

Welcome to Your FreeStyle Libre System

IN-SERVICE GUIDE



FreeStyle
Libre

FLASH GLUCOSE MONITORING SYSTEM

See Indications and Important Safety Information inside.




Abbott

Important Safety Information


Indications For Use

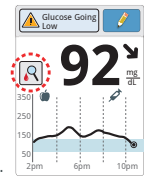
The FreeStyle Libre Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device indicated for the management of diabetes in persons age 18 and older. It is designed to replace blood glucose testing for diabetes treatment decisions. The System detects trends and tracks patterns aiding 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 intended for single patient use and requires a prescription.

Contraindications

 **MRI/CT/Diathermy:** The FreeStyle Libre Flash Glucose Monitoring 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.
- **Checking Sensor glucose readings with a blood glucose meter:** Under the following conditions, Sensor glucose readings may not be accurate and you should conduct a fingerstick test using a blood glucose meter. You should not use Sensor glucose readings to make a diabetes treatment decision:
 - If you suspect that your reading may be inaccurate for any reason
 - When you are experiencing symptoms that may be due to low or high blood glucose
 - When you are experiencing symptoms that do not match FreeStyle Libre System readings
 - During times of rapidly changing glucose (more than 2 mg/dL per minute), when interstitial fluid glucose levels as measured by the Sensor may not accurately reflect blood glucose levels
 - When the Sensor glucose reading does not include a Current Glucose number or Glucose Trend Arrow
 - In order to confirm hypoglycemia or impending hypoglycemia as reported by the Sensor
- When you see the  symbol, you must check your blood glucose with a blood glucose meter before making any treatment decisions. Sensor readings may not accurately reflect blood glucose levels.
- **Hypoglycemic unawareness:** The FreeStyle Libre System has not been evaluated for use in patients with hypoglycemic unawareness and will not automatically alert you of a hypoglycemic event without you scanning your Sensor.
- **No alarms without a Sensor scan:** The FreeStyle Libre System does not have alarms that will automatically notify you when you are having a severe low (hypoglycemic) or high (hyperglycemic) glucose event unless you scan your Sensor. For example, the System does not have an alarm that can alert or wake you when you are sleeping in the case of low or high glucose.
- **Choking hazard:** The FreeStyle Libre 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 Alarms/Alerts:**
 - There are NO alarms or alerts unless you scan the Sensor.
-  **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.

Important Safety Information

Who should not use the Systems:

- **Do not use the System in people less than 18 years of age.** The System is not approved for use in people under 18 years of age and Sensor readings in this population may be inaccurate. In general, continuous glucose monitoring systems are recognized to be less accurate in children than in adults.
- **Do not use the System in critically ill patients.** The System is not approved for use in these patients. It is not known how different conditions or medications common to the critically ill population may affect performance of the System. Sensor glucose readings may be inaccurate in critically ill patients.
- **Do not use the System in pregnant women or persons on dialysis.** The System is not approved for use in pregnant women or persons on dialysis and has not been evaluated in these populations.
- 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:

- After the 12 hour start-up period, the Sensor can be worn for up to 10 days.
- 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 FreeStyle Libre System. Contact your health care professional before continuing to use the FreeStyle Libre System.
- Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. Remove and replace your Sensor if it starts to loosen and follow the instructions to select an appropriate application site.
- 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 inaccurate results.
- If a Sensor breaks inside your body, call your health care professional.

How to Store the Sensor Kit:

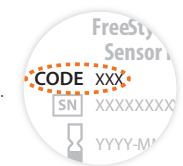
- Store the Sensor Kit between 39°F and 77°F. Storage outside of this range may cause inaccurate Sensor glucose readings. While you don't need to keep your Sensor Kit in a refrigerator, you can as long as the refrigerator is between 39°F and 77°F. Do not freeze.
- Store the Sensor Kit between 10-90% 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.
- Clean the application site and ensure that it is dry prior to Sensor insertion. This helps the Sensor stay attached to your body.
- 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.
- Sensor placement is not approved for sites other than the back of the 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.



Important Safety Information

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 interfering substances such as Vitamin C and Aspirin:

- Taking ascorbic acid (vitamin C) while wearing the Sensor may falsely raise Sensor glucose readings. Taking salicylic acid (used in some pain relievers such as aspirin and some skin care products) may slightly lower Sensor glucose readings. The level of inaccuracy depends on the amount of the interfering substance active in the body.
- Test results did not indicate interference for methyldopa (used in some drugs to treat high blood pressure) or tolbutamide (infrequently used in some drugs to treat diabetes in the US) at maximum circulating levels. However, concentrations of potential interferents in interstitial fluid are unknown compared to circulating blood.

