



FreeStyle Libre 2 System

IN-SERVICE GUIDE



**MORE
PATIENTS
CAN
DO IT
WITHOUT
FINGERSTICKS***




FreeStyle
Libre 2


life. to the fullest.®
Abbott

*Fingersticks are required if your glucose alarms and readings do not match symptoms or when you see Check Blood Glucose symbol during the first 12 hours. Sensor is water-resistant in up to 1 meter (3 feet) of water. Do not immerse longer than 30 minutes. See inside for Indications and Important Safety Information.

Important Safety Information

Indications For Use

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

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

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

Compatible Devices, Apps, and Software

For a list of compatible devices, apps, and software that can be used with the FreeStyle Libre 2 Sensor, please go to: <https://freestylelibre.us/support/overview.html>.

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


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.

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 Glucose Alarms:

- For you to receive alarms, they must be on and your Reader should be within 20 feet of you at all times. The transmission range is 20 feet unobstructed. If you are out of range, you may not receive glucose alarms.

To prevent missed alarms, make sure the Reader has sufficient charge and that sound and/or vibration are turned on.

Important Safety Information

Alarms you receive do not include your glucose reading so you must scan your Sensor to check your glucose.

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 Reader and Sensor kits are kept in a safe place, under your control. 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.
- You must scan the Sensor to get your real-time current glucose level as the Reader will not provide this information without a scan.
- 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.

Important Safety Information

- 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:

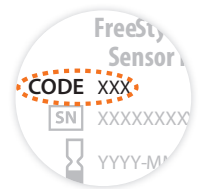
- Store the Sensor Kit between 36°F and 82°F. Storage outside of this range may cause inaccurate Sensor glucose readings.
- If you suspect that the temperature may exceed 82°F (for example, in an un-airconditioned home in summer), you should refrigerate your Sensor Kit. Do not freeze your Sensor Kit.
- 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, Sensor Pack, or Sensor Applicator appear to be damaged or already opened due to risk of no results and/or infection.
- Do NOT use if Sensor Kit contents are past expiration date.
- Do NOT use if the Reader appears to be damaged due to risk of electric shock and/or no results.

What to know before you Apply the Sensor:

- The Sensor Pack and Sensor Applicator are packaged as a set (separately from the Reader) and have the same Sensor code. Check that the Sensor codes match before using your Sensor Pack and Sensor Applicator. Do not use Sensor Packs and Sensor Applicators with different Sensor codes together as this will result in incorrect glucose readings.
- 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.

Important Safety Information

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.

What to know about the Reader's Built-in Meter:

- The FreeStyle Libre 2 Reader has a built-in blood glucose meter that is designed to be used only with FreeStyle Precision Neo blood glucose test strips and MediSense Glucose and Ketone Control Solution. Using other test strips with the Reader's built-in meter will produce an error or cause the Reader's built-in meter to not turn on or start a test. The Reader's built-in meter does not have ketone testing functionality.
- The Reader's built-in meter is not for use on people who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.
- The Reader's built-in meter is not for use on neonates, in critically-ill patients, or for diagnosis or screening of diabetes.
- See *Using the Reader's Built-in meter* section for additional important information on the use of the Reader's built-in meter.

Where to charge your Reader:

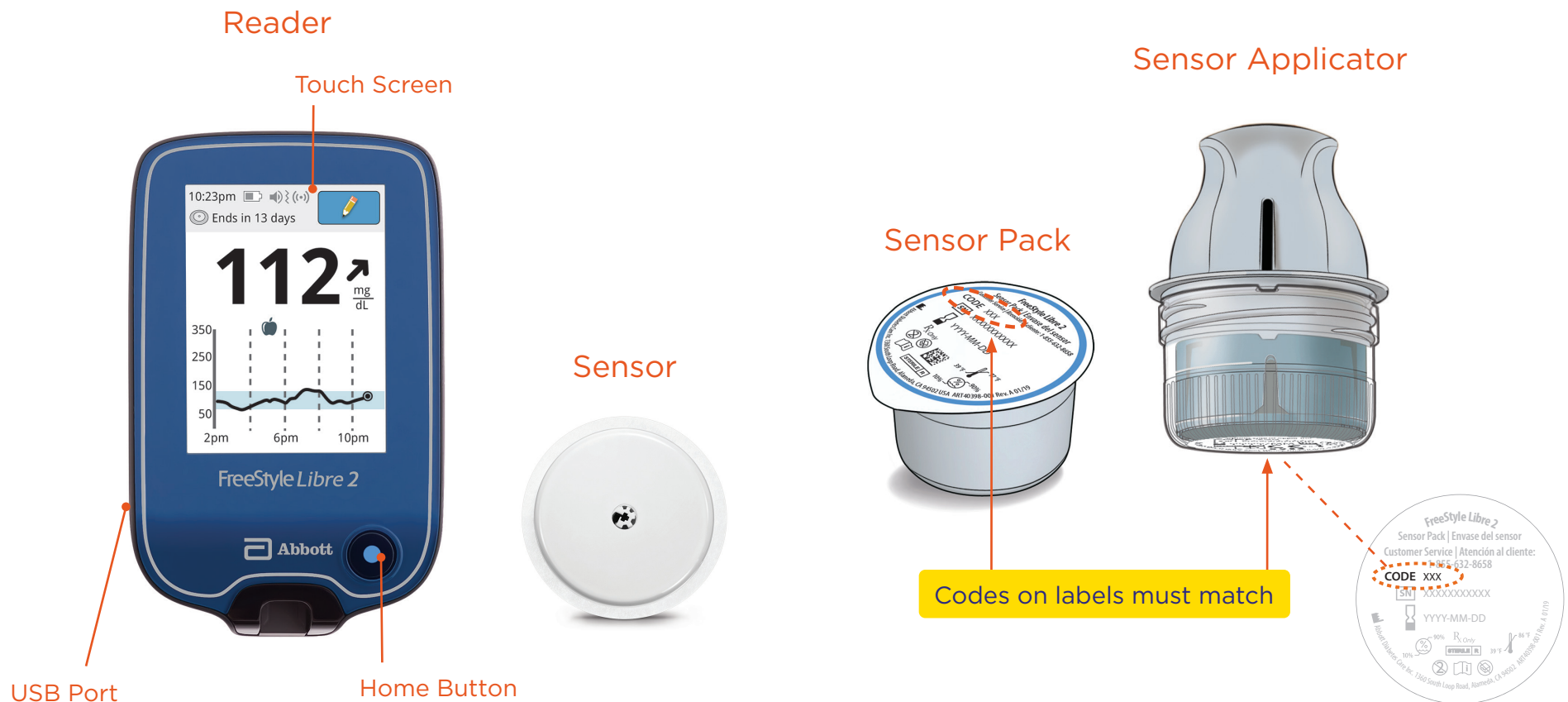
- Be sure to select a location for charging that allows the power adapter to be easily unplugged. Do NOT block access to the charger due to the potential risk of electrical shock.

