Abbott

FreeStyle Libre 3

CONTINUOUS GLUCOSE MONITORING SYSTEM
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FreeStyle Libre 3

User's Manual

$R_{X\ Only}$ **CAUTION:** Federal law restricts this device to sale by or on the order of a physician.

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.

Important Safety Information

Indications for Use

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.

Compatible Devices, Apps, and Software

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

www.FreeStyleLibre.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.

Contraindications

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

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.

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.
- 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

Below 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 App Alarms:

- 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.
- Do not force close the App. The App must be running in the background to receive alarms. If you force close the App you will not receive alarms. Re-open the App to ensure you will receive alarms.
- If you restart your phone, open your App to make sure it’s working properly.
- The App will ask for phone permissions which are needed to receive alarms. Allow these permissions when requested.
- Check to make sure that you have the correct phone settings and permissions enabled. If your phone is not configured properly, you will not be able to use the App, so you will not receive alarms or be able to check your glucose. In the phone settings for the App under Notifications, keep Allow Critical Alerts **ON**.
- If you adjust the phone ringer volume 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.

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

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 less than 4 years of age.** The System is not cleared for use in people under 4 years of age.
- **Do not use the System if you are pregnant, 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 14 day wear period and help prevent it from falling off early.
- The Sensor can be worn for up to 14 days. 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 14 day wear period. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Standard Time.
- 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 Standard Time.

- 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.

⚠ 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.
- Do NOT use if Sensor Kit contents are past expiration date.

⚠ 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.

⚠ 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 14 day wear period 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 Standard Time.

Interfering Substances

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.

App Symbols

	App icon
	Alarms are unavailable
	Scan New Sensor / Start New Sensor
	Direction your glucose is going. See Understanding Your Glucose Readings for more information
	Caution
	When you see this symbol during the first 12 hours of

	wearing a Sensor, confirm Sensor glucose readings with a blood glucose test before making treatment decisions
	Add/edit notes
	Food note
	Insulin (Rapid or Long-acting) note
	Alarm
	Exercise note
	Time change
	Main menu
	Multiple/Custom notes
	Share report
	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 mobile App to wirelessly receive and display glucose readings from the Sensor. When they’re in range, the Sensor and app automatically communicate to give you glucose alarms. These alarms are on by default.

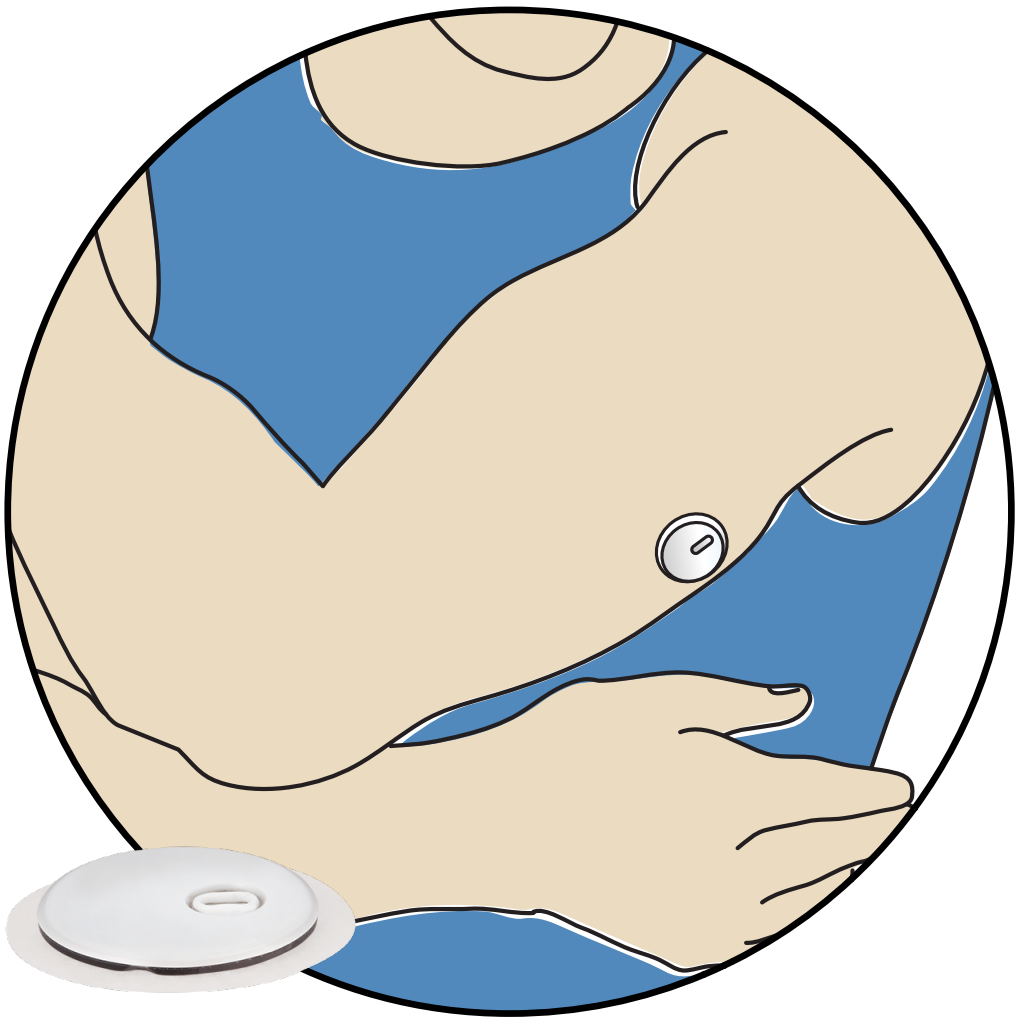
When the Sensor and App are not in range or unable to communicate, the Sensor will store all 14 days of glucose data. This data is automatically sent from the Sensor to the App when the devices are back within range.

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, 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 Standard Time. FreeStyle Libre 3 app is available for download from the App Store.

Sensor Kit



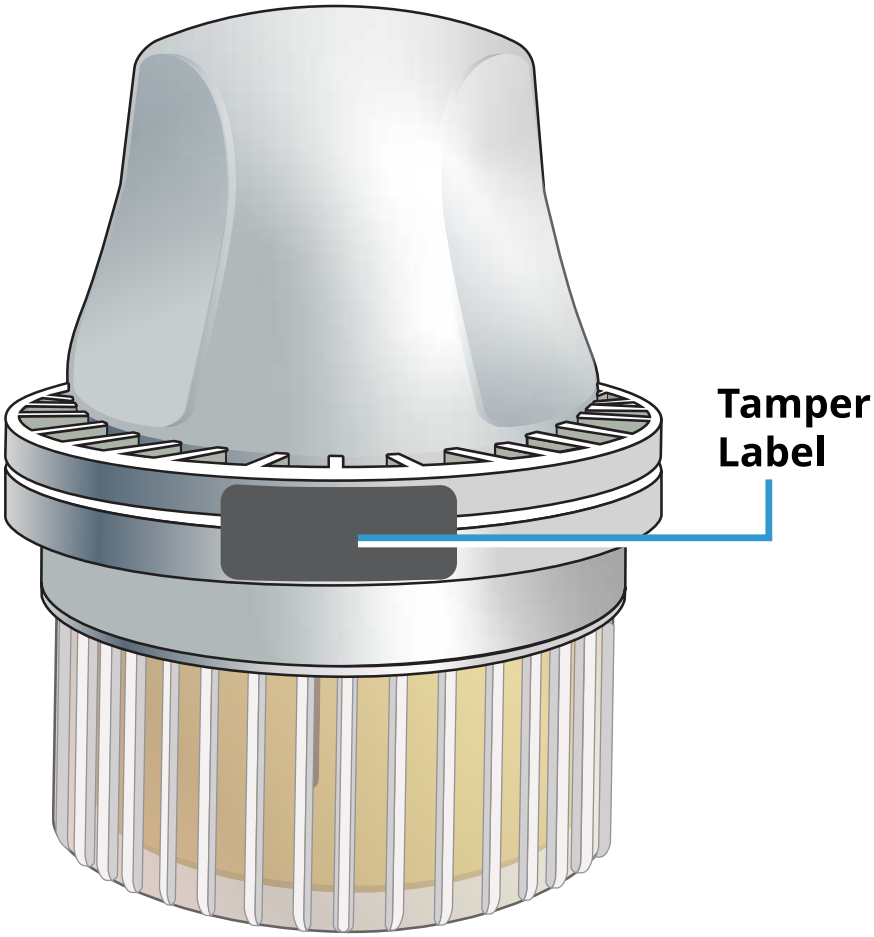
The FreeStyle Libre 3 Sensor Kit includes:

- Sensor Applicator
- Alcohol wipe
- Product insert

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 14 days.

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

Sensor Applicator – Applies the Sensor to your body.



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.

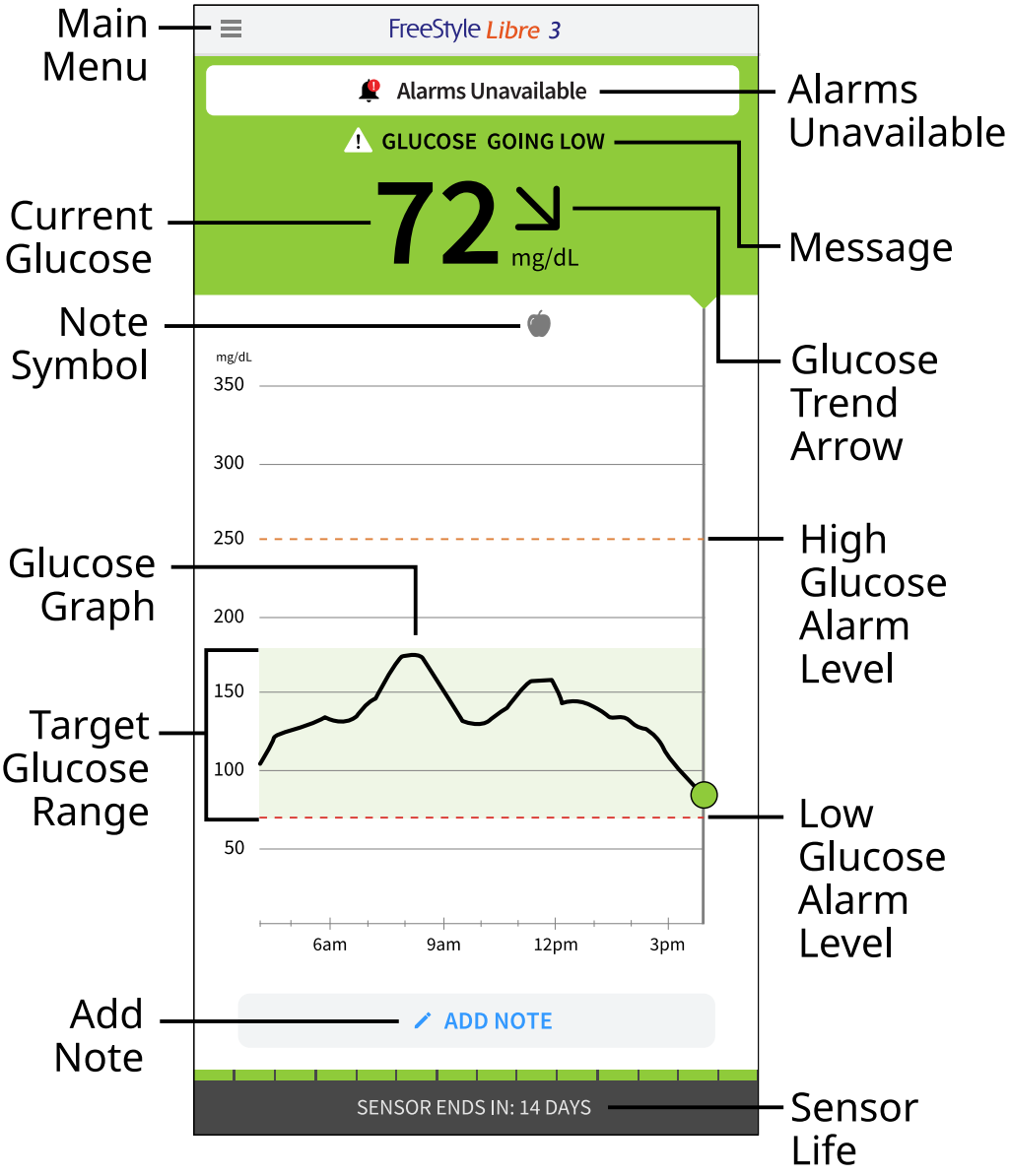
The App is not compatible with all phones. Before upgrading your phone or its operating system, check www.FreeStyleLibre.com.

- You must keep Critical Alerts on. If this setting is 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 FreeStyle Libre 3, 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.

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

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

Current Glucose – Your most recent glucose value

Glucose Trend Arrow – Direction your glucose is going

Glucose Graph – Graph of your current and stored glucose readings

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

High Glucose Alarm Level – Your High Glucose Alarm level

Low Glucose Alarm Level – Your Low Glucose Alarm level

Sensor Life – Remaining life time of Sensor

Add Note – Tap to add notes to the glucose reading

Note Symbol – Tap to review notes you've entered

Reporting Software

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

Setting up Your System for the First Time

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.

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. 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.
3. Confirm phone and OS compatibility and tap **NEXT**.
4. Confirm your country and tap **NEXT**.
5. You 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.
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.