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 and apply a new one.
- 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 and apply a new one.

What to do if you are dehydrated:

- Severe dehydration and excessive water loss may cause inaccurate Sensor glucose readings. If you believe you are suffering from dehydration, consult your health care professional immediately.

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

- The FreeStyle Libre Flash Glucose Monitoring System 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 of the User's Manual 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.

Getting to Know Your System

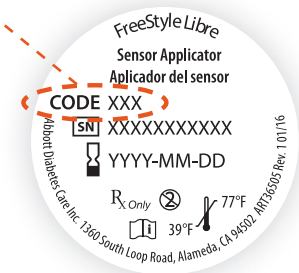
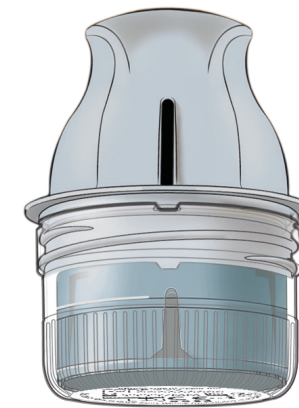
- The reader scans the sensor for glucose readings and stores up to 90 days of glucose history
- The reader activates the sensor and initiates the 12-hour start-up period
- The reader is rechargeable

- The sensor is worn on the back of the upper arm and stores glucose readings every 15 minutes
- Follow the instructions to prepare and apply the sensor
- The sensor may be worn for up to 10 days with no routine fingersticks for calibration or insulin dosing*

Reader



Sensor Applicator



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

*Lancing is not required except when symptoms do not match glucose reading, when reader prompts a blood glucose test, or when glucose readings are not available with system.

Sensor Application

1 Assemble sensor and apply it to your body

Get Ready

STEP 1

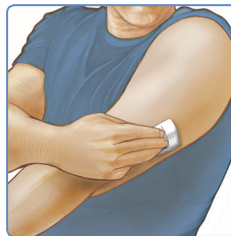


Select site on **back of upper arm**. Do not use other sites as these are not approved and may result in inaccurate glucose readings.

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).

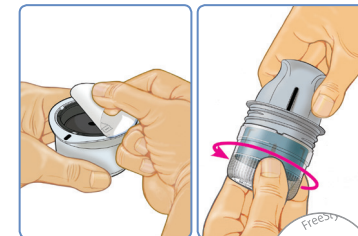
STEP 2



Clean site with alcohol wipe. **Allow site to dry completely before proceeding.**

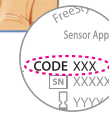
TIP: The area **MUST** be clean and dry or the sensor may not stick to the site.

STEP 3



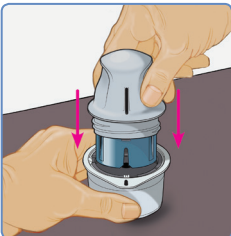
Peel lid completely off sensor pack. Unscrew cap from sensor applicator.

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



Prepare Sensor Applicator

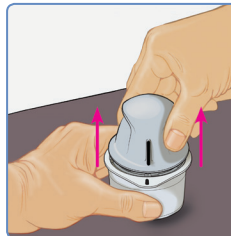
STEP 4



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 and you hear an audible click.

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

STEP 5



Lift sensor applicator straight out of sensor pack.

STEP 6

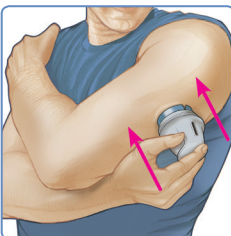


Sensor applicator is ready to apply sensor.

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

Apply Sensor

STEP 7

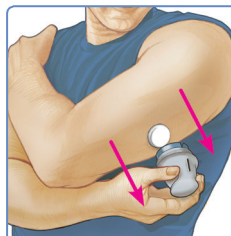


Place sensor applicator over site and push down firmly to apply sensor.

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

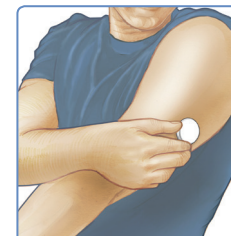
TIP: For video of sensor application, visit <https://www.myfreestyle.com/provider/resources>

STEP 8



Gently pull sensor applicator straight down and away from your body.

