

User's Manual



FreeStyle
Libre

FLASH GLUCOSE MONITORING SYSTEM



 **Abbott**

Your Name _____











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Reader Symbols

| Symbol | What It Means |
|---|--|
|  | Active sensor |
|  | Direction your glucose is going. See <i>Checking Your Glucose</i> section for more information |
|  | Caution |
|  | View previous/next screen |
|  | Notes |
|  | Add more information to notes |
|  | Food note |
|  | Rapid-acting insulin note |
|  | Time changed on Reader |
|  | Reminders |

| Symbol | What It Means |
|---|--|
|  | Blood glucose or ketone test |
|  | Settings |
|  | Control solution test result |
|  | Rapid-acting insulin calculator |
|  | Details of your suggested insulin dose |
|  | Estimated rapid-acting insulin remaining in body |
|  | Low battery |
|  | Battery charging |
|  | Sensor too cold |
|  | Sensor too hot |

Important Safety Information

Indications for Use

The FreeStyle Libre Flash Glucose Monitoring System is indicated for measuring interstitial fluid glucose levels in people (age 4 and older) with diabetes mellitus, including pregnant women. The indication for children (age 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 FreeStyle Libre Flash Glucose Monitoring System and also for interpreting or assisting the child to interpret FreeStyle Libre readings. It is designed to replace blood glucose testing in the self-management of diabetes with the exceptions listed below. Under the following circumstances, use a blood glucose meter to check the current glucose readings from the FreeStyle Libre Flash Glucose Monitoring System Sensor:

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

Contraindications

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

WARNING:

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

CAUTION:

- On rare occasions, you may get inaccurate Sensor glucose readings. If you believe your glucose readings are not correct or are inconsistent with how you feel, perform a blood glucose test on your finger to confirm your glucose. If the problem continues, remove the current Sensor and apply a new one.
- Performance of the System when used with other implanted medical devices, such as pacemakers, has not been evaluated.
- The Reader is for use by a single person. It must not be used on more than one person including other family members due to the risk of spreading infection. All parts of the Reader are considered biohazardous and can potentially transmit infectious diseases, even after performing the cleaning procedure.
- 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 FreeStyle Libre system. Contact your health care professional before continuing to use the FreeStyle Libre system.

System-Related Information

- The FreeStyle Libre Flash Glucose Monitoring System is designed to be used only with FreeStyle Optium blood glucose and blood ketone test strips and MediSense control solution.
- Avoid getting dust, dirt, blood, control solution, water or other substances in the Reader's USB and test strip ports.
- Physiologic differences between the interstitial fluid and capillary blood may result in differences in glucose readings. Differences in glucose readings between interstitial fluid and capillary blood may be observed during times of rapid change in blood glucose, such as after eating, dosing insulin or exercising.
- Severe dehydration and excessive water loss may cause inaccurate results. If you believe you are suffering from dehydration, consult your health care professional **immediately**.
- Store the Sensor Kit between 4°C-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-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 these types of procedures on the performance of the system has not been evaluated.
- The FreeStyle Libre Flash Glucose Monitoring System has not been evaluated for use in persons on dialysis or people less than 4 years of age.

Getting to Know Your System

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



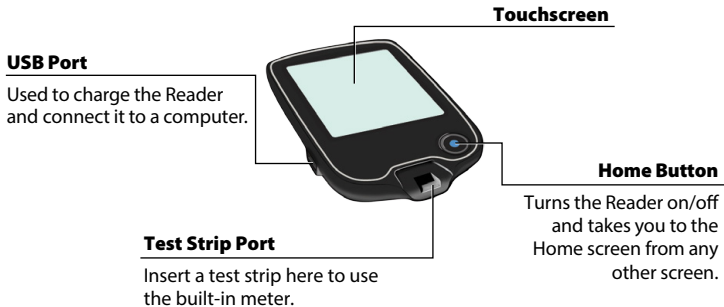
IMPORTANT: Safety information about the System is in this User's Manual. Read all of the information in the User's Manual and the FreeStyle Optium blood glucose and ketone test strip instructions for use before using your System.

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

Reader Kit

The Reader Kit includes:

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



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

Sensor Kit

The Sensor Kit includes:

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



Sensor Pack

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



Sensor Applicator

Applies the Sensor to your body.

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



Sensor

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

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

Home Screen

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

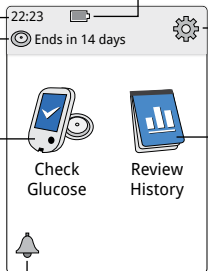
Touch to check your Sensor glucose.

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

Message

Touch for more information.

Add Notes

Touch to add notes to the glucose reading.

Current Glucose

Glucose from your latest scan.

Glucose Trend Arrow

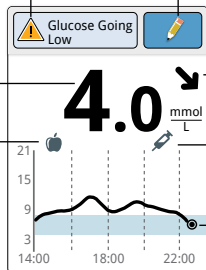
Direction your glucose is going.

Food Note

Rapid-Acting Insulin Note

Glucose Graph

Graph of your current and stored glucose readings.



FreeStyle Libre Software

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



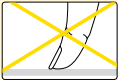
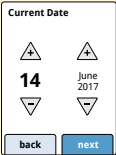
INTENDED USE

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

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

Setting up Your Reader for the First Time

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

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

Step

Action

4

Current Time

▲ ▲

12 : 00

▼ ▼

back next

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

Target Glucose Range ?

▲ ▲

4.4 to 7.8 mmol/L

▼ ▼

back next

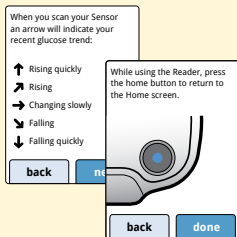
Set your **Target Glucose Range**. Work with your health care professional to determine your Target Glucose Range. Touch **next** to continue.

