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FreeStyle Libre 2

FLASH GLUCOSE MONITORING SYSTEM

User's Manual

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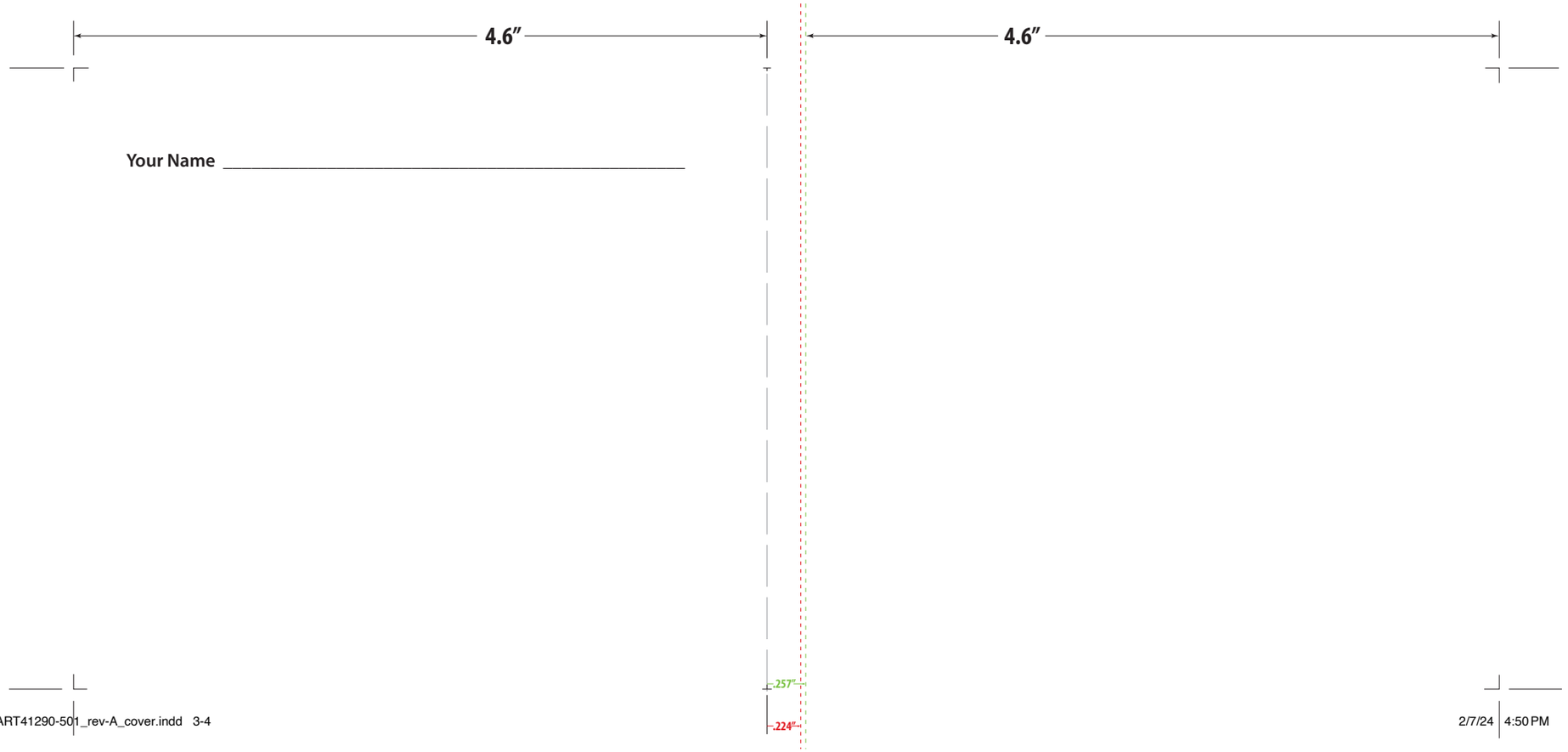


Contents

Reader Symbols

Symbol	What It Means
	Active Sensor
	Direction that your glucose is going. See *Checking Your Glucose* section for more information.
	Caution
	View previous/next screen
	Notes
	Add more information to notes
	Food note
	Rapid-acting insulin note
	Time changed on Reader
	Sound and Vibration **ON**
	Sound **ON**, Vibration **OFF**
	Sound **OFF**, Vibration **ON**
	Sound and Vibration **OFF**

Symbol	What It Means
	Sensor communicating with Reader
	Sensor not communicating with Reader
	Blood glucose or ketone test
	Settings
	Control solution test result
	Rapid-acting insulin calculator
	Details of your suggested insulin dose
	Estimated rapid-acting insulin remaining in body
	Low battery
	Battery charging
	Sensor too cold
	Sensor too hot

Important Safety Information

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.

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.

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.

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.

Getting to Know Your System

The FreeStyle Libre 2 Flash Glucose Monitoring System ('System') has two main parts: a handheld Reader and a disposable Sensor that you wear on your body. You use the Reader to wirelessly scan the Sensor and display your glucose readings. The Reader only works with FreeStyle Libre 2 Sensors and cannot be used with other Sensors. When they're in range, the Sensor and Reader automatically communicate to give you glucose alarms. These alarms are on by default. The Reader also has a built-in meter for blood glucose and ketone testing.

IMPORTANT:

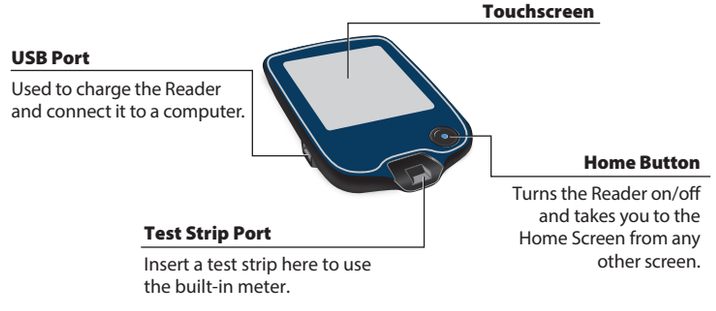
- Before you use your System, review all the product instructions. The Quick Reference Guide gives you quick access to important aspects of the System. The User's Manual includes all safety information and instructions for use.
- Go to www.FreeStyleLibre.com to view the "Tips for Kids".
- Talk to your health care professional about how you should use your Sensor glucose information to help manage your diabetes.

Your System comes in a **Reader Kit** and a **Sensor Kit**. When opening your kits, check that the contents are undamaged and that you have all parts listed. If any parts are missing or damaged, contact Customer Service.

Reader Kit

The Reader Kit includes:

- FreeStyle Libre 2 Reader
- Power Adaptor
- Quick Start Guide
- Yellow Cable USB
- User's Manual
- Quick Reference Guide



The Reader gets glucose readings from your Sensor and can issue glucose alarms. It can store approximately 90-days of glucose history and notes that you enter about activities, such as taking insulin, eating food or exercising. This information can help you understand how these activities affect your glucose.

IMPORTANT:

- If the Reader is dropped or subjected to impact, do a Reader Test to check that it is still working properly. See *Perform a Reader Test* section for instructions.
- If the Reader becomes too hot to hold, do NOT use and contact Customer Service about replacing your Reader, yellow USB cable and power adaptor.

Sensor Kit

The Sensor Kit includes:

- Sensor Pack
- Sensor Applicator
- Alcohol wipe
- Product insert

Sensor Pack
Used with the Sensor Applicator to prepare the Sensor for use.

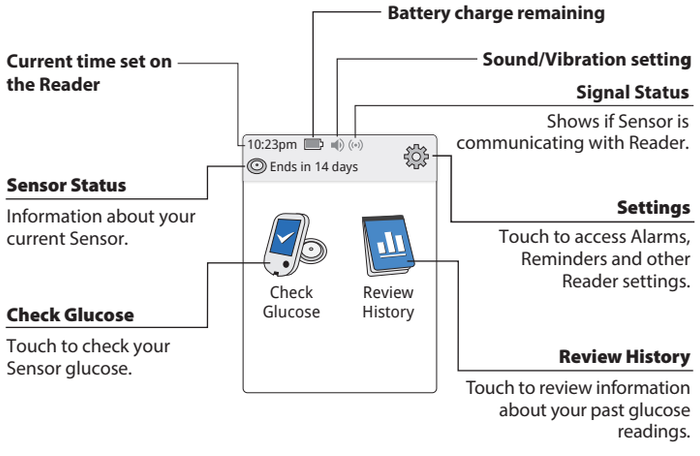
Sensor Applicator
Applies the Sensor to your body.

The Sensor measures and stores glucose readings when worn on your body. It initially comes in two parts. One part is in the Sensor Pack, and the other part is in the Sensor Applicator. By following the instructions, you prepare and apply the Sensor on the back of your upper arm. The Sensor has a small, flexible tip that is inserted just under the skin. The Sensor can be worn for up to 14 days.

Sensor
Measures your glucose while on your body (only visible after applied).

The Reader Home Screen provides access to information about your glucose and the System. You can press the Home Button to get to the Home Screen.

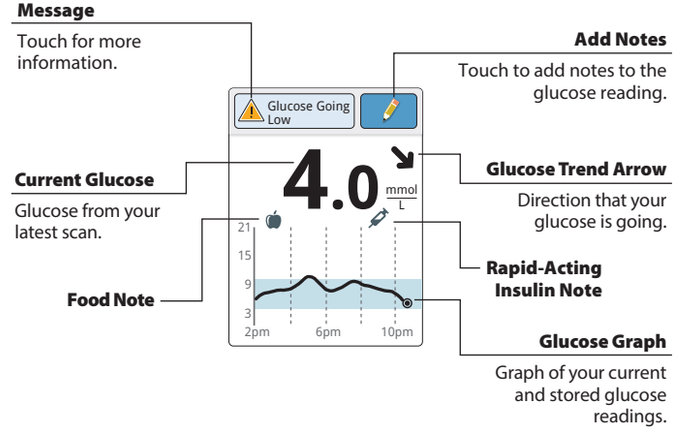
Home Screen



Note: Sound/Vibration setting and Signal Status symbols only display when any alarm is on.

The Sensor Glucose Readings screen appears after you use the Reader to scan your Sensor. Your Reading includes your Current Glucose, a Glucose Trend Arrow indicating which way your glucose is going, and a graph of your current and stored glucose readings.

Sensor Glucose Readings

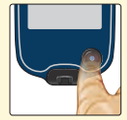
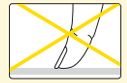


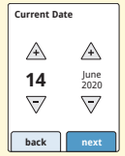
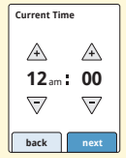
Data Management Software

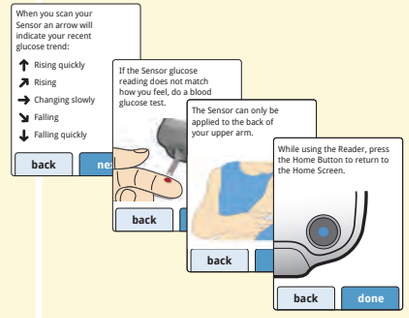
To upload data from the Reader, please visit www.FreeStyleLibre.com and learn more about the data management software that you can use.

Setting up Your Reader for the First Time

Before using the System for the first time, the Reader must be set up.

Step	Action
1	 Press the Home Button to turn on the Reader.
2	  If prompted, use the touchscreen to select your preferred language for the Reader. Touch **OK** to continue. **Note:** Use the pad of your finger. Do NOT use your fingernail or any other object on the screen.

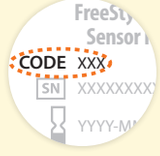
Step	Action
3	 Set the **Current Date** using the arrows on the touchscreen. Touch **next** to continue.
4	 Set the **Current Time**. Touch **next** to continue. **CAUTION:** It is very important to set the time and date correctly. These values affect the Reader data and settings.

Step	Action
5	The Reader now displays important information about key topics to help you use the System: • How to understand the Glucose Trend Arrow included on the Glucose Reading screen. • When to do a blood glucose test. • Where to apply the Sensor. • How to return to the Home Screen from any other screen.  Touch **next** to move to the next topic. At the end of the Reader setup, touch **done** to go to the Home Screen.

Using Your Sensor

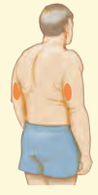
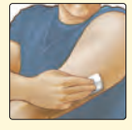
CAUTION:

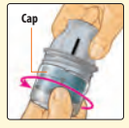
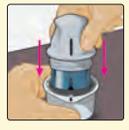
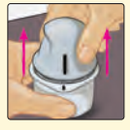
- The Sensor Pack and Sensor Applicator are packaged as a set (separately from the Reader) and have the same Sensor code. Check that the Sensor codes match before using your Sensor Pack and Sensor Applicator. Sensor Packs and Sensor Applicators with the same Sensor code should be used together or your Sensor glucose readings may be incorrect.

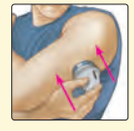


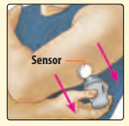
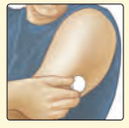
- Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. If your Sensor comes loose, you may get no readings or unreliable readings, which may not match how you feel. Follow the instructions to select an appropriate application site.

Applying Your Sensor

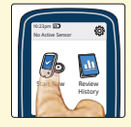
Step	Action
1	 Apply Sensors only on the back of your upper arm. Avoid areas with scars, moles, stretch marks or lumps. Select an area of skin that generally stays flat during your normal daily activities (no bending or folding). Choose a site that is at least 2.5 cm (1 inch) away from an insulin injection site. To prevent discomfort or skin irritation, you should select a different site other than the one most recently used.
2	 Wash application site for at least 10 seconds using a plain soap and dry with a towel. Make sure the site is 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. **Note:** The area **MUST** be clean and dry, or the Sensor may not stick to the site.

Step	Action
3	  Open the Sensor Pack by peeling the lid off completely. Unscrew the cap from the Sensor Applicator and set the cap aside. **CAUTION:** 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.
4	 Line up the dark mark on the Sensor Applicator with the dark mark on the Sensor Pack. On a hard surface, press down firmly on the Sensor Applicator until it comes to a stop.
5	 Lift the Sensor Applicator out of the Sensor Pack.

Step	Action
6	 The Sensor Applicator is prepared and ready to apply the Sensor. **CAUTION:** The Sensor Applicator now contains a needle. Do NOT touch inside the Sensor Applicator or put it back into the Sensor Pack.
7	 Place the Sensor Applicator over the prepared site and push down firmly to apply the Sensor to your body. **CAUTION:** Do NOT push down on the Sensor Applicator until placed over prepared site to prevent unintended results or injury.

