



FreeStyle *Libre*

FLASH GLUCOSE MONITORING SYSTEM



User's Manual













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



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Reader Symbols

Symbol	What It Means
	Active sensor
	Direction your glucose is going. See <i>Checking Your Glucose</i> 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
	Reminders

Symbol	What It Means
	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 Flash Glucose Monitoring System is indicated for measuring interstitial fluid glucose levels in adults aged 18 years and older. It is designed to replace blood glucose testing in the self-management of diabetes with the exceptions listed below. Under the following circumstances, use a blood glucose meter to check the current glucose readings from the FreeStyle Libre Flash Glucose Monitoring System Sensor:

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

Contraindications

The FreeStyle Libre Flash Glucose Monitoring System must be removed prior to Magnetic Resonance Imaging (MRI).

WARNING:

- The FreeStyle Libre Flash Glucose Monitoring System contains small parts that may be dangerous if swallowed.
- During times of rapidly changing glucose (more than 0.1 mmol/L per minute), interstitial fluid glucose levels as measured by the FreeStyle Libre Flash Glucose Monitoring System Sensor may not accurately reflect blood glucose levels. Under these circumstances, check the Sensor glucose readings by conducting a fingerstick test using a blood glucose meter.
- In order to confirm hypoglycaemia or impending hypoglycaemia as reported by the FreeStyle Libre Flash Glucose Monitoring System Sensor, conduct a fingerstick test using a blood glucose meter.
- Do not ignore symptoms that may be due to low or high blood glucose. If you have symptoms that do not match the FreeStyle Libre Flash Glucose Monitoring System reading or suspect that your reading may be inaccurate, check the reading by conducting a fingerstick test using a blood glucose meter. If you are experiencing symptoms that are not consistent with your glucose readings, consult your health care professional.

CAUTION:

- On rare occasions, you may get inaccurate Sensor glucose readings. If you believe your glucose readings are not correct or are inconsistent with how you feel, perform a blood glucose test on your finger to confirm your glucose. If the problem continues, remove the current Sensor and apply a new one.
- Performance of the System when used with other implanted medical devices, such as pacemakers, has not been evaluated.
- 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 performing the cleaning procedure.

System-Related Information

- The FreeStyle Libre Flash Glucose Monitoring System is designed to be used only with FreeStyle Optium blood glucose and blood ketone test strips and MediSense control solution.
- Avoid getting dust, dirt, blood, control solution, water or other substances in the Reader's USB and test strip ports.
- Physiologic differences between the interstitial fluid and capillary blood may result in differences in glucose readings. Differences in glucose readings between interstitial fluid and capillary blood may be observed during times of rapid change in blood glucose, such as after eating, dosing insulin or exercising.
- Severe dehydration and excessive water loss may cause inaccurate results. If you believe you are suffering from dehydration, consult your health care professional **immediately**.

- If you have a medical appointment that includes strong magnetic or electromagnetic radiation, for example an X-ray, MRI (Magnetic Resonance Imaging), or CT (Computed Tomography) scan, remove the Sensor you are wearing and apply a new one after the appointment. The effect of these types of procedures on the performance of the system has not been evaluated.
- The FreeStyle Libre Flash Glucose Monitoring System has not been evaluated for use in pregnant women, persons on dialysis, or people less than 18 years of age.

Getting to Know Your System

The FreeStyle Libre Flash Glucose Monitoring System has two main parts: a handheld Reader and a disposable Sensor, which you wear on your body. You use the Reader to wirelessly scan the Sensor and get your glucose readings. The Reader also has a built-in blood glucose and ketone meter, which works with FreeStyle Optium blood glucose and blood ketone test strips.



IMPORTANT: Safety information about the System is in this User's Manual. Read all of the information in the User's Manual and the FreeStyle Optium blood glucose and ketone test strip instructions for use before using your System.

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:

- 1 FreeStyle Libre Reader
- 1 Power Adapter
- Quick Start Guide
- 1 USB Cable
- User's Manual



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

Sensor Kit

The Sensor Kit includes:

- 1 Sensor Pack
- 1 Sensor Applicator
- 1 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

Time

Current time set on the Reader.

Battery Level

Battery charge remaining.

Sensor Status

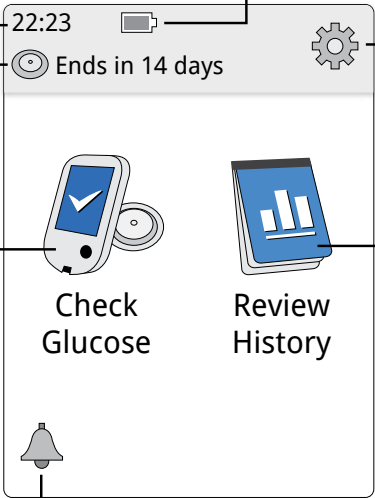
Information about your current Sensor.

Check Glucose

Touch to check your Sensor glucose.

Reminder

Touch to set or change reminders.



Settings

Touch to change the Reader's settings.

Review History

Touch to review information about your past glucose readings.

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

Message

Touch for more information.

Add Notes

Touch to add notes to the glucose reading.

Current Glucose

Glucose from your latest scan.

Glucose Trend Arrow

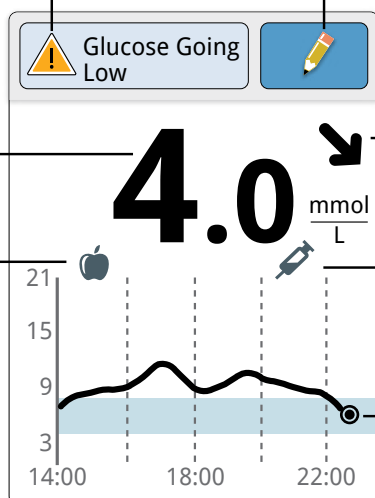
Direction your glucose is going.

Food Note

Rapid-Acting Insulin Note

Glucose Graph

Graph of your current and stored glucose readings.



FreeStyle Libre Software

FreeStyle Libre software can be used to view reports and change Reader settings. The software is compatible with most Windows and Mac operating systems. Go to www.FreeStyleLibre.com and follow onscreen instructions to download and install the software.


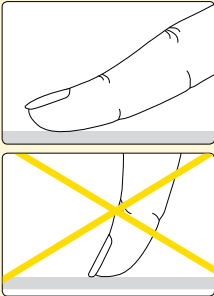
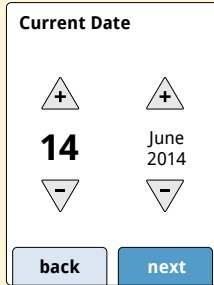
INTENDED USE

FreeStyle Libre software is intended for use by individuals and health care professionals to aid in the review, analysis, and evaluation of information such as Sensor glucose readings, blood glucose test results, blood ketone test results, and other data uploaded from the FreeStyle Libre Flash Glucose Monitoring System, in support of an effective diabetes health management program.

FreeStyle Libre software is not intended for the diagnosis of or screening for diabetes mellitus. Users should be aware that FreeStyle Libre software is merely an information management tool and it is therefore not intended to substitute for the support of a health care professional. Individuals should always consult their health care professional if they have any queries or concerns about diabetes management.

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.
3	 Set the Current Date using the arrows on the touchscreen. Touch next to continue.