Note: Your Target Glucose Range is displayed on glucose graphs on the Reader and used to calculate your Time In Target.

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.

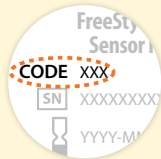


Touch **next** to move to the next topic. At the end of the Reader setup, touch **done** to go to the Home Screen.



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

CAUTIONS:

- The Sensor Pack and Sensor Applicator are packaged as a set (separately from the Reader) and have the same Sensor code. Check that the Sensor codes match before using your Sensor Pack and Sensor Applicator. Sensor Packs and Sensor Applicators with the same Sensor code should be used together or your Sensor glucose readings may be incorrect.
- Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. If your Sensor comes loose, you may get no readings or unreliable readings, which may not match how you feel. Follow the instructions to select an appropriate application site.

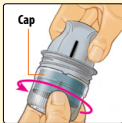


Applying Your Sensor

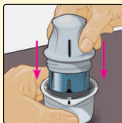
| Step | Action |
|------|--|
| 1 |  <p>Apply Sensors only on the back of your upper arm. Avoid areas with scars, moles, stretch marks or lumps.</p> <p>Select an area of skin that generally stays flat during your normal daily activities (no bending or folding). Choose a site that is at least 2.5 cm (1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

Step**Action****3**

Open the Sensor Pack by peeling the lid off completely. Unscrew the cap from the Sensor Applicator and set the cap aside.



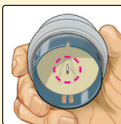
CAUTION: Do NOT use if the Sensor Pack or the Sensor Applicator seem to be damaged or already opened. Do NOT use if past expiry date.

4

Line up the dark mark on the Sensor Applicator with the dark mark on the Sensor Pack. On a hard surface, press firmly down on the Sensor Applicator until it comes to a stop.

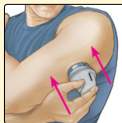
5

Lift the Sensor Applicator out of the Sensor Pack.

Step**Action****6**

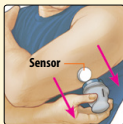
The Sensor Applicator is prepared and ready to apply the Sensor.

CAUTION: The Sensor Applicator now contains a needle. Do NOT touch inside the Sensor Applicator or put it back into the Sensor Pack.

7

Place the Sensor Applicator over the prepared site and push down firmly to apply the Sensor to your body.

CAUTION: Do NOT push down on the Sensor Applicator until placed over prepared site to prevent unintended results or injury.

Step**Action****8**


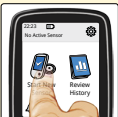

Gently pull the Sensor Applicator away from your body. The Sensor should now be attached to your skin.

Note: Applying the Sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the Sensor, and apply a new one at a different site.




9

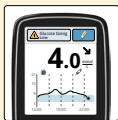
Make sure the Sensor is secure after application. Put the cap back on the Sensor Applicator. Discard the used Sensor Pack and Sensor Applicator according to local regulations.

Starting Your Sensor

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

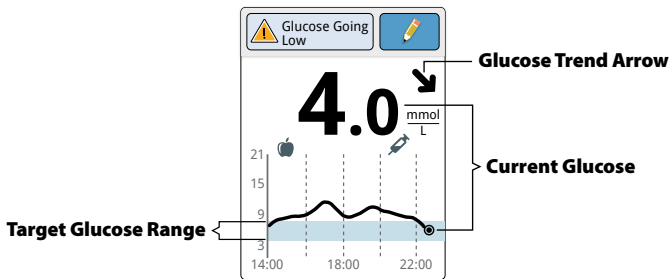
Checking Your Glucose

| Step | Action | |
|------|---|--|
| 1 |  | <p data-bbox="388 221 429 249">OR</p>  <p data-bbox="624 163 1037 298">Turn the Reader on by pressing the Home Button or touch Check Glucose from the Home Screen.</p> |
| 2 |  | <p data-bbox="394 397 1019 567">Hold the Reader within 4 cm (1.5 inches) of your Sensor to scan it. Your Sensor wirelessly sends glucose readings to the Reader. If sounds are turned on, the Reader beeps when the Sensor has been successfully scanned.</p> <p data-bbox="215 594 965 729">Note: If the Sensor is not successfully scanned within 15 seconds, the Reader displays a prompt to scan the Sensor again. Touch OK to return to the Home Screen and touch Check Glucose to scan your Sensor.</p> |

Step**Action****3**

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)



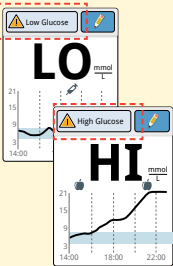
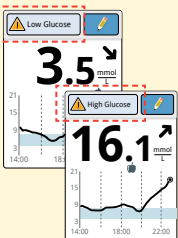
Glucose is falling
(between 0.06 and 0.1 mmol/L per minute)



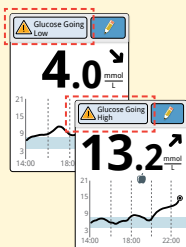
Glucose is falling quickly
(more than 0.1 mmol/L per minute)