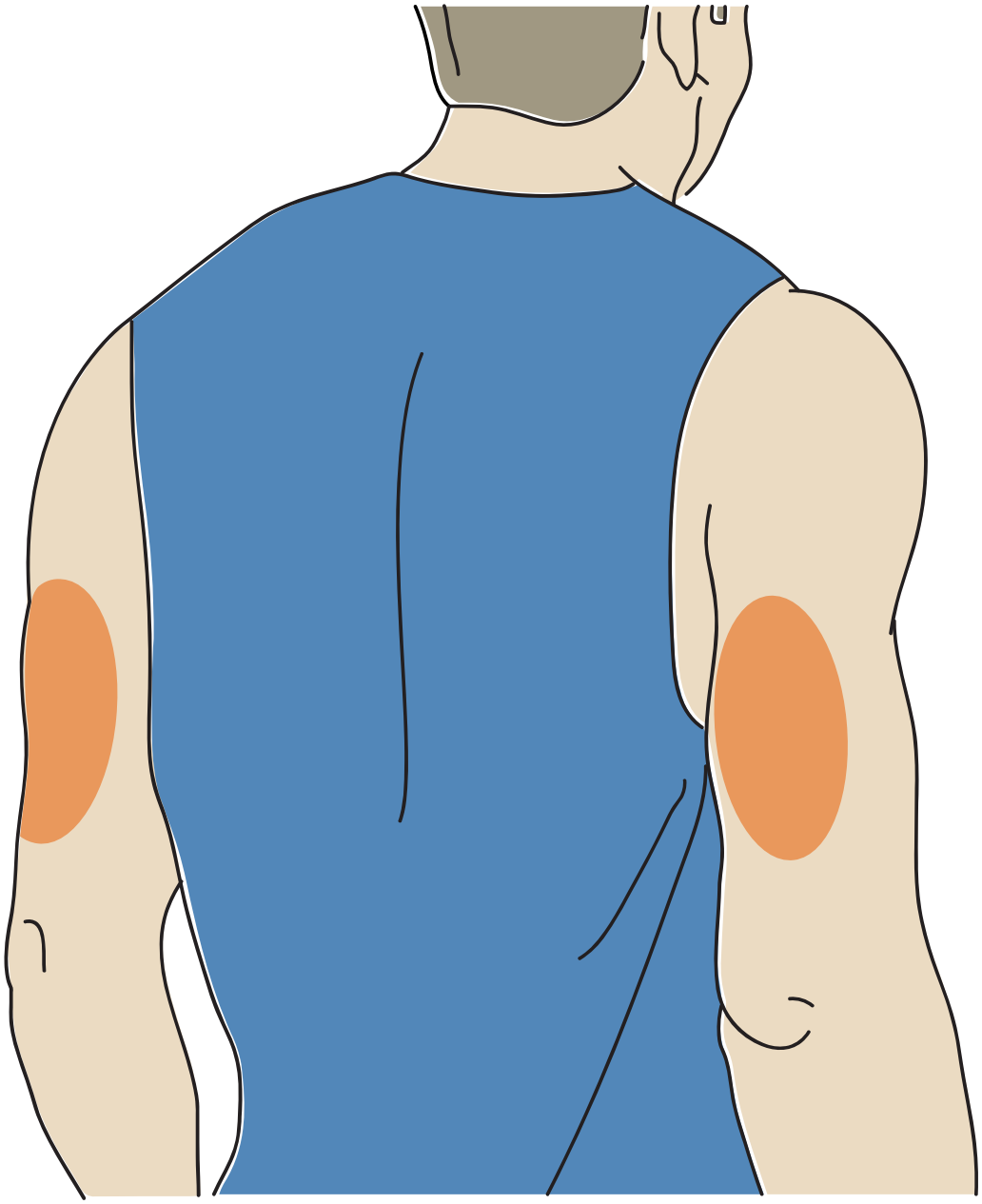
   Note: If you need help applying your Sensor, tap **HOW TO APPLY A SENSOR** or go to Applying Your Sensor.

Applying Your Sensor

CAUTION:

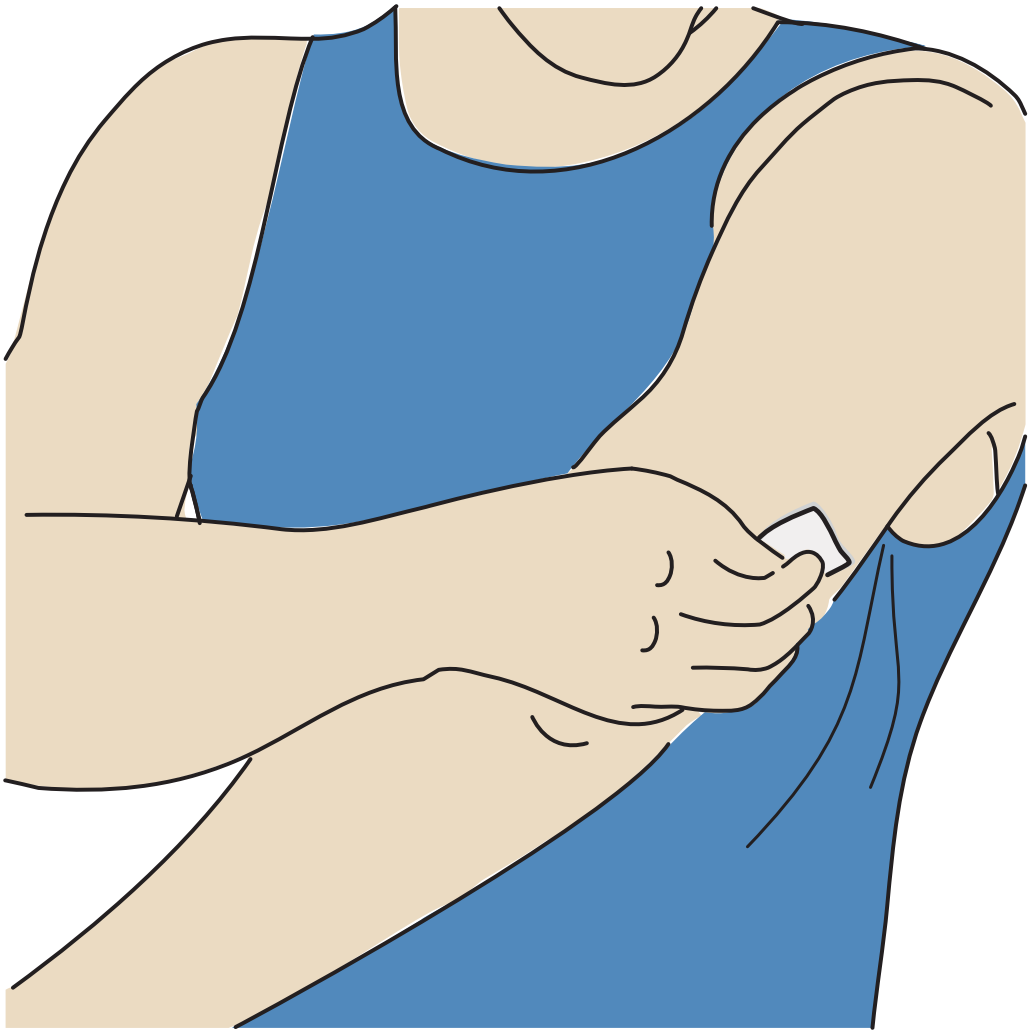
Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. If the Sensor is becoming loose or if the Sensor tip is coming out of your skin, you may get no readings or unreliable low readings. Remove and replace your Sensor if it starts to loosen and follow the instructions 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 Standard Time.

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 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.

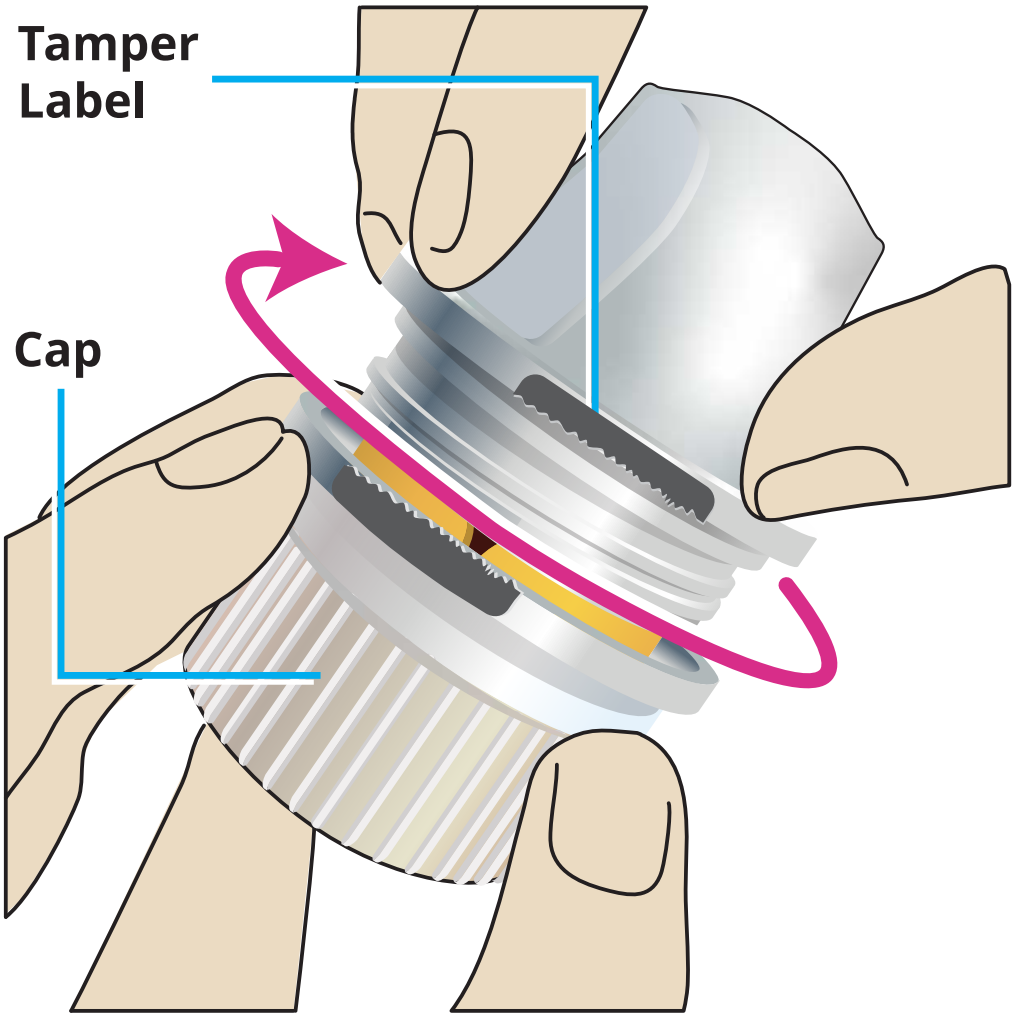
Note: The area **MUST** be clean and dry following these instructions, or the Sensor may not stay on for the full 14 day wear period.



3. Unscrew the cap from the Sensor Applicator and set the cap aside.

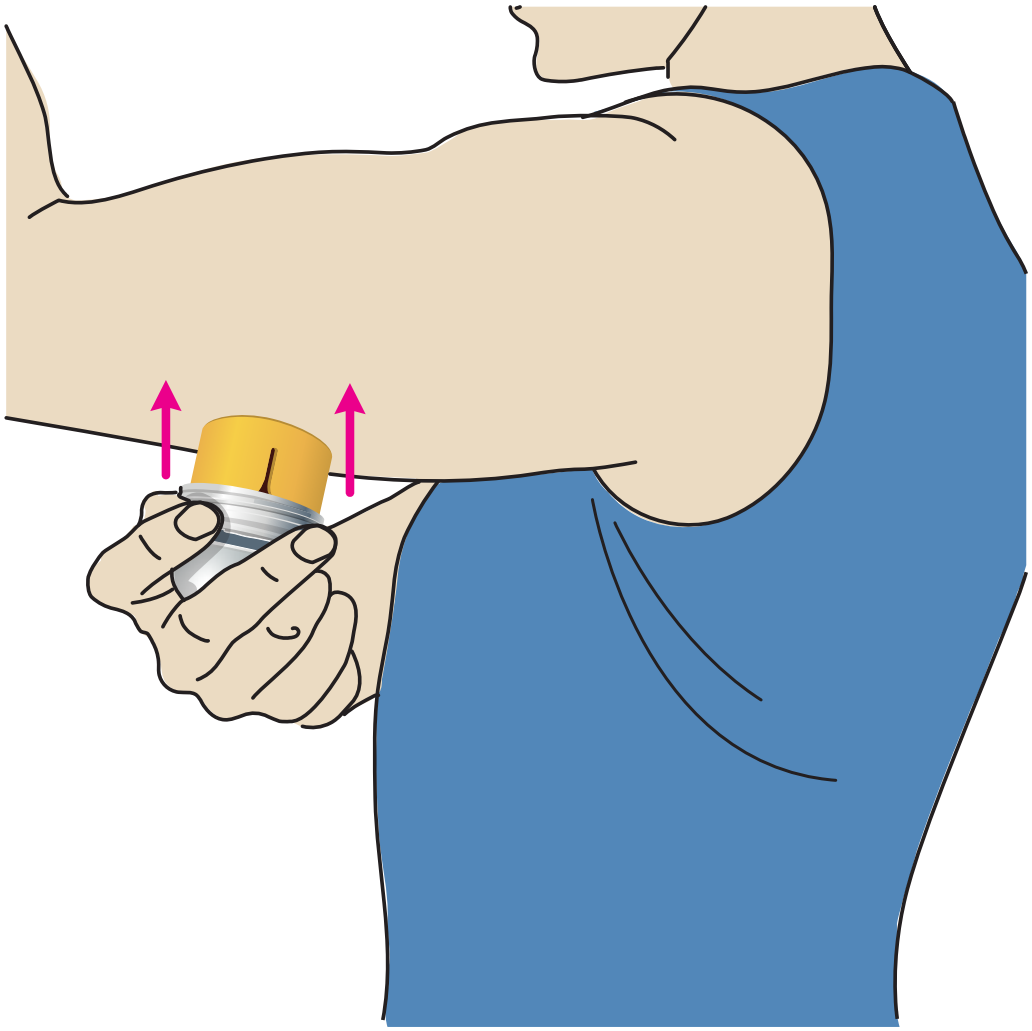
CAUTION:

- 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.



