



# FreeStyle



## Libre 14 day

FLASH GLUCOSE MONITORING SYSTEM

### Quick Reference Guide



#### IMPORTANT USER INFORMATION

- Before you use your System, review all the product instructions and the Interactive Tutorial. The Quick Reference Guide and Interactive Tutorial give you quick access to important aspects and limitations of the System. The User's Manual includes all safety information and instructions for use.
- During the first 12 hours after insertion of a Sensor, Sensor readings will be accompanied by the  symbol. Whenever  is displayed, a blood glucose test should be performed to confirm the Sensor reading prior to treatment.
- Talk to your health care professional about how you should use your Sensor glucose information to help manage your diabetes.



## **INDICATIONS FOR USE**

The FreeStyle Libre 14 day 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.

## What you need to understand in the Indications For Use:

You can use the FreeStyle Libre 14 day System if you're 18 or older.



### 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 a few 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:




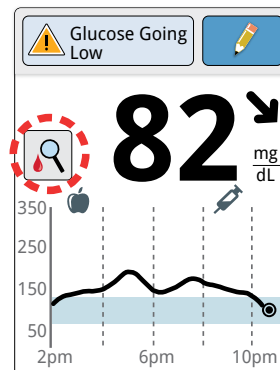
**Do a blood glucose test** if you see the Check Blood Glucose  symbol. The  symbol means your Sensor glucose reading may not be accurate. For example, there may be times when you get a low glucose reading but you do not actually have low glucose.



**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.

**Note:** The  symbol will **NOT** appear in this situation.

**WARNING:** 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.




## CONTRAINDICATIONS:



**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.
- **Check Sensor glucose readings by conducting a fingerstick test with a blood glucose meter under the following conditions, when Sensor glucose readings may not be accurate and should not be used 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 the Sensor glucose readings
  - During the first 12 hours of wearing a FreeStyle Libre 14 day Sensor
  - During times of rapidly changing glucose (more than 2 mg/dL per minute)
  - 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 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 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 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.



### Who should not use the System:

- **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:

- The Sensor can be worn for up to 14 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 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. Remove and replace your Sensor if it starts to loosen and follow the instructions to select an appropriate application site.
- The System uses all available glucose data to give you readings so you should scan your Sensor at least once every 8 hours for the most accurate performance. Scanning less frequently may result in decreased performance.

- 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.



#### **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 14 day 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 Reader Kit User's Manual for additional important information on the use of the Reader's built-in meter.



**Where to charge your Reader:**

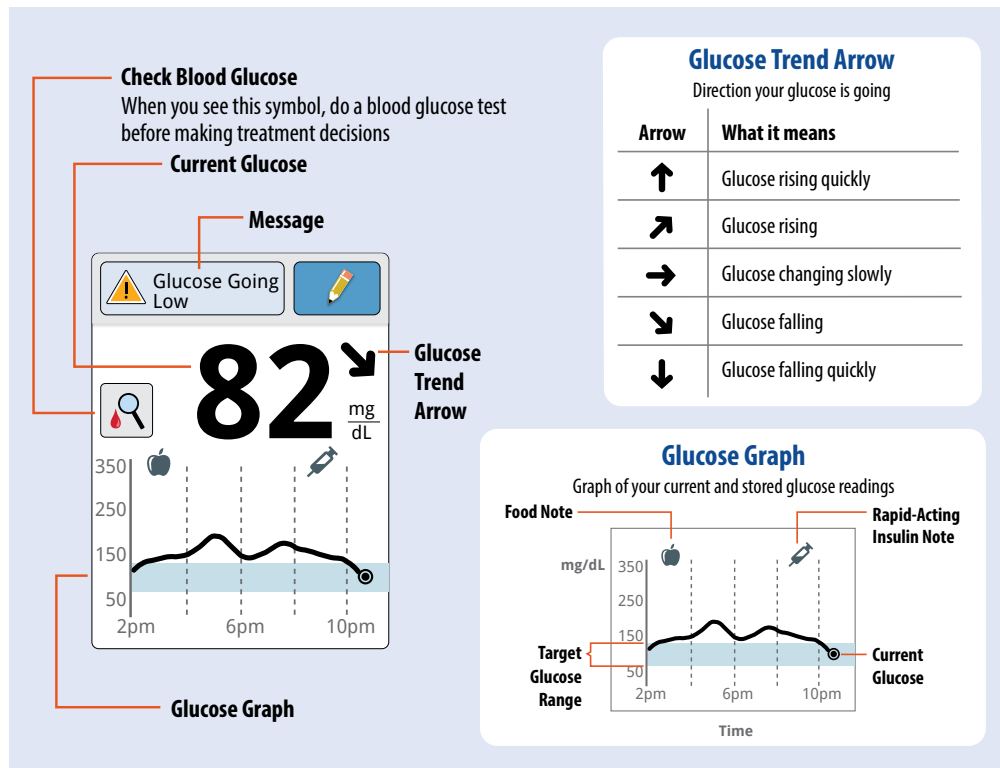
- Be sure to select a location for charging that allows the power adapter to be easily unplugged. Do NOT block access to the charger due to the potential risk of electrical shock.



## 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



### WARNING:


The System can replace blood glucose testing except in a few 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 see the Check Blood Glucose  symbol. The  symbol means your Sensor glucose reading may not be accurate. For example, there may be times when you get a low glucose reading but you do not actually have low glucose.