STEP 9

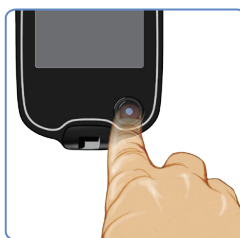


Make sure sensor is secure by gently pressing adhesive to the skin. Discard used sensor applicator and sensor pack according to local regulations.

Start New Sensor

2 Start new sensor with reader

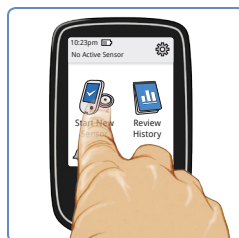
STEP 1



Press Home Button to turn on reader.

NOTE: If using reader for the first time, follow the prompts to set date, time, and target glucose range.

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 12 hours.

STEP 4

During the 12-hour start-up, check your blood glucose as your health care professional recommends.

NOTE: You can use the reader's built-in meter to check your blood glucose with FreeStyle Precision Neo test strips.

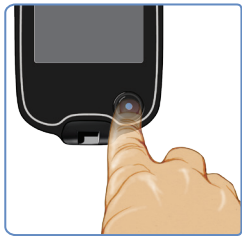
After the 12 hour start-up period, the sensor can be worn for up to 10 days. Your sensor automatically stops working after 10 days of data and must be replaced.

Accessing Your Glucose Data

You can scan to get a real-time glucose reading anytime. The reader stores up to 90 days of data.

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.

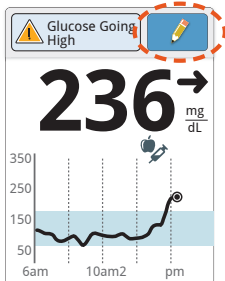
NOTE: If the sensor is not successfully scanned within 15 seconds, the reader displays a prompt to scan the sensor again. Touch OK to return to the Home Screen and touch Check Glucose to scan your sensor.


STEP 3

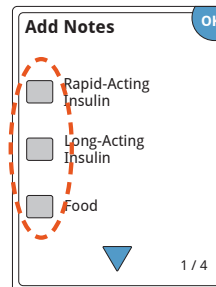


Reader shows your glucose reading along with your glucose graph and an arrow indicating the direction your glucose is going.

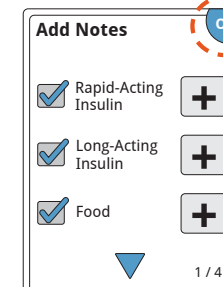
Adding notes



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.

Review Your History

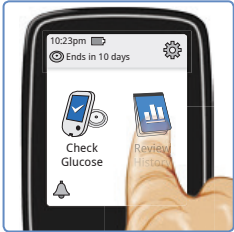
The reader provides insightful information to identify 7-, 14-, 30-, and 90-day trends.

STEP 1



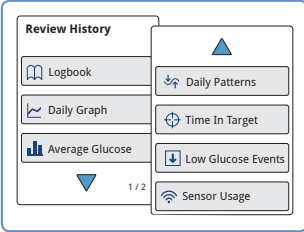
Press Home Button to turn on the reader and go to Home Screen.

STEP 2



Touch Review History.

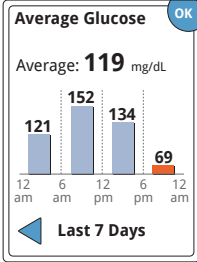
STEP 3



Use the arrows to view the available options.

Average Glucose OK

Information about the average sensor glucose readings¹



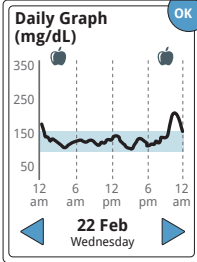
Time	Reading (mg/dL)
12 am	121
6 am	152
12 pm	134
6 pm	69
12 am	-

Average: **119** mg/dL

◀ Last 7 Days

Daily Graph OK

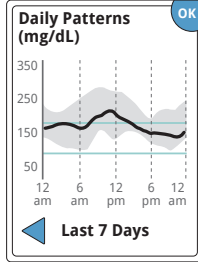
Sensor glucose readings by day²



22 Feb
Wednesday

Daily Patterns OK

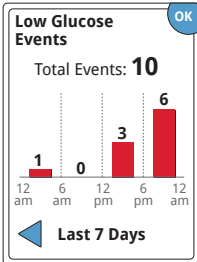
The pattern and variability of your sensor glucose over a typical day^{2,3,4}



