



# FreeStyle LibreLink

## Health Care Professional (HCP) Quick Reference Guide for FreeStyle LibreLink app

### Part of the FreeStyle Libre Flash Glucose Monitoring System

FreeStyle LibreLink app comes with two Quick Reference Guides: a **Patient Quick Reference Guide**, which is provided within the App and an **HCP Quick Reference Guide**, which is provided to you directly.

This **HCP Quick Reference Guide** is designed to help you educate your patient on the limitations and residual risks associated with using the FreeStyle LibreLink app with the FreeStyle Libre Sensor.

This guide is laid out as follows:

The content on the right side of each page is identical to the content in the Patient Quick Reference Guide.

The content on the left side of each page is additional information useful to an HCP.

**HCP  
Content**



**Patient  
Content**

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## Understanding the Difference between the FreeStyle Libre Sensor and BGM

Before you get started using the FreeStyle Libre Sensor, it's important to understand how the Sensor is different from a blood glucose meter.

A traditional blood glucose meter provides current glucose at a point in time. The FreeStyle Libre Sensor continuously measures and automatically stores glucose readings for 8 hours. Since the Sensor is continually measuring glucose, it provides more information than a traditional blood glucose meter. In addition to the Current Glucose number, each Sensor scan also includes a Glucose Trend Arrow that indicates which way and how fast the glucose is going, and a Glucose Graph that charts current and stored glucose readings.

## What you need to understand in the Indications for Use

### Who can use FreeStyle LibreLink with the FreeStyle Libre Sensor

- Adults ages 18 and older with at least 2 years of experience in self-managing diabetes.

### How to use FreeStyle LibreLink with the FreeStyle Libre Sensor to Make Treatment Decisions

- Always use a combination of the Current Glucose, the Glucose Trend Arrow, the Glucose Graph, and any Glucose Messages for treatment decisions.
- Failure to use all of the information available may result in an incorrect treatment decision.

### When to do a Blood Glucose Test

- There are several conditions where the Sensor glucose readings should not be used to make treatment decisions as they may be different from blood glucose results. Under these circumstances, treatment decisions based on Sensor glucose readings may result in injury.
- Always use a blood glucose meter for treatment decisions if:
  - Glucose is rising quickly or falling quickly.
  - Low Glucose or Glucose Going Low message is received.
  - Glucose Trend Arrow or Current Glucose number is missing.
  - You think glucose readings are incorrect or don't match how you feel.
  - You see the Confirm Blood Glucose  symbol.



# FreeStyle LibreLink

## Quick Reference Guide

**Part of the FreeStyle Libre Flash Glucose Monitoring System**

### IMPORTANT USER INFORMATION

Please review all the product instructions before using the FreeStyle LibreLink app with the FreeStyle Libre Sensor ("Sensor"). This guide gives you quick access to important aspects and limitations of the Sensor. 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 LibreLink app ("App") is indicated for measuring interstitial fluid glucose levels in adults aged 18 years and older who have at least 2 years of experience in self-managing their diabetes, when used with the FreeStyle Libre Flash Glucose Monitoring System Sensor ("Sensor"). It is designed to replace blood glucose testing in the self-management of diabetes with the exceptions listed below. Treatment decisions should not be based on real-time Sensor glucose readings alone and instead should be based on the combination of the Sensor glucose reading, the Glucose Trend Arrow, and Glucose Graph. Under the following circumstances, use a blood glucose meter to check the current glucose readings:

- During times of rapidly changing glucose levels, interstitial glucose levels as measured by the Sensor and reported as current may not accurately reflect blood glucose levels. When glucose levels are falling rapidly, glucose readings from the Sensor may be higher than blood glucose levels. Conversely when glucose levels are rising rapidly, glucose readings from the Sensor may be lower than blood glucose levels.
- In order to confirm hypoglycaemia or impending hypoglycaemia as reported by the Glucose Messages.
- If symptoms do not match the reading. Do not ignore symptoms that may be due to low blood glucose or high blood glucose.

## **Contraindications, Warnings, and Cautions**

The next two pages in your patient's guide contain important contraindications, warnings, and cautions that you should understand and review with your patient.

**CONTRAINDICATIONS:**

**MRI/X-ray/CT:** Remove the Sensor 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.

**WARNINGS:**

- If you are using FreeStyle LibreLink, you must also have access to a blood glucose monitoring system as the App does not provide one.
- **Choking hazard:** The Sensor contains small parts that may be dangerous if swallowed.
- When your glucose is changing quickly (more than 0.1 mmol/L per minute), interstitial fluid glucose levels measured by the Sensor may not accurately match blood glucose levels. When your glucose is rising quickly or falling quickly, check the Sensor glucose readings by doing a blood glucose test on your finger with a blood glucose meter.
- Do a blood glucose test on your finger with a blood glucose meter if you get a Low Glucose or Glucose Going Low message.
- Do a blood glucose test on your finger with a blood glucose meter if you do not see a Current Glucose number or Glucose Trend Arrow.
- 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 think that your reading may be inaccurate, check the reading by doing a blood glucose test on your finger with a blood glucose meter. If you have symptoms that do not match your glucose readings, consult your health care professional. **If you have been diagnosed with hypoglycaemic unawareness and do not experience symptoms of hypoglycaemia, ask your health care professional when you should perform a blood glucose test to confirm your glucose.**
- 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.

