



FreeStyle Libre 3 Continuous Glucose Monitoring System User Guide

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FreeStyle
Libre 3


Abbott
CONTINUOUS GLUCOSE MONITORING SYSTEM
Quick Reference Guide

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Libre 3 Continuous Glucose Monitoring System



For use with
FreeStyle Libre 3 Sensors



FreeStyle Libre 3 app
A FreeStyle Libre product



IMPORTANT USER INFORMATION

- Before you use your System, review all the product instructions and the Interactive Tutorial. You can access the Interactive Tutorial at www.FreeStyleLibre.com. The Quick Reference Guide and Interactive Tutorial give you quick access to important aspects and limitations of the System. The User's Manual includes all safety information and instructions for use. A printed copy of the User's Manual is available upon request. The latest version of the User's Manual is available at www.FreeStyleLibre.us/support/overview.html



- Go to www.FreeStyleLibre.com to view the "Tips for Kids".
- Talk to your health care professional about how you should use your Sensor glucose information to help

manage your diabetes.

- During the first 12 hours of Sensor wear the  symbol will display, and you cannot use Sensor values to make treatment decisions during this time. Confirm Sensor glucose readings with a blood glucose test before making treatment decisions during the first 12 hours of Sensor wear when you see the  symbol.

INDICATIONS FOR USE

The FreeStyle Libre 3 Continuous Glucose Monitoring System is a real time continuous glucose monitoring (CGM) device with alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.

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

The System is also intended to autonomously communicate with digitally connected devices. The System can be used alone or in conjunction

with these digitally connected devices where the user manually controls actions for therapy decisions.

What you need to understand in the

Indications For Use:

You can use the FreeStyle Libre 3 System if you're 4 or older.

IMPORTANT:


- When you check your glucose, 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.

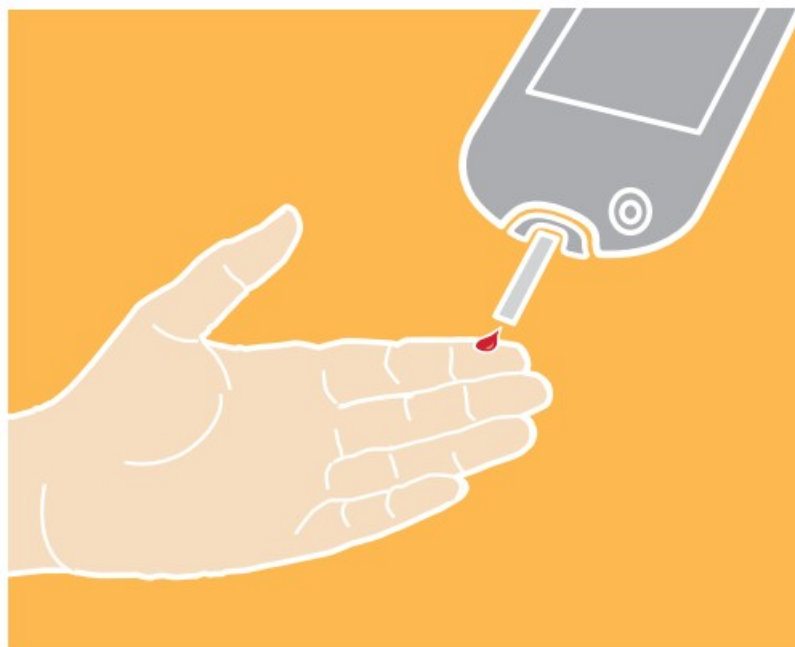
This may result in "insulin stacking" and low glucose.

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.




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.
- If you are using the FreeStyle Libre 3 app, you must have access to a blood glucose monitoring system as the App does not provide one.
- Choking hazard: The System contains small parts that may be dangerous if swallowed.

Cautions and Limitations:

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 33 feet of you at all times. The transmission range is 33 feet unobstructed. If you are out of range, you may not receive alarms.
- To prevent missed alarms, make sure your device has sufficient charge. If using the Reader, make sure that sounds and/or vibration are turned on.
- 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's Manual to make sure you have the correct settings and permissions enabled on your phone.

