User's Manual

FreeStyle Libre 14 day

FLASH GLUCOSE MONITORING SYSTEM

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

Abbott

Your Name _____

Contents

Important Safety Information

Indications For Use

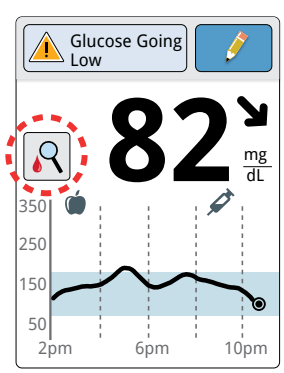
The FreeStyle Libre 14 day Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device indicated for the management of diabetes in persons age 18 and older. It is designed to replace blood glucose testing for diabetes treatment decisions.
The System detects trends and tracks patterns aiding 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 intended for single patient use and requires a prescription.

Contraindications

MRI/CT/Diathermy: The FreeStyle Libre 14 day Flash Glucose Monitoring 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.

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.
- **Check Sensor glucose readings by conducting a fingerstick test with a blood glucose meter under the following conditions, when Sensor glucose readings may not be accurate and should not be used to make a diabetes treatment decision:**
  - If you suspect that your reading may be inaccurate for any reason
  - When you are experiencing symptoms that may be due to low or high blood glucose
  - When you are experiencing symptoms that do not match the Sensor glucose readings
  - During the first 12 hours of wearing a FreeStyle Libre 14 day Sensor
  - During times of rapidly changing glucose (more than 2 mg/dL per minute)
  - When the Sensor glucose reading does not include a Current Glucose number or Glucose Trend Arrow
  - In order to confirm hypoglycemia or impending hypoglycemia as reported by the Sensor
- When you see the symbol, you must check your blood glucose with a blood glucose meter before making any treatment decisions. Sensor readings may not accurately reflect blood glucose levels.



WARNINGS *(cont.)*

- **Hypoglycemic unawareness:** The System has not been evaluated for use in patients with hypoglycemic unawareness and will not automatically alert you of a hypoglycemic event without you scanning your Sensor.
- **No alarms without a Sensor scan:** The System does not have alarms that will automatically notify you when you are having a severe low (hypoglycemic) or high (hyperglycemic) glucose event unless you scan your Sensor. For example, the System does not have an alarm that can alert or wake you when you are sleeping in the case of low or high glucose.
- **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 Alarms/Alerts:

- There are NO alarms or alerts unless you scan the Sensor.

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.

Who should not use the System:

- **Do not use the System in people less than 18 years of age.** The System is not approved for use in people under 18 years of age and Sensor readings in this population may be inaccurate. In general, continuous glucose monitoring systems are recognized to be less accurate in children than in adults.
- **Do not use the System in critically ill patients.** The System is not approved for use in these patients. It is not known how different conditions or medications common to the critically ill population may affect performance of the System. Sensor glucose readings may be inaccurate in critically ill patients.
- **Do not use the System in pregnant women or persons on dialysis.** The System is not approved for use in pregnant women or persons on dialysis and has not been evaluated in these populations.
- Performance of the System when used with other implanted medical devices, such as pacemakers, has not been evaluated.

What should you know about wearing a Sensor:

- The Sensor can be worn for up to 14 days.
- 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. Remove and replace your Sensor if it starts to loosen and follow the instructions to select an appropriate application site.
- The System uses all available glucose data to give you readings so you should scan your Sensor at least once every 8 hours for the most accurate performance. Scanning less frequently may result in decreased performance.
- Do not reuse Sensors. The Sensor and Sensor Applicator are designed for single use. Reuse may result in no glucose readings and infection. Not suitable for re-sterilization. Further exposure to irradiation may cause inaccurate results.
- If a Sensor breaks inside your body, call your health care professional.

How to Store the Sensor Kit:

- Store the Sensor Kit between 39°F and 77°F. Storage outside of this range may cause inaccurate Sensor glucose readings. While you don't need to keep your Sensor Kit in a refrigerator, you can as long as the refrigerator is between 39°F and 77°F. Do not freeze.
- Store the Sensor Kit between 10-90% non-condensing humidity.

How to Store the Reader:

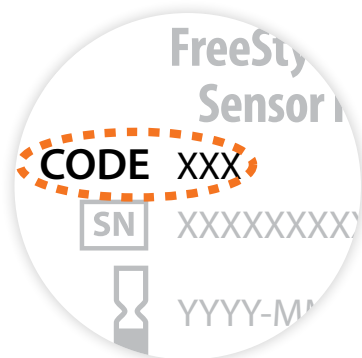
- Store the Reader between -4°F and 140°F. Storage in temperatures outside of this range, such as in a parked car on a hot day, may cause the Reader to not function properly.