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

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

| Display | What To Do |
|--|---|
|  The image shows two screenshots of a glucose reader's display. The top screenshot shows a 'Low Glucose' alert with a yellow warning triangle and the text 'LO mmol/L'. Below the alert is a line graph showing a low glucose level. The bottom screenshot shows a 'High Glucose' alert with a yellow warning triangle and the text 'HI mmol/L'. Below the alert is a line graph showing a high glucose level. Both screenshots have a red dashed box around the alert icon and the 'LO' or 'HI' text. | <p>If LO appears on the Reader, your reading is lower than 2.2 mmol/L. If HI appears on the Reader, your reading is higher than 27.8 mmol/L. You can touch the message button for more information. Check your blood glucose on your finger with a test strip. If you get a second LO or HI result, contact your health care professional immediately.</p> |
|  The image shows two screenshots of a glucose reader's display. The top screenshot shows a glucose reading of '3.5 mmol/L' with a yellow warning triangle and the text 'Low Glucose'. Below the reading is a line graph showing a low glucose level. The bottom screenshot shows a glucose reading of '16.1 mmol/L' with a yellow warning triangle and the text 'High Glucose'. Below the reading is a line graph showing a high glucose level. Both screenshots have a red dashed box around the alert icon and the numerical reading. | <p>If your glucose is higher than 13.3 mmol/L or lower than 3.9 mmol/L, you will see a message on the screen. You can touch the message button for more information and set a reminder to check your glucose.</p> |

Display



What To Do

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

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

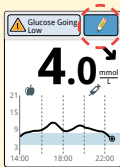
Adding Notes


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

Step

Action

1

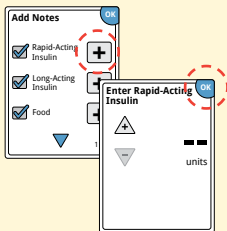



From the Glucose Reading screen, add notes by touching the  symbol in the upper right corner of the touchscreen. If you do not want to add notes, you can press the Home Button to go to the Home Screen or hold the Home Button to turn the Reader off.

2



The "Add Notes" dialog box contains three options, each with an unchecked checkbox: "Rapid-Acting Insulin", "Long-Acting Insulin", and "Food". There is a blue downward-pointing arrow at the bottom center and "1 / 4" in the bottom right corner. An "OK" button is in the top right corner.

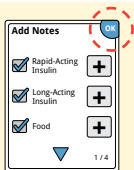
Select the tickbox next to the notes you would like to add. Touch the down arrow to view other Note options.

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

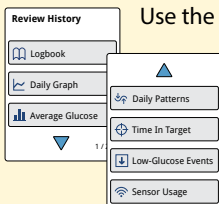
Reviewing and understanding your glucose history can be an important tool for improving your glucose control. The Reader stores about 90 days of information and has several ways to review your past glucose readings, notes, and other information.

| Step | Action | |
|------|---|--|
| 1 |  The first illustration shows a close-up of the physical Home button on the bottom of the device, with a finger about to press it. The second illustration shows the device's screen with the Home button highlighted. The screen displays the text "Check Glucose" at the top and "Scan Sensor to check glucose" at the bottom. | Press the Home Button to turn on the Reader. Press the Home Button again to go to the Home Screen. |
| 2 |  The illustration shows the Home screen of the device. At the top, it displays the time "10:22" and the battery level "80% in 14 days". Below this are two icons: "Check Glucose" and "Review History". A finger is shown touching the "Review History" icon. | Touch the Review History icon. |

Step

Action

3

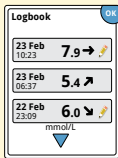



Use the arrows to view the available options.

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.

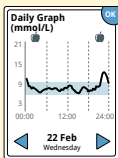
Logbook



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 you entered. You can add or edit (change) Notes for the most recent Logbook entry, provided your glucose reading was within the last 15 minutes and you have not used FreeStyle Libre software to create reports.

Daily Graph



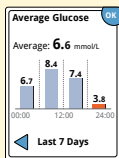
A graph of your Sensor glucose readings by day. The graph shows your Target Glucose Range and symbols for food or rapid-acting insulin notes you have entered.

Notes:

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

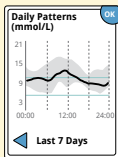
Other History Options

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



Average Glucose

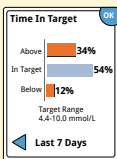
Information about the average of your Sensor glucose readings. The overall average for the time is displayed above the graph. The average is also shown for four different 6-hour periods of the day. Readings above or below your Target Glucose Range are orange, while readings in range are blue.



Daily Patterns

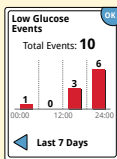
A graph showing the pattern and variability of your Sensor glucose over a typical day. The thick black line shows the median (midpoint) of your glucose readings. The gray shading represents a range (10-90 percentiles) of your Sensor readings.

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



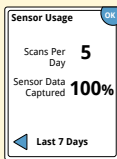
Time In Target

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



Low Glucose Events

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



Sensor Usage

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

Removing Your Sensor

Step

Action

1



Pull up the edge of the adhesive that keeps your Sensor attached to your skin. Slowly peel away from your skin in one motion.

Note: Any remaining adhesive residue on the skin can be removed with warm soapy water or isopropyl alcohol.

2

Discard the used Sensor according to local regulations. See *Maintenance and 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.


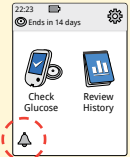

Replacing Your Sensor

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.

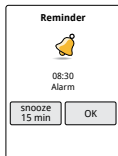
CAUTION: If the glucose readings from the FreeStyle Libre Flash Glucose Monitoring System do NOT seem to match with how you feel, check to make sure that your Sensor has not come loose. If the Sensor tip has come out of your skin, or your Sensor is coming loose, remove the Sensor and apply a new one.