Interfering Substances

Taking ascorbic acid (vitamin C) supplements while wearing the Sensor may falsely raise Sensor glucose readings. You can take doses of ascorbic acid up to 500 mg per day and make treatment decisions with the Sensor. 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.

Getting To Know The System

- The reader scans the sensor for glucose readings and stores up to 90 days of glucose history
- The reader activates the sensor and initiates the 1-hour warm up period
- The reader is rechargeable
- The sensor is worn on the back of the upper arm and measures and stores glucose readings every minute
- Follow the instructions to prepare and apply the sensor
- The sensor may be worn for up to 14 days with no fingersticks for calibration[†] or insulin dosing^{*}



*Fingersticks are required if your glucose alarms and readings do not match symptoms or when you see Check Blood Glucose symbol during the first 12 hours.

[†]Calibration or coding not required by the user.

See User's Manual for instruction on setting up the reader for the first time.

Sensor Application

1 Wash, clean, and dry before you apply your sensor

Get Ready

STEP 1



Select site on **back of your upper arm**. Do not use other sites as these are not approved and may result in inaccurate glucose readings.

Note: Avoid scars, moles, stretch marks, lumps, and insulin injection sites. To prevent skin irritation, rotate sites between applications.

TIP: Select an area on the back of the upper arm that generally stays flat during normal daily activities (no bending or folding).

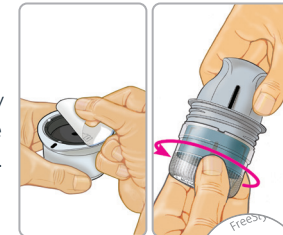
STEP 2



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 completely dry before proceeding.

TIP: The area **MUST** be clean and dry or the Sensor may not stay on for the full 14 day wear period.

STEP 3



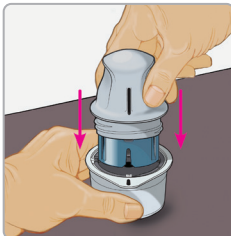
Peel lid completely off sensor pack. Unscrew cap from sensor applicator.

CAUTION: Sensor codes must match on sensor pack and sensor applicator or glucose readings will be incorrect.



Prepare Sensor Applicator

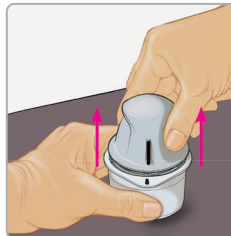
STEP 4



Line up dark mark on sensor applicator with dark mark on sensor pack. On a hard surface, press down firmly on sensor applicator until it comes to a stop.

TIP: Assemble on a hard surface, such as a table.

STEP 5



Lift sensor applicator straight out of sensor pack.

STEP 6

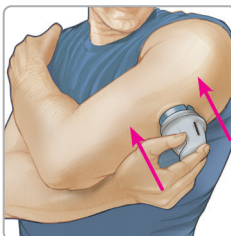


Sensor applicator is ready to apply sensor.

CAUTION: Sensor applicator now contains a needle. Do not touch inside sensor applicator or put it back into sensor pack.

Apply Sensor

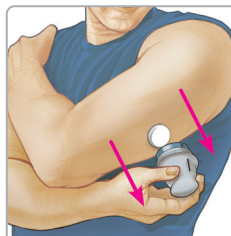
STEP 7



Place sensor applicator over site and push down firmly to apply sensor.

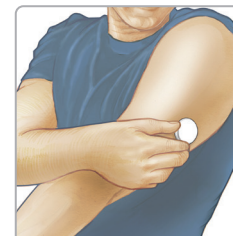
CAUTION: Do not push down on sensor applicator until placed over prepared site to prevent unintended results or injury.

STEP 8



Gently pull back applicator to remove, leaving sensor on body.

STEP 9



Make sure sensor is secure by gently pressing adhesive to the skin. Discard used sensor applicator and sensor pack according to local regulations.

TIP: For video of sensor application, visit <https://provider.myfreestyle.com/freestyle-libre-resources.html>

Starting a New Sensor

2 Start new sensor with reader

Start New Sensor

STEP 1



Press Home Button to turn on reader.

Follow the prompts to set date and time.

The reader now displays important information about key topics to help you use the system. The screens are shown below.

Important Screens

IMPORTANT READER SCREENS

When you scan your Sensor an arrow will indicate your recent glucose trend:

- ↑ Rising quickly
- ↗ Rising
- Changing slowly
- ↘ Falling
- ↓ Falling quickly

back

next

If you see this symbol, do a blood glucose test before making treatment decisions.



back

next

If the Sensor glucose reading does not match how you feel, do a blood glucose test.



back

next

The Sensor can only be applied to the back of your upper arm.



back

next

Important

Do not take high doses of vitamin C (more than 500 mg per day). This may falsely raise your Sensor readings. Supplements like Airborne® or Emergen-C® have high doses of vitamin C. Read labeling for all supplements to determine vitamin C content.

back

next

While using the Reader, press the Home button to return to the Home screen.