**Cautions and Important Information:****Who should not use the Sensor:**

- Performance of the Sensor when used with other implanted medical devices, such as pacemakers, has not been evaluated.
- The Sensor has not been evaluated for use in pregnant women, persons on dialysis, or people less than 18 years of age.

**How to store the Sensor:**

- 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.

Continue to review the cautions and important information on this page with your patient.

### **Additional Information about Interfering Substances – Vitamin C and Aspirin**

The information below can help you address any questions you may receive about limitations related to interfering substances.

Taking ascorbic acid (vitamin C) while wearing the Sensor may falsely raise Sensor glucose readings.

- For example, at a concentration of 0.06 mmol/L in interstitial fluid (ISF), ascorbic acid will falsely raise Sensor glucose readings by 1.1 mmol/L.
- While absorption of ascorbic acid into ISF is not well documented, 0.06 mmol/L is approximately 50% of the maximum therapeutic concentration in circulating blood.

Taking salicylic acid (used in some pain relievers such as aspirin and some skin care products) may slightly lower Sensor glucose readings.

- For example, at a concentration of 0.50 mmol/L in ISF, salicylic acid will falsely lower Sensor glucose readings by 1.1 mmol/L.
- While absorption of salicylic acid into ISF is not well documented, 0.50 mmol/L is approximately 25% of the maximum therapeutic concentration in circulating blood.

**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.

**What to do if you are dehydrated:**

- Severe dehydration and excessive water loss may cause inaccurate results. If you think you are dehydrated, consult your health care professional immediately.

**What to know about taking Vitamin C or Aspirin:**

- Taking ascorbic acid (vitamin C) while wearing the Sensor may falsely raise your Sensor glucose readings. Taking salicylic acid (used in some pain relievers such as aspirin and some skin care products) may slightly lower your Sensor glucose readings. The level of inaccuracy depends on the amount of the interfering substance active in the body.

**What to know about Glucose Messages:**

- 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.

**When to remove the Sensor early:**

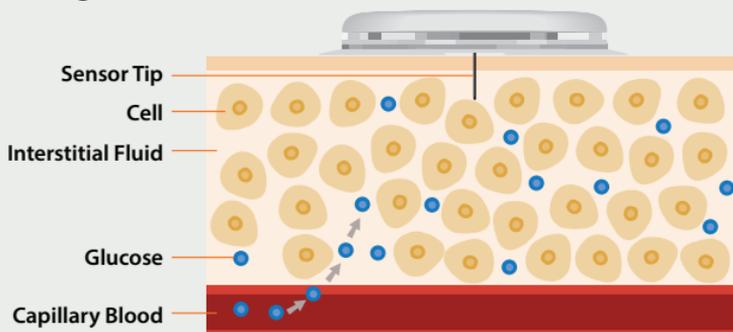
- Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If you notice significant skin irritation around or under your Sensor, remove the Sensor and stop using the Sensor. Contact your health care professional before continuing to use the Sensor.
- On rare occasions, 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 FreeStyle LibreLink:**

- FreeStyle LibreLink installed on a smartphone 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 LibreLink and FreeStyle Libre Readers do not share data. For complete information on a device, be sure to scan your Sensor every 8 hours with that device; otherwise, your reports will not include all your data.

## Understanding the Difference between ISF Glucose and Blood Glucose

The FreeStyle Libre Sensor measures interstitial fluid (ISF) instead of blood glucose.



For illustrative purposes only. Image not drawn to scale.

**Lag:** ISF glucose levels tend to lag behind blood glucose levels because it can take a few minutes for glucose to move from the blood into the ISF. This is particularly true when blood glucose levels are changing quickly. As a result, when glucose levels are falling quickly, glucose readings from the Sensor may be higher than blood glucose levels. Conversely, when glucose levels are rising quickly, glucose readings from the Sensor may be lower than blood glucose levels.

**Sensor Glucose on Day 1:** During the first day of a Sensor wear, Sensor glucose readings may be lower and more variable since it takes some time for the body to adjust to a newly inserted Sensor. The severity of this phenomenon is based on the body's physiological response to a Sensor insertion and can vary from one patient to another and from one insertion to another. Due to the possibility of lower readings during this time, it's important to conduct a blood glucose test when you see a Low Glucose message.