◀ Last 7 Days

Low Glucose Events OK

The number of low glucose events measured



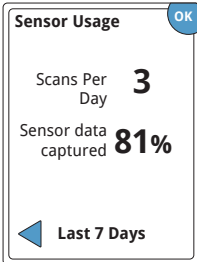
Time	Events
12 am	1
6 am	0
12 pm	3
6 pm	6
12 am	-

Total Events: **10**

◀ Last 7 Days

Sensor Usage OK

Report on how often you scan the sensor



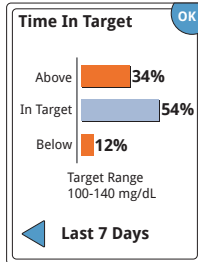
Scans Per Day: **3**

Sensor data captured: **81%**

◀ Last 7 Days

Time in Target Range OK

The percentage of time glucose readings were above, below, or within Target Glucose Range¹



Above: **34%**

In Target: **54%**

Below: **12%**

Target Range: 100-140 mg/dL

◀ Last 7 Days

1. Readings above or below your Target Glucose Range are orange, while readings in range are blue.
2. The thick black line shows the median (midpoint) of your glucose readings.
3. The gray shading represents a range (10-90 percentiles) of your sensor readings. This is not the Ambulatory Glucose Profile.
4. Daily Patterns needs at least 5 days of glucose data.

Maintenance and Disposal

Your sensor automatically stops working after 10 days of data is collected and 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.

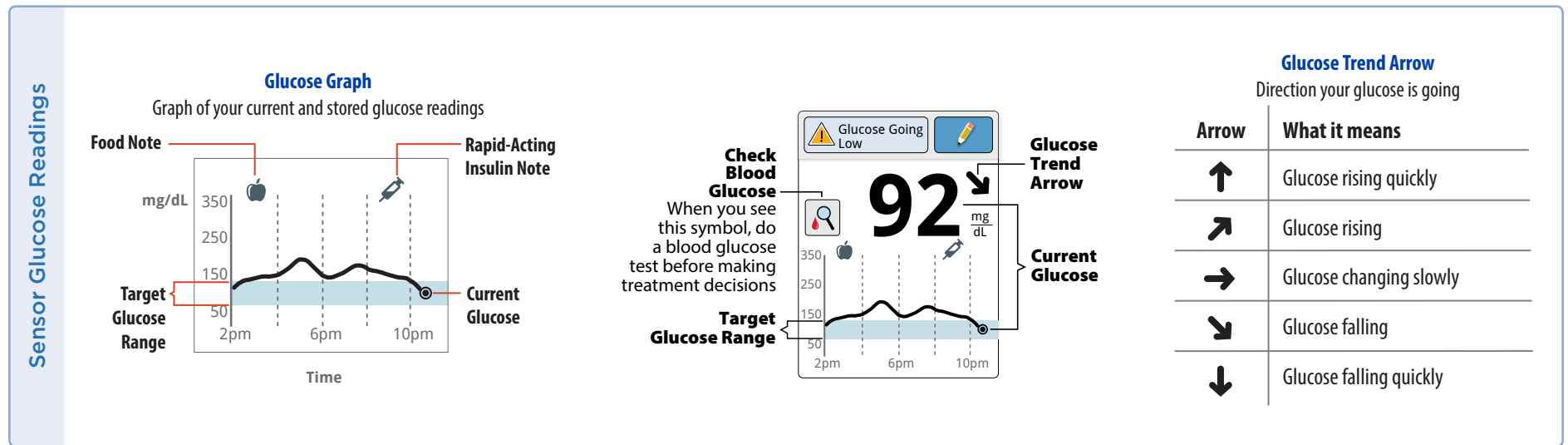
NOTE: Make sure liquid does not get into the test strip and USB ports.

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 using the reader to scan 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.

