

FreeStyle Libre 2 Flash Glucose Monitoring System



FreeStyle Libre 2 Flash Glucose Monitoring System User Guide

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FreeStyle Libre 2 Flash Glucose Monitoring System



IMPORTANT USER INFORMATION

- Before you use your System, review all the product instructions and the Interactive Tutorial.
- The Quick Reference Guide and Interactive Tutorials give you quick access to important aspects and limitations of the System. The User's Manual includes all safety information and instructions for use.
- The latest version of the User's Manual, including performance data, can always be accessed at www.FreeStyleLibre.us/support/overview.html.
- You can also order a free printed copy from Customer Service: 1-855-632-8658, 7 Days a Week from 8 AM to 8 PM Eastern Time; excluding holidays.
- Go to www.FreeStyleLibre.com to view the "Tips for Kids".
- Talk to your healthcare professional about how you should use your Sensor glucose information to help manage your diabetes.
- During the first 12 hours of Sensor wear the  symbol will display, and you cannot use Sensor values to make treatment decisions during this time.
- Confirm Sensor glucose readings with a blood glucose test before making treatment decisions during the first 12 hours of Sensor wear when you see the  symbol.

You can use the FreeStyle Libre 2 System with either the FreeStyle Libre 2 Sensor or the FreeStyle Libre 2 Plus Sensor. Make sure you have a FreeStyle Libre 2 Plus Sensor if you plan to connect with a compatible automated insulin dosing (AID) system.

FreeStyle Libre 2 Sensor

- 14-day wear duration
- Can be used by children aged 4 and older
- Cannot be used with automated insulin dosing (AID) systems

- Taking more than 500 mg of Vitamin C per day may affect Sensor readings, which could cause you to miss a severe low glucose event.

FreeStyle Libre 2 Plus Sensor

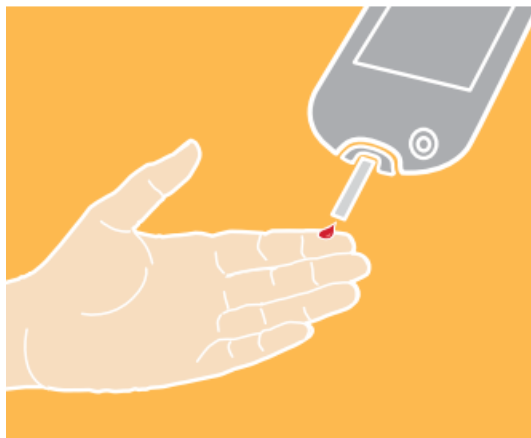
- 15-day wear duration
- Can be used by children aged 2 and older
- Can be used with compatible automated insulin dosing (AID) systems
- Taking more than 1000 mg of Vitamin C per day may falsely raise
- Sensor readings, which could cause you to miss a severe low glucose event.
- You can take up to 1000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

IMPORTANT

- After you scan the Sensor, consider all the information on your screen before deciding what to do or what treatment decision to make.
- Don't take a correction dose within 2 hours of your meal dose. This may result in "insulin stacking" and low glucose.

WARNING

The System can replace blood glucose testing except in the below situations. These are the times when you need to do a blood glucose test before deciding what to do or what treatment decision to make as Sensor readings may not accurately reflect blood glucose levels: Do a blood glucose test if you think your glucose readings are not correct or do not match how you feel. Do not ignore symptoms that may be due to low or high glucose. Do a blood glucose test when you see the symbol during the first 12 hours of wearing a Sensor or the Sensor glucose reading does not include a Current Glucose number.



INDICATIONS FOR USE

FreeStyle Libre 2 Sensor users:

The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real-time alarm capability indicated for the management of diabetes in persons aged 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions unless otherwise indicated. The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time.

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


FreeStyle Libre 2 Plus Sensor users

The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real-time alarm capability indicated for the management of diabetes in persons aged 2 and older. It is intended to replace blood glucose testing for diabetes treatment decisions unless otherwise indicated. The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time. The System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The System can be used alone or in conjunction with these digitally connected devices to manage diabetes.

CONTRAINDICATIONS

MRI/CT/Diathermy: The System must be removed before 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 the proper function of the device which could cause incorrect readings. **Automated Insulin Dosing:** FreeStyle Libre 2 Sensors must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems.