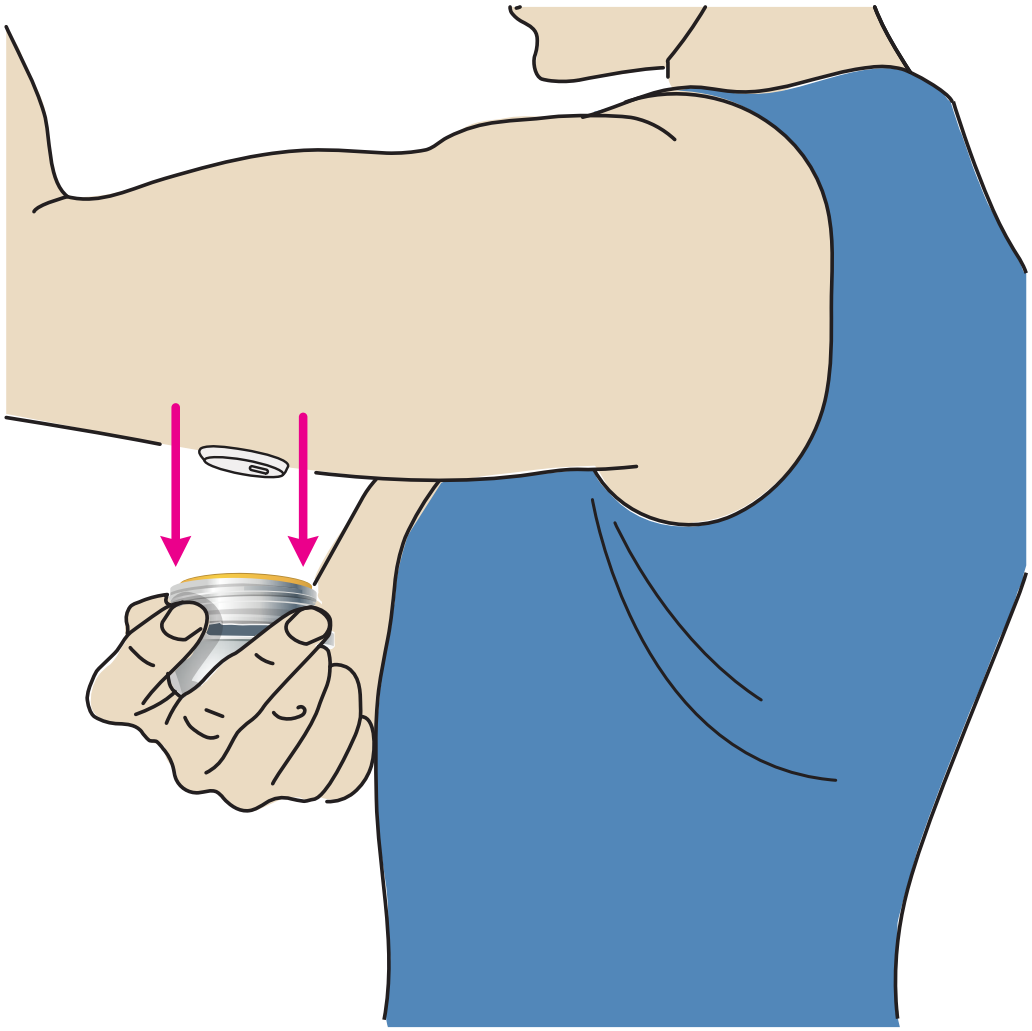
4. Place the Sensor Applicator over the prepared site and push down firmly to apply the Sensor to your body.

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



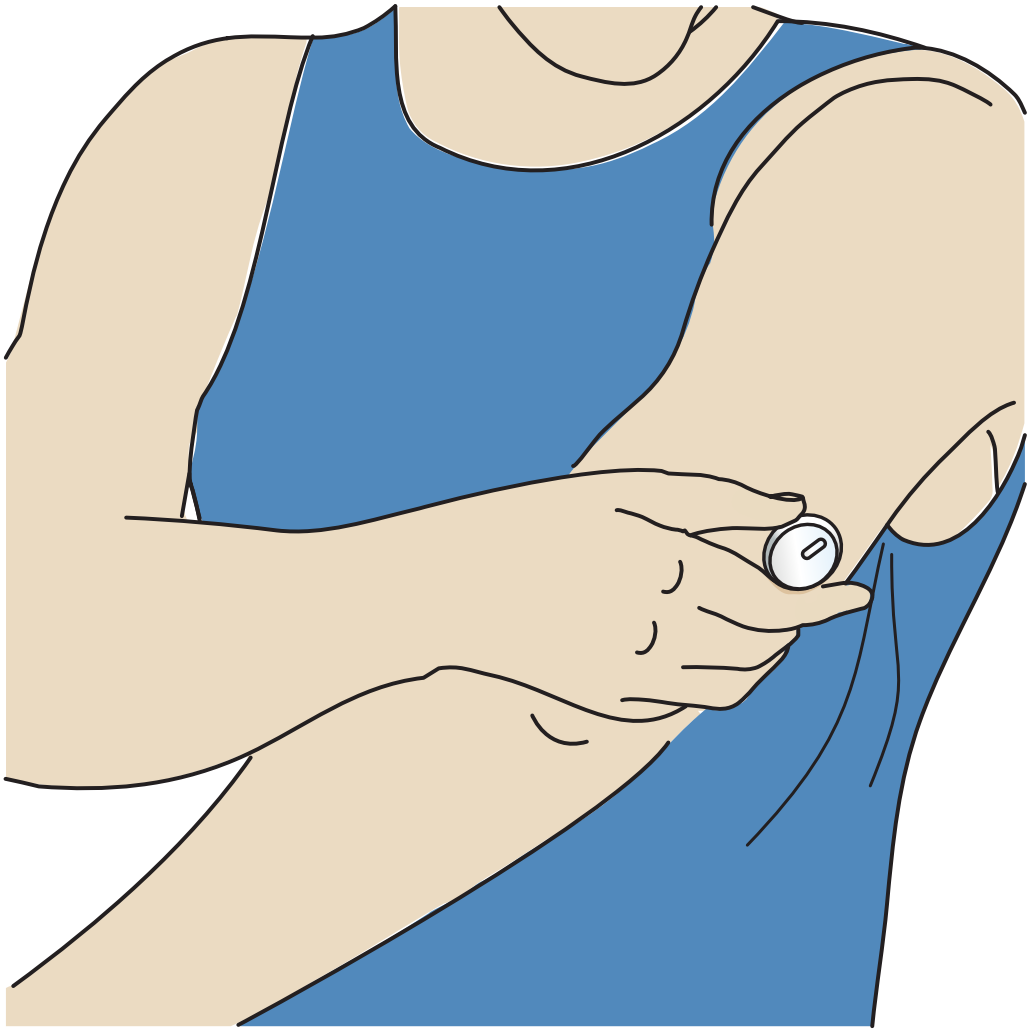
5. Gently pull the Sensor Applicator away from your body. The Sensor should now be attached to your skin.

   Note: Applying the Sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the Sensor, and contact your health care professional.



6. Make sure Sensor is secure after application. Put the cap back on the Sensor Applicator. Discard the used Sensor Applicator according to local regulations.

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



Starting Your Sensor

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.
- 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.

- For more information on device compatibility, access the Mobile Device & OS Compatibility guide at www.FreeStyleLibre.com.

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1. From the App Home Screen, tap the Scan New Sensor button. Your phone is now ready to scan the Sensor to start it.
2. Touch the Sensor with the TOP of your phone. You will receive a tone and vibration after you have successfully started the Sensor. If your phone's volume is turned off, you will not hear the tone.
3. The Sensor can be used to check your glucose after 60 minutes. While the Sensor is starting up, you can navigate away from the App. If notifications are enabled, you will see a notification when the Sensor is ready.

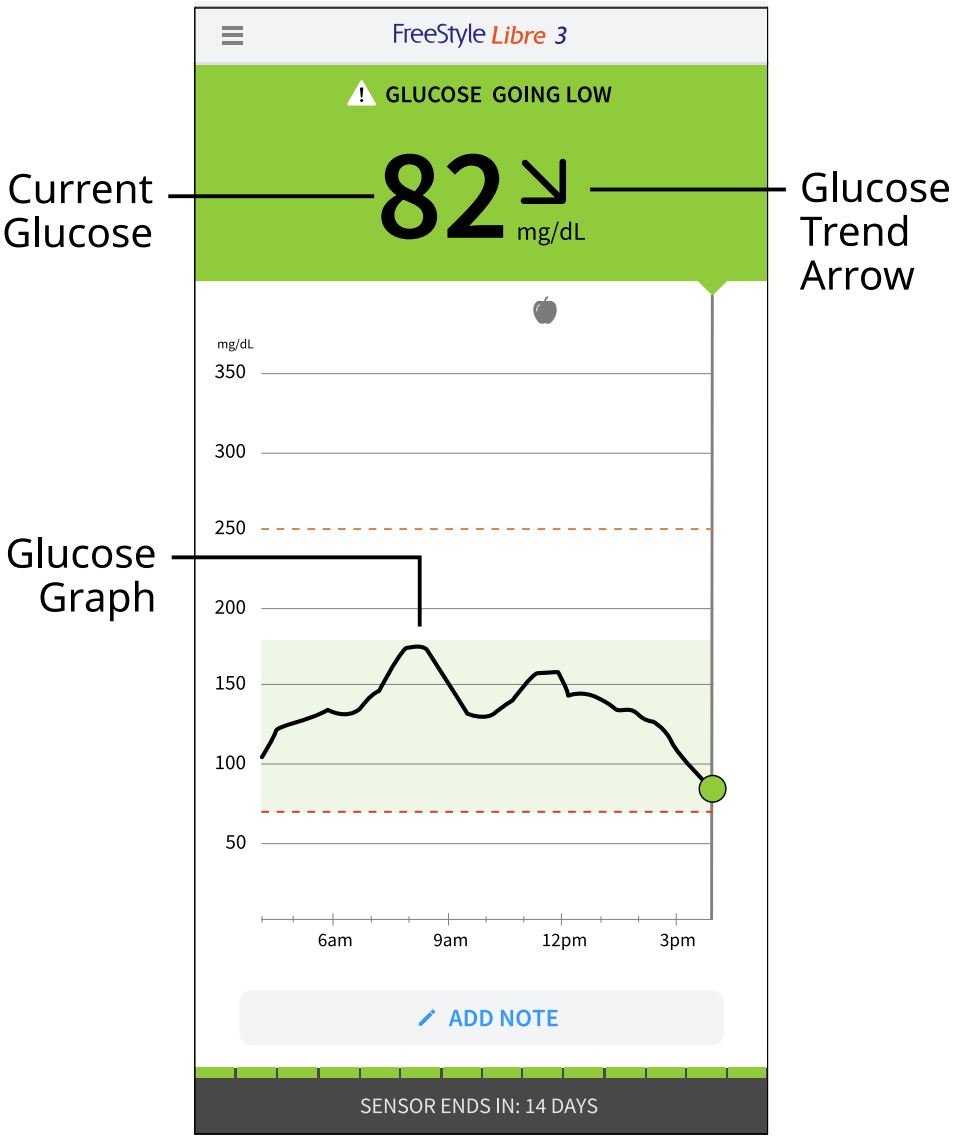
   Note: If you have an active Sensor and want to start a new Sensor, go to the Menu and tap Start New Sensor .

Note:

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

Checking Your Glucose

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



Current Glucose – Your most recent glucose value

Glucose Trend Arrow – Direction your glucose is going

Glucose Graph – Graph of your current and stored glucose readings

Note:

- The graph displays glucose readings above 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)

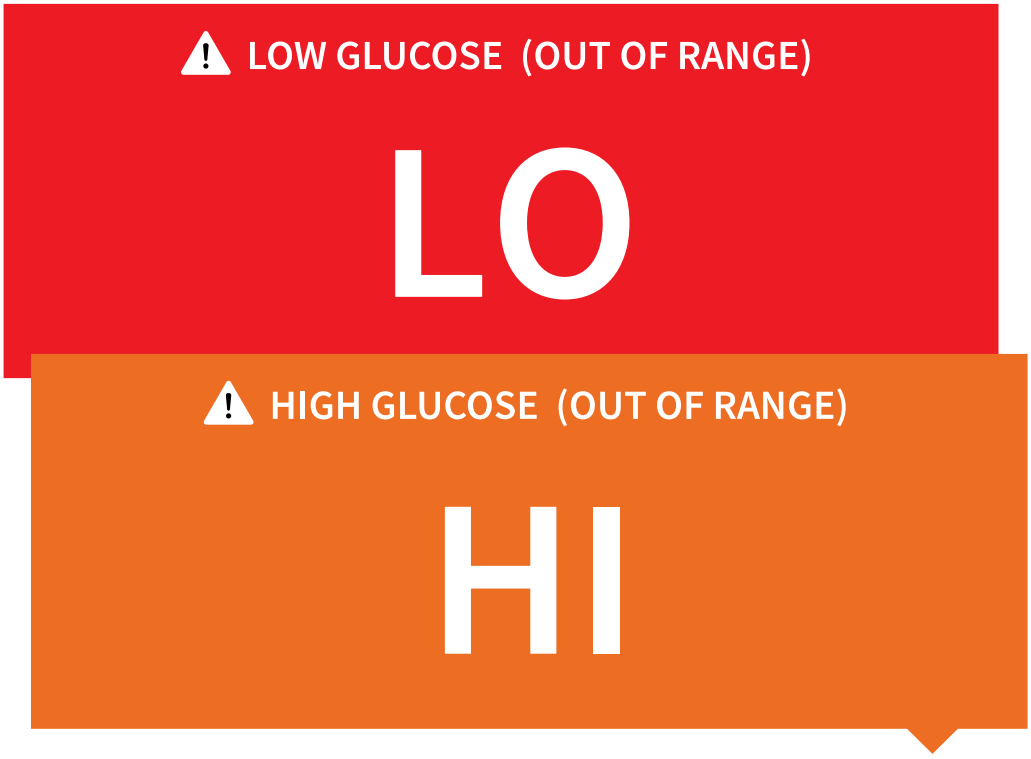
Glucose is falling (between 1 and 2 mg/dL per minute)

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

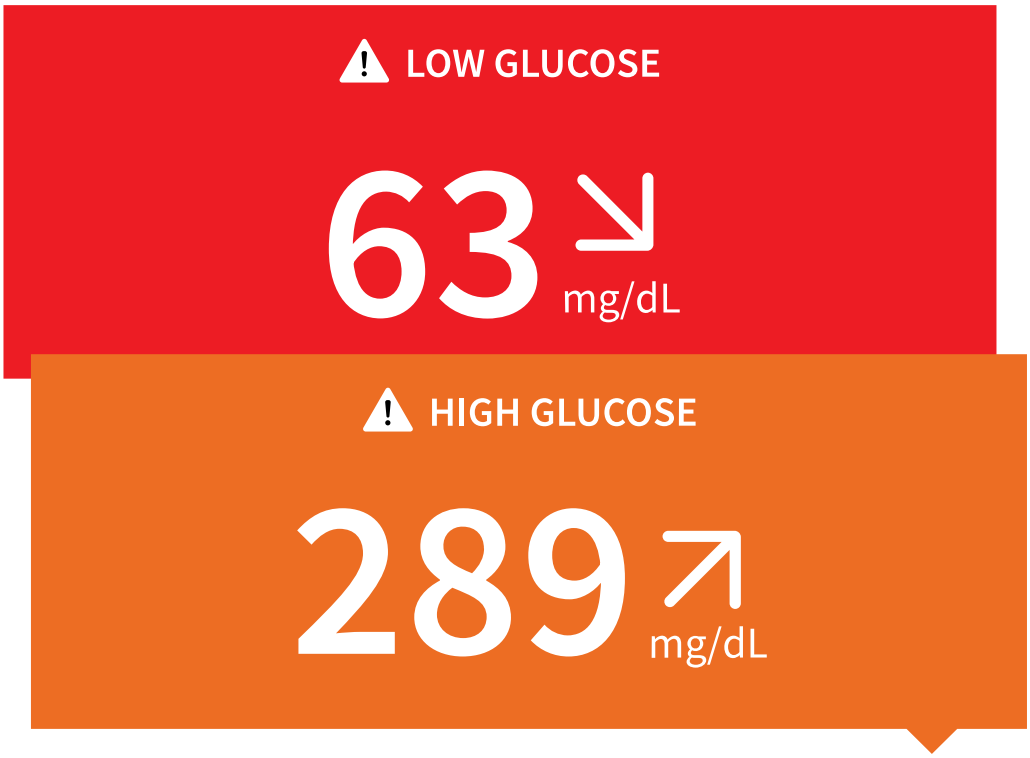
Messages

Below are messages you may see with your glucose readings.