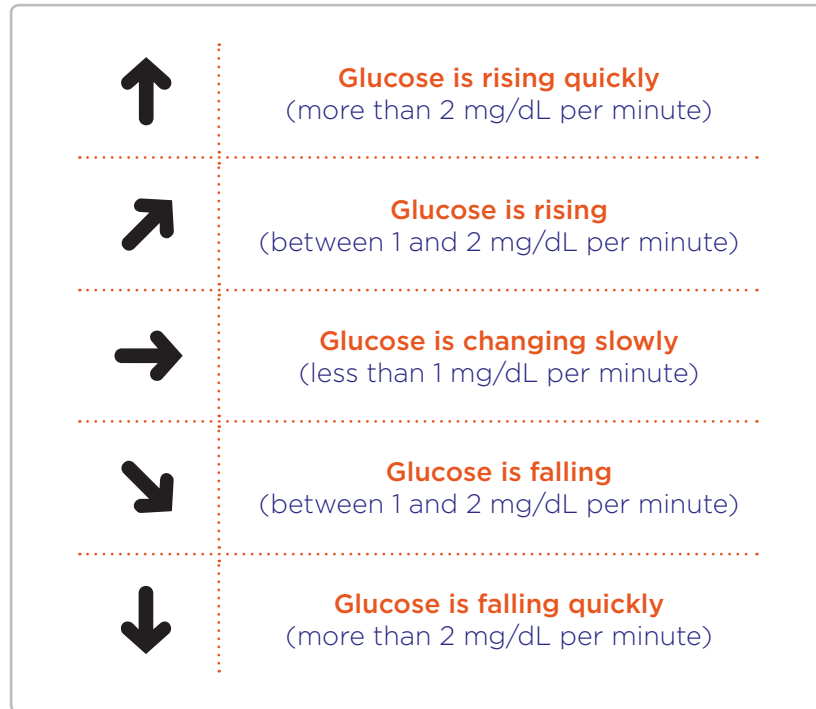



NOTE: While sensor glucose readings are gathered in the system range of 40-500 mg/dL, the graph display range is 0-350 mg/dL for ease of review on screen. Glucose readings above 350 mg/dL are displayed at 350 mg/dL.

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

Trend Arrows

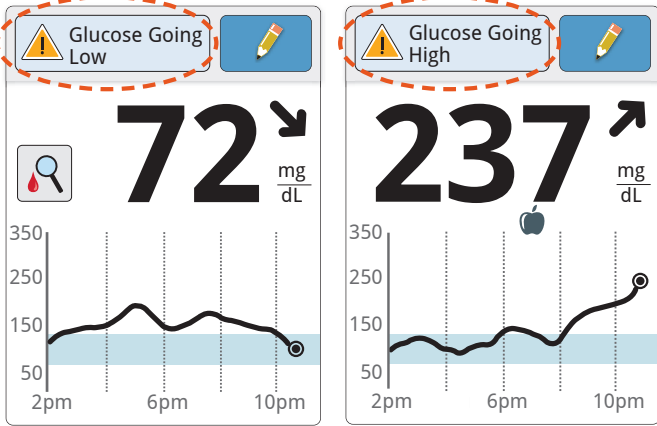

The Glucose Trend Arrow indicates which direction your glucose is going.



NOTE: The Glucose Trend Arrow may not always appear with your reading. When there is no Glucose Trend Arrow, the system can't tell if your glucose is rising quickly or falling quickly and will display the  symbol. Whenever you see this symbol, you should do a blood glucose test and treat based on that result.

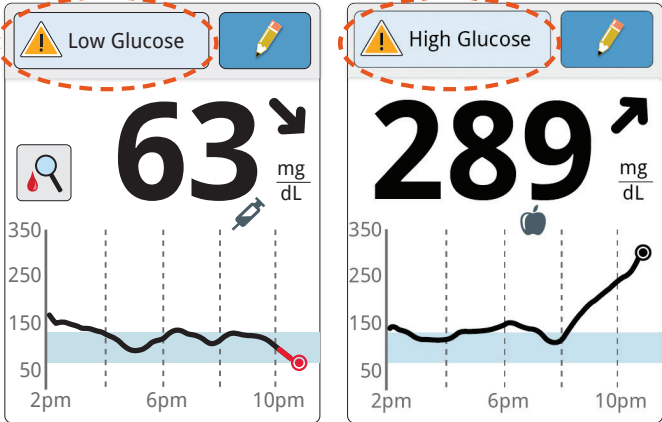

Going High/Low Reading

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

DISPLAY	WHAT TO DO
 <p>The left screenshot displays a glucose reading of 72 mg/dL with a downward trend arrow. A warning message 'Glucose Going Low' is shown at the top, circled in red. The right screenshot displays a glucose reading of 237 mg/dL with an upward trend arrow. A warning message 'Glucose Going High' is shown at the top, also circled in red. Both screenshots include a graph showing glucose levels over time from 2pm to 10pm.</p>	<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. Touch the message button for more information and set a reminder to check your glucose again.</p> <p>If your glucose reading is less than 70 mg/dL, projected to be less than 70 mg/dL, rapidly changing, or there is no number or trend arrow, you will see this symbol . You can touch the symbol for more information. Check your blood glucose on your finger with a test strip before making treatment decisions.</p>

