

# **Quick Reference Guide**



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# **IMPORTANT USER INFORMATION**

- Before you use your System, review all the product instructions. This Quick Reference Guide gives you quick access to important aspects of the System. The User's Manual includes all safety information and instructions for use.
- 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.



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#### **INDICATIONS FOR USE**

The FreeStyle Libre 2 Flash Glucose Monitoring System (FreeStyle Libre 2 Reader or FreeStyle Libre 2 app or FreeStyle Libre 2 special edition app used with FreeStyle Libre 2 Sensor) is indicated for measuring interstitial fluid glucose levels in people aged 4 years and older with diabetes mellitus. The System is designed to replace blood glucose testing in the self-management of diabetes, including dosing of insulin. Treatment decisions should be based on real-time Sensor glucose readings and other information on the results screen, including trend arrow and recent sequential readings on the glucose graph. The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycaemia and hypoglycaemia, facilitating both acute and long-term therapy adjustments.

#### **CONTRAINDICATIONS:**

MRI/X-ray/CT: Remove the Sensor that you are wearing if you have a medical appointment that includes strong magnetic or electromagnetic radiation, e.g. an X-ray, MRI (Magnetic Resonance Imaging) or CT (Computed Tomography) scan. Apply a new Sensor after the appointment.

# What you need to understand in the Indications for use:

You can use the FreeStyle Libre 2 System if you're 4 or older.

#### MPORTANT:

- 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** if the Sensor glucose reading does not include a Current Glucose number.

#### **WARNINGS:**

- Do not ignore symptoms that may be due to low or high blood glucose. If you have symptoms that do not match the Sensor glucose reading or suspect that your reading may be inaccurate, check the reading by conducting a fingerstick test using a blood glucose meter. If you have symptoms that do not match your glucose readings, consult your health care professional.
- **Choking hazard:** The System contains small parts that may be dangerous if swallowed.

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# **Cautions and Important System Information**



#### What to know about Glucose Alarms:

- For you to receive alarms, they must be on, and your Reader should be within 6 metres (20 ft) of you at all times. The transmission range is 6 metres (20 ft) unobstructed. If you are out of range, you may not receive glucose alarms.
- To prevent missed alarms, make sure that the Reader has sufficient charge and that sound and/or vibration are turned on.



# Who should not use the System:

- The System has not been evaluated for use with other implanted medical devices, such as pacemakers.
- The System has not been evaluated for use in pregnant women, persons on dialysis or people less than 4 years of age.
- Do not use the System if you are critically ill. The System has not been evaluated for use by critically ill patients and it is not known how different conditions or medications common to this population may affect performance of the System.



# What to know about wearing the Sensor:

- 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. Do not try to treat any skin irritation with lotions/creams/ ointments/sprays/barrier patches in order to continue wearing the Sensor. 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 your Sensor comes loose, you may get no readings or unreliable readings, which may not match how you feel. Follow the instructions to select an appropriate application site.
- Glucose Going Low and Glucose Going High messages may mean that your actual blood glucose is already <3.9 mmol/L or >13.3 mmol/L. Consider this before making an activity or treatment decision.

- If you are going to participate in activities that could result in harm to yourself or others in the event of a severe hypoglycaemic episode (e.g. driving a motor vehicle without following the Canadian Diabetes Association Recommendations for Private and Commercial Drivers), do not rely on Glucose Messages (High Glucose, Low Glucose, Glucose Going High and Glucose Going Low) alone. Talk to your health care professional about checking your glucose before and while driving.
- When using the System to replace blood glucose testing for making diabetes treatment decisions, including insulin dosing, you should have a good understanding of how to self-manage your diabetes, as determined by your health care professional.



#### How to store the Sensor Kit:

• Store the Sensor Kit between 4°C and 25°C. While you don't need to keep your Sensor Kit in a refrigerator, you can as long as the refrigerator is between 4°C and 25°C.



#### How to store the Reader:

• Store the Reader between -20°C and 60°C. 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 Pack or the Sensor Applicator seem to be damaged or already opened.
- Do NOT use if past expiry date.



#### What to know before you apply the Sensor:

• Clean the application site and ensure that it is dry prior to Sensor insertion. This helps the Sensor stay attached to your body.



# When is Sensor Glucose different from Blood Glucose:

• Glucose levels in the interstitial fluid can be different from blood glucose levels and may mean that Sensor glucose readings are different from blood glucose. You may notice this difference during times when your blood glucose is changing quickly; for example, after eating, taking insulin or exercising.

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#### 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.
- On rare occasions, you may get inaccurate Sensor glucose readings.
  If you believe your glucose readings are not correct or do not match
  how you feel, perform a blood glucose test on your finger to confirm
  your glucose. If the problem continues, remove your Sensor and apply
  a new one.