When not to use the System:

- Do NOT use if the Sensor 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.



- Clean the application site and ensure that it is dry prior to Sensor insertion. This helps the Sensor stay attached to your body.
- 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.

- Sensor placement is not approved for sites other than the back of the 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 interfering substances such as Vitamin C and Aspirin:

- Taking ascorbic acid (vitamin C) while wearing the Sensor may falsely raise Sensor glucose readings. Taking salicylic acid (used in some pain relievers such as aspirin and some skin care products) may slightly lower Sensor glucose readings. The level of inaccuracy depends on the amount of the interfering substance active in the body.

- Test results did not indicate interference for methyldopa (used in some drugs to treat high blood pressure) or tolbutamide (infrequently used in some drugs to treat diabetes in the US) at maximum circulating levels. However, concentrations of potential interferents in interstitial fluid are unknown compared to circulating blood.

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 and apply a new one.
- If you believe your glucose readings are not correct or are inconsistent with how you feel, perform a blood glucose test on your finger to confirm your glucose. If the problem continues, remove the current Sensor and apply a new one.

What to do if you are dehydrated:

- Severe dehydration and excessive water loss may cause inaccurate Sensor glucose readings. If you believe you are suffering from dehydration, consult your health care professional immediately.

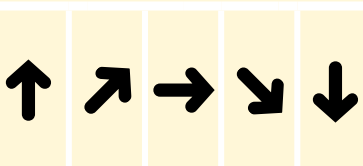
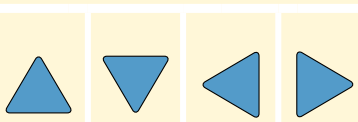
What to know about the Reader's Built-in Meter:

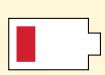
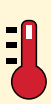
- The FreeStyle Libre 14 day Reader has a built-in blood glucose meter that is designed to be used only with FreeStyle Precision Neo blood glucose test strips and MediSense Glucose and Ketone Control Solution. Using other test strips with the Reader's built-in meter will produce an error or cause the 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.

What to know about charging your Reader:

- Always use the Abbott provided power adapter and yellow USB cable that came with your Reader to minimize the risk of fire or burns. Take care when plugging and unplugging your USB cable. Do not force or bend the end of the USB cable into the Reader's USB port.
- Choose a location for charging where you can easily access the power adapter and quickly disconnect to prevent the potential risk of electrical shock.
- The maximum surface temperature of the Reader and/or the power adapter could go as warm as 120°F when it's charging or 118°F during normal use. Under these conditions, do not hold the Reader or the power adapter for five minutes or more. People with disorders of peripheral circulation or sensation should use caution at this temperature.
- Do NOT expose the USB cable or power adapter to water or other liquids as this may cause them to not function properly and may lead to risk of fire or burns.

Reader Symbols

Symbol	What It Means
	Sensor may be inaccurate. Check blood glucose with a test strip before making any treatment decisions
	Active Sensor
	Direction your glucose is going. See *Checking Your Glucose* section for more information
	Caution
	View previous/next screen
	Notes
	Add more information to notes
	Food note
	Rapid-acting insulin note

Symbol	What It Means
	Time changed on Reader
	Reminders
	Blood glucose test
	Settings
	Control solution test result
	Low battery
	Battery charging
	Sensor too cold
	Sensor too hot

Getting to Know Your System

The FreeStyle Libre 14 day Flash Glucose Monitoring System has two main parts: a handheld Reader and a disposable Sensor that you wear on your body. The Sensor does not need to be calibrated with blood glucose values. You use the Reader to wirelessly scan the Sensor and get your glucose readings. The Reader also has a built-in blood glucose meter, which works with FreeStyle Precision Neo blood glucose test strips.

IMPORTANT:

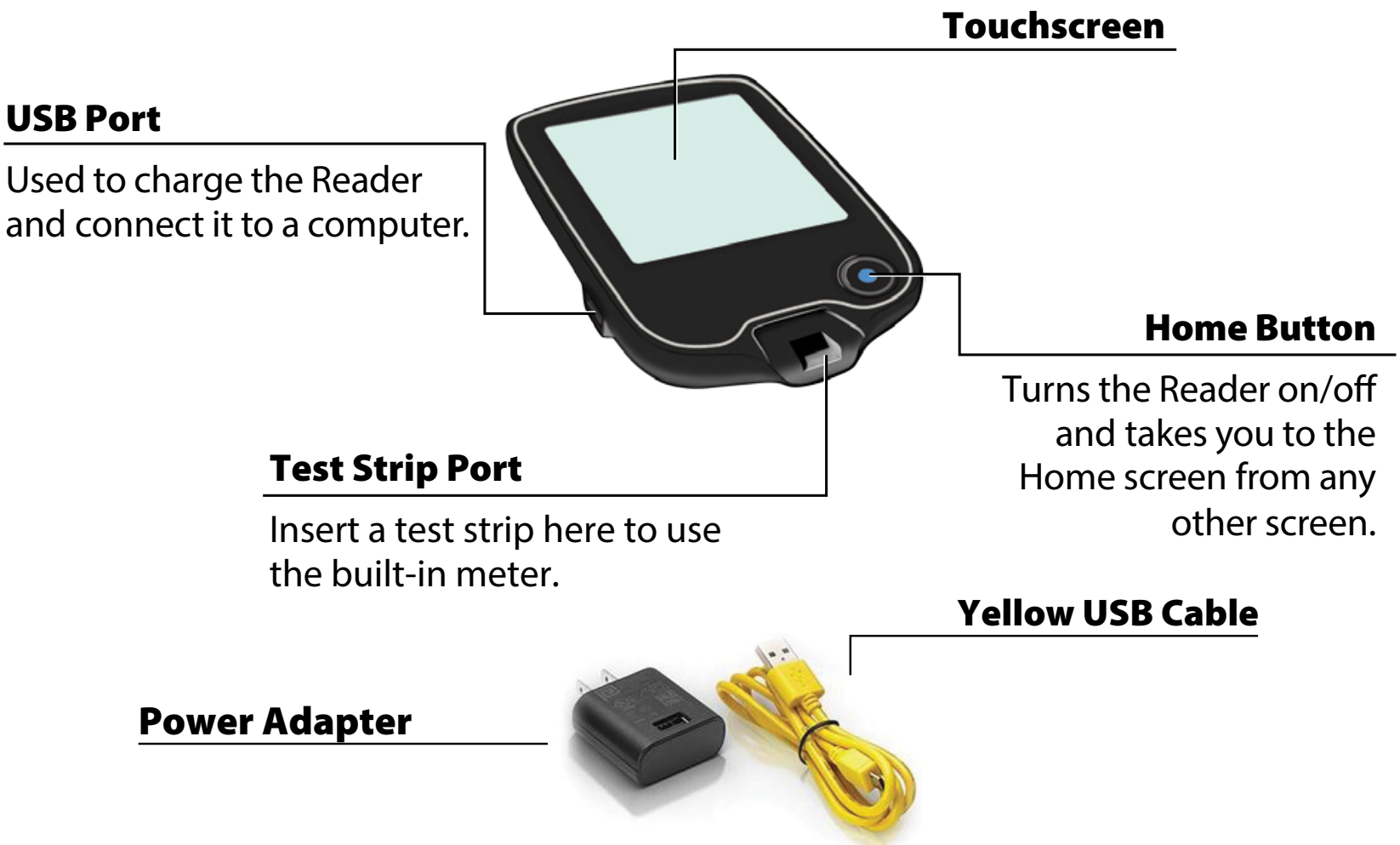
- Before you use your System, review all the product instructions and the Interactive Tutorial. The Quick Reference Guide and Interactive Tutorial give you quick access to important aspects and limitations of the System. The User's Manual includes all safety information and instructions for use.
- During the first 12 hours after insertion of a Sensor, Sensor readings will be accompanied by the  symbol. Whenever  is displayed, a blood glucose test should be performed to confirm the Sensor reading prior to treatment.
- Talk to your health care professional about how you should use your Sensor glucose information to help manage your diabetes.

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

Reader Kit

The Reader Kit includes:

- FreeStyle Libre 14 day Reader
- Yellow USB Cable
- Interactive Tutorial on USB
- Power Adapter
- User's Manual
- Quick Start Guide
- Quick Reference Guide



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

IMPORTANT:

- If the Reader is dropped or subjected to impact, do a Reader Test to check that it is still working properly. See *Perform a Reader Test* section for instructions.
- If the Reader becomes too hot to hold, do NOT use and contact Customer Service about replacing your Reader, yellow USB cable, and power adapter. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

Sensor Kit

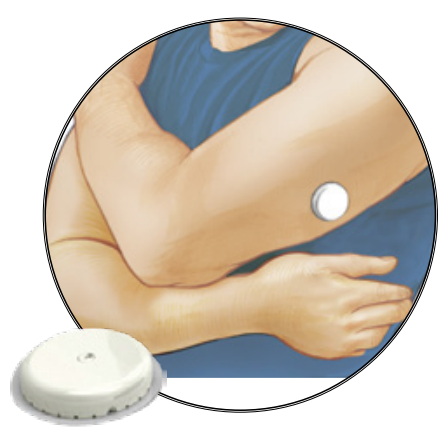
The Sensor Kit includes:

- Sensor Pack
- Sensor Applicator
- Product insert

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

Sensor Applicator
Applies the Sensor to your body.