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



What to know before using the System:

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



Who should not use the System:

- Do not use the System in people less than 4 years of age. The System is not cleared for use in people under 4 years of age.
- Do not use the System if you are on dialysis or critically ill. The System is not cleared for use in these groups and it is not known how different conditions or medications common to these populations may affect performance of the System.
- Performance of the System when used with other implanted medical devices, such as pacemakers, has not been evaluated.



What should you know about wearing a Sensor:

- Wash application site on the back of your upper arm using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the Sensor from sticking properly. Allow site to air dry before proceeding. Carefully preparing the site according to these instructions will help the Sensor stay on your body for the full wear duration specified by your Sensor insert and help prevent it from falling off early.
- The Sensor can be worn for up to the wear duration specified by your Sensor insert. Remember to always have your next Sensor available before your current one ends so you can keep getting your glucose readings.
- In the event that your Sensor stops working and you do not have another Sensor readily available, you must

use an alternate method to measure your glucose levels and inform your treatment decisions.

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



How to Store the Sensor Kit:

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



How to Store the Reader:

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



When not to use the System:

- Do NOT use if the Sensor Kit package or Sensor Applicator appear to be damaged or if tamper label indicates Sensor Applicator has already been opened.
- Do NOT use if Sensor Kit contents are past expiration date.

- Do NOT use if the Reader appears to be damaged due to risk of electric shock and/or no results.



What to know about the System:

- The FreeStyle Libre 3 System is intended for use by a single person. It must not be used by more than one person due to the risk of misinterpreting glucose information.
- FreeStyle Libre 3 app and FreeStyle Libre 3 Readers do not share data. Before you start a Sensor, you must choose whether to use the Reader or the App with the Sensor. Once you start a Sensor, you cannot switch your device.

What to know before you Apply the Sensor:

- Wash application site on the back of your upper arm using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the Sensor from sticking properly. Allow site to air dry before proceeding. Carefully preparing the site according to these instructions will help the Sensor stay on your body for the full wear duration specified by your Sensor insert and help prevent it from falling off early.
- Clean hands prior to Sensor handling/insertion to help prevent infection.
- Change the application site for the next Sensor application to prevent discomfort or skin irritation.
- Only apply the Sensor to the back of the upper arm. If placed in other areas, the Sensor may not function properly.
- Select an appropriate Sensor site to help the Sensor stay attached to the body and prevent discomfort or skin irritation. Avoid areas with scars, moles, stretch marks, or lumps. Select an area of skin that generally stays flat during normal daily activities (no bending or folding). Choose a site that is at least 1 inch away from an insulin injection site.



When is Sensor Glucose different from Blood Glucose:

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



What to know about X-Rays:

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



When to remove the Sensor:

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



What to know about the Reader:

- Do NOT place the Reader in water or other liquids as this may cause it to not function properly and may lead to risk of fire or burns.
- The FreeStyle Libre 3 Reader has a built-in blood glucose meter that is designed to be used only with FreeStyle Precision Neo blood glucose test strips and MediSense Glucose and Ketone Control Solution. Using other test strips with the Reader's built-in meter will produce an error or cause the Reader's built-in meter to not turn on or start a test. The Reader's built-in meter does not have ketone testing functionality.
- The Reader's built-in meter is not for use on people who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic hyperosmolar state, with or without ketosis.
- The Reader's built-in meter is not for use on neonates, in critically-ill patients, or for diagnosis or screening of diabetes.
- See Using the Reader's Built-in meter section 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 to prevent the potential risk of electrical shock.
- The maximum surface temperature of the Reader and/or the power adapter could go as warm as 111°F when it's charging or 117°F during normal use. 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.