Using Reminders


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

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

| Step | Action |
|------|---|
| 4 | Set the reminder Time using the arrows on the touchscreen. Touch save . |
| 5 | <div data-bbox="230 263 379 464"> <p>The screenshot shows a 'Reminders' screen with a list of four items. Each item has a time and a toggle switch. The first item is 08:30 with an 'On' toggle. The second is 12:30 with an 'Off' toggle. The third is 00:00:00 with an 'On' toggle. At the bottom, there are two buttons: 'add new' and 'done'.</p> </div> <p>From the Reminders screen, you can turn the reminder On/Off or add new reminders. Touch done to return to the Home Screen.</p> |



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

For example,  08:30

Your reminder comes on even if the Reader is turned off. Touch **OK** to dismiss your reminder or **snooze** to be reminded again in 15 minutes.

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

Using the Built-in Meter

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

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

IMPORTANT:

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

Blood Glucose Testing

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

Step

Action

1



CAUTION: If you think you have low glucose (hypoglycaemia) or you suffer from hypoglycaemia unawareness, test on your fingers.

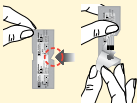
Wash your hands and the test site with warm soapy water for accurate results. Thoroughly dry your hands and the test site. To warm the site, apply a warm dry pad or rub vigorously for a few seconds.

Note: Avoid areas near bones and areas with lots of hair. If a bruise forms, consider selecting another site.

Step**Action****2**

E.g. Expiry date:
March 31, 2016

Check the test strip expiry date.

3

Open the foil test strip packet at the notch and tear down to remove the test strip. Use the test strip immediately after removing from the foil packet.

4

Insert the test strip with the three black lines at the end facing up. Push the strip in until it stops.

5

Use your lancing device to obtain a blood drop and apply blood to the white area at the end of the test strip.

If sounds are turned on, the Reader beeps once to let you know you have applied enough blood.

Note: See test strip instructions for use for re-application instructions.

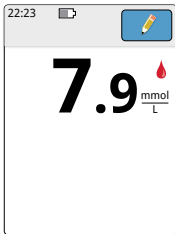
Step**Action**


You will see a butterfly on the screen while you wait for your result. If sounds are turned on, the Reader beeps once when your result is ready.

6

After reviewing your result, remove and discard the used test strip according to local regulations.

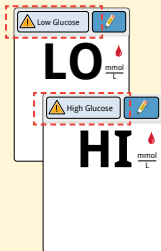
IMPORTANT: After performing a blood glucose test, wash your hands and the test site with soap and water and thoroughly dry them.

**Your Blood Glucose Results**

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

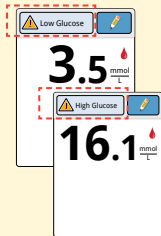
Note: Contact your health care professional if you have symptoms that do not match your test results.

Display




What To Do

If **LO** appears on the Reader, your result is lower than 1.1 mmol/L. If **HI** appears on the Reader, your result is higher than 27.8 mmol/L. You can touch the message button for more information. Check your blood glucose again with a test strip. If you get a second **LO** or **HI** result, contact your health care professional **immediately**.



If your glucose is higher than 13.3 mmol/L or lower than 3.9 mmol/L, you will see a message on the screen. You can touch the message button for more information and set a reminder to check your glucose.


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

Blood Ketone Testing

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

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

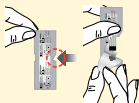
Note: Be sure to read the test strip instructions for use prior to performing a ketone test.

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

Step**Action****2**

E.g. Expiry date:
March 31, 2016

Check the test strip expiry date.

3

Open the foil test strip packet at the notch and tear down to remove the test strip. Use the test strip immediately after removing from the foil packet.

4

Note: Use only blood ketone test strips. Do not put urine on the test strip.

Insert the test strip with the three black lines facing up. Push the strip in until it stops.

Step

Action

5



Use your lancing device to obtain a blood drop and apply blood to the white area at the end of the test strip.

If sounds are turned on, the Reader beeps once to let you know you have applied enough blood.

Note: See test strip instructions for use for re-application instructions.

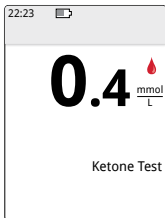


You will see a butterfly on the screen while you wait for your result. If sounds are turned on, the Reader beeps once when your result is ready.

6

After reviewing your result, remove and discard the used test strip according to local regulations.

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



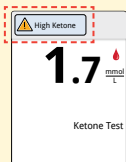
Your Blood Ketone Results

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

Notes:

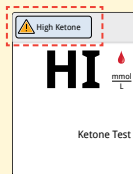
- Blood ketone is expected to be lower than 0.6 mmol/L.
- Blood ketone may be higher when you are sick, fasting, have exercised hard or if glucose levels are not controlled.
- If your blood ketone result remains high or becomes higher than 1.5 mmol/L, contact your health care professional **immediately**.

Display



What To Do

If your blood ketone is high, you will see a message on the screen. You can touch the message button for more information.



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

Control Solution Testing

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

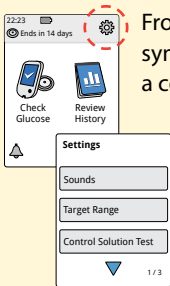
IMPORTANT:


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

Step

Action

1



From the Home Screen, touch the Settings symbol . Touch **Control Solution Test** to do a control solution test.

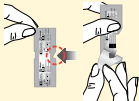
2



Check the test strip expiry date.

E.g. Expiry date:
March 31, 2016

3



Open the foil test strip packet at the notch and tear down to remove the test strip.

Step**Action****4**

Insert the test strip with the three black lines facing up. Push the strip until it stops.

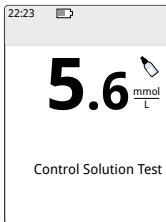
5

Shake the control solution bottle to mix the solution. Apply a drop of control solution to the white area at the end of the test strip.

If sounds are turned on, the Reader beeps once to let you know that you have applied enough control solution.