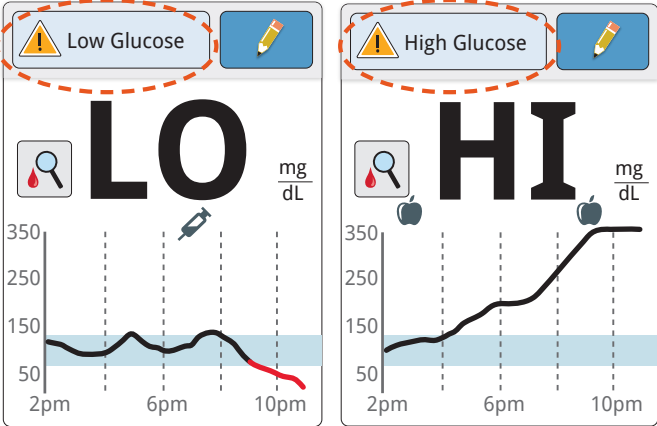

High/Low Reading

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

DISPLAY	WHAT TO DO
 <p>The 'DISPLAY' section shows two screenshots of the FreeStyle Libre Reader interface. The left screenshot displays a 'Low Glucose' warning with a reading of 63 mg/dL and a downward trend arrow. The right screenshot displays a 'High Glucose' warning with a reading of 289 mg/dL and an upward trend arrow. Both screens include a graph of glucose levels over time (2pm, 6pm, 10pm) and a message button with a pencil icon.</p>	<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> <p>If your glucose reading is less than 70 mg/dL, projected to be less than 70 mg/dL, rapidly changing, or there is no number or trend arrow, you will see this symbol . You can touch the symbol for more information. Check your blood glucose on your finger with a test strip before making treatment decisions.</p>

HI/LO Reading

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

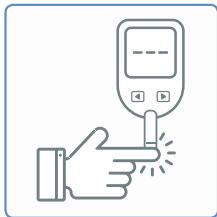
DISPLAY	WHAT TO DO
 <p>The image shows two side-by-side glucose monitor displays. The left display is labeled 'Low Glucose' and shows 'LO' in large letters. The right display is labeled 'High Glucose' and shows 'HI' in large letters. Both displays have a graph showing glucose levels over time from 2pm to 10pm. The left graph shows a low reading at 10pm, and the right graph shows a high reading at 10pm.</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 500 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 health care professional immediately.</p> <p>If your glucose reading is less than 70 mg/dL, projected to be less than 70 mg/dL, rapidly changing, or there is no number or trend arrow, you will see this symbol . You can touch the symbol for more information. Check your blood glucose on your finger with a test strip before making treatment decisions.</p>

Treatment Decisions–Getting Started

Before you start using the FreeStyle Libre 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 health care 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

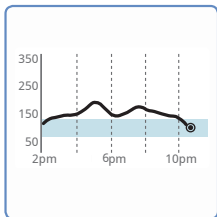
HELPFUL TIPS



CONFIRM SENSOR GLUCOSE READINGS

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

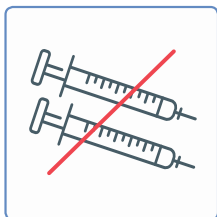
- Sensor accuracy may vary between sensors
- Sensor accuracy may vary during a sensor wear session
- Sensor accuracy may vary in different situations (meals, exercise, first day of use, etc.)



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"

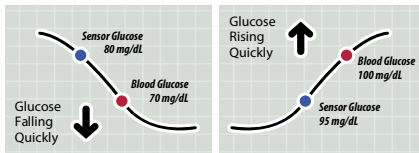
If your glucose is high and going up, your first instinct may be to take more insulin to lower your glucose. However, depending on when you last took insulin or your recent activity, the right treatment decision may be to do nothing and scan again later.

Treatment Decisions—When Not to Use Sensor Readings

Whenever you see this symbol,



do a blood glucose test and treat based on that result!



Glucose is Falling Quickly or Rising Quickly

Interstitial fluid can be different from blood glucose levels, particularly during times when your blood glucose is changing quickly, for example, after eating, taking insulin, or exercising.



Low Glucose or Glucose Going Low Message

Low sensor glucose readings may not accurately reflect blood glucose.



No Glucose Trend Arrow

When there is no Glucose Trend Arrow, the system can't tell if your glucose is rising quickly or falling quickly.