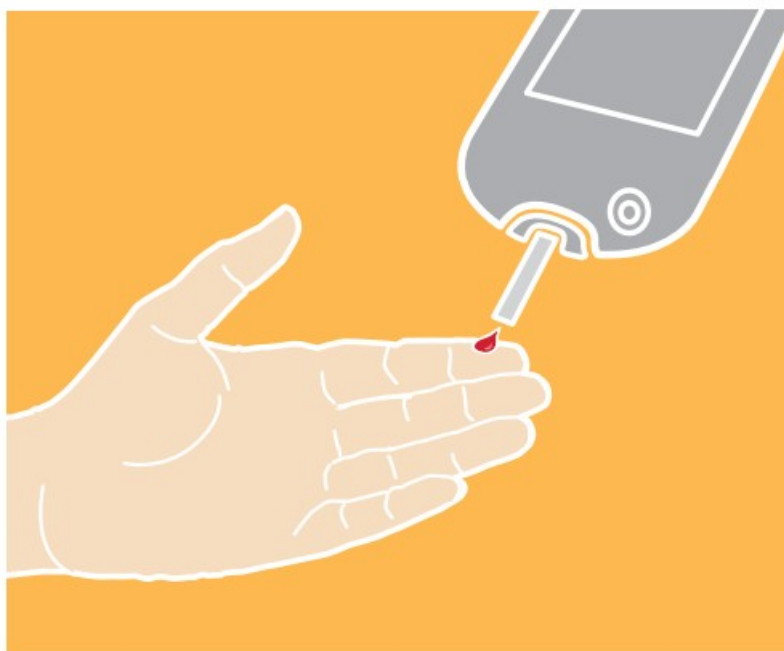
Interfering Substances:

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.


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.

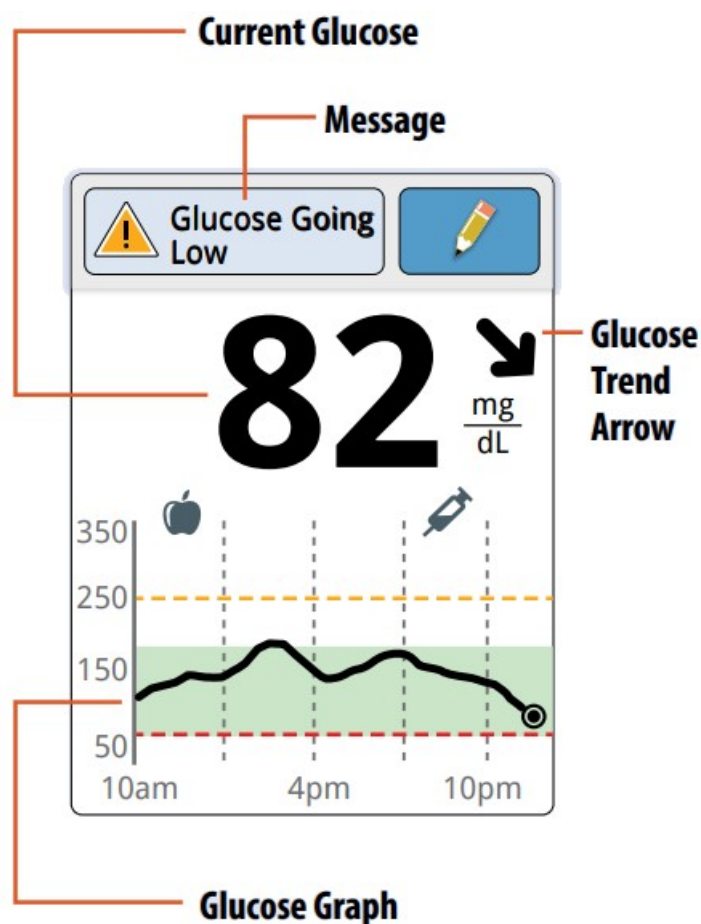


Do a blood glucose test when you see the  symbol during the first 12 hours of wearing a Sensor or the Sensor glucose reading does not include a Current Glucose number.

Using Sensor Glucose Readings for Treatment Decisions

Use all of the information on the screen when deciding what to do or what treatment decision to make.