WARNINGS

- Do not ignore symptoms that may be due to low or high blood glucose: If you are experiencing symptoms that are not consistent with your glucose readings, consult your health care professional.
- Use your blood glucose meter to make diabetes treatment decisions when you see the symbol  during the first 12 hours of wearing a Sensor .
- if your Sensor glucose reading does not match how you feel, or if the reading does not include a number.
- If you are using the FreeStyle Libre 2 app, you must have access to a blood glucose monitoring system as the App does not provide one.
- Choking hazard: The System contains small parts that may be dangerous if swallowed.

Cautions and Limitations

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

- For you to receive alarms, they must be on and your device 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 alarms.
- To prevent missed alarms, make sure your device has sufficient charge. If using the Reader, make sure that sounds and/or vibrations are turned on.
- Alarms you receive do not include your glucose reading so you must scan your Sensor to check your glucose.
- If your phone is not configured properly, you will not be able to use the App, so you will not receive alarms or be able to check your glucose.
- Refer to the User Manual to make sure you have the correct settings and permissions enabled on your phone.
- Disable your phone's automatic operating system (OS) updates.

- Before updating your phone's OS or updating the App, you should check the Mobile Device and OS Compatibility Guide to determine if the
- FreeStyle Libre 2 app is compatible with your OS and your phone. The OS Compatibility Guide is available in the Help Section of the App or on www.FreeStyleLibre.com.
- You should check the OS Compatibility Guide periodically to make sure that your OS and your phone continue to be compatible with the App.
- If an App or OS update causes your previously compatible phone to become incompatible, you may be notified ahead of time via e-mail or through the App. Make sure that your LibreView account has your current email address to receive important information.
- After an OS update, open your App and check your device settings to make sure it's working properly. Some OS features may impact your ability to receive alarms. For example, if you use an iPhone and the iOS Screen Time feature, add the FreeStyle Libre 2 app to the list of Always Allow apps to ensure that you receive alarms or if you use an Android Phone do not use the Android Digital Wellbeing app.

What to know before using the System

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

Who should not use the System?

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

What should you know about wearing a Sensor?

- Wash the application site on the back of your upper arm using plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the Sensor from sticking properly. Allow the site to air dry before proceeding. Carefully preparing the site according to these instructions will help the Sensor stay on your body for the full wear duration specified by your Sensor insert and help prevent it from falling off early.
- The Sensor can be worn for up to the wear duration specified by your Sensor insert. Remember to always have your next Sensor available before your current one ends so you can keep getting your glucose readings.
- You must scan the Sensor to get your real-time current glucose level as both the Reader and App will not provide this information without a scan.
- If 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 that may occur where the Sensor is not working as

intended and shut it off, telling you to replace your Sensor. This may occur if the Sensor gets knocked off from the skin or if the System detects that the Sensor may not be performing as intended. Contact Customer Service if you receive a Replace Sensor message before the end of the wear duration specified by your Sensor insert. Customer Service is available at 1-855- 632-8658 7 Days a Week from 8 AM to 8 PM Eastern Time; excluding holidays.

- Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If you notice significant skin irritation around or under your Sensor, remove the Sensor and stop using the System. Contact your healthcare 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 8 AM to 8 PM Eastern Time; excluding holidays.
- Do not reuse Sensors. The Sensor and Sensor Applicator are designed for single use. Reuse may result in no glucose readings and infection. Not suitable for re-sterilization. Further exposure to irradiation may cause unreliable low results.
- If a Sensor breaks inside your body, call your health care professional.

How to store the Sensor Kit

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

How to store the Reader

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

When not to use the System

- Do NOT use if the Sensor Kit package, Sensor Pack, or SensorApplicator appear to be damaged or already opened due to the risk of no results and/or infection.
- Do NOT use if Sensor Kit contents are past the expiration date.
- Do NOT use if the Reader appears to be damaged due to the risk of electric shock and/or no results.

What to know about the System

- The FreeStyle Libre 2 System is intended for use by a single person.
- It must not be used by more than one person due to the risk of misinterpreting glucose information.

- FreeStyle Libre 2 app and FreeStyle Libre 2 Readers do not share data. Before you start a Sensor, you must choose whether to use the Reader or the App with the Sensor. Once you start a Sensor, you cannot switch your device.

