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Distributed by:
Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502 USA

Customer Service: 1-855-632-8658
7 Days a Week from 8AM to 8PM Eastern Standard Time

www.FreeStyleLibre.com

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Patent: https://www.abbott.com/patents

Abbott

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Manufacturer
Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502 USA

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User's Manual

FreeStyle Libre 2

FLASH GLUCOSE MONITORING SYSTEM

Rx Only **CAUTION:** Federal law restricts this device to sale by or on the order of a physician.

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Your Name _____

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WARNING:

Before you use the FreeStyle Libre 2 System, review all the product instructions and the Interactive Tutorial. The Quick Reference Guide and Interactive Tutorial give you quick access to important aspects and limitations of the System. The User's Manual includes all safety information and instructions for use. Talk to your health care professional about how you should use your Sensor glucose information to help manage your diabetes.

Failure to use the System according to the instructions for use may result in you missing a severe low blood glucose or high blood glucose event and/or making a treatment decision that may result in injury. If your glucose alarms and readings from the System do not match symptoms or expectations, use a fingerstick blood glucose value from a blood glucose meter to make diabetes treatment decisions. Seek medical attention when appropriate.

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Important Safety Information

Indications For Use

The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.

The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time.

The System is also intended to autonomously communicate with digitally connected devices. The System can be used alone or in conjunction with these digitally connected devices where the user manually controls actions for therapy decisions.

Compatible Devices, Apps, and Software

For a list of compatible devices, apps, and software that can be used with the FreeStyle Libre 2 Sensor please go to: https://freestylelibre.us/support/overview.html

Use of the Sensor with devices, apps, and software that are not listed may cause inaccurate glucose readings.

Contraindications

Automated Insulin Dosing: The System must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems.

MRI/CT/Diathermy: The System must be removed prior to Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The effect of MRI, CT scans, or diathermy on the performance of the System has not been evaluated. The exposure may damage the Sensor and may impact proper function of the device which could cause incorrect readings.

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WARNINGS:

- **Do not ignore symptoms that may be due to low or high blood glucose:** If you are experiencing symptoms that are not consistent with your glucose readings, consult your health care professional.
- Use your blood glucose meter to make diabetes treatment decisions when you see the symbol during the first 12 hours of wearing a Sensor, if your Sensor glucose reading does not match how you feel, or if the reading does not include a number.
- **Choking hazard:** The System contains small parts that may be dangerous if swallowed.

Cautions and Limitations

Below are important cautions and limitations to keep in mind so you can use the System safely. They are grouped into categories for easy reference.

What to know about Glucose Alarms:

- For you to receive alarms, they must be on and your Reader should be within 20 feet of you at all times. The transmission range is 20 feet unobstructed. If you are out of range, you may not receive glucose alarms.

- To prevent missed alarms, make sure the Reader has sufficient charge and that sound and/or vibration are turned on.
- Alarms you receive do not include your glucose reading so you must scan your Sensor to check your glucose.

What to know before using the System:

- Review all product information before use.
- Take standard precautions for transmission of blood borne pathogens to avoid contamination.
- Make sure that your Reader and Sensor kits are kept in a safe place, under your control. This is important to help prevent anyone from accessing or tampering with the System.

Who should not use the System:

- **Do not use the System in people less than 4 years of age.** The System is not cleared for use in people under 4 years of age.
- **Do not use the System if you are pregnant, on dialysis, or critically ill.** The System is not cleared for use in these groups and it is not known how different conditions or medications common to these populations may affect performance of the System.
- Performance of the System when used with other implanted medical devices, such as pacemakers, has not been evaluated.

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What should you know about wearing a Sensor:

- Wash application site on the back of your upper arm using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the Sensor from sticking properly. Allow site to air dry before proceeding. Carefully preparing the site according to these instructions will help the Sensor stay on your body for the full 14 day wear period and help prevent it from falling off early.
- The Sensor can be worn for up to 14 days. Remember to always have your next Sensor available before your current one ends so you can keep getting your glucose readings.
- You must scan the Sensor to get your real-time current glucose level as the Reader will not provide this information without a scan.
- In the event that your Sensor stops working and you do not have another Sensor readily available, you must use an alternate method to measure your glucose levels and inform your treatment decisions.
- The System is designed to detect certain conditions which may occur where the Sensor is not working as intended and shut it off, telling you to replace your Sensor. This may occur if the Sensor gets knocked off from the skin or if the System detects that the Sensor may not be performing as intended. Contact Customer Service if you receive a Replace Sensor message before the end of the 14 day wear period. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Standard Time.
- Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If you notice significant skin irritation around or under your Sensor, remove the Sensor and stop using the System. Contact your health care professional before continuing to use the System.
- Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. If the Sensor is becoming loose or if the Sensor tip is coming out of your skin, you may get no readings or unreliable low readings. Remove and replace your Sensor if it starts to loosen and follow the instructions to select an appropriate application site. Do not attempt to reinsert the Sensor. Contact Customer Service if your Sensor becomes loose or falls off before the end of the wear period. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Standard Time.
- Do not reuse Sensors. The Sensor and Sensor Applicator are designed for single use. Reuse may result in no glucose readings and infection.

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Not suitable for re-sterilization. Further exposure to irradiation may cause unreliable low results.

- If a Sensor breaks inside your body, call your health care professional.

How to Store the Sensor Kit:

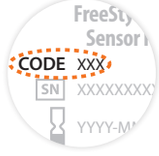
- Store the Sensor Kit between 36°F and 82°F. Storage outside of this range may cause inaccurate Sensor glucose readings.
- If you suspect that the temperature may exceed 82°F (for example, in an un-airconditioned home in summer), you should refrigerate your Sensor Kit. Do not freeze your Sensor Kit.
- Store your Sensor Kit in a cool, dry place. Do not store your Sensor Kit in a parked car on a hot day.
- Store the Sensor Kit between 10-90% non-condensing humidity.

When not to use the System:

- Do NOT use if the Sensor Kit package, Sensor Pack, or Sensor Applicator appear to be damaged or already opened due to risk of no results and/or infection.
- Do NOT use if Sensor Kit contents are past expiration date.

- Do NOT use if the Reader appears to be damaged due to risk of electric shock and/or no results.

What to know before you Apply the Sensor:



- 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. Do not use Sensor Packs and Sensor Applicators with different Sensor codes together as this will result in incorrect glucose readings.
- Wash application site on the back of your upper arm using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the Sensor from sticking properly. Allow site to air dry before proceeding. Carefully preparing the site according to these instructions will help the Sensor stay on your body for the full 14 day wear period and help prevent it from falling off early.

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- Clean hands prior to Sensor handling/insertion to help prevent infection.
- Change the application site for the next Sensor application to prevent discomfort or skin irritation.
- Only apply the Sensor to the back of the upper arm. If placed in other areas, the Sensor may not function properly.
- Select an appropriate Sensor site to help the Sensor stay attached to the body and prevent discomfort or skin irritation. Avoid areas with scars, moles, stretch marks, or lumps. Select an area of skin that generally stays flat during normal daily activities (no bending or folding). Choose a site that is at least 1 inch away from an insulin injection site.

When is Sensor Glucose different from Blood Glucose:

- Physiological differences between the interstitial fluid and capillary blood may result in differences in glucose readings between the System and results from a fingerstick test using a blood glucose meter. 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.

What to know about X-Rays:

- The Sensor should be removed prior to exposing it to an X-ray machine. The effect of X-rays on the performance of the System has not been evaluated. The exposure may damage the Sensor and may impact proper function of the device to detect trends and track patterns in glucose values during the wear period.

When to remove the Sensor:

- If the Sensor is becoming loose or if the Sensor tip is coming out of your skin, you may get no readings or unreliable readings, which may not match how you feel. Check to make sure your Sensor has not come loose. If it has come loose, remove it, apply a new one, and contact Customer Service.
- 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, apply a new one, and contact Customer Service. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Standard Time.

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What to know about the Reader's Built-in Meter:

- The FreeStyle Libre 2 Reader has a built-in blood glucose meter that is designed to be used only with FreeStyle Precision Neo blood glucose test strips and MediSense Glucose and Ketone Control Solution. Using other test strips with the Reader's built-in meter will produce an error or cause the Reader's built-in meter to not turn on or start a test. The Reader's built-in meter does not have ketone testing functionality.
- The Reader's built-in meter is not for use on people who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.
- The Reader's built-in meter is not for use on neonates, in critically-ill patients, or for diagnosis or screening of diabetes.
- See *Using the Reader's Built-in meter* section for additional important information on the use of the Reader's built-in meter.

Where to charge your Reader:

- Be sure to select a location for charging that allows the power adapter to be easily unplugged. Do NOT block access to the charger due to the potential risk of electrical shock.

Interfering Substances

Taking ascorbic acid (vitamin C) supplements while wearing the Sensor may falsely raise Sensor glucose readings. Taking more than 500 mg of ascorbic acid per day may affect the Sensor readings which could cause you to miss a severe low glucose event. Ascorbic acid can be found in supplements including multivitamins. Some supplements, including cold remedies such as Airborne® and Emergen-C®, may contain high doses of 1000 mg of ascorbic acid and should not be taken while using the Sensor. See your health care professional to understand how long ascorbic acid is active in your body.

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Reader Symbols

Symbol	What It Means
	Active Sensor
↑ ↗ → ↘ ↓	Direction your glucose is going. See *Checking Your Glucose* section for more information.
	Caution
▲ ▼ ◀ ▶	View previous/next screen
	Sound and Vibration **ON**
	Sound **ON**, Vibration **OFF**
	Sound **OFF**, Vibration **ON**
	Sound and Vibration **OFF**
	Sensor communicating with Reader
	Sensor not communicating with Reader

Symbol	What It Means
	When you see this symbol during the first 12 hours of wearing a Sensor, confirm Sensor glucose readings with a blood glucose test before making treatment decisions.
	Notes
	Add more information to notes
	Food note
	Rapid-acting insulin note
	Time changed on Reader
	Blood glucose test
	Settings
	Control solution test result
	Low battery
	Battery charging
	Sensor too cold
	Sensor too hot

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Getting to Know Your System

The FreeStyle Libre 2 System ("System") has two main parts: a handheld Reader and a disposable Sensor that you wear on your body. You use the Reader to wirelessly scan the Sensor and display your glucose readings. The Reader only works with FreeStyle Libre 2 Sensors and cannot be used with other Sensors. When they're in range, the Sensor and Reader automatically communicate to give you glucose alarms. These alarms are on by default. Remember that alarms you receive will not include your glucose reading, so you need to scan your Sensor to check your glucose.

IMPORTANT:

- Before you use your System, review all the product instructions and the Interactive Tutorial. The Quick Reference Guide and Interactive Tutorial give you quick access to important aspects and limitations of the System. The User's Manual includes all safety information and instructions for use.
- Go to www.FreeStyleLibre.com to view the "Tips for Kids".
- Talk to your health care professional about how you should use your Sensor glucose information to help manage your diabetes.
- During the first 12 hours of Sensor wear the symbol will display, and you cannot use Sensor values to make treatment decisions during this time. Confirm Sensor glucose readings with a blood glucose test before making treatment decisions during the first 12 hours of Sensor wear when you see the symbol.

