User's Manual

FreeStyle *Libre*

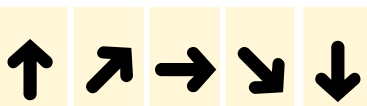
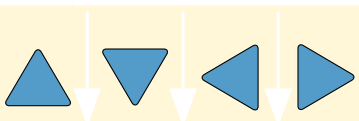
FLASH GLUCOSE MONITORING SYSTEM

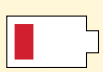
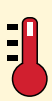
Abbott

Your Name _____

Contents

Reader Symbols

Symbol	What It Means
	Active Sensor
	Direction your glucose is going. See *Checking Your Glucose* section for more information
	Caution
	View previous/next screen
	Notes
	Add more information to notes
	Food note
	Rapid-acting insulin note
	Time changed on Reader
	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 Reader ("Reader") when used with a FreeStyle Libre or FreeStyle Libre 2 Flash Glucose Monitoring System Sensor ("Sensor") is indicated for measuring interstitial fluid glucose levels in people (age 4 and older) with diabetes mellitus, including pregnant women. The Reader and Sensor are designed to replace blood glucose testing in the self-management of diabetes, including dosing of insulin.

The indication for children (aged 4 -12) is limited to those who are supervised by a caregiver who is at least 18 years of age. The caregiver is responsible for managing or assisting the child to manage the Reader and Sensor and also for interpreting or assisting the child to interpret Sensor glucose readings.

Contraindications

The Sensor must be removed prior to Magnetic Resonance Imaging (MRI).

WARNING:

- Do not ignore symptoms that may be due to low or high blood glucose. If you have symptoms that do not match the Sensor glucose reading or suspect that your reading may be inaccurate, check the reading by conducting a fingerstick test using a blood glucose meter. If you are experiencing symptoms that are not consistent with your glucose readings, consult your health care professional.
- The FreeStyle Libre Flash Glucose Monitoring System ("System") contains small parts that may be dangerous if swallowed.
- The FreeStyle Libre Reader can be used with either the FreeStyle Libre Sensor or FreeStyle Libre 2 Sensor but will NOT issue alarms. Not all Sensors are available in all countries.

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.
- Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If you notice significant skin irritation around or under your Sensor, remove the Sensor and stop using the Sensor. Contact your health care professional before continuing to use the Sensor.
- The System uses all available glucose data to give you readings so you should scan your Sensor at least once every eight hours for the most accurate performance. Scanning less frequently may result in decreased performance.

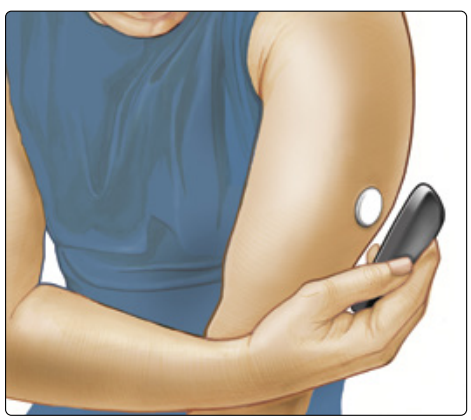
System-Related Information

- The Reader 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.
- Physiological 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.
- Do not reuse Sensors. The Sensor and Sensor Applicator are designed for single use. Reuse may result in infection and no glucose readings. Not suitable for re-sterilisation. Further exposure to irradiation may cause inaccurate results.
- Store the Sensor Kit between 4°C and 25°C. While you don't need to keep your Sensor Kit in a refrigerator, you can as long as the refrigerator is between 4°C and 25°C.

- 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 this type of procedures on the performance of the system has not been evaluated.
- The System has not been evaluated for use in persons on dialysis or people less than 4 years of age.

Getting to Know Your System

The FreeStyle Libre Flash Glucose Monitoring System ("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:

- FreeStyle Libre Reader
- USB Cable
- Power Adaptor
- User's Manual
- Quick Start Guide
- Performance Data Insert

Touchscreen

USB Port

Used to charge the Reader and connect it to a computer.

Home Button

Turns the Reader on/off and takes you to the Home screen from any other screen.

Test Strip Port

Insert a test strip here to use the built-in meter.

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

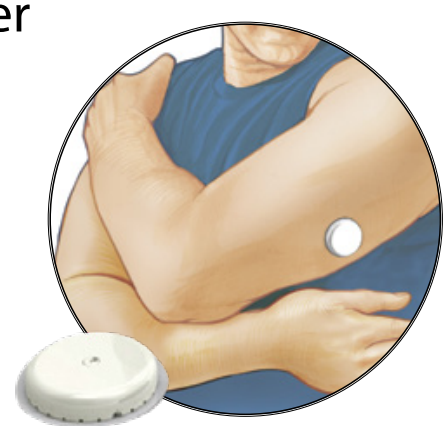
The Sensor Kit includes:

- Sensor Pack
- Sensor Applicator
- Product insert

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

Sensor Applicator
Applies the Sensor to your body.

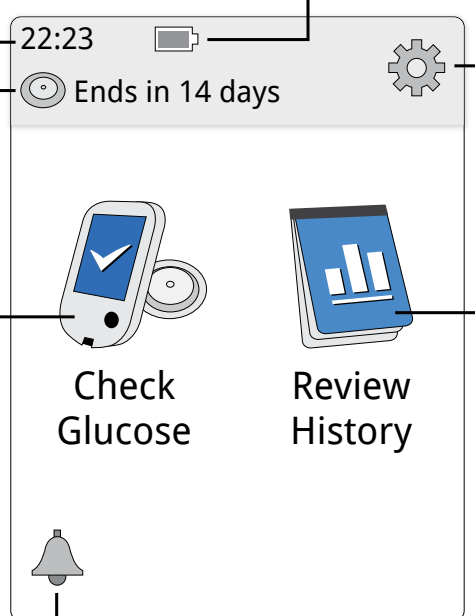
The Sensor measures and stores glucose readings when worn on your body. It initially comes in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. By following the instructions, you prepare and apply the Sensor on the back of your upper arm. The Sensor has a small, 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.

Settings

Touch to change the Reader's settings.

Check Glucose

Touch to check your Sensor glucose.

Review History

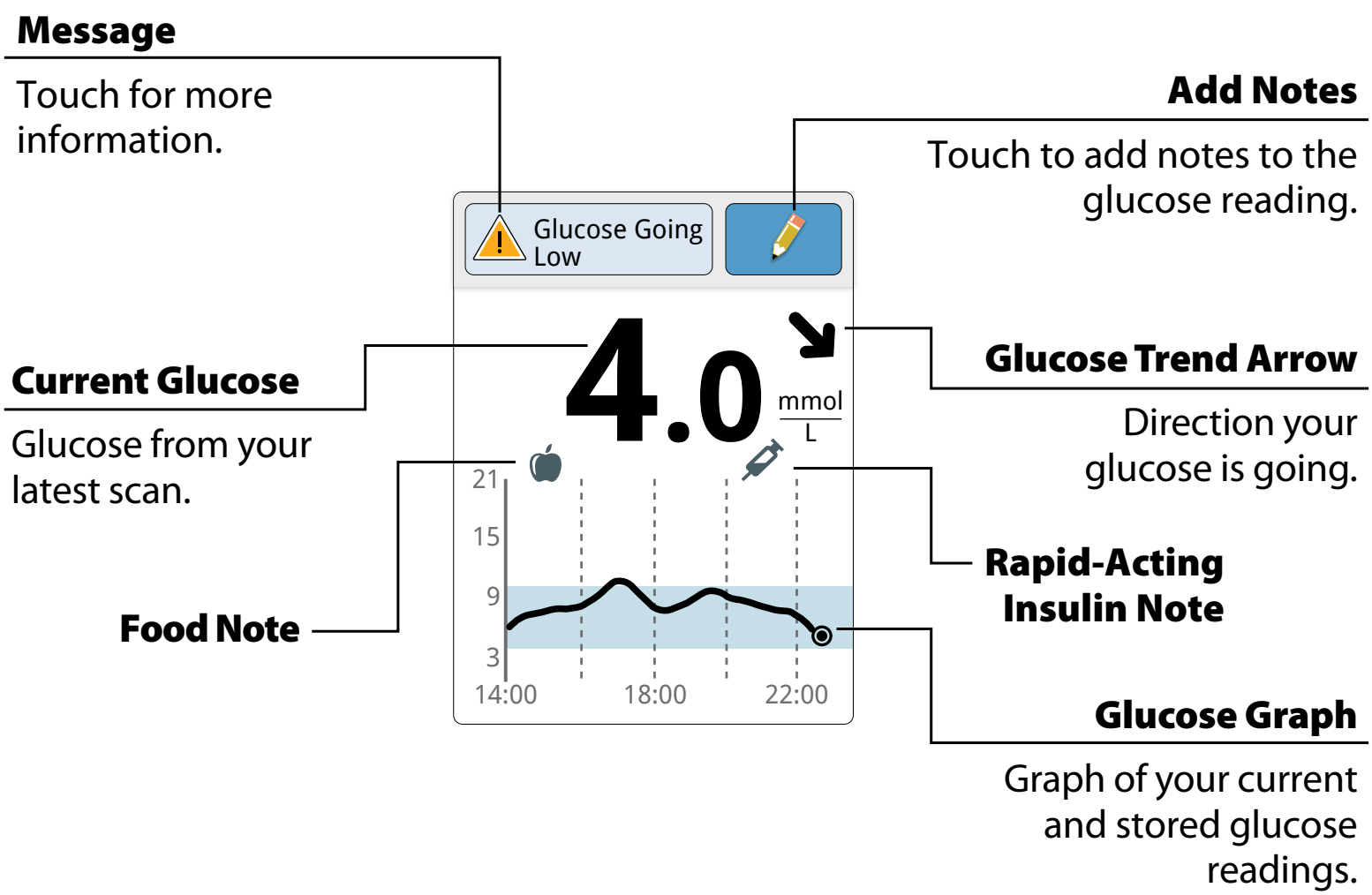
Touch to review information about your past glucose readings.

Reminder

Touch to set or change reminders.