What to know before you apply the Sensor

- 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 the application site on the back of your upper arm using plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the Sensor from sticking properly.
- Allow the site to air dry before proceeding. Carefully preparing the site according to these instructions will help the Sensor stay on your body for the full wear duration specified by your Sensor insert and help prevent it from falling off early.
- Clean hands before Sensor handling/insertion to help prevent infection.
- Change the application site for the next Sensor application to prevent discomfort or skin irritation.
- Only apply the Sensor to the back of the upper arm. If placed in other areas, the Sensor may not function properly.
- Select an appropriate Sensor site to help the Sensor stay attached to the body and prevent discomfort or skin irritation.
- Avoid areas with scars, moles, stretch marks, or lumps. Select an area of skin that generally stays flat during normal daily activities (no bending or folding). Choose a site that is at least 1 inch away from an insulin injection site.
- When is Sensor Glucose different from Blood Glucose:
- Physiological differences between the interstitial fluid and capillary blood may result in differences in glucose readings between the System and results from a fingerstick test using a blood glucose meter.
- Differences in glucose readings between interstitial fluid and capillary blood may be observed during times of rapid change in blood glucose, such as after eating, dosing insulin, or exercising. What to know about X-rays:
- The Sensor should be removed before 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 the 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 8 PM Eastern Time; excluding holidays.

What to know about the Reader

- Do NOT place the Reader in water or other liquids as this may cause it to not function properly and may lead to risk of fire or burns.
- The FreeStyle Libre 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 the 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.

What to know about charging your Reader

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

Interfering Substances

FreeStyle Libre 2 Sensor users:

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

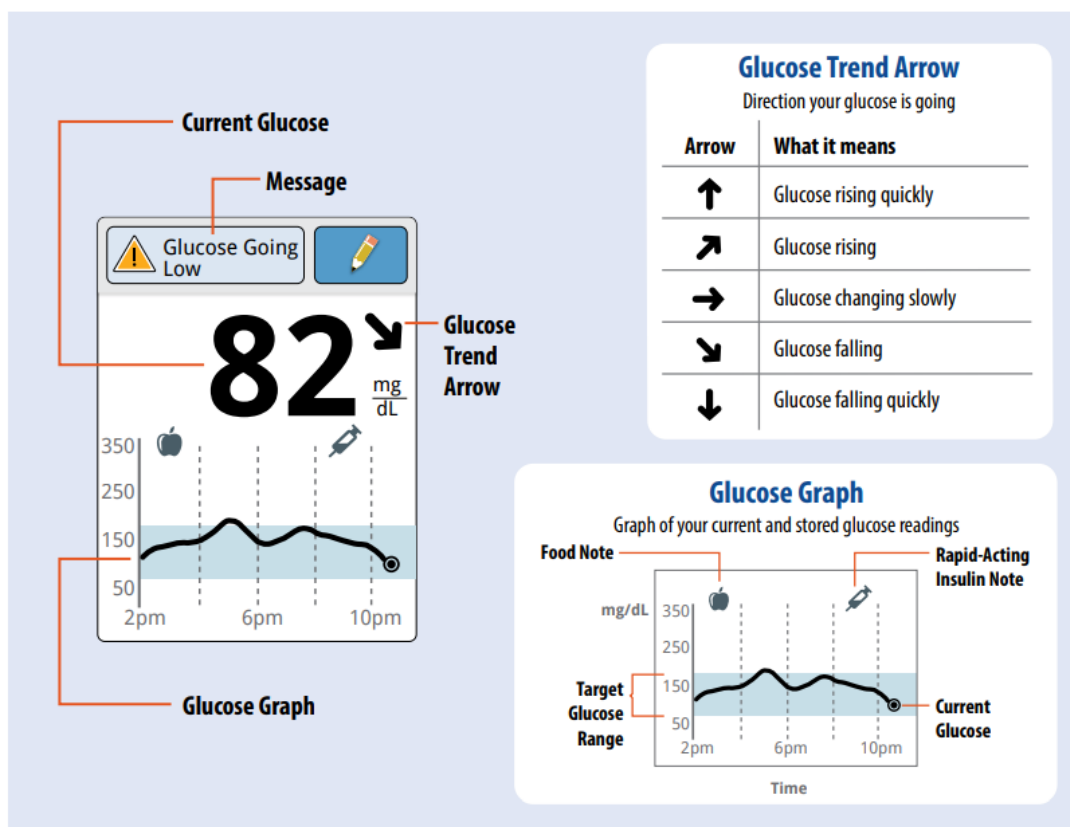
FreeStyle Libre 2 Plus Sensor users

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

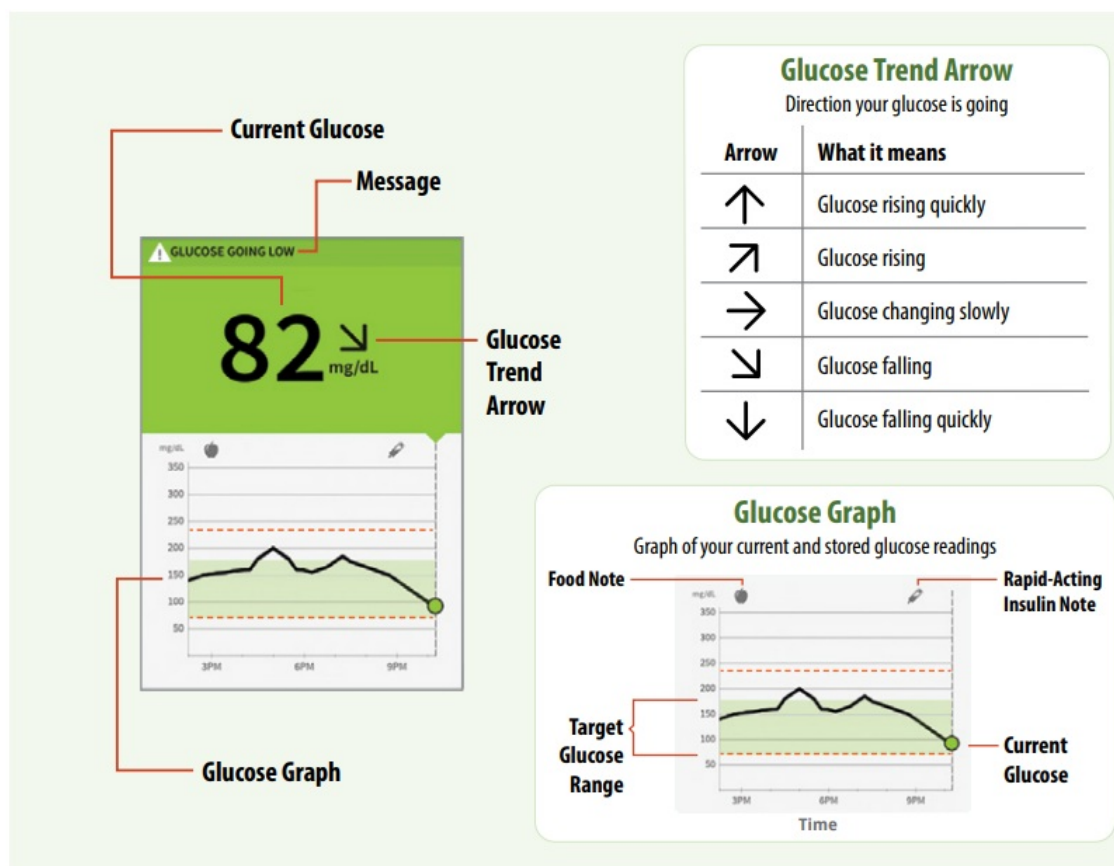
Using Sensor Glucose Readings for Treatment Decisions

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

Reader

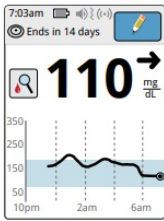




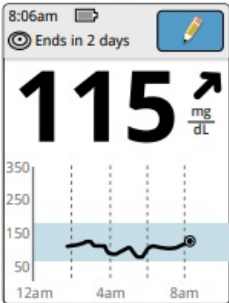





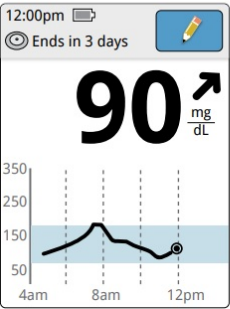


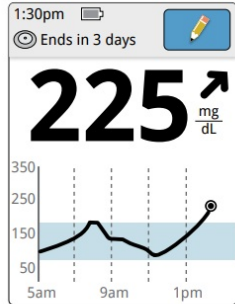


App



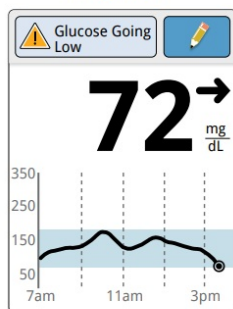
Example Scenarios

Here are some example scenarios to help you understand how to use the information on your screen. If you are not sure about what to do, consult your healthcare professional.