LO | HI: 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**.

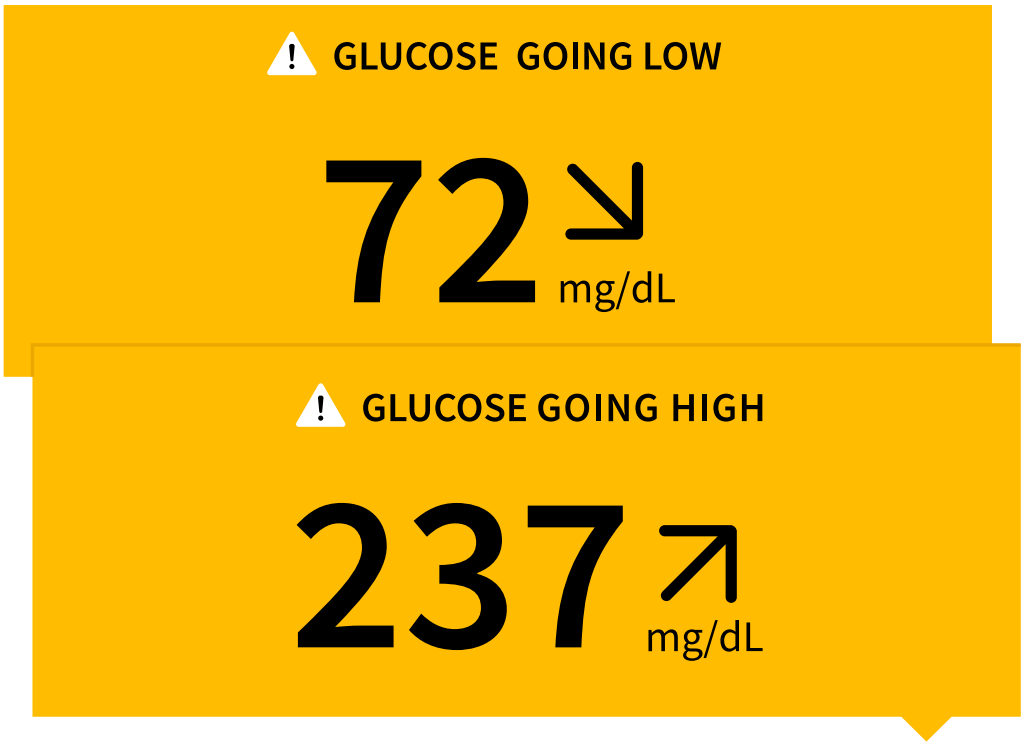


Low Glucose | High Glucose: If your glucose is higher than 250 mg/dL or lower than 70 mg/dL, you will see a message on the screen. You can tap the ⚠ symbol for more information and set a reminder to check your glucose.

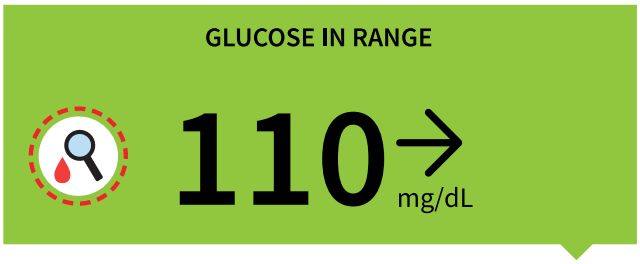


Glucose Going Low | Glucose Going High: If your glucose is projected to be higher than 250 mg/dL or lower than 70 mg/dL within 15 minutes, you will see a message on the screen. You can tap the ⚠ symbol for more information and set a reminder to check your glucose.

Note: The background color corresponds to your current glucose value.



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

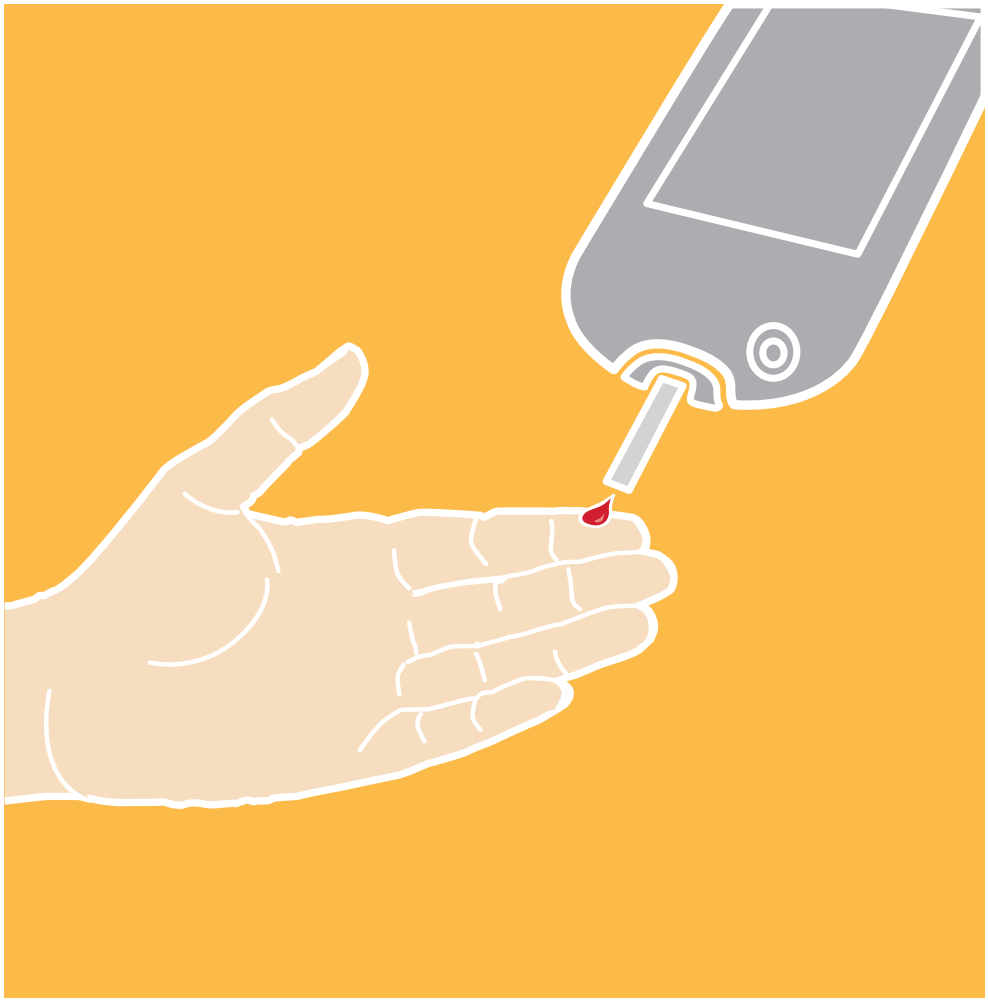
Work with your health care professional to put together a plan for managing your diabetes that includes when to use the System information for making treatment decisions. You should also talk to your health care professional about the best times to check your glucose. Consider checking your glucose before a period when you will not be monitoring your glucose, such as before driving, exercise 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 (up to 14 days), 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

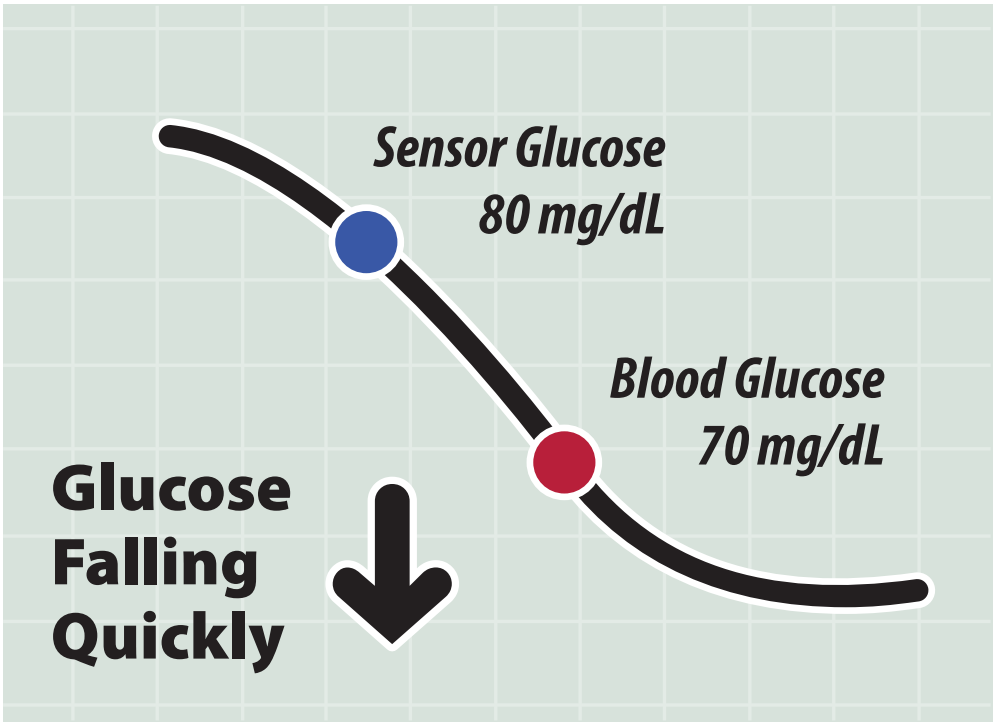
more you check readings from the System with a blood glucose meter, the better you will understand how the System works for you.

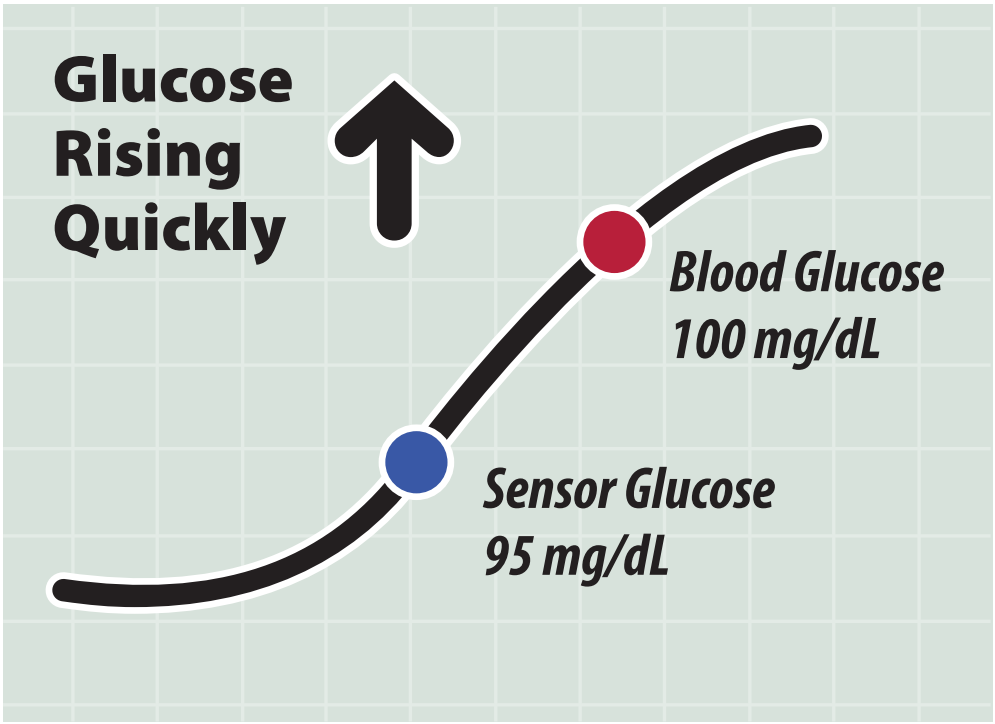
Work with your health care professional to put together a plan for managing your diabetes that includes when to use the System information for making treatment decisions.

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.

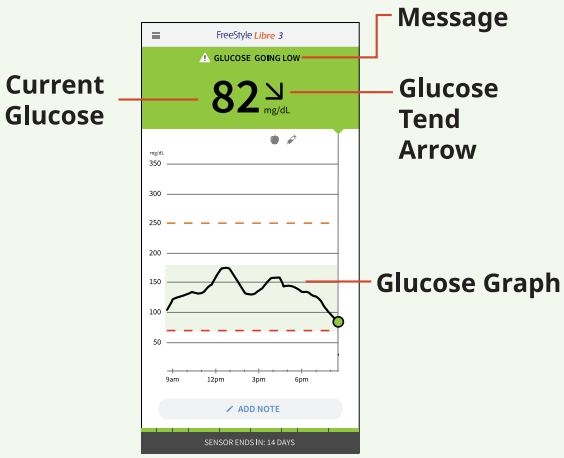
Don’t take a correction dose within 2 hours of your meal dose. This may result in “insulin stacking” and low glucose.