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

Sensor Glucose Readings

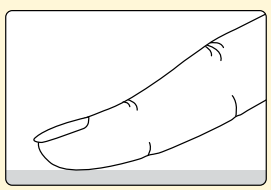
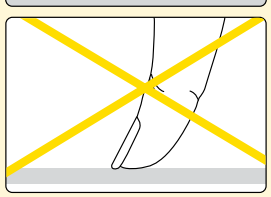
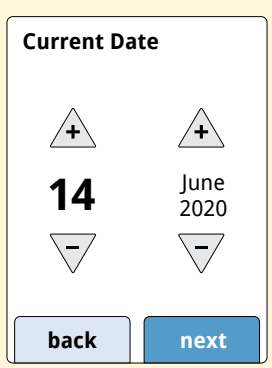


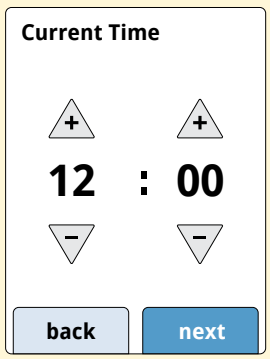
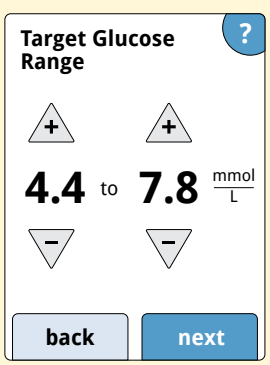
Data Management Software

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

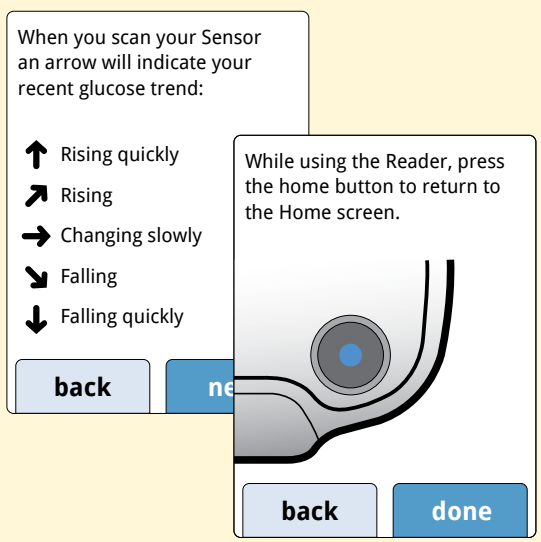
Setting up Your Reader for the First Time

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

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

Step	Action
4	 Set the **Current Time**. Touch **next** to continue. **CAUTION:** It is very important to set the time and date correctly. These values affect the Reader data and settings.
5	 Set your **Target Glucose Range**. Work with your health care professional to determine your Target Glucose Range. Touch **next** to continue. **Note:** Your Target Glucose Range is displayed on glucose graphs on the Reader and used to calculate your Time In Target.

Step	Action
6	The Reader now displays important information about two key topics to help you use the system: • How to understand the Glucose Trend Arrow included on the Glucose Reading screen. • How to return to the Home Screen from any other screen.



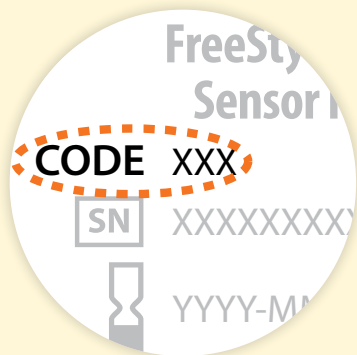
Touch **next** to move to the next topic. At the end of the Reader setup, touch **done** to go to the Home Screen.

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

Using Your Sensor

CAUTIONS:

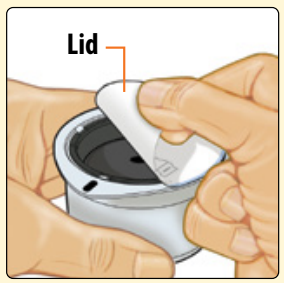
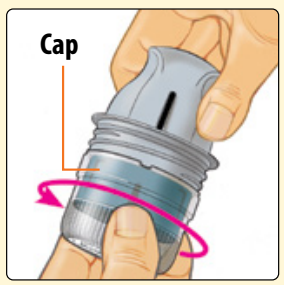
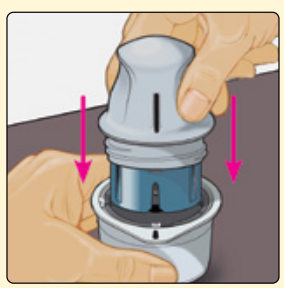
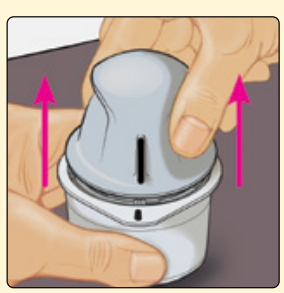
- The Sensor Pack and Sensor Applicator are packaged as a set (separately from the Reader) and have the same Sensor code. Check that the Sensor codes match before using your Sensor Pack and Sensor Applicator. Sensor Packs and Sensor Applicators with the same Sensor code should be used together or your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

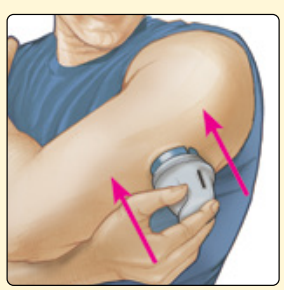


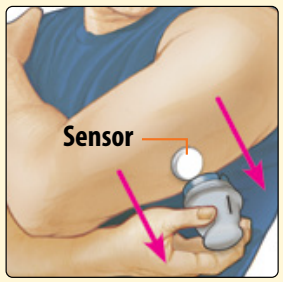
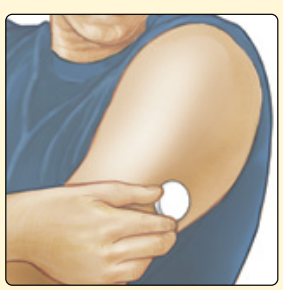
- Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. If your Sensor comes loose, you may get no readings or unreliable readings, which may not match how you feel. Follow the instructions to select an appropriate application site.

Applying Your Sensor

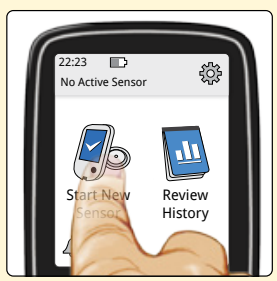
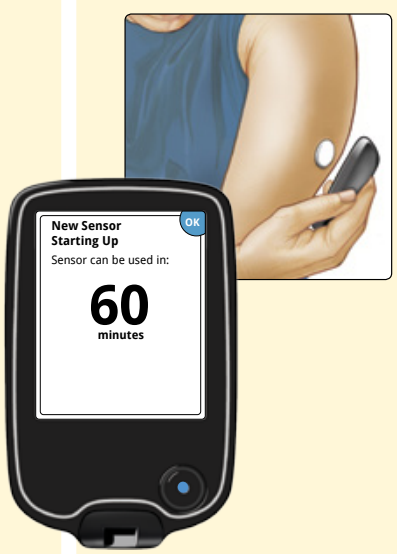
Step	Action
1	 Apply Sensors only on the back of your upper arm. Avoid areas with scars, moles, stretch marks or lumps. Select an area of skin that generally stays flat during your normal daily activities (no bending or folding). Choose a site that is at least 2.5 cm (1 inch) away from an insulin injection site. To prevent discomfort or skin irritation, you should select a site other than the one most recently used.
2	 Wash application site using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the Sensor from sticking properly. Allow site to air dry before proceeding. **Note:** The area **MUST** be clean and dry, or the Sensor may not stick to the site.

Step	Action
3	  Open the Sensor Pack by peeling the lid off completely. Unscrew the cap from the Sensor Applicator and set the cap aside. **CAUTION:** Do NOT use if the Sensor Pack or the Sensor Applicator seem to be damaged or already opened. Do NOT use if past expiry date.
4	 Line up the dark mark on the Sensor Applicator with the dark mark on the Sensor Pack. On a hard surface, press down firmly on the Sensor Applicator until it comes to a stop.
5	 Lift the Sensor Applicator out of the Sensor Pack.

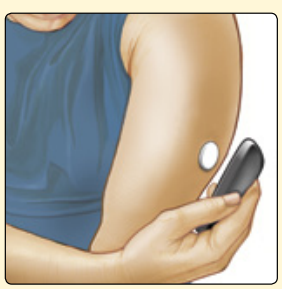
Step	Action
6	 The Sensor Applicator is prepared and ready to apply the Sensor. **CAUTION:** The Sensor Applicator now contains a needle. Do NOT touch inside the Sensor Applicator or put it back into the Sensor Pack.
7	 Place the Sensor Applicator over the prepared site and push down firmly to apply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

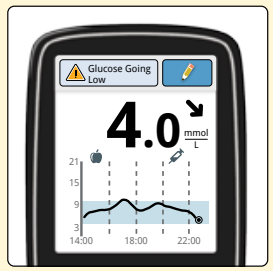
Step	Action
8	 Gently pull the Sensor Applicator away from your body. The Sensor should now be attached to your skin. **Note:** Applying the Sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the Sensor and apply a new one at a different site.
9	 Make sure the Sensor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

Starting Your Sensor

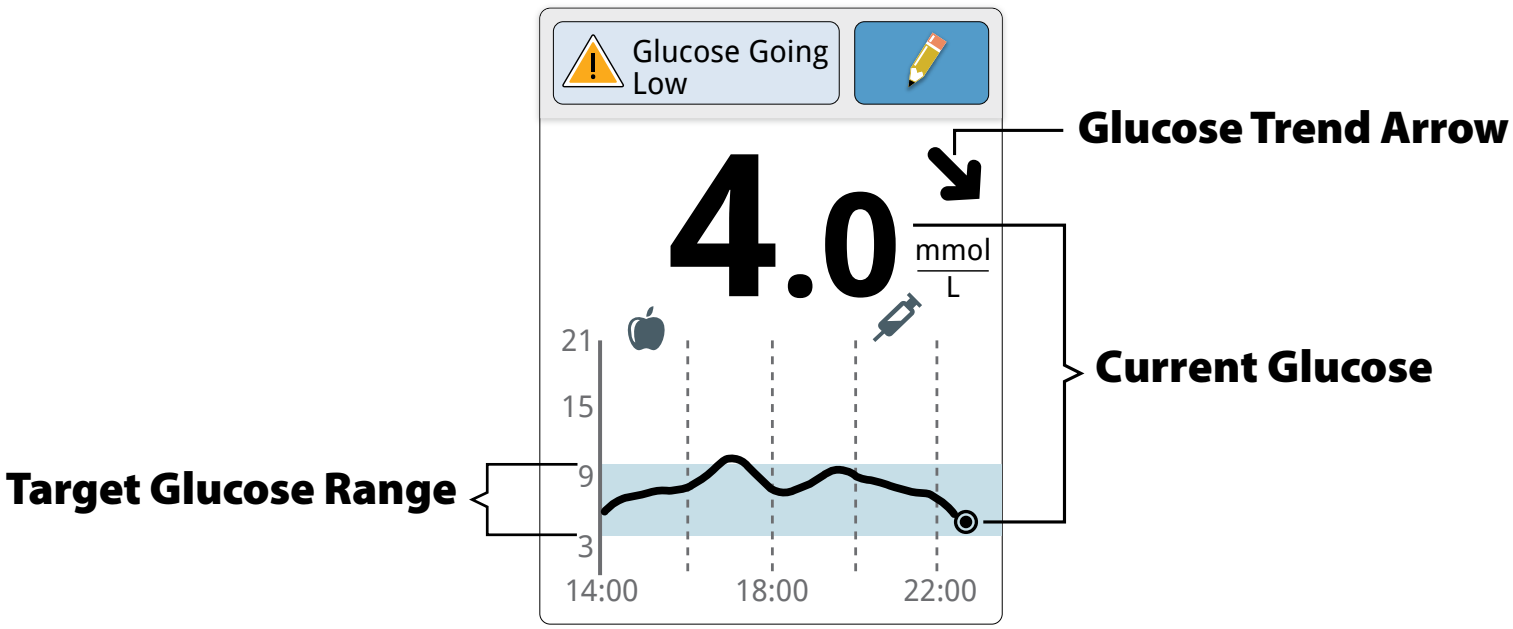
Step	Action
1	 Press the Home Button to turn on the Reader.
2	 Touch **Start New Sensor**.
3	 Hold the Reader within 4 cm (1.5 inches) of the Sensor to scan it. This starts your Sensor. If sounds are turned on, the Reader beeps when the Sensor has been successfully activated. The Sensor can be used to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