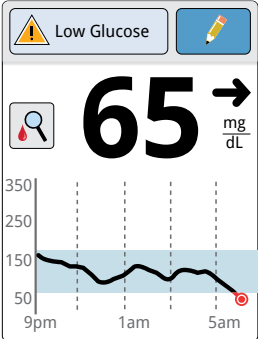
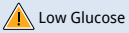


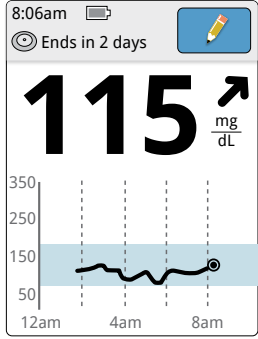
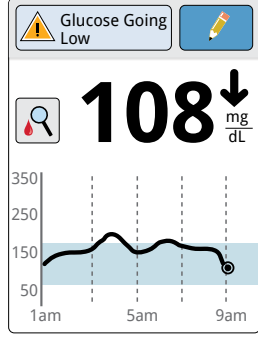
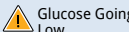




**Do a blood glucose test** if you think your glucose readings are not correct or do not match how you feel. Do not ignore symptoms that may be due to low or high glucose.

**Note:** The  symbol will **NOT** appear in this situation.

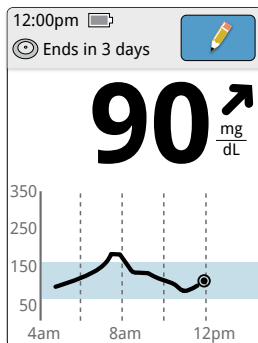
## Example Scenarios

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.

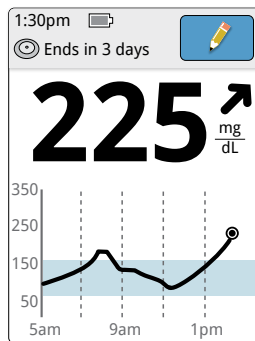
What you see	What it means
<p><b>When you wake-up:</b></p>  <p>The screenshot shows a 'Low Glucose' warning at the top left. The current glucose level is 65 mg/dL, with a right-pointing arrow indicating a slow increase. Below the number is a line graph showing glucose levels from 9pm to 5am, with a shaded target zone between 50 and 150 mg/dL. The current reading is at the 5am mark, which is below the target zone.</p>	<p>When you wake up, your current glucose is 65 mg/dL and the trend arrow shows it is changing slowly →. There is also a  message at the top of the screen and the  symbol.</p> <p>Anytime you see the  symbol, you should do a blood glucose test before deciding what to do.</p>
<p><b>Before breakfast:</b></p>  <p>The screenshot shows the time 8:06am and a battery icon. A message 'Ends in 2 days' is visible. The current glucose level is 115 mg/dL, with an upward-pointing arrow indicating a rising trend. Below the number is a line graph showing glucose levels from 12am to 8am, with a shaded target zone between 50 and 150 mg/dL. The current reading is at the 8am mark, which is above the target zone.</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"><li>• How much insulin should you take before your meal?</li><li>• Since you see ↗, should you consider taking a little more insulin?</li></ul>
<p><b>After breakfast:</b></p>  <p>The screenshot shows a 'Glucose Going Low' warning at the top left. The current glucose level is 108 mg/dL, with a downward-pointing arrow indicating a quick decrease. Below the number is a line graph showing glucose levels from 1am to 9am, with a shaded target zone between 50 and 150 mg/dL. The current reading is at the 9am mark, which is below the target zone.</p>	<p>After breakfast, your current glucose is 108 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 you see the  symbol, you should do a blood glucose test before deciding what to do.</p>

## What you see

### Before lunch:



### After lunch:



## What it means

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

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

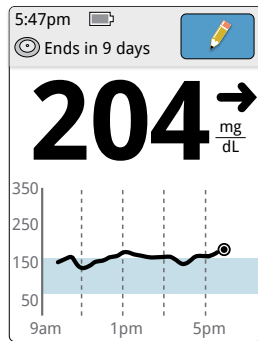
**Don't take a correction dose within 2 hours of your meal dose.** This may result in "insulin stacking" and low glucose.

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

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

## What you see

### After exercising:



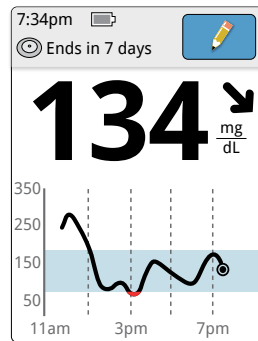
## What it means

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

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

**Note:** The Check Blood Glucose symbol will **NOT** appear in this situation.

### Before dinner:

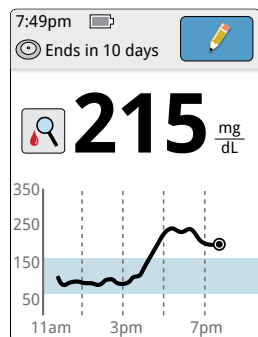


Before dinner, your current glucose is 134 mg/dL. The graph shows that your glucose is going down and so does the trend arrow ↘.

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?

### After dinner:



After dinner, your current glucose is 215 mg/dL but there is no trend arrow. There is also the symbol on the screen.

Anytime you see the symbol, you should do a blood glucose test before deciding what to do.







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Consult instructions for use



Manufacturer:  
Abbott Diabetes Care Inc.  
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