Using Your Glucose Reading to Make a Treatment Decision

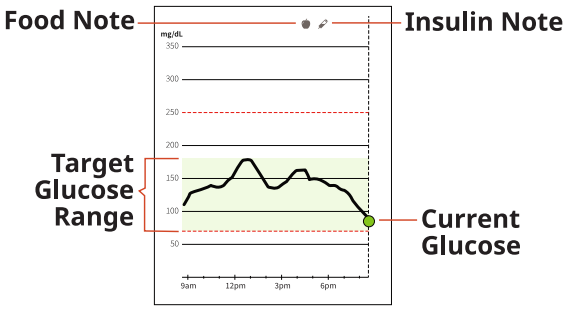
After you check your glucose, use all of the information on the screen when deciding what to do or what treatment decision to make.

Glucose Trend Arrow
Direction your glucose is going

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



Glucose Graph
Graph of your current and stored glucose readings



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

Treatment Decision Considerations for Glucose Trend Arrow: ↑

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

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

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

Avoid "insulin stacking".

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

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

Avoid "insulin stacking".

Treatment Decision Considerations for Glucose Trend Arrow: ↗

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

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

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

Avoid "insulin stacking".

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

If this is between meals, consider taking an insulin correction dose, unless you

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

Avoid “insulin stacking”.

Treatment Decision Considerations for Glucose Trend Arrow: →

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

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

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

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

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

Avoid “insulin stacking”.

Treatment Decision Considerations for Glucose Trend Arrow: ↘

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

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

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

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

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

Avoid “insulin stacking”.

Treatment Decision Considerations for Glucose Trend Arrow: ↓

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

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

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

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

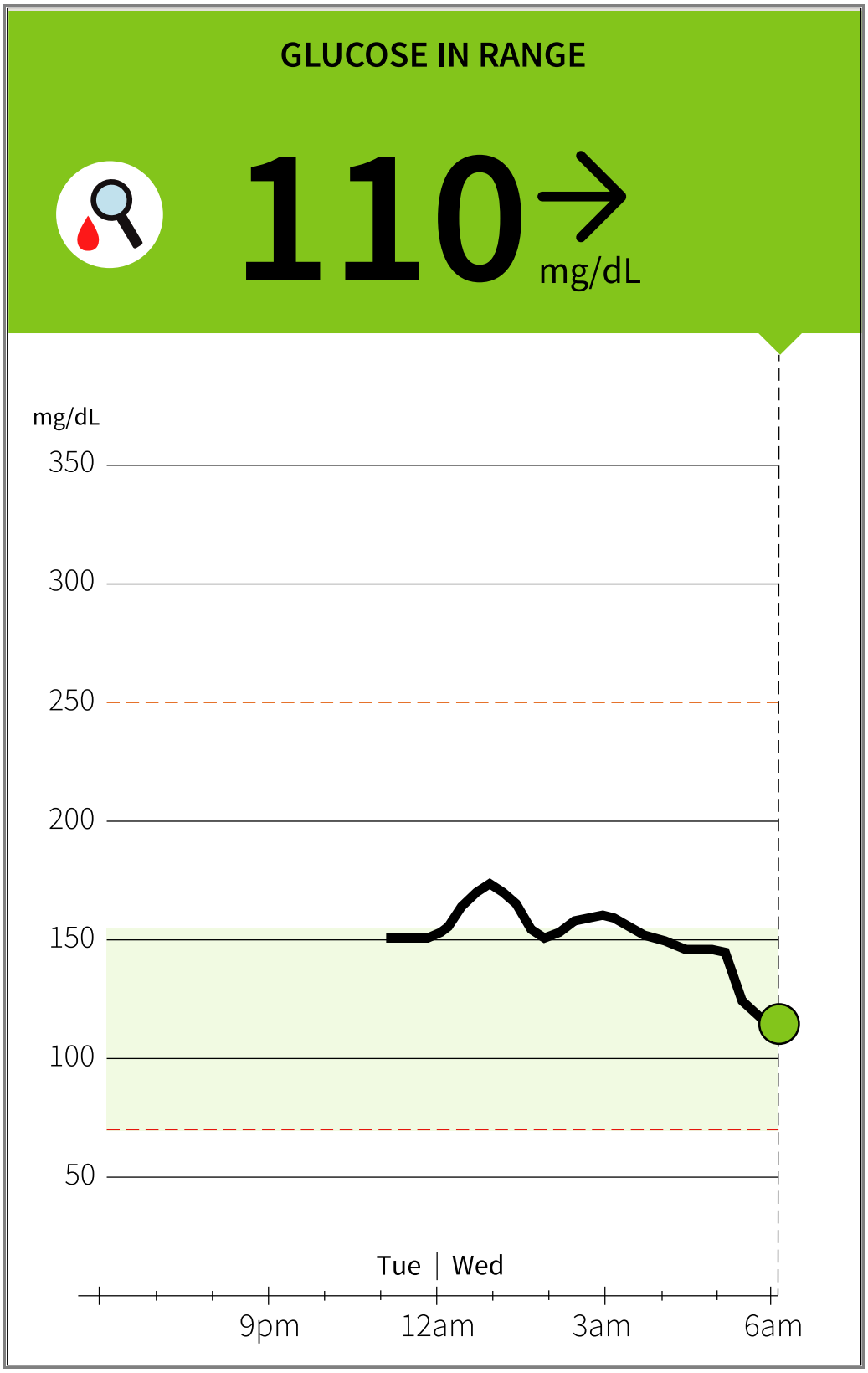
If this is between meals, consider doing nothing and check again later.

Avoid "insulin stacking".

Example Scenarios

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

What you see - *When you wake-up*



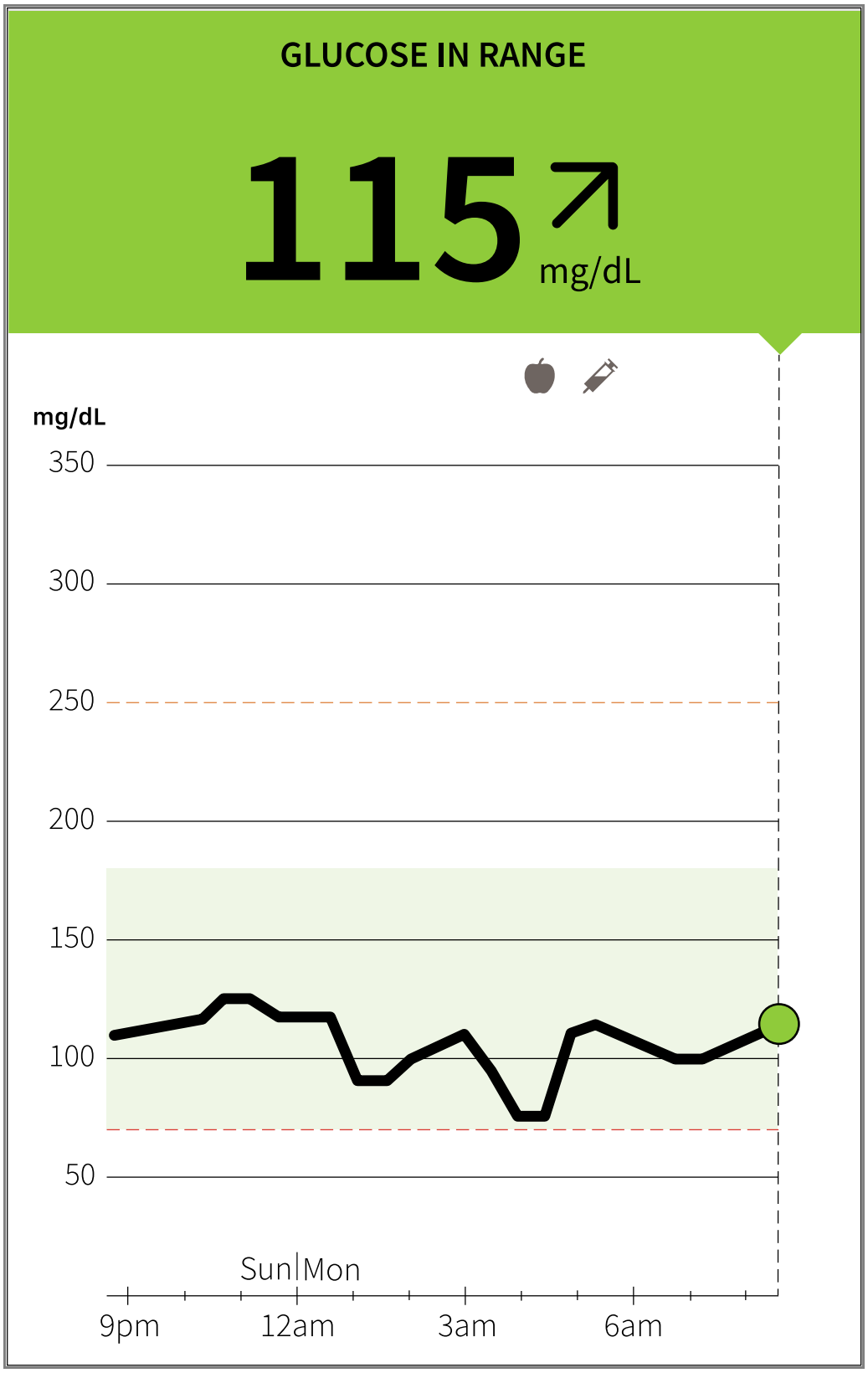
What it means

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

During the first 12 hours of Sensor wear the symbol will display, and you cannot

use Sensor values to make treatment decisions during this time. Confirm Sensor glucose readings with a blood glucose test before making treatment decisions during the first 12 hours of Sensor wear when you see the 🔍 symbol.

What you see - *Before breakfast*



What it means

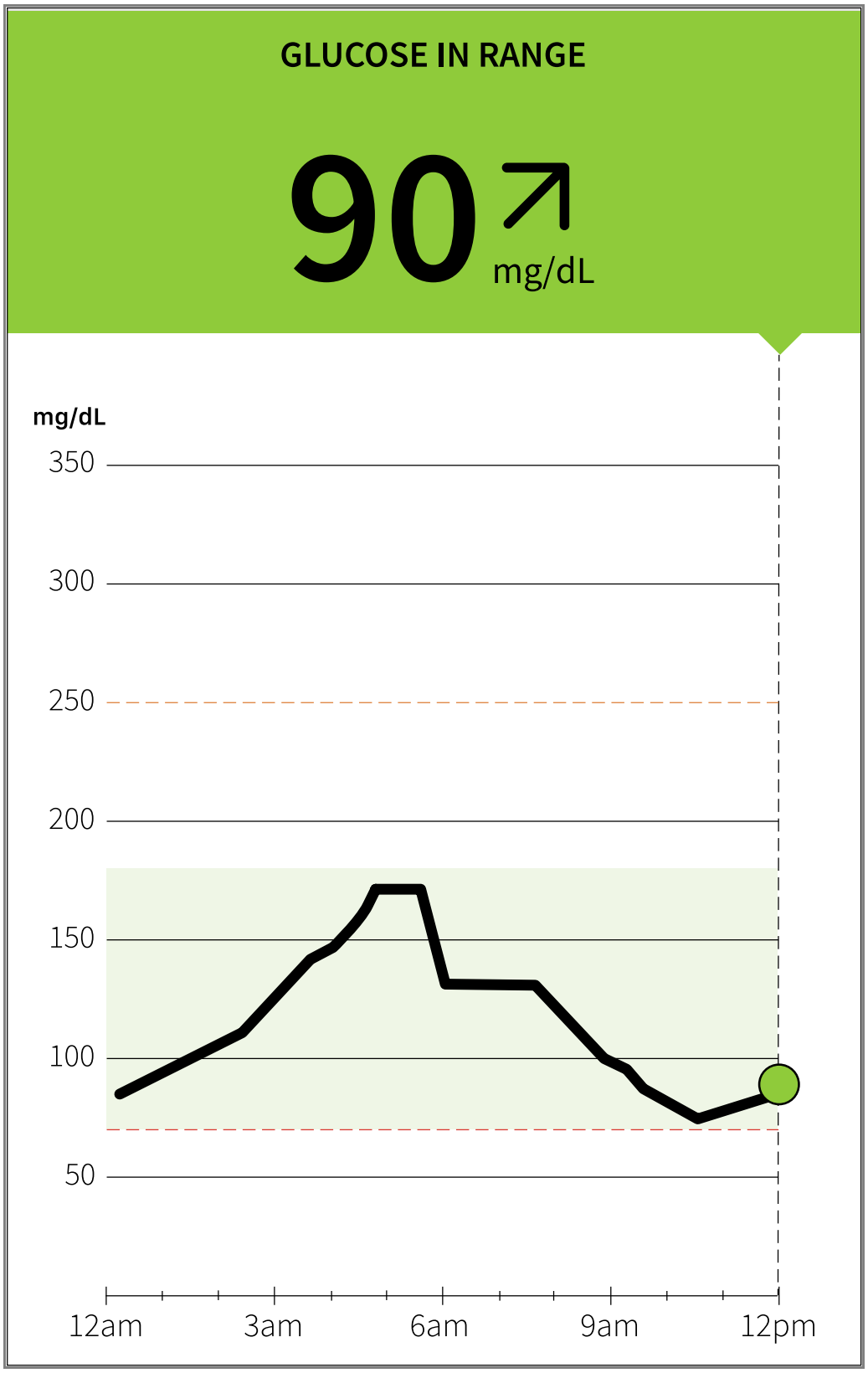
Before breakfast, your current glucose is 115 mg/dL. The graph shows that your glucose is going up and so does the trend arrow ↗.