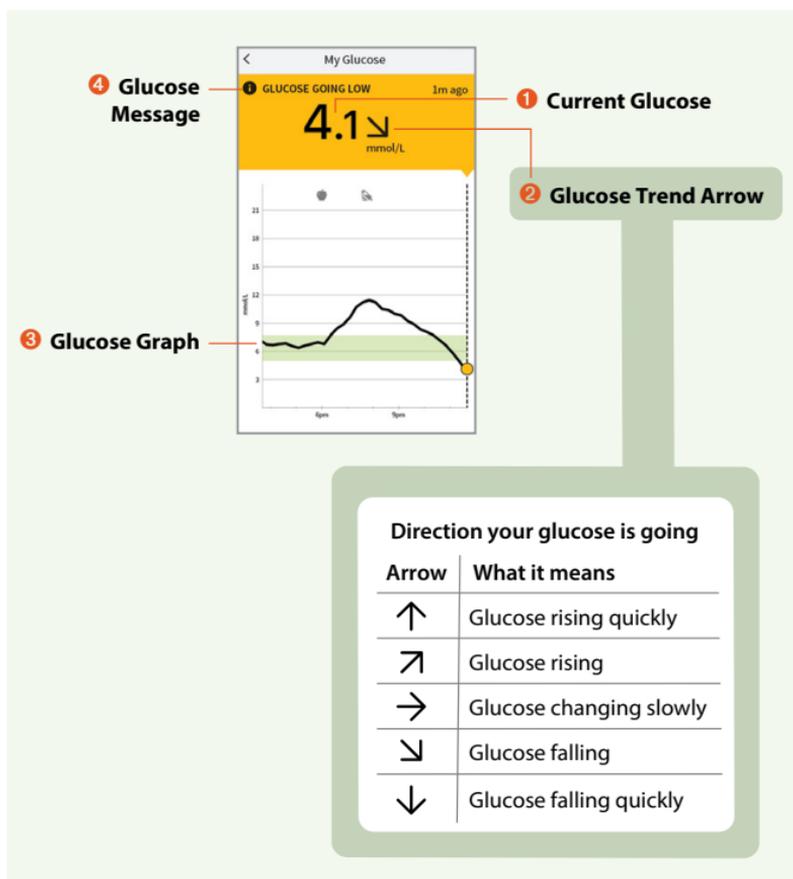
**Noise:** In addition, there may be rare occasions of noise, or random disturbances/ fluctuations in the Sensor glucose data. The Sensor is designed to filter out as much noise as possible. However, there may be rare instances when noise can't be filtered out completely, resulting in slight variations in the Sensor glucose data. Patients should conduct a Sensor Accuracy Check if they are unsure about the Sensor glucose readings they are receiving, or if they want to confirm their Sensor is functioning properly. See *How to Perform a Sensor Accuracy Check* for more information.

Keep this information in mind and don't use just the Current Glucose number to make treatment decisions. It is important to use **all of the information** provided by the Sensor including the Current Glucose, Glucose Trend Arrow, the Glucose Graph and any Glucose Messages. Sometimes, the most appropriate action to take may be to do nothing and scan again later.

## Understanding Sensor Glucose Readings

The Sensor continuously measures your glucose, which means it gives you more information than a single blood test. A blood test gives you a result for one point in time but the Sensor provides additional information about where your glucose has been and where it is going. Use all the information on the screen to decide what to do or what treatment decision to make.

Each time you scan the Sensor, look for these four pieces of information:



You need to look for all four pieces of information before deciding what to do. If you do not use all the information, you may make an incorrect treatment decision.

## **When to do a Blood Glucose Test**

Understanding when you can and can't use Sensor glucose readings to make treatment decisions is critical to safe use. Ensure your patient understands this important concept.

## When to do a Blood Glucose Test

**IMPORTANT:** FreeStyle LibreLink, when used with the FreeStyle Libre Sensor, 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:



**Do a blood glucose test** if you see the Confirm 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 your glucose reading includes a Glucose Going Low message ⓘ GLUCOSE GOING LOW .



**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.



## What you need to understand about Sensor Accuracy

Ensure your patient understands the Sensor Accuracy limitations highlighted on this page.

### How to factor Sensor Accuracy into treatment decisions

- To account for the Sensor Accuracy limitations, always consider all four pieces of information on the screen when deciding what to do or what treatment decision to make.
- **Treatment based on inaccurate results can lead to hypoglycaemia or hyperglycaemia.**

## What you need to understand about Sensor Accuracy

**4 Glucose Message Accuracy**  
Glucose Messages may not always be right.

**3 Glucose Graph Accuracy**  
Readings from some Sensors may be 20% or more different from blood glucose.

**1 Current Glucose Accuracy**  
Readings from some Sensors may be 20% or more different from blood glucose.

**2 Glucose Trend Arrow Accuracy**  
The Glucose Trend Arrow may not always point in the right direction.

### How to factor Sensor Accuracy into treatment decisions

Always consider all four pieces of information on your screen when deciding what to do or what treatment decision to make.

- 1 Current Glucose
- 2 Glucose Trend Arrow
- 3 Glucose Graph
- 4 Glucose Message

### What to know about Sensor Glucose Readings on the 1st day of a Wear

Sensors may tend to give lower and more variable glucose readings on day 1 of Sensor wear since it takes some time for your body to adjust to a newly inserted Sensor.

Go to **Important Information about the Sensor's Performance** to learn more about Sensor performance.

## Sensor Accuracy Check

Your patients can check to see if their Sensor is accurate or working properly by following the instructions on the right for ***How to Perform a Sensor Accuracy Check***.

The Sensor Accuracy Check compares the Current Glucose number from the Sensor to a blood glucose test result.

The check should only be performed when:

- Blood glucose test result is above 4.4 mmol/L. **Note:** The Sensor Accuracy Check should be performed when blood glucose is above 4.4 mmol/L because the Sensor is least accurate at low blood glucose levels and may not be representative of the overall Sensor accuracy.
- Sensor glucose is changing slowly → to avoid the effects of blood to ISF lag.

If the blood glucose result is within 20% of the Current Glucose number, the Sensor is working properly. If it is not, instruct your patient to use their blood glucose meter. If the issue persists, your patient should replace the Sensor with a new one.

**Treatment based on inaccurate results can lead to hypoglycaemia or hyperglycaemia.**

## How to Perform a Sensor Accuracy Check

In some situations, individual Sensors may give glucose readings more than 20% higher or lower than blood glucose. You can check to see if your Sensor is working properly by using the FreeStyle Libre Reader's built-in meter or another blood glucose meter.