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. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Standard Time.

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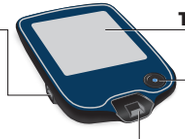
Reader Kit

The Reader Kit includes:

- FreeStyle Libre 2 Reader
- USB Cable
- Interactive Tutorial on USB
- Power Adapter
- User's Manual
- Quick Start Guide
- Quick Reference Guide



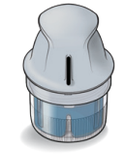
The Reader gets glucose readings from a scan of your Sensor and can issue glucose alarms. The Reader can store approximately 90-days of glucose history and notes you enter about activities, such as taking insulin, eating food, or exercising. This information can help you understand how these activities affect your glucose. The Reader also includes a built-in meter for blood glucose testing. To use the built-in meter, you need FreeStyle Precision Neo blood glucose test strips, control solution, a lancing device, and lancets. These items are not included in the Reader kit and must be obtained separately from your FreeStyle Libre 2 System provider (pharmacy or mail order supplier).

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).

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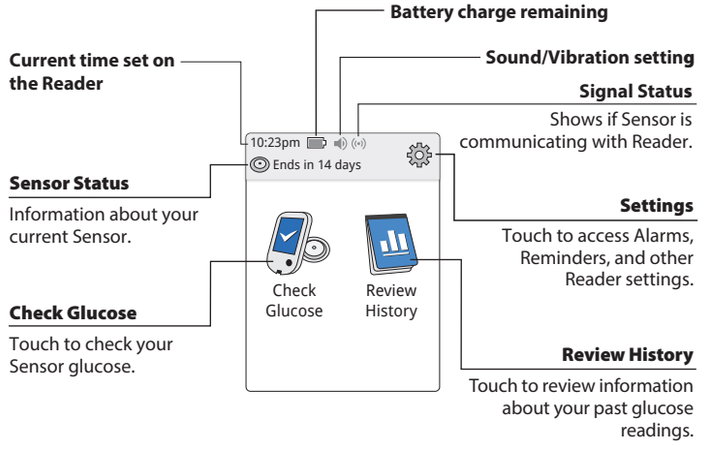
The Reader Home Screen provides access to information about your glucose and the System. You can press the Home Button to get to the Home Screen.

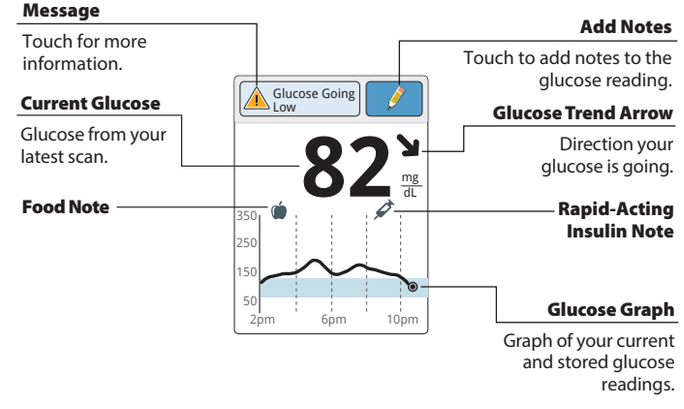
Home Screen



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

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

Sensor Glucose Readings



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FreeStyle Libre Software

FreeStyle Libre software can be used to view reports and change Reader settings. The software also allows you to change the name and/or ID that will be printed on the reports. The name and ID will be saved to the Reader but will not be visible on the Reader itself. 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. You are responsible for keeping your computer secure and up to date, for example by using anti-virus software and installing system updates.

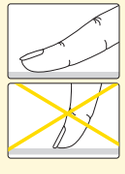
INTENDED USE

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, and other data uploaded from the FreeStyle Libre 2 Flash Glucose Monitoring System, in support of an effective diabetes health management program.

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

Setting up Your Reader for the First Time

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

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

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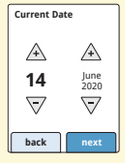
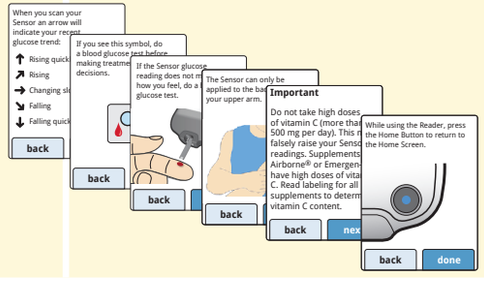
Step	Action
3	 Set the **Current Date** using the arrows on the touchscreen. Touch **next** to continue.
4	Set the **Current Time**. Touch **next** to continue. **CAUSTION:** It is very important to set the time and date correctly. These values affect the Reader data and settings.

Step	Action
5	The Reader now displays important information about key topics to help you use the System: • How to understand the Glucose Trend Arrow included on the Glucose Reading screen. • When to do a blood glucose test. • Where to apply the Sensor. • Why not to take more than 500 mg of Vitamin C supplements per day. • 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. A fully charged battery should last up to 4 days but this may vary depending on your usage.

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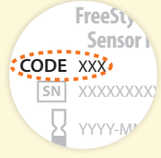
Using Your Sensor

CAUTIONS:



- The Sensor Pack and Sensor Applicator are packaged as a set (separately from the Reader) and have the same Sensor code. Check that the Sensor codes match before using your Sensor Pack and Sensor Applicator. Do not use Sensor Packs and Sensor Applicators with different Sensor codes together as this will result in incorrect glucose readings.
- Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. If the Sensor is becoming loose or if the Sensor tip is coming out of your skin, you may get no readings or unreliable low readings. Remove and replace your Sensor if it starts to loosen and follow the instructions to select an appropriate application site. Do not attempt to reinsert the Sensor. Contact Customer Service if your Sensor becomes loose or falls off before the end of the wear period. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Standard Time.

Applying Your Sensor

Step	Action
1	Apply Sensors only on the back of your upper arm. If placed in other areas, the Sensor may not function properly and could give inaccurate readings. Avoid areas with scars, moles, stretch marks, or lumps. Select an area of skin that generally stays flat during your normal daily activities (no bending or folding). Choose a site that is at least 1 inch (2.5 cm) away from an insulin injection site. To prevent discomfort or skin irritation, you should select a different site other than the one most recently used.
2	Wash application site using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the Sensor from sticking properly. Allow site to air dry before proceeding. **Note:** The area **MUST** be clean and dry following these instructions, or the Sensor may not stay on for the full 14 day wear period.

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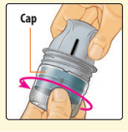
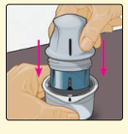
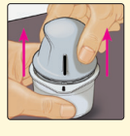
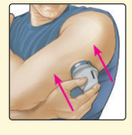
Step	Action
3	 Open the Sensor Pack by peeling the lid off completely. Unscrew the cap from the Sensor Applicator and set the cap aside. **CAUTION:** Do NOT use if the Sensor Pack or the Sensor Applicator seem to be damaged or already opened. Do NOT use if past expiration date.
4	 Line up the dark mark 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.

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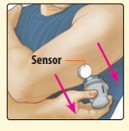
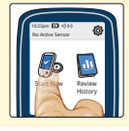
Step	Action
8	 Gently pull the Sensor Applicator away from your body. The Sensor should now be attached to your skin. **Note:** Applying the Sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the Sensor and contact your health care professional.
9	Make sure the Sensor 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	Press the Home Button to turn on the Reader.
2	 Touch **Start New Sensor**.
3	Hold the Reader within 1.5 inches (4 cm) of the Sensor to scan it. This starts your Sensor. If sounds are turned on, the Reader beeps when the Sensor has been successfully activated. The Sensor can be used to check your glucose after 60 minutes. **Note:** If the Sensor is not successfully scanned within 15 seconds, the Reader displays a prompt to scan the Sensor again. Touch **OK** to return to the Home Screen and touch **Start New Sensor** to scan your Sensor.

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Checking Your Glucose

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

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

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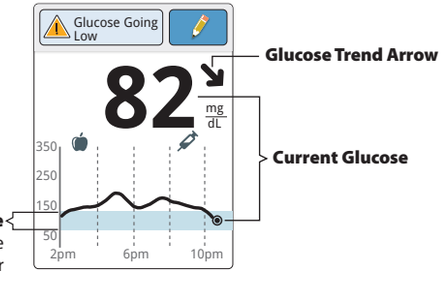
Sensor Glucose Readings



Notes:

- The graph displays glucose readings above 350 mg/dL at 350 mg/dL. For sequential readings above 350 mg/dL, a line is displayed at 350 mg/dL. You can get your Current Glucose number up to 400 mg/dL and Glucose Trend Arrow when you scan your Sensor.
- The ◷ symbol may appear, indicating the Reader time was changed. Gaps in the graph may result or glucose readings may be hidden.
- All available glucose data is used to make your graph so you can expect to see some differences between the graph line and previous current glucose readings.

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

↑	**Glucose is rising quickly** (more than 2 mg/dL per minute)
↗	**Glucose is rising** (between 1 and 2 mg/dL per minute)
→	**Glucose is changing slowly** (less than 1 mg/dL per minute)
↘	**Glucose is falling** (between 1 and 2 mg/dL per minute)
↓	**Glucose is falling quickly** (more than 2 mg/dL per minute)

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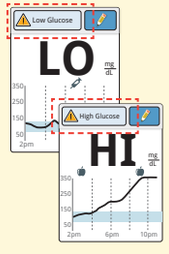
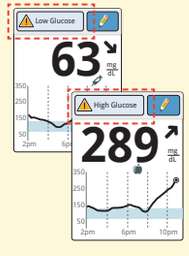
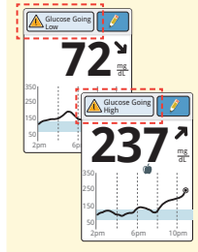
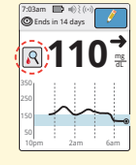
The following table shows messages you may see with your glucose readings.

Display	What To Do
	If **LO** appears on the Reader, your reading is lower than 40 mg/dL. If **HI** appears on the Reader, your reading is higher than 400 mg/dL. 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 after doing a blood glucose test, contact your health care professional **immediately**.
	If your glucose is higher than 240 mg/dL or lower than 70 mg/dL, you will see a message on the screen. You can touch the message button for more information and set a reminder to check your glucose.

Display	What To Do
	If your glucose is projected to be higher than 240 mg/dL or lower than 70 mg/dL 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.
	During the first 12 hours of Sensor wear the symbol will display, and you cannot use Sensor values to make treatment decisions during this time. Confirm Sensor glucose readings with a blood glucose test before making treatment decisions during the first 12 hours of Sensor wear when you see the symbol.

Notes:

- If you are not sure about a message or reading, contact your health care professional before you do anything.
- Messages you receive with your glucose readings are not related to your glucose alarm settings.

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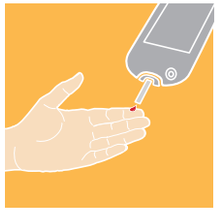
Making Treatment Decisions

Work with your health care professional to put together a plan for managing your diabetes that includes when to use the System information for making treatment decisions. You should also talk to your health care professional about the best times to scan your Sensor. Consider scanning your Sensor before a period when you will not be monitoring your glucose, such as before driving, exercise or sleeping.