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.



You 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. Don't make treatment decisions if you think your sensor glucose readings are incorrect.

NOTE: The  symbol will NOT display in these situations.



You Have Low or High Blood Glucose Symptoms

Don't ignore symptoms that may be due to low or high blood glucose. 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. You may feel shaky, sweaty, and dizzy—symptoms you generally get when you have low glucose—but your glucose is within your target range. Don't ignore symptoms that may be due to low or high blood glucose.

NOTE: The  symbol will NOT display in these situations.

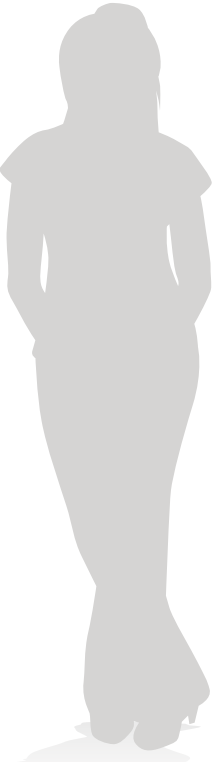

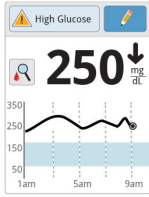




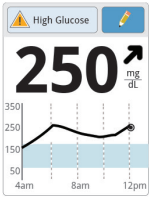


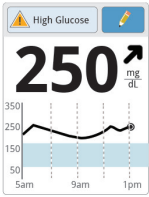


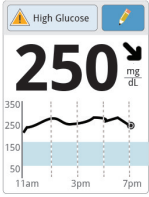

Treatment Decisions–Glucose Trend Arrows

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

Glucose Trend Arrow	TREATMENT DECISION CONSIDERATIONS		
	Low Glucose (< 70 mg/dL)	Glucose in Target Range	High Glucose (> 240 mg/dL)
No Arrow or No Number	You will see the  symbol. Do not treat based on sensor glucose reading. Do a blood glucose test.		
	You will see the  symbol. Do not treat based on sensor glucose reading. Do a blood glucose test.		
	You will see the  symbol. Do not treat based on sensor glucose reading. Do a blood glucose test.	<p>If you are about to eat, take insulin to cover your meal. Consider taking a little more since glucose is rising.</p> <p>If you have taken insulin recently, do nothing and scan again later.</p> <p>Avoid “insulin stacking.”</p>	<p>If you are about to eat, take insulin to cover your meal. Consider taking a little more since glucose is high and rising.</p> <p>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 scan again later.</p> <p>Avoid “insulin stacking.”</p>
	You will see the  symbol. Do not treat based on sensor glucose reading. Do a blood glucose test.	<p>If you are about to eat, take insulin to cover your meal.</p> <p>If this is between meals, do nothing and scan again later.</p>	<p>If you are about to eat, take insulin to cover your meal. Consider taking a little more since glucose is high.</p> <p>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 scan again later.</p> <p>Avoid “insulin stacking.”</p>
	You will see the  symbol. Do not treat based on sensor glucose reading. Do a blood glucose test.	<p>If you are about to eat, take insulin to cover your meal. Consider taking a little less since glucose is falling.</p> <p>If this is between meals, consider eating a snack or fast-acting carbohydrates to stay within target and scan again later.</p>	<p>If you are about to eat, take insulin to cover your meal. Consider taking a little less since glucose is falling.</p> <p>If this is between meals, consider doing nothing and scan again later.</p> <p>Avoid “insulin stacking.”</p>
	You will see the  symbol. Do not treat based on sensor glucose reading. Do a blood glucose test.		

Treatment Decisions-Example Scenarios

Example scenarios to help you understand how to use all of the information on the screen. The recommendations below are based on a clinical article published in a peer reviewed journal.