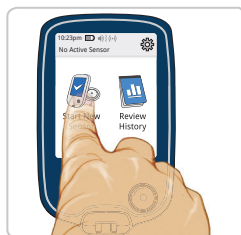
back

done

- How to understand the Glucose Trend Arrow included on the Glucose Reading screen
- When to do a blood glucose test
- Where to apply the Sensor
- Why not to take more than 500 mg of Vitamin C supplements per day
- How to return to the Home Screen from any other screen

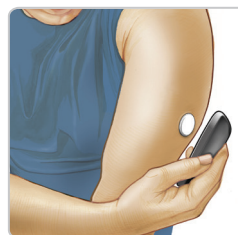
Start New Sensor

STEP 2



Touch Start New Sensor.

STEP 3



Hold reader within 1.5 inches (4 cm) of sensor to scan it.
Sensor can be used to check your glucose after 1 hour.

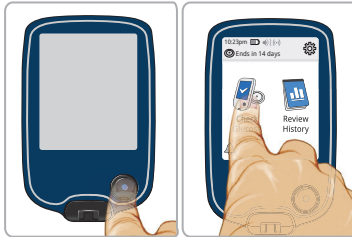
Start New
Sensor

Getting a Glucose Reading

Scan your sensor anytime to get a real-time glucose reading.

Check your glucose

STEP 1



Press Home Button to turn on reader **OR** touch Check Glucose from the Home Screen.

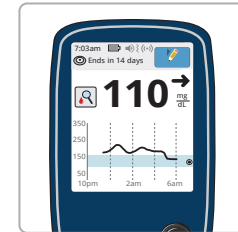
STEP 2



Hold reader within 1.5 inches (4 cm) of sensor to scan it.

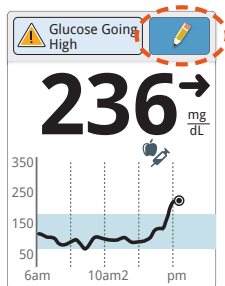
NOTE: If the sensor is not successfully scanned within 15 seconds, the reader displays a prompt to scan the sensor again. Touch **OK** to return to the Home Screen and touch **Check Glucose** to scan your sensor.


STEP 3

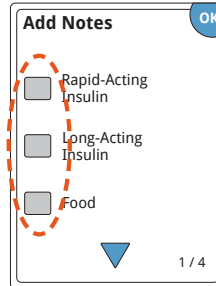


Reader shows your glucose reading along with your glucose graph and an arrow indicating the direction your glucose is going.

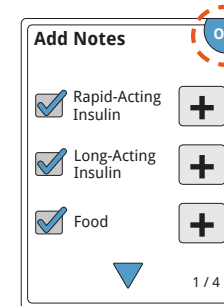
Adding notes



From the Glucose Reading screen, add a note by touching the  in the upper right corner of the screen.



Select the checkbox next to the information you'd like to add. Options include insulin, food, exercise, and any medication you take.



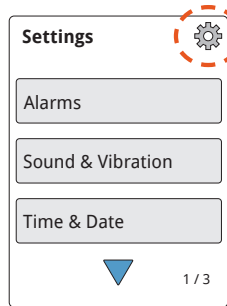
Touch **OK** to save your notes. Notes are viewable in the logbook.

Customizing Your Optional, Real-Time Glucose Alarms*

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

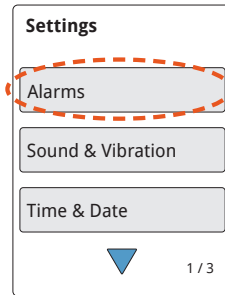
Alarm Settings

STEP 1



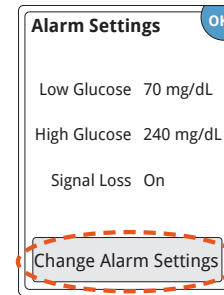
From the home screen, touch the Settings symbol.

STEP 2



Touch **Alarms**.

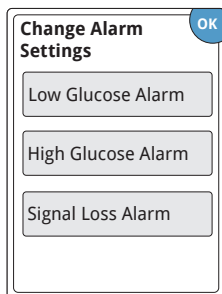
STEP 3



Touch **Change Alarm Settings**.

The Alarms Setting screen shows your current alarm settings. These alarms are on by default.

STEP 4



Select the alarm you want to change or turn off.

Low Glucose Alarm:

Notifies you when your glucose is below the level you set.

High Glucose Alarm:

Notifies you when your glucose is above the level you set.

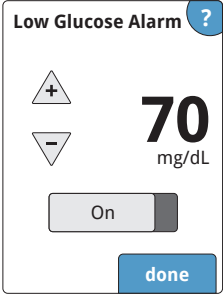
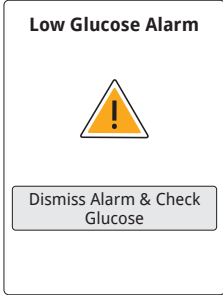
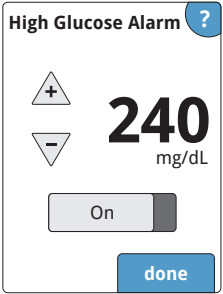
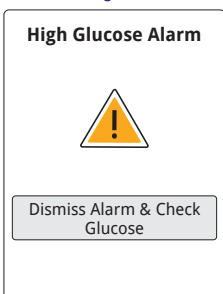
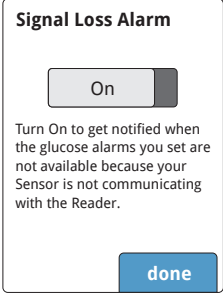
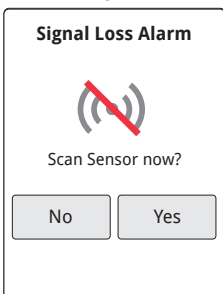
Signal Loss Alarm:

Notifies you when your Sensor is not communicating with the Reader and that you will not receive Low or High Glucose Alarms.