Checking Your Glucose

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

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

Sensor Glucose Readings



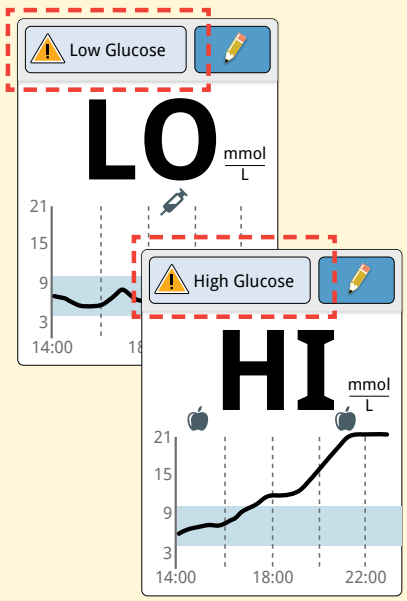
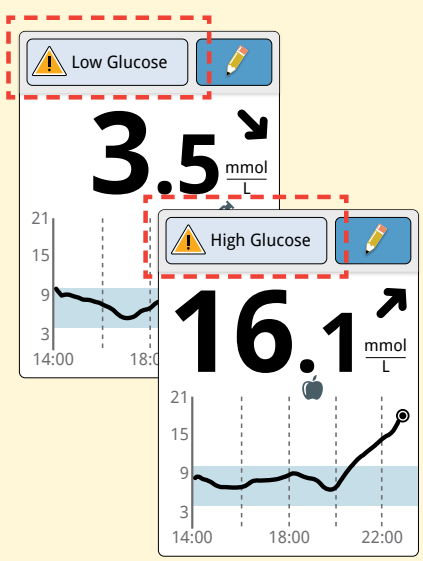
Notes:

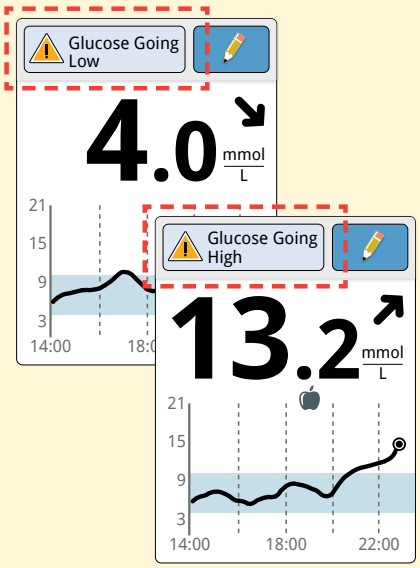
- The graph displays glucose readings up to 21 mmol/L. Glucose readings above 21 mmol/L are displayed at 21 mmol/L.
- The symbol may appear, indicating the Reader time was changed. Gaps in the graph may result or glucose readings may be hidden.

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)

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

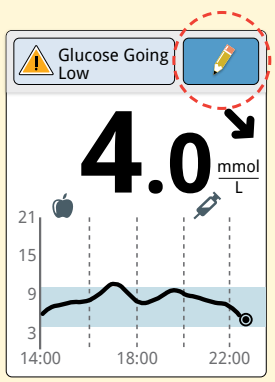
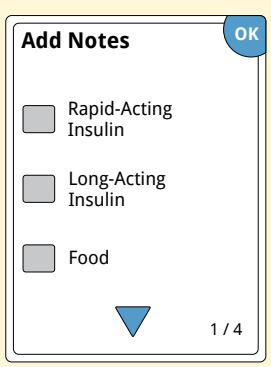
Display	What To Do
	If **LO** appears on the Reader, your reading is lower than 2.2 mmol/L. If **HI** appears on the Reader, your reading is higher than 27.8 mmol/L. You can touch the message button for more information. Check your blood glucose on your finger with a test strip. If you get a second **LO** or **HI** result, contact your health care professional **immediately**.
	If your glucose is higher than 13.3 mmol/L or lower than 3.9 mmol/L, you will see a message on the screen. You can touch the message button for more information and set a reminder to check your glucose.

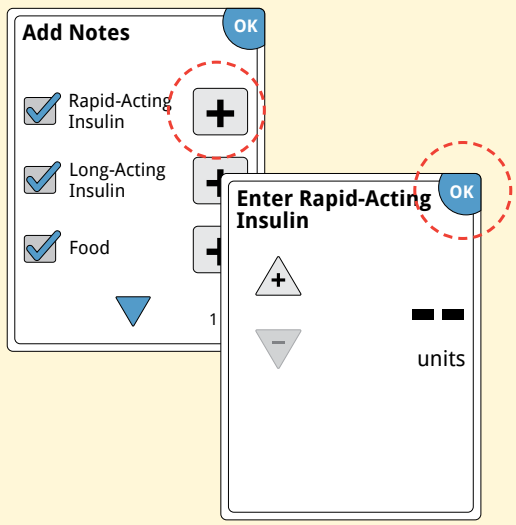
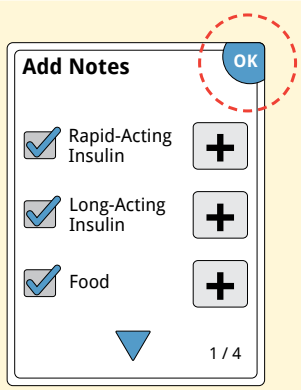
Display	What To Do
	If your glucose is projected to be higher than 13.3 mmol/L or lower than 3.9 mmol/L within 15 minutes, you will see a message on the screen. You can touch the message button for more information and set a reminder to check your glucose.

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 of your reading being obtained. You can track food, insulin, exercise and any medication you take.

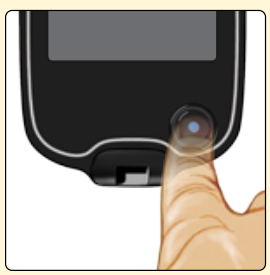
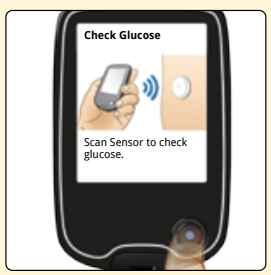
Step	Action
1	 From the Glucose Reading screen, add notes by touching the symbol in the upper right corner of the touchscreen. If you do not want to add notes, you can press the Home Button to go to the Home Screen or hold the Home Button to turn the Reader off.
2	 Select the tick box next to the notes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

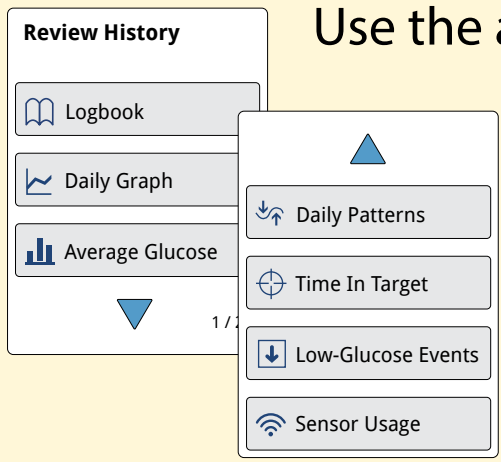
Step	Action
3	 After you tick the box for food and insulin notes, the + symbol appears to the right of the Note. You can touch it to add more specific information to your note. Then touch **OK**. • Insulin notes: Enter the number of units taken. • Food notes: Enter grams or carb portion information.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

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

Reviewing Your History

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

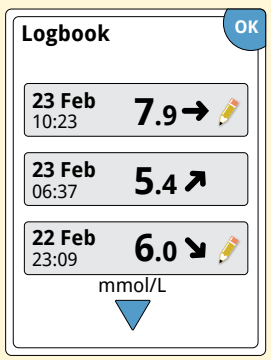
Step	Action
1	  Press the Home Button to turn on the Reader. Press the Home Button again to go to the Home Screen.
2	 Touch the **Review History** icon.

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

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

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

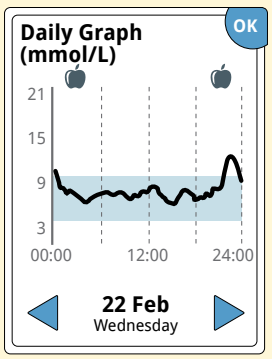
Logbook



Entries for each time 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 that you have entered. You can edit (change) Notes for the most recent Logbook entry, provided that your glucose reading was within the last 15 minutes.

Daily Graph



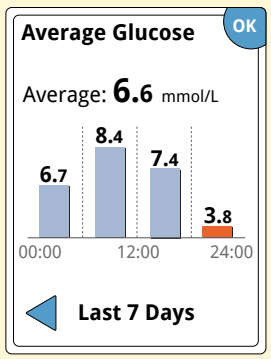
A graph of your Sensor glucose readings by day. The graph shows your Target Glucose Range and symbols for food or rapid-acting insulin notes you have entered.

Notes:

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

Other History Options

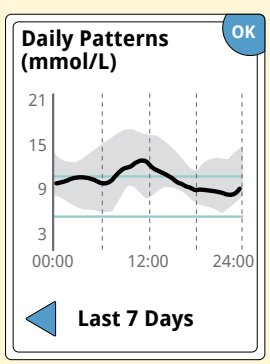
Use the arrows to view information about your last 7, 14, 30, or 90 days.



Average Glucose

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

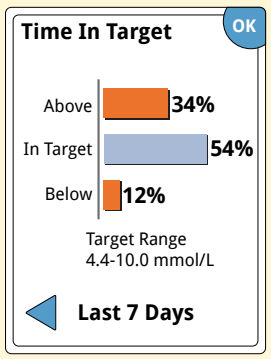
Readings above or below your Target Glucose Range are orange, while readings in range are blue.