Consider what might be causing your glucose to go up and what you might do to

prevent a high glucose. For example:

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

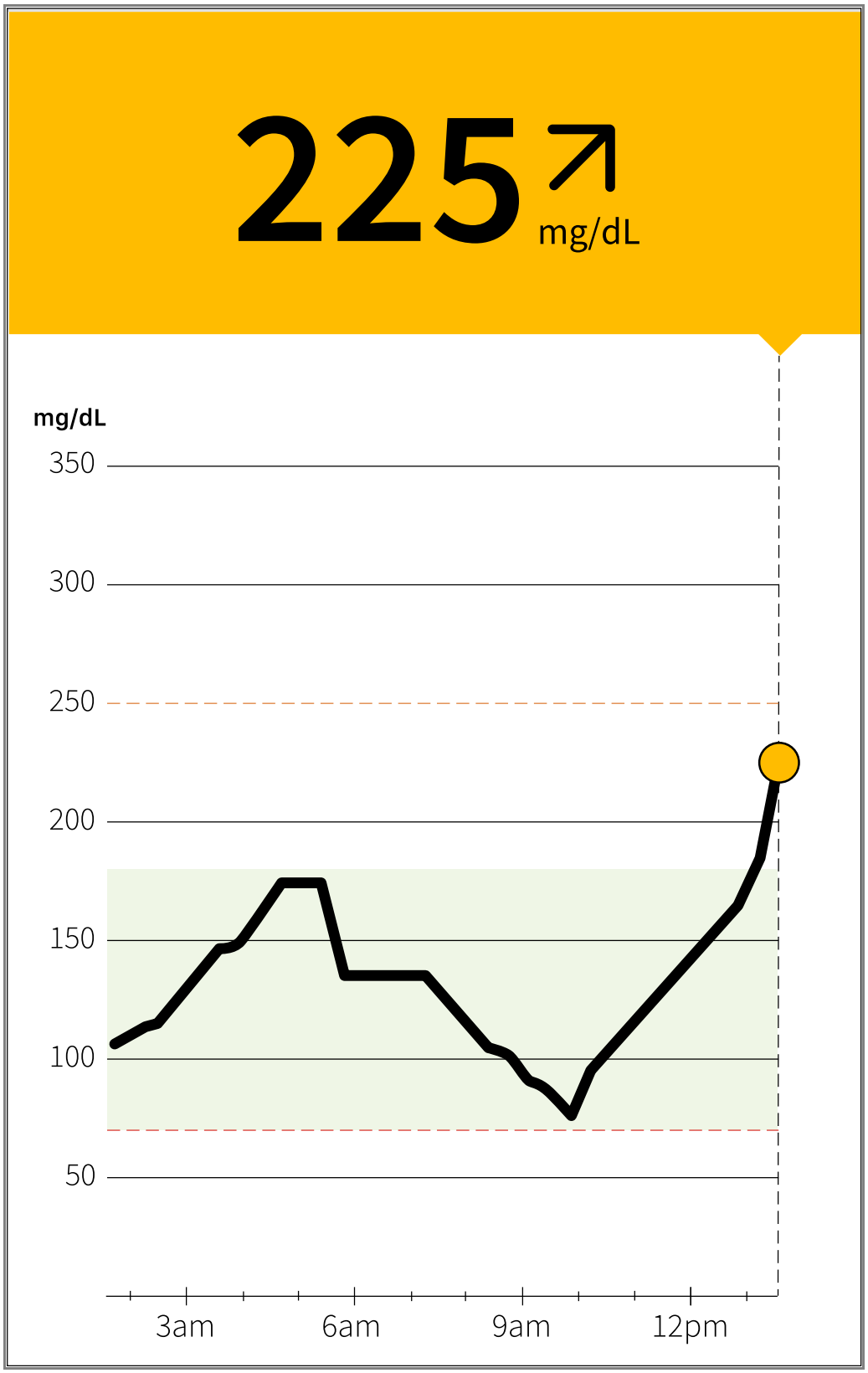
What you see - *Before lunch*



What it means

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

What you see - *After lunch*



What it means

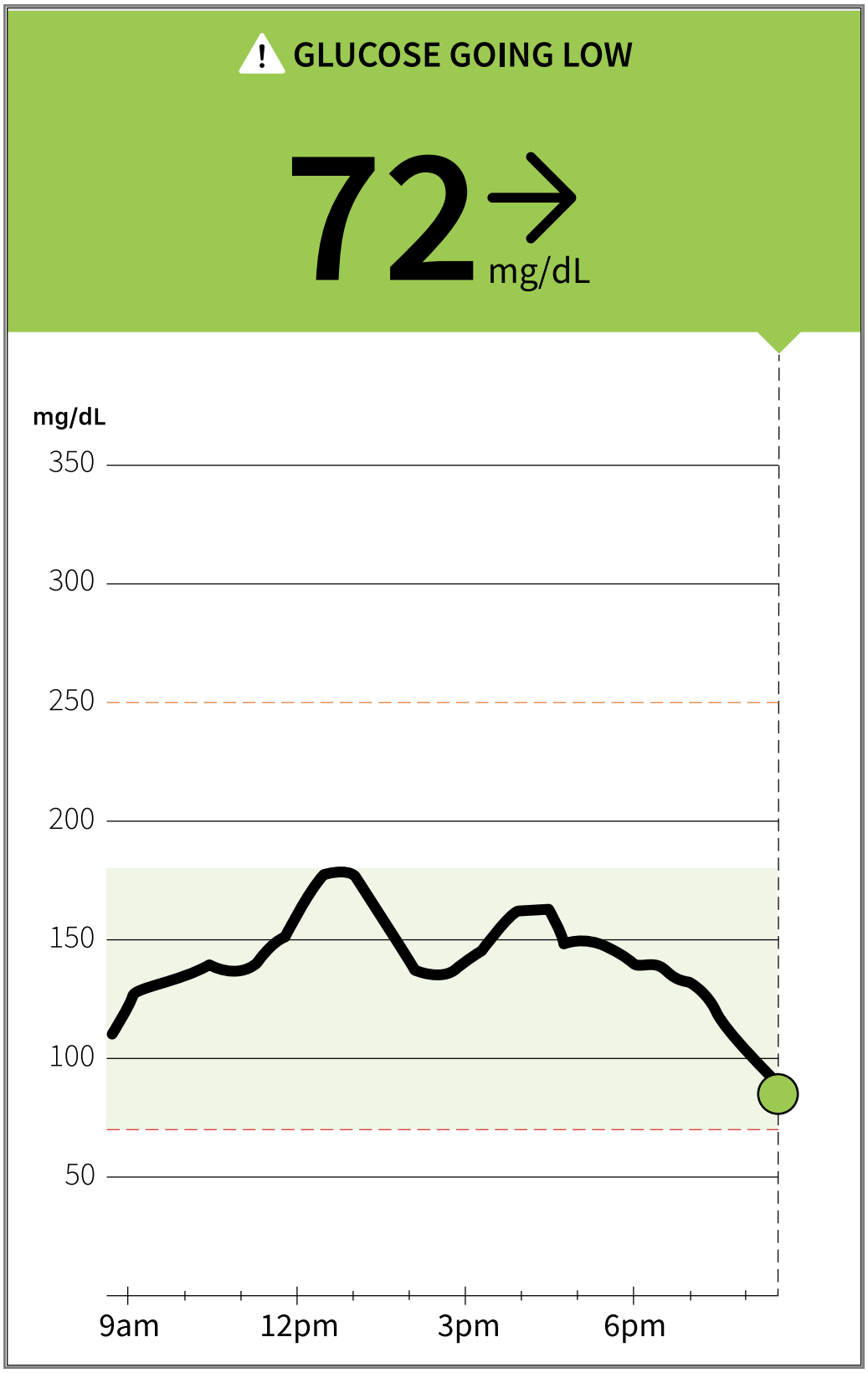
90 minutes later, your current glucose is 225 mg/dL. The graph shows that your glucose is still going up, and so does the trend arrow ↗.

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

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

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

What you see - *In the afternoon*



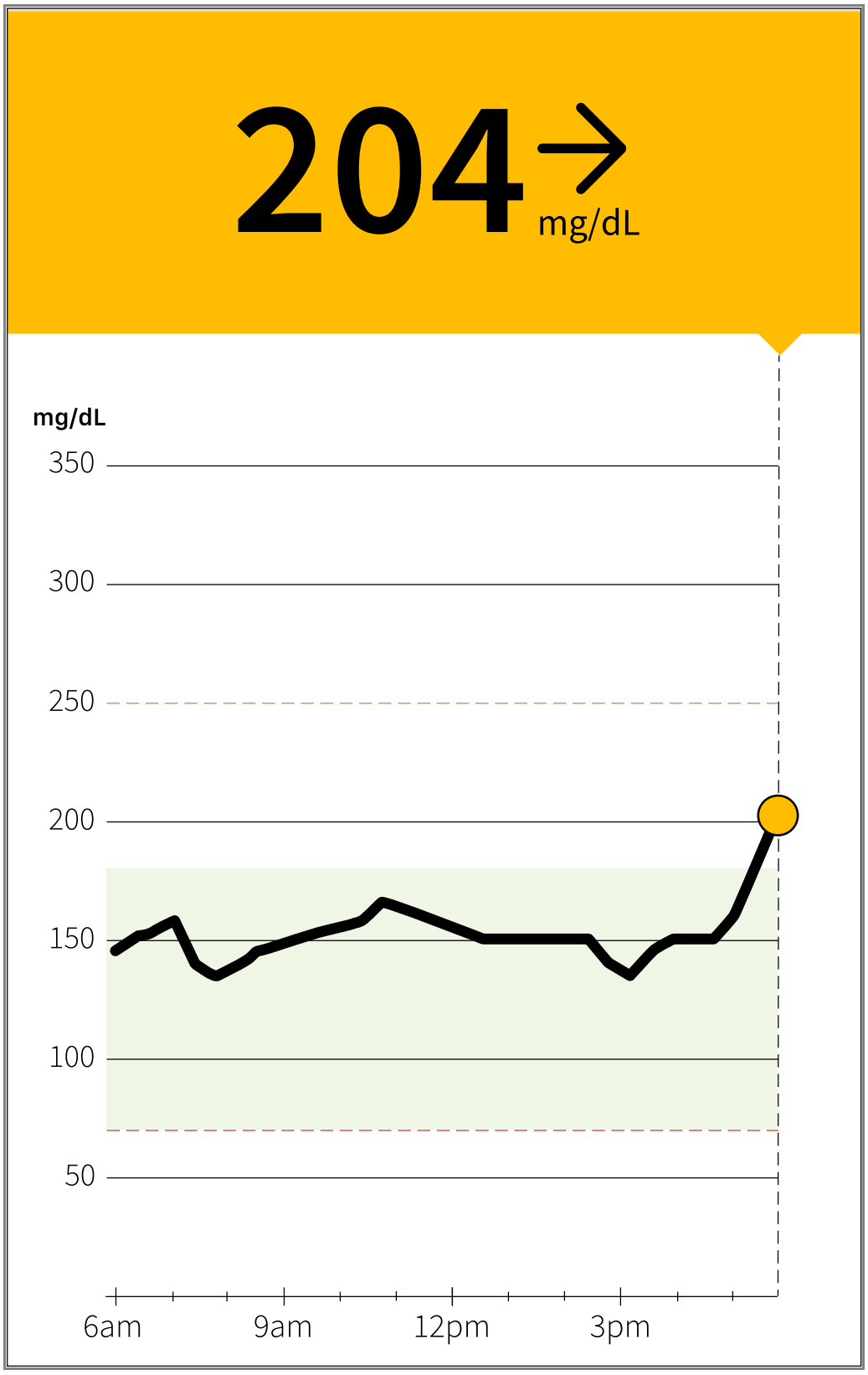
What it means

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

Think about what might be causing your glucose to go low. Consider eating a

snack to stay within target. **Avoid taking insulin as this can cause low glucose.**

What you see - *After exercising*

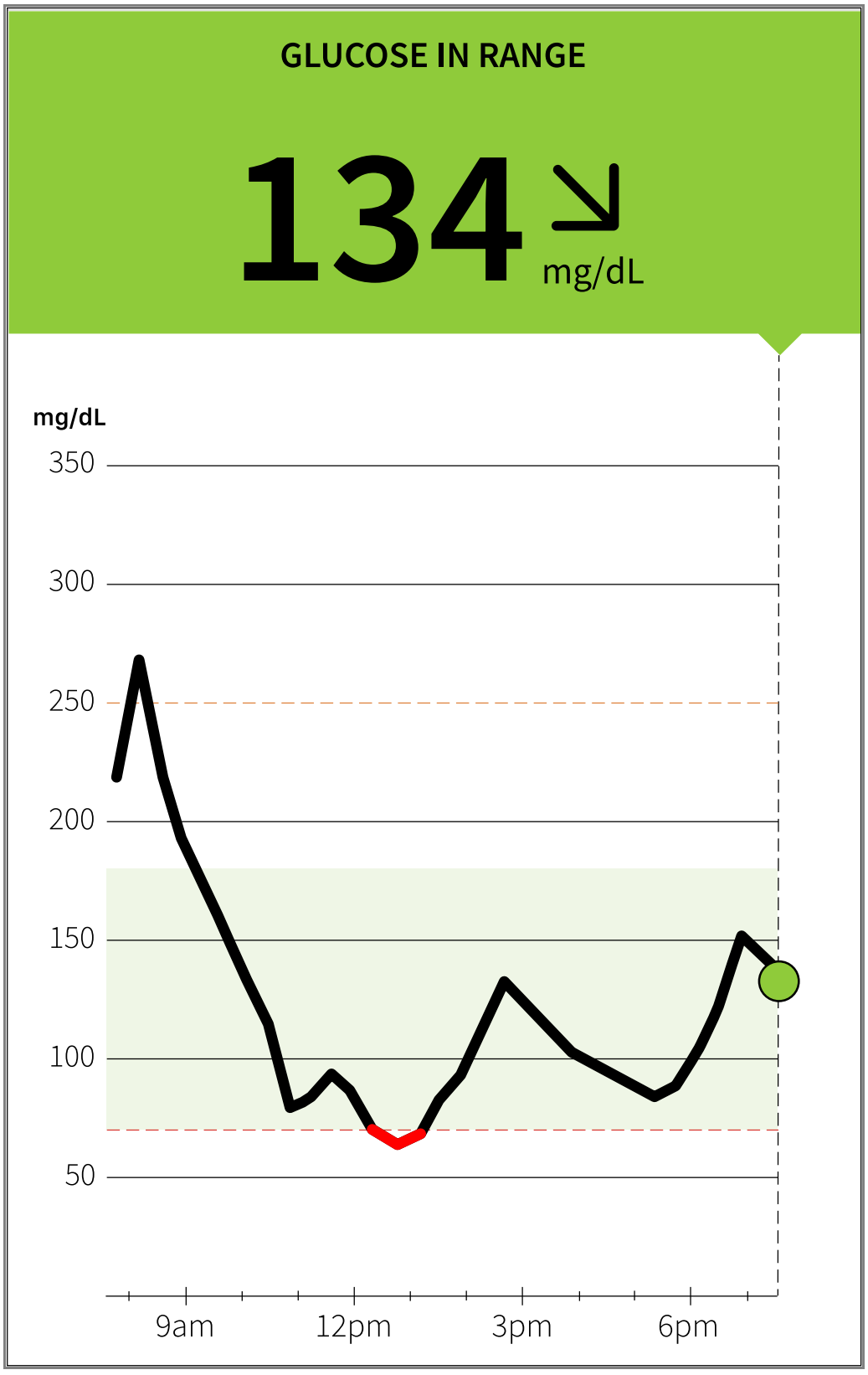


What it means

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

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

What you see - *Before dinner*



What it means

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

Consider what might be causing your glucose to go down and what you might do

to prevent a low glucose. For example:

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

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?