You will see a butterfly on the screen while you wait for the result. If sounds are turned on, the Reader beeps once when the result is ready.

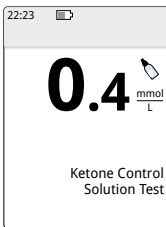


**Blood Glucose Control
Solution Test**

Control Solution Results

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

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



Ketone Control Solution Test

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

Using the Rapid-Acting Insulin Calculator

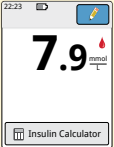
This optional feature requires an understanding of the use of insulin. Misuse or misunderstanding of this feature and the suggested dose may lead to inappropriate insulin dosing. The calculator suggests doses for rapid-acting insulin only. The calculator is only for use with fingerstick blood glucose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

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

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

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

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

| Step | Action |
|------|---|
| 1 |  A screenshot of a blood glucose meter's display. The top left shows the time '22:23'. The main display shows a large '7.9' with 'mmol/L' and a red drop icon to its right. At the bottom, there is a button labeled 'Insulin Calculator' with a calculator icon to its left. <p>Test your blood glucose on your finger. Touch Insulin Calculator from the blood glucose results screen. You can also access the insulin calculator by touching the calculator icon next to Rapid-Acting Insulin from the Add Notes screen.</p> |

Step

2

Have you forgotten to log any rapid-acting insulin you have taken since X:XX?

no

Enter any rapid-acting insulin you have forgotten to log.

2 units

back

How long ago was the unlogged dose of rapid-acting insulin?

15 minutes or less

back next

Action

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

A screenshot of a mobile application interface for meal selection. It features four radio button options: Breakfast, Lunch (which is selected), Dinner, and No meal. At the bottom, there are two buttons: 'back' and 'next'.

If your calculator was programmed with **Easy Setup**, touch the meal you plan to eat now. Touch **next**.

Or

A screenshot of a mobile application interface for entering carbohydrate amounts. The title is 'Enter Carbs' with a question mark icon. It shows a large '20' followed by 'grams'. There are plus and minus buttons on the left for adjustment. At the bottom, there are 'back' and 'done' buttons.

If your calculator was programmed with **Advanced Setup**, enter the grams of carbohydrates or carbohydrate portions you plan to eat now. Touch **done**.

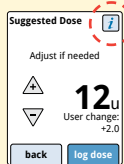
Or


A screenshot of a mobile application interface for entering carbohydrate portions. The title is 'Enter carb portions' with a question mark icon. It shows a large '2.0' followed by 'carb. portions = 30g carbs'. There are plus and minus buttons on the left for adjustment. At the bottom, there are 'back' and 'done' buttons.

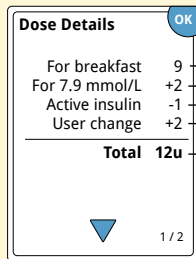
Step

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  symbol to see details of what is included in your suggested dose.



Insulin to cover your meal

Insulin to correct for your current glucose level

Insulin remaining in your body

A change you have made to the suggested insulin dose

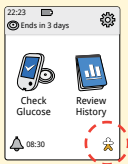
Your **total** suggested dose



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**.

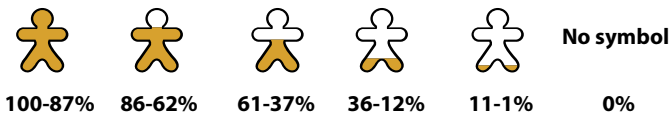
CAUTION: It is important to log all your rapid-acting insulin doses so your Reader can account for active insulin when calculating your suggested doses. Failure to log all your rapid-acting insulin doses may result in a suggested dose that is too high.

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



Charging the Reader

A fully charged Reader battery should last up to 7 days. Your battery life may vary depending on your usage. A **Low Battery** message accompanies your result when you have enough charge remaining for about one day of use.




Charging

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

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

Notes:

- You must charge the Reader when the battery is low  to keep using the Reader.
- To fully charge the battery, charge the Reader for at least 3 hours.
- Only use the USB cable and power adapter included with the system.
- Fully charge your Reader before storing it for more than 3 months.

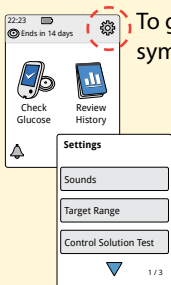
Changing the Reader Settings


You can go to the Settings menu to change many settings on the Reader, like Time & Date or Sounds. The Settings menu is also where you go to do a Control Solution Test or to check the System Status.

Step

Action

1



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

2

Touch the setting you want to change:

Sounds – Set tones 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 of most recent Sensors (up to three)
 - Sensor version for most recent Sensor
 - Number of Sensors that have been used with Reader
 - Number of tests that have been performed using test strips

| Step | Action |
|----------------------------|--|
| 2 (cont.) | <ul style="list-style-type: none">• View Event Logs: A list of events recorded by the Reader, which may be used by Customer Service to help troubleshoot your System• Perform a Reader Test: The Reader Test will perform internal diagnostics and allow you to check that the Display is showing all pixels, Sounds (including both tones and vibrations) are working and the Touchscreen is responding when touched <p>Calculator Settings – Review the currently programmed settings (option only available if your health care professional has activated your insulin calculator)</p> <p>Reader Basics – Review the information screens shown during the Reader setup</p> <p>Professional Options – Set by health care professionals only</p> <p>Touch OK when you are done.</p> |

Living With Your FreeStyle Libre System

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

| Activity | What You Need To Know |
|--|--|
| Bathing, Showering and Swimming | <p>The Reader is not water-resistant and should NEVER be submerged in water or other liquids. Your Sensor is water-resistant and can be worn while bathing, showering or swimming.</p> <p>Note: Do NOT take your Sensor deeper than 1 metre (3 feet) or immerse it longer than 30 minutes in water.</p> |
| Sleeping | <p>Your Sensor should not interfere with your sleep. It is recommended that you scan your Sensor before going to sleep and when you wake up because your Sensor holds 8 hours of data at a time.</p> <p>If you have reminders set to go off while you are sleeping, place the Reader nearby.</p> |



Activity

Travelling by Air

What You Need To Know

Check with the airline prior to departure as rules and regulations may change without notice. Follow these guidelines when travelling:

- Notify security personnel of the presence of the device when going through security systems.
- Do not scan your Sensor or power on the Reader using the Home Button while flying, if restricted by flight regulations. You may insert a strip to perform a blood glucose or ketone test.