Daily Patterns

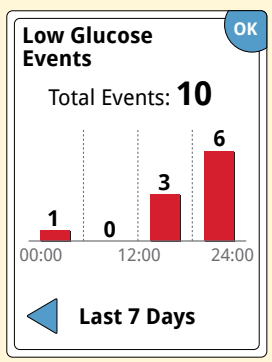
A graph showing the pattern and variability of your Sensor glucose over a typical day. The thick black line shows the median (midpoint) of your glucose readings. The grey shading represents a range (10-90 percentiles) of your Sensor readings.

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



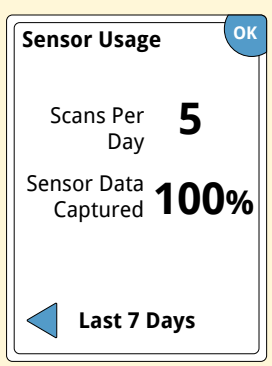
Time In Target

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

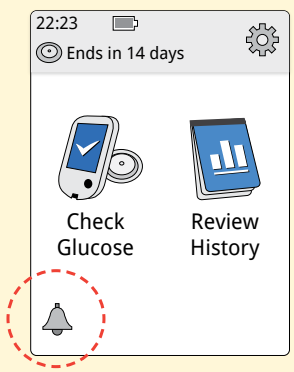
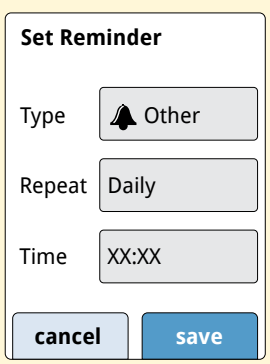
Replacing Your Sensor

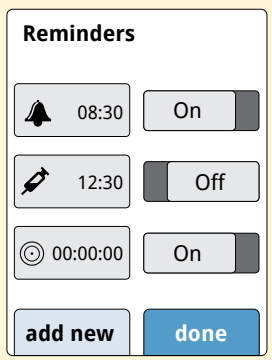
Your Sensor automatically stops working after 14 days of wear and must be replaced. You should also replace your Sensor if you notice any irritation or discomfort at the application site or if the Reader reports a problem with the Sensor currently in use. Taking action early can keep small problems from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

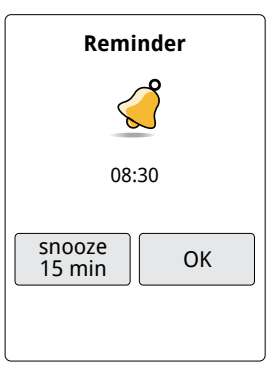
CAUTION: If the glucose readings from the Sensor do NOT seem to match how you feel, check to make sure that your Sensor has not come loose. If the Sensor tip has come out of your skin, or your Sensor is coming loose, remove the Sensor and apply a new one.

Using Reminders

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

Step	Action
1	 From the Home Screen, touch the symbol.
2	 Touch to select which **Type** of reminder you want to set: Check Glucose, Take Insulin or Other.
3	Touch to select how often you want the reminder to **Repeat**: Once, Daily or Timer. **Note:** You can set the reminders for a specific time (e.g. 8:30 am) or as a timer (e.g. 3 hours from the current time).

Step	Action
4	Set the reminder **Time** using the arrows on the touchscreen. Touch **save**.
5	 From the Reminders screen, you can turn the reminder **On/Off** or **add new** reminders. Touch **done** to return to the Home Screen.



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.

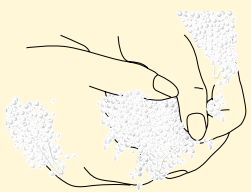
> **WARNING:** Do NOT use the built-in meter while the Reader is connected to an electrical outlet or a computer.

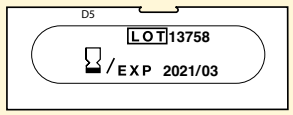
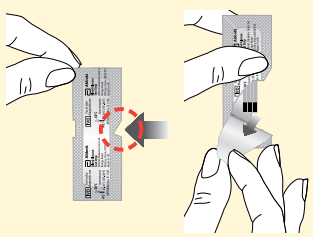
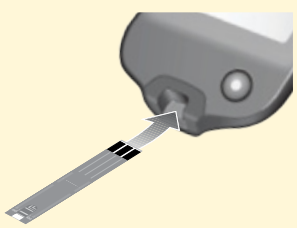
IMPORTANT:

- 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 it 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 instructions on how to use your lancing device.

Blood Glucose Testing

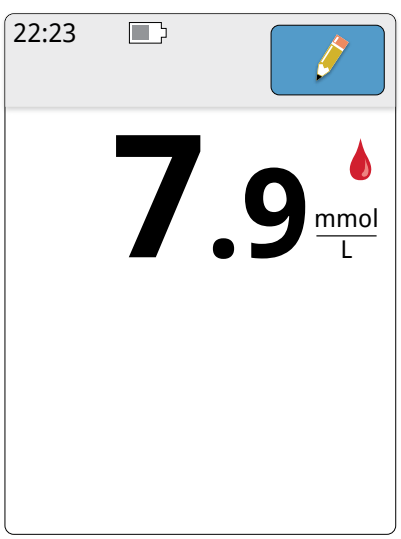
You can use the built-in meter to check your blood glucose, whether you are wearing a Sensor or not. You can perform a blood glucose test on your fingertip or approved alternative site. Be sure to read the test strip instructions for use prior to using the built-in meter.

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

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

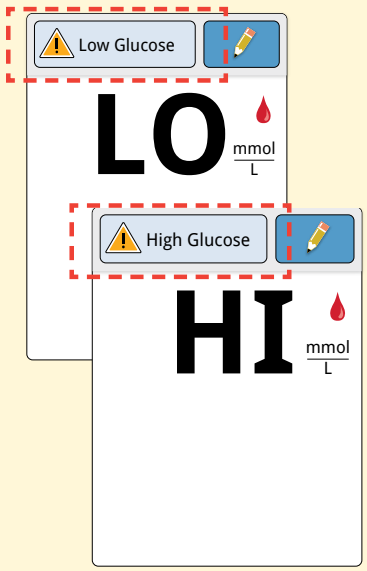
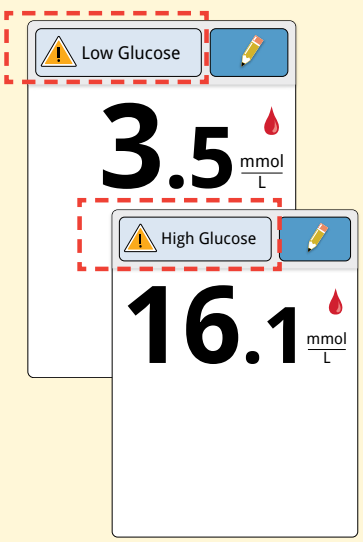
Step	Action
	 You will see a butterfly on the screen while you wait for your result. If sounds are turned on, the Reader beeps once when your result is ready.
6	After reviewing your result, remove and discard the used test strip according to test strip instructions for use.

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



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

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

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

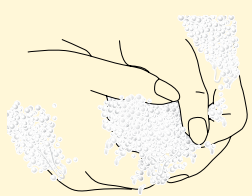
After you get your blood glucose result, you can add Notes by touching the symbol. If you do not want to add a Note, press the Home Button to go to the Home Screen or hold the Home Button to turn the Reader off.

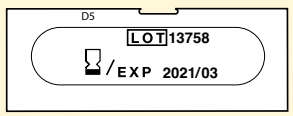
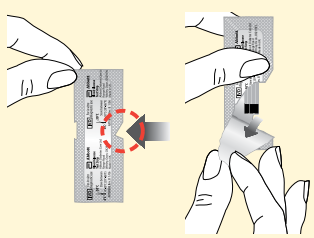
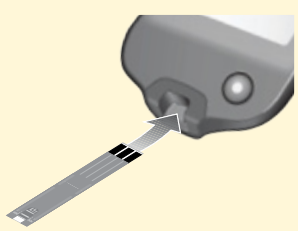
Blood Ketone Testing

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

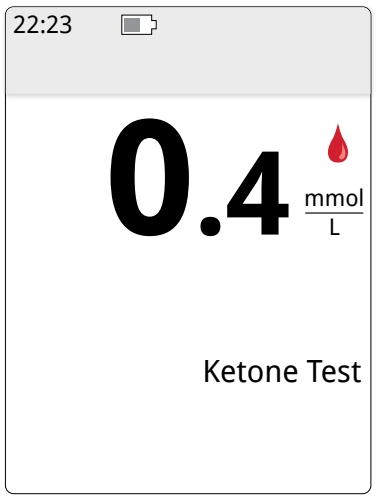
- You are unwell
- Your glucose is higher than 13.3 mmol/L
- You and your health care professional decide you should

Note: Ensure that you read the test strip instructions for use prior to performing a ketone test.

Step	Action
1	 Wash your hands with warm, soapy water for accurate results. Thoroughly dry your hands. To warm the site, apply a warm, dry pad or rub vigorously for a few seconds. **Note:** Use only fingertip samples for blood ketone testing.

Step	Action
2	 E.g. Expiry date: 31 March 2021 Check the test strip expiry date.
3	 Open the foil test strip packet at the notch and tear down to remove the test strip. Use the test strip immediately after removing it from the foil packet.
4	 **Note:** Use only blood ketone test strips. Do not put urine on the test strip. Insert the test strip with the three black lines facing up. Push the strip in until it stops.