Step	Action
<p>4</p>	<div data-bbox="315 485 527 768"> </div> <p>Set the Current Time. Touch next to continue.</p> <div data-bbox="561 554 1445 739"> <p>CAUTION: It is very important to set the time and date correctly. These values affect the Reader data and settings.</p> </div>
<p>5</p>	<div data-bbox="315 1050 527 1333"> </div> <p>Set your Target Glucose Range. Work with your health care professional to determine your Target Glucose Range. Touch next to continue.</p> <p>Note: Your Target Glucose Range is displayed on glucose graphs on the Reader and used to calculate your Time In Target.</p>

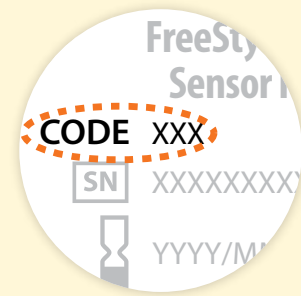
Step	Action
<p>6</p>	<p>The Reader now displays important information about two key topics to help you use the system:</p> <ul style="list-style-type: none"> • How to understand the Glucose Trend Arrow included on the Glucose Reading screen. • How to return to the Home Screen from any other screen. <div data-bbox="423 787 854 1215"> <p>When you scan your Sensor an arrow will indicate your recent glucose trend:</p> <ul style="list-style-type: none"> ↑ Rising quickly ↗ Rising → Changing slowly ↘ Falling ↓ Falling quickly <p>back</p> <p>While using the Reader, press the home button to return to the Home screen.</p> <p>back done</p> </div> <p>Touch next to move to the next topic. At the end of the Reader setup, touch done to go to the Home Screen.</p>

Note: Charge the Reader if the battery level is low. Only use the USB cable and power adapter included with the System.



Using Your Sensor

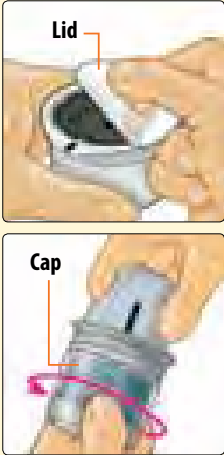

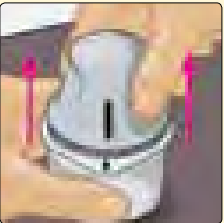
CAUTIONS:

- 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


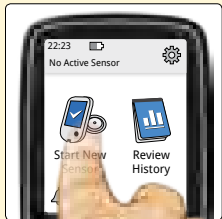
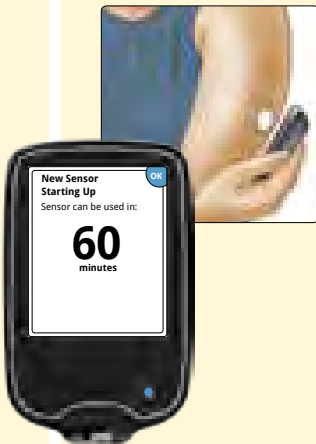
Step	Action
1	 <p>Apply Sensors only on the back of your upper arm. Avoid areas with scars, moles, stretch marks or lumps.</p> <p>Select an area of skin that generally stays flat during your normal daily activities (no bending or folding). Choose a site that is at least 2.5 cm (1 inch) away from an insulin injection site. To prevent discomfort or skin irritation, you should select a different site other than the one most recently used.</p>
2	 <p>Clean application site with an alcohol wipe and allow site to dry before proceeding. This helps the Sensor stay attached to your body.</p> <p>Note: The area MUST be clean and dry, otherwise the Sensor may not stick to the site.</p>

Step	Action
3	<div data-bbox="302 489 524 940">  </div> <p data-bbox="560 478 1396 625">Open the Sensor Pack by peeling the lid off completely. Unscrew the cap from the Sensor Applicator and set the cap aside.</p> <div data-bbox="560 653 1446 890" style="border: 1px solid black; padding: 10px;"> <p>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.</p> </div>
4	<div data-bbox="302 1005 524 1226">  </div> <p data-bbox="560 999 1429 1192">Line up the dark mark on the Sensor Applicator with the dark mark on the Sensor Pack. Press firmly down on the Sensor Applicator until it comes to a stop.</p>
5	<div data-bbox="302 1362 524 1583">  </div> <p data-bbox="560 1356 1456 1409">Lift the Sensor Applicator out of the Sensor Pack.</p>


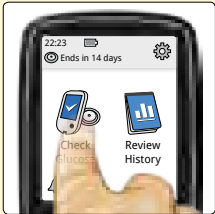

Step	Action
<p>6</p>	<div data-bbox="321 489 545 709" data-label="Image"> </div> <p>The Sensor Applicator is prepared and ready to apply the Sensor.</p> <div data-bbox="578 604 1461 835" data-label="Text"> <p>CAUTION: The Sensor Applicator now contains a needle. Do NOT touch inside the Sensor Applicator or put it back into the Sensor Pack.</p> </div>
<p>7</p>	<div data-bbox="318 1062 540 1283" data-label="Image"> </div> <p>Place the Sensor Applicator over the prepared site and push down firmly to apply the Sensor to your body.</p> <div data-bbox="578 1224 1461 1419" data-label="Text"> <p>CAUTION: Do NOT push down on the Sensor Applicator until placed over prepared site to prevent unintended results or injury.</p> </div>

Step	Action
8	<div data-bbox="302 489 524 709" data-label="Image"> </div> <p data-bbox="560 478 1451 617">Gently pull the Sensor Applicator away from your body. The Sensor should now be attached to your skin.</p> <p data-bbox="560 636 1451 827">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.</p>
9	<div data-bbox="302 1060 524 1281" data-label="Image"> </div> <p data-bbox="560 1052 1442 1255">Make sure 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.</p>

Starting Your Sensor

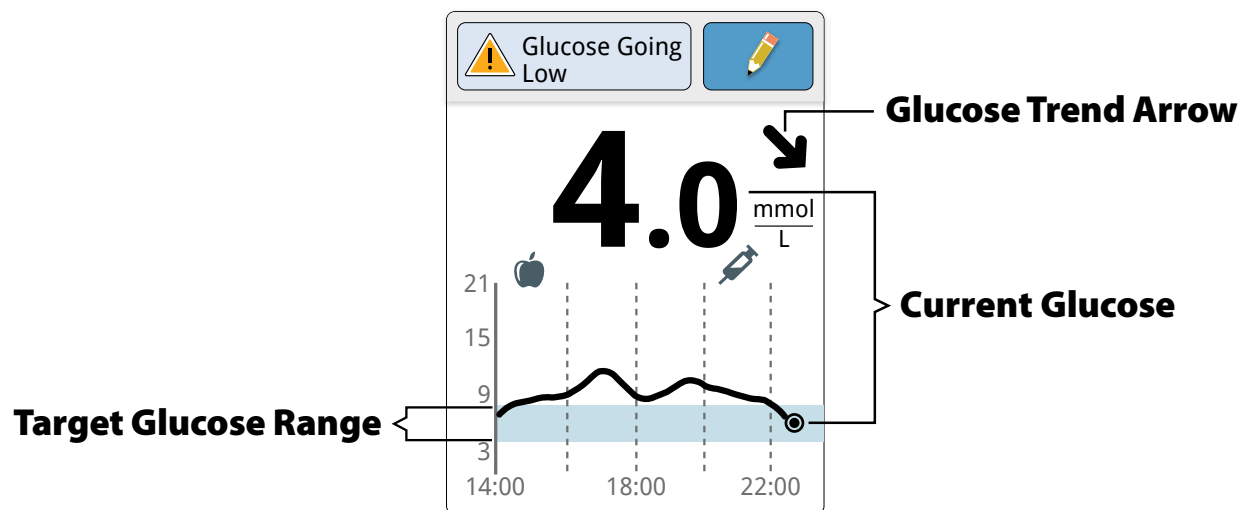
Step	Action	
1		Press the Home Button to turn on the Reader.
2		Touch Start New Sensor .
3		<p>Hold the Reader within 4 cm (1.5 inches) of the Sensor to scan it. This starts your Sensor. If sounds are turned on, the Reader beeps when the Sensor has been successfully activated. The Sensor can be used to check your glucose after 60 minutes.</p> <p>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.</p>

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		<p>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.</p> <p>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.</p>