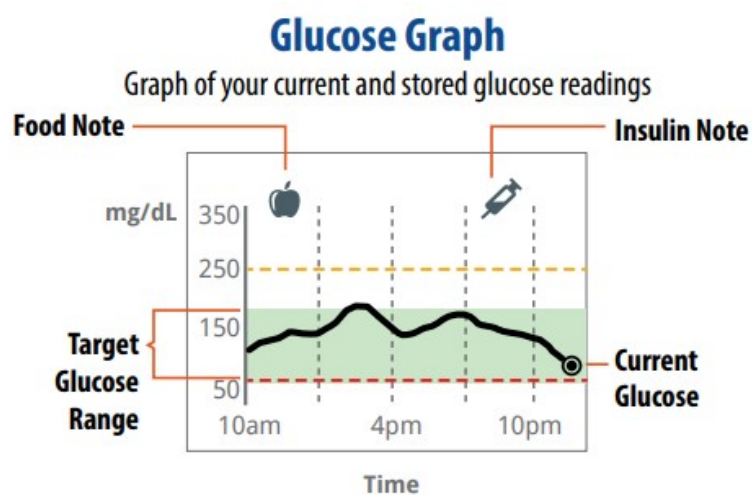
Reader



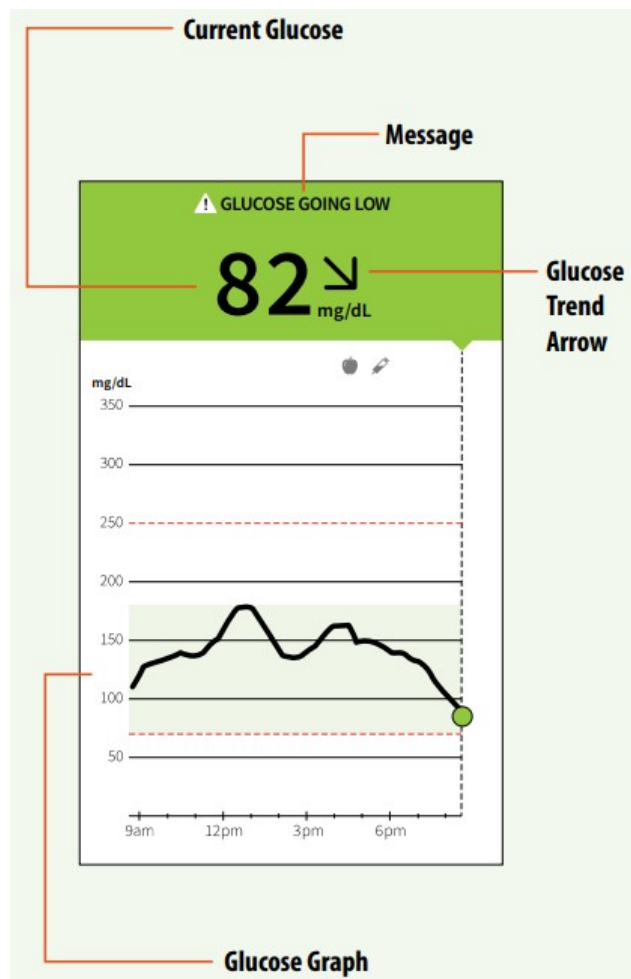
Glucose Trend Arrow

Direction your glucose is going

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



App



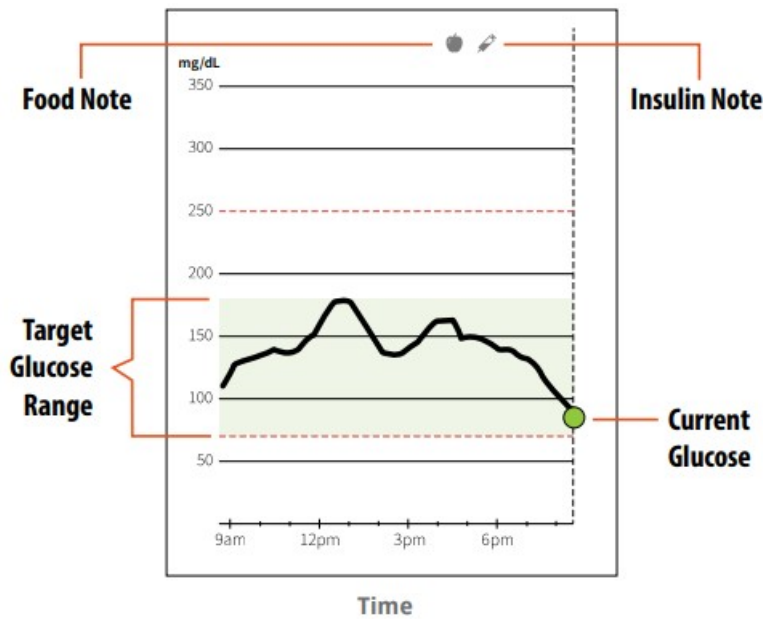
Glucose Trend Arrow

Direction your glucose is going

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

Glucose Graph

Graph of your current and stored glucose readings



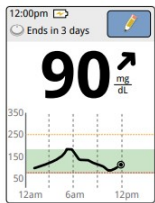
Example Scenarios

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 health care professional.