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

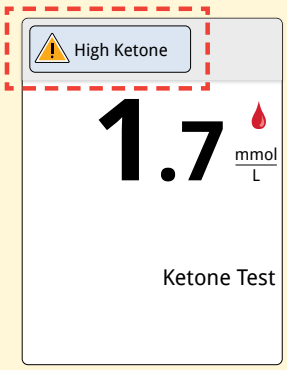
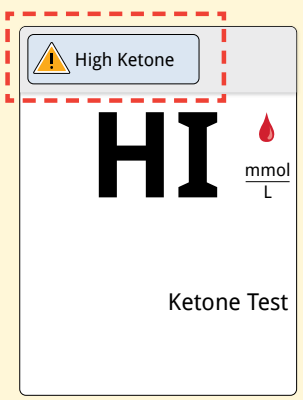


Your Blood Ketone Results

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

Notes:

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

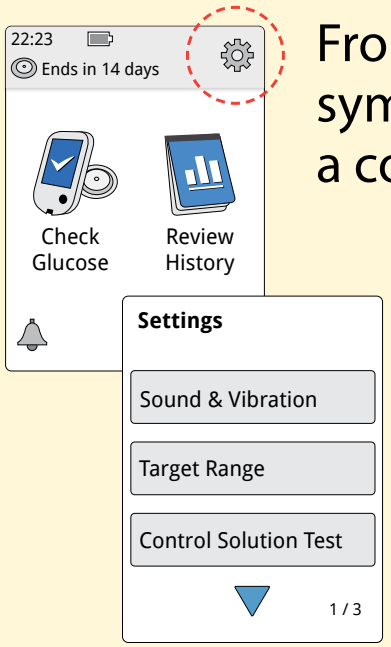
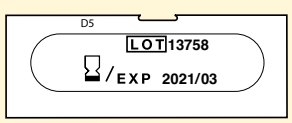
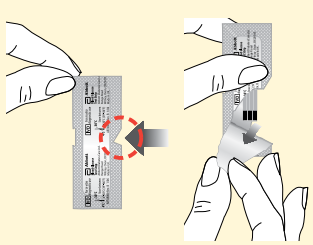
Display	What To Do
	If your blood ketone is high, you will see a message on the screen. You can touch the message button for more information.
	If **HI** appears on the Reader, your ketone result is higher than 8 mmol/L. You can touch the message button for more information. Repeat the ketone test with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

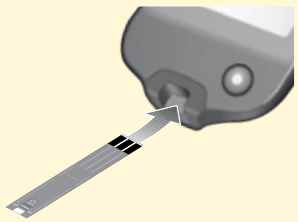
Control Solution Testing

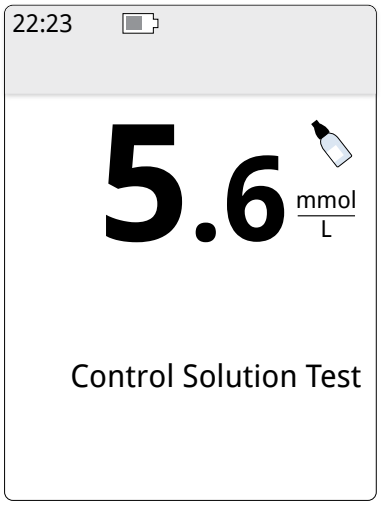
You should do a control solution test when you are not sure of your test strip results and want to check that your Reader and test strips are working properly. You can do a control solution test with a blood glucose or ketone test strip.

IMPORTANT:

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

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

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

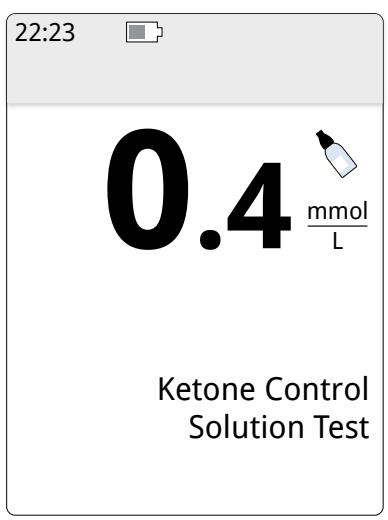


Blood Glucose Control Solution Test

Control Solution Results

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

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



Ketone Control Solution Test

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

Using the Rapid-Acting Insulin Calculator

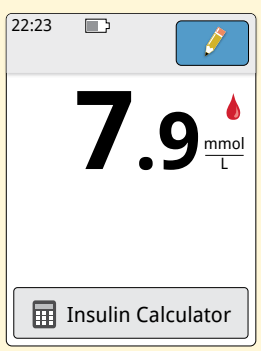
This optional feature requires an understanding of the use of insulin. Misuse or misunderstanding of this feature and the suggested dose may lead to inappropriate insulin dosing. The calculator suggests doses for rapid-acting insulin only. The calculator is only for use with fingerstick blood glucose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

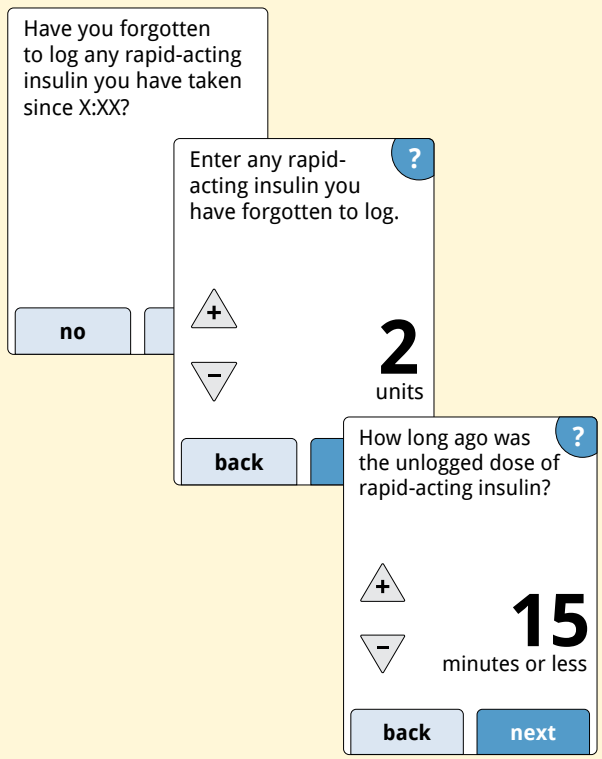
An access code is required to set up or change the rapid-acting insulin calculator settings. This access code is available only to your health care professional. Work with your health care professional to set up or change the calculator for you.

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

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

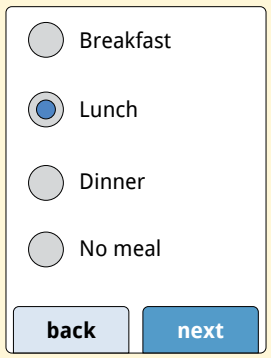
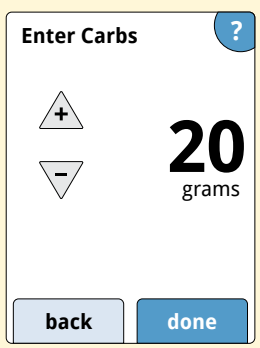
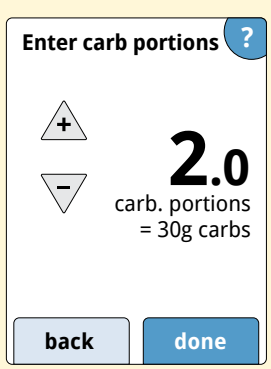
If you have added a rapid-acting insulin note to a glucose result without indicating how much insulin you took, the calculator will not be available for up to 8 hours.

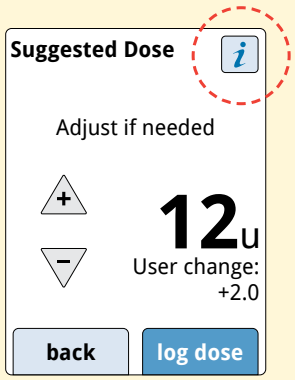
Step	Action
1	 Test your blood glucose on your finger. Touch **Insulin Calculator** from the blood glucose results screen. You can also access the insulin calculator by touching the calculator icon next to **Rapid-Acting Insulin** from the **Add Notes** screen.

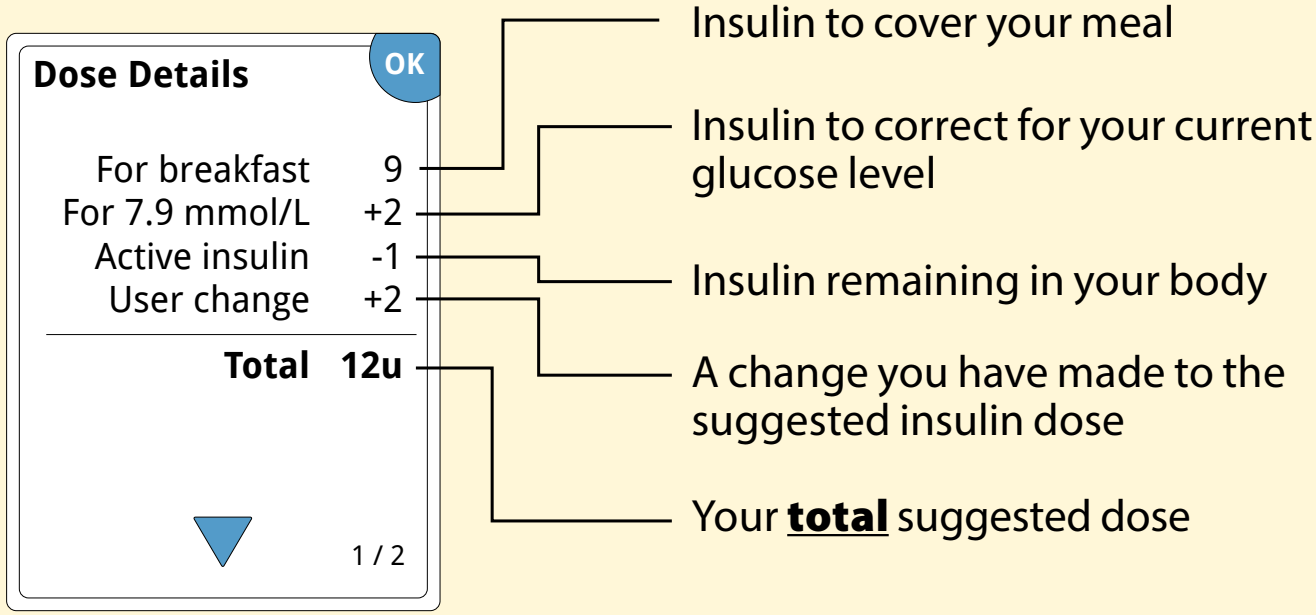
Step	Action
2	 Enter information about any rapid-acting insulin you may have forgotten to log. Touch **next**.

Notes:

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

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

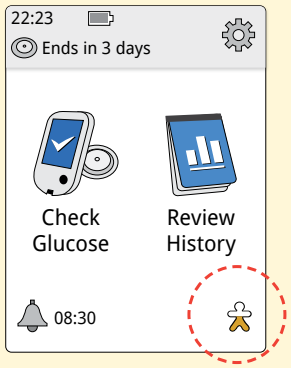
Step	Action
4	 Review your suggested dose. If needed, use the arrow buttons to adjust your suggested dose for any planned activity, a smaller or larger meal, sickness, etc. Touch the *i* symbol to see details of what is included in your suggested dose.



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

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

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



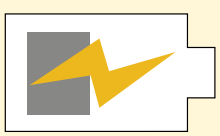
If your health care professional turned on the Active Insulin feature, the symbol may appear on your Home Screen. It shows an estimate of the amount of rapid-acting insulin left in your body and how much longer it may be active. Touch the symbol to see more information about the remaining rapid-acting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

Estimated percentage of active insulin remaining in your body

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

Charging the Reader

A fully charged Reader battery should last up to 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 a plug socket using the included power adaptor. Then, plug the other end of the USB cable into the USB port on the Reader.