App Alarms

FreeStyle Libre 3 App includes several types of alarms.

- **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. The Override Do Not Disturb setting is turned on by default for each of these alarms, so you will receive a visual and audio notification regardless of your phone's sound or Do Not Disturb settings.

  Note:

  Turn OFF Override Do Not Disturb if you want the Optional Glucose Alarm volume to follow your phone's volume setting, and be silent when Do Not Disturb setting is enabled. Visual and Vibratory notification for the alarm may be presented based on your phone's settings.

- **Urgent Low Glucose:** Urgent Low Glucose Alarm will be delivered when your glucose goes below 55 mg/dL. You will receive a visual and audio notification regardless of your phone's sound or Do Not Disturb settings. This alarm cannot be turned off or customized.
- **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

it can be customized based on your preference. The Override Do Not Disturb setting is turned on by default for this alarm, so you will receive a visual and audio notification regardless of your phone's sound or Do Not Disturb settings.

Note:

Turn OFF Override Do Not Disturb if you want the Optional Signal Loss Alarm volume to follow your phone's volume setting, and be silent when Do Not Disturb setting is enabled. Visual and Vibratory notification for the alarm may be presented based on your phone's settings.

- **Fixed System Alarms:** Replace Sensor and Sensor Ended Alarms will be delivered when your Sensor needs to be replaced. You will receive a visual and audio notification regardless of your phone's sound or Do Not Disturb settings. These alarms cannot be modified or turned off and indicate you are no longer receiving glucose readings or glucose alarms.

  Note: 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:

- 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.
- Do not force close the App. The App must be running in the background to receive alarms. If you force close the App you will not receive alarms. Re-open the App to ensure you will receive alarms.
- If you restart your phone, open your App to make sure it's working properly.
- The App will ask for phone permissions which are needed to receive alarms. Allow these permissions when requested.
- Check to make sure that you have the correct phone settings and permissions enabled. If your phone is not configured properly, you will not be able to use the App, so you will not receive alarms or be able to check your glucose.
  - In the phone settings for the App under Notifications, keep Allow Critical Alerts **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, follow the instructions in the App.
- If you adjust the phone ringer volume 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.
- Disable your phone's automatic operating system updates. After an operating system update, open your App and check your device settings to make sure it's working properly.
- Some operating system features may impact your ability to receive alarms. For example, if you use the iOS Screen Time feature, add FreeStyle Libre 3 to the list of always allowed apps to ensure that you receive alarms.

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 you may not receive alarms when the Override Do Not Disturb setting within the App is disabled.

  Confirm your settings are as follows:

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

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 set or turn off your optional glucose alarms, go to the Main Menu and tap **Alarms**. Select the alarm you want to change. Work with your health care professional to determine your alarm settings.

Low Glucose Alarm

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 always 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.

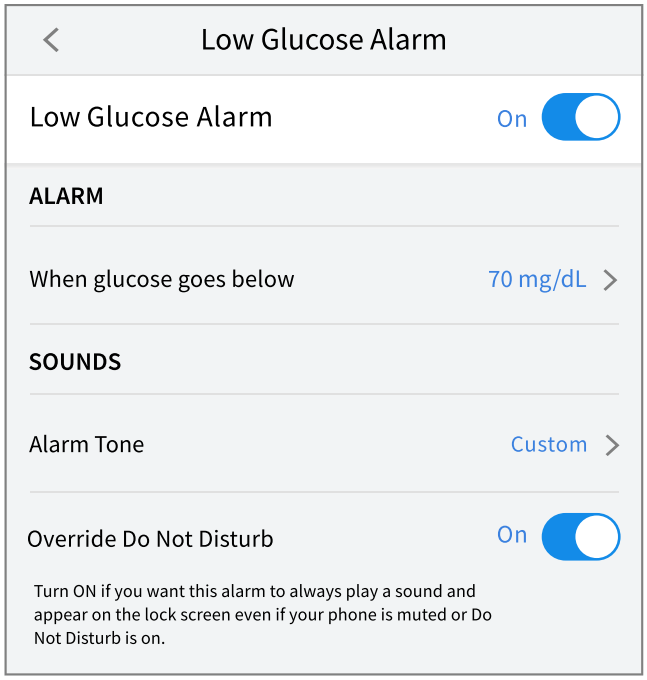
   Note:

   - Turn OFF Override Do Not Disturb if you want the alarm volume to follow your phone's volume setting, and be silent when Do Not Disturb setting is

enabled. Visual and Vibratory notification for the alarm may be presented based on your phone's settings.

- You must keep Allow Critical Alerts ON for the App in the phone settings.

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



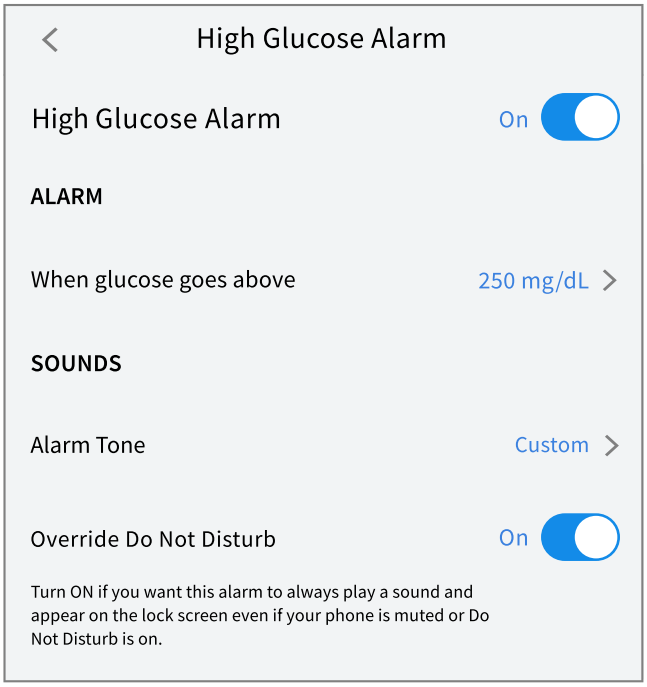
High Glucose Alarm

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 always 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.

   Note:

   - Turn OFF Override Do Not Disturb if you want the alarm volume to follow your phone's volume setting, and be silent when Do Not Disturb setting is enabled. Visual and Vibratory notification for the alarm may be presented based on your phone's settings.
   - You must keep Allow Critical Alerts ON for the App in the phone settings.

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



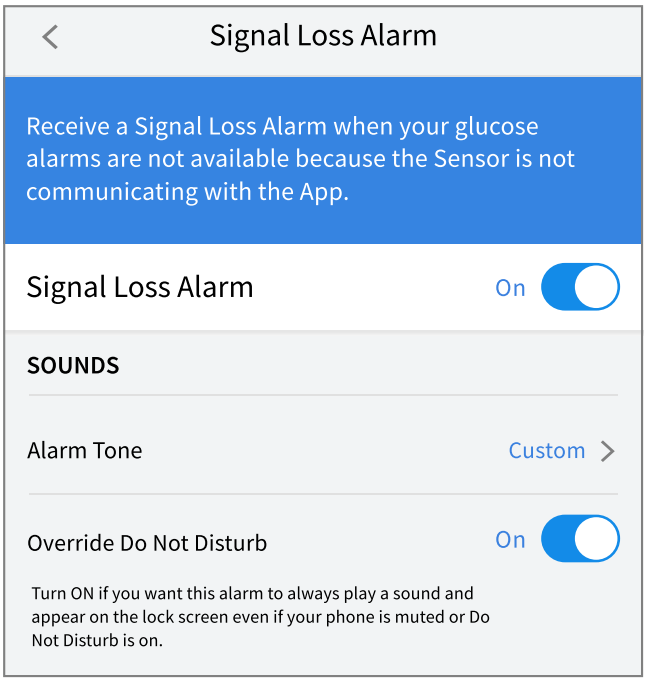
Signal Loss Alarm

1. If the alarm is on, you will be notified when your Sensor has not communicated with the App for 20 minutes and you are not receiving 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 always 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.

   Note:

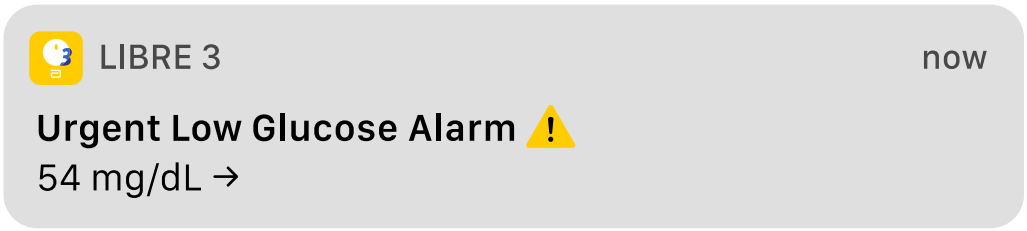
   - Turn OFF Override Do Not Disturb if you want the alarm volume to follow your phone's volume setting, and be silent when Do Not Disturb setting is enabled. Visual and Vibratory notification for the alarm may be presented based on your phone's settings.
   - You must keep Allow Critical Alerts ON for the App in operating system settings.

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



Using App Alarms

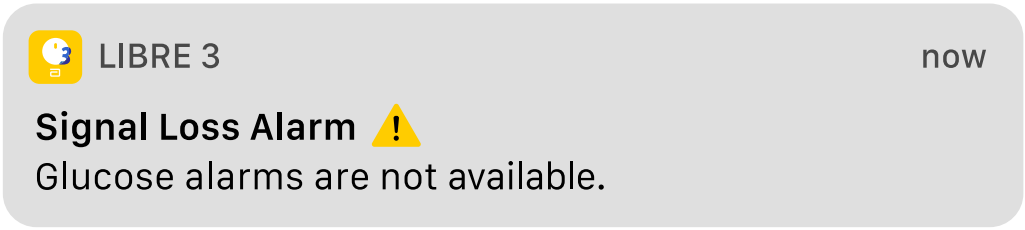
Urgent Low Glucose Alarm: Notifies you if your glucose drops below 55 mg/dL. Open the App or tap the Dismiss button to dismiss the alarm. You will receive the Urgent Low Glucose Alarm every 30 minutes until your glucose reading is at or above 55 mg/dL.



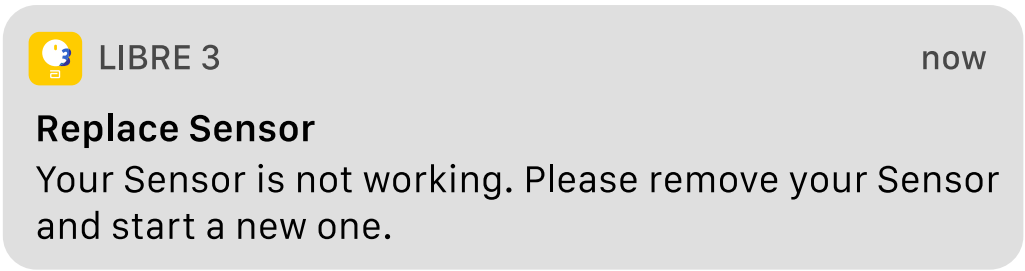
Low Glucose Alarm: Notifies you if your glucose drops below the level you set. Open the App or tap the Dismiss button to dismiss the alarm. You will only receive one alarm per low glucose episode.

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

Signal Loss Alarm: Notifies you if your Sensor has not communicated with the App for 20 minutes and you are not receiving glucose readings or 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.

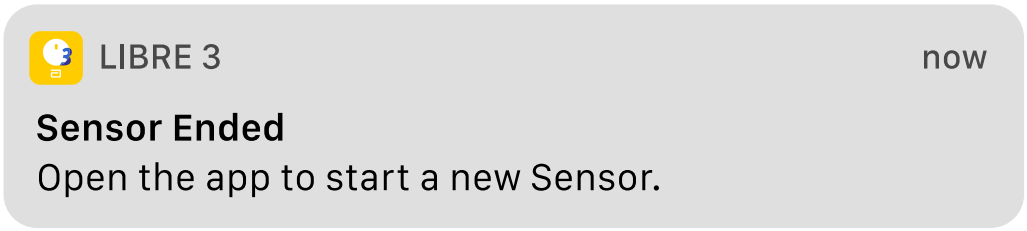


Replace Sensor Alarm: Notifies you if your Sensor has ended. You will not receive glucose alarms after this time unless you start a new Sensor. Remove your Sensor and start a new Sensor to check your glucose. Open the App or tap the Dismiss button to dismiss the alarm.

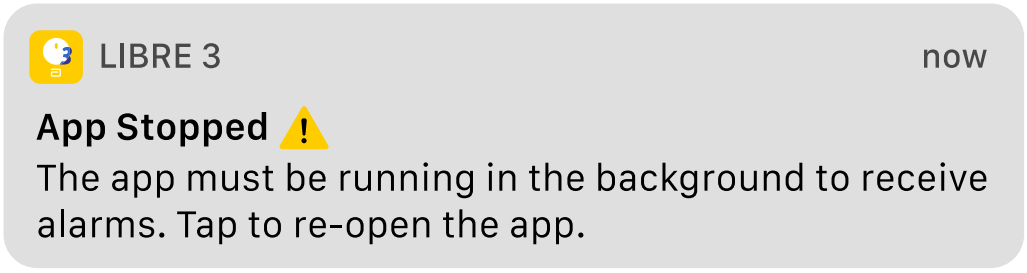


Note: For all of the above alarms: If you ignore an alarm, you will receive it again in 5 minutes if the condition still exists. Only your most recent alarms will display on your screen.