Check your Sensor is working properly by following these steps:

1. Scan your Sensor. Make sure your glucose is changing slowly →.
  2. Perform a blood glucose test. Your blood glucose result must be above 4.4 mmol/L in order to perform the check.
  3. Compare the blood glucose result to the Sensor reading.
- You'll know the Sensor is performing correctly if the blood glucose result is within 20% of the Sensor glucose reading. For example, when the Sensor reads 10.0 mmol/L, the blood glucose result should be between 8.0 and 12.0 mmol/L.
  - If the blood glucose result is not within 20% of the Sensor glucose reading, use your blood glucose meter instead of your Sensor and try the check again later. **Treatment based on inaccurate results can lead to low glucose or high glucose.**
  - If the problem continues, use your blood glucose meter instead of your Sensor and contact your health care professional for guidance on when you can use your Sensor.

## **Understanding the Difference between ISF Glucose and Blood Glucose**

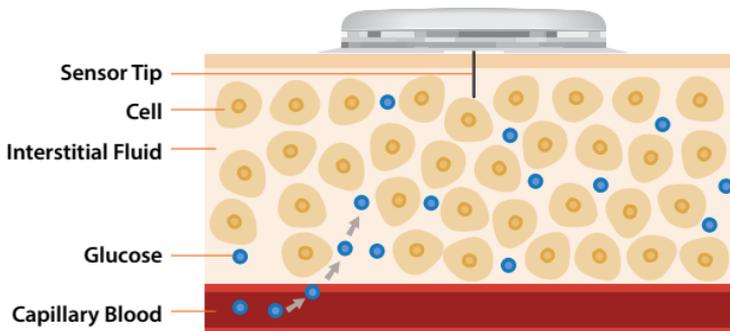
The information provided in the patient guide is the same as what you have earlier in this guide.

Explain the concepts on this page and make sure your patient understands that there are differences between Sensor glucose and blood glucose measurements. They should keep these in mind while using the FreeStyle Libre Sensor. Remind them that they should always consider all the information on the screen when deciding what to do or what treatment decision to make.

## Understanding the Difference between ISF Glucose and Blood Glucose

Please contact your health care professional if you need help understanding the information on this page.

The Sensor measures interstitial fluid (ISF) instead of blood glucose.



For illustrative purposes only. Image not drawn to scale.

**Lag:** ISF glucose levels tend to lag behind blood glucose levels because it can take a few minutes for glucose to move from the blood into the ISF. This is particularly true when blood glucose levels are changing quickly. As a result, when glucose levels are falling quickly, glucose readings from the Sensor may be higher than blood glucose levels. Conversely, when glucose levels are rising quickly, glucose readings from the Sensor may be lower than blood glucose levels.

**Sensor Glucose on Day 1:** During the first day of a Sensor wear, Sensor glucose readings may be lower and more variable since it takes some time for the body to adjust to a newly inserted Sensor. The severity of this phenomenon is based on the body's physiological response to a Sensor insertion and can vary from one person to another and from one insertion to another. Due to the possibility of lower readings during this time, it's important to conduct a blood glucose test when you see a Low Glucose message.

**Noise:** In addition, there may be rare occasions of noise, or random disturbances/ fluctuations in the Sensor glucose data. The Sensor is designed to filter out as much noise as possible. However, there may be rare instances when noise can't be filtered out completely, resulting in slight variations in the Sensor glucose data. You should conduct a Sensor Accuracy Check if you are unsure about the Sensor glucose readings you are receiving, or if you want to confirm your Sensor is functioning properly. See *How to Perform a Sensor Accuracy Check* for more information.

Keep this information in mind and don't use just the Current Glucose number to make treatment decisions. It is important to use **all of the information** provided by the Sensor including the Current Glucose, Glucose Trend Arrow, the Glucose Graph and any Glucose Messages. Sometimes, the most appropriate action to take may be to do nothing and scan again later.

## Understanding Performance Data

The Performance Data section of the User's Manual in the App describes key performance measures for the Sensor. Some of the important information for your patient has been highlighted in their guide. Additional information that is important to you is included in the following pages.

## Important Information about the Sensor's Performance

Important information from the Performance Data section of the User's Manual in the App has been highlighted in this section to help you understand how to factor performance data into your treatment decisions.

The product's clinical study examined 72 subjects with diabetes, each wearing two Sensors at a time. During the study, their blood samples were measured with a laboratory blood glucose reference (YSI - Yellow Springs Instrument) and compared to their Sensor glucose readings.

Most of the time, their Sensor glucose readings were found to be accurate. 24% of points were found to be outside the standard\* for blood glucose meter accuracy.

### Note:

- Sensor glucose readings may have a delay or lag when compared to a blood glucose reference. In the study, the average Sensor lag time was 4.2 minutes and ranged from 18.1 minutes behind the blood glucose value to 6.8 minutes ahead of the blood glucose value.
- The data shows the average performance of 167 Sensors. However, the performance of individual Sensors may vary.

\*The current international standard for blood glucose meters defines an accurate result as one that is within  $\pm 15\%$  of an actual blood glucose value when blood glucose is  $\geq 5.5$  mmol/L or  $\pm 0.83$  mmol/L when blood glucose is  $< 5.5$  mmol/L.

You can find all the tables referenced in this section in the Performance Data section of the User's Manual in the App.