WARNING: The System can replace blood glucose testing except in the below situations. These are the times when you need to do a blood glucose test before deciding what to do or what treatment decision to make as Sensor readings may not accurately reflect blood glucose levels:



Do a blood glucose test if you think your glucose readings are not correct or do not match how you feel. Do not ignore symptoms that may be due to low or high glucose.

Do a blood glucose test when you see the symbol during the first 12 hours of wearing a Sensor or the Sensor glucose reading does not include a Current Glucose number.

Making Treatment Decisions – Getting Started

Before you start using the System for treatment decisions, make sure you have a good understanding of how the System works for your body. **Continue to use your blood glucose meter for treatment decisions until you are comfortable with the information you receive from your System.** This includes understanding that: Sensor performance can vary in between Sensors, within a Sensor wear period (up to 14 days), and in different situations. There may be variations between Sensors during the first 12 hours after insertion, so pay attention to how each newly inserted Sensor is working for you when deciding whether to make treatment decisions based on your Sensor readings.

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

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

Helpful Tips

- Confirm your Sensor glucose readings with a blood glucose meter until you understand:
  - Sensor accuracy may vary between Sensors.
  - Sensor accuracy may vary during a Sensor wear session.
  - Sensor accuracy may vary in different situations (meals, exercise, first day of use, etc.).

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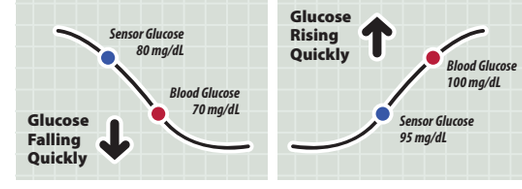
- Scan your Sensor often to see how carbs, medication, exercise, illness, or stress levels impact your Sensor glucose readings. The information you get can help you figure out why your glucose sometimes goes too high or too low, and how to prevent it from doing so in the future.
- Talk to your health care professional about how your insulin works. The more you understand about your insulin, including how long it takes to start working and how long it lasts in your body, the more likely you will be to make better treatment decisions.
- Making a treatment decision doesn't just mean taking insulin. Treatment decisions can also include things like taking fast-acting carbs, eating, or even doing nothing and scanning again later.
- Your health care professional can also help you to understand when doing nothing and scanning again later is the right treatment decision. For example, if your glucose is high and going up, your first instinct may be to take more insulin to lower your glucose, however depending on when you last took insulin or your recent activity, the right treatment decision may be to do nothing and scan again later. Avoid "insulin stacking".

- Sensor glucose values, which are based on interstitial fluid glucose levels, can be different from blood glucose levels (fingersticks), particularly during times when your blood glucose is changing quickly. If your glucose readings and alarms from the System do not match your symptoms or expectations, use a fingerstick blood glucose value from a blood glucose meter to make diabetes treatment decisions.



When <u>not</u> to use Sensor Glucose readings for treatment decisions

No Current Glucose Number

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

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When you see the symbol during the first 12 hours of wearing a Sensor

During the first 12 hours of Sensor wear the symbol will display, and you cannot use Sensor values to make treatment decisions during this time. Confirm Sensor glucose readings with a blood glucose test before making treatment decisions during the first 12 hours of Sensor wear when you see the symbol.

Think Your Readings are Incorrect?

Don't trust Sensor glucose readings that you think may be incorrect or that don't match what you would expect based on your recent activity. For example, if you ate dinner but forgot to take insulin before eating, you would expect your glucose to be high. If your glucose reading is low, then it doesn't match your recent activity, so don't use it to make treatment decisions. Don't make treatment decisions if you think your Sensor glucose readings are incorrect. Do a blood glucose test and treat based on that result.

Symptoms Don't Match Readings

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

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

When to do Nothing and Scan Again Later

Your health care professional can help you understand when doing nothing and scanning again later is the right treatment decision. For example, if your glucose is high and going up, your first instinct may be to take more insulin to lower your glucose, however depending on when you last took insulin or your recent activity, the right treatment decision may be to do nothing and scan again later.

Don't take a correction dose within 2 hours of your meal dose. This may result in "insulin stacking" and low glucose.

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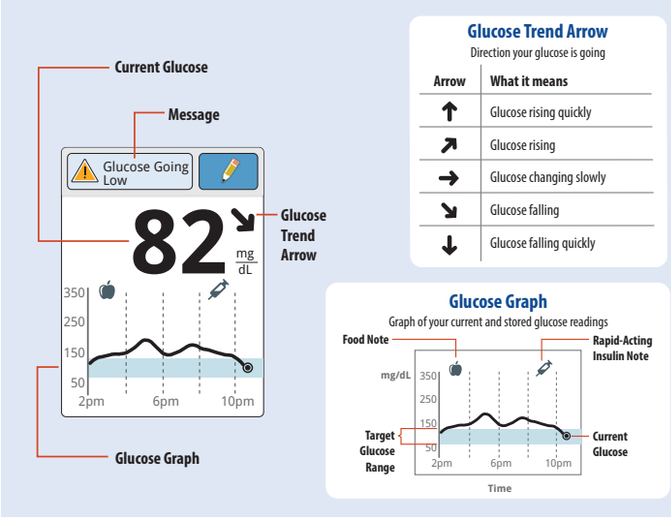
Using Your Glucose Reading to Make a Treatment Decision

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



This table provides some information on how you can factor the Glucose Trend Arrow into your treatment decisions. Remember that you should never make a treatment decision based on the Glucose Trend Arrow alone.

Glucose Trend Arrow	Treatment Decision Considerations		
	Low Glucose (< 70 mg/dL)	**Glucose in Target Range**	**High Glucose (> 240 mg/dL)**
↑	Treat low glucose according to your health care professional's recommendation.	If you are about to eat, take insulin to cover your meal. Consider taking a little more since glucose is rising quickly. If you have taken insulin recently, do nothing and scan again later. Avoid "insulin stacking".	If you are about to eat, take insulin to cover your meal. Consider taking a little more since glucose is high and rising quickly. If this is between meals, consider taking an insulin correction dose, unless you have taken insulin recently. If you have taken insulin recently, do nothing and scan again later. Avoid "insulin stacking".

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Glucose Trend Arrow	Treatment Decision Considerations		
	Low Glucose (< 70 mg/dL)	Glucose in Target Range	High Glucose (> 240 mg/dL)
↗	Treat low glucose according to your health care professional's recommendation.	If you are about to eat, take insulin to cover your meal. Consider taking a little more since glucose is rising. If you have taken insulin recently, do nothing and scan again later. Avoid "insulin stacking".	If you are about to eat, take insulin to cover your meal. Consider taking a little more since glucose is high and rising. If this is between meals, consider taking an insulin correction dose, unless you have taken insulin recently. If you have taken insulin recently, do nothing and scan again later. Avoid "insulin stacking".

Glucose Trend Arrow	Treatment Decision Considerations		
	Low Glucose (< 70 mg/dL)	Glucose in Target Range	High Glucose (> 240 mg/dL)
→	Treat low glucose according to your health care professional's recommendation.	If you are about to eat, take insulin to cover your meal. If this is between meals, do nothing and scan again later.	If you are about to eat, take insulin to cover your meal. Consider taking a little more since glucose is high. If this is between meals, consider taking an insulin correction dose, unless you have taken insulin recently. If you have taken insulin recently, do nothing and scan again later. Avoid "insulin stacking".

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Glucose Trend Arrow	Treatment Decision Considerations		
	Low Glucose (< 70 mg/dL)	Glucose in Target Range	High Glucose (> 240 mg/dL)
↘	Treat low glucose according to your health care professional's recommendation.	If you are about to eat, take insulin to cover your meal. Consider taking a little less since glucose is falling. If this is between meals, consider eating a snack or fast-acting carbohydrates to stay within target and scan again later.	If you are about to eat, take insulin to cover your meal. Consider taking a little less since glucose is falling. If this is between meals, consider doing nothing and scan again later. Avoid "insulin stacking".

Glucose Trend Arrow	Treatment Decision Considerations		
	Low Glucose (< 70 mg/dL)	Glucose in Target Range	High Glucose (> 240 mg/dL)
↓	Treat low glucose according to your health care professional's recommendation.	If you are about to eat, take insulin to cover your meal. Consider taking a little less since glucose is falling quickly. If this is between meals, consider eating a snack or fast-acting carbohydrates to stay within target and scan again later.	If you are about to eat, take insulin to cover your meal. Consider taking a little less since glucose is falling quickly. If this is between meals, consider doing nothing and scan again later. Avoid "insulin stacking".

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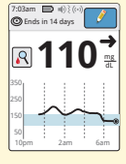
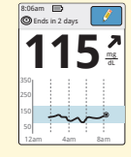
Example Scenarios

Next are some example scenarios to help you understand how to use the information on your screen. Always use all of the information on the screen before deciding what to do or what treatment decision to make. If you are not sure about what to do, consult your health care professional.

What you see	What it means
When you wake-up: 	When you wake-up on your first day of wearing a Sensor, your current glucose is 110 mg/dL. There is also the symbol on the screen. During the first 12 hours of Sensor wear the symbol will display, and you cannot use Sensor values to make treatment decisions during this time. Confirm Sensor glucose readings with a blood glucose test before making treatment decisions during the first 12 hours of Sensor wear when you see the symbol.

What you see	What it means
Before breakfast: 	Before breakfast, your current glucose is 115 mg/dL. The graph shows that your glucose is going up and so does the trend arrow ↗. Consider what might be causing your glucose to go up and what you might do to prevent a high glucose. For example: • How much insulin should you take before your meal? • Since you see ↗, should you consider taking a little more insulin?

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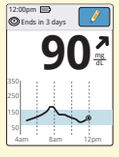
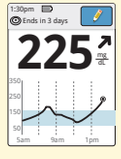
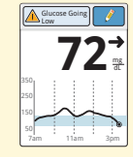
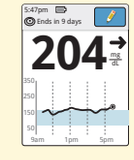
What you see	What it means
Before lunch: 	When you checked your glucose before lunch, it was 90 mg/dL and rising. Before eating lunch, you took enough insulin to cover the meal and a little more since your trend arrow was ↗ .
After lunch: 	90 minutes later, your current glucose is 225 mg/dL. The graph shows that your glucose is still going up, and so does the trend arrow ↗ . **Don't take a correction dose within 2 hours of your meal dose.** This may result in "insulin stacking" and low glucose. Consider what might be causing your glucose to go up and what you might do to prevent a high glucose. For example: • Has the insulin you took for your meal reached its full effect? • Scan your Sensor again later.

What you see	What it means
In the afternoon: 	Between meals, your current glucose is 72 mg/dL. The Glucose Going Low message tells you that your glucose is projected to be low within 15 minutes. Think about what might be causing your glucose to go low. Consider eating a snack to stay within target. **Avoid taking insulin as this can cause low glucose**.
After exercising: 	After exercising, you are feeling shaky, sweaty, and dizzy – symptoms you generally get when you have low glucose. But, your current glucose is 204 mg/dL. Anytime you get a reading that doesn't match how you feel, do a blood glucose test.