Step	Action
3	<div data-bbox="324 485 539 699" data-label="Figure"> <p>The image shows a digital glucose meter screen. At the top, there is a warning icon and the text 'Glucose Going Low'. The main display shows a large number '4.0' followed by 'mmol/L'. Below this, there is a line graph showing glucose levels over time, with a peak and a dip. The x-axis is labeled with times: 14:00, 18:00, and 22:00. The y-axis has markers at 15 and 21. An upward arrow is positioned to the right of the '4.0' reading, indicating the direction of the glucose level change.</p> </div> <p data-bbox="570 485 1484 625">The Reader displays your current glucose reading along with your glucose graph and an arrow indicating the direction your glucose is going.</p>






Sensor Glucose Readings



Notes:

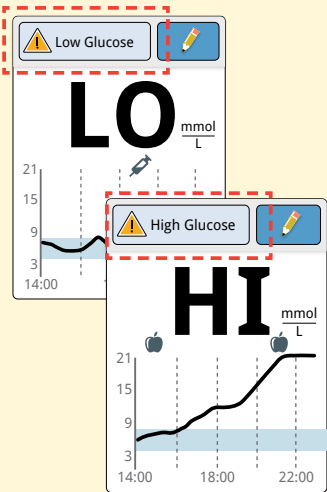
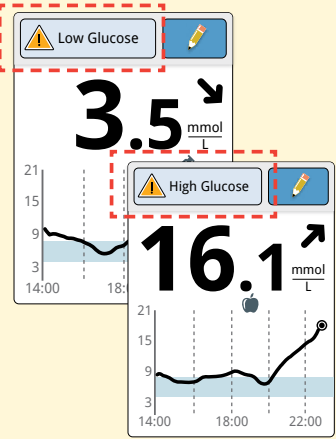
- The graph displays glucose readings up to 21 mmol/L. Glucose readings above 21 mmol/L are displayed at 21 mmol/L.
- The ⌚ symbol may appear, indicating the Reader time was changed. Gaps in the graph may result or glucose readings may be hidden.

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

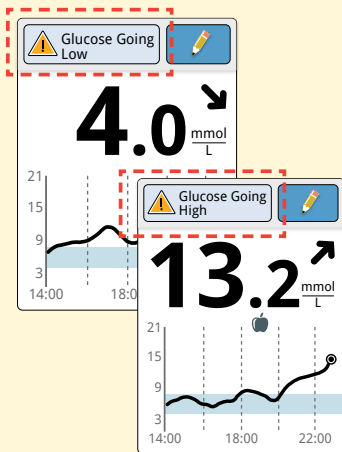
	Glucose is rising quickly (more than 0.1 mmol/L per minute)
	Glucose is rising (between 0.06 and 0.1 mmol/L per minute)
	Glucose is changing slowly (less than 0.06 mmol/L per minute)
	Glucose is falling (between 0.06 and 0.1 mmol/L per minute)
	Glucose is falling quickly (more than 0.1 mmol/L per minute)

Note: The Glucose Trend Arrow may not always appear with your reading.

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

Display	What To Do
	<p>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 27.8 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.</p>
	<p>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.</p>

Display



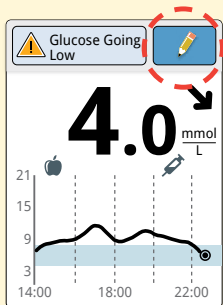

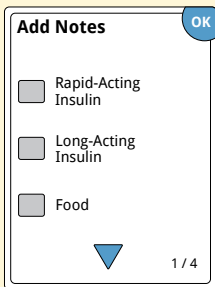
What To Do

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.

Note: If you are not sure about a message or reading, contact your health care professional before you do anything.

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 you take.


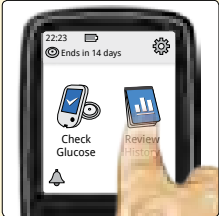
Step	Action
1	 <p>From the Glucose Reading screen, add notes by touching the  symbol in the upper right corner of the touchscreen. If you do not want to add notes, you can press the Home Button to go to the Home Screen or hold the Home Button to turn the Reader off.</p>
2	 <p>Select the tickbox next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








Step	Action
3	<div data-bbox="326 489 738 909"> </div> <p>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.</p> <ul style="list-style-type: none"> • Insulin notes: Enter the number of units taken. • Food notes: Enter grams or carb portion information. <p>Note: Food 🍏 and rapid-acting insulin 🪡 notes are shown on your glucose graphs and in your Logbook as symbols.</p>
4	<div data-bbox="326 1171 565 1476"> </div> <p>Touch OK to save your Notes.</p>

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

Reviewing Your History

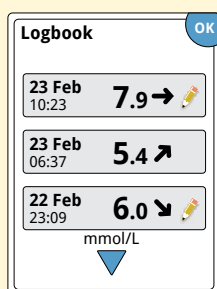
Reviewing and understanding your glucose history can be an important tool for improving your glucose control. The Reader stores about 90 days of information and has several ways to review your past glucose readings, notes, and other information.


Step	Action
1	<div></div> <p>Press the Home Button to turn on the Reader. Press the Home Button again to go to the Home Screen.</p>
2	<div></div> <p>Touch the Review History icon.</p>

Step	Action
3	<div data-bbox="326 480 727 848"><div data-bbox="326 480 537 764"><div data-bbox="326 480 537 533">Review History</div><div data-bbox="326 533 537 596"> Logbook</div><div data-bbox="326 596 537 659"> Daily Graph</div><div data-bbox="326 659 537 722"> Average Glucose</div><div data-bbox="418 722 446 751">▼</div></div><div data-bbox="516 567 727 848"><div data-bbox="609 583 636 613">▲</div><div data-bbox="527 634 719 676"> Daily Patterns</div><div data-bbox="527 688 719 730"> Time In Target</div><div data-bbox="527 743 719 785"> Low-Glucose Events</div><div data-bbox="527 798 719 840"> Sensor Usage</div></div></div> <p data-bbox="578 480 1393 522">Use the arrows to view the available options.</p> <div data-bbox="401 932 1463 1089"><p>IMPORTANT: Work with your health care professional to understand your glucose history.</p></div>

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

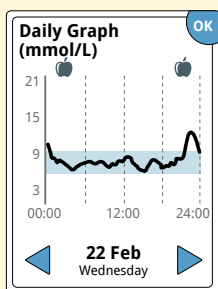
Logbook



Entries for each time you scanned your Sensor or performed a blood glucose or ketone test. If you 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 add or edit (change) Notes for the most recent Logbook entry, provided your glucose reading was within the last 15 minutes and you have not used FreeStyle Libre software to create reports.

Daily Graph



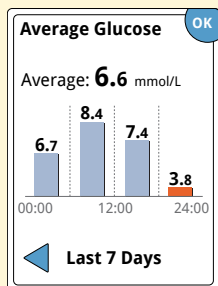
A graph of your Sensor glucose readings by day. The graph shows your Target Glucose Range and symbols for food or rapid-acting insulin notes you have entered.

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.

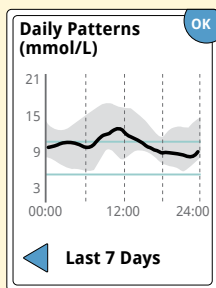
Other History Options

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



Average Glucose

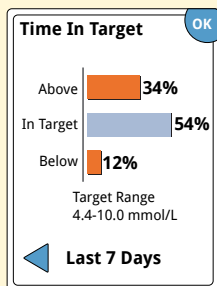
Information about the average of your Sensor glucose readings. The overall average for the time is displayed above the graph. The average is also shown for four different 6-hour periods of the day. Readings above or below your Target Glucose Range are orange, while readings in range are blue.