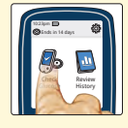
Step	Action
8	 Gently pull the Sensor Applicator away from your body. The Sensor should now be attached to your skin. **Note:** Applying the Sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the Sensor and apply a new one at a different site.
9	 Make sure that the Sensor is secure after application. Put the cap back on the Sensor Applicator. Discard the used Sensor Pack and Sensor Applicator according to local regulations.

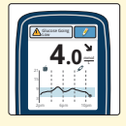
Starting Your Sensor

Step	Action
1	 Press the Home Button to turn on the Reader.
2	 Touch **Start New Sensor**. **Note:** Before you start your Sensor, choose which device you want to use. If you start the Sensor with the Reader, you will be unable to use an app to check your glucose or receive alarms.

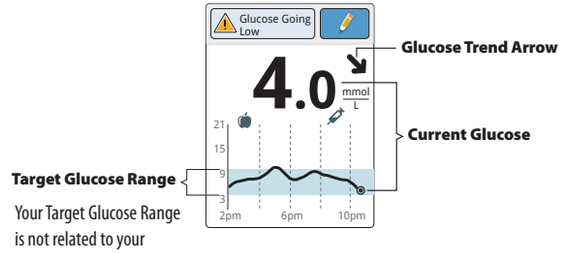
Step	Action
3	 Hold the Reader within 4 cm (1.5 inches) of the Sensor to scan it. This starts your Sensor. If sounds are turned on, the Reader beeps when the Sensor has been successfully activated. The Sensor can be used to check your glucose after 60 minutes. **CAUTION:** Low and High Glucose Alarms are not available during the 60 minute startup period. **Note:** If the Sensor is not successfully scanned within 15 seconds, the Reader displays a prompt to scan the Sensor again. Touch **OK** to return to the Home Screen and touch **Start New Sensor** to scan your Sensor

Checking Your Glucose

Step	Action
1	 *OR*  Turn the Reader on by pressing the Home Button or touch **Check Glucose** from the Home Screen.
2	 Hold the Reader within 4 cm (1.5 inches) of your Sensor to scan it. Your Sensor wirelessly sends glucose readings to the Reader. If sounds are turned on, the Reader beeps when the Sensor has been successfully scanned. **Note:** If the Sensor is not successfully scanned within 15 seconds, the Reader displays a prompt to scan the Sensor again. Touch **OK** to return to the Home Screen and touch **Check Glucose** to scan your Sensor.

Step	Action
3	 The Reader displays your current glucose reading along with your glucose graph and an arrow indicating the direction that your glucose is going.

Sensor Glucose Readings



Your Target Glucose Range is not related to your glucose alarm settings.

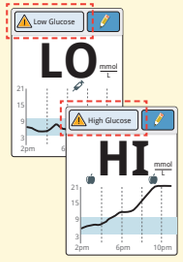
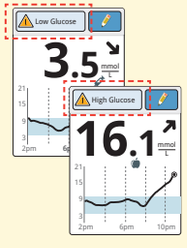
Notes:

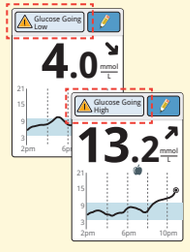
- The graph displays glucose readings up to 21 mmol/L. Glucose readings above 21 mmol/L are displayed at 21 mmol/L.
- The ◷ symbol may appear, indicating that the Reader time was changed. Gaps in the graph may result or glucose readings may be hidden.
- All available glucose data is used to make your graph, so you can expect to see some differences between the graph line and previous current glucose readings.
- A Sensor can store up to 8 hours of glucose data, so scan it at least once every 8 hours to capture all of your available glucose data.
- The Reader's glucose graph does not display your glucose alarm levels.

The Glucose Trend Arrow gives you an indication of the direction that your glucose is going.

↑	**Glucose is rising quickly** (more than 0.1 mmol/L per minute)
↗	**Glucose is rising** (between 0.06 and 0.1 mmol/L per minute)
→	**Glucose is changing slowly** (less than 0.06 mmol/L per minute)
↘	**Glucose is falling** (between 0.06 and 0.1 mmol/L per minute)
↓	**Glucose is falling quickly** (more than 0.1 mmol/L per minute)

The following table shows messages that you may see with your glucose readings.

Display	What To Do
	If **LO** appears on the Reader, your reading is lower than 2.2 mmol/L. If **HI** appears on the Reader, your reading is higher than 22.2 mmol/L. You can touch the message button for more information. Check your blood glucose on your finger with a test strip. If you get a second **LO** or **HI** result, contact your health care professional **immediately**.
	If your glucose is higher than 13.3 mmol/L or lower than 3.9 mmol/L, you will see a message on the screen. You can touch the message button for more information and set a reminder to check your glucose.

Display	What To Do
	If your glucose is projected to be higher than 13.3 mmol/L or lower than 3.9 mmol/L within 15 minutes, you will see a message on the screen. You can touch the message button for more information and set a reminder to check your glucose.

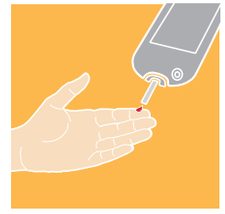
Notes:

- If you are not sure about a message or reading, contact your health care professional before you do anything.
- Messages you receive with your glucose readings (LO, HI, Low Glucose, High Glucose, Glucose Going Low, Glucose Going High) are only shown when you scan your Sensor and are not related to your glucose alarm settings.

Making Treatment Decisions

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

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.

Making Treatment Decisions - Getting Started

Before you start using the System for treatment decisions, make sure you have a good understanding of how the System works for your body. **Continue to use your blood glucose meter for treatment decisions until you are comfortable with the information you receive from your System.** This includes understanding that: Sensor performance can vary in between Sensors, within a Sensor wear period and in different situations.

Getting familiar with the System could take days, weeks or even months. The more you check readings from the System with a blood glucose meter, the better you will understand how the System works for you.

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

Helpful Tips

- Confirm your Sensor glucose readings with a blood glucose meter until you understand:
  - Sensor accuracy may vary between Sensors. Some individual Sensors may read higher or lower than true blood glucose levels. This may be temporary. For example, when glucose is going up or down quickly. Alternatively, it could apply to all Sensor glucose readings over the 14-day wear period due to variability in factory calibration and changes in the Sensor during storage.
  - Sensor accuracy may vary during a Sensor wear session.
  - Sensor accuracy may vary in different situations (meals, exercise, first day of use, etc.). 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.
- Scan your Sensor often to see how carbs, medication, exercise, illness or stress levels 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.
- 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.
- Your health care professional can also help you to 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. Avoid 'insulin stacking'.

When not to use Sensor Glucose readings for treatment decisions

No Current Glucose number

When there is no Current Glucose number, such as when you receive an error message or a LO or HI result, you don't have enough information to make a treatment decision. Do a blood glucose test and treat based on that result.

Think your readings are incorrect?

Don't trust Sensor glucose readings that you think may be incorrect or that 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 glucose reading is low, then it doesn't match your recent activity, so don't use it to make treatment decisions. Don't make treatment decisions if you think your Sensor glucose readings are incorrect. Do a blood glucose test and treat based on that result.

Symptoms don't match readings

There may be times when your symptoms don't match your Sensor glucose readings. For example, you are feeling shaky, sweaty and dizzy – symptoms you generally get when you have low glucose, but your glucose reading is within your target range. When symptoms don't match readings, do a blood glucose test and treat based on that result. Don't ignore symptoms that may be due to low or high blood glucose.

If you're the caregiver, pay attention to times when the symptoms of the one you're caring for don't match their Sensor glucose readings. When symptoms don't match readings, do a blood glucose test and treat based on that result.

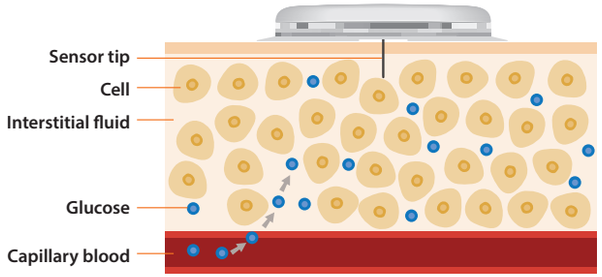
If you continue to feel that Sensor glucose readings are not correct, compare the blood glucose result to the Sensor glucose reading. You'll know the Sensor is performing correctly if these results are within 20% of each other (for example, when the Sensor reads 10.0 mmol/L, the blood glucose result 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 a blood glucose meter instead of the Sensor and try the check again later. If the problem continues, keep using the blood glucose meter instead of the Sensor and contact your health care professional for guidance on when you can use the Sensor.

When to do nothing and scan again later

Your health care professional can 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.
Don't take a correction dose within 2 hours of your meal dose. This may result in 'insulin stacking' and low glucose.

Understanding the Difference between ISF Glucose and Blood Glucose

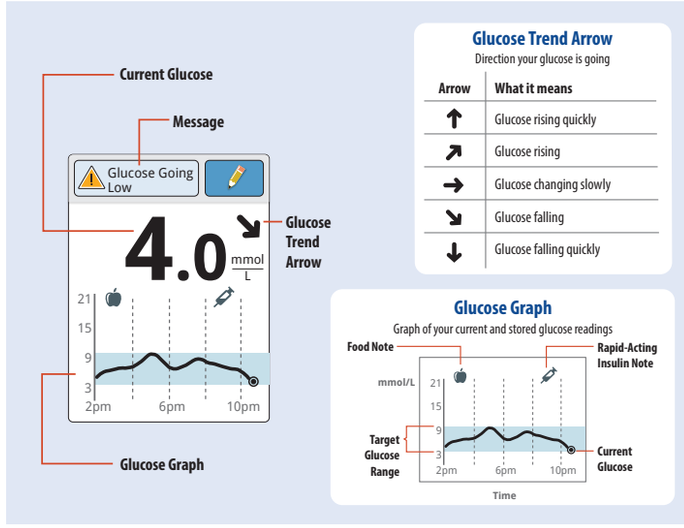
Please contact your health care professional if you need help understanding the information on this page. The Sensor measures interstitial fluid (ISF) instead of blood glucose. ISF glucose levels tend to lag behind blood glucose levels because it can take a few minutes for glucose to move from the blood 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.



For illustrative purposes only. Image not drawn to scale.

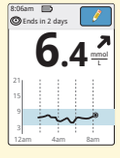
Using Your Glucose Reading to Make a Treatment Decision

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

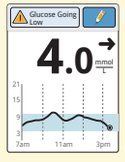


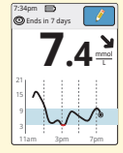
Example Scenarios

Next are some example scenarios to help you understand how to use the information on your screen. Always use all of the information on the 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
Before breakfast: 	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 ↗. 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?

What you see	What it means
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 ↗.
After lunch: 	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.

What you see	What it means
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**.
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.

What you see	What it means
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?

Alarms

When in range of the Reader, your Sensor automatically communicates with the Reader to give you Low and High Glucose Alarms. These alarms are on by default.

This section explains how to set and use alarms as well as how to turn them off. Please read all the information in this section before setting and using alarms.

CAUTION:

- 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 the Reader has sufficient charge and that sound and/or vibration are turned on.

IMPORTANT: What you need to know about glucose alarms

- The Sensor itself will not issue alarms.
- Scan your Sensor often to check your glucose. If you get a Low or High Glucose Alarm, you must obtain a glucose result to determine what to do next.
- The Low and High Glucose Alarms should not be used exclusively to detect low or high glucose conditions. The glucose alarms should always be used along with your current glucose, glucose trend arrow and glucose graph.
- Low and High Glucose Alarm levels are different from your Target Glucose Range values. Low and High Glucose Alarms tell you when your glucose has passed the level you set in the alarm. Your Target Glucose Range is displayed on glucose graphs on the Reader and used to calculate your Time In Target.
- Make sure the Signal Loss Alarm is turned on so you will be notified if the System is unable to provide Low or High Glucose alarms.

IMPORTANT: How to prevent missed alarms

- Alarms must be kept on for you to receive them and you should ensure that your Reader is within 6 metres (20 ft) of you at all times. The Sensor itself will not issue alarms.
- If the Sensor is not communicating with the Reader, you will not receive glucose alarms, and you may miss detecting low glucose or high glucose episodes. You will see the symbol on the Home screen when the Sensor is not communicating with the Reader. The symbol will also display when the System is unable to calculate a glucose reading due to an error. A message on the screen will give you directions to resolve the error. Make sure the Signal Loss Alarm is on so you will be notified if your Sensor has not communicated with the Reader for 20 minutes.
- Make sure the Reader's sound and/or vibration settings are on and your Reader is near you. The Home screen indicates the sound/vibration setting when any alarm is on:

  Sound and Vibration **ON**

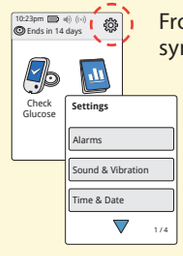
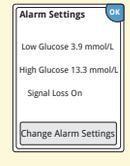
  Sound **ON**, Vibration **OFF**

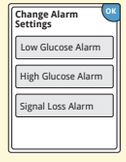
  Sound **OFF**, Vibration **ON**

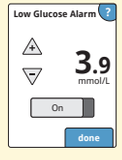
  Sound and Vibration **OFF**

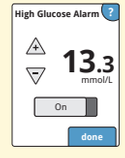
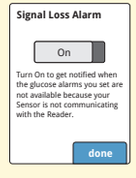
Setting Alarms

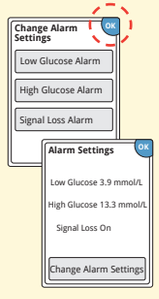
Work with your health care professional to determine your alarm settings.

Step	Action
1	 From the Home Screen, touch the Settings symbol. Touch **Alarms**.
2	 Touch **Change Alarm Settings**.

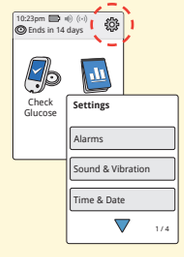
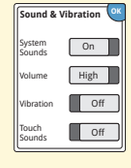
Step	Action
3	 Select the alarm that you want to set or turn off. Low Glucose Alarm: Notifies you when your glucose is below the level you set. High Glucose Alarm: Notifies you when your glucose is above the level you set. Signal Loss Alarm: Notifies you when your Sensor is not communicating with the Reader and that you will not receive Low or High Glucose Alarms.

Alarm	How to Set
Low Glucose Alarm	The Low Glucose Alarm is on by default. The alarm level is initially set to 3.9 mmol/L. You can use the arrows to change this value between 3.3 mmol/L and 5.6 mmol/L. If the alarm is on, you will be notified when your glucose falls below the level you set. Touch the slider to turn the alarm off.  Touch **done** to save.