CLAIRE		WHAT CLAIRE SEES	WHAT CLAIRE DOES									
<p>Claire has a target of 100 mg/dL and a correction factor of 1:50. This means she would take 1 unit of rapid-acting insulin to lower her glucose about 50 mg/dL.</p>  <p>For more scenarios, consult your FreeStyle Libre System User Guide.</p>	<p>After breakfast</p> 	 <p>After breakfast, Claire sees her glucose is 250 mg/dL. The trend arrow shows it is going down quickly. There is also a  message at the top of the screen and the  symbol.</p>	<p>Anytime Claire sees the  symbol, she does a blood glucose test before deciding what to do.</p>									
	<p>Before lunch</p> 	 <p>Claire sees her glucose is 250 mg/dL and rising.</p>	<p>Before eating lunch, Claire takes enough insulin to cover the meal and a little more since her trend arrow was rising .</p>	<table border="1"> <tr> <td>Claire adds 50 mg/dL because of the rising trend arrow*</td> <td>250 +50</td> </tr> <tr> <td>Claire subtracts her target number</td> <td>300 -100</td> </tr> <tr> <td>Claire divides by her correction factor</td> <td>200 ÷ 50</td> </tr> <tr> <td>Claire takes 4 units of insulin</td> <td>= 4</td> </tr> </table>	Claire adds 50 mg/dL because of the rising trend arrow*	250 +50	Claire subtracts her target number	300 -100	Claire divides by her correction factor	200 ÷ 50	Claire takes 4 units of insulin	= 4
	Claire adds 50 mg/dL because of the rising trend arrow*	250 +50										
	Claire subtracts her target number	300 -100										
Claire divides by her correction factor	200 ÷ 50											
Claire takes 4 units of insulin	= 4											
<p>After lunch</p> 	 <p>Ninety minutes later, Claire's glucose is still 250 mg/dL. The graph shows her glucose is still rising and so does the trend arrow .</p>	<p>Claire does not take a correction dose as it is within 2 hours of her meal dose. This could result in "insulin stacking" and low glucose. The insulin she took for her meal may not have reached its full effect. Claire decides to wait and scan again later.</p>										
<p>Before dinner</p> 	 <p>Claire sees her current glucose is 250 mg/dL. The graph shows that her glucose is going down and so does the trend arrow .</p>	<p>Claire considers what might be causing her glucose to go down and what she might do to prevent a low glucose. She considers how much insulin she should take before her meal. Because she sees  she considers taking a little less insulin.</p>	<table border="1"> <tr> <td>Claire subtracts 50 mg/dL because of the falling trend arrow*</td> <td>250 -50</td> </tr> <tr> <td>Claire subtracts her target number</td> <td>200 -100</td> </tr> <tr> <td>Claire divides by her correction factor</td> <td>100 ÷ 50</td> </tr> <tr> <td>Claire takes 2 units of insulin</td> <td>= 2</td> </tr> </table>	Claire subtracts 50 mg/dL because of the falling trend arrow*	250 -50	Claire subtracts her target number	200 -100	Claire divides by her correction factor	100 ÷ 50	Claire takes 2 units of insulin	= 2	
Claire subtracts 50 mg/dL because of the falling trend arrow*	250 -50											
Claire subtracts her target number	200 -100											
Claire divides by her correction factor	100 ÷ 50											
Claire takes 2 units of insulin	= 2											

*This method was based on: Pettus J., Edelman S.V. Recommendations for using Real-Time Continuous Glucose Monitoring (rtCGM) Data for Insulin Adjustments in Type 1 Diabetes. Journal of Diabetes Science and Technology. 2017;11:138-147.

When to Contact your Health Care Professional

As instructed by the FreeStyle Libre labeling



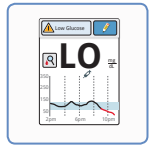
Symptoms

- 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 blood 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 Disposal

- How to discard a used sensor

Contact HCP

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 patients don't feel pain when applying the FreeStyle Libre sensor.*

Is it necessary to apply a sensor in a different location if I feel discomfort or in case of a mis-application?

To prevent discomfort or skin irritation, you should select a different site other than the one most recently used.

When applying the sensor to my arm, do I need to stretch or pinch the skin?

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. For more information please refer to the FreeStyle Libre User's Manual.

Patient 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.*

Were there any skin reactions reported by patients wearing FreeStyle Libre sensors?

Mild skin irritations, such as erythema, edema, rash, bleeding, itching, induration, and infection were reported around the insertion site and adhesive area by a moderate frequency of subjects (5 out of 48 or 10.4%).*

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 1 meter of water (3 feet), 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 10 days after the start-up period.

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 10 days after the start-up period. After the 10 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 10 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 10 days have completed, then the user should call Customer Service at 1-855-632-8658.

*Data on file. Abbott Diabetes Care.



FreeStyle
Libre

FLASH GLUCOSE MONITORING SYSTEM

FreeStyle, Libre and related brand marks are trademarks of Abbott Diabetes Care Inc. in various jurisdictions.
©2017 Abbott. ADC-05821 v2.0 10/17



Abbott