When you are finished setting your alarms touch **OK**.

*Notifications will only be received when alarms are turned on and the sensor is within 20 feet of the reading device.

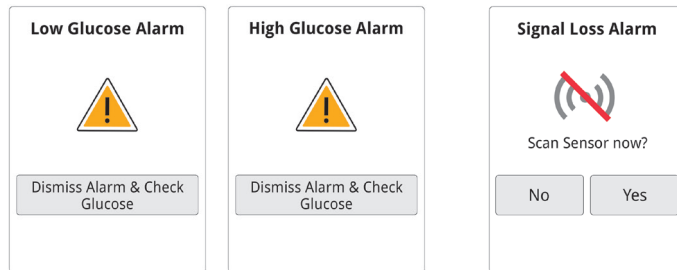
Customizing Your Optional, Real-Time Glucose Alarms*

Low Glucose Alarm		<p>The Low Glucose Alarm is on by default.</p> <p>The alarm level is initially set to 70 mg/dL. You can use the arrows to change this value between 60 mg/dL and 100 mg/dL. When the alarm is on, you will be notified when your glucose crosses below the level you set. Touch the slider to turn the alarm off.</p> <p>Touch done to save.</p>	<p>What you See</p> 	<p>What it Means</p> <p>The Low Glucose Alarm notifies you if your glucose crosses below the level you set. The alarm does not include your glucose reading, so you need to scan your Sensor to check your glucose.</p>
High Glucose Alarm		<p>The High Glucose Alarm is on by default.</p> <p>The alarm level is initially set to 240 mg/dL. You can use the arrows to change this value between 120 mg/dL and 400 mg/dL. When the alarm is on, you will be notified when your glucose crosses above the level you set. Touch the slider to turn the alarm off.</p> <p>Touch done to save.</p>	<p>What you See</p> 	<p>What it Means</p> <p>The High Glucose Alarm notifies you if your glucose crosses above the level you set. The alarm does not include your glucose reading, so you need to scan your Sensor to check your glucose.</p>
Signal Loss Alarm		<p>The Signal Loss Alarm is on by default.</p> <p>When the alarm is on, you will be notified when your Sensor has not communicated with your Reader for 20 minutes and you are not receiving Low or High Glucose Alarms. Touch the slider to turn the alarm off.</p> <p>Touch done to save.</p>	<p>What you See</p> 	<p>What it Means</p> <p>The Signal Loss Alarm notifies you if your Sensor has not communicated with the Reader for 20 minutes and you are not receiving Low or High Glucose Alarms. Signal loss could be caused by the Sensor being too far away from the Reader (over 20 feet) or another issue such as an error or problem with your Sensor or Reader.</p> <p>Touch No to dismiss the alarm.</p> <p>Touch Yes or press the Home Button to dismiss the alarm and scan the Sensor.</p>

*Notifications will only be received when alarms are turned on and the sensor is within 20 feet of the reading device.

Customizing Your Optional, Real-Time Glucose Alarms*

How To Accept the Alarms



Touch **Dismiss Alarm & Check Glucose** or press the Home Button to dismiss alarm and check glucose.

Touch **No** to dismiss alarm.
Touch **Yes** or press the Home Button to dismiss alarm and scan the Sensor.

What it Means

The reader alarms for about 1 minute.

If the user does not tap “dismiss and check glucose” or they do not touch the home button and the condition still exists, then:

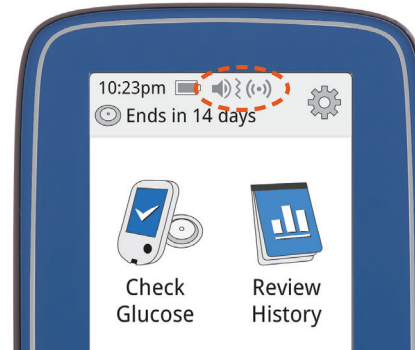
There will be a pause for 5 minutes.

The alarm then repeats itself until the user dismisses it.

Alarm Sounds and Vibration



Adjust Alarms sound and vibration Settings through “Sound & Vibration” in the setting menu.



When any alarm is on, sound/vibration and signal states display on the Home Screen.

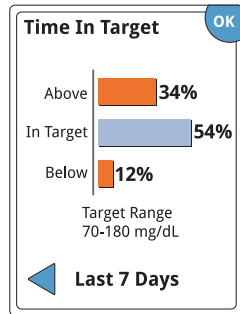
Symbol	What it means
	Sound and Vibration ON
	Sound and Vibration OFF
	Sensor communicating with Reader
	Sensor not communicating with Reader

Refer to User's Manual for additional symbols.

*Notifications will only be received when alarms are turned on and the sensor is within 20 feet of the reading device.

Determining The Time In Range

Time in Range

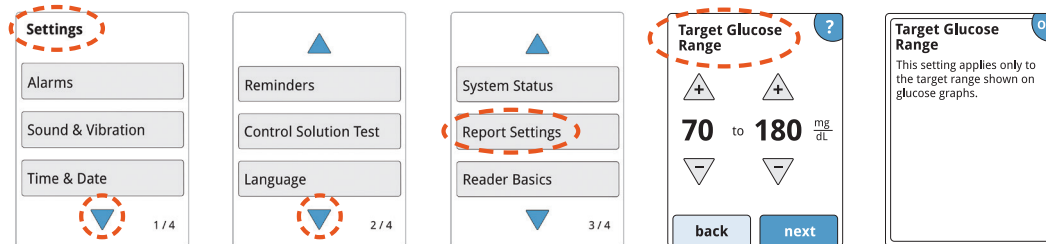


The FreeStyle Libre 2 system automatically calculates the percentage of time spent in, above, or below target range, allowing for a better understanding of how daily activities impact glucose levels.