Alarm	How to Set
High Glucose Alarm	The High Glucose Alarm is on by default. The alarm level is initially set to 13.3 mmol/L. You can use the arrows to change this value between 6.7 mmol/L and 22.2 mmol/L. If the alarm is on, you will be notified when your glucose rises above the level you set. Touch the slider to turn the alarm off.  Touch **done** to save.
Signal Loss Alarm	If the alarm is on, you will be notified when your Sensor has not communicated with your Reader for 20 minutes and you are not receiving Low or High Glucose Alarms. Touch the slider to turn the alarm off.  Touch **done** to save.

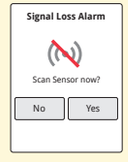
Step	Action
4	 When you are finished setting your alarms, touch **OK**. The Alarms Settings screen now shows your current alarm settings. Touch **OK** to return to the main settings menu, or touch **Change Alarm Settings** to make additional updates.

Setting Alarm Sounds

Step	Action
1	 From the Home Screen, touch the Settings symbol ⚙. Touch **Sound & Vibration** to change the alarm sounds.
2	 Touch the sound or vibration setting that you would like to change. **Note:** These settings apply to the alarms as well as other Reader functions. Touch **OK** to save.

Using Alarms

What you See	What it Means
	The Low Glucose Alarm notifies you if your glucose drops below the level that you set. The alarm does not include your glucose reading, so you need to scan your Sensor to check your glucose. Touch **Dismiss Alarm & Check Glucose** or press the Home Button to dismiss the alarm and check your glucose. You will only receive one alarm per low glucose episode.
	The High Glucose Alarm notifies you if your glucose rises above the level you set. The alarm does not include your glucose reading, so you need to scan your Sensor to check your glucose. Touch **Dismiss Alarm & Check Glucose** or press the Home Button to dismiss the alarm and check your glucose. You will only receive one alarm per high-glucose episode.

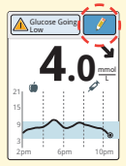
What you See	What it Means
	The Signal Loss Alarm notifies you if your Sensor has not communicated with the Reader for 20 minutes and you are not receiving Low or High Glucose Alarms. Signal loss could be caused by the Sensor being too far away from the Reader (over 6 metres (20 ft)) or another issue such as an error or problem with your Sensor or Reader. Touch **No** to dismiss the alarm. Touch **Yes** or press the Home Button to dismiss the alarm and scan the Sensor.

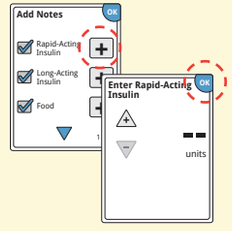
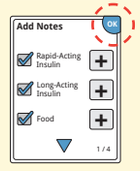
Notes:

- If you ignore an alarm, you will receive it again in 5 minutes if the condition still exists.
- If you receive an alarm while the Reader is connected to a computer, you must first unplug the Reader to scan the Sensor.

Adding Notes

Notes can be saved with your glucose readings. You can add a note at the time of your glucose reading or within 15 minutes after your reading was obtained. You can track food, insulin, exercise and any medication that you take.

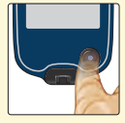
Step	Action
1	 From the Glucose Reading screen, add notes by touching the symbol in the upper right corner of the touchscreen. If you do not want to add notes, you can press the Home Button to go to the Home Screen or hold the Home Button to turn the Reader off.
2	 Select the tick box next to the notes that you would like to add. Touch the down arrow to view other note options.

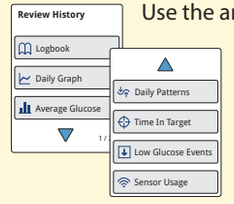
Step	Action
3	 After you tick the box for food and insulin notes, the ⊞ symbol appears to the right of the note. You can touch it to add more specific information to your note. Then touch **OK**. • Insulin notes: Enter the number of units taken. • Food notes: Enter grams or carb portion information. **Note:** Food and rapid-acting insulin notes are shown on your glucose graphs and in your Logbook as symbols.
4	 Touch **OK** to save your notes.

You can review your notes from the Logbook. See *Reviewing Your History* section for more information.

Reviewing Your History

Reviewing and understanding your glucose history can be an important tool for improving your glucose control. The Reader stores about 90 days of information and has several ways to review your past glucose readings, notes and other information.

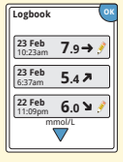
Step	Action
1	  Press the Home Button to turn on the Reader. Press the Home Button again to go to the Home Screen.
2	 Touch the **Review History** icon.

Step	Action
3	 Use the arrows to view the available options.

IMPORTANT: Work with your health care professional to understand your glucose history.

The Logbook and Daily Graph show detailed information, while other history options show summaries of information over a number of days.

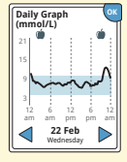
Logbook



Entries for each time that you have scanned your Sensor or performed a blood glucose or ketone test. If you have entered Notes with a glucose reading, the symbol appears in that row. For more information about the symbols, see *Reader Symbols* section.

Touch the entry to review the detailed information, including any Notes you entered. You can edit (change) Notes for the most recent Logbook entry, provided your glucose reading was within the last 15 minutes.

Daily Graph



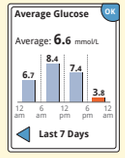
A graph of your Sensor glucose readings by day. The graph shows your Target Glucose Range and symbols for food or rapid-acting insulin notes you have entered.

Notes:

- The graph displays glucose readings up to 21 mmol/L. Glucose readings above 21 mmol/L are displayed at 21 mmol/L.
- You might see gaps in the graph during times when you have not scanned at least once in 8 hours.
- The symbol may appear indicating the Reader time was changed. Gaps in the graph may result or glucose readings may be hidden.

Other History Options

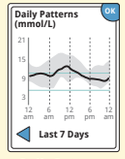
Use the arrows to view information about your last 7, 14, 30 or 90 days.



Average Glucose

Information about the average of your Sensor glucose readings. The overall average for the time is displayed above the graph. The average is also shown for four different 6-hour periods of the day.

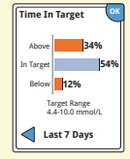
Readings above or below your Target Glucose Range are orange, while readings in range are blue.



Daily Patterns

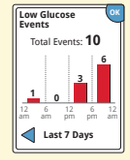
A graph showing the pattern and variability of your Sensor glucose over a typical day. The thick black line shows the median (midpoint) of your glucose readings. The gray shading represents a range (10-90 percentiles) of your Sensor readings.

Note: Daily Patterns needs at least 5 days of glucose data.



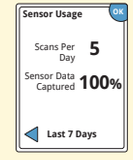
Time In Target

A graph showing the percentage of time your Sensor glucose readings were above, below or within your Target Glucose Range.



Low Glucose Events

Information about the number of low glucose events measured by your Sensor. A low glucose event is recorded when your Sensor glucose reading is lower than 3.9 mmol/L for 15 minutes or longer. The total number of events is displayed above the graph. The bar graph displays the low glucose events in four different 6-hour periods of the day.



Sensor Usage

Information about how often you scan your Sensor. The Reader reports an average of how many times you scanned your Sensor each day and the percentage of possible Sensor data the Reader recorded from your scans.

Removing Your Sensor

Step	Action
1	 Pull up the edge of the adhesive that keeps your Sensor attached to your skin. Slowly peel away from your skin in one motion. **Note:** Any remaining adhesive residue on the skin can be removed with warm soapy water or isopropyl alcohol.
2	Discard the used Sensor according to local regulations. See *Disposal* section. When you are ready to apply a new Sensor, follow the instructions in the *Applying Your Sensor* and *Starting Your Sensor* sections. If you removed your last Sensor before 14 days of use, you will be prompted to confirm that you would like to start a new Sensor when you first scan it.

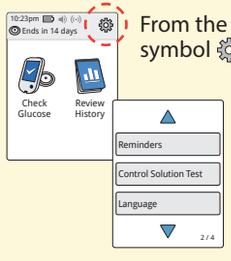
Replacing Your Sensor

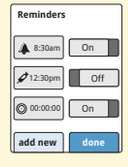
Your Sensor automatically stops working after 14 days of wear and must be replaced. You should also replace your Sensor if you notice any irritation or discomfort at the application site or if the Reader reports a problem with the Sensor currently in use. Taking action early can keep small problems from turning into larger ones.

CAUTION: 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.

Using Reminders

You can use Reminders to help you remember things like checking your glucose or taking insulin.

Step	Action
1	 From the Home Screen, touch the Settings symbol . Scroll down using the arrow and touch **Reminders**.
2	 Touch to select which **Type** of reminder you want to set: Check Glucose, Take Insulin or Other, which is a general reminder to help you remember something.

Step	Action
3	Touch to select how often you want the reminder to **Repeat**: Once, Daily or Timer. **Note:** You can set the reminders for a specific time (e.g. 8:30 am) or as a timer (e.g. 3 hours from the current time).
4	Set the reminder **Time** using the arrows on the touchscreen. Touch **save**.
5	 From the Reminders screen, you can turn the reminder **On/Off** or **add new** reminders. Touch **done** to return to the Home Screen.

You will get your reminder even if the Reader is turned off. Touch **OK** to dismiss your reminder or **snooze** to be reminded again in 15 minutes.

Note: Reminders will not appear if the Reader is connected to a computer.

Using the Built-in Meter

The Reader has a built-in meter that can be used to test your blood glucose and blood ketone or to test the meter and strips with control solution.

> **WARNING:** Do NOT use the built-in meter while the Reader is connected to an electrical outlet or a computer.

Intended Use

The FreeStyle Libre 2 Reader's built-in meter is for use outside the body only (in vitro diagnostic use) for self testing or professional use as an aid in the management of diabetes. The meter is not intended for the diagnosis of diabetes and is not intended for neonatal testing.

The FreeStyle Precision blood glucose test strips are for use with the FreeStyle Libre 2 Reader's built-in meter to qualitatively measure glucose in fresh capillary whole blood from the fingertip, the forearm, the upper arm or the base of the thumb.

The FreeStyle Precision blood β-Ketone test strips are for use with the FreeStyle Libre 2 Reader's built-in meter to qualitatively measure blood β-Ketone (Beta-Hydroxybutyrate) in fresh capillary whole blood from the fingertip.

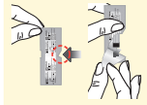
IMPORTANT:

- Use the Reader within the test strip operating temperature range as blood glucose and ketone results obtained outside the range may be less accurate.
- Use only FreeStyle Precision test strips.
- Use a test strip immediately after removing from its foil packet.
- Only use a test strip once.
- Do not use expired test strips as they may cause inaccurate results.
- Do not use a wet, bent, scratched or damaged test strip.
- Do not use the test strip if the foil packet has a hole or is torn.
- Results from the built-in meter are shown only in your Logbook and not in other history options.
- Refer to your lancing device instructions for use for how to use your lancing device.

Blood Glucose Testing

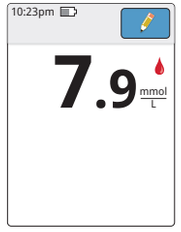
You can use the built-in meter to check your blood glucose, whether you are wearing a Sensor or not. You can perform a blood glucose test on your fingertip or approved alternative site. Be sure to read the test strip instructions for use prior to using the built-in meter.

Step	Action
1	 **CAUTION:** If you think you have low glucose (hypoglycaemia) or you suffer from hypoglycaemia unawareness, test on your fingers. Wash your hands and the test site with warm, soapy water for accurate results. Thoroughly dry your hands and the test site. To warm the site, apply a warm, dry pad or rub vigorously for a few seconds. **Note:** Avoid moles, veins, tendons, areas near bones and areas with lots of hair. If you get a bruise, consider selecting another site.

Step	Action
2	 E.g. Expiry date: 31 March 2021 Check the test strip expiry date.
3	 Open the foil test strip packet at the notch and tear down to remove the test strip. Use the test strip immediately after removing from the foil packet.
4	 Insert the test strip with the three black lines at the end facing up. Push the strip in until it stops.
5	 Use your lancing device to obtain a blood drop and apply blood to the white area at the end of the test strip. If sounds are turned on, the Reader beeps once to let you know that you have applied enough blood. **Note:** See test strip instructions for use for re-application instructions.

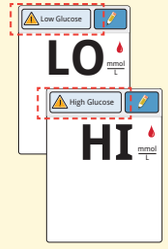
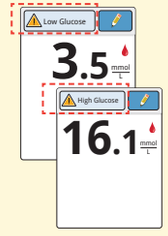
Step	Action
	 You will see a butterfly on the screen while you wait for your result. If sounds are turned on, the Reader beeps once when your result is ready.
6	After reviewing your result, remove and discard the used test strip according to local regulations.

IMPORTANT: After performing a blood glucose test, wash your hands and the test site with soap and water and thoroughly dry them.



Your Blood Glucose Results
Blood glucose results are marked on the results screen and in the Logbook with the symbol.

Note: Contact your health care professional if you have symptoms that do not match your test results.

Display	What To Do
	If **LO** appears on the Reader, your result is lower than 1.1 mmol/L. If **HI** appears on the Reader, your result is higher than 27.8 mmol/L. You can touch the message button for more information. Check your blood glucose again with a test strip. If you get a second **LO** or **HI** result, contact your health care professional **immediately**.
	If your glucose is higher than 13.3 mmol/L or lower than 3.9 mmol/L, you will see a message on the screen. You can touch the message button for more information and set a reminder to check your glucose.

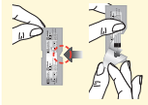
After you get your blood glucose result, you can add Notes by touching the symbol. If you do not want to add a Note, press the Home Button to go to the Home Screen or hold the Home Button to turn the Reader off.

Blood Ketone Testing

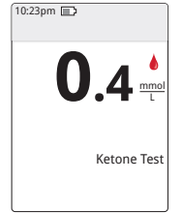
You can use the built-in meter to check your blood ketone (β-hydroxybutyrate). It is important to consider doing this when:

- You are unwell
- Your glucose is higher than 13.3 mmol/L
- You and your health care professional decide you should

Note: Be sure to read the test strip instructions for use prior to performing a ketone test.

Step	Action
1	 Wash your hands with warm, soapy water for accurate results. Thoroughly dry your hands. To warm the site, apply a warm, dry pad or rub vigorously for a few seconds. **Note:** Use only fingertip samples for blood ketone testing.
2	 E.g. Expiry date: 31 March 2021 Check the test strip expiry date.
3	 Open the foil test strip packet at the notch and tear down to remove the test strip. Use the test strip immediately after removing from the foil packet.
4	 **Note:** Use only blood ketone test strips. Do not put urine on the test strip. Insert the test strip with the three black lines facing up. Push the strip in until it stops.

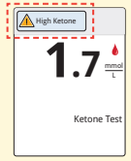
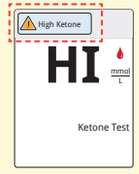
Step	Action
5	 Use your lancing device to obtain a blood drop and apply blood to the white area at the end of the test strip. If sounds are turned on, the Reader beeps once to let you know that you have applied enough blood. **Note:** See test strip instructions for use for re-application instructions.  You will see a butterfly on the screen while you wait for your result. If sounds are turned on, the Reader beeps once when your result is ready.
6	After reviewing your result, remove and discard the used test strip according to local regulations. **IMPORTANT:** After performing a blood ketone test, wash your hands with soap and water and thoroughly dry them.