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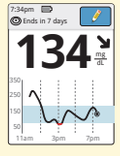
What you see	What it means
Before dinner: 	Before dinner, your current glucose is 134 mg/dL. The graph shows that your glucose is going down and so does the trend arrow ↘. Consider what might be causing your glucose to go down and what you might do to prevent a low glucose. For example: • How much insulin should you take before your meal? • Since you see ↘, should you consider taking a little less insulin?

Other considerations

Deciding how much rapid-acting insulin to take for different meals and situations can be difficult. Work with your health care professional to discuss different situations and what might work best for you. Here are some questions to consider:

Meal dosing

- What do you do if your before meal glucose is high?
- What do you do if your before meal glucose is low?
- How much time do you wait to eat after taking your meal insulin?
- Do you adjust the amount of meal insulin based on the number of carbs or how much you are planning to eat?
- Do you adjust your meal insulin dose for high fat foods such as pizza?
- Do you know how to adjust your insulin doses when drinking alcoholic beverages?

High glucose corrections

- Do you take extra insulin if your glucose is high?
- How do you decide how much insulin to take for a high glucose?
- How long do you wait between insulin doses to avoid insulin stacking?

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Bedtime

- How often do you check your glucose before bed?
- What do you consider a safe bedtime glucose?
- What do you do if your bedtime glucose is high?
- What do you do if your bedtime glucose is low?
- When should you eat a bedtime snack?
- What do you do if your before meal glucose is high?
- What do you do if your before meal glucose is low?

Other factors

- How do you adjust your insulin dose based on the Glucose Trend Arrow?
- How do you adjust your insulin dose for different types of exercise or activities?
- How do you adjust your insulin doses for stress?
- How do you adjust your insulin doses for illness?

Alarms

When in range of the Reader, your Sensor automatically communicates with the Reader to give you Low and High Glucose Alarms. These alarms are on by default.
This section explains how to set and use alarms as well as how to turn them off.

IMPORTANT: Glucose alarms are an important safety feature for some people. For example, those that have impaired awareness of hypoglycemia or a history of severe hypoglycemia. Before you turn alarms off or change their settings, please consult your health care professional.

Please read all the information in this section before setting and using alarms.

CAUTION:

- For you to receive alarms, they must be on and your Reader should be within 20 feet of you at all times. The transmission range is 20 feet unobstructed. If you are out of range, you may not receive glucose alarms.
- To prevent missed alarms, make sure the Reader has sufficient charge and that sound and/or vibration are turned on.

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IMPORTANT: What to know about glucose alarms

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

IMPORTANT: How to prevent missed alarms

- Alarms must be kept on for you to receive them and you should ensure that your Reader is within 20 feet of you at all times. The Sensor itself will not issue alarms.
- **If the Sensor is not communicating with the Reader, you will not receive glucose alarms, and you may miss detecting low glucose or high glucose episodes**. You will see the symbol on the Home screen when the Sensor is not communicating with the Reader. Make sure the Signal Loss Alarm is on so you will be notified if your Sensor has not communicated with the Reader for 20 minutes.
- Make sure the Reader's sound and/or vibration settings are on and your Reader is near you. The Home screen indicates the sound/vibration setting when any alarm is on:

  Sound and Vibration **ON**

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

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

  Sound and Vibration **OFF**

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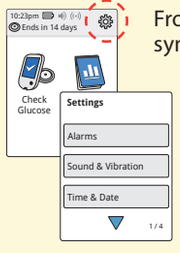
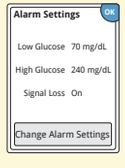
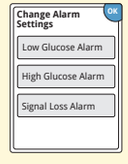
Setting Alarms

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

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

Step	Action
3	 Select the alarm you want to set or turn off. **CAUTION:** If alarms are turned off, you will not get a notification when you have low glucose or high glucose. Low Glucose Alarm: Notifies you when your glucose is below the level you set. High Glucose Alarm: Notifies you when your glucose is above the level you set. Signal Loss Alarm: Notifies you when your Sensor is not communicating with the Reader and that you will not receive Low or High Glucose Alarms.

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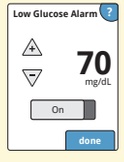
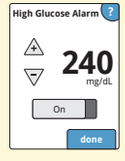
Alarm	How to Set
Low Glucose Alarm	The Low Glucose Alarm is on by default. The alarm level is initially set to 70 mg/dL. You can use the arrows to change this value between 60 mg/dL and 100 mg/dL. If the alarm is on, you will be notified when your glucose falls below the level you set. Touch the slider to turn the alarm off.  Touch **done** to save.

Alarm	How to Set
High Glucose Alarm	The High Glucose Alarm is on by default. The alarm level is initially set to 240 mg/dL. You can use the arrows to change this value between 120 mg/dL and 400 mg/dL. If the alarm is on, you will be notified when your glucose rises above the level you set. Touch the slider to turn the alarm off.  Touch **done** to save.
Signal Loss Alarm	If the alarm is on, you will be notified when your Sensor has not communicated with your Reader for 20 minutes and you are not receiving Low or High Glucose Alarms. Touch the slider to turn the alarm off. Touch **done** to save.

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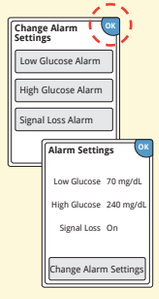
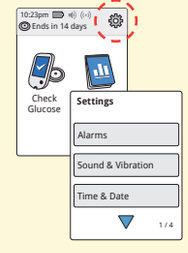
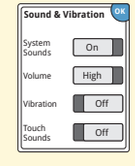
Step	Action
4	 When you are finished setting your alarms, touch **OK**. The Alarms Settings screen now shows your current alarm settings. Touch **OK** to return to the main settings menu, or touch **Change Alarm Settings** to make additional updates.

Setting Alarm Sounds

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

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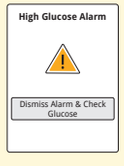
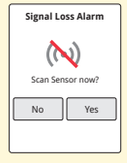
Using Alarms

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

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

Notes:

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

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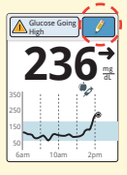
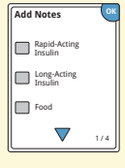
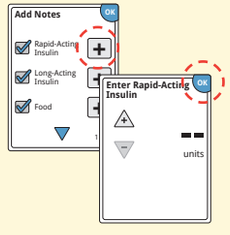
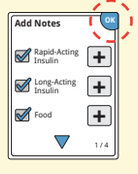
Adding Notes

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

Step	Action
3	 After you check 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 serving 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.

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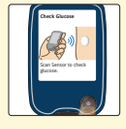
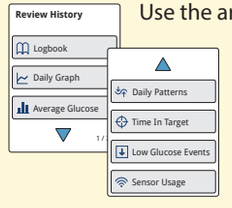
Reviewing Your History

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

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

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

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

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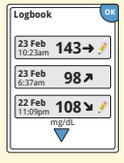
The Logbook and Daily Graph show detailed information, while other history options show summaries of information over a number of days.

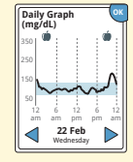
Logbook



Entries for each time you scanned your Sensor or performed a blood glucose 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:

- While Sensor glucose readings are gathered in the System range of 40-400 mg/dL, the Daily Graph display range is 0-350 mg/dL for ease of review on screen. Glucose readings above 350 mg/dL are displayed at 350 mg/dL. For sequential readings above 350 mg/dL, a line is displayed at 350 mg/dL.
- 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.

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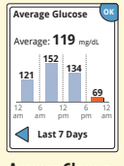
Other History Options

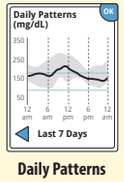
Use the arrows to view information about your last 7, 14, 30, or 90 days.



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.

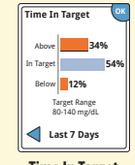
Readings above or below your Target Glucose Range are orange, while readings in range are blue.



Daily Patterns

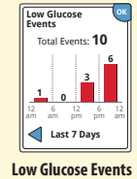
A graph showing the pattern and variability of your Sensor glucose over a typical day. The thick black line shows the median (midpoint) of your glucose readings. The gray shading represents a range (10-90 percentiles) of your Sensor readings.

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



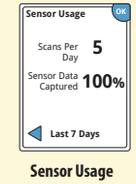
Time In Target

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 70 mg/dL for 15 minutes or longer. The total number of events is displayed above the graph. The bar graph displays the low glucose events in four different 6-hour periods of the day.



Sensor Usage

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

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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 following directions from your health care professional. 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 it ended, you will be prompted to confirm that you would like to start a new Sensor when you first scan it.

Replacing Your Sensor

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

CAUTION: If the Sensor is becoming loose or if the Sensor tip is coming out of your skin, you may get no readings or unreliable readings, which may not match how you feel. Check to make sure your Sensor has not come loose. If it has come loose, remove it, apply a new one, and contact Customer Service. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Standard Time.

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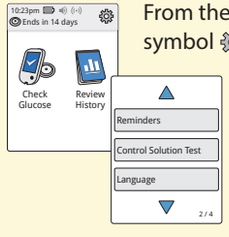
Using Reminders

You can use Reminders to help you remember things like checking your glucose or taking insulin. You can also set a reminder to remind you to check your alarm settings if you have disabled your alarms temporarily.

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

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

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

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

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Using the Reader's Built-in Meter

The Reader has a built-in meter that can be used to test your blood glucose, 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 due to the potential risk of electrical shock.

Intended Use

The FreeStyle Libre 2 Reader's built-in meter is for use outside the body only (*in vitro* diagnostic use) in the quantitative measurement of glucose in fresh whole blood for self testing by lay users from the fingers. It is not intended to be used for testing neonatal blood samples or for the diagnosis or screening of diabetes.

The FreeStyle Libre 2 Reader's built-in meter is indicated for the home (lay) user in the management of patients with diabetes. It is intended to be used by a single person and should not be shared.

The FreeStyle Precision Neo Blood Glucose Test Strips are for use with the FreeStyle Libre 2 Reader's built-in meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

IMPORTANT:

- Use only FreeStyle Precision Neo test strips. Other test strips may produce inaccurate results.
- Read all the instructions in this section. Failure to follow instructions may cause incorrect blood glucose results. Practice the testing procedures before using the Reader's built-in meter.
- Read the test strip instructions for use before performing your first blood glucose test as they contain important information. They also let you know how to store and handle the test strips and give you information about sample types.
- The Reader's built-in meter is not for use on people who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.
- The Reader's built-in meter is not for use on neonates, in critically-ill patients, or for diagnosis or screening of diabetes.
- Follow your health care professional's advice when testing blood glucose levels.
- Severe dehydration (excessive water loss) may cause false low test strip results. If you believe you are suffering from dehydration, consult your health care professional right away.