How to Set Your Time in Range

The target glucose range is not related to the glucose alarm settings

Target Glucose Range is in Settings Menu under “Report Settings”



Target glucose range is pre-set to: 70 to 180 mg/dL on the FreeStyle Libre 2 reader.
The allowable range is 70-180 mg/dL.

Your Target Glucose Range goals can be entirely specific to you and may change over time.

To set a target glucose range on your reader, which is different from your alarm settings, go to the Settings menu and set your Target Glucose Range under the Report Settings menu.

Reviewing Your History

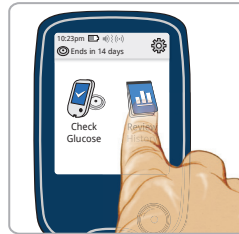
The system provides insightful information to identify 7-, 14-, 30-, and 90-day trends.

STEP 1



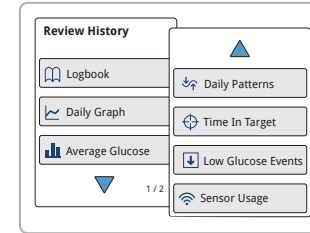
Press Home Button to turn on the reader and go to Home Screen.

STEP 2



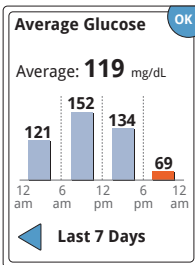
Touch Review History.

STEP 3



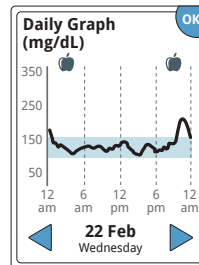
Use the arrows to view the available options.

Average Glucose



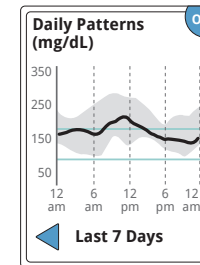
Information about your average sensor glucose readings.*

Daily Graph



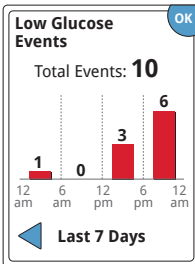
Your sensor glucose readings by day.†

Daily Patterns



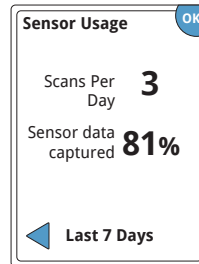
The pattern and variability of your sensor glucose over a typical day.†§

Low Glucose Events



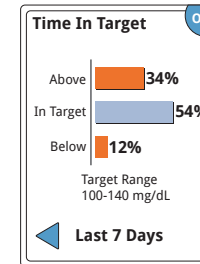
The number of low glucose events measured.

Sensor Usage



Report on how often you scan the sensor.

Time in Target Range



The percentage of time glucose readings were above, below, or within Target Glucose Range.*

*Readings above or below your Target Glucose Range are orange, while readings in range are blue.

†The thick black line shows the median (midpoint) of your glucose readings.

‡The gray shading represents a range (10-90 percentiles) of your sensor readings. This is not the Ambulatory Glucose Profile.

§Daily Patterns needs at least 5 days of glucose data.

Maintenance and Disposal

Your sensor automatically stops working after 14 days must be replaced. You should also replace your sensor if you notice any irritation or discomfort at the application site or if the reader reports a problem with the sensor currently in use.

Sensor Removal



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

If you removed your last sensor before it ended, you will be prompted to confirm that you would like to start a new sensor when you first scan it.

When you are ready to apply a new sensor, follow the instructions previously outlined.

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

Reader Cleaning & Disinfection



You should clean and disinfect the reader once a week. Use Clorox Healthcare Bleach Germicidal Wipes.*

NOTE: *Turn off the reader before you clean and disinfect it.*

For cleaning, wipe outside surfaces of the reader with one bleach wipe.

For disinfection, use a second bleach wipe to wipe outside surfaces of the reader until surfaces are wet.

NOTE: *Make sure liquid does not get into the test strip and USB ports.*

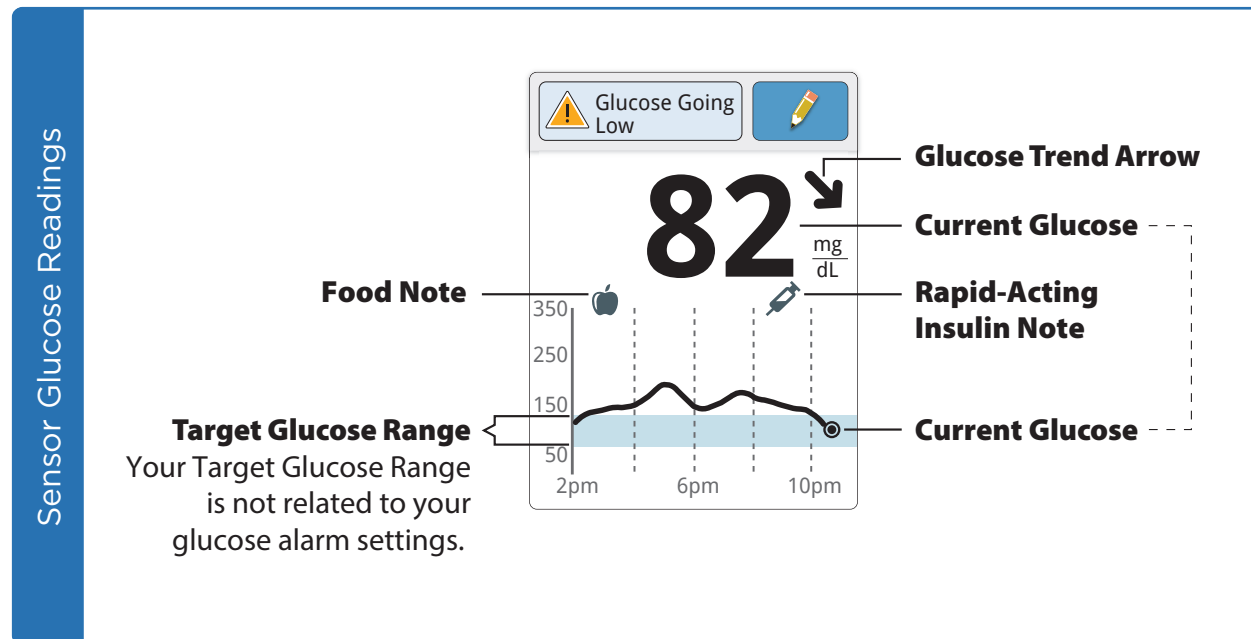
Allow the reader surfaces to remain wet for 60 seconds. After 1 full minute, immediately dry with a clean paper towel to remove any residual moisture. When finished, thoroughly wash your hands with soap and water.