Daily Patterns

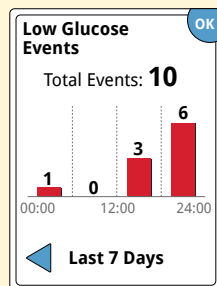
A graph showing the pattern and variability of your Sensor glucose over a typical day. The thick black line shows the median (midpoint) of your glucose readings. The gray shading represents a range (10-90 percentiles) of your Sensor readings.

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



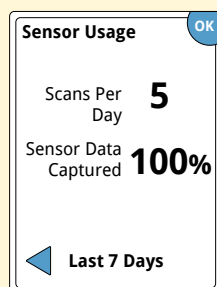
Time In Target

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 longer than 15 minutes. 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	 <p>Pull up the edge of the adhesive that keeps your Sensor attached to your skin. Slowly peel away from your skin in one motion.</p> <p>Note: Any remaining adhesive residue on the skin can be removed with warm soapy water or isopropyl alcohol.</p>
2	<p>Discard the used Sensor according to local regulations. See <i>Maintenance and Disposal</i> section.</p> <p>When you are ready to apply a new Sensor, follow the instructions in the <i>Applying Your Sensor</i> and <i>Starting Your Sensor</i> 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.</p>


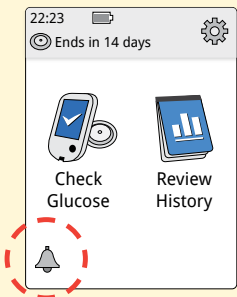
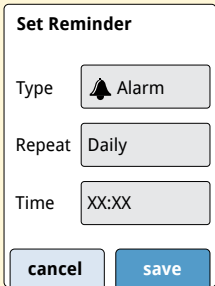
Replacing Your Sensor

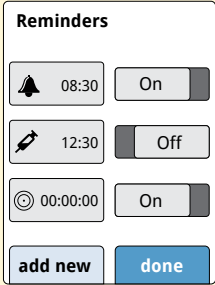
Your Sensor automatically stops working after 14 days of wear and must be replaced. You should also replace your Sensor if you notice any irritation or discomfort at the application site or if the Reader reports a problem with the Sensor currently in use. Taking action early can keep small problems from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

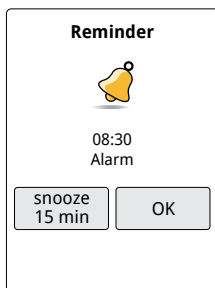
CAUTION: If the glucose readings from the FreeStyle Libre Flash Glucose Monitoring System do NOT seem to match with how you feel, check to make sure that your Sensor has not come loose. If the Sensor tip has come out of your skin, or your Sensor is coming loose, remove the Sensor and apply a new one.

Using Reminders

You can use Reminders to help you remember to check your glucose, take insulin or as a general alarm.

Step	Action
1	<p>From the Home Screen, touch the  symbol.</p> 
2	<p>Touch to select which Type of reminder you want to set: Check Glucose, Take Insulin or Alarm.</p> 
3	<p>Touch to select how often you want the reminder to Repeat: Once, Daily, or Timer.</p> <p>Note: You can set the reminders for a specific time (e.g. 08:30) or as a timer (e.g. 3 hours from the current time).</p>

Step	Action
4	Set the reminder Time using the arrows on the touchscreen. Touch save .
5	<div data-bbox="326 693 539 976">  </div> <p>From the Reminders screen, you can turn the reminder On/Off or add new reminders. Touch done to return to the Home Screen.</p>



When reminders are On, the next reminder time appears next to the reminder symbol on the Home Screen.

For example,  08:30

Your reminder comes on 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.

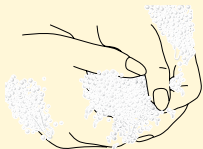
WARNING: Do NOT use the built-in meter while the Reader is connected to an electrical outlet or a computer.

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 Optium 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

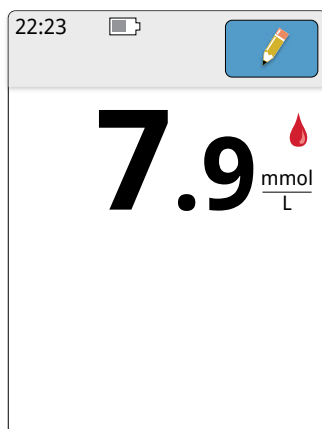
You can use the built-in meter to check your blood glucose, whether you are wearing a Sensor or not. You can perform a blood glucose test on your fingertip or approved alternate site. Be sure to read the test strip instructions for use prior to using the built-in meter.

Step	Action
1	<div></div> <div>CAUTION: If you think you have low glucose (hypoglycaemia) or you suffer from hypoglycaemia unawareness, test on your fingers.</div> <p>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.</p> <p>Note: Avoid areas near bones and areas with lots of hair. If a bruise forms, consider selecting another site.</p>


Step	Action
<p>2</p>	<div data-bbox="310 478 542 564" data-label="Image"> </div> <p>Check the test strip expiry date.</p> <p>E.g. Expiry date: March 31, 2016</p>
<p>3</p>	<div data-bbox="289 724 539 907" data-label="Image"> </div> <p>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.</p>
<p>4</p>	<div data-bbox="305 978 542 1155" data-label="Image"> </div> <p>Insert the test strip with the three black lines at the end facing up. Push the strip in until it stops.</p>
<p>5</p>	<div data-bbox="326 1226 535 1505" data-label="Image"> </div> <p>Use your lancing device to obtain a blood drop and apply blood to the white area at the end of the test strip.</p> <p>If sounds are turned on, the Reader beeps once to let you know you have applied enough blood.</p> <p>Note: See test strip instructions for use for re-application instructions.</p>

Step	Action
	 <p>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.</p>
6	<p>After reviewing your result, remove and discard the used test strip according to local regulations.</p>

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

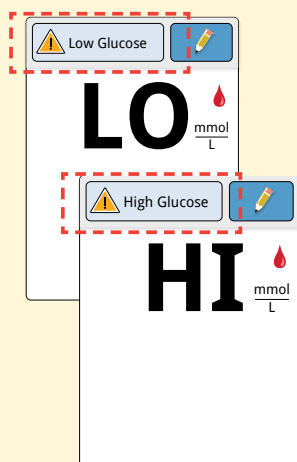


Your Blood Glucose Results

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

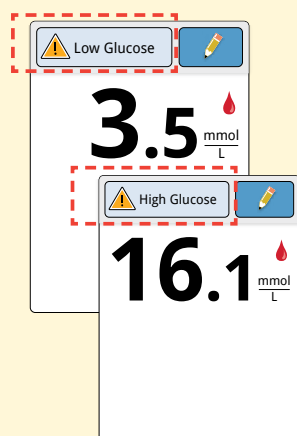
Note: Contact your health care professional if you have symptoms that do not match your test results.

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.

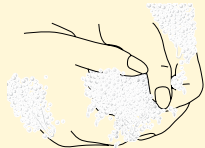
After you get your blood glucose result, you can add Notes by touching the  symbol. If you do not want to add a Note, press the Home Button to go to the Home Screen or hold the Home Button to turn the Reader off.