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IMPORTANT: ***(cont.)***

- Inaccurate test strip results may occur in severely hypotensive individuals or patients in shock.
- Inaccurate test strip results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.
- Observe caution when using around children. Small parts may constitute a choking hazard.
- You should clean and disinfect the Reader once per week. The Reader should also be cleaned and disinfected prior to being handled by any person providing testing assistance to the user.
- 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 and disinfection procedure.[1, 2]
- Use the Reader's built-in meter within the test strip operating temperature range (59˚F – 104˚F) or you will see Error Message E-1.
- Use a test strip immediately after removing from its foil packet.
- Only use a test strip once.

IMPORTANT: ***(cont.)***

- Do not put urine on the test strip.
- Do not use expired test strips as they may cause inaccurate results.
- Do not use at altitudes higher than 10,000 feet above sea level.
- 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.
- This device is not intended for use with multiple patients in health care or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

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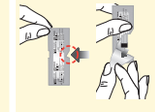
Blood Glucose Testing

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

Step	Action
1	**CAUTION:** Test on your fingers in accordance with the Intended Use in this section. Wash your hands with warm soapy water for accurate results. Thoroughly dry your hands. To warm the site, apply a warm dry pad or rub vigorously for a few seconds. **Note:** Do not use lotion or cream on the test site. Avoid moles, veins, bones, and tendons. Bruising may occur at the test site. If you get a bruise, consider selecting another site.

Step	Action
2	Check the test strip expiration date. Do not use expired test strips as they may give inaccurate results.
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. **Note:** The Reader's built-in meter turns off after 2 minutes of inactivity.

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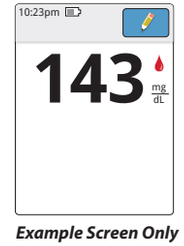
Step	Action
5	Use your lancing device to obtain a blood drop and apply blood to the white area at the end of the test strip. Refer to your lancing device instructions for use if you need help using your lancing device. If sounds are turned on, the Reader beeps once to let you know you have applied enough blood. You will see a butterfly on the screen while you wait for your result. Do not remove the test strip while the butterfly is on the screen. If sounds are turned on, the Reader beeps once when your result is ready. If the butterfly does not appear, you may not have applied enough blood to the test strip. Apply a second drop of blood to the test strip within 5 seconds of the first drop. If the butterfly still does not appear or if more than 5 seconds have passed, discard the test strip. Turn off the Reader and repeat the steps in this section with a new test strip.

Step	Action
5 *(cont.)*	**Note:** • **E-3** means the blood drop is too small, or incorrect test procedure, or there may be a problem with the test strip. • **E-4** means the blood glucose level may be too high to be read by the system or there may be a problem with the test strip. See *Troubleshooting* section for more information.
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 with soap and water and thoroughly dry them.



Example Screen Only

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.

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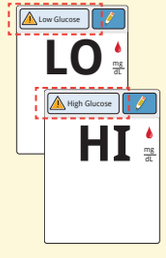
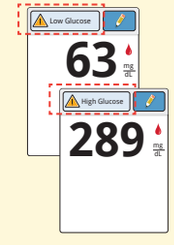
IMPORTANT: The built-in meter displays results from 20 - 500 mg/dL. Low or high blood glucose results can indicate a potentially serious medical condition.

The normal glucose level for a non-diabetic adult is below 100 mg/dL when fasting, and less than 140 mg/dL within two hours of a meal.[3] Consult your health care professional to determine the range that is appropriate for you.

Display	What To Do
	If **LO** appears on the Reader, your result is lower than 20 mg/dL. If **HI** appears on the Reader, your result is higher than 500 mg/dL. 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**.

Display	What To Do
	If your glucose is higher than 240 mg/dL or lower than 70 mg/dL, 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.

IMPORTANT: You should clean and disinfect your Reader once per week. Refer to the *Maintenance and Disposal* section for instructions.

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Accuracy of the Reader's built-in meter

Results from the Reader's built-in meter may vary slightly from your actual blood glucose value. This may be due to slight differences in technique and natural variation in test technology. The table below shows the results of a study where 119 typical users used the built-in meter to check their blood glucose level. For example, in the study, the built-in meter gave results within 15% of true blood glucose level 115 out of 119 times.

Accuracy results for all glucose concentrations

Difference range between the true blood glucose level and the built-in meter result	Within ± 5 mg/dL and 5%	Within ± 10 mg/dL and 10%	Within ± 15 mg/dL and 15%	Within ± 15 mg/dL and 20%
The number and percent that match true blood glucose level within X%	68/119 (57.1%)	105/119 (88.2%)	115/119 (96.6%)	116/119 (97.5%)

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's built-in meter and test strips are working properly.

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 expiration date. Discard control solution 3 months after opening or on the expiration date printed on the bottle, whichever comes first. (Example: open April 15, discard July 15; write the discard date on the side of the bottle.).
- The control solution range is a target range for control solution only, not for your blood glucose results.
- The control solution test does not reflect your blood glucose level.
- Use only MediSense (low, medium or high) Glucose and Ketone Control Solution with the Reader's built-in meter.
- 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 your FreeStyle Libre 2 System provider (pharmacy or mail order supplier) for how to obtain control solution.

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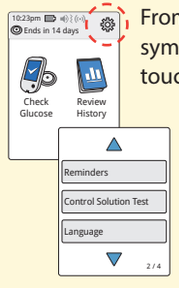
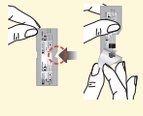
Step	Action
1	 From the Home Screen, touch the Settings symbol ⚙. Scroll down using the arrow and touch **Control Solution Test**.
2	Check the test strip expiration date.
3	 Open the foil test strip packet at the notch and tear down to remove the test strip.

Step	Action
4	Insert the test strip with the three black lines facing up. Push the strip until it stops. **Note:** The Reader's built-in meter turns off after 2 minutes of inactivity.
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.

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Step	Action
5 ***(cont.)***	You will see a butterfly on the screen while you wait for the result. Do not remove the test strip while the butterfly is on the screen. If sounds are turned on, the Reader beeps once when the result is ready. If the butterfly does not appear, you may not have applied enough control solution to the test strip. Apply a second drop of control solution to the test strip within 5 seconds of the first drop. If the butterfly still does not appear or if more than 5 seconds have passed, discard the test strip. Turn off the Reader and repeat the steps in this section with a new test strip.

Example Screen Only

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.

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. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Standard Time.

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Charging the Reader

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

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.

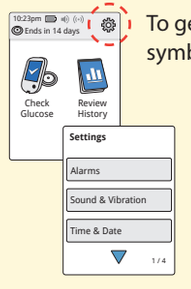
CAUTION: Be sure to select a location for charging that allows the power adapter to be easily unplugged. Don't block access to the charger due to the potential risk of electrical shock.

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 alarm settings, sound & vibration, time & date, and target range. 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.

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

Step	Action
2 ***(cont.)***	• View Event Logs: A list of events recorded by the Reader, which may be used by Customer Service to help troubleshoot your System • Perform a Reader Test: The Reader Test will perform internal diagnostics and allow you to check that the Display is showing all pixels, sounds and vibrations are working, and the Touchscreen is responding when touched **Report Settings** – Work with your health care professional to set your Target Glucose Range, which is displayed on glucose graphs on the Reader and used to calculate your Time In Target. Your Target Glucose Range is not related to your alarm settings **Reader Basics** – Review the information screens shown during the Reader setup **Dose Increment** – You can set the insulin dose increment to either 1.0 or 0.5 units for use with insulin notes

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Living With Your System

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

Activity	What You Need To Know
Bathing, Showering, and Swimming	The Reader is not water-resistant and should NEVER be submerged in water or other liquid. Your Sensor is water-resistant and can be worn while bathing, showering, or swimming. **Note:** Do NOT take your Sensor deeper than 3 feet (1 meter) or immerse it longer than 30 minutes in water.
Sleeping	Your Sensor should not interfere with your sleep. It is recommended that you scan your Sensor before going to sleep and when you wake up because your Sensor holds only 8 hours of data at a time. For example, if you sleep for 9 hours without scanning your Sensor, 1 hour of data will not be collected and a gap will appear on your glucose graph. If you want to receive alarms or reminders while you are sleeping, place the Reader nearby. You should also make sure sound and/or vibration is turned on.

Activity	What You Need To Know
Traveling by Air	You may use your System while on an aircraft, following any requests from the flight crew. • The Reader is classed as a Medical-Portable Electronic Device (M-PED) that meets all required M-PED emission standards for safe use onboard an aircraft: RTCA/DO160, Section 21, Category M. • Some airport full-body scanners include x-ray or millimeter radio-wave, which you cannot expose your System to. The effect of these scanners has not been evaluated and the exposure may damage the System or cause inaccurate results. To avoid removing your System, you may request another type of screening. If you do choose to go through a full-body scanner, you must remove your Sensor.

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Activity	What You Need To Know
Traveling by Air ***(cont.)***	• The System can be exposed to common electrostatic (ESD) and electromagnetic interference (EMI), including airport metal detectors. You can keep your Reader on while going through these. **Note:** If you are changing time zones, you can change the time and date settings on the Reader by touching the Settings symbol ⚙ from the Home Screen, then **Time & Date**. Changing the time and date affects the graphs and statistics. 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 and Disinfecting the Reader

Cleaning and disinfecting your Reader is important to prevent the spread of infectious diseases. The Reader has a mean use life of 3 years and has been validated for 156 cleaning and disinfection cycles (the equivalent of 1 cycle per week for 3 years).

You should clean and disinfect the Reader once a week. The Reader should also be cleaned and disinfected prior to being handled by any person providing testing assistance to the user.

Cleaning is the physical removal of organic soil from the Reader surfaces. Keeping the Reader clean helps ensure that it is working properly and that no dirt gets in the device. Cleaning allows for successful, subsequent disinfection.

Disinfection is a process that destroys pathogens, such as viruses and other microorganisms, on the Reader surfaces. Disinfecting the Reader helps ensure that no infection is passed on when you or others come in contact with the Reader.

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This device is not intended for use with multiple patients in health care or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures.

Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

To clean and disinfect your Reader, you will need Clorox Healthcare Bleach Germicidal Wipes, EPA Reg. #67619-12.

These disinfectant wipes contain a 0.55% Sodium Hypochlorite (NaOCl) solution and have been shown to be safe for use with the Reader. They may be purchased at major online retailers, such as Walmart.com, Amazon.com, and OfficeDepot.com.

Note: Additional information about the risks for transmitting bloodborne pathogens to persons undergoing fingerstick procedures for blood sampling can be found. See *References* section for more information.

Step	Action
1	Turn off the Reader before you clean and disinfect it.
2	Clean the outside surfaces of the Reader with a bleach wipe until visibly clean. Make sure liquid does not get into the test strip and USB ports.

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Step	Action
3	For disinfection, use a second bleach wipe to wipe all outside surfaces of the Reader until they are wet. Make sure liquid does not get into the test strip and USB ports. Allow the Reader surfaces to remain wet for 60 seconds.
4	Dry with clean paper towel to remove any residual moisture.
5	When finished, thoroughly wash your hands with soap and water.

IMPORTANT: If you require assistance or if you notice any signs of deterioration on the Reader (such as clouding or crazing on the display of the Reader, corroding or eroding of the plastic housing, or cracking of plastic housing or display) or if the Reader does not turn on, discontinue use of the Reader and contact Customer Service at 1-855-632-8658. Customer Service is available 7 Days a Week from 8AM to 8PM Eastern Standard Time.