Discard the used sensor in accordance with all applicable local regulations related to the disposal of electronic equipment, batteries, and materials potentially exposed to body fluids.

*Clorox Healthcare Bleach Germicidal Wipes may be purchased at major online retailers, such as Walmart.com, Amazon.com, and OfficeDepot.com.

Interpreting Sensor Readings

Sensor glucose readings appear after scanning your sensor. Before making treatment decisions, it is important to understand your sensor readings. **Use all of the information on the screen** when deciding what to do or what treatment decision to make.

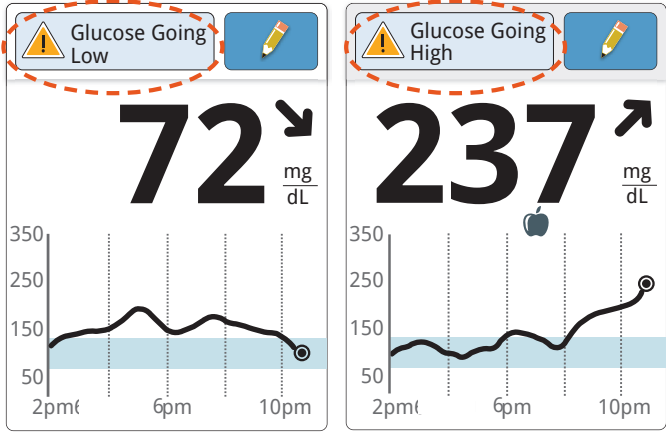


NOTE: While sensor glucose readings are gathered in the system range of 40-400 mg/dL, the graph display range is 0-350 mg/dL for ease of review on screen. Glucose readings above 350 mg/dL are displayed at 350 mg/dL.

NOTE: The ⌚ symbol may appear, indicating the reader time was changed. Gaps in the graph may result or glucose readings may be hidden.

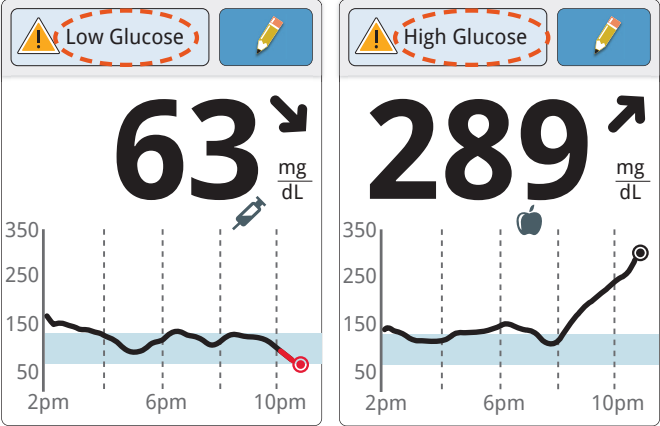
Going Low/High Message

Messages will appear on the Reader when glucose readings are trending.

DISPLAY	WHAT TO DO
	<p>If your glucose is projected to be higher than 240 mg/dL or lower than 70 mg/dL within 15 minutes, a message will appear on the screen.</p> <p>Touch the message button for more information and set a reminder to check your glucose again.</p>

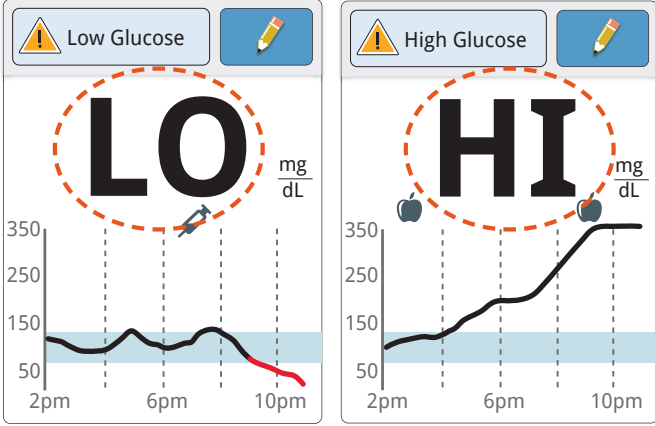
Low Glucose/High Glucose Message

Messages will appear on the Reader when the glucose reading is low or high.

DISPLAY	WHAT TO DO
	<p>If your glucose is higher than 240 mg/dL or lower than 70 mg/dL, you will see a message on the screen. You can touch the message button for more information and set a reminder to check your glucose.</p>

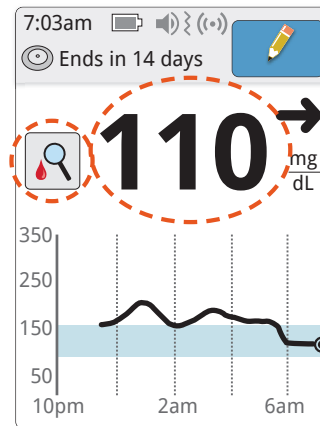
LO/HI Reading


Current Glucose will display LO or HI when glucose readings are outside measuring range.