**Performance Characteristics**

**Figure 1** 

**Table 1** 

**Table 3** 

**Table 10** 

**Table 11** 

**Table 12** 

## Understanding Current Glucose Number Performance

Overall, the Mean Absolute Relative Difference (MARD) was 11.2% when compared to Yellow Springs Instrument (YSI) laboratory blood glucose reference. MARD is a measure of accuracy. A lower MARD indicates a closer agreement between the Sensor and blood glucose reference numbers.

Individual Sensors may give glucose readings more than 20% higher or lower than blood glucose. This may be temporary, e.g. when glucose is going up or down quickly, or during the first day of a Sensor wear.

**Table 10** in the Performance Data section highlights the performance of the Sensor by day of wear:

	Day 1	Day 2	Day 7	Day 13	Day 14
<b>Within <math>\pm 0.83</math> mmol/L and within <math>\pm 20\%</math> of reference</b>	74.8%	82.6%	87.4%	90.2%	92.4%
<b>MARD (%)</b>	14.9	12.6	10.4	10.3	9.2

### How to factor this into treatment decisions

- Don't rely on just one piece of information. Always use all the information on the screen for a treatment decision.
- When in doubt, confirm the Sensor is functioning properly by conducting a Sensor Accuracy Check. See *How to Perform a Sensor Accuracy Check* for more information.

### Current Glucose Number (See Table 10)

#### What to know:

Some individual Sensors may read greater than 20% higher or lower than true blood glucose levels.

**Note:** This may be temporary. For example, when glucose is going up or down quickly. Or, as **Table 10** shows, during the first day of a Sensor wear.

**Alternatively, it could apply to all Sensor glucose readings over the 14-day wear period due to poor Sensor calibration during manufacturing.**

For Sensors in the study that had a mean relative difference greater than  $\pm 20\%$  from YSI, 62.3% of points were outside the accuracy bounds of  $\pm 15\%/0.83$  mmol/L, representing 2.6% of the total number of points in the study.

#### Why it happens:

During the first day of a Sensor wear, your Sensor glucose readings may be lower and more variable since it takes some time for your body to adjust to a newly inserted Sensor. Performance may vary between Sensors and may be affected by environmental factors, e.g. storage conditions. Sensor error may be greater than 20% if the Sensor is near its expiry date (i.e. stored for a long time prior to use) and has been stored at room temperature.

The data in the Consensus Error Grid (**Figure 1 and Table 1**) provides an alternative risk assessment approach to Current Glucose Number accuracy.

Zone A: no effect on clinical action

Zone B: altered clinical action or little or no effect on clinical outcome

Zone C: altered clinical action—likely to effect clinical outcome

Zone D: altered clinical action—could have significant medical risk

Zone E: altered clinical action—could have dangerous consequences

### Glucose Trend Arrow (See Table 3)

#### What to know:

Sometimes the Glucose Trend Arrow may not match the direction and how fast blood glucose is actually changing. For example, you may see  $\downarrow$  or  $\searrow$  when blood glucose is rising quickly or see  $\uparrow$  or  $\nearrow$  when blood glucose is falling quickly. This happens about 1-2% of the time based on the performance reported in **Table 3**.

#### Why it happens:

It can take a few minutes for glucose to move from your blood into your interstitial fluid. This means that if your blood glucose was going up and changes to going down, the Glucose Trend Arrow may not match the blood glucose direction right away.

## Understanding Glucose Trend Arrow Performance

Due to differences between the ISF glucose as measured by the Sensor and blood glucose, the trend arrow may not always match the blood glucose rate of change.

**Table 3** in the Performance Data section highlights the accuracy of the Sensor rate of change when blood glucose (YSI) was falling quickly or rising quickly compared to Sensor glucose measurement (GM) rate of change:

Trend Arrow Accuracy (Table 3).

YSI Rate of Change	GM Rate of Change					No. GM and YSI Paired Readings
	Glucose is falling quickly (more than 0.1 mmol/L per minute)	Glucose is falling (between 0.06 and 0.1 mmol/L per minute)	Glucose is changing slowly (less than 0.06 mmol/L per minute)	Glucose is rising (between 0.06 and 0.1 mmol/L per minute)	Glucose is rising quickly (more than 0.1 mmol/L per minute)	
Glucose is falling quickly (more than 0.1 mmol/L per minute)	26.3%	43.8%	27.7%	2.2%	0.0%	224
Glucose is rising quickly (more than 0.1 mmol/L per minute)	0.2%	1.1%	16.7%	27.5%	54.5%	455

**Note:** The Sensor rate of change is representative of the Glucose Trend Arrow and includes times that the Glucose Trend Arrow would not display after a scan.

### How to factor this into treatment decisions

- Don't rely on just one piece of information. Always use all the information on the screen for a treatment decision.
- Do a blood glucose test when the Glucose Trend Arrow shows glucose is falling quickly or rising quickly or if there is no Glucose Trend Arrow.

### Current Glucose Number (See Table 10)

#### What to know:

Some individual Sensors may read greater than 20% higher or lower than true blood glucose levels.

**Note:** This may be temporary. For example, when glucose is going up or down quickly. Or, as **Table 10** shows, during the first day of a Sensor wear.

**Alternatively, it could apply to all Sensor glucose readings over the 14-day wear period due to poor Sensor calibration during manufacturing.**

For Sensors in the study that had a mean relative difference greater than  $\pm 20\%$  from YSI, 62.3% of points were outside the accuracy bounds of  $\pm 15\%/0.83$  mmol/L, representing 2.6% of the total number of points in the study.