Sensor Ended 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.



App Stopped Alarm: Notifies you if your App has been closed. The App must be running in the background to receive alarms. Tap the alarm to re-open the App.



Adding Notes

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

1. Tap ✎ on the Home Screen.
2. Select the 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
3. Tap **DONE** to save your note.

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

Food

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

Reviewing Your History

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

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

IMPORTANT: Work with your health care professional to understand your glucose history.

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 at 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.

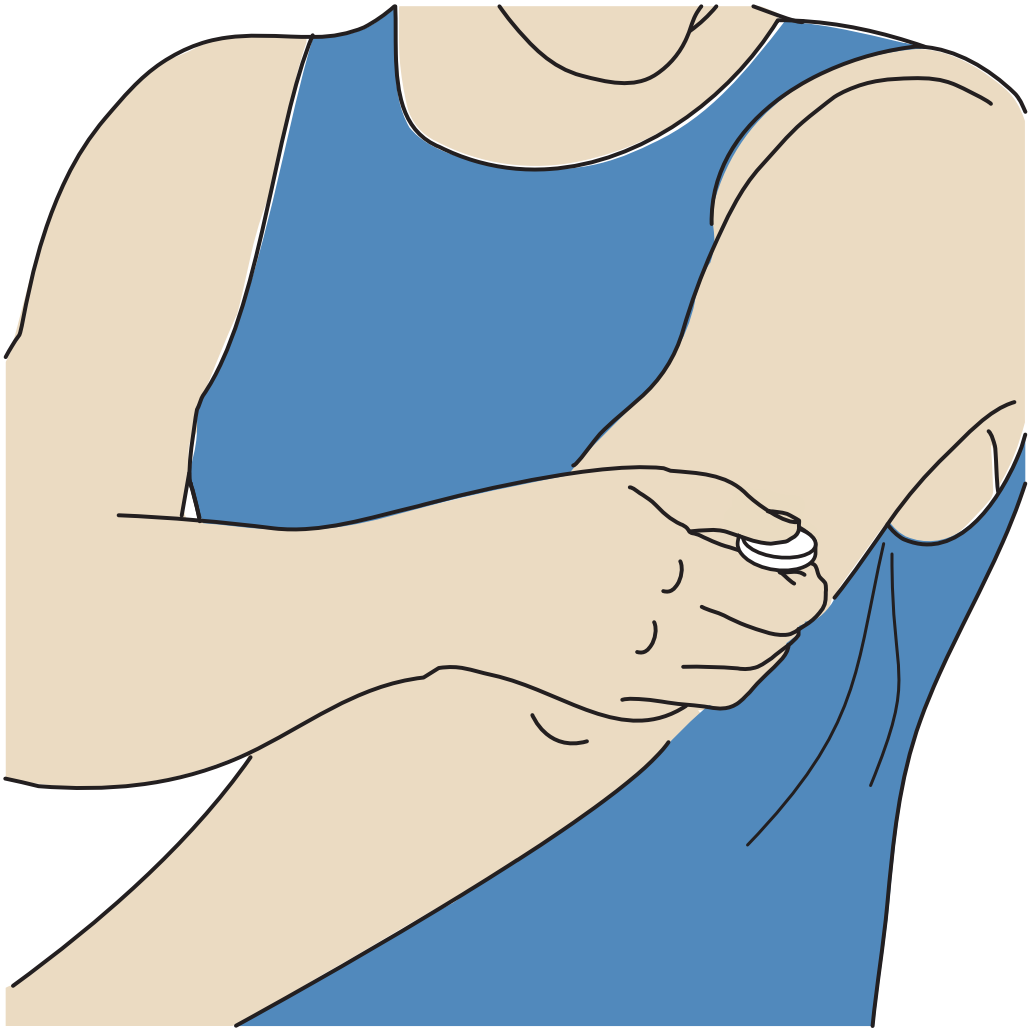
Note:

- Tap the symbol 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

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

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

Replacing Your Sensor

Your Sensor automatically stops working after 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.

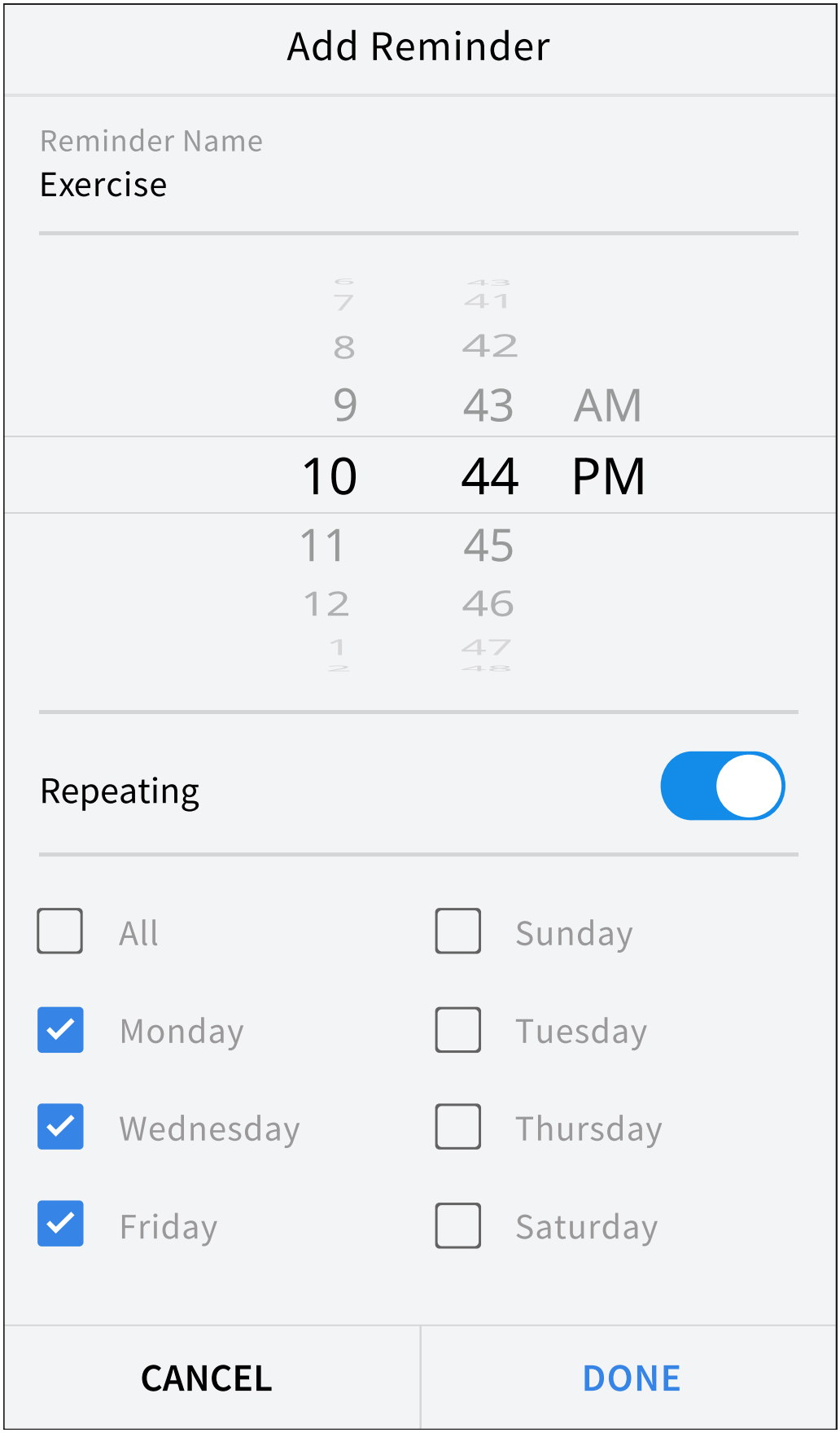
CAUTION: If the Sensor is becoming loose or if the Sensor tip is coming out of your skin, you may get no readings or unreliable readings, which may not match how you feel. Check to make sure your Sensor has not come loose. If it has come loose, remove it, apply a new one, and contact Customer Service.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

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.

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

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



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

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

will receive it.

Note:

- 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 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.

Living With Your System

Activities

Bathing, Showering, and Swimming: 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.

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.

- Some airport full-body scanners include x-ray or millimeter radio-wave, which you cannot expose your Sensor to. The effect of these scanners has not been evaluated and the exposure may damage the Sensor or cause inaccurate results. To avoid removing your Sensor, you may request another type of screening. If

you do choose to go through a full-body scanner, you must remove your Sensor.

- The Sensor can be exposed to common electrostatic (ESD) and electromagnetic interference (EMI), including airport metal detectors.

Note: Changing the time 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.

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 the Time in Ranges Custom report. The Target Glucose Range setting will not set glucose alarm levels. Tap **SAVE** when you are done.

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

Account Settings:

Account Settings – View/change your LibreView account information.

Account Password – Change your LibreView account password.

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

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 Standard Time.

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 Standard Time.

Problems at the Sensor Application Site

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

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

What to do:

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

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

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

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

Problems Starting Your Sensor

Display: **Scan Error**

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

What to do: 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.

Display: **Sensor Already in Use**

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

What to do: Your App can only be used with a Sensor started with the same LibreView account. If you're unable to use the Sensor with your App, check your glucose with the device that started it. Or, apply and start a new Sensor.

Display: **Enable Bluetooth**

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

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

Display: **Incompatible Sensor**

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

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

Display: **Replace Sensor**

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

What to do: Apply and start a new Sensor.

Display: **Allow Access to Critical Alerts**

What it may mean: Access to Critical Alerts was disabled.

What to do: Follow the instructions on the screen to allow permission for Critical Alerts. You will not be able to receive Sensor readings or start a new Sensor until these permissions are allowed.

Problems Receiving Sensor Readings

Display: **Sensor ready in X minutes**

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

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

Display: **Replace Sensor**

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

What to do: Apply and start a new Sensor.

Display: **Check Sensor**

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

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

Display: **Sensor Ended**

What it may mean: Your Sensor has ended.

What to do: Apply and start a new Sensor.

Display: **Signal Loss**

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

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

then ON again.

Display: **Bluetooth Off**

What it may mean: Bluetooth is turned off.

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

Display: **Sensor Error**

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

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

Display: **Sensor Too Hot**

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

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

Display: **Sensor Too Cold**

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

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

Display: **Allow Access to Critical Alerts**

What it may mean: Access to Critical Alerts was disabled.

What to do: Follow the instructions on the screen to allow permission for Critical Alerts. You will not be able to use the App to check your glucose or start a new Sensor until the permission is allowed.

Display: **Unexpected Application Error**

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

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

Problems Receiving Alarms

What it may mean: You have turned alarms off.

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

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

What to do: The Sensor must be within range (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 screen 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. Try turning Bluetooth OFF then ON again. If that doesn't work, try turning your phone OFF then ON again. If the Signal Loss Alarm persists, contact Customer Service.

What it may mean: One or more of the following is turned off in your phone settings: Allow Critical Alerts, Notifications, Lock Screen and Banner alerts, Notification sounds, or general phone sounds or vibration.

What to do: Check to make sure that you have the correct settings and

permissions enabled on your phone to receive alarms.

Go to Setting App Alarms for more information.

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

What to do: Confirm your alarm settings are appropriate.

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

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

What it may mean: Your Sensor has ended.

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

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

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

What it may mean: You have closed the App.

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

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 Standard Time. A printed copy of this User's Manual is available upon request.

System 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: Up to 14 days

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

Sensor transmission range: 33 ft (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 ft (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

Security Measures and Quality of Service

Security Measures:

The communication between the App 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 App and Sensor for glucose data is a standard Bluetooth Low Energy (BLE) connection. Mutual authentication is performed between the App 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 App that is paired with the Sensor will be able to reconnect and receive glucose data. Only apps logged into the same LibreView account that activated the Sensor are able to complete pairing with the Sensor.

Quality of Service (QoS):

QoS for the FreeStyle Libre 3 App and Sensor wireless communications using BLE is assured at regular 1-minute intervals. If connection is lost between the App and Sensor for 5-minutes, the App will display an indication of “Signal Loss” on the 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.

Labeling Symbols

	Consult instructions for use
	Temperature limit
	Manufacturer
	Batch code
	Type BF applied part
	Do not re-use
	MR unsafe
	FCC Declaration of Conformity mark

	Use-by date
REF	Catalog number
SN	Serial number
	Keep Dry
	Non-ionizing radiation
	Caution
STERILE R	Sterilized by irradiation
	Humidity limitation
	Do not use if package is damaged
	Not made with natural rubber latex
$R_{X\ Only}$	**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.

Performance Characteristics

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 71.1% of the time, between 121 and 160 mg/dL 19.1% of the time, between 161 and 200 mg/dL 1.0% 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 subject group 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 subject group 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% / ±15mg/dL	Within ±20% / ±20mg/dL	Within ±40% / ±40mg/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% / ±15mg/dL	Within ±20% / ±20mg/dL	Within ±40% / ±40mg/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.

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)

	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

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.

Ascorbic Acid Interference

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.

Electromagnetic Compatibility (EMC)

FreeStyle Libre 3 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: RF emissions; CISPR 11

Compliance: Group 1

Electromagnetic environment – guidance: 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.

Emissions test: RF emissions; CISPR 11

Compliance: Class B

Electromagnetic environment – guidance: 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.

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

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

Compliance level: ± 8 kV contact; ± 15 kV air

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

Immunity test: Magnetic; IEC 61000-4-8

IEC 60601 test level: 30 A/m

Compliance level: 30 A/m

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

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

IEC 60601 test level: 10 V/m; 80 MHz to 2.7 GHz

Compliance level: 10 V/m

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

IEC 60601 test level: See table below

Compliance level: Compliance to the tested levels

Electromagnetic environment - guidance:

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

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

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

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

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

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

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

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

[d] Field strengths from fixed transmitters, such as base stations for radio (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.

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

[2] "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)

http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

[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

Customer Service: www.FreeStyleLibre.com

Patent: https://www.abbott.com/patents

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