CAUTION: Ensure that you select a location for charging that allows the power adaptor to be easily unplugged.

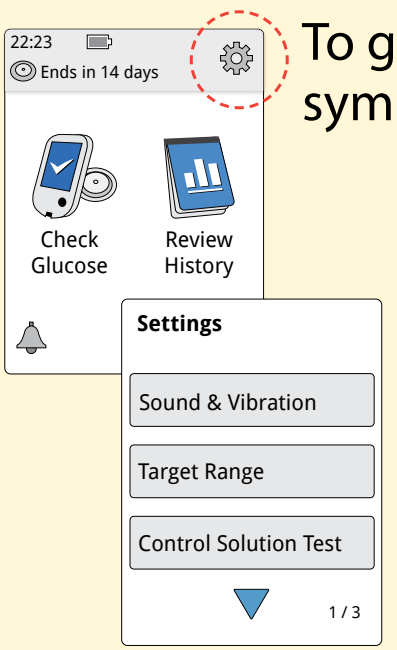
CAUTION: The maximum surface temperature of the Reader and/or the power adaptor could get as warm as 53°C when it's charging or 48°C during normal use. Under these conditions, do not hold the Reader or the power adaptor for 5 minutes or more. People with disorders of peripheral circulation or sensation should use caution at this temperature.

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 three hours.
- Only use the USB cable and power adaptor included with the system.
- Fully charge your Reader before storing it for more than three 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	 To get to the Settings menu, touch the Settings symbol ⚙ on the Home Screen.

Step	Action
2	Touch the setting you want to change: **Sound & Vibration** – Set sounds and vibrations **Target Range** – Set range displayed on Reader glucose graphs **Control Solution Test** – Perform a Control Solution test **Time & Date** – Change the Time or Date **Language** – Change the language on the Reader (option only available on Readers with multiple languages) **System Status** – Check Reader information and performance • View System Information: The Reader will display information about your System including: - Current Sensor end date and time - Reader serial number and version number - Serial numbers and status codes of most recent Sensors (up to three) - Sensor version for most recent Sensor - Number of Sensors that have been used with Reader - Number of tests that have been performed using test strips

Step	Action
2 ***(cont.)***	• View Event Logs: A list of events recorded by the Reader, which may be used by Customer Service to help troubleshoot your System • Perform a Reader Test: The Reader Test will perform internal diagnostics and allow you to check that the Display is showing all pixels, sounds and vibration are working and the Touchscreen is responding when touched **Calculator Settings** – Review the currently programmed settings (option only available if your health care professional has activated your insulin calculator) **Reader Basics** – Review the information screens shown during the Reader setup **Professional Options** – Set by health care professionals only Touch **OK** when you are done.

Activities

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

Activity	What You Need To Know
Bathing, Showering and Swimming	The Reader is not water-resistant and should NEVER be submerged in water or other liquid. Your Sensor is water-resistant and can be worn while bathing, showering, or swimming. **Note:** Do NOT take your Sensor deeper than 1 metre (3 feet) or immerse it longer than 30 minutes in water.
Sleeping	Your Sensor should not interfere with your sleep. It is recommended that you scan your Sensor before going to sleep and when you wake up because your Sensor holds eight hours of data at a time. If you have reminders set to go off while you are sleeping, place the Reader nearby.

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

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

Cleaning

You may clean the Reader as often as desired 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. Cracking or flaking of or damage to the Reader housing are signs of deterioration. If you notice any of these signs, stop using the Reader and contact Customer Service.

CAUTION: Do NOT place the Reader in water or other liquids. Avoid getting dust, dirt, blood, control solution, water or any other substance in the test strip or USB ports.

Maintenance

The System has no serviceable parts.

Disposal

Reader, Sensor, USB Cable and Power Adaptor:
These devices must not be disposed of via municipal waste collection. Separate collection for electrical and electronic equipment waste as per Directive 2012/19/EC in the European Union is required. Contact the manufacturer for details. As Readers and Sensors may have been exposed to bodily fluids, you may wipe prior to disposing, such as by using a cloth dampened with a mixture of one part household bleach and nine parts water.

Note: Readers and Sensors contain non-removeable batteries and must not be incinerated. Batteries may explode upon incineration.

Sensor Applicator:
Please consult your local waste management authority for instructions on how to dispose of Sensor Applicators at a designated sharps collection site. Ensure the cap is on the Sensor Applicator as it contains a needle.

Sensor Pack:
Used Sensor Packs may be disposed of via municipal waste collection.

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 its operating temperature range.	Move the Reader to a temperature between 10°C and 45°C and then try to power it on.

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

Problems at the Sensor Application Site

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

Problems Starting Your Sensor or Receiving Sensor Readings

Display	What It May Mean	What To Do
New Sensor Starting Up	Sensor is not ready to read glucose.	Wait until the 60 minute Sensor start-up period has completed.
Scan Timeout	The Reader is not held close enough to the Sensor.	Hold the Reader within 4 cm (1.5 inches) of the Sensor. Bring the screen of the Reader close to the Sensor.
Sensor Ended	The Sensor life has ended.	Apply and start a new Sensor.

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

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

Blood Glucose or Ketone Error Messages

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

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

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

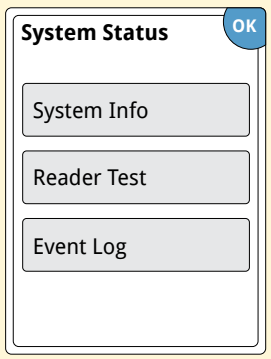
Error Message	What It May Mean	What To Do
E-7	Test strip may be damaged, used or the Reader does not recognise it.	1. Check that you are using the correct test strip for the Reader. (See test strip instructions for use to verify your strip is compatible with the Reader). 2. Repeat the test using a test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

Problems Checking Your Blood Glucose or Ketone

Problem	What It May Mean	What To Do
The Reader does not start a test after inserting a test strip.	Test strip is not inserted correctly or not inserted fully into the strip port.	1. With the three 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 its operating temperature range.	Move the Reader to a temperature between 10°C and 45°C and then try to power it on.
	Reader is in a power saving mode.	Press the Home Button then insert a test strip.

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

Perform a Reader Test



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

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

Customer Service

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

Reporting of Serious Incidents

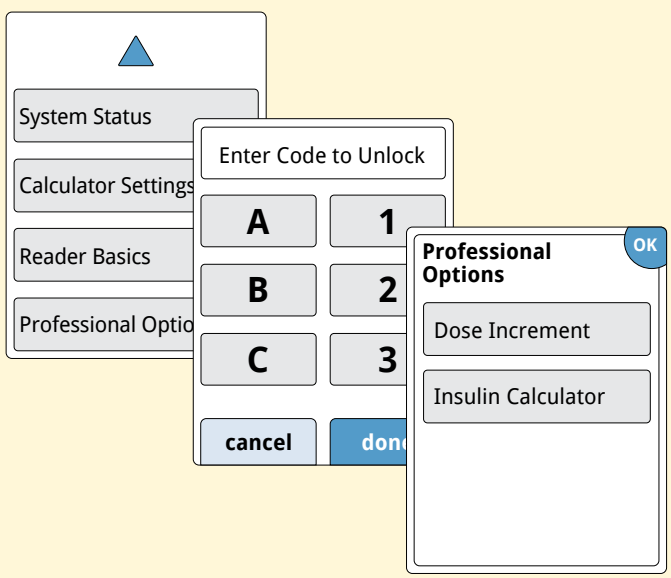
If a serious incident has occurred in relation to this device, it should be reported to Customer Service. In European Union Member States, serious incidents should also be reported to the competent authority (the government department responsible for medical devices) in your country. Please refer to your government website for details of how to contact your competent authority.

A 'serious incident' means any incident that directly or indirectly led, might have led or might lead to:

- the death of a patient, user or other person,
- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health.

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.

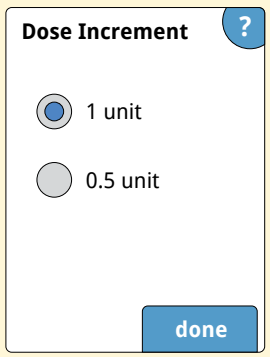


From the Home Screen, touch the Settings symbol ⚙. Scroll down using the arrows and touch **Professional Options**. Enter the access code.

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.



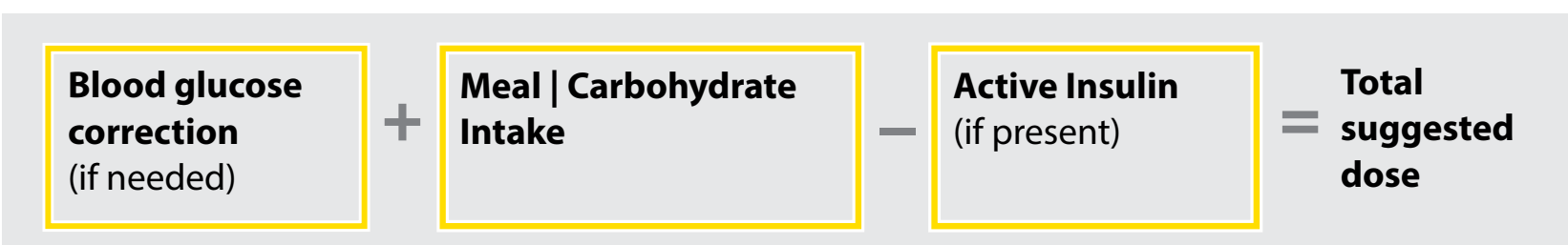
From the **Professional Options** screen, select **Dose Increment**. Then choose **1** unit or **0.5** unit. Touch **done**.

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:

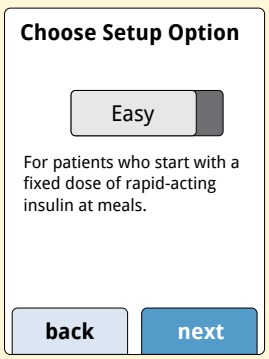
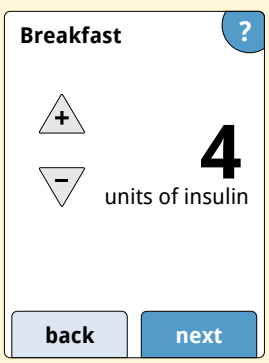
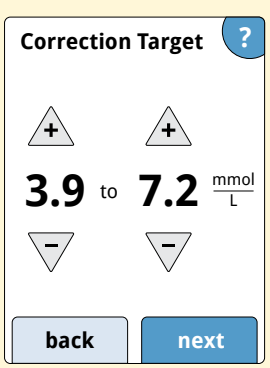


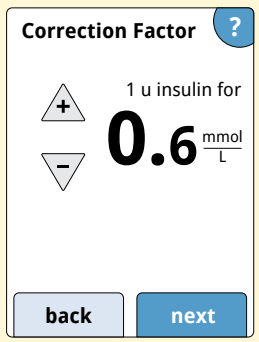
You can set up the insulin calculator using the Easy or Advanced settings. The Easy Setup is for patients who start with a fixed dose of rapid-acting insulin for meals. The Advanced Setup is for patients who count carbohydrates (in grams or carbohydrate portions) to adjust their rapid-acting insulin 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	 Choose the **Easy** option on the slide bar and touch **next**. **Note:** You need to know your patient's meal-time insulin doses, target glucose range and correction factor.
2	 Enter the meal-time rapid-acting insulin doses. Touch **next** after each entry.
3	 Enter the blood glucose **Correction Target**. This is the desired target range for blood glucose values before meals. Touch **next**. **Note:** If you just want to set one target instead of a range, set both the low and high values to the same number.