Your Blood Ketone Results
Blood ketone results are marked on the results screen and in the Logbook with the word **Ketone**.

Notes:

- Blood ketone is expected to be lower than 0.6 mmol/L.
- Blood ketone may be higher when you are unwell, fasting, have exercised hard or if glucose levels are not controlled.
- If your blood ketone result remains high or becomes higher than 1.5 mmol/L, contact your health care professional **immediately**.

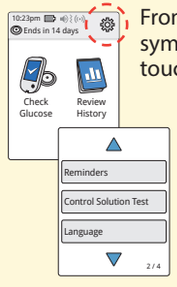
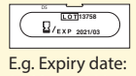
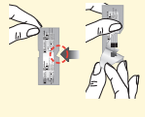
Display	What To Do
	If your blood ketone is high, you will see a message on the screen. You can touch the message button for more information.
	If **HI** appears on the Reader, your ketone result is higher than 8 mmol/L. You can touch the message button for more information. Repeat the ketone test with a new test strip. If you get a second **HI** result, contact your health care professional **immediately**.

Control Solution Testing

You should do a control solution test when you are not sure of your test strip results and want to check that your Reader and test strips are working properly. You can do a control solution test with a blood glucose or ketone test strip.

IMPORTANT:

- Control solution results should fall within the control solution range printed on the test strip instructions for use.
- Do NOT use control solution past the expiry date. Discard control solution 3 months after opening.
- The control solution range is a target range for control solution only, not for your blood glucose or ketone results.
- The control solution test does not reflect your blood glucose or ketone levels.
- Use only MediSense glucose and ketone control solution.
- Check that the LOT number printed on the test strip foil packet and instructions for use match.
- Replace the cap securely on the bottle immediately after use.
- Do NOT add water or other liquid to the control solution.
- Contact Customer Service for information on how to obtain control solution.

Step	Action
1	 From the Home Screen, touch the Settings symbol ⚙. Scroll down using the arrow and touch **Control Solution Test**.
2	 Check the test strip expiry date. E.g. Expiry date: 31 March 2021
3	 Open the foil test strip packet at the notch and tear down to remove the test strip.

Step	Action
4	 Insert the test strip with the three black lines facing up. Push the strip until it stops.
5	 Shake the control solution bottle to mix the solution. Apply a drop of control solution to the white area at the end of the test strip. If sounds are turned on, the Reader beeps once to let you know that you have applied enough control solution.  You will see a butterfly on the screen while you wait for the result. If sounds are turned on, the Reader beeps once when the result is ready.

Blood Glucose Control Solution Test

Control Solution Results
Compare the control solution result to the range printed on the test strip instructions for use. The result on your screen should be in this range.

Control solution results are marked on the results screen and in the Logbook with a symbol.

Ketone Control Solution Test

Note: Repeat the control solution test if the results are outside of the range printed on the test strip instructions for use. Stop using the built-in meter if the control solution results are repeatedly outside of the printed range. Contact Customer Service.

Using the Rapid-Acting Insulin Calculator

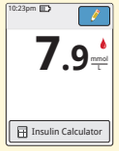
This optional feature requires an understanding of the use of insulin. Misuse or misunderstanding of this feature and the suggested dose may lead to inappropriate insulin dosing. The calculator suggests doses for rapid-acting insulin only. The calculator is only for use with fingerstick blood glucose results from the built-in meter. You cannot use the insulin calculator with Sensor glucose readings.

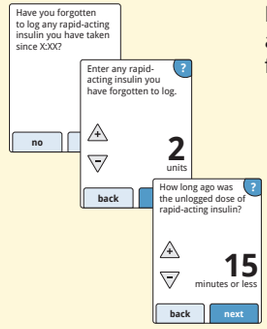
An access code is required to set up or change the rapid-acting insulin calculator settings. This access code is available only to your health care professional. Work with your health care professional to set up or change the calculator for you.

If you are not sure about the calculator's suggested dose, you can adjust it based on instructions from your health care professional.

CAUTION: The rapid-acting insulin calculator cannot account for all the factors that may affect your insulin dose. These include incorrectly entered data, incorrectly set date or time, un-logged insulin, smaller or larger meals, sickness, exercise, etc. It is important that you review your suggested dose and account for these factors before taking insulin.

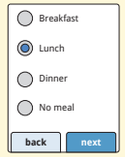
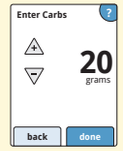
If you have added a rapid-acting insulin note to a glucose result without indicating how much insulin you took, the calculator will not be available for up to 8 hours.

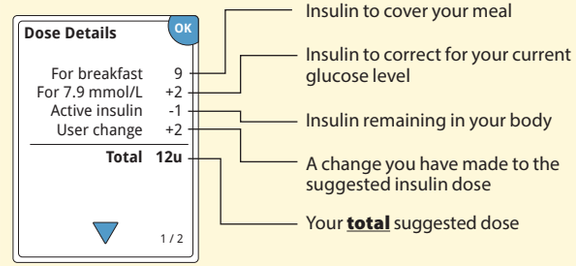
Step	Action
1	 Test your blood glucose on your finger. Touch **Insulin Calculator** from the blood glucose results screen. You can also access the insulin calculator by touching the calculator icon next to **Rapid-Acting Insulin** from the **Add Notes** screen.

Step	Action
2	 Enter information about any rapid-acting insulin that you may have forgotten to log. Touch **next**.

Notes:

- You have up to 15 minutes after testing your blood glucose to access the calculator. If the Reader turns off or if you have navigated away from the result screen, you can go to the Logbook and touch **add or edit notes** to access the calculator from your last blood glucose entry.
- If your blood glucose result is below 3.3 mmol/L, the calculator is not available.
- Do not use control solution to obtain a suggested dose.

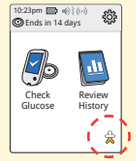
Step	Action
3	 If your calculator was programmed with **Easy** Setup, touch the meal that you plan to eat now. Touch **next**. **Or**  If your calculator was programmed with **Advanced** Setup, enter the grams of carbohydrates or carbohydrate portions you plan to eat now. Touch **done**. **Or** 

Step	Action
4	 Review your suggested dose. If needed, use the arrow buttons to adjust your suggested dose for any planned activity, a smaller or larger meal, sickness, etc. Touch the *i* symbol to see details of what is included in your suggested dose. 

Step	Action
5	Touch **log dose** to save to your Logbook and take your dose. Your dose is only saved to the Logbook if you touch **log dose**.

CAUTION: It is important to log all your rapid-acting insulin doses so your Reader can account for active insulin when calculating your suggested doses. Failure to log all your rapid-acting insulin doses may result in a suggested dose that is too high.

Note: The total dose is rounded up or down to the nearest whole number unless your health care professional has changed your Reader to count by half unit steps.



If your health care professional turned on the Active Insulin feature, the symbol may appear on your Home Screen. It shows an estimate of the amount of rapid-acting insulin left in your body and how much longer it may be active. Touch the symbol to see more information about the remaining rapid-acting insulin from your logged doses.

Estimated percentage of active insulin remaining in your body

					No symbol
100-87%	86-62%	61-37%	36-12%	11-1%	0%

Charging the Reader

A fully charged Reader battery should last up to 4 days. Your battery life may vary depending on your usage. A **Low Battery** message accompanies your result when you have enough charge remaining for about one day of use.

CAUTION:

- 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**.

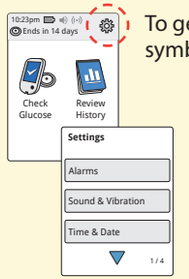
Step	Action
1	Before charging, to minimise the **risk of fire or burns**: • Check the provided power adaptor and yellow USB cable to make sure they are not damaged. • Check the Reader's USB port and make sure it is dry and free of debris.
2	 Plug the yellow USB cable into an electrical outlet using the power adaptor. Then, plug the other end of the USB cable into the USB port on the Reader.

Note:

- You must charge the Reader when the battery is low to keep using the Reader.
- To fully charge the battery, charge the Reader for at least 3 hours.
- If the Reader does not turn on after being charged or you notice a significant deterioration in battery life, contact Customer Service about replacing your Reader, yellow USB cable, and power adaptor.
- Fully charge your Reader before storing it for more than 3 months.

Changing the Reader Settings

You can go to the Settings menu to change many settings on the Reader, like alarm settings, sound & vibration, time & date and report settings. The Settings menu is also where you go to do a control solution test or to check the System status.

Step	Action
1	 To get to the Settings menu, touch the Settings symbol on the Home Screen.

Step	Action
2	Touch the setting that you want to change: **Alarms** – See *Alarms* section for information on setting alarms **Sound & Vibration** – Set Reader sound and vibration. These also apply to alarms **Time & Date** – Change the Time or Date **Reminders** – See *Using Reminders* section for information on setting reminders **Control Solution Test** – Perform a control solution test **Language** – Change the language on the Reader (option only available on Readers with multiple languages) **System Status** – Check Reader information and performance • View System Information: The Reader will display information about your System including: - Current Sensor end date and time - Reader serial number and version number - Serial numbers and status codes of most recent Sensors (up to three) - Sensor version for most recent Sensor - Number of Sensors that have been used with Reader - Number of tests that have been performed using test strips

Step	Action
2 ***(cont.)***	• View Event Logs: A list of events recorded by the Reader, which may be used by Customer Service to help troubleshoot your System • Perform a Reader Test: The Reader Test will perform internal diagnostics and allow you to check that the display is showing all pixels, sounds and vibrations are working, and the Touchscreen is responding when touched **Report Settings** – Work with your health care professional to set your Target Glucose Range, which is displayed on glucose graphs on the Reader and used to calculate your Time In Target. Your Target Glucose Range is not related to your alarm settings **Calculator Settings** – Review the currently programmed settings (option only available if your health care professional has activated your insulin calculator) **Reader Basics** – Review the information screens shown during the Reader setup **Professional Options** – Set by health care professionals only

Living With Your System

Activities

Your System can be used during a wide variety of activities.

Activity	What You Need To Know
Bathing, Showering, and Swimming	**CAUTION:** 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**. Your Sensor is water-resistant and can be worn while bathing, showering or swimming. **Note:** Do NOT take your Sensor deeper than 1 metre (3 ft) or immerse it longer than 30 minutes in water.
Sleeping	Your Sensor should not interfere with your sleep. It is recommended that you scan your Sensor before going to sleep and when you wake up because your Sensor holds 8 hours of data at a time. If you want to receive alarms or reminders while you are sleeping, place the Reader nearby. You should also make sure that sound and/or vibration is turned on.

Activity	What You Need To Know
Travelling by Air	You may use your System while on an aircraft, following any requests from the flight crew. • Some airport full-body scanners include x-ray or millimetre radio-wave, which you cannot expose your Sensor to. The effect of these scanners has not been evaluated, and the exposure may damage the Sensor or cause inaccurate results. To avoid removing your Sensor, you may request another type of screening. If you do choose to go through a full-body scanner, you must remove your Sensor. • The Sensor can be exposed to common electrostatic (ESD) and electromagnetic interference (EMI), including airport metal detectors. You can keep your Reader on while going through these. **Note:** If you are changing time zones, you can change the time and date settings on the Reader by touching the Settings symbol ⚙ from the Home Screen, then **Time & Date**. Changing the time and date affects the graphs and statistics.

Activity	What You Need To Know
Travelling by Air ***(cont.)***	The 🕒 symbol may appear on your glucose graph indicating the Reader time was changed. Gaps in the graph may result or glucose readings may be hidden.

Cleaning and Disinfection

Step	Action
1	**Cleaning** For cleaning, wipe the outside surfaces of the Reader with a disinfectant wipe until the Reader is visibly clean. Avoid forcing liquids into test strip port or other openings. Dry with a drying towel and discard wipe. Clean your Reader once a day when visibly dirty.

Step	Action
2	**Disinfection** Select new bleach wipe (disinfectant towels containing 0.55% Sodium Hypochlorite (NaOCl) have been found to be effective) and remove excess liquid from the wipe. Wipe the outer surfaces of the Reader with the wipe. Avoid getting bleach solution in test strip or USB ports as this may damage the Reader. Surfaces must remain wet for a full one (1) minute. Disinfect your Reader at least once a week.
3	Allow the Reader to air dry completely before using.

Step	Action
4	When finished, thoroughly wash your hands with soap and water. If you require assistance, contact Customer Service.

CAUTION: Do NOT place the Reader in water or other liquids. Avoid getting dust, dirt, blood, control solution, water or any other substance in the test strip or USB port as this may cause the Reader to not function properly and may lead to **risk of fire or burns**.

IMPORTANT: Do NOT use the Reader if you notice any signs of deterioration on the Reader (such as clouding or crazing on the display of the Reader, corroding, eroding or swelling of the plastic housing, or cracking of plastic housing or display) or if the Reader does not turn on. Contact Customer Service about replacing your Reader.

Maintenance

The System has no serviceable parts.

Disposal

This product should be disposed of in accordance with all applicable local regulations related to the disposal of electronic equipment, batteries, sharps and materials potentially exposed to body fluids. Contact Customer Service for further information on the appropriate disposal of system components.

Troubleshooting

This section lists problems or observations that you may have, the possible cause(s) and recommended actions. If the Reader experiences an error, a message will appear on the screen with directions to resolve the error.

Reader Does Not Power On

Problem	What It May Mean	What To Do
Reader does not power on after you press the Home Button or insert a test strip.	Reader battery is too low.	Charge the Reader.
	Reader is outside of its operating temperature range.	Move the Reader to a temperature between 10°C and 45°C and then try to power it on.

If the Reader still does not power on after trying these steps, contact Customer Service.

Problems at the Sensor Application Site

Problem	What It May Mean	What To Do
The Sensor is not sticking to your skin.	The site is not free of dirt, oil, hair or sweat.	1. Remove the Sensor. 2. Clean the site with a plain soap and water and consider shaving. 3. Follow the instructions in *Applying Your Sensor* and *Starting Your Sensor* sections.
Skin irritation at the Sensor application site.	Seams or other constrictive clothing or accessories causing friction at the site.	Ensure that nothing rubs on the site.
	You may be sensitive to the adhesive material.	If the irritation is where the adhesive touches skin, contact your health care professional to identify the best solution.