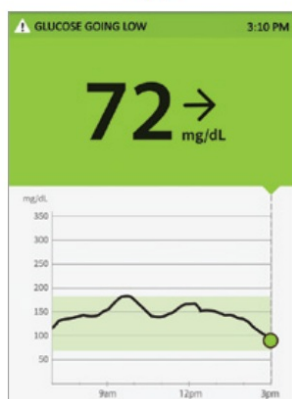
What you see	What it means
<p>When you wake up:</p> <p>Reader</p>  <p>App</p> 	<p>When you wake-up on your first day of wearing a Sensor, your current glucose is 110 mg/dL. There is also the symbol  on the screen.</p> <p>During the first 12 hours of Sensor wear the  symbol will display, and you cannot 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 .</p>
<p>Before breakfast:</p> <p>Reader</p>  <p>App</p> 	<p>Before breakfast, your current glucose is 115 mg/dL. The graph shows that your glucose is going up and so does the trend arrow .</p> <p>Consider what might be causing your glucose to go up and what you might do to prevent a high glucose. For example:</p> <ul style="list-style-type: none"> • How much insulin should you take before your meal? • Since you see , should you consider taking a little more insulin?

What you see	What it means
<p>Before lunch:</p> <p>Reader</p>  <p>App</p> 	<p>When you checked your glucose before lunch, it was 90 mg/dL and rising. Before eating lunch, you took enough insulin to cover the meal and a little more since your trend arrow was .</p>
<p>After lunch:</p> <p>Reader</p>  <p>App</p> 	<p>90 minutes later, your current glucose is 225 mg/dL. The graph shows that your glucose is still going up, and so does the trend arrow .</p> <p>Don't take a correction dose within 2 hours of your meal dose. This may result in "insulin stacking" and low glucose.</p> <p>Consider what might be causing your glucose to go up and what you might do to prevent a high glucose. For example:</p> <ul style="list-style-type: none"> • Has the insulin you took for your meal reached its full effect? • Scan your Sensor again later.

Reader



App

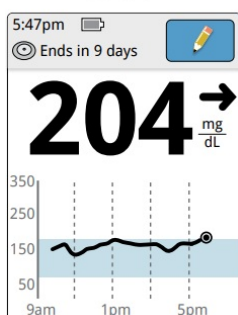


Between meals, your current glucose is 72 mg/dL. The Glucose Going Low message tells you that your glucose is projected to be low within 15 minutes.

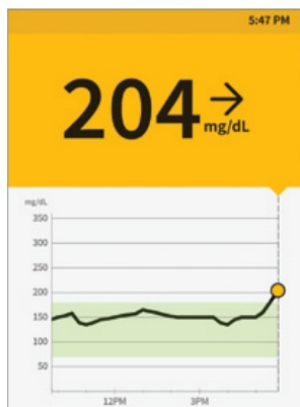
Think about what might be causing your glucose to go low. Consider eating a snack to stay within target. **Avoid taking insulin as this can cause low glucose.**

After exercising:

Reader



App

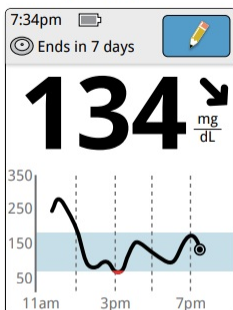


After exercising, you are feeling shaky, sweaty, and dizzy – symptoms you generally get when you have low glucose. But, your current glucose is 204 mg/dL.

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


Before dinner:

Reader




App




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

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


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

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Documents / Resources

	<p>FreeStyle Libre 2 Flash Glucose Monitoring System [pdf] User Guide</p> <p>Libre 2 Flash Glucose Monitoring System, Libre 2, Flash Glucose Monitoring System, Glucose Monitoring System, Monitoring System</p>
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References

-  [FreeStyle Libre Continuous Glucose Monitoring | FreeStyle Libre US](#)
-  [FreeStyle Libre Continuous Glucose Monitoring | FreeStyle Libre US](#)
- [User Manual](#)

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