CAUTION: Do NOT place the Reader in water or other liquids. Avoid getting dust, dirt, blood, control solution, water, bleach, or any other substance in the test strip or USB ports as this may cause the Reader to not function properly.

Maintenance
The System has no serviceable parts.

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

Contact Customer Service for further information on the appropriate disposal of system components. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Standard Time.

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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 50 °F and 113 °F and then try to power it on.

If the Reader still does not power on after trying these steps, contact Customer Service. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Standard Time.

Problems at the Sensor Application Site

Problem	What It May Mean	What To Do
The Sensor is not sticking to your skin.	The site is not free of dirt, oil, hair, or sweat.	1. Remove the Sensor. 2. Clean the site with a plain soap and water and then clean with an alcohol wipe. 3. Follow the instructions in *Applying and Starting Your Sensor* sections. Consider shaving the site, avoiding use of lotions prior to insertion, and applying the Sensor to your non-dominant arm.
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.

Customer Service: 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Standard Time.

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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 1.5 inches (4 cm) 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
Signal Loss Alarm	Sensor has not automatically communicated with the Reader in the last 20 minutes.	Make sure the Reader is within 20 feet of the Sensor. Try scanning the Sensor to get a glucose reading. If the Signal Loss Alarm shows again after scanning your Sensor, contact Customer Service.
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.

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Display	What It May Mean	What To Do
Sensor Error	The System is unable to provide a glucose reading.	Scan again after the duration specified in the message. **Note:** If you receive this error during your first 12 hours of wearing a Sensor, it may mean that your body is still adjusting to the Sensor. Use a blood glucose meter to check your glucose while you wait. You do not need to remove your Sensor.
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.

Display	What It May Mean	What To Do
Sensor Already in Use	The Sensor was started by another device.	Your Reader can only be used with a Sensor that it started. Scan the Sensor again with the device that started it. Or, apply and start a new Sensor.
Check Sensor	The Sensor tip may not be under your skin.	Try to start your Sensor again. If Reader displays “Check Sensor” again, your Sensor was not applied properly. Apply and start a new Sensor.
Replace Sensor	The System has detected a problem with your Sensor.	Apply and start a new Sensor.

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Problems Receiving Glucose Alarms

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

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

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Blood Glucose Error Messages

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

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

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

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

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Problems Checking Your Blood Glucose

Problem	What It May Mean	What To Do
The Reader does not start a test after inserting a test strip.	Test strip is not inserted correctly or not inserted fully into the strip port.	1. With the 3 black lines facing up, insert the test strip into the strip port until it stops. 2. If the Reader still does not start a test, contact Customer Service.
	Reader battery is too low.	Charge the Reader.
	The test strip is damaged, used, or unrecognizable by the Reader.	Insert a new FreeStyle Precision Neo test strip.
	Reader is outside of its operating temperature range.	Move the Reader to a temperature between 50 °F and 113 °F and then try to power it on.

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

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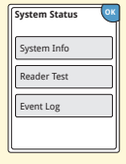
Perform a Reader Test



If you think the Reader is not working properly, you can check the Reader by performing a Reader Test.

Touch the Settings symbol from the Home Screen, select **System Status** and then select **Reader Test**.

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

Customer Service

Customer Service is available to answer any questions you may have about your System. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Standard Time.

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	40 to 400 mg/dL
Sensor size	5 mm height and 35 mm diameter
Sensor weight	5 grams
Sensor power source	One silver oxide battery
Sensor data	Up to 14 days

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Sensor memory	8 hours (glucose readings stored every 15 minutes)
Sensor transmission range	20 feet (6 meters) unobstructed
Operating temperature	50 °F to 113 °F
Sensor Applicator and Sensor Pack storage temperature	36 °F to 82 °F
Operating and storage relative humidity	10-90%, non-condensing
Sensor water resistance and ingress protection	IP27: Can withstand immersion into 3 ft (one meter) of water for up to 30 minutes. Protected against insertion of objects > 12 mm diameter.
Operating and storage altitude	-1,250 ft (-381 meters) to 10,000 ft (3,048 meters)
Radio Frequency	2.402-2.480 GHz BLE; GFSK; 0dBm EIRP*

Reader Specifications

Blood glucose assay range	20 to 500 mg/dL
Reader size	95 mm x 60 mm x 16 mm
Reader weight	65 grams
Reader power source	One lithium-ion rechargeable battery
Reader battery life	4 days of typical use
Reader memory	90 days of typical use
Reader operating temperature	50 °F to 113 °F
Reader storage temperature	-4 °F to 140 °F
Operating and storage relative humidity	10-90%, non-condensing

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Reader moisture protection	Keep dry
Operating and storage altitude	-1,250 ft (-381 meters) to 10,000 ft (3,048 meters)
Reader display timeout	60 seconds (120 seconds when test strip is inserted)
Radio Frequency	Near Field Communication (13.56 MHz RFID); ASK Modulation; 124 dBuV/m; 1.5 inch communication range 2.402-2.480 GHz BLE; GFSK; 2dBm EIRP*
Data port	Micro USB
Minimum Computer Requirements	System must only be used with EN60950-1 rated computers
Mean use life	3 years of typical use
Reader cleaning and disinfection	The Reader has a mean use life of 3 years, which is 156 cleaning and disinfection cycles (1 cycle per week for 3 years).

Power Adapter	Abbott Diabetes Care PRT25611 Operating temperature: 50 °F to 104 °F
USB Cable	Abbott Diabetes Care PRT21373 Length: 37 inches (94 cm)

* Security measures: The communication between the Reader and Sensor during a scan is a short range Near Field Communication (NFC) method which makes it difficult to interfere with or intercept during transmission. The transmitted data is protected by a proprietary data format, encryption, and memory map. The integrity of transmitted data is ensured by a cyclic redundancy check (CRC) generated by the Sensor and verified by the Reader. The communication between the Reader and Sensor for Alarm data is a standard Bluetooth Low Energy (BLE) connection. The pairing of the Sensor to the Reader is accomplished during activation with an authenticated login procedure that uses an Out-of-band key exchange (NFC). This prevents unauthorized devices from connecting to the Sensor. The transmitted data is protected by a proprietary data format and encryption. This prevents unauthorized devices from accessing the data if they are within range and intercept the transmission. Under normal operation, the industry standard BLE protocols allow for many users to be in the same vicinity. In the case where the connection is lost due to out-of-range or interference, reconnection is only possible with the authenticated Reader that activated the Sensor.

Quality of Service (QoS): QoS for the FreeStyle Libre 2 Reader and Sensor wireless communications using NFC is assured within the effective range of 4 cm between the Sensor and Reader that is specified to occur within 15 seconds. QoS for the wireless communication using BLE is assured between the Reader and Sensor at regular 1-minute intervals. If connection is lost between the Reader and Sensor for 5-minutes, the connection lost symbol displays. If connection is lost for

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20 minutes, the Reader alarms the user if the alarm is turned on. If connection is lost between the Sensor and the Reader, up to 8 hours of glucose results can be retrieved by performing a scan with the Reader. The Reader is designed to only accept radio frequency (RF) communications from recognized and paired Sensors.

Labeling Symbols

	Consult instructions for use		Use-by date
	Temperature limit	REF	Catalog number
	Manufacturer	SN	Serial number
LOT	Batch code		Keep dry
	Type BF applied part		Non-ionizing radiation
CODE	Sensor code		Caution
	Do not re-use	STERILE R	Sterilized using irradiation
MR	MR unsafe		Humidity limitation
FC	FCC Declaration of Conformity mark		Do not use if package is damaged

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LATEX	Not made with natural rubber latex
Rx Only	**CAUTION:** Federal law restricts this device to sale by or on the order of a physician.
	This product contains electronic equipment, batteries, sharps and materials that may contact bodily fluids during use. Dispose of product in accordance with all applicable local regulations.

Performance Characteristics

Overview of Clinical Studies

Two studies were conducted in the United States (US) to evaluate the performance, safety, effectiveness, and precision of the FreeStyle Libre 2 Flash Glucose Monitoring System (System). One study included adults (Adult study) and the other study included children (Pediatric study). All subjects in both studies required insulin to manage their diabetes. To measure the precision of the System, each subject wore two Sensors, one on the back of each upper arm, for a period of up to 14 days. While in the clinic, subjects had their venous blood glucose analyzed using a laboratory reference method, the Yellow Springs Instrument Life Sciences 2300 STAT Plus™ Glucose & Lactate Analyzer (YSI). Sensor glucose readings were then compared to the YSI glucose results in subjects 6 years and older to evaluate the System's performance. In the pediatric study, System performance was compared against a self-monitoring blood glucose meter for subjects 4-5 years old.

Adult study: The Adult study was conducted at 5 centers with 146 subjects in total (91.1% Type 1, 8.9% Type 2), all aged eighteen and older. Subjects had their venous blood glucose analyzed over three separate visits to the clinical center. Each visit lasted up to ten hours. 144 subjects were analyzed during the beginning of the Sensor wear period (day 1, 2, or 3), 91 subjects were analyzed during the early middle period (day 7 or 8), 55 subjects were analyzed during the late middle period (day 9 or 12), and 76 subjects were analyzed during the end period (day 13 or 14). During each visit, adult subjects had their glucose levels deliberately manipulated per the study protocol to raise or lower glucose. This was done to assess performance of the System over the range that the System measures glucose (40 – 400 mg/dL).

Pediatric study: The Pediatric study was conducted at 4 centers with 139 subjects in total (98.6% Type 1, 1.4% Type 2), all aged four to seventeen. Subjects age six and older had their venous blood glucose analyzed for up to 16 hours over one or two separate visits to the clinical center. Each visit lasted up to eight hours. During each visit, subjects age 11 and older had their glucose levels deliberately

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manipulated per the study protocol to raise or lower glucose. This was done to assess performance of the System over the range that the System measures glucose (40 – 400 mg/dL). 48 subjects were analyzed during the beginning of the Sensor wear period (day 1 or 2), 50 subjects were analyzed during the early middle period (day 7 or 8), 51 subjects were analyzed during the late middle period (day 9 or 12), and 51 subjects were analyzed during the end period (day 13 or 14). All subjects tested their blood glucose using fingerstick capillary samples at least four times during each day of the study.

Accuracy

Accuracy of the System was measured by comparing paired System Glucose Measurement (CGM) and YSI blood glucose values. The percentage of total System readings that were within 20 mg/dL for YSI blood glucose values < 70 mg/dL or 20% of YSI for blood glucose values ≥ 70 mg/dL is displayed in **Table 1a**. The Mean Absolute Relative Difference (MARD) gives an indication of the average percent disagreement between the CGM and the reference. For example, in the Adult study, 92.4% of the readings fell within ± 20 mg/dL of YSI blood glucose values < 70 mg/dL and within ± 20% of YSI blood glucose values ≥ 70 mg/dL. The total number of data pairs considered in the analysis was 18,735. In the Adult study, the Mean Absolute Relative Difference was 9.2% for the comparison with YSI reference. In the Pediatric study, the Mean Absolute Relative Difference was 9.7% for the comparison with YSI reference.