Problems Starting Your Sensor or Receiving Sensor Readings

Display	What It May Mean	What To Do
New Sensor Starting Up	Sensor is not ready to read glucose.	Wait until the 60 minute Sensor start-up period has completed.
Scan Timeout	The Reader is not held close enough to the Sensor.	Hold the Reader within 4 cm (1.5 inches) of the Sensor. Bring the screen of the Reader close to the Sensor.
Sensor Ended	The Sensor life has ended.	Apply and start a new Sensor.
Signal Loss Alarm	Sensor has not automatically communicated with the Reader in the last 20 minutes.	Make sure that the Reader is within 6 metres (20 ft) of the Sensor. Try scanning the Sensor to get a glucose reading. If the Signal Loss Alarm shows again after scanning your Sensor, contact Customer Service.

Display	What It May Mean	What To Do
New Sensor Found	You scanned a new Sensor before your previous Sensor ended.	Your Reader can only be used with one Sensor at a time. If you start a new Sensor, you will no longer be able to scan your old Sensor. If you would like to begin using the new Sensor, select 'Yes'.
Scan Error	The Reader was unable to communicate with the Sensor.	Try scanning again. **Note:** You may need to move away from potential sources of electromagnetic interference.
Sensor Error	The System is unable to provide a glucose reading.	Scan again in 10 minutes.

Display	What It May Mean	What To Do
Glucose Reading Unavailable	Your Sensor is too hot or too cold.	Move to a location where the temperature is appropriate and scan again in a few minutes.
Sensor Already in Use	The Sensor was started by another device.	Your Reader can only be used with a Sensor that it started. Scan the Sensor again with the device that started it. Or, apply and start a new Sensor.
Check Sensor	The Sensor tip may not be under your skin.	Try to start your Sensor again. If Reader displays 'Check Sensor' again, your Sensor was not applied properly. Apply and start a new Sensor.
Replace Sensor	The System has detected a problem with your Sensor.	Apply and start a new Sensor.

Problems Receiving Glucose Alarms

Problem	What It May Mean	What To Do
You are not receiving glucose alarms.	You have turned alarms off.	Touch the Settings symbol and then select **Alarms**.
	The Sensor is not communicating with your Reader. or There may be a problem with your Sensor or Reader.	The Sensor must be within range (6 metres (20 ft)) of the Reader for you to receive alarms. Make sure that you are within this range. You will see the symbol at the top of the Home screen when your Sensor has not communicated with the Reader in 5 minutes. If the Signal Loss Alarm is on, you will be notified if there has been no communication for 20 minutes. Try scanning your Sensor. If the Signal Loss Alarm is on and shows again after scanning your Sensor, contact Customer Service.
	Sound/vibration are turned off.	Check the Reader's sound and vibration settings to confirm sound/vibration are on.

Problem	What It May Mean	What To Do
You are not receiving glucose alarms. *(cont.)*	You may have set an alarm level that is higher or lower than you intended.	Confirm your alarm settings are appropriate.
	You have already dismissed this type of alarm.	You will receive another alarm when a new low- or high-glucose episode starts.
	Your Sensor has ended.	Replace your Sensor with a new one.
	Your Reader battery is dead.	Charge your Reader with the included USB cable.

Blood Glucose or Ketone Error Messages

Error Message	What It May Mean	What To Do
E-1	The temperature is too hot or too cold for the Reader to work correctly.	1. Move the Reader and test strips to a location where the temperature is within the test strip operating range. (See test strip instructions for use for the appropriate range.) 2. Wait for the Reader and test strips to adjust to the new temperature. 3. Repeat the test using a new test strip. 4. If the error reappears, contact Customer Service.
E-2	Reader error.	1. Turn off the Reader. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Service.

Error Message	What It May Mean	What To Do
E-3	Blood drop is too small. or Incorrect test procedure. or There may be a problem with the test strip.	1. Review the testing instructions. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Service.
E-4	The blood glucose level may be too high to be read by the system. or There may be a problem with the test strip.	1. Repeat the test using a new test strip. 2. If the error reappears, contact your health care professional **immediately**.

Error Message	What It May Mean	What To Do
E-5	Blood was applied to the test strip too soon.	1. Review the testing instructions. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Service.
E-6	The test strip may not be compatible with the Reader.	1. Check that you are using the correct test strip for the Reader. (See test strip instructions for use to verify your strip is compatible with the Reader.) 2. Repeat the test using a test strip for use with your Reader. 3. If the error reappears, contact Customer Service.

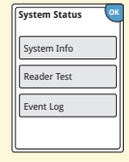
Error Message	What It May Mean	What To Do
E-7	Test strip may be damaged, used or the Reader does not recognise it.	1. Check that you are using the correct test strip for the Reader. (See test strip instructions for use to verify your strip is compatible with the Reader.) 2. Repeat the test using a test strip for use with your Reader. 3. If the error reappears, contact Customer Service.
E-9	Reader error.	1. Turn off the Reader. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Service.

Problems Checking Your Blood Glucose or Ketone

Problem	What It May Mean	What To Do
The Reader does not start a test after inserting a test strip.	Test strip is not inserted correctly or not inserted fully into the strip port.	1. With the 3 black lines facing up, insert the test strip into the strip port until it stops. 2. If the Reader still does not start a test, contact Customer Service.
	Reader battery is too low.	Charge the Reader.
	The test strip is damaged, used or unrecognisable by the Reader.	Insert a new FreeStyle Precision test strip.
	Reader is outside of its operating temperature range.	Move the Reader to a temperature between 10°C and 45°C and then try to power it on.
	Reader is in a power saving mode.	Press the Home Button then insert a test strip.

Problem	What It May Mean	What To Do
The test does not start after applying the blood sample.	Blood sample is too small.	1. See test strip instructions for use for re-application instructions. 2. Repeat the test using a new test strip. 3. If the test still does not start, contact Customer Service.
	Sample applied after the Reader turned off.	1. Review the testing instructions. 2. Repeat the test using a new test strip. 3. If the test still does not start, contact Customer Service.
	Problem with Reader or test strip.	1. Repeat the test using a new test strip. 2. If the test still does not start, contact Customer Service.

Perform a Reader Test



If you think the Reader is not working properly, you can check the Reader by performing a Reader Test. Touch the Settings symbol from the Home Screen, select **System Status** and then select **Reader Test**.

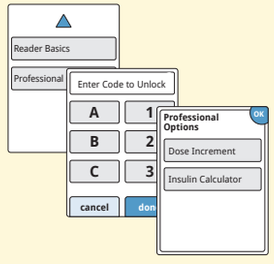
Note: The Reader Test will perform internal diagnostics and will allow you to check that the display, sounds and touchscreen are working properly.

Customer Service

Customer Service is available to answer any questions that you may have about your System. Please go to the back cover of this manual for your Customer Service phone number.

Professional Options

This section is only meant for health care professionals. It describes the access code-protected features of the Reader. Health care professionals can change dose increments or set up the insulin calculator.

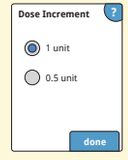


From the Home Screen, touch the Settings symbol ⚙. Scroll down using the arrows and touch **Professional Options**. Enter the access code.

Note: If you are a health care professional, contact Customer Service for more information.

Changing Dose Increments

You can set the insulin dose increments to either 1.0 or 0.5 units for use with the Rapid-acting insulin calculator and insulin notes.



From the **Professional Options** screen, select **Dose Increment**. Then choose **1** unit or **0.5** unit. Touch **done**.

Setting up the Insulin Calculator

The insulin calculator can help your patients calculate their rapid-acting insulin doses based on meal and fingerstick blood glucose level information. From the **Professional Options** screen, select **Insulin Calculator**.

> **CAUTION:** This feature requires an understanding of the use of insulin. Misuse or misunderstanding of this feature and the suggested dose may lead to inappropriate insulin dosing. The calculator suggests doses for rapid-acting insulin only.

Complete the setup to store your patient's individual insulin settings in the Reader. The calculator uses the fingerstick blood glucose results, meal information and the stored settings to calculate a suggested insulin dose based on this formula:

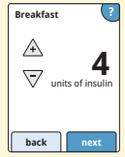
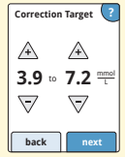
Blood glucose correction (if needed) + **Meal | Carbohydrate Intake** − **Active Insulin** (if present) = **Total suggested dose**

You can set up the insulin calculator using the Easy or Advanced settings. The Easy Setup is for patients who start with a fixed dose of rapid-acting insulin for meals. The Advanced Setup is for patients who count carbohydrates (in grams or carbohydrate portions) to adjust their rapid-acting insulin dose for meals.

You must complete all of the steps in the insulin calculator setup in order for the patient to use the calculator. When you have finished setting up the insulin calculator, you can review the settings to make sure that they are correct for your patient. You can also review settings at a later time. Touch the Settings symbol ⚙ from the Home Screen, then select **Calculator Settings**.

> **IMPORTANT:** If the time on the Reader is wrong, this may lead to an incorrect suggested dose.

Easy Setup of the Insulin Calculator

Step	Action
1	 Choose the **Easy** option on the slide bar and touch **next**. **Note:** You need to know your patient's mealtime insulin doses, target glucose range and correction factor.
2	 Enter the mealtime rapid-acting insulin doses. Touch **next** after each entry.
3	 Enter the blood glucose **Correction Target**. This is the desired target range for blood glucose values before meals. Touch **next**. **Note:** If you just want to set one target instead of a range, set both the low and high values to the same number.

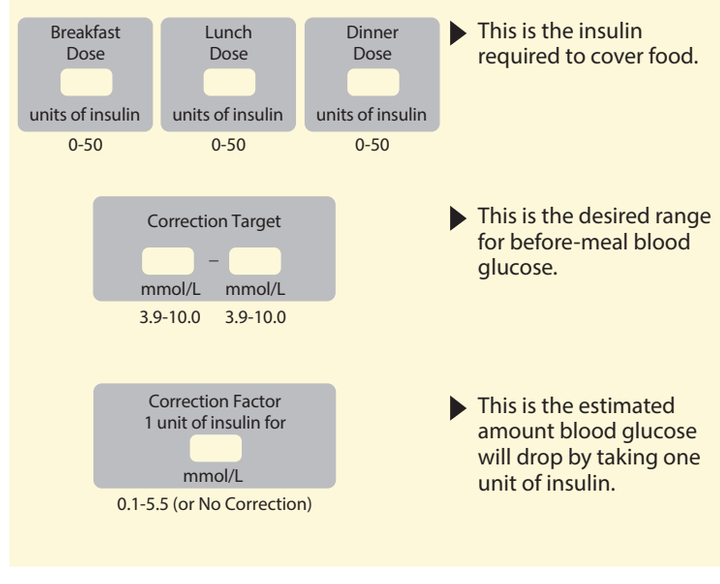
Step	Action
4	 Enter the **Correction Factor** (for example: if 1 unit of insulin lowers blood glucose 2.8 mmol/L, then the correction factor is 2.8). If the blood glucose value is outside the blood glucose target, the calculator will use the correction target and factor to calculate a correction dose. **Notes:** • If your patient does not take correction insulin, touch the down arrow to go below 1 to set 'No correction insulin'. If you set 'No correction insulin', the calculator only includes meal doses. Additionally, active insulin is not tracked or calculated. • The calculator corrects a blood glucose value to the single target or the average of the target range. • The calculator will not suggest a dose that is estimated to drop the blood glucose below the lower end of the target range or single target. Touch **next**. Then touch **done** to complete the setup. You can now review the calculator settings. Touch **OK** when done.

Notes about the Easy Option:

- The calculator estimates the amount of rapid-acting insulin still in the body and how much longer it may be active (if the correction factor is set to 'No correction insulin', active insulin is not calculated). The active insulin estimate is based on a 4-hour insulin duration calculated from the time and amount of the last logged rapid-acting insulin dose.
- Both meal and correction doses are included in the active insulin tracking.
- Insulin doses calculated 0-2 hours after a previously logged dose will only include a meal dose. Active insulin will not be subtracted from the meal or carbohydrate dose, and a correction dose will not be included even if the blood glucose is outside the target. During this time period, the previous dose has not reached peak action and additional correction doses, referred to as `insulin stacking', may result in hypoglycaemia.
- Insulin doses calculated 2-4 hours after a previously logged dose will have active insulin subtracted from the suggested dose.
- All previously injected rapid-acting insulin should be logged to ensure accurate active insulin tracking and calculations.

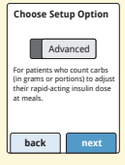
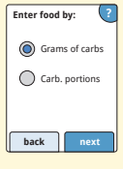
Calculator Settings - Easy Option

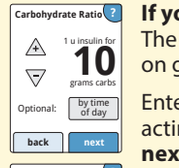
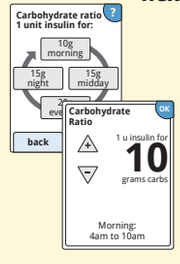
This page can be used to record insulin calculator settings.



Changes to these settings can only be made by a health care professional.

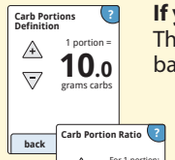
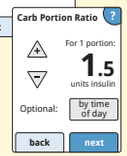
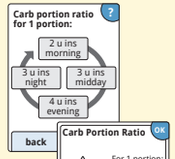
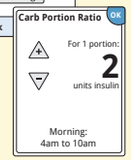
Advanced Setup of the Insulin Calculator

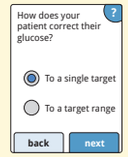
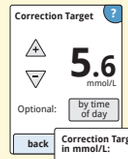
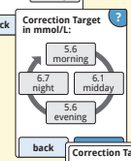
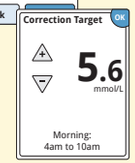
Step	Action
1	 Choose the **Advanced** option on the slide bar and touch **next**. **Note:** You need to know your patient's mealtime insulin settings, target glucose range, correction factor and insulin duration.
2	 Touch to select how meal/carbohydrate information will be entered. Touch **next**. For **Grams of carbs**, go to Step 3. For **Carb portions**, go to Step 4.

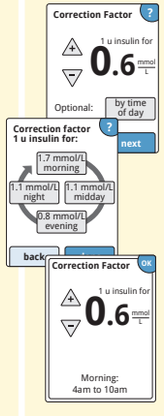
Step	Action
3	  **If you chose to enter Grams of carbs in Step 2:** The rapid-acting insulin dose suggestion is based on grams of carbs. Enter the **Carbohydrate Ratio** (1 unit of rapid-acting insulin for _____ grams of carbs). Touch **next** when complete. **Note:** If you want to set different carbohydrate ratios for different times of day, touch the option **by time of day**. Touch each time period to change the carbohydrate ratio. Touch **OK** after each entry to save. Touch **done**. Go to Step 5.