#### Why it happens:

During the first day of a Sensor wear, your Sensor glucose readings may be lower and more variable since it takes some time for your body to adjust to a newly inserted Sensor. Performance may vary between Sensors and may be affected by environmental factors, e.g. storage conditions. Sensor error may be greater than 20% if the Sensor is near its expiry date (i.e. stored for a long time prior to use) and has been stored at room temperature.

The data in the Consensus Error Grid (**Figure 1 and Table 1**) provides an alternative risk assessment approach to Current Glucose Number accuracy.

Zone A: no effect on clinical action

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### Glucose Trend Arrow (See Table 3)

#### What to know:

Sometimes the Glucose Trend Arrow may not match the direction and how fast blood glucose is actually changing. For example, you may see  $\downarrow$  or  $\searrow$  when blood glucose is rising quickly or see  $\uparrow$  or  $\nearrow$  when blood glucose is falling quickly. This happens about 1-2% of the time based on the performance reported in **Table 3**.

#### Why it happens:

It can take a few minutes for glucose to move from your blood into your interstitial fluid. This means that if your blood glucose was going up and changes to going down, the Glucose Trend Arrow may not match the blood glucose direction right away.

## Understanding Glucose Message Performance

Glucose Messages inform the patient of low, high, impending low, and impending high glucose events. Since the Sensor measures interstitial fluid instead of blood, there will not always be an exact match between low and high glucose events detected by the Sensor versus those detected by a blood test. **Tables 11 & 12** in the Performance Data section highlight the accuracy of the Glucose Messages with respect to three different parameters:

- Detection rate – amount of time a Glucose Message displays correctly.
- Missed detection rate – amount of time a Glucose Message did not display when it should have.
- False notification rate – amount of time a Glucose Message displays when it shouldn't have.

For example, the Sensor was able to detect 82.9% of actual low glucose events (detection rate), but 53.5% of the time a Low Glucose message was displayed in error (false notification rate) and 17.1% of the time a Low Glucose message was not displayed when it should have been (missed detection rate).

Performance of threshold (Low Glucose and High Glucose) Glucose Messages (Table 11).

Type of Notification	Notification Status	15 Minutes Interval	30 Minutes Interval
Threshold Notification of Hypoglycaemic Events at 3.9 mmol/L	Detection Rate (%)	72.1	82.9
	Missed Detection Rate (%)	27.9	17.1
	False Notification Rate (%)	58.5	53.5

Type of Notification	Notification Status	15 Minutes Interval	30 Minutes Interval
Threshold Notification of Hyperglycaemic Events at 13.3 mmol/L	Detection Rate (%)	88.7	92.0
	Missed Detection Rate (%)	11.3	8.0
	False Notification Rate (%)	17.0	13.5

Performance of threshold and impending (Glucose Going Low and Glucose Going High) Glucose Messages (Table 12).

Type of Notification	Notification Status	15 Minutes Interval	30 Minutes Interval
Threshold or Impending Notification of Hypoglycaemic Events at 3.9 mmol/L	Detection Rate (%)	88.4	91.2
	Missed Detection Rate (%)	11.6	8.8
	False Notification Rate (%)	67.8	63.3

Type of Notification	Notification Status	15 Minutes Interval	30 Minutes Interval
Threshold or Impending Notification of Hyperglycaemic Events at 13.3 mmol/L	Detection Rate (%)	89.4	92.1
	Missed Detection Rate (%)	10.6	7.9
	False Notification Rate (%)	27.4	25.2

### How to factor this into treatment decisions

- Don't rely on just one piece of information. Always use all the information on the screen for a treatment decision.
- Do a blood glucose test if you see a Low Glucose or Glucose Going Low message.

## Glucose Message *(See Tables 11 and 12)*

### What to know:

Sometimes you may receive an incorrect Glucose Message or no Glucose Message when you should get one. **Tables 11 and 12** highlight the accuracy of the Threshold notifications (Low and High Glucose messages) and Impending notifications (Glucose Going Low and Glucose Going High messages) with respect to three different parameters:

- Detection rate – amount of time a Glucose Message displays correctly.
- Missed detection rate – amount of time a Glucose Message did not display when it should have.
- False notification rate – amount of time a Glucose Message displays when it shouldn't have.

**IMPORTANT:** Glucose Messages only appear when you scan your Sensor. You will not automatically get low and high glucose warnings.

### What to know about Table 11:

The 15 minute interval column in **Table 11** shows the Sensor's ability to issue a Low Glucose or High Glucose message within 15 minutes before or after the true low or high blood glucose value.

The 30 minute interval column in **Table 11** shows the Sensor's ability to issue a Low Glucose or High Glucose message within 30 minutes before or after the true low or high blood glucose value.

#### **Low Glucose**

When your blood glucose\* is low, you should note the following:

- 82.9% of the time the Sensor will correctly display a Low Glucose message
- 17.1% of the time the Sensor will not display a Low Glucose message

\* Percentages are based on comparison between Sensor glucose and true blood glucose values within 30 minutes before or after true low glucose.

If you receive a Low Glucose message\*, you should note the following:

- 53.5% of the time this Glucose Message is wrong
- 46.5% of the time this Glucose Message is correct

\* Percentages are based on comparison between Sensor glucose and true blood glucose values within 30 minutes before or after the Low Glucose message.