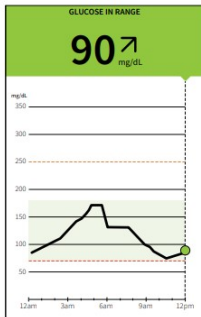
What you see	What it means
<p>When you wake up:</p> <p>Reader</p> <p>App</p>	<p>When you wake-up on your first day of wearing a Sensor, your current glucose is 110 mg/dL. There is also the symbol on the screen.</p> <p>During the first 12 hours of Sensor wear the symbol will display, and you cannot use 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.</p> <p>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?

Before lunch:


Reader




App



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 .

90 minutes later, your current glucose is 225 mg/dL. The graph shows that yo

ur glucose is still going up, and so does the trend arrow .

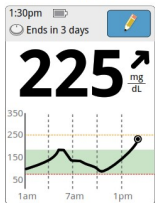
Don't take a correction dose within 2 hours of your meal dose. This may result in "insulin stacking" and low glucose.

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

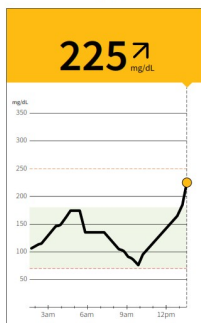
For example:

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

Reader

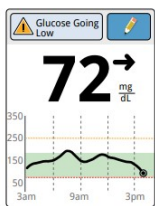


App

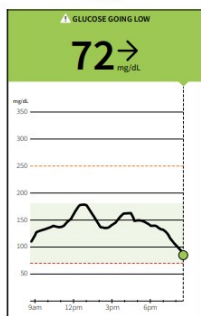


In the afternoon:

Reader



App



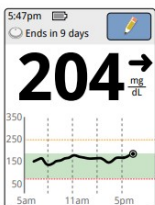
Between meals, your current glucose is 72 mg/dL. The Glucose Going Low message tells you that your glucose is projected to be low within 15 minutes.

Think about what might be causing your glucose to go low. Consider eating a snack to stay within target.

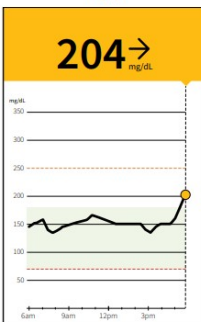
Avoid taking insulin as this can cause low glucose.

After exercising:

Reader



App

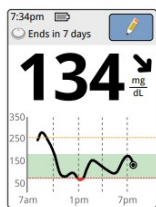


After exercising, you are feeling shaky, sweaty, and dizzy – symptoms you generally get when you have low glucose. But, your current glucose is 204 mg/dL.

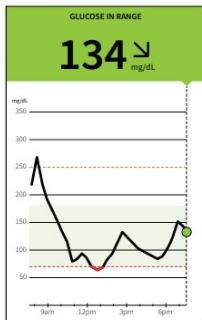
Anytime you get a reading that doesn't match how you feel, do a blood glucose test.


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?



FreeStyle Libre 3

The circular shape of the sensor housing, FreeStyle, Libre, and related brand marks are marks of Abbott. Other trademarks are the property of their respective owners.

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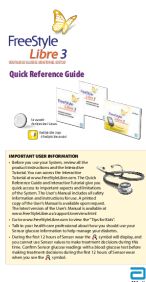
Consult instructions for use



Manufacturer

Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502 USA

Documents / Resources



[FreeStyle Libre 3 Continuous Glucose Monitoring System](#) [pdf] User Guide

Libre 3 Continuous Glucose Monitoring System, Libre 3, Continuous Glucose Monitoring System, Glucose Monitoring System, Monitoring System

References

-  [Continuous Glucose Monitoring \(CGM\) | FreeStyle Libre \(CGM\) systems](#)
-  [Support | Product Guides & Tutorials | FreeStyle Libre \(CGM\) systems](#)