Blood Ketone Testing

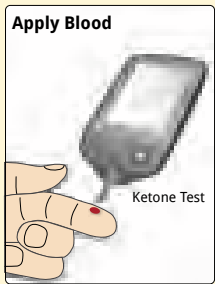

You can use the built-in meter to check your blood ketone (β -hydroxybutyrate). It is important to consider doing this when:

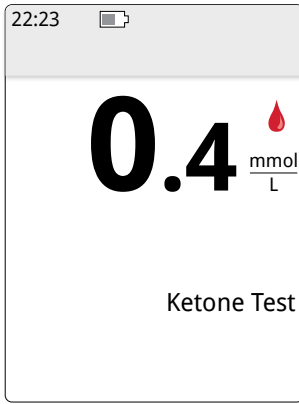
- You are sick
- Your glucose is higher than 13.3 mmol/L
- You and your health care professional decide you should

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

Step	Action
1	 <p>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.</p> <p>Note: Use only fingertip samples for blood ketone testing.</p>

Step	Action
<p>2</p>	<div data-bbox="310 480 542 567" data-label="Image"> </div> <p>Check the test strip expiry date.</p> <p>E.g. Expiry date: March 31, 2016</p>
<p>3</p>	<div data-bbox="298 898 548 1081" data-label="Image"> </div> <p>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.</p>
<p>4</p>	<div data-bbox="321 1293 558 1470" data-label="Image"> </div> <p>Note: Use only blood ketone test strips. Do not put urine on the test strip.</p> <p>Insert the test strip with the three black lines facing up. Push the strip in until it stops.</p>

Step	Action
<p>5</p>	<div data-bbox="313 487 526 768">  </div> <p>Use your lancing device to obtain a blood drop and apply blood to the white area at the end of the test strip.</p> <p>If sounds are turned on, the Reader beeps once to let you know you have applied enough blood.</p> <p>Note: See test strip instructions for use for re-application instructions.</p> <div data-bbox="360 890 531 1064">  </div> <p>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.</p>
<p>6</p>	<p>After reviewing your result, remove and discard the used test strip according to local regulations.</p> <div data-bbox="388 1388 1450 1583"> <p>IMPORTANT: After performing a blood ketone test, wash your hands with soap and water and thoroughly dry them.</p> </div>



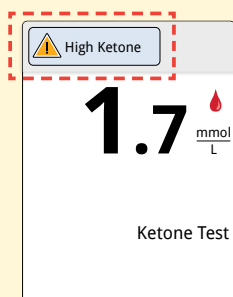
Your Blood Ketone Results

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

Notes:

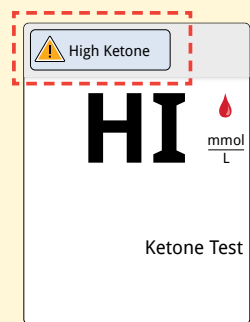
- Blood ketone is expected to be lower than 0.6 mmol/L.
- Blood ketone may be higher when you are sick, fasting, have exercised hard or if glucose levels are not controlled.
- If your blood ketone result remains high or becomes higher than 1.5 mmol/L, contact your health care professional **immediately**.

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.



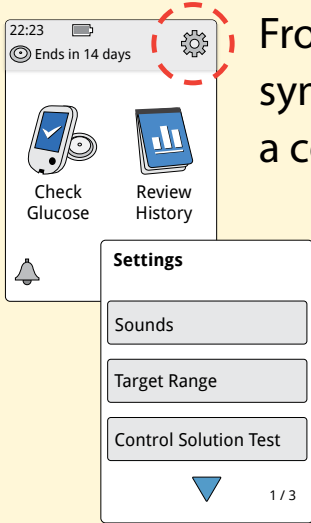

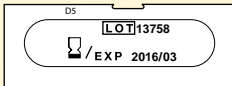
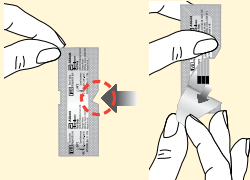
If **HI** appears on the Reader, your ketone result is higher than 8 mmol/L. You can touch the message button for more information. Repeat the ketone test with a new test strip. If you get a second **HI** result, contact your health care professional **immediately**.

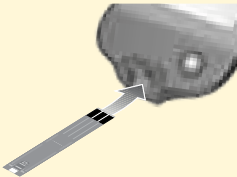
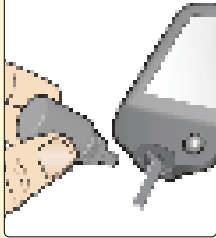

Control Solution Testing

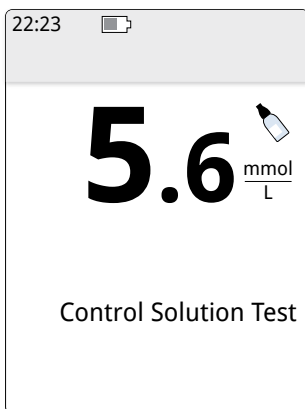
You should do a control solution test when you are not sure of your test strip results and want to check that your Reader and test strips are working properly. You can do a control solution test with a blood glucose or ketone test strip.

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	<div data-bbox="305 468 613 987">  </div> <p>From the Home Screen, touch the Settings symbol . Touch Control Solution Test to do a control solution test.</p>
2	<div data-bbox="305 1060 535 1144">  </div> <p>Check the test strip expiry date.</p> <p>E.g. Expiry date: March 31, 2016</p>
3	<div data-bbox="292 1386 540 1564">  </div> <p>Open the foil test strip packet at the notch and tear down to remove the test strip.</p>


Step	Action
4	 <p>Insert the test strip with the three black lines facing up. Push the strip until it stops.</p>
5	<div data-bbox="326 766 540 1050">  <p>Apply Control Solution</p> </div> <p>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.</p> <p>If sounds are turned on, the Reader beeps once to let you know that you have applied enough control solution.</p> <div data-bbox="370 1087 540 1255">  </div> <p>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.</p>

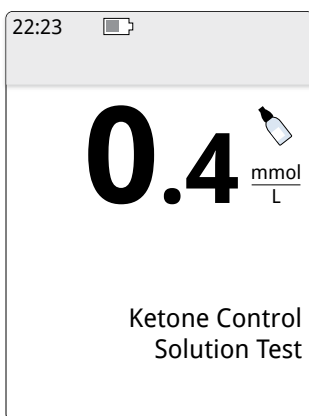


**Blood Glucose Control
Solution Test**

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

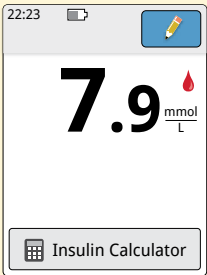
This optional feature requires an understanding of the use of insulin. Misuse or misunderstanding of this feature and the suggested dose may lead to inappropriate insulin dosing. The calculator suggests doses for rapid-acting insulin only. The calculator is only for use with fingerstick blood glucose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

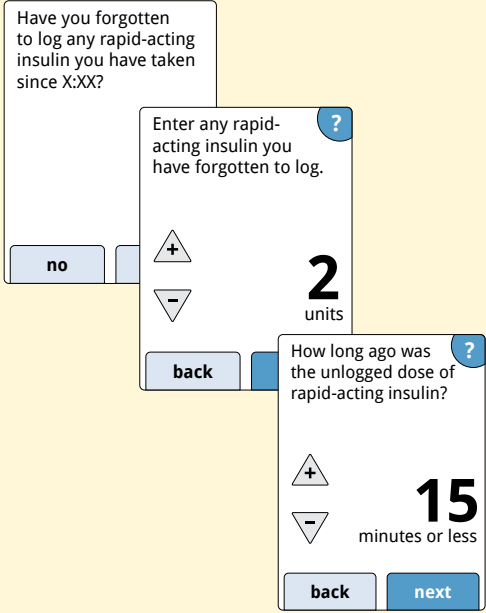
An access code is required to set up or change the rapid-acting insulin calculator settings. This access code is available only to your health care professional. Work with your health care professional to set up or change the calculator for you.

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.


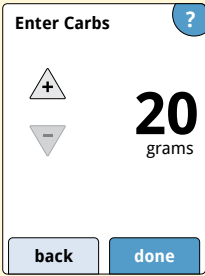
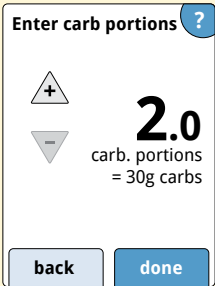
If you have added a rapid-acting insulin note to a glucose result without indicating how much insulin you took, the calculator will not be available for up to 8 hours.