Note: If you are changing time zones, you can change the time and date settings on the Reader by touching the Settings symbol  from the Home Screen, then **Time & Date**. Changing the time and date affects the graphs, statistics, and settings programmed by time of day. The  symbol may appear on your glucose graph indicating the Reader time was changed. Gaps in the graph may result, or glucose readings may be hidden.

Maintenance and Disposal

Cleaning

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

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

Maintenance

The FreeStyle Libre Flash Glucose Monitoring System has no serviceable parts.

Disposal

This product should be disposed of in accordance with all applicable local regulations related to the disposal of electronic equipment, batteries, sharps, and materials potentially exposed to body fluids.

Contact Customer Service for further information on the appropriate disposal of system components.

Troubleshooting

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

Reader Does Not Power On

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

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

Problems at the Sensor Application Site

| Problem | What It May Mean | What To Do |
|---|---|--|
| The Sensor is not sticking to your skin. | The site is not free of dirt, oil, hair or sweat. | <ol style="list-style-type: none">1. Remove the Sensor.2. Consider shaving and/or cleaning the site with soap and water.3. Follow the instructions in <i>Applying and Starting Your Sensor</i> sections. |
| Skin irritation at the Sensor application site. | Seams or other constrictive clothing or accessories causing friction at the site. | Ensure that nothing rubs on the site. |
| | You may be sensitive to the adhesive material. | If the irritation is where the adhesive touches skin, contact your health care professional to identify the best solution. |

Problems Starting Your Sensor or Receiving Sensor Readings

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

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

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

Blood Glucose or Ketone Error Messages

| Error Message | What It May Mean | What To Do |
|---------------|--|--|
| E-1 | The temperature is too hot or too cold for the Reader to work correctly. | <ol style="list-style-type: none">1. Move the Reader and test strips to a location where the temperature is within the test strip operating range. (See test strip instructions for use for the appropriate range).2. Wait for the Reader and test strips to adjust to the new temperature.3. Repeat the test using a new test strip.4. If the error reappears, contact Customer Service. |
| E-2 | Reader error. | <ol style="list-style-type: none">1. Turn off the Reader.2. Repeat the test using a new test strip.3. If the error reappears, contact Customer Service. |

| Error Message | What It May Mean | What To Do |
|---------------|--|---|
| E-3 | Blood drop is too small. or Incorrect test procedure. or There may be a problem with the test strip. | <ol style="list-style-type: none">1. Review the testing instructions.2. Repeat the test using a new test strip.3. If the error reappears, contact Customer Service. |
| E-4 | The blood glucose level may be too high to be read by the system. or There may be a problem with the test strip. | <ol style="list-style-type: none">1. Repeat the test using a new test strip.2. If the error reappears, contact your health care professional immediately. |

| Error Message | What It May Mean | What To Do |
|----------------------|---|---|
| E-5 | Blood was applied to the test strip too soon. | <ol style="list-style-type: none">1. Review the testing instructions.2. Repeat the test using a new test strip.3. If the error reappears, contact Customer Service. |
| E-6 | The test strip may not be compatible with the Reader. | <ol style="list-style-type: none">1. Check that you are using the correct test strip for the Reader. (See test strip instructions for use to verify your strip is compatible with the Reader).2. Repeat the test using a test strip for use with your Reader.3. If the error reappears, contact Customer Service. |

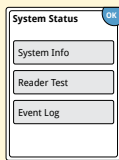
| Error Message | What It May Mean | What To Do |
|----------------------|--|---|
| E-7 | Test strip may be damaged, used or the Reader does not recognise it. | <ol style="list-style-type: none">1. Check that you are using the correct test strip for the Reader. (See test strip instructions for use to verify your strip is compatible with the Reader).2. Repeat the test using a test strip for use with your Reader.3. If the error reappears, contact Customer Service. |
| E-9 | Reader error. | <ol style="list-style-type: none">1. Turn off the Reader.2. Repeat the test using a new test strip.3. If the error reappears, contact Customer Service. |


Problems Checking Your Blood Glucose or Ketone

| Problem | What It May Mean | What To Do |
|--|---|--|
| The Reader does not start a test after inserting a test strip. | Test strip is not inserted correctly or not inserted fully into the strip port. | <ol style="list-style-type: none">1. With the 3 black lines facing up, insert the test strip into the strip port until it stops.2. If the Reader still does not start a test, contact Customer Service. |
| | Reader battery is too low. | Charge the Reader. |
| | The test strip is damaged, used or unrecognisable by the Reader. | Insert a new FreeStyle Optium test strip. |
| | Reader is outside of its operating temperature range. | Move the Reader to a temperature between 10 °C and 45 °C and then try to power it on. |
| | Reader is in a power saving mode. | Press the Home Button then insert a test strip. |

| Problem | What It May Mean | What To Do |
|---|--|---|
| <p>The test does not start after applying the blood sample.</p> | <p>Blood sample is too small.</p> | <ol style="list-style-type: none"> 1. See test strip instructions for use for re-application instructions. 2. Repeat the test using a new test strip. 3. If the test still does not start, contact Customer Service. |
| | <p>Sample applied after the Reader turned off.</p> | <ol style="list-style-type: none"> 1. Review the testing instructions. 2. Repeat the test using a new test strip. 3. If the test still does not start, contact Customer Service. |
| | <p>Problem with Reader or test strip.</p> | <ol style="list-style-type: none"> 1. Repeat the test using a new test strip. 2. If the test still does not start, contact Customer Service. |