**Note:** This high false notification rate for low glucose is an important indicator of why it is crucial to confirm Low Glucose messages with a blood glucose test before making any treatment decisions.

Continue to review the information about Glucose Message performance with your patient.



## Glucose Message (See Tables 11 and 12)

### What to know about Table 11 (cont.):

#### High Glucose

When your blood glucose\* is high, you should note the following:

- 92.0% of the time the Sensor will correctly display a High Glucose message
- 8.0% of the time the Sensor will not display a High Glucose message

\* Percentages are based on comparison between Sensor glucose and true blood glucose values within 30 minutes before or after true high glucose.

If you receive a High Glucose message\*, you should note the following:

- 13.5% of the time this Glucose Message is wrong
- 86.5% of the time this Glucose Message is correct

\* Percentages are based on comparison between Sensor glucose and true blood glucose values within 30 minutes before or after the High Glucose message.

### What to know about Table 12:

The 15 minute interval column in **Table 12** shows the Sensor's ability to issue a Low Glucose, High Glucose, Glucose Going Low, or Glucose Going High message up to 15 minutes before the true low or high blood glucose value.

The 30 minute interval column in **Table 12** shows the Sensor's ability to issue a Low Glucose, High Glucose, Glucose Going Low, or Glucose Going High message up to 30 minutes before the true low or high blood glucose value.

#### Low Glucose or Glucose Going Low

When your blood glucose\* is low or going low, you should note the following:

- 91.2% of the time the Sensor will correctly display a Low Glucose or Glucose Going Low message
- 8.8 % of the time the Sensor will not display a Low Glucose or Glucose Going Low message

\* Percentages are based on comparison between Sensor glucose and true blood glucose values up to 30 minutes before true low glucose.

If you receive a Low Glucose or Glucose Going Low message\*, you should note the following:

- 63.3 % of the time this Glucose Message is wrong
- 36.7 % of the time this Glucose Message is correct

\* Percentages are based on comparison between Sensor glucose and true blood glucose values up to 30 minutes before the Low Glucose or Glucose Going Low message.

Continue to review the information about Glucose Message performance with your patient.



## Glucose Message *(See Tables 11 and 12)*

### What to know about Table 12 (cont.):

#### High Glucose or Glucose Going High

When your blood glucose\* is high or going high, you should note the following:

- 92.1% of the time the Sensor will correctly display a High Glucose or Glucose Going High message
- 7.9% of the time the Sensor will not display a High Glucose or Glucose Going High message

\* Percentages are based on comparison between Sensor glucose and true blood glucose values up to 30 minutes before true high glucose.

If you receive a High Glucose or Glucose Going High message\*, you should note the following:

- 25.2% of the time this Glucose Message is wrong
- 74.8% of the time this Glucose Message is correct

\* Percentages are based on comparison between Sensor glucose and true blood glucose values up to 30 minutes before the High Glucose or Glucose Going High message.

### Why it happens:

Some individual Sensors may read greater than 20% higher or lower than true blood glucose. Since the Sensor glucose readings may not match blood glucose, the Glucose Messages may differ as well. The Sensor is least accurate at low blood glucose levels, which is illustrated by the rate of missed Low Glucose messages and high rate of false Low Glucose messages (**Table 11**).

## Example Scenarios

The page on the right contains example scenarios designed to help your patient understand how to use FreeStyle LibreLink with the FreeStyle Libre Sensor to make treatment decisions. Below are some talking points for each scenario.

### ***After breakfast***

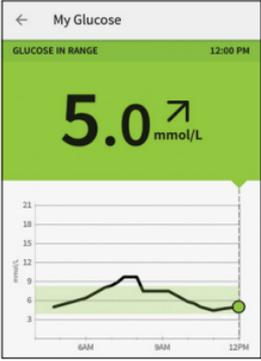
In the after breakfast scenario, the  symbol displays. Make sure your patient understands that whenever they see the  symbol, they must do a blood glucose test before making treatment decisions.

### ***Before lunch***

In the before lunch scenario, glucose is within target range but is rising. If appropriate, provide recommendations or guidance on how to modify rapid-acting insulin doses based on the Glucose Trend Arrow and the Glucose Graph. You may want to be more specific than 'take a little more' when the arrow and graph are trending up.

## Example Scenarios

Below are some example scenarios. They show why it is important to use **all the information on your screen** before deciding what to do or what treatment decision to make. If you are not sure about what to do, consult your health care professional.