Table 1a: Overall Accuracy to YSI

Subject Group	Number of CGM-Reference Pairs	Number of Subjects	Percent Within ±20% / ±20 mg/dL	Percent Within ±20% / ±20 mg/dL on Day 1	Percent Within ±20% / ±20 mg/dL in first 12 hours	MARD (%)
Adults	18735	144	92.4	87.5	81.7	9.2
Children (age 6-17)	6546	129	91.6	84.1	80.3	9.7
Children (age 4-5)*	341	8	85.9	87.9	90.9	11.8

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

The accuracy of different CGM glucose ranges versus YSI reference was assessed by calculating the percentage of System readings that were within 15%, 20%, and 40% for reference values ≥ 70 mg/dL, and within 15 mg/dL, 20 mg/dL, and 40 mg/dL for values < 70 mg/dL. For blood glucose values < 70 mg/dL, the difference in mg/dL between the CGM and YSI blood glucose values was calculated. For values ≥ 70 mg/dL, the relative difference (%) to the YSI blood glucose values was calculated. The results categorized within CGM glucose ranges are presented in **Tables 1b and 1c**. The results categorized within YSI glucose ranges are presented in **Tables 1d and 1e**.

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

CGM Glucose Level † (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mg/dL)	MARD (%)
<54	518	85.9	93.8	99.4				-6.4	13.8
54-69	3012	89.5	94.2	99.1				-3.3	10.8
70-180	7785				76.5	86.6	99.2	-4.8	10.6
181-250	3037				89.1	95.0	99.9	-10.1	7.8
>250	4383				94.0	97.9	100.0	-6.3	6.1

† System range is 40-400 mg/dL.

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

CGM Glucose Level † (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mg/dL)	MARD (%)
<54	139	71.9	79.1	97.1				-9.9	17.1
54-69	863	86.4	90.5	97.1				-4.9	12.0
70-180	2690				77.4	87.6	98.7	-3.4	10.6
181-250	1236				86.0	94.7	99.7	-8.9	8.3
>250	1618				92.2	97.7	99.8	-2.2	7.2

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

† System range is 40-400 mg/dL.

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

YSI Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mg/dL)	MARD (%)
<54	440	91.1	97.5	100.0				7.4	15.5
54-69	3028	94.7	98.6	100.0				1.5	10.2
70-180	7504				77.5	86.9	99.4	-4.8	10.4
181-250	2937				87.9	93.7	99.7	-8.0	8.0
>250	4826				90.9	95.9	99.7	-11.8	6.9

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

YSI Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mg/dL)	MARD (%)
<54	131	93.9	98.5	100.0				6.6	14.2
54-69	751	96.5	98.8	100.0				1.0	9.3
70-180	2743				74.3	84.8	98.0	-3.0	11.4
181-250	1104				86.6	92.9	99.0	-3.9	8.4
>250	1817				90.2	97.5	99.9	-10.2	7.6

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

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

The System reports glucose concentrations between 40 and 400 mg/dL. When the System determines that glucose level is below 40 mg/dL, it will report as 'LO'. When the System determines that glucose level is above 400 mg/dL, it will report as 'HI'. **Tables 2a and 2b** display the concurrence between the CGM and YSI reference glucose when CGM reads 'LO'. For example, in the Adult study, when CGM reading was 'LO', YSI glucose values were less than 50 mg/dL 20.0% of the time, less than 60 mg/dL 40.0% of the time, less than 70 mg/dL 40.0% of the time, less than 80 mg/dL 80.0% of the time, and equal to or above 80 mg/dL 20.0 % of the time.

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

CGM-Reference Pairs	YSI (mg/dL)					N
	<50	<60	<70	<80	≥80	
n	1	2	2	4	1	5
Cumulative %	20.0	40.0	40.0	80.0	20.0	

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

CGM-Reference Pairs	YSI (mg/dL)					N
	<50	<60	<70	<80	≥80	
n	0	1	2	2	0	2
Cumulative %	0.0	50.0	100.0	100.0	0.0	

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

Tables 2c and 2d display the concurrence between the CGM and YSI reference glucose when CGM reads 'HI'. In the Adult study, when CGM reading was 'HI', YSI glucose values were above 350 mg/dL 97.5% of the time, above 300 mg/dL 100.0% of the time, above 250 mg/dL 100.0 % of the time, and less than or equal to 250 mg/dL 0.0% of the time.

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

CGM-Reference Pairs	YSI (mg/dL)				N
	>350	>300	>250	≤250	
n	118	121	121	0	121
Cumulative %	97.5	100.0	100.0	0.0	

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

CGM-Reference Pairs	YSI (mg/dL)				N
	>350	>300	>250	≤250	
n	40	43	45	0	45
Cumulative %	88.9	95.6	100.0	0.0	

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Concurrence of System and Reference (CGM vs. YSI)

The percentage of concurring glucose values (CGM vs. YSI) in each glucose reference range is presented for each CGM range in **Tables 3a and 3b** and for each YSI range in **Tables 3c and 3d**. For example, in the Adult study, when the System glucose readings were within the 81 to 120 mg/dL range, actual blood glucose values were between 40 and 60 mg/dL 0.2% of the time, between 61 and 80 mg/dL 11.0% of the time, between 81 and 120 mg/dL 70.1% of the time, between 121 and 160 mg/dL 17.8% of the time, between 161 and 200 mg/dL 0.8% of the time, and between 201 and 250 mg/dL 0.1% of the time.

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

CGM Glucose Level (mg/dL)	YSI Glucose Level (mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40†	20.0	20.0	40.0	20.0	.	.	.	.	.	.	.	5
40-60	0.4	52.9	43.3	3.3	.	0.1	.	.	.	.	.	1889
61-80	.	18.9	62.7	18.1	0.4	0.0	.	.	.	.	.	3090
81-120	.	0.2	11.0	70.1	17.8	0.8	0.1	.	.	.	.	3040
121-160	.	.	0.1	9.1	69.9	18.9	1.6	0.3	0.2	.	.	2407
161-200	.	.	.	.	10.6	60.6	26.9	1.6	0.3	.	.	1745
201-250	.	.	.	.	.	7.0	65.5	25.6	1.9	0.1	.	2181
251-300	.	.	.	.	.	0.1	8.4	66.9	22.7	1.8	0.1	2327
301-350	.	.	.	.	.	.	0.4	13.6	68.8	16.0	1.2	1522
351-400	.	.	.	.	.	.	.	0.6	27.5	63.3	8.6	534
>400†	.	.	.	.	.	.	.	.	2.5	62.8	34.7	121

† Levels out of System dynamic range.

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

CGM Glucose Level (mg/dL)	YSI Glucose Level (mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40†	.	50.0	50.0	.	.	.	.	.	.	.	.	2
40-60	0.6	48.6	42.5	7.8	0.6	.	.	.	.	.	.	527
61-80	.	12.1	61.9	24.3	1.7	.	.	.	.	.	.	915
81-120	.	0.2	11.2	69.0	18.2	1.3	0.1	.	.	.	.	1006
121-160	.	.	.	11.4	71.0	15.8	1.8	.	.	.	.	868
161-200	.	.	.	0.1	18.2	61.3	20.1	0.3	.	.	.	703
201-250	.	.	.	.	0.2	9.6	55.3	33.6	1.2	0.1	.	909
251-300	.	.	.	.	.	0.1	14.1	60.8	23.7	1.3	.	818
301-350	.	.	.	.	.	.	0.3	24.8	58.2	16.5	0.2	593
351-400	.	.	.	.	.	1.0	.	0.5	33.8	59.4	5.3	207
>400†	.	.	.	.	.	.	.	4.4	6.7	33.3	55.6	45

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

† Levels out of System dynamic range.

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

YSI Glucose Level (mg/dL)	CGM Glucose Level (mg/dL)											N
	<40†	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400†	
<40	12.5	87.5	.	.	.	.	.	.	.	.	.	8
40-60	0.1	62.9	36.6	0.4	.	.	.	.	.	.	.	1591
61-80	0.1	26.4	62.6	10.8	0.1	.	.	.	.	.	.	3093
81-120	0.0	2.1	18.8	71.7	7.3	.	.	.	.	.	.	2971
121-160	.	.	0.5	22.3	69.6	7.7	.	.	.	.	.	2418
161-200	.	0.1	0.1	1.5	26.9	62.5	9.0	0.1	.	.	.	1694
201-250	.	.	.	0.1	1.8	21.9	66.8	9.1	0.3	.	.	2139
251-300	.	.	.	.	0.3	1.2	23.7	66.0	8.8	0.1	.	2359
301-350	.	.	.	.	0.3	0.3	2.3	29.8	58.9	8.3	0.2	1777
351-400	.	.	.	.	.	.	0.3	6.1	34.7	48.1	10.8	703
>400	.	.	.	.	.	.	.	1.9	16.7	42.6	38.9	108

† Levels out of System dynamic range.

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

YSI Glucose Level (mg/dL)	CGM Glucose Level (mg/dL)											N
	<40†	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400†	
<40	.	100.0	.	.	.	.	.	.	.	.	.	3
40-60	0.3	69.2	30.0	0.5	.	.	.	.	.	.	.	370
61-80	0.1	24.8	62.6	12.5	.	.	.	.	.	.	.	904
81-120	.	3.9	21.0	65.7	9.4	0.1	.	.	.	.	.	1057
121-160	.	0.3	1.7	19.3	65.0	13.5	0.2	.	.	.	.	948
161-200	.	.	.	1.9	20.4	64.2	13.0	0.1	.	0.3	.	671
201-250	.	.	.	0.1	2.1	18.1	64.7	14.8	0.3	.	.	778
251-300	.	.	.	.	.	0.2	32.0	52.1	15.4	0.1	0.2	954
301-350	.	.	.	.	.	.	1.8	31.1	55.4	11.2	0.5	623
351-400	.	.	.	.	.	.	0.4	4.4	39.5	49.6	6.0	248
>400	.	.	.	.	.	.	.	.	2.7	29.7	67.6	37

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

† Levels out of System dynamic range.

Glucose Rate of Change Accuracy

The System's glucose rate of change accuracy, as assessed by concurrence analysis, is presented in **Tables 4a and 4b**. For example, in the Adult study, when the Sensor glucose trend arrow indicated that glucose was changing slowly downward (-1 to 0 mg/dL/min (→)), actual glucose levels in the body were falling quickly (<-2 mg/dL/min) 1.2% of the time, falling (-2 to -1 mg/dL/min) 8.3% of the time, changing slowly downward (-1 to 0 mg/dL/min) 67.1% of the time, changing slowly upward (0 to 1 mg/dL/min) 19.7% of the time, rising (1 to 2 mg/dL/min) 2.6% of the time, and were rising quickly (>2 mg/dL/min) 1.2% of the time. Digitally connected systems which do not utilize the System's trend arrow calculations may see different glucose rate of change accuracy.