Time of day blocks cannot be adjusted. They correspond to the following times:

Morning	4:00 AM-9:59 AM	(04:00-09:59)
Midday	10:00 AM-3:59 PM	(10:00-15:59)
Evening	4:00 PM-9:59 PM	(16:00-21:59)
Night	10:00 PM-3:59 AM	(22:00-03:59)

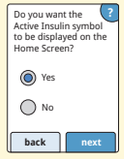
Step	Action
4	  **If you chose to enter Carb Portions in Step 2:** The rapid-acting insulin dose suggestion is based on carbohydrate portions. Enter the **Carb Portions Definition** (10 to 15 grams of carbs) and touch **next**. Enter the **Carb Portion Ratio** (____ units of rapid-acting insulin per 1 carb portion). Touch **next** when complete.   **Note:** If you want to set different carb portion ratios for different times of day, touch the option **by time of day**. Touch each time period to change the carb portion ratio. Touch **OK** after each entry to save. Touch **done**.

Step	Action
5	 Select how you want your patient to correct their glucose. Touch **next**.
6	   Enter the **Correction Target** value or range. This is the desired target value or range for blood glucose values before meals. Touch **next** when complete. **Note:** If the Correction Target is based on time of day, touch the option **by time of day**. Touch each time period to change the correction target for that period. Touch **OK** after each entry to save. Touch **done**.

Step	Action
7	 Enter the **Correction Factor** (for example: if 1 unit of insulin lowers blood glucose 2.8 mmol/L, then the correction factor is 2.8). If the blood glucose reading is outside the blood glucose target, the calculator will use the correction target and factor to calculate a correction dose. Touch **next** when complete. **Notes:** • If the Correction Factor is based on time of day, touch the option **by time of day**. Touch each time period to change the correction factor for that period. Touch **OK** after each entry to save. Touch **done**. • The calculator corrects a blood glucose value to the single target or the average of the target range. • The calculator will not suggest a dose that is estimated to drop the blood glucose below the lower end of the target range or single target.

Step	Action
8	 Enter the **Insulin Duration**. This is the amount of time that rapid-acting insulin remains active in the patient's body. Touch **next**. **IMPORTANT:** In general, the insulin duration for rapid-acting insulin ranges from 3-5 hours, and can vary for each person[1]. The Reader allows an insulin duration from 3-8 hours.

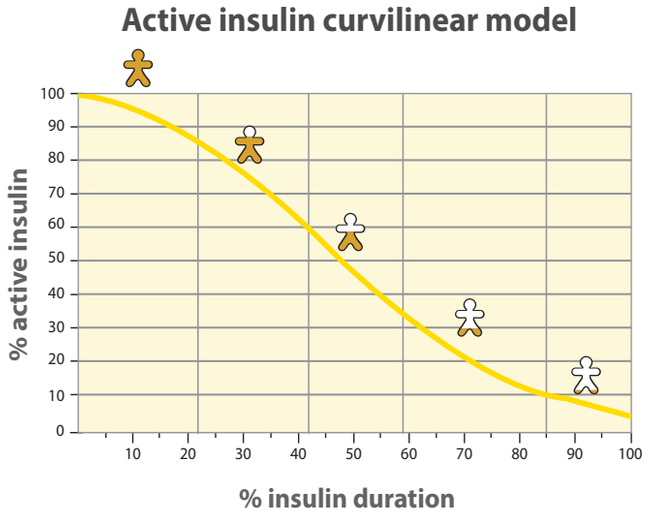
[1] Product Inserts: HumaLog®, NovoLog®, Apidra®

Step	Action
9	 Select whether or not to show the **Active Insulin** symbol on the Home Screen. This symbol shows an estimate of the amount of rapid-acting insulin still in the body and how much longer it may be active. If you select 'No', active insulin is still included in the suggested dose calculation. Touch **next**. Then touch **done** to complete the setup. You can now review the calculator settings. Touch **OK** when done.

Notes about the Advanced Option:

- The calculator estimates the amount of rapid-acting insulin still in the body and how much longer it may be active. The active insulin estimate is calculated from the set insulin duration, the time and the amount of the last logged rapid-acting insulin dose.
- Both meal and correction doses are included in the active insulin tracking.
- Insulin doses calculated 0-2 hours after a previously logged dose will only include a meal dose. Active insulin will not be subtracted from the meal or carbohydrate dose, and a correction dose will not be included even if the blood glucose is outside the target. During this time period, the previous dose has not reached peak action and additional correction doses, referred to as `insulin stacking', may result in hypoglycaemia.
- Insulin doses calculated between 2 hours and the set insulin duration will have active insulin subtracted from the suggested dose (for example if insulin duration is set at 5 hours, active insulin will be subtracted from doses calculated between 2-5 hours).
- All previously injected rapid-acting insulin should be logged to ensure accurate active insulin tracking and calculations.

This graph shows how the insulin calculator estimates the amount of active insulin as a function of logged insulin dose and insulin duration over time. It also shows the relationship between the symbol and amount of active insulin.



Adapted from Mudaliar et al. Diabetes Care, Volume 22(9), Sept 1999, pp 1501-1506

Calculator Settings - Advanced Option

This page can be used to record insulin calculator settings.

Carbohydrate Ratio
1 unit of insulin for
_____ grams of carbs
1-50

OR

Carb Portions Definition
_____ grams of carbs
10-15

Carb Portion Ratio
For 1 carb portion take
_____ units of insulin
0.5-15

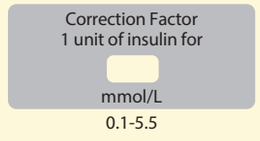
▶ This is the number of grams of carbs that one unit of rapid-acting insulin will cover OR the number of units of rapid-acting insulin that will cover one carb portion. (Option to enter by time of day.)

Correction Target
_____ mmol/L
3.9-10.0

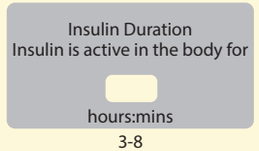
OR

Correction Target Range
_____ to _____ mmol/L
3.9-10.0 3.9-10.0

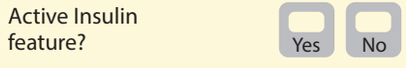
▶ This is the desired target or range for before-meal blood glucose. (Option to enter by time of day.)



▶ This is the estimated amount blood glucose will drop by taking one unit of insulin. (Option to enter by time of day.)

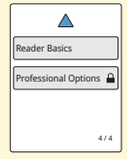
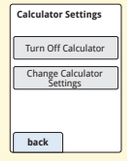


▶ This is the amount of time that a dose of rapid-acting insulin remains active in the body.



Changes to these settings can only be made by a health care professional.

Changing the Insulin Calculator Settings

Step	Action
1	 From the Home Screen, touch the Settings symbol ⚙. Scroll down using the arrows and touch **Professional Options**. Enter the access code. Touch **Insulin Calculator**.
2	 Touch **Turn Off Calculator** to turn off the insulin calculator or **Change Calculator Settings** to change the insulin calculator settings. **Note:** If you turn off the insulin calculator, your patient will no longer see the calculator button after a blood glucose test. You can turn the calculator back on by repeating the insulin calculator setup.

System Specifications

See test strip and control solution instructions for use for additional specifications.

Sensor Specifications

Sensor glucose assay method	Amperometric electrochemical sensor
Sensor glucose reading range	2.2 to 22.2 mmol/L
Sensor size	5 mm height and 35 mm diameter
Sensor weight	5 grams
Sensor power source	One silver oxide battery
Sensor life	Up to 14 days
Sensor memory	8 hours (glucose readings stored every 15 minutes)
Sensor transmission range	6 metres (20 ft) unobstructed
Operating temperature	10°C to 45°C
Sensor Applicator and Sensor Pack storage temperature	4°C to 25°C
Operating and storage relative humidity	10-90%, non-condensing
Sensor water resistance and ingress protection	IP27: Can withstand immersion into one metre (3 ft) of water for up to 30 minutes. Protected against insertion of objects >12 mm diameter
Operating and storage altitude	-381 metres (-1,250 ft) to 3,048 metres (10,000 ft)
Radio Frequency	2.402-2.480 GHz BLE; GFSK; 0dBm EIRP

Reader Specifications

Blood glucose assay range	1.1 to 27.8 mmol/L
Blood ketone assay range	0.0 to 8.0 mmol/L
Reader size	95 mm x 60 mm x 16 mm
Reader weight	65 grams
Reader power source	One lithium-ion rechargeable battery
Reader battery life	4 days of typical use
Reader memory	90 days of typical use
Reader operating temperature	10°C to 45°C
Reader storage temperature	-20°C to 60°C
Operating and storage relative humidity	10-90%, non-condensing
Reader moisture protection	Keep dry
Operating and storage altitude	-381 metres (-1,250 ft) to 3,048 metres (10,000 ft)
Reader display timeout	60 seconds (120 seconds when test strip is inserted)
Radio Frequency	13.56 MHz RFID; ASK Modulation; 124 dBuV/m 2.402-2.480 GHz BLE; GFSK; 2dBm EIRP
Data port	Micro USB
Minimum Computer Requirements	System must only be used with EN60950-1 rated computers
Mean service life	3 years of typical use
Power Adaptor	Abbott Diabetes Care PRT31887 Output: 5 V, 550 mA or 0.55A Operating temperature: 10°C to 40°C
USB Cable	Abbott Diabetes Care PRT21373 Length: 94 cm (37 inches) Colour: Yellow

Rapid-Acting Insulin Calculator Specifications

Parameter	Unit	Range or Value
Correction target	mmol/L	3.9 to 10.0
Carbohydrate ratio	1 unit per X grams of carbs	1 to 50
Carb portion ratio	Units of insulin per carb portion	0.5 to 15
Carb portions definition	Grams of carbs	10 to 15
Mealtime insulin doses (breakfast, lunch, dinner)	Units of insulin	0 to 50
Correction factor	1 unit per X mmol/L	0.1 to 5.5
Insulin duration (duration of insulin action)	Hours	Easy: 4 Advanced: 3 to 8
Dose increments	Units of insulin	0.5 or 1
Maximum insulin dose	Units of insulin	50

Labelling Symbols

	Consult instructions for use		Use-by date
	Temperature limit	REF	Catalogue number
	Manufacturer	SN	Serial number
LOT	Batch code		Do not use if package is damaged
	Type BF applied part		Keep dry
CODE	Sensor code		Non-ionising radiation
	Do not re-use		Caution
STERILE R	Sterilised using irradiation		Humidity limitation
	This product must not be disposed of via municipal waste collection. Contact the manufacturer for details.		

Performance Characteristics

Overview of Clinical Studies

Two studies were conducted in the United States (US) to evaluate the performance, safety, effectiveness and precision of the FreeStyle Libre 2 Flash Glucose Monitoring System (System). One study included adults (Adult study) and the other study included children (Paediatric study). All subjects in both studies required insulin to manage their diabetes. To measure the precision of the System, each subject wore two Sensors, one on the back of each upper arm, for a period of up to 14 days. While in the clinic, subjects had their venous blood glucose analysed using a laboratory reference method, the Yellow Springs Instrument Life Sciences 2300 STAT Plus™ Glucose & Lactate Analyser (YSI). Sensor glucose readings were then compared to the YSI glucose results to evaluate the System's performance. In the Paediatric study, no YSI measurements were obtained for children under the age of six.

Adult study: The Adult study was conducted at 5 centres with 146 subjects in total (91.1% Type 1, 8.9% Type 2), all aged eighteen and older. Subjects had their venous blood glucose analysed over three separate visits to the clinical centre. Each visit lasted up to ten hours. 144 subjects were analysed during the beginning of the Sensor wear period (day 1, 2, or 3), 91 subjects were analysed during the early middle period (day 7 or 8), 55 subjects were analysed during the late middle period (day 9 or 12), and 76 subjects were analysed during the end period (day 13 or 14). During each visit, adult subjects had their glucose levels deliberately manipulated per the study protocol to raise or lower glucose. This was done to assess performance of the System over the range that the System measures glucose (2.2-22.2 mmol/L).

Paediatric study: The Paediatric study was conducted at 4 centres with 139 subjects in total (98.6% Type 1, 1.4% Type 2), all aged four to seventeen. Subjects aged six and older had their venous blood glucose analysed for up to 16 hours over one or two separate visits to the clinical centre. Each visit lasted up to eight hours. During each visit, subjects aged 11 and older had their glucose levels deliberately manipulated per the study protocol to raise or lower glucose. This was done to assess performance of the System over the range that the System measures glucose (2.2-22.2 mmol/L). 48 subjects were analysed during the beginning of the Sensor wear period (day 1 or 2), 50 subjects were analysed during the early middle period (day 7 or 8), 51 subjects were analysed during the late middle period (day 9 or 12), and 51 subjects were analysed during the end period (day 13 or 14). All subjects tested their blood glucose using fingerstick capillary samples at least four times during each day of the study.

Accuracy

Accuracy of the System was measured by comparing paired System Glucose Measurement (GM) and YSI blood glucose values. The percentage of total System readings that were within ±1.11 mmol/L for YSI blood glucose values <3.9 mmol/L or ±20% of YSI for blood glucose values ≥3.9 mmol/L is displayed in **Table 1a**. The Mean Absolute Relative Difference (MARD) gives an indication of the average percent disagreement between the GM and the reference. For example, in the Adult study, 92.3% of the readings fell within ±1.11 mmol/L of YSI blood glucose values <3.9 mmol/L and within ±20% of YSI blood glucose values ≥3.9 mmol/L. The total number of data pairs considered in the analysis was 18,807. In the Adult study, the Mean Absolute Relative Difference was 9.2% for the comparison with YSI reference. In the Paediatric study, the Mean Absolute Relative Difference was 9.7% for the comparison with YSI reference.

Table 1a: Overall Accuracy to YSI

Subject Group	Number of GM-Reference Pairs	Number of Subjects	Percent Within ±20% / ±1.11 mmol/L	Percent Within ±20% / ±1.11 mmol/L on Day 1	MARD (%)
Adults	18807	144	92.3	87.0	9.2
Children (aged 6-17)	6546	129	91.6	84.1	9.7
Children (aged 4-5)*	341	8	85.9	87.9	11.8

* No YSI measurements were obtained for children ages 4-5; results displayed are from GM-SMBG matched paired measurements.

The accuracy of different GM glucose ranges versus YSI reference was assessed by calculating the percentage of System readings that were within 15%, 20% and 40% for GM glucose values ≥3.9 mmol/L, and within 0.83 mmol/L, 1.11 mmol/L and 2.2 mmol/L for values <3.9 mmol/L. For blood glucose values <3.9 mmol/L , the difference in mmol/L between the GM and YSI blood glucose values was calculated. For values ≥3.9 mmol/L , the relative difference (%) to the YSI blood glucose values was calculated. The results categorised within GM glucose ranges are presented in **Tables 1b and 1c**. The results categorised within YSI glucose ranges are presented in **Tables 1d and 1e**.