DISPLAY	WHAT TO DO
 <p>The diagram shows two side-by-side sensor displays. The left display is labeled 'Low Glucose' and shows a large 'LO' in a dashed red circle. Below it is a line graph of glucose levels over time (2pm to 10pm) with a shaded blue area representing the normal range (50-150 mg/dL). The right display is labeled 'High Glucose' and shows a large 'HI' in a dashed red circle. Below it is a line graph of glucose levels over time (2pm to 10pm) with a shaded blue area representing the normal range (50-150 mg/dL). Both displays have a 'mg/dL' unit label and a pencil icon for more information.</p>	<p>If LO appears on the reader, your reading is lower than 40 mg/dL. If HI appears on the reader, your reading is higher than 400 mg/dL. You can touch the message button for more information. Check your blood glucose on your finger with a test strip. If you get a second LO or HI result, contact your healthcare professional immediately.</p>

Check Blood Glucose Symbol






The Check Blood Glucose Symbol will appear during the first 12 hours of sensor wear.



When you see the  symbol during the first 12 hours of wearing a Sensor, this is a reminder that your body might still be getting used to the new Sensor. Confirm Sensor glucose readings with a blood glucose test before making treatment decisions.

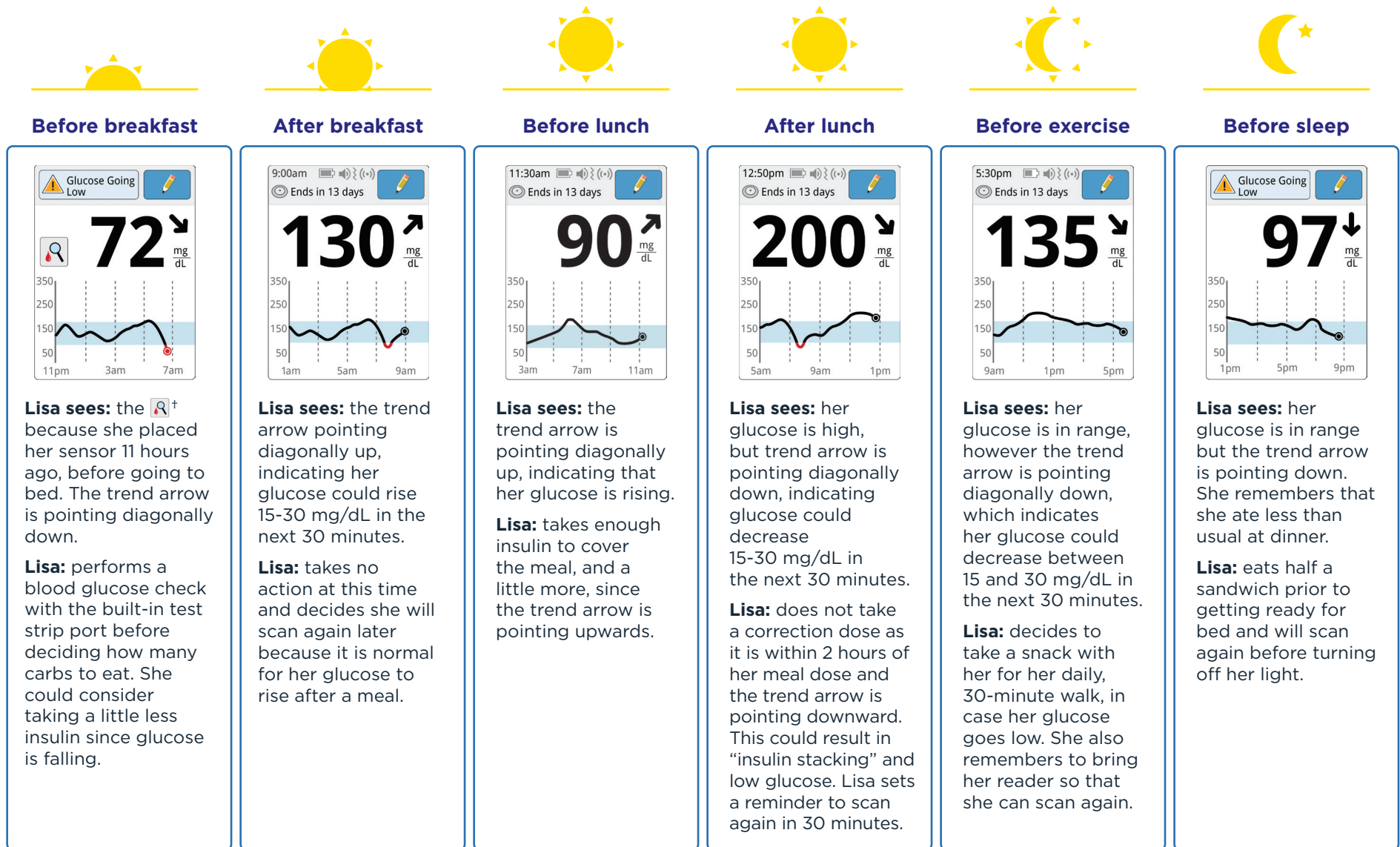
Interpreting Glucose Trend Arrows

The Glucose Trend Arrow indicates which 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)

A Day in the Life

How Lisa manages her diabetes with FreeStyle Libre 2 system*



*The patient study provided is intended for educational purposes only. Individual symptoms, situations, and circumstances may vary. †When you see the symbol during the first 12 hours of wearing a Sensor, this is a reminder that your body might still be getting used to the new Sensor. Confirm Sensor glucose readings with a blood glucose test before making treatment decisions.