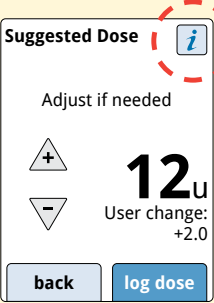
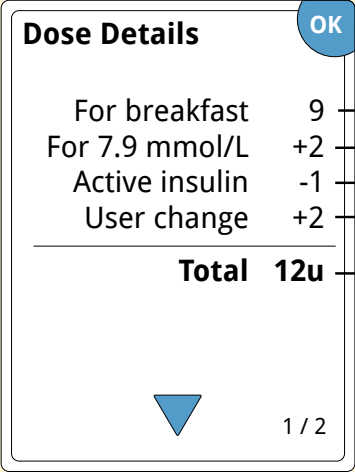
Step	Action
1	<div>A screenshot of a blood glucose meter screen. At the top, it shows the time 22:23 and a battery icon. The main display shows a large number '7.9' followed by 'mmol/L' and a small red blood drop icon. At the bottom, there is a button labeled 'Insulin Calculator' with a calculator icon.</div> <p>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.</p>

Step	Action
<p>2</p>	<p>Enter information about any rapid-acting insulin you may have forgotten to log. Touch next.</p> 

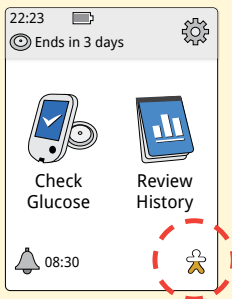
Notes:



- 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	<div data-bbox="313 487 526 770">  </div> <p data-bbox="560 478 1468 619">If your calculator was programmed with Easy Setup, touch the meal you plan to eat now. Touch next.</p> <p data-bbox="560 751 610 793">Or</p> <div data-bbox="318 888 521 1161">  </div> <p data-bbox="560 884 1372 1077">If your calculator was programmed with Advanced Setup, enter the grams of carbohydrates or carbohydrate portions you plan to eat now. Touch done.</p> <p data-bbox="399 1199 449 1241">Or</p> <div data-bbox="318 1266 531 1549">  </div>

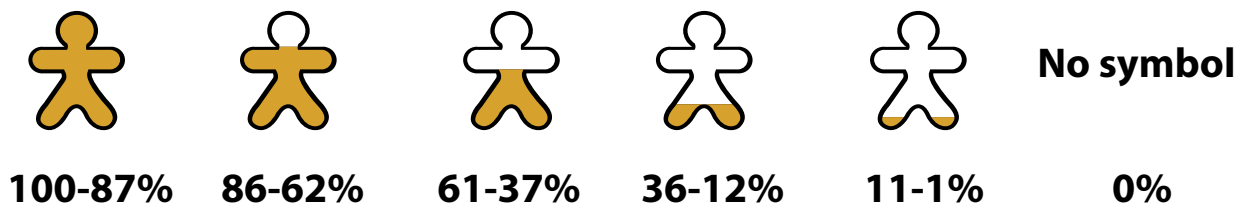
Step	Action
4	<p>Review your suggested dose. If needed, use the arrow buttons to adjust your suggested dose for any planned activity, a smaller or larger meal, sickness, etc. Touch the  symbol to see details of what is included in your suggested dose.</p> <div>  </div> <div>  <div> <p>Insulin to cover your meal</p> <p>Insulin to correct for your current glucose level</p> <p>Insulin remaining in your body</p> <p>A change you have made to the suggested insulin dose</p> <p>Your total suggested dose</p> </div> </div>

Step	Action
5	<p data-bbox="313 478 1446 573">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.</p> <div data-bbox="355 644 1414 942" style="border: 1px solid black; padding: 10px;"> <p data-bbox="376 665 1393 909">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.</p> </div> <p data-bbox="313 1024 1386 1171">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.</p>



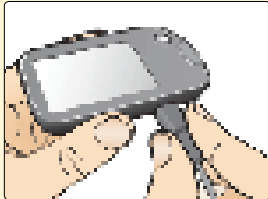
If your health care professional turned on the Active Insulin feature, the  symbol may appear on your Home Screen. It shows an estimate of the amount of rapid-acting insulin left in your body and how much longer it may be active. Touch the  symbol to see more information about the remaining rapid-acting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

Estimated percentage of active insulin remaining in your body



Charging the Reader

A fully charged Reader battery should last up to 7 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.




Charging

Plug the included USB cable into an electrical outlet using the included power adapter. Then, plug the other end of the USB cable into the USB port on the Reader.

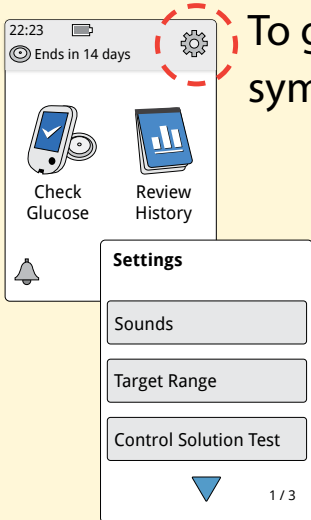

CAUTION: Be sure to select a location for charging that allows the power adapter to be easily unplugged.

Notes:

- 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.
- Only use the USB cable and power adapter included with the system.
- 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 Time & Date or Sounds. The Settings menu is also where you go to do a Control Solution Test or to check the System Status.

Step	Action
1	<div>The screenshot shows a mobile device's home screen. At the top, the time is 22:23 and there's a battery icon. Below that, it says 'Ends in 14 days' with a circular arrow icon. There are two main app icons: 'Check Glucose' with a glucose meter icon and 'Review History' with a bar chart icon. At the bottom left is a bell icon for notifications. A 'Settings' menu is open, showing options: 'Sounds', 'Target Range', and 'Control Solution Test'. At the bottom of the menu is a blue downward arrow and the text '1 / 3'. A red dashed circle highlights the gear icon (Settings) in the top right corner of the home screen.<p>To get to the Settings menu, touch the Settings symbol  on the Home Screen.</p></div>



Step	Action
2	<p>Touch the setting you want to change:</p> <p>Sounds – Set tones and vibrations</p> <p>Target Range – Set range displayed on Reader glucose graphs</p> <p>Control Solution Test – Perform a Control Solution test</p> <p>Time & Date – Change the Time or Date</p> <p>Language – Change the language on the Reader (option only available on Readers with multiple languages)</p> <p>System Status – Check Reader information and performance</p> <ul style="list-style-type: none"> • View System Information: The Reader will display information about your System including: <ul style="list-style-type: none"> - Current Sensor end date and time - Reader serial number and version number - Serial numbers 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.)	<ul style="list-style-type: none"> • 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 (including both tones and vibrations) are working and the Touchscreen is responding when touched <p>Calculator Settings – Review the currently programmed settings (option only available if your health care professional has activated your insulin calculator)</p> <p>Reader Basics – Review the information screens shown during the Reader setup</p> <p>Professional Options – Set by health care professionals only</p> <p>Touch OK when you are done.</p>

Living With Your FreeStyle Libre System

Your FreeStyle Libre Flash Glucose Monitoring System can be used during a wide variety of activities.

Activity	What You Need To Know
Bathing, Showering and Swimming	<p>The Reader is not water-resistant and should NEVER be submerged in water or other liquids. Your Sensor is water-resistant and can be worn while bathing, showering or swimming.</p> <p>Note: Do NOT take your Sensor deeper than 1 metre (3 feet) or immerse it longer than 30 minutes in water.</p>
Sleeping	<p>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.</p> <p>If you have reminders set to go off while you are sleeping, place the Reader nearby.</p>

Activity	What You Need To Know
Travelling by Air	<p>Check with the airline prior to departure as rules and regulations may change without notice. Follow these guidelines when travelling:</p> <ul style="list-style-type: none"> • Notify security personnel of the presence of the device when going through security systems. • Do not scan your Sensor or power on the Reader using the Home Button while flying, if restricted by flight regulations. You may insert a strip to perform a blood glucose or ketone test. <p>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, statistics, and settings programmed by time of day. 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.</p>

Maintenance and Disposal

Cleaning

You may clean the Reader using a cloth dampened with a mixture of 1 part household bleach to 9 parts water. Gently wipe the exterior of the Reader and allow to air dry.