Table 1b: Accuracy to YSI within GM Glucose Ranges (Adult; n=144)

GM Glucose Level† (mmol/L)	Number of GM-Reference Pairs	Percent Within ±0.83 mmol/L	Percent Within ±1.11 mmol/L	Percent Within ±2.2 mmol/L	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mmol/L)	MARD (%)
<3.0	521	85.6	93.7	99.4				-0.36	13.9
3.0-3.9	3021	89.5	94.2	99.1				-0.19	10.9
3.9-10.0	7828				76.3	86.4	99.1	-0.27	10.6
10.0-13.9	3041				89.1	95.0	99.9	-0.56	7.8
13.9-19.4	3858				93.7	97.6	100.0	-0.43	6.2
>19.4	538				95.9	99.3	100.0	0.21	5.5

† System range is 2.2-22.2 mmol/L.

Table 1c: Accuracy to YSI within GM Glucose Ranges (Paediatric*; n=129)

GM Glucose Level† (mmol/L)	Number of GM-Reference Pairs	Percent Within ±0.83 mmol/L	Percent Within ±1.11 mmol/L	Percent Within ±2.2 mmol/L	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mmol/L)	MARD (%)
<3.0	139	71.9	79.1	97.1				-0.55	17.1
3.0-3.9	863	86.4	90.5	97.1				-0.27	12.0
3.9-10.0	2690				77.4	87.6	98.7	-0.19	10.6
10.0-13.9	1236				86.0	94.7	99.7	-0.50	8.3
13.9-19.4	1411				91.6	97.6	99.9	-0.23	7.3
>19.4	207				96.6	98.6	98.6	0.63	6.6

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

† System range is 2.2-22.2 mmol/L.

Table 1d: Accuracy to YSI within YSI Glucose Ranges (Adult; n=144)

YSI Glucose Level (mmol/L)	Number of GM-Reference Pairs	Percent Within ±0.83 mmol/L	Percent Within ±1.11 mmol/L	Percent Within ±2.2 mmol/L	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mmol/L)	MARD (%)
<3.0	440	91.1	97.5	100.0				0.41	15.5
3.0-3.9	3033	94.7	98.6	100.0				0.08	10.2
3.9-10.0	7544				77.3	86.8	99.4	-0.27	10.4
10.0-13.9	2950				87.7	93.5	99.6	-0.45	8.1
13.9-19.4	4142				91.8	96.3	99.6	-0.54	6.8
>19.4	698				85.2	93.4	100.0	-1.32	7.9

Table 1e: Accuracy to YSI within YSI Glucose Ranges (Paediatric*; n=129)

YSI Glucose Level (mmol/L)	Number of GM-Reference Pairs	Percent Within ±0.83 mmol/L	Percent Within ±1.11 mmol/L	Percent Within ±2.2 mmol/L	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mmol/L)	MARD (%)
<3.0	131	93.9	98.5	100.0				0.37	14.2
3.0-3.9	751	96.5	98.8	100.0				0.06	9.3
3.9-10.0	2743				74.3	84.8	98.0	-0.16	11.4
10.0-13.9	1104				86.6	92.9	99.0	-0.21	8.4
13.9-19.4	1572				90.1	97.5	99.9	-0.49	7.7
>19.4	245				90.6	97.6	100.0	-1.06	7.1

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

Agreement with 'LO' and 'HI' GM Reading against YSI Reference

The System reports glucose concentrations between 2.2 and 22.2 mmol/L. When the System determines that glucose level is below 2.2 mmol/L, it will report as 'LO'. When the System determines that glucose level is above 22.2 mmol/L, it will report as 'HI'. **Tables 2a and 2b** display the concurrence between the GM and YSI reference glucose when GM reads 'LO'. For example, in the Adult study, when GM reading was 'LO', YSI glucose values were less than 2.8 mmol/L 20.0% of the time, less than 3.3 mmol/L 40.0% of the time, less than 3.9 mmol/L 40.0% of the time, less than 4.4 mmol/L 80.0% of the time and equal to or above 4.4 mmol/L 20.0% of the time.

Table 2a: Concurrence Analysis with 'LO' GM Reading (Adult; n=144)

GM-Reference Pairs	YSI (mmol/L)					N
	<2.8	<3.3	<3.9	<4.4	≥4.4	
n	1	2	2	4	1	5
Cumulative %	20.0	40.0	40.0	80.0	20.0	

Table 2b: Concurrence Analysis with 'LO' GM Reading (Paediatric*; n=129)

GM-Reference Pairs	YSI (mmol/L)					N
	<2.8	<3.3	<3.9	<4.4	≥4.4	
n	0	1	2	2	0	2
Cumulative %	0.0	50.0	100.0	100.0	0.0	

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

Tables 2c and 2d display the concurrence between the GM and YSI reference glucose when GM reads 'HI'. In the Adult study, when GM reading was 'HI', YSI glucose values were above 22.2 mmol/L 34.4% of the time, above 19.4 mmol/L 97.5% of the time, above 16.7 mmol/L 100.0% of the time, above 13.9 mmol/L 100.0% of the time, and below or equal to 13.9 mmol/L 0.0% of the time.

Table 2c: Concurrence Analysis with 'HI' GM Reading (Adult; n=144)

GM-Reference Pairs	YSI (mmol/L)					N
	>22.2	>19.4	>16.7	>13.9	≤13.9	
n	42	119	122	122	0	122
Cumulative %	34.4	97.5	100.0	100.0	0.0	

Table 2d: Concurrence Analysis with 'HI' GM Reading (Paediatric; n=129)

GM-Reference Pairs	YSI (mmol/L)					N
	>22.2	>19.4	>16.7	>13.9	≤13.9	
n	25	40	43	45	0	45
Cumulative %	55.6	88.9	95.6	100.0	0.0	

Concurrence of System and Reference (GM vs. YSI)

The percentage of concurring glucose values (GM vs. YSI) in each glucose reference range is presented for each GM range in **Tables 3a and 3b** and for each YSI range in **Tables 3c and 3d**. For example, in the Adult study, when the System glucose readings were within the 4.5 and 6.7 mmol/L range, actual blood glucose values were between 2.2 and 3.3 mmol/L 0.2% of the time, between 3.4 and 4.4 mmol/L 10.9% of the time, between 4.5 and 6.7 mmol/L 70.0% of the time, between 6.7 and 8.9 mmol/L 17.9% of the time, between 8.9 and 11.1 mmol/L 0.9% of the time, and between 11.2 and 13.9 mmol/L 0.1% of the time.

Table 3a: Concurrence Analysis by GM Glucose Level (Adult; n=144)

GM Glucose Level (mmol/L)	YSI Glucose Level (mmol/L)											N
	<2.2	2.2-3.3	3.4-4.4	4.5-6.7	6.7-8.9	8.9-11.1	11.2-13.9	13.9-16.7	16.7-19.4	19.5-22.2	>22.2	
<2.2†	20.0	20.0	40.0	20.0	.	.	.	.	.	.	.	5
2.2-3.3	0.4	52.7	43.6	3.3	.	0.1	.	.	.	.	.	1899
3.4-4.4	.	18.8	62.6	18.2	0.4	0.0	.	.	.	.	.	3095
4.5-6.7	.	0.2	10.9	70.0	17.9	0.9	0.1	.	.	.	.	3055
6.7-8.9	.	.	0.1	9.1	69.6	19.1	1.6	0.3	0.2	.	.	2425
8.9-11.1	.	.	.	.	10.6	60.5	27.0	1.6	0.3	.	.	1753
11.2-13.9	.	.	.	.	.	7.0	65.4	25.6	1.9	0.1	.	2184
13.9-16.7	.	.	.	.	.	0.1	8.4	66.8	22.8	1.9	0.1	2330
16.7-19.4	.	.	.	.	.	.	0.4	13.6	68.8	16.0	1.2	1528
19.5-22.2	.	.	.	.	.	.	.	0.6	27.3	63.6	8.6	538
>22.2†	.	.	.	.	.	.	.	.	2.5	63.1	34.4	122

† Levels out of System dynamic range.

Table 3b: Concurrence Analysis by GM Glucose Level (Paediatric*; n=129)

GM Glucose Level (mmol/L)	YSI Glucose Level (mmol/L)											N
	<2.2	2.2-3.3	3.4-4.4	4.5-6.7	6.7-8.9	8.9-11.1	11.2-13.9	13.9-16.7	16.7-19.4	19.5-22.2	>22.2	
<2.2†	.	50.0	50.0	.	.	.	.	.	.	.	.	2
2.2-3.3	0.6	48.6	42.5	7.8	0.6	.	.	.	.	.	.	527
3.4-4.4	.	12.1	61.9	24.3	1.7	.	.	.	.	.	.	915
4.5-6.7	.	0.2	11.2	69.0	18.2	1.3	0.1	.	.	.	.	1006
6.7-8.9	.	.	.	11.4	71.0	15.8	1.8	.	.	.	.	868
8.9-11.1	.	.	.	0.1	18.2	61.3	20.1	0.3	.	.	.	703
11.2-13.9	.	.	.	.	0.2	9.6	55.3	33.6	1.2	0.1	.	909
13.9-16.7	.	.	.	.	.	0.1	14.1	60.8	23.7	1.3	.	818
16.7-19.4	.	.	.	.	.	.	0.3	24.8	58.2	16.5	0.2	593
19.5-22.2	.	.	.	.	.	1.0	.	0.5	33.8	59.4	5.3	207
>22.2†	.	.	.	.	.	.	.	4.4	6.7	33.3	55.6	45

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.
† Levels out of System dynamic range.

Table 3c: Concurrence Analysis by YSI Glucose Level (Adult; n=144)

YSI Glucose Level (mmol/L)	GM Glucose Level (mmol/L)											N
	<2.2†	2.2-3.3	3.4-4.4	4.5-6.7	6.7-8.9	8.9-11.1	11.2-13.9	13.9-16.7	16.7-19.4	19.5-22.2	>22.2†	
<2.2	12.5	87.5	.	.	.	.	.	.	.	.	.	8
2.2-3.3	0.1	62.9	36.6	0.4	.	.	.	.	.	.	.	1591
3.4-4.4	0.1	26.7	62.4	10.8	0.1	.	.	.	.	.	.	3103
4.5-6.7	0.0	2.1	18.9	71.6	7.4	.	.	.	.	.	.	2984
6.7-8.9	.	.	0.5	22.5	69.5	7.6	.	.	.	.	.	2430
8.9-11.1	.	0.1	0.1	1.6	27.1	62.1	9.0	0.1	.	.	.	1709
11.2-13.9	.	.	.	0.1	1.9	22.1	66.6	9.1	0.3	.	.	2147
13.9-16.7	.	.	.	.	0.3	1.2	23.7	65.9	8.8	0.1	.	2361
16.7-19.4	.	.	.	.	0.3	0.3	2.3	29.8	59.0	8.2	0.2	1784
19.5-22.2	.	.	.	.	.	.	0.3	6.2	34.4	48.2	10.9	709
>22.2	.	.	.	.	.	.	.	1.9	16.7	42.6	38.9	108

† Levels out of System dynamic range.

Table 3d: Concurrence Analysis by YSI Glucose Level (Paediatric*; n=129)

YSI Glucose Level (mmol/L)	GM Glucose Level (mmol/L)											N
	<2.2†	2.2-3.3	3.4-4.4	4.5-6.7	6.7-8.9	8.9-11.1	11.2-13.9	13.9-16.7	16.7-19.4	19.5-22.2	>22.2†	
<2.2	.	100.0	.	.	.	.	.	.	.	.	.	3
2.2-3.3	0.3	69.2	30.0	0.5	.	.	.	.	.	.	.	370
3.4-4.4	0.1	24.8	62.6	12.5	.	.	.	.	.	.	.	904
4.5-6.7	.	3.9	21.0	65.7	9.4	0.1	.	.	.	.	.	1057
6.7-8.9	.	0.3	1.7	19.3	65.0	13.5	0.2	.	.	.	.	948
8.9-11.1	.	.	.	1.9	20.4	64.2	13.0	0.1	.	0.3	.	671
11.2-13.9	.	.	.	0.1	2.1	18.1	64.7	14.8	0.3	.	.	778
13.9-16.7	.	.	.	.	.	0.2	32.0	52.1	15.4	0.1	0.2	954
16.7-19.4	.	.	.	.	.	.	1.8	31.1	55.4	11.2	0.5	623
19.5-22.2	.	.	.	.	.	.	0.4	4.4	39.5	49.6	6.0	248
>22.2	.	.	.	.	.	.	.	.	2.7	29.7	67.6	37

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.
† Levels out of System dynamic range.

Glucose Rate of Change Accuracy

The System's glucose rate of change (ROC) accuracy, as assessed by concurrence analysis, is presented in **Tables 4a and 4b**. For example, in the Adult study, when the Sensor glucose rate of change indicated that glucose was changing slowly (-0.06 to 0.06 mmol/L/min), actual glucose levels in the body were falling quickly (<-0.1 mmol/L/min) 1.1% of the time, falling (-0.1 to -0.06 mmol/L/min) 6.5% of the time, changing slowly (-0.06 to 0.06 mmol/L/min) 81.7% of the time, rising (0.06 to 0.1 mmol/L/min) 7.3% of the time and were rising quickly (>0.1 mmol/L/min) 3.5% of the time.

Table 4a: Concurrence Analysis by Glucose Rate of Change (Adult; n=144)

GM Rate (mmol/L/min)	YSI Rate (mmol/L/min)					N
	<-0.1	[-0.1, -0.06)	[-0.06, 0.06]	(0.06, 0.1]	>0.1	
<-0.1	33.8	44.5	21.3	0.3	.	328
[-0.1 to -0.06)	6.8	46.5	45.2	0.9	0.5	1092
[-0.06 to 0.06]	1.1	6.5	81.7	7.3	3.5	14865
(0.06 to 0.1]	0.1	1.6	39.3	38.4	20.5	1154
>0.1	0.1	0.2	17.7	32.9	49.0	885

Table 4b: Concurrence Analysis by Glucose Rate of Change (Paediatric*; n=129)

GM Rate (mmol/L/min)	YSI Rate (mmol/L/min)					N
	<-0.1	[-0.1, -0.06)	[-0.06, 0.06]	(0.06, 0.1]	>0.1	
<-0.1	44.1	44.7	11.2	.	.	170
[-0.1 to -0.06)	11.4	49.5	38.0	0.4	0.6	463
[-0.06 to 0.06]	1.8	8.7	75.2	8.8	5.4	4682
(0.06 to 0.1]	0.2	2.6	40.2	35.5	21.5	498
>0.1	.	0.9	19.2	29.7	50.2	448

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

Alarm Performance

The tables in this section show the accuracy of the System's Low and High Glucose Alarms. The Alarm Rate tells you how often the alarm is right or wrong. The Detection Rate tells you how often the System is able to recognise and notify you about a low or high glucose event.

Low Glucose Alarm Performance

Tables 5a and 5b display the percentages for these parameters:

True Alarm Rate

Tells you: When you got a low glucose alarm, were you actually low?