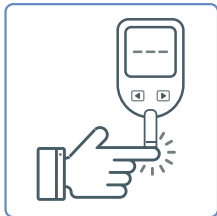
Reference: 1. Kudva, Yogish C., et al. “Approach to using trend arrows in the FreeStyle Libre flash glucose monitoring systems in adults.” *Journal of the Endocrine Society* 2, no. 12 (2018): 1320-1337.

Treatment Decisions: Getting Started

Before you start using the FreeStyle Libre 2 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
- Getting familiar with the system could take days, weeks, or even months
- Work with your healthcare professional to put together a plan for making treatment decisions
- Scan often to see how carbs, medication, exercise, illness, or stress levels impact your sensor glucose readings

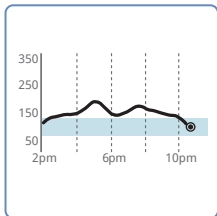
HELPFUL TIPS



CONFIRM SENSOR GLUCOSE READINGS

Confirm your Sensor glucose readings with a blood glucose meter until you understand:

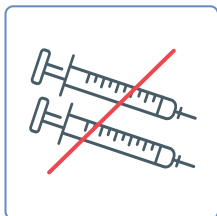
- Sensor accuracy may vary between sensors
- Sensor accuracy may vary during a sensor wear session
- Sensor accuracy may vary in different situations (meals, exercise, first day of use, etc.)



UNDERSTAND YOUR INSULIN

Understand how your insulin works, including how long it takes to start working and how long it lasts in your body.

NOTE: *Making a treatment decision doesn't just mean taking insulin. Treatment decisions can include taking fast-acting carbs, eating, or doing nothing and scanning again later.*

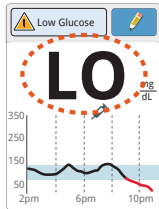


AVOID "INSULIN STACKING"

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 scan again later.

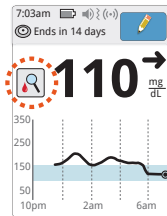
Treatment Decisions

When not 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 Reading

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 are 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.

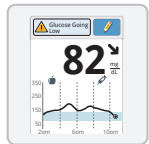
When to Contact your Healthcare Professional

Refer to the FreeStyle Libre 2 system User's Manual for more details.



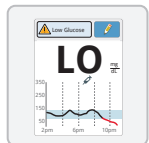
SYMPTOMS

- If you are experiencing symptoms that are not consistent with your glucose readings
- If you have significant skin irritation around the sensor
- If the sensor breaks in your body
- If you are suffering from dehydration
- If bleeding does not stop after removing sensor



TREATMENT DECISIONS

- To determine how you should use your sensor glucose information to help manage your diabetes
- To determine and set your target glucose range
- To understand how insulin works
- To determine when to do nothing/scan again later
- To determine how to use your blood glucose results
- To discuss what to do if symptoms don't match your sensor glucose results



SENSOR READINGS

- If you get a LO or HI sensor reading followed by a LO or HI blood glucose result
- If you are not sure about the reader message or the glucose reading



MAINTENANCE AND SENSOR DISPOSAL

- How to discard a used sensor

Frequently Asked Questions

SENSOR APPLICATION

How is the sensor applied to the body?

The sensor is applied to the back of the upper arm with a simple, disposable device called an applicator. When the sensor is applied, a small (5mm) filament is inserted just under the skin, and held in place with a small adhesive pad. Most users don't feel pain when applying the FreeStyle Libre 2 sensor.*¹

Is it necessary to apply a sensor in a different location if the user feels discomfort?

To prevent discomfort or skin irritation, select a different site other than the one most recently used or on the back of the other arm.

When applying the sensor to the arm, should the skin be stretched or pinched?

No, there is no need to stretch or pinch the skin to apply the sensor. The sensor should be applied only on the back of your upper arm. Avoid areas with scars, moles, stretch marks, or lumps. Select an area of skin that generally stays flat during normal daily activities (no bending or folding). Choose a site that is at least 2.5 cm (1 inch) away from an insulin injection site. To prevent discomfort or skin irritation, you should select a different site other than the one most recently used or on the back of the other arm. For more information please refer to the FreeStyle Libre 2 User's Manual.

SENSOR WEAR

Will the user feel the sensor while wearing it?

The portion of the sensor that gets inserted under the skin is less than 0.4 millimeter wide (1mm is about the thickness of a few strands of human hair) and it's inserted only about 5mm under the skin, so most people will not feel the sensor while it is being worn.*¹

Can users bathe, shower, swim, or exercise while wearing a sensor?

Yes. The sensor can be worn while bathing, showering, swimming or exercise. The sensor should not be taken below 3 feet of water (1 meter), and should not be submerged in water for more than 30 minutes. The adhesive is designed to keep the sensor securely and comfortably in place for up to 14 days.

How long can the sensor be worn?

The disposable sensor is designed to adhere to the back of the upper arm and provide accurate glucose readings for up to 14 days after the warm up period. After the 14 days, the user removes the sensor by peeling off the adhesive pad.

How do you remove the sensor?

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

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

What if the user needs to remove the sensor before 14 days (or if it falls off)?

Users should remove the sensor and start a new sensor. The reader will identify that it is a new sensor and ask users if they want to start it. If a sensor falls off before 14 days have completed, then the user should call Customer Service at 1-855-632-8658.

ALARMS

Does the FreeStyle Libre 2 system have alarms?

Yes, the FreeStyle Libre 2 system has optional, real-time glucose alarms.[†]

*Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 2 has the same features as FreeStyle Libre 14 day system with optional real-time glucose alarms. Therefore the study data is applicable to both products. [†]Notifications will only be received when alarms are turned on and the sensor is within 20 feet of the reading device.

Reference: 1. Haak, T. Diabetes Therapy (2017); <https://doi.org/10.1007/s13300-016-0223-6>.

Learn more at **FreeStyleLibre.us**