Step	Action
4	 Enter the **Correction Factor** (for example: if 1 unit of insulin lowers blood glucose 2.8 mmol/L, then the correction factor is 2.8). If the blood glucose value is outside the blood glucose target, the calculator will use the correction target and factor to calculate a correction dose.

Notes:

- If your patient does not take correction insulin, touch the down arrow to go below 1 to set "No correction insulin". If you set "No correction insulin", the calculator only includes meal doses. Additionally, active insulin is not tracked or calculated.
- The calculator corrects a blood glucose value to the single target or the average of the target range.
- The calculator will not suggest a dose that is estimated to drop the blood glucose below the lower end of the target range or single target.

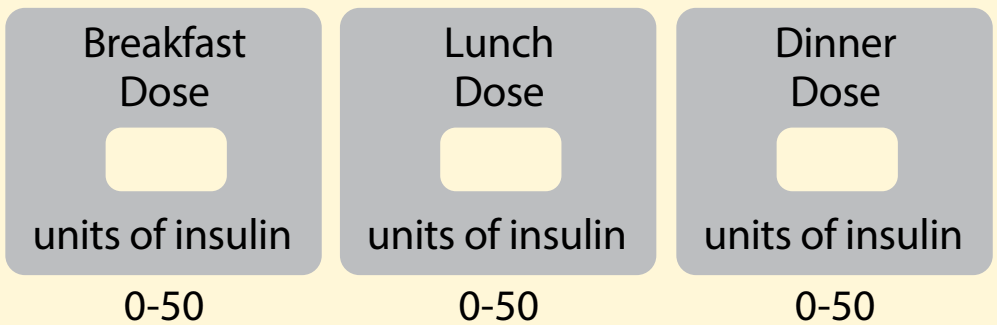
Touch **next**. Then touch **done** to complete the setup. You can now review the calculator settings. Touch **OK** when done.

Notes about the Easy Option:

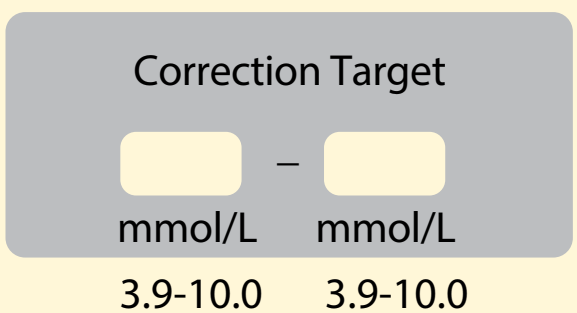
- The calculator estimates the amount of rapid-acting insulin still in the body and how much longer it may be active (if the correction factor is set to "no correction insulin", active insulin is not calculated). The active insulin estimate is based on a 4-hour insulin duration calculated from the time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

Calculator Settings – Easy Option

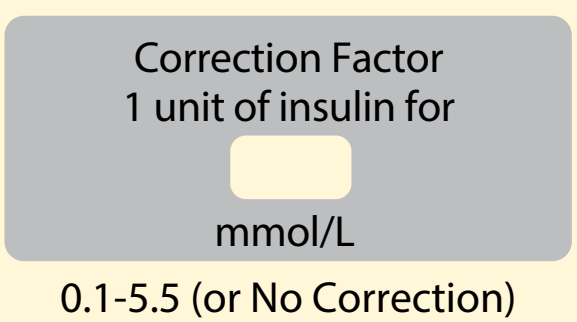
This page can be used to record insulin calculator settings.



▶ This is the insulin required to cover food.



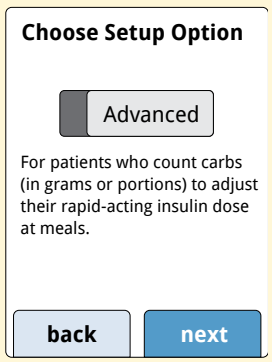
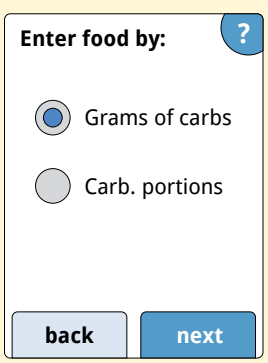
▶ This is the desired range for before-meal blood glucose.

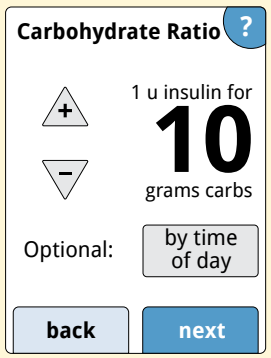


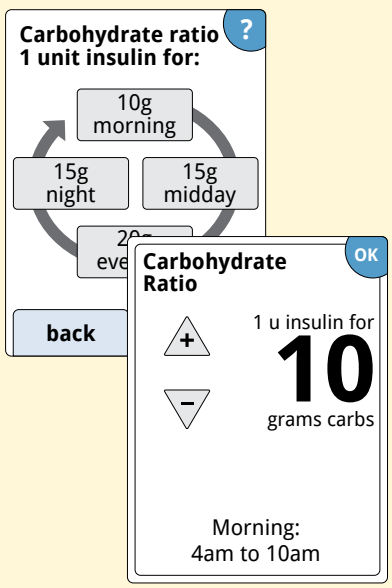
▶ This is the estimated amount blood glucose will drop by taking one unit of insulin.

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

Advanced Setup of the Insulin Calculator

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

Step	Action
3	 **If you chose to enter grams of carbs in Step 2:** The rapid-acting insulin dose suggestion is based on grams of carbs. Enter the **Carbohydrate Ratio** (1 unit of rapid-acting insulin for _____ grams of carbs). Touch **next** when complete.



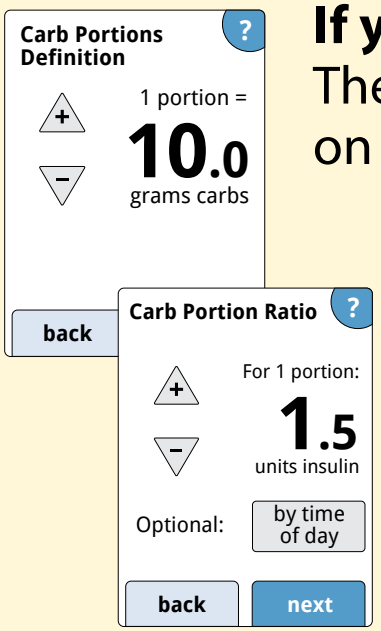
Note: If you want to set different carbohydrate ratios for different times of day, touch the option **by time of day**. Touch each time period to change the carbohydrate ratio. Touch **OK** after each entry to save. Touch **done**.

Go to Step 5.

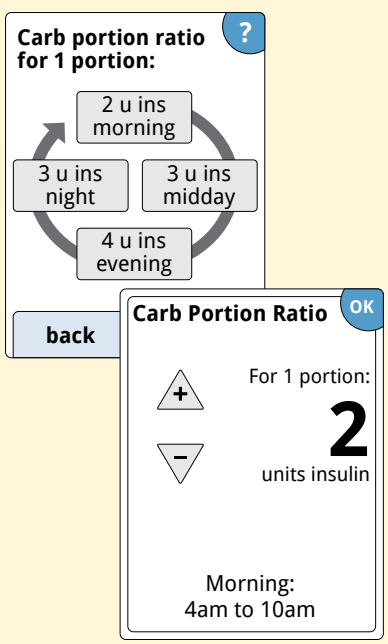
Time of day blocks cannot be adjusted. They correspond to the following times:

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

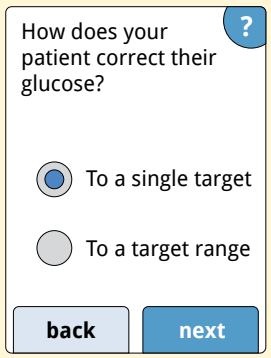
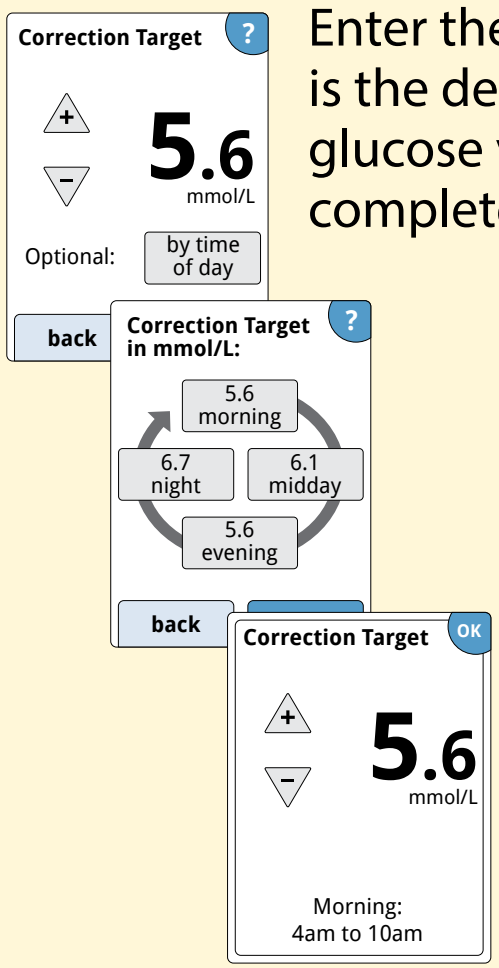
Step	Action
4	**If you chose to enter Carb Portions in Step 2:** The rapid-acting insulin dose suggestion is based on carbohydrate portions.