What you see	What it means
<p data-bbox="149 333 319 360"><b>After breakfast</b></p>  <p>The screenshot shows a mobile app interface titled 'My Glucose'. At the top, there is a red banner with a white exclamation mark icon, the text 'LOW GLUCOSE', and the time '9:30 AM'. Below this, the current glucose reading is '3.5 mmol/L' with a downward-pointing trend arrow. A small blue and red icon is visible to the left of the reading. Below the reading is a line graph showing glucose levels over time. The y-axis is labeled 'mmol/L' and ranges from 3 to 21. The x-axis has markers for 8AM, 9AM, and 10AM. The graph shows a baseline around 4 mmol/L, a rise to a peak of approximately 11 mmol/L at 9AM, and then a decline towards 3 mmol/L at 10AM. A red dot on the graph indicates the current reading at 9:30 AM.</p>	<p data-bbox="439 333 919 425">After breakfast, your current glucose is 3.5 mmol/L. The trend arrow shows it is going down.</p> <p data-bbox="439 429 886 529">There is also a Low Glucose message at the top of the screen and the  symbol.</p> <p data-bbox="439 538 907 638">Anytime you see the  symbol, you should do a blood glucose test before deciding what to do.</p>
<p data-bbox="149 960 288 988"><b>Before lunch</b></p>  <p>The screenshot shows a mobile app interface titled 'My Glucose'. At the top, there is a green banner with the text 'GLUCOSE IN RANGE' and the time '12:00 PM'. Below this, the current glucose reading is '5.0 mmol/L' with an upward-pointing trend arrow. Below the reading is a line graph showing glucose levels over time. The y-axis is labeled 'mmol/L' and ranges from 3 to 21. The x-axis has markers for 8AM, 9AM, and 12PM. The graph shows a baseline around 4 mmol/L, a rise to a peak of approximately 10 mmol/L at 9AM, and then a decline towards 4 mmol/L at 12PM. A green dot on the graph indicates the current reading at 12:00 PM.</p>	<p data-bbox="439 960 924 1130">Before lunch, your current glucose is 5.0 mmol/L and within target range. The graph shows that your glucose is going up and so does the trend arrow .</p> <p data-bbox="439 1139 891 1275">Consider what might be causing your glucose to go up and what you might do to prevent a high glucose. For example:</p> <ul data-bbox="425 1288 909 1430" style="list-style-type: none"> <li data-bbox="425 1288 855 1352">• How much insulin should you take before your meal?</li> <li data-bbox="425 1361 909 1430">• Since you see , should you consider taking a little more insulin?</li> </ul>

***After lunch***

In the after lunch scenario, glucose is high and rising 90 minutes after taking insulin to cover lunch and a little more since the trend arrow was ↗. Review how long to wait between rapid-acting insulin doses to avoid “insulin stacking”. Patients may have the tendency to take more insulin when they see consecutive high or rising Sensor glucose readings. If the previous insulin dose is still active in the body, “insulin stacking” and hypoglycaemia could occur.

***Before dinner***

In the before dinner scenario, glucose is within target range but is falling. If appropriate, provide recommendations or guidance on how to modify rapid-acting insulin doses based on the Glucose Trend Arrow and the Glucose Graph. You may want to be more specific than ‘take a little less’ when the arrow and graph are trending down.

## What you see

### After lunch



## What it means

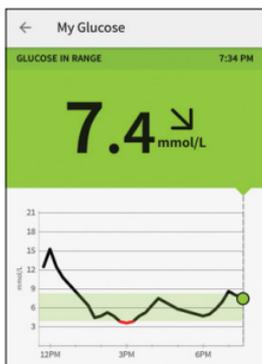
When you checked your glucose before lunch, it was 5.0 mmol/L and rising. Before eating lunch, you took enough insulin to cover the meal and a little more since your trend arrow was  $\nearrow$ . 90 minutes later, your current glucose is 12.5 mmol/L. The graph shows that your glucose is still going up, and so does the trend arrow  $\nearrow$ .

**Don't take a correction dose too close to 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.

### 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  $\searrow$ .

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  $\searrow$ , should you think about taking a little less insulin?

## Helpful Tips

Make sure your patient understands the differences between using FreeStyle LibreLink with the FreeStyle Libre Sensor and using the traditional blood glucose meters they are familiar with. For example, there may be differences between the ISF glucose as measured by the Sensor and blood glucose as measured by a blood glucose meter. Also, since the FreeStyle Libre Sensor is continually measuring glucose, it provides more information than a traditional blood glucose meter. In addition to the Current Glucose, each Sensor scan also includes a Glucose Trend Arrow that indicates which way and how fast the glucose is going, and a Glucose Graph that charts current and stored glucose readings. Patients should understand that it's important to use all of the information provided by the Sensor to make treatment decisions.

Work with your patient to put together a plan for managing their diabetes that includes when to use the FreeStyle Libre Sensor information for making treatment decisions.

Help your patient to understand how insulin works for them, including how long it takes to start working and how long it lasts in the body.

## Helpful Tips

Work with your health care professional to put together a plan for managing your diabetes that includes when to use information from the Sensor for making treatment decisions.

Some things to think about when making a treatment decision:

- Making a treatment decision doesn't just mean taking insulin. Treatment decisions can also include things like taking fast-acting carbs, eating, or even doing nothing and scanning again later.
- Scan your Sensor often to see how food, medication, and physical activity impact your Sensor glucose readings. The information you get can help you figure out why your glucose sometimes goes too high or too low, and how to prevent it from doing so in the future.
- Talk to your health care professional about how your insulin works. The more you understand about your insulin, including how long it takes to start working and how long it lasts in your body, the more likely you will be to make better treatment decisions.



*You took insulin and ate lunch.*



*Now, 90 minutes later, your glucose is high and gradually rising.*

### ***This may be normal***

*Wait until your before meal insulin has a chance to work. Sometimes it's best to do nothing and scan again later.*

*Don't take a correction dose too close to your meal dose. This may result in "insulin stacking" and low glucose.*

- Your health care professional can also help you understand when doing nothing and scanning again later is the right treatment decision. For example, 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.
- Do not use the Sensor glucose readings to make treatment decisions if the results 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 Sensor glucose reading is low, then it doesn't match your recent activity, so don't use it to make treatment decisions.

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Abbott Diabetes Care Ltd.  
Range Road  
Witney, Oxon  
OX29 0YL, UK

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