Definition: Percentage of time the alarm issued and blood glucose was below the alarm level within 15 minutes before or after the alarm.

False Alarm Rate
Tells you: Did you get a low glucose alarm that you shouldn't have?
Definition: Percentage of time the alarm issued and blood glucose was not below the alarm level within 15 minutes before or after the alarm.

Detection Rate
Tells you: When you were low, did you get a low glucose alarm?
Definition: Percentage of time blood glucose was below the alarm level and the alarm issued within 15 minutes before or after the glucose event.

Missed Detection Rate
Tells you: When you were low, did you miss a low glucose alarm?
Definition: Percentage of time blood glucose was below the alarm level and the alarm didn't issue within 15 minutes before or after the glucose event.

For example, the Adult study found that for a Low Glucose alarm level set to 3.9 mmol/L:
86.0% of the time a low glucose alarm was received when blood glucose was indeed below the alarm level but 14.0% of the time a low glucose alarm was received when blood glucose wasn't below the alarm level.

89.3% of the time blood glucose was below the alarm level and a low glucose alarm was appropriately issued but 10.7% of the time the glucose event was missed and no alarm was issued.

Table 5a: Low Glucose Alarm Performance (Adult; n=144)

Low Glucose Alarm level (mmol/L)	Alarm Rate		Detection Rate	
	True Alarm Rate (%)	False Alarm Rate (%)	Correct Detection Rate (%)	Missed Detection Rate (%)
3.3	72.3	27.7	75.7	24.3
3.9	86.0	14.0	89.3	10.7
4.4	91.3	8.7	97.3	2.7
5.0	93.6	6.4	98.5	1.5

Table 5b: Low Glucose Alarm Performance (Paediatric*; n=129)

Low Glucose Alarm level (mmol/L)	Alarm Rate		Detection Rate	
	True Alarm Rate (%)	False Alarm Rate (%)	Correct Detection Rate (%)	Missed Detection Rate (%)
3.3	62.9	37.1	87.4	12.6
3.9	80.3	19.7	93.5	6.5
4.4	85.6	14.4	96.4	3.6
5.0	92.2	7.8	97.3	2.7

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

High Glucose Alarm Performance

Tables 5c and 5d display the percentages for these parameters:

True Alarm Rate
Tells you: When you got a high glucose alarm, were you actually high?
Definition: Percentage of time the alarm issued and blood glucose was above the alarm level within 15 minutes before or after the alarm.

False Alarm Rate
Tells you: Did you get a high glucose alarm that you shouldn't have?
Definition: Percentage of time the alarm issued and blood glucose was not above the alarm level within 15 minutes before or after the alarm.

Detection Rate
Tells you: When you were high, did you get a high glucose alarm?
Definition: Percentage of time blood glucose was above the alarm level and the alarm issued within 15 minutes before or after the glucose event.

Missed Detection Rate
Tells you: When you were high, did you miss a high glucose alarm?
Definition: Amount of time blood glucose was above the alarm level and the alarm didn't issue within 15 minutes before or after the glucose event.

For example, the Adult study found that for a High Glucose alarm level set to 11.1 mmol/L:
99.2% of the time a high glucose alarm was received when blood glucose was indeed above the alarm level but 0.8% of the time a high glucose alarm was received when blood glucose wasn't actually above the alarm level.
97.0% of the time blood glucose was above the alarm level and a high glucose alarm was appropriately issued but 3.0% of the time the glucose event was missed and no alarm was issued.

Table 5c: High Glucose Alarm Performance (Adult; n=144)

High Glucose Alarm level (mmol/L)	Alarm Rate		Detection Rate	
	True Alarm Rate (%)	False Alarm Rate (%)	Correct Detection Rate (%)	Missed Detection Rate (%)
6.7	99.1	0.9	98.2	1.8
7.8	99.1	0.9	98.1	1.9
10.0	99.2	0.8	97.8	2.2
11.1	99.2	0.8	97.0	3.0
12.2	99.0	1.0	96.9	3.1
13.3	98.4	1.6	95.6	4.4
16.7	96.3	3.7	90.0	10.0

Table 5d: High Glucose Alarm Performance (Paediatric*; n=129)

High Glucose Alarm level (mmol/L)	Alarm Rate		Detection Rate	
	True Alarm Rate (%)	False Alarm Rate (%)	Correct Detection Rate (%)	Missed Detection Rate (%)
6.7	98.8	1.2	98.2	1.8
7.8	98.0	2.0	98.4	1.6
10.0	98.4	1.6	98.0	2.0
11.1	98.0	2.0	98.0	2.0
12.2	98.2	1.8	96.9	3.1
13.3	98.0	2.0	95.7	4.3
16.7	90.8	9.2	91.0	9.0

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

Sensor Accuracy Over Time

The Sensor can be worn for up to 14 days. The percentage of System readings within YSI values and the Mean Absolute Relative Difference (MARD) is presented for the following different wear periods in **Tables 6a and 6b**: Beginning (Adult: 144 Subjects, Day 1, 2 or 3; Paediatric: 48 Subjects, Day 1 or 2) Early Middle (Adult: 91 Subjects, Day 7 or 8; Paediatric: 50 Subjects, Day 7 or 8), Late Middle (Adult: 55 Subjects, Day 9 or 12; Paediatric: 51 Subjects, Day 9 or 12), and End (Adult: 76 Subjects, Day 13 or 14; Paediatric: 51 Subjects, Day 13 or 14). For values ≥3.9 mmol/L, the percentage of readings within 15%, 20%, and 40% of the YSI value was calculated. For values <3.9 mmol/L, the percentage of readings within 0.83 mmol/L, 1.11 mmol/L, and 2.2 mmol/L of the YSI value was calculated. The percentage of System readings within YSI values for the first 12 hours of a Sensor wear is presented in **Table 6c**.

Table 6a: Sensor Accuracy Relative to YSI over the wear duration (Adult; n=144)

Wear Period	Number of GM-Reference Pairs	MARD (%)	Within ±15% / ±0.83 mmol/L	Within ±20% / ±1.11 mmol/L	Within ±40% / ±2.2 mmol/L
Beginning	7027	10.0	83.0	90.2	99.3
Early Middle	4522	8.5	87.7	94.5	99.8
Late Middle	3503	8.8	86.8	93.4	99.7
End	3755	9.1	86.4	92.9	100.0

Table 6b: Sensor Accuracy Relative to YSI over the wear duration (Paediatric*; n=129)

Wear Period	Number of GM-Reference Pairs	MARD (%)	Within ±15% / ±0.83 mmol/L	Within ±20% / ±1.11 mmol/L	Within ±40% / ±2.2 mmol/L
Beginning	1828	10.7	79.6	88.5	98.6
Early Middle	1642	8.0	89.5	94.2	98.5
Late Middle	1534	9.7	83.6	92.9	99.5
End	1542	10.2	82.6	91.1	99.3

* Includes children 6-17 years of age. No YSI measurements were obtained for children 4-5 years of age.

Table 6c: Sensor Accuracy Relative to YSI over the First 12 Hours of Sensor Wear

Population	Number of GM-Reference pairs	Percent Within ±20% / ±1.11 mmol/L	Percent Within ±40% / ±2.2 mmol/L
Adult	1292	81.0	97.4
Pediatric	548	80.3	97.3

Sensor Wear Duration

The Sensor can be worn for up to 14 days. To estimate how long a Sensor will work over the wear duration, 146 Sensors were evaluated in the Adult study and 139 Sensors were evaluated in the Paediatric study to determine how many days of readings each Sensor provided. Of the 146 Sensors in the Adult study, 71.1% lasted until the final day of use. In the Paediatric study, 78.1% of the Sensors lasted until the final day of use. **Tables 7a and 7b** display the data for each day in the wear duration for the Adult & Paediatric studies.

Table 7a: Sensor Survival Rate Over Wear Duration (Adult; n=146)

Day of Wear	Number of Sensors	Survival Rate (%)
1	145	99.3
2	142	97.3
3	140	95.9
4	137	93.8
5	134	91.8
6	133	91.1
7	132	90.4
8	127	87.0
9	123	84.9
10	119	82.2
11	112	77.3
12	111	76.6
13	104	71.8
14	100	71.1

Table 7b: Sensor Survival Rate Over Wear Duration (Paediatric; n=139)

Day of Wear	Number of Sensors	Survival Rate (%)
1	137	98.6
2	136	97.8
3	134	97.1
4	133	96.4
5	133	96.4
6	133	96.4
7	133	96.4
8	131	94.9
9	126	91.3
10	124	89.9
11	122	88.4
12	120	87.0
13	114	83.4
14	104	78.1

Glucose Reading Availability

The System is designed to show a Sensor glucose reading after each scan that is performed throughout the wear period after the start-up time. **Tables 8a and 8b** show the glucose reading capture rate for each day of the wear duration.

Table 8a: Glucose Reading Capture Rate Over Wear Duration (Adult; n=146)

Day of Wear	Number of Sensors	Capture Rate (%)
1	146	98.2
2	145	98.0
3	143	98.2
4	140	98.3
5	138	98.3
6	135	98.3
7	134	98.3
8	131	98.4
9	128	98.4
10	123	98.4
11	120	98.4
12	113	98.5
13	112	98.5
14	104	98.5

Table 8b: Glucose Reading Capture Rate over Wear Duration (Paediatric; n=139)

Day of Wear	Number of Sensors	Capture Rate (%)
1	139	94.4
2	137	94.7
3	136	95.1
4	133	95.2
5	134	95.4
6	133	95.5
7	133	95.9
8	133	95.8
9	130	95.7
10	125	95.6
11	125	95.6
12	122	95.7
13	119	95.8
14	116	95.8

Precision

Precision of the System was evaluated by comparing the results from two separate Sensors worn on the same subject at the same time. **Table 9a** provides data from 146 subjects in the Adult study; **Table 9b** provides data from 137 subjects in the Paediatric study. For adults, the paired absolute relative difference (PARD) between the two Sensors was 8.1% with coefficient of variation (CV) of 5.8%. For children ages 4-5, PARD was 6.7% with CV of 4.8%. For children ages 6-17, PARD was 8.3% with CV of 5.9%. Paired absolute difference (PAD) is a measurement of average absolute differences (in mmol/L) between paired GM readings, while PARD is the average of absolute relative differences (in %) between paired GM readings.

Table 9a: Overall between Sensor Precision (Adult; n=146)

	Mean Coefficient of Variation (%)	Paired Absolute Difference (mmol/L)	Paired Absolute Relative Difference (%)	Number of Paired Readings
Adults ages 18+	5.8	0.7	8.1	26891

Table 9b: Overall between Sensor Precision (Paediatric; n=137)

	Mean Coefficient of Variation (%)	Paired Absolute Difference (mmol/L)	Paired Absolute Relative Difference (%)	Number of Paired Readings
Children aged 4-5	4.8	0.6	6.7	248
Children aged 6-17	5.9	0.7	8.3	10643

Adverse Events

No device related serious adverse events occurred during the studies. In the Adult study, mild skin irritations (such as erythema, bruising, bleeding and scabbing) and mild pain were reported around the insertion site and adhesive area by a small number of subjects (10 out of 146 or 6.8%).

In the Paediatric study, there were 8 instances of erythema (4 'well-defined redness', and 4 'slight pink'), 5 instances of oedema (3 slight oedema, 2 instances of slight oedema with defined edges), 2 instances of mild bleeding, one instance of mild induration and one instance of mild rash.

Ascorbic Acid Study

A clinical study was conducted to evaluate the effect of ascorbic acid supplements on Sensor performance. Data from 57 adult subjects with diabetes was collected over a 13-hour period. Each subject had a one-hour baseline phase where venous blood was collected every 10 minutes. After this first hour, a 1000 mg ascorbic acid supplement was given with a meal and venous samples were collected every 20 minutes for the next four hours. A maximum average Sensor bias of 0.5 mmol/L was observed around 3 hours after the 1000 mg ascorbic acid dose. Subjects then received a second 1000 mg ascorbic acid supplement with a meal and the same process was continued for another 4 hours. A third 1000 mg ascorbic acid supplement was then given and study subjects were followed for 4 more hours. After the second dose of ascorbic acid the maximum average Sensor bias increased, with minimal change in Sensor bias after the third dose, suggesting that saturation had occurred by the second 1000 mg dose of ascorbic acid. The maximum average Sensor bias after the three 1000 mg doses of ascorbic acid was less than 1.1 mmol/L.

Bench studies were conducted to test higher levels of ascorbic acid. These studies showed that ascorbic acid doses greater than 1000 mg every four hours could significantly raise Sensor glucose readings.

Electromagnetic Compatibility

Model: FreeStyle Libre 2 Sensor
IC: 12106A-LIB02S

- The System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect the System.
- Use of accessories, transducers and cables other than those specified or provided by Abbott Diabetes Care could result in increased electromagnetic emissions or decreased electromagnetic immunity of the System and result in improper operation.
- The System should not be used adjacent to or stacked with other equipment, and if adjacent or stacked use is necessary, the System should be observed to verify normal operation in the configuration in which it will be used.
- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.
- Changes or modifications not approved by Abbott could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

— Reorientate or relocate the receiving antenna.

— Increase the separation between the equipment and receiver.

— Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

— Consult the dealer or an experienced radio/TV technician for help.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

This device complies with Industry Canada's licence-exempt RSS standard(s). Operation is subject to the following two conditions:

(1) This device may not cause interference; and

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

Guidance and manufacturer's declaration – electromagnetic emissions

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should ensure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines (100kHz frequency) ± 1 kV for signal lines (100kHz frequency)	± 2 kV for power supply lines (100kHz frequency) ± 1 kV for signal lines (100kHz frequency)	Mains power quality should be that of a typical domestic, commercial or hospital environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical domestic, commercial, or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0.5 cycle At 0^0, 45^0, 90^0, 135^0, 180^0, 225^0, 270^0 and 315^0 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0^0 0 % U_T; 250/300 cycle	0 % U_T; 0.5 cycle At 0^0, 45^0, 90^0, 135^0, 180^0, 225^0, 270^0 and 315^0 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0^0 0 % U_T; 250/300 cycle	Mains power quality should be that of a typical domestic, commercial or hospital environment. If the user of the System requires continued operation during power mains interruptions, it is recommended that the System be powered from an uninterruptible power supply or a battery.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

IMMUNITY test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	6 Vrms 150 kHz to 80 MHz	6 Vrms	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the System, including cables specified by Abbott Diabetes Care. Otherwise, degradation of the performance of the System could result.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See table on next page	Compliance to the tested levels	

The table below lists the immunity test levels at specific test frequencies for testing the effects of some wireless communications equipment. The frequencies and services listed in the table are representative examples in healthcare and in various locations where the System may be used.

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
385	380 – 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50% duty cycle square wave signal.
[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used, because while it does not represent actual modulation, it would be worst case.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol: 

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

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