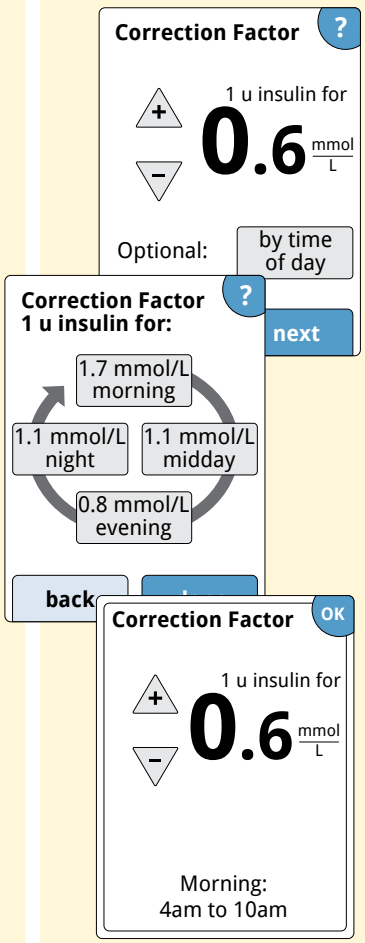


Enter the **Carb Portions Definition** (10 to 15 grams of carbs) and touch **next**. Enter the **Carb Portion Ratio** (_____ units of rapid-acting insulin per 1 carb portion). Touch **next** when complete.



Note: If you want to set different carb portion ratios for different times of day, touch the option **by time of day**. Touch each time period to change the carb portion ratio. Touch **OK** after each entry to save. Touch **done**.

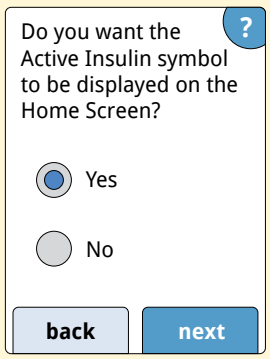
Step	Action
5	 Select how you want your patient to correct their glucose. Touch **next**.
6	 Enter the **Correction Target** value or range. This is the desired target value or range for blood glucose values before meals. Touch **next** when complete. **Note:** If the Correction Target is based on time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

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

Step	Action
8	 Enter the **Insulin Duration**. This is the amount of time that rapid-acting insulin remains active in the patient's body. Touch **next**.

IMPORTANT: In general, the insulin duration for rapid-acting insulin ranges from 3-5 hours, and can vary for each person[1]. The Reader allows an insulin duration from 3-8 hours.

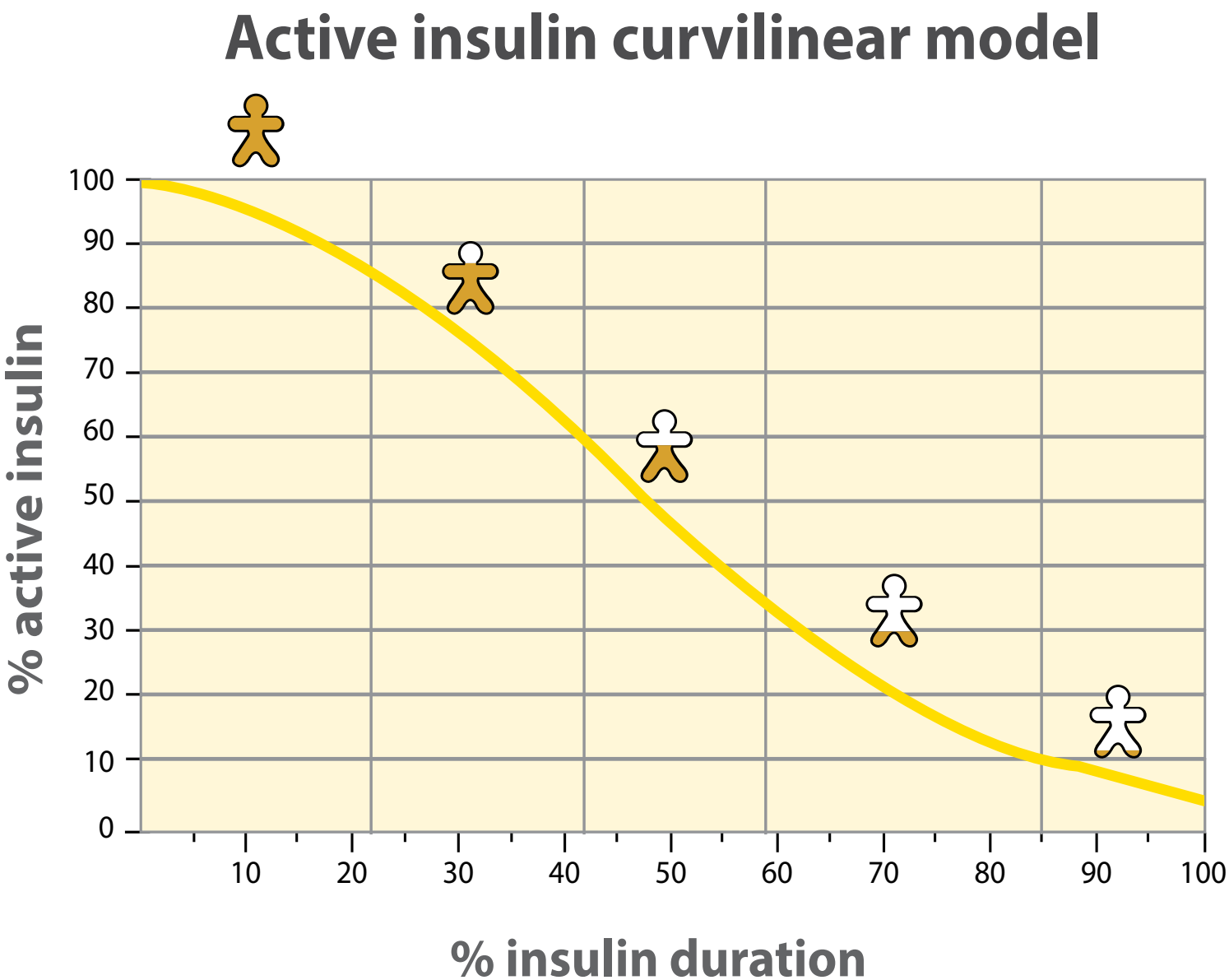
[1] Product Inserts: HumaLog®, NovoLog®, Apidra®

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

Notes about the Advanced Option:

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

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



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

Calculator Settings – Advanced Option

This page can be used to record insulin calculator settings.

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

OR

Carb Portions Definition
_____
grams of carbs
10-15

Carb 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

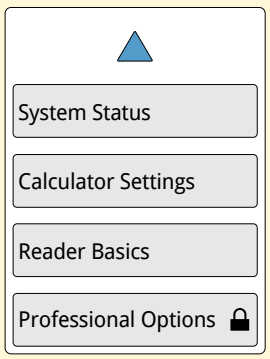
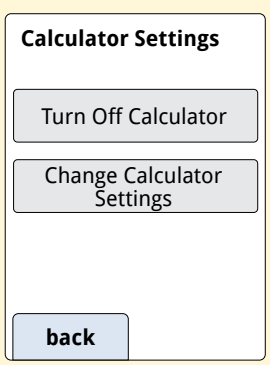
▶ This is the amount of time that a dose of rapid-acting insulin remains active in the body.

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

System Specifications

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

Sensor Specifications

Sensor glucose assay method	Amperometric electrochemical sensor
Sensor glucose reading range	2.2 to 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 25°C
Operating and storage relative humidity	10-90%, non-condensing
Sensor water resistance and ingress protection	IP27: Can withstand immersion into one metre (three ft) of water for up to 30 minutes. Protected against insertion of objects >12 mm diameter.
Operating and storage altitude	-381 metres (-1,250 ft) to 3,048 metres (10,000 ft)
Radio Frequency (FreeStyle Libre 2 Sensor)	2.402-2.480 GHz BLE; GFSK; 0dBm EIRP

Reader Specifications

Blood glucose assay range	1.1 to 27.8 mmol/L
Blood ketone assay range	0.0 to 8.0 mmol/L
Reader size	95 mm x 60 mm x 16 mm
Reader weight	65 grams
Reader power source	One lithium-ion rechargeable battery
Reader battery life	Seven days of typical use
Reader memory	90 days of typical use
Reader operating temperature	10°C to 45°C
Reader storage temperature	-20°C to 60°C

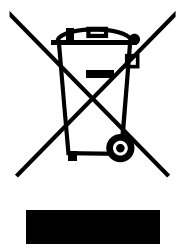
Operating and storage relative humidity	10-90%, non-condensing
Reader moisture protection	Keep dry
Operating and storage altitude	-381 metres (-1,250 ft) to 3,048 metres (10,000 ft)
Reader display timeout	60 seconds (120 seconds when test strip is inserted)
Radio Frequency	13.56 MHz RFID; ASK Modulation; 124 dBuV/m
Data port	Micro USB
Minimum Computer Requirements	System must only be used with EN60950-1 rated computers
Mean service life	Three years of typical use
Power Adaptor	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
Dose increments	Units of insulin	0.5 or 1
Maximum insulin dose	Units of insulin	50

Labelling Symbols

	Consult instructions for use		Use-by date
	Temperature limit	REF	Catalogue number
	Manufacturer		Date of Manufacture
CE	CE Mark	SN	Serial number
EC REP	Authorised Representative in the European Community		Single sterile barrier system
LOT	Batch code		Keep dry
	Type BF applied part		Non-ionising radiation
CODE	Sensor code		Caution
	Do not re-use		Humidity limitation
STERILE R	Sterilised using irradiation		

	Sterile Barrier. Refer to Instructions for Use if opened or damaged.
	Do not use if package is damaged **For Sterile Barrier:** Do not use if the product sterile barrier system or its packaging is compromised.
	This product must not be disposed of via municipal waste collection. Separate collection for electrical and electronic equipment waste as 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.
- Use of accessories, transducers and cables other than those specified or provided by Abbott Diabetes Care could result in increased electromagnetic emissions or decreased electromagnetic immunity of the System and result in improper operation.
- The System should not be used adjacent to or stacked with other equipment. 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	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 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	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.

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

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	6 Vrms 150 kHz to 80 MHz	6 Vrms	Portable 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. **Recommended separation distance** $d = 1.2\sqrt{P}$

If you are using the Reader with FreeStyle Libre Sensor, refer to the test information and guidance below.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 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 (mobile/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-orientating or relocating the System.

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

For the FreeStyle Libre 2 Sensor, refer to the test information and the guidance below.

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

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

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

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
1,720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1,845						
1,970						
2,450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5,240	5100–5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5,500						
5,785						

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50% duty cycle square wave signal.

[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used, because while it does not represent actual modulation, it would be worst case.

Abbott Diabetes Care Ltd. hereby declares that the radio equipment type FreeStyle Libre Reader is in compliance with Directive 2014/53/EU.
The full text of the EU declaration of conformity is available at the following internet address: www.diabetescare.abbott/doc

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