Perform a Reader Test



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

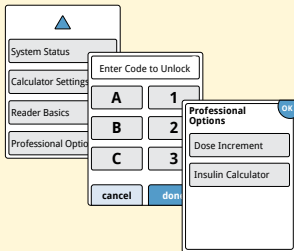
Note: The Reader Test will perform internal diagnostics and will allow you to check that the display, sounds and touchscreen are working properly.


Customer Service

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

Professional Options

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

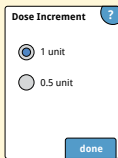


From the Home Screen, touch the Settings symbol . Scroll down using the arrows and touch **Professional Options**. Enter the access code.

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

Changing Dose Increments

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



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

Setting up the Insulin Calculator

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

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

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

Blood glucose correction
(if needed)

+

Meal | Carbohydrate Intake


-

Active Insulin
(if present)

=

Total suggested dose

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

You must complete all of the steps in the insulin calculator setup in order for the patient to use the calculator. When you have finished setting up the insulin calculator, you can review the settings to make sure 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.

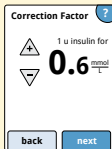
Easy Setup of the Insulin Calculator

| Step | Action |
|-----------------|--|
| <p>1</p> | <div data-bbox="230 168 379 370"> </div> <p>Choose the Easy option on the slide bar and touch next.</p> <p>Note: You need to know your patient's mealtime insulin doses, target glucose range and correction factor.</p> |
| <p>2</p> | <div data-bbox="230 438 379 640"> </div> <p>Enter the mealtime rapid-acting insulin doses. Touch next after each entry.</p> |
| <p>3</p> | <div data-bbox="230 702 379 904"> </div> <p>Enter the blood glucose Correction Target. This is the desired target range for blood glucose values before meals. Touch next.</p> <p>Note: If you just want to set one target instead of a range, set both the low and high values to the same number.</p> |

Step

Action

4



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

Notes:

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

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

Notes about the Easy Option:

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

Calculator Settings - Easy Option

This page can be used to record insulin calculator settings.

Breakfast
Dose

units of insulin

0-50

Lunch
Dose

units of insulin

0-50

Dinner
Dose

units of insulin

0-50

► This is the insulin required to cover food.

Correction Target

 -

mmol/L mmol/L

3.9-10.0

3.9-10.0

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

Correction Factor
1 unit of insulin for

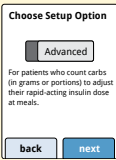
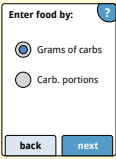
mmol/L

0.1-5.5 (or No Correction)

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

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

Advanced Setup of the Insulin Calculator

| Step | Action |
|------|--|
| 1 | <div data-bbox="229 163 379 370"></div> <p>Choose the Advanced option on the slide bar and touch next.</p> <p>Note: You need to know your patient's mealtime insulin settings, target glucose range, correction factor and insulin duration.</p> |
| 2 | <div data-bbox="229 547 379 754"></div> <p>Touch to select how meal/carbohydrate information will be entered. Touch next.</p> <p>For Grams of carbs, go to Step 3.</p> <p>For Carb portions, go to Step 4.</p> |

Step

Action

3

Carbohydrate Ratio ?

1 u insulin for
10
grams carbs

Optional:

back next

If you chose to enter Grams of carbs in Step 2: The rapid-acting insulin dose suggestion is based on grams of carbs.

Enter the **Carbohydrate Ratio** (1 unit of rapid-acting insulin for _____ grams of carbs). Touch **next** when complete.

Carbohydrate ratio ?

1 unit insulin for:

10g morning

15g night 15g midday

2g evn

back

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**.

Carbohydrate Ratio ?

1 u insulin for
10
grams carbs

Morning:
4am to 10am

OK

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)

4

Carb Portions Definition ?

1 portion =
10.0
grams carbs

back

Carb Portion Ratio ?

For 1 portion:
1.5
units insulin

Optional: by time of day

back next

Carb portion ratio for 1 portion: ?

2 u ins morning
3 u ins night
3 u ins midday
4 u ins evening

back

Carb Portion Ratio OK

For 1 portion:
2
units insulin

Morning:
4am to 10am

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

Step

Action

5

How does your patient correct their glucose?

To a single target

To a target range

back next

Select how you want your patient to correct their glucose. Touch **next**.

6

Correction Target ?

▲

5.6 mmol/L

▼

Optional: by time of day

back

Correction Target ?

Correction Target in mmol/L:

5.6 morning

6.7 night

6.1 midday

5.6 evening

back

Correction Target OK

▲

5.6 mmol/L

▼

Morning:
4am to 10am

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**.

7

Correction Factor ?

1 u insulin for
 $0.6 \frac{\text{mmol}}{\text{L}}$

Optional: by time of day

next

Correction Factor ?

1 u insulin for:

1.7 mmol/L morning

1.1 mmol/L night

1.1 mmol/L midday

0.8 mmol/L evening

back

Correction Factor OK

1 u insulin for
 $0.6 \frac{\text{mmol}}{\text{L}}$

Morning:
4am to 10am

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.

