Characteristics of FreeStyle Libre 3 Continuous Glucose Monitoring System with FreeStyle Libre 3 Plus Sensor:

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 3 Continuous Glucose Monitoring System (System). 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 System Glucose Measurement (CGM) and YSI blood glucose values. The percentage of total System readings that were within 20 mg/dL for YSI blood glucose values < 70 mg/dL or 20% of YSI for blood glucose values ≥ 70 mg/dL is displayed in **Table 1a**. 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 1a: Overall Accuracy to YSI

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 accuracy of different CGM glucose ranges versus YSI reference was assessed by calculating the percentage of System readings that were within 15%, 20%, and 40% for reference values ≥ 70 mg/dL, and within 15 mg/dL, 20 mg/dL, and 40 mg/dL for values < 70 mg/dL. 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 results categorized within CGM glucose ranges are presented in **Tables 1b and 1c**. The results categorized within YSI glucose ranges are presented in **Tables 1d and 1e**.

Table 1b: 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 1c: 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 1d: 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 1e: 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 with 'LO' and 'HI' CGM Reading against 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'. **Tables 2a and 2b** display the concurrence between the CGM and YSI reference glucose when CGM reads 'LO'. 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 2a: Concurrence Analysis with 'LO' CGM Reading (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 2b: Concurrence Analysis with 'LO' CGM Reading (Pediatric*; n=124)

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

Tables 2c and 2d display the concurrence between the CGM and YSI reference glucose when CGM reads 'HI'. 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 2c: Concurrence Analysis with 'HI' CGM Reading (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 2d: Concurrence Analysis with 'HI' CGM Reading (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 percentage of concurring glucose values (CGM vs. YSI) in each glucose reference range is presented for each CGM range in **Tables 3a and 3b** and for each YSI range in **Tables 3c and 3d**. 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 3a: 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 3b: 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 3c: Concurrence Analysis by YSI Glucose Level (Adult; n=149)

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	.	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 3d: 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 Rate of Change Accuracy

The System's glucose rate of change accuracy, as assessed by concurrence analysis, is presented in **Tables 4a and 4b**. For example, for adult participants, when the Sensor 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. Digitally connected systems which do not utilize the System's trend arrow calculations may see different glucose rate of change accuracy.

Table 4a: Concurrence Analysis by Glucose Rate of Change (Adult; n=149)

CGM (mg/dL/min)	YSI (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 4b: Concurrence Analysis by Glucose Rate of Change (Pediatric*; n=124)

CGM (mg/dL/min)	YSI (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

Tables 5a and 5b 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 5a: 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 5b: 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

Tables 5c and 5d 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 5c: 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 5d: 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 FreeStyle Libre 3 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 **Tables 6a and 6b**: 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 6a: Sensor Accuracy Relative to YSI over the 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 6b: Sensor Accuracy Relative to YSI over the 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 FreeStyle Libre 3 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. **Tables 7a and 7b** 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 7a: 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 7b: 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 log a glucose reading every minute throughout the wear period after the start-up time. **Tables 8a and 8b** show the glucose reading capture rate for each day of the wear duration.

Table 8a: 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 8b: 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 results from two separate Sensors worn on the same subject at the same time. **Table 9** 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 9: 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 (FreeStyle Libre 3 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 FreeStyle Libre 3 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 FreeStyle Libre 3 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 FreeStyle Libre 3 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.

Electromagnetic Compatibility (EMC)

FreeStyle Libre 3 Reader - FCC ID: QXS-LIB02

FreeStyle Libre 3 Sensor and FreeStyle Libre 3 Plus Sensor - FCC ID: QXS-LIB03S

- The System 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 System.
- Use of accessories, transducers, and cables other than those specified or provided by Abbott Diabetes Care could result in increased electromagnetic emissions or decreased electromagnetic immunity of the System and result in improper operation.
- The System should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the System should be observed to verify normal operation in the configuration in which it will be used.
- The device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) The device may not cause harmful interference, and (2) the device 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 System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The System 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.
RF emissions CISPR 11	Class B	The System 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines (100kHz frequency) ± 1 kV for signal lines (100kHz frequency)	± 2 kV for power supply lines (100kHz frequency) ± 1 kV for signal lines (100kHz frequency)	Mains power quality should be that of a typical domestic, commercial, or hospital environment.

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0.5 cycle At 0^0, 45^0, 90^0, 135^0, 180^0, 225^0, 270^0 and 315^0 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0^0 0% U_T; 250/300 cycle	0% U_T; 0.5 cycle At 0^0, 45^0, 90^0, 135^0, 180^0, 225^0, 270^0 and 315^0 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0^0 0% U_T; 250/300 cycle	Mains power quality should be that of a typical domestic, commercial, or hospital environment. If the user of the System requires continued operation during power mains interruptions, it is recommended that the System be powered from an uninterruptible power supply or a battery.

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial, or hospital environment.
Magnetic; IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial, or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level

IMMUNITY test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	6 Vrms 150 kHz to 80 MHz	6 Vrms	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the System, including cables specified by Abbott Diabetes Care. Otherwise degradation of the performance of the System could result.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See table on next page	Compliance to the tested levels	

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 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						

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

[a] For some services, only the uplink frequencies are included.
[b] The carrier is modulated using a 50% duty cycle square wave signal.
[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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

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

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

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

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References:

[1] "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) http://wayback.archive-it.org/7993/20170111013014/http:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

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[3] American Diabetes Association, 2019. 2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2019. Diabetes Care, 42(Supplement 1), pp.S13-S28

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