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

CGM (mg/dL/min)	YSI (mg/dL/min)						N
	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2 (↓)	34.4	44.9	18.3	2.2	0.3	.	323
-2 to -1 (↘)	6.8	46.5	41.2	4.0	0.9	0.6	1090
-1 to 0 (→)	1.2	8.3	67.1	19.7	2.6	1.2	9389
0 to 1 (→)	0.9	3.4	26.0	46.9	15.5	7.3	5420
1 to 2 (↗)	0.1	1.7	7.7	31.6	38.4	20.5	1151
>2 (↑)	0.1	0.2	3.1	14.6	32.9	49.0	881

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

CGM (mg/dL/min)	YSI (mg/dL/min)						N
	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2 (↓)	44.1	44.7	8.8	2.4	.	.	170
-2 to -1 (↘)	11.4	49.5	32.8	5.2	0.4	0.6	463
-1 to 0 (→)	2.1	11.2	60.0	20.8	3.9	1.9	2587
0 to 1 (→)	1.4	5.6	25.2	43.2	14.8	9.7	2095
1 to 2 (↗)	0.2	2.6	10.4	29.7	35.5	21.5	498
>2 (↑)	.	0.9	4.2	15.0	29.7	50.2	448

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

Alarm Performance

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

Low Glucose Alarm Performance

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

True Alarm Rate

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

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

False Alarm Rate

Tells you: Did you get a low glucose alarm that you shouldn't have?

Definition: Percentage of time the alarm issued and blood glucose was not below the alarm level within 15 minutes before or after the alarm.

Detection Rate

Tells you: When you were low, did you get a low glucose alarm?

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

Missed Detection Rate

Tells you: When you were low, did you miss a low glucose alarm?

Definition: Percentage of time blood glucose was below the alarm level and the alarm didn't issue within 15 minutes before or after the glucose event.

For example, the Adult study found that for a Low Glucose alarm level set to 70 mg/dL:

86.0% of the time a low glucose alarm was received when blood glucose was indeed below the alarm level but 14.0% of the time a low glucose alarm was received when blood glucose wasn't actually below the alarm level.

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

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

Low Glucose Alarm level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
60	9861	72.6	27.4	1527	75.7	24.3
70	21504	86.0	14.0	3652	89.3	10.7
80	32784	91.3	8.7	4753	97.3	2.7
90	41299	93.6	6.4	5591	98.5	1.5

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

Low Glucose Alarm level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate(%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
60	2780	62.9	37.1	373	87.4	12.6
70	6363	80.3	19.7	963	93.5	6.5
80	9747	85.6	14.4	1318	96.4	3.6
90	12550	92.2	7.8	1656	97.3	2.7

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

High Glucose Alarm Performance

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

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

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

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

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

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For example, the Adult study found that for a High Glucose alarm level set to 200 mg/dL:
99.2% of the time a high glucose alarm was received when blood glucose was indeed above the alarm level but 0.8% of the time a high glucose alarm was received when blood glucose wasn't actually above the alarm level.
97.1% of the time blood glucose was above the alarm level and a high glucose alarm was appropriately issued but 2.9% of the time the glucose event was missed and no alarm was issued.

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

High Glucose Alarm level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
120	105544	99.1	0.9	11417	98.2	1.8
140	93574	99.1	0.9	10152	98.1	1.9
180	74290	99.2	0.8	8080	97.8	2.2
200	66039	99.2	0.8	7269	97.1	2.9
220	57549	99.0	1.0	6390	96.9	3.1
240	48733	98.4	1.6	5550	95.6	4.4
300	21512	96.3	3.7	2672	90.0	10.0

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

High Glucose Alarm level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
120	34176	98.8	1.2	4441	98.2	1.8
140	30107	98.0	2.0	3945	98.4	1.6
180	22430	98.4	1.6	3125	98.0	2.0
200	19425	98.0	2.0	2791	98.0	2.0
220	16371	98.2	1.8	2492	96.9	3.1
240	13559	98.0	2.0	2172	95.7	4.3
300	6064	90.8	9.2	962	91.0	9.0

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

Sensor Accuracy Over Time

The Sensor can be worn for up to 14 days. The percentage of System readings within YSI values and the Mean Absolute Relative Difference (MARD) is presented for the following different wear periods in **Tables 6a and 6b**: Beginning (Adult: 144 Subjects, Day 1, 2 or 3; Pediatric: 48 Subjects, Day 1 or 2) Early Middle (Adult: 91 Subjects, Day 7 or 8; Pediatric: 50 Subjects, Day 7 or 8), Late Middle (Adult: 55 Subjects, Day 9 or 12; Pediatric: 51 Subjects, Day 9 or 12), and End (Adult: 76 Subjects, Day 13 or 14; Pediatric: 51 Subjects, Day 13 or 14). For values 70 mg/dL and above, the percentage of readings within 15%, 20%, and 40% of the YSI value was calculated. For values below 70 mg/dL, the percentage of readings within 15 mg/dL, 20 mg/dL, and 40 mg/dL of the YSI value was calculated.

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

Wear Period	Number of CGM-reference pairs	MARD (%)	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±40% / ±40 mg/dL
Beginning	6955	9.9	83.4	90.4	99.3
Early Middle	4522	8.5	87.7	94.5	99.8
Late Middle	3503	8.8	86.8	93.4	99.7
End	3755	9.1	86.4	92.9	100.0

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

Wear Period	Number of CGM-reference pairs	MARD (%)	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±40% / ±40 mg/dL
Beginning	1828	10.7	79.6	88.5	98.6
Early Middle	1642	8.0	89.5	94.2	98.5
Late Middle	1534	9.7	83.6	92.9	99.5
End	1542	10.2	82.6	91.1	99.3

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

Sensor Wear Duration

The Sensor can be worn for up to 14 days. To estimate how long a Sensor will work over the wear duration, 146 Sensors were evaluated in the Adult study and 139 Sensors were evaluated in the Pediatric study to determine how many days of readings each Sensor provided. Subjects did not wash the insertion site with soap and water before applying the Sensors and wore two Sensors simultaneously. Of the 146 Sensors in the Adult study, 71.1% lasted until the final day of use. 6 Sensors (4.1%) had "early sensor shut-off" where the Sensor algorithm detected that the Sensors did not function as intended and presented the user with a Replace Sensor message. In the Pediatric study, 78.1% of the Sensors lasted until the final day of use. 3 Sensors (2.2%) had "early sensor shut-off" where the Sensor algorithm detected that the Sensors did not function as intended and presented the user with a Replace Sensor message. **Tables 7a and 7b** display the data for each day in the wear duration for the Adult & Pediatric studies.

A third clinical study was also conducted to further evaluate wear duration in subjects who first washed the insertion site with a plain soap and water, according to the full instructions in the labeling and wore only a single Sensor. Of the 39 Sensors evaluated in this study, 97% lasted until the final day of use.

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

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

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

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

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Glucose Reading Availability

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

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

Day of Wear	Number of Sensors	Capture Rate (%)
1	146	98.3
2	145	98.1
3	143	98.3
4	140	98.3
5	138	98.4
6	135	98.3
7	134	98.4
8	131	98.4
9	128	98.4
10	123	98.4
11	120	98.4
12	113	98.5
13	112	98.5
14	104	98.6

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

Day of Wear	Number of Sensors	Capture Rate (%)
1	139	94.6
2	137	94.9
3	136	95.2
4	133	95.3
5	134	95.5
6	133	95.6
7	133	96.0
8	133	95.9
9	130	95.7
10	125	95.6
11	125	95.6
12	122	95.8
13	119	95.9
14	116	95.8

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Precision

Precision of the System was evaluated by comparing the results from two separate Sensors worn on the same subject at the same time. **Table 9a** provides data from 146 subjects in the Adult study; **Table 9b** provides data from 137 subjects in the Pediatric study. For adults, the paired absolute relative difference (PARD) between the two Sensors was 8.1% with coefficient of variation (CV) of 5.7%. For children ages 4-5, PARD was 6.7% with CV of 4.8%. For children ages 6-17, PARD was 8.2% with CV of 5.8%. Paired absolute difference (PAD) is a measurement of absolute difference (in mg/dL) between paired CGM readings, while PARD is the absolute relative difference (in %) between paired CGM readings.

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

	Coefficient of Variation (%)	Paired Absolute Difference (mg/dL)	Paired Absolute Relative Difference (%)	Number of Paired Readings
Adults ages 18+	5.7	12.4	8.1	26791

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

	Coefficient of Variation (%)	Paired Absolute Difference (mg/dL)	Paired Absolute Relative Difference (%)	Number of Paired Readings
Children ages 4-5	4.8	10.7	6.7	248
Children ages 6-17	5.8	13.0	8.2	10623

Adverse Events

No device related serious adverse events occurred during the studies. In the Adult study, mild skin irritations, such as erythema, bruising, bleeding, and scabbing were reported around the insertion site and adhesive area by a small number of subjects (10 out of 146 or 6.8%). Pain was mostly reported as none with only one instance of mild pain. In the Pediatric study, there were 8 instances of erythema (4 "well-defined redness", and 4 "slight pink"), 5 instances of edema (3 slight edema, 2 slight edema with defined edges), 2 instances of mild bleeding, one instance of mild induration and one instance of mild rash.

Ascorbic Acid Interference

Taking ascorbic acid (vitamin C) supplements while wearing the Sensor may falsely raise Sensor glucose readings. Taking more than 500 mg of ascorbic acid per day may affect the Sensor readings which could cause you to miss a severe low glucose event. Ascorbic acid can be found in supplements including multivitamins. Some supplements, including cold remedies such as Airborne® and Emergen-C®, may contain high doses of 1000 mg of ascorbic acid and should not be taken while using the Sensor. See your health care professional to understand how long ascorbic acid is active in your body.

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Additional notes for Health Care Professionals

A clinical study was conducted to evaluate the effect of ascorbic acid on Sensor performance. Data from 57 adult subjects with diabetes was collected over a 13-hour period. Each subject had a one-hour baseline phase where venous blood was collected every 10 minutes. After this first hour, a dose of 1000 mg ascorbic acid was given with a meal and venous samples were collected every 20 minutes for the next four hours. A maximum average sensor bias of 9.3 mg/dL was observed around 3 hours after the 1000 mg ascorbic acid dose. Subjects then received a second dose of 1000 mg ascorbic acid with a meal and the same process was continued for another 4 hours. A third dose of 1000 mg ascorbic acid was then given and study subjects were followed for 4 more hours. After the second dose of ascorbic acid the maximum average sensor bias increased, with minimal change in sensor bias after the third dose, suggesting that saturation had occurred by the second 1000 mg dose of ascorbic acid. The maximum average sensor bias after the three 1000 mg doses of ascorbic acid was less than 20 mg/dL.

Electromagnetic Compatibility (EMC)

FreeStyle Libre 2 Reader - FCC ID: QXS-LIB02
FreeStyle Libre 2 Sensor - FCC ID: QXS-LIB02S

- The System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect the System.
- 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.
- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- Changes or modifications not approved by Abbott could void the user's authority to operate the equipment.

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Guidance and manufacturer's declaration – electromagnetic emissions

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

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

Guidance and manufacturer's declaration – electromagnetic immunity

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

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

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

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

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

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

IMMUNITY test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	**Recommended separation distance** $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

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

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

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

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

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For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (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.

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References:

[1] "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

[2] "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

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