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



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

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

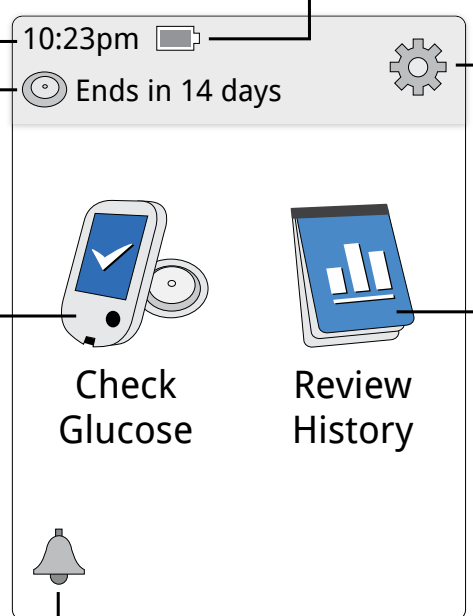
Home Screen

Time

Current time set on the Reader.

Battery Level

Battery charge remaining.



Sensor Status

Information about your current Sensor.

Settings

Touch to change the Reader's settings.

Check Glucose

Touch to check your Sensor glucose.

Review History

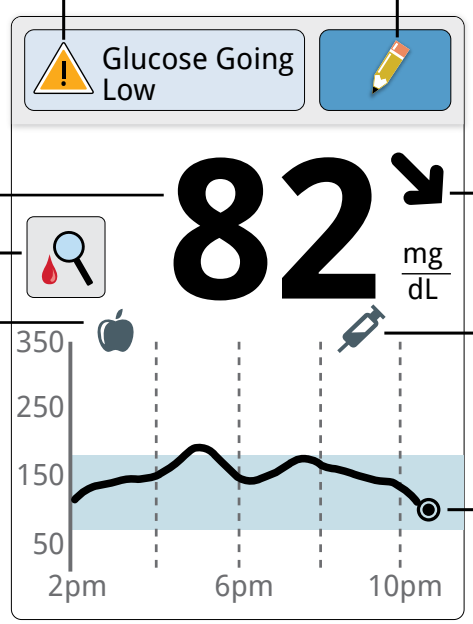
Touch to review information about your past glucose readings.

Reminder

Touch to set or change reminders.

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

Sensor Glucose Readings



Message

Touch for more information.

Current Glucose

Glucose from your latest scan.

Check Blood Glucose symbol

Touch for more information.

Food Note

Add Notes

Touch to add notes to the glucose reading.

Glucose Trend Arrow

Direction your glucose is going.

Rapid-Acting Insulin Note

Glucose Graph

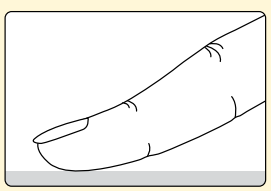
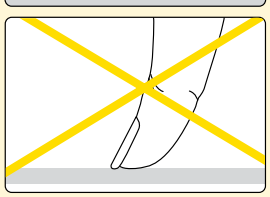
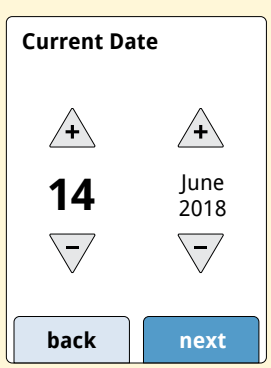
Graph of your current and stored glucose readings.

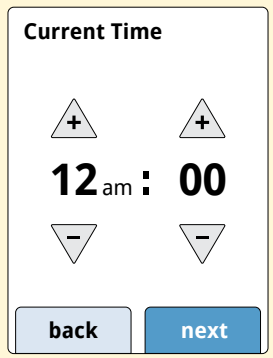
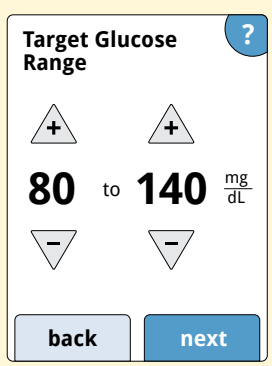
Reporting Software

Software can be used to create reports based on glucose readings from FreeStyle Libre 14 day Sensors. Go to **www.FreeStyleLibre.com** and follow onscreen instructions to download and install the compatible software. You are responsible for keeping your computer secure and up to date, for example by using anti-virus software and installing system updates.