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

- The Reader is designed to be used only with FreeStyle Precision blood glucose and blood ketone test strips and MediSense control solution.
- The Reader is for use by a single person. It must not be used on more than one person including other family members due to the risk of spreading infection. All parts of the Reader are considered biohazardous and can potentially transmit infectious diseases, even after cleaning and disinfecting the Reader.
- Avoid getting dust, dirt, blood, control solution, water or other substances in the Reader's USB and test strip ports.



# What to know about charging your Reader:

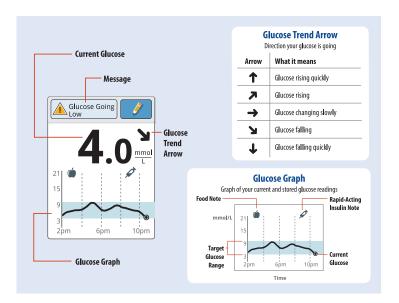
- Always use the Abbott-provided power adaptor and yellow USB cable that came with your Reader to minimise the **risk of fire or burns**. Take care when plugging and unplugging your USB cable. Do not force or bend the end of the USB cable into the Reader's USB port.
- Choose a location for charging where you can easily access the power adaptor and quickly disconnect to prevent the potential risk of electrical shock.
- The maximum surface temperature of the Reader could go as warm as 47°C. The maximum surface temperature of the power adaptor when charging could go as warm as 54°C. Under these conditions, do not hold the Reader or the power adaptor 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 adaptor 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 more than 500 mg of ascorbic acid per day may affect the Sensor readings which could cause you to miss a low glucose event. Ascorbic acid can be found in supplements including multivitamins. Some supplements, including cold remedies, may contain high doses of 1000 mg of ascorbic acid. Do not use the Sensor while taking supplements that contain high doses of 1000 mg of ascorbic acid.

# **Using Sensor Glucose Readings for Treatment Decisions**

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



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#### **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.

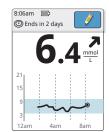
**Do a blood glucose test** if the Sensor glucose reading does not include a Current Glucose number.

# **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

### Before breakfast:



# What it means

Before breakfast, your current glucose is 6.4 mmol/L. The graph shows that your glucose is going up and so does the trend arrow

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

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

#### **Before lunch:**



When you checked your glucose before lunch, it was 5.0 mmol/L and rising. Before eating lunch, you took enough insulin to cover the meal and a little more since your trend arrow was .

# What you see

#### After lunch:



# What it means

90 minutes later, your current glucose is 12.5 mmol/L. 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 to do prevent a high glucose. For example:

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

# In the afternoon:



Between meals, your current glucose is 4.0 mmol/L. 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**.

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#### What you see

# What it means

# After exercising:



After exercising, you are feeling shaky, sweaty and dizzy symptoms you generally get when you have low glucose. But, your current glucose is 11.3 mmol/L.

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

# Before dinner:



Before dinner, your current glucose is 7.4 mmol/L and within target range. The graph shows that your glucose is going down and so does the trend arrow **\( \)**.

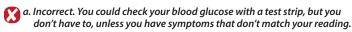
Consider what might be causing your glucose to go down and what you might do to prevent a low glucose. For example:

- How much insulin should you take to cover your meal?
- Since you see 🤰 , should you think about taking a little less insulin?

# **Treatment Decisions - Knowledge Check**

- 1. What would you do if you are getting ready to eat lunch, you scan your Sensor and you get a reading that your glucose level is above your target range and changing slowly  $\rightarrow$ .
- a. Do not treat based on this reading check my blood glucose with a test strip.
- b. Make a treatment decision, such as take insulin.

#### What did you select?





b. Correct! Based on your reading and what you are about to eat, consider how much insulin you should take.

- 2. What would you do if your body was telling you that your glucose was low, but when you scanned your Sensor your reading was high?
- a. Do not treat based on this reading check my blood glucose with
- b. Do something to lower glucose, such as take insulin.

#### What did you select?



a. Correct! Whenever you get a reading that doesn't match how you feel, check your blood glucose with a test strip before you make a treatment

b. Incorrect. If you feel low, trust your symptoms. Check your blood glucose with a test strip and treat accordingly. The Sensor may be inaccurate

- 3. 'Insulin stacking' is when you take two or more doses of rapid-acting insulin too close together. Which of the following scenarios would avoid 'insulin stacking'?
  - a. You took your full breakfast insulin dose and ate breakfast. 75 minutes later your glucose was high, so you took a correction
  - b. You took your full breakfast insulin dose and ate breakfast. 75 minutes later your glucose was high. You know insulin takes some time to work, so you decided to do nothing and scan again later.

# What did you select?



a. Incorrect. Taking multiple doses of rapid-acting insulin too close together may lead to 'insulin stacking' and low glucose. Don't take a correction dose within 2 hours of your meal dose.



b. Correct! Since you did not take multiple doses of rapid-acting insulin too close together, you avoided 'insulin stacking' and low glucose. Don't take a correction dose within 2 hours of your meal dose.

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