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 ports.

Maintenance

The FreeStyle Libre Flash Glucose Monitoring 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.	<ol style="list-style-type: none"> 1. Remove the Sensor. 2. Consider shaving and/or cleaning the site with soap and water. 3. Follow the instructions in <i>Applying and Starting Your Sensor</i> 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.

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 Reader.	A Sensor can only be scanned by the Reader that started it. Scan the Sensor again with the Reader 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.

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.	<ol style="list-style-type: none">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.	<ol style="list-style-type: none">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	<p>Blood drop is too small.</p> <p>or</p> <p>Incorrect test procedure.</p> <p>or</p> <p>There may be a problem with the test strip.</p>	<ol style="list-style-type: none"> 1. Review the testing instructions. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Service.
E-4	<p>The blood glucose level may be too high to be read by the system.</p> <p>or</p> <p>There may be a problem with the test strip.</p>	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.

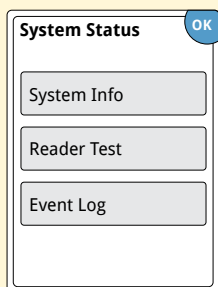
Error Message	What It May Mean	What To Do
E-7	Test strip may be damaged, used or the Reader does not recognise it.	<ol style="list-style-type: none"> 1. Check that you are using the correct test strip for the Reader. (See test strip instructions for use to verify your strip is compatible with the Reader). 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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 Optium 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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.	<ol style="list-style-type: none"> 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 Options symbol  from the Home Screen, select **System Status** and then select **Reader Test**.

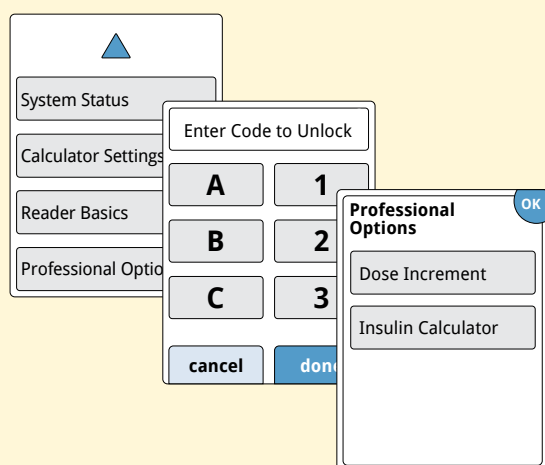
Note: The Reader Test will perform internal diagnostics and will allow you to check that the display, sounds and touchscreen are working properly.


Customer Service

Customer Service is available to answer any questions you may have about your FreeStyle Libre Flash Glucose Monitoring System. Please go 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.

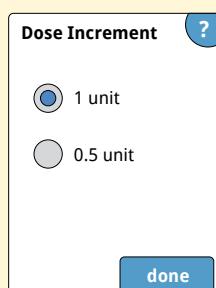


From the Home Screen, touch the Settings symbol . Scroll down using the arrows and touch **Professional Options**. Enter the access code.

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)

=

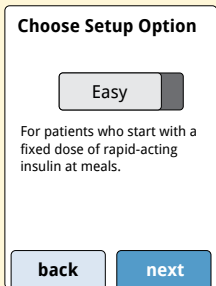
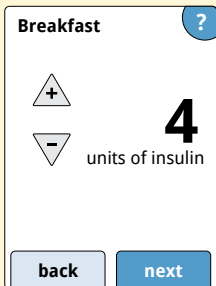
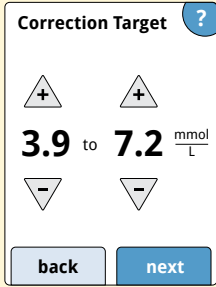
**Total
suggested
dose**

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

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.

Breakfast
Dose

units of insulin

0-50

Lunch
Dose

units of insulin

0-50

Dinner
Dose

units of insulin

0-50

► This is the insulin required to cover food.

Correction Target

 –

mmol/L mmol/L

3.9-10.0 3.9-10.0

► This is the desired range for before meal blood glucose.

Correction Factor
1 unit of insulin for

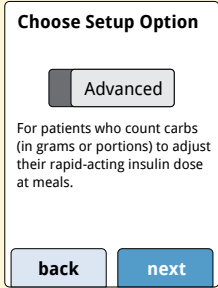
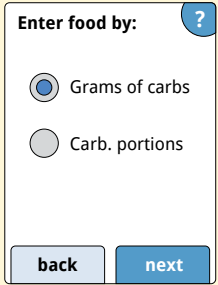
mmol/L

0.1-5.5 (or No Correction)

► This is the estimated amount blood glucose will drop by taking one unit of insulin.

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

Advanced Setup of the Insulin Calculator

Step	Action
1	<div data-bbox="323 556 539 842">  </div> <p>Choose the Advanced option on the slide bar and touch next.</p> <p>Note: You need to know your patient's mealtime insulin settings, target glucose range, correction factor and insulin duration.</p>
2	<div data-bbox="323 1094 539 1377">  </div> <p>Touch to select how meal/carbohydrate information will be entered. Touch next.</p> <p>For Grams of carbs, go to Step 3.</p> <p>For Carb portions, go to Step 4.</p>

Step

Action

3

Carbohydrate Ratio ?

1 u insulin for **10** grams carbs

Optional:

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.

Carbohydrate ratio ?

1 unit insulin for:

10g morning

15g midday

20g evening

15g night

Carbohydrate Ratio OK

1 u insulin for **10** grams carbs

Morning: 4am to 10am

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

Carb Portions Definition ?

1 portion = **10.0** grams carbs

back

Carb Portion Ratio ?

For 1 portion: **1.5** units insulin

Optional:

back next

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** (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.

Carb portion ratio for 1 portion: ?

2 u ins morning

3 u ins night

3 u ins midday

4 u ins evening

back

Carb Portion Ratio OK

For 1 portion: **2** units insulin

Morning:
4am to 10am

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 portions ratio. Touch **OK** after each entry to save. Touch **done**.

Step	Action
5	<div data-bbox="305 485 521 768"> <p>How does your patient correct their glucose?</p> <p><input checked="" type="radio"/> To a single target</p> <p><input type="radio"/> To a target range</p> <p>back next</p> </div> <p>Select how you want your patient to correct their glucose. Touch next.</p>
6	<div data-bbox="313 852 529 1136"> <p>Correction Target</p> <p>5.6 mmol/L</p> <p>Optional: by time of day</p> <p>back</p> </div> <div data-bbox="399 1087 615 1371"> <p>Correction Target in mmol/L:</p> <p>5.6 morning</p> <p>6.7 night</p> <p>6.1 midday</p> <p>5.6 evening</p> <p>back</p> </div> <div data-bbox="493 1339 709 1623"> <p>Correction Target OK</p> <p>5.6 mmol/L</p> <p>Morning: 4am to 10am</p> </div> <p>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.</p> <p>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.</p>

Step	Action
7	<div data-bbox="256 485 545 1241"> </div> <p>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.</p> <p>Notes:</p> <ul style="list-style-type: none"> • 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

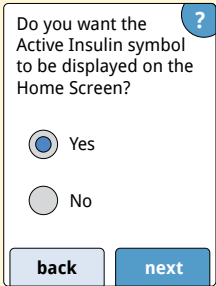

8

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 person¹. The Reader allows an insulin duration from 3-8 hours.