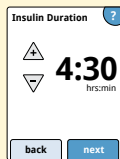
Notes:

- 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



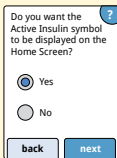
Enter the **Insulin Duration**. This is the amount of time that rapid-acting insulin remains active in the patient's body.


Touch **next**.

IMPORTANT: In general, the insulin duration for rapid-acting insulin ranges from 3-5 hours, and can vary for each person¹. The Reader allows an insulin duration from 3-8 hours.

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

9



Select whether or not to show the **Active Insulin** symbol  on the Home Screen.

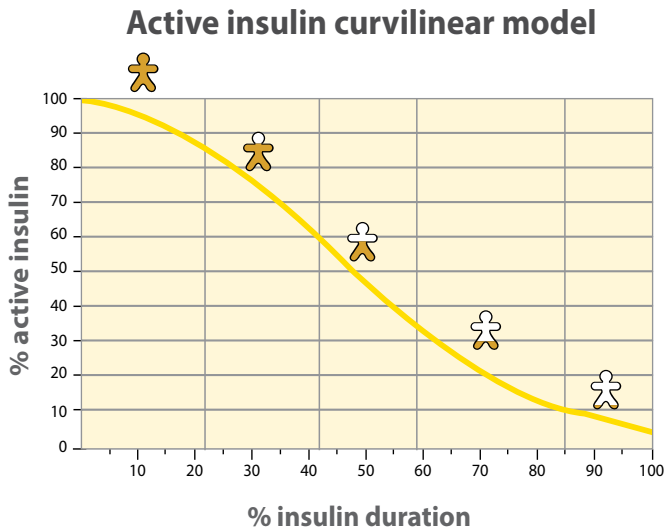
This symbol shows an estimate of the amount of rapid-acting insulin still in the body and how much longer it may be active. If you select “No”, active insulin is still included in the suggested dose calculation.

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

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



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

Professional Options 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?

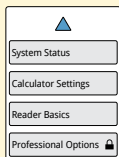
Yes
No


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

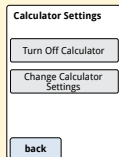
Changing the Insulin Calculator Settings

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 | IP27: Can withstand immersion into one metre (3 ft) of water for up to 30 minutes |
| Operating and storage altitude | -381 metres (-1,250 ft) to 3,048 metres (10,000 ft) |

Reader Specifications

| | |
|-------------------------------------|--------------------------------------|
| Blood glucose assay range | 1.1 to 27.8 mmol/L |
| Blood ketone assay range | 0.0 to 8.0 mmol/L |
| Reader size | 95 mm x 60 mm x 16 mm |
| Reader weight | 65 grams |
| Reader power source | One lithium-ion rechargeable battery |
| Reader battery life | 7 days of typical use |
| Reader memory | 90 days of typical use |
| Reader operating temperature | 10 °C to 45 °C |
| Reader storage temperature | -20 °C to 60 °C |




















| | |
|--|--|
| Operating and storage relative humidity | 10-90%, non-condensing |
| Reader moisture protection | Keep dry |
| Operating and storage altitude | -381 metres (-1,250 ft) to 3,048 metres (10,000 ft) |
| Reader display timeout | 60 seconds (120 seconds when test strip is inserted) |
| Radio Frequency | 13.56 MHz 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 | 3 years of typical use |
| Power Adapter | Abbott Diabetes Care PRT25612 Operating temperature: 10 °C to 40 °C |
| USB Cable | Abbott Diabetes Care PRT21373 Length: 94 cm (37 inches) |

Rapid-Acting Insulin Calculator Specifications

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

| Parameter | Unit | Range or Value |
|-----------------------------|------------------|-----------------------|
| Dose increments | Units of insulin | 0.5 or 1 |
| Maximum insulin dose | Units of insulin | 50 |

Labelling Symbols

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

Electromagnetic Compatibility

- The System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect the System.
- The use of accessories, transducers and cables other than those specified by Abbott Diabetes Care may result in increased EMISSIONS or decreased IMMUNITY of the System.
- The System should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the System should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic emissions

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

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

Guidance and manufacturer's declaration – electromagnetic immunity

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

| IMMUNITY test | IEC 60601 test level | Compliance Level | Electromagnetic environment – guidance |
|--|--|--|--|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6 kV contact ± 8 kV air | ± 6 kV contact ± 8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | ± 2 kV for power supply lines ± 1 kV for input/output lines | Mains power quality should be that of a typical domestic, commercial or hospital environment. |

| IMMUNITY test | IEC 60601 test level | Compliance Level | Electromagnetic environment – guidance |
|--|---|---|--|
| Surge IEC 61000-4-5 | ±1 kV differential mode ±2 kV common mode | ±1 kV differential mode ±2 kV common mode | Mains power quality should be that of a typical domestic, commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 seconds | <5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 seconds | Mains power quality should be that of a typical domestic, commercial or hospital environment. If the user of the System requires continued operation during power mains interruptions, it is recommended that the System be powered from an uninterruptible power supply or a battery. |

| IMMUNITY test | IEC 60601 test level | Compliance Level | Electromagnetic environment – guidance |
|--|----------------------|------------------|---|
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment. |

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

| IMMUNITY test | IEC 60601 test level | Compliance Level | Electromagnetic environment – guidance |
|-------------------------------|--------------------------------|------------------|---|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | <p>Portable and mobile RF communications equipment should be used no closer to any part of the System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2 \sqrt{P}$ |

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

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

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

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

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

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

- ^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System.
- ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

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

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

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

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

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

Hereby, Abbott Diabetes Care Ltd., declares that the 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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