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

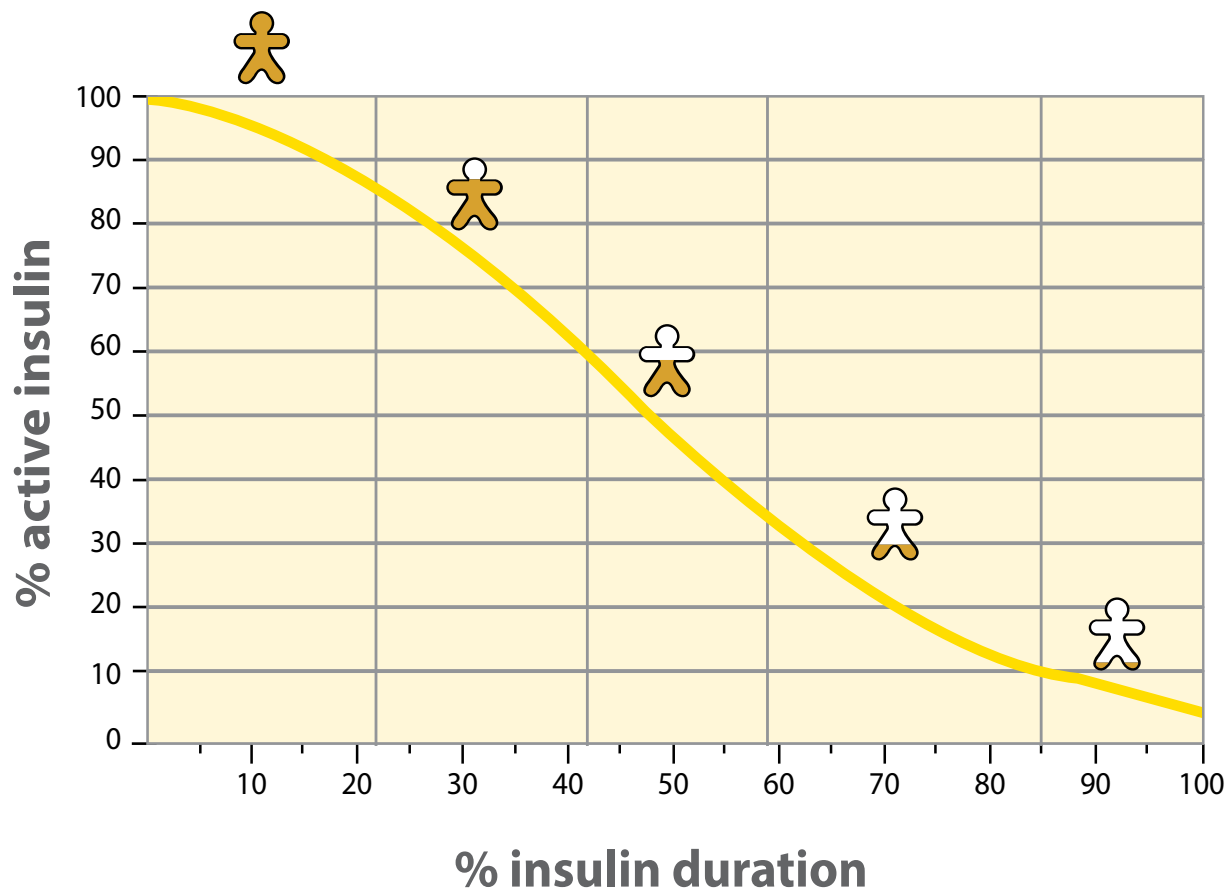
Step	Action
9	<div data-bbox="326 485 540 768"></div> <p data-bbox="574 478 1474 573">Select whether or not to show the Active Insulin symbol  on the Home Screen.</p> <p data-bbox="574 590 1442 831">This symbol shows an estimate of the amount of rapid-acting insulin still in the body and how much longer it may be active. If you select “No”, active insulin is still included in the suggested dose calculation.</p> <p data-bbox="574 856 1484 999">Touch next. Then touch done to complete the setup. You can now review the calculator settings. Touch OK when done.</p>

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 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.

Active insulin curvilinear model



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 Portions 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 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.)

Correction Factor
1 unit of insulin for

mmol/L
0.1-5.5

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

Insulin Duration
Insulin is active in the body for

hours:mins
3-8

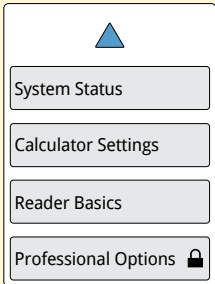

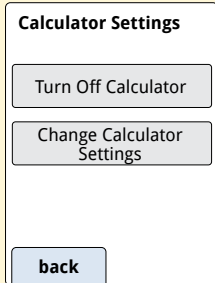
- This is the amount of time that a dose of rapid-acting insulin remains active in the body.

Active Insulin feature?

☐
Yes☐
No

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

Changing the Insulin Calculator Settings

Step	Action
1	<div></div> <p>From the Home Screen, touch the Settings symbol . Scroll down using the arrows and touch Professional Options. Enter the access code. Touch Insulin Calculator.</p>
2	<div></div> <p>Touch Turn Off Calculator to turn off the insulin calculator or Change Calculator Settings to change the insulin calculator settings.</p> <p>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.</p>

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 27.8 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)
Operating temperature	10 °C to 45 °C
Sensor Applicator and Sensor Pack storage temperature	4 °C to 30 °C
Operating and storage relative humidity	10-90%, non-condensing
Sensor water resistance	IP27: Can withstand immersion into one metre (3 ft) of water for up to 30 minutes
Operating and storage altitude	-381 metres (-1,250 ft) to 3,048 metres (10,000 ft)

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	7 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

















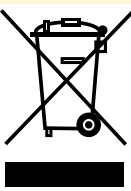
Operating and storage relative humidity	10-90%, non-condensing
Reader moisture protection	Keep dry
Operating and storage altitude	-381 metres (-1,250 ft) to 3,048 metres (10,000 ft)
Reader display timeout	60 seconds (120 seconds when test strip is inserted)
Radio Frequency	13.56 MHz
Data port	Micro USB
Minimum Computer Requirements	System must only be used with EN60950-1 rated computers
Mean service life	3 years of typical use
Power Adapter	Abbott Diabetes Care PRT25612 Operating temperature: 10 °C to 40 °C
USB Cable	Abbott Diabetes Care PRT21373 Length: 94 cm (37 inches)

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

Parameter	Unit	Range or Value
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		Catalogue number
	Manufacturer		Serial number
	CE Mark		Do not use if package is damaged
	Batch code		Keep dry
	Type BF applied part		Non-ionizing radiation
	Sensor code		Caution
	Do not re-use		Sterilised using irradiation
	This product must not be disposed of via municipal waste collection. Separate collection for electrical and electronic equipment waste per Directive 2012/19/EC in the European Union is required. Contact the manufacturer for details.		

Electromagnetic Compatibility

- 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.
- The use of accessories, transducers and cables other than those specified by Abbott Diabetes Care may result in increased EMISSIONS or decreased IMMUNITY of the System.
- The System should not be used adjacent to or stacked with other equipment and that 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.

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 assure 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 assure 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	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	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 seconds	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 seconds	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	3 A/m	3 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	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2 \sqrt{P}$

IMMUNITY test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Recommended separation distance $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz

P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).

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: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- ^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 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the System

The System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Hereby, Abbott Diabetes Care Ltd, declares that the FreeStyle Libre Flash Glucose Monitoring System is in compliance with the essential requirements and other relevant provisions of the R&TTE Directive. A copy of the original declaration of conformity may be obtained from Abbott Diabetes Care Ltd., Range Road, Witney, Oxon, OX29 0YL, UK.

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Additional patents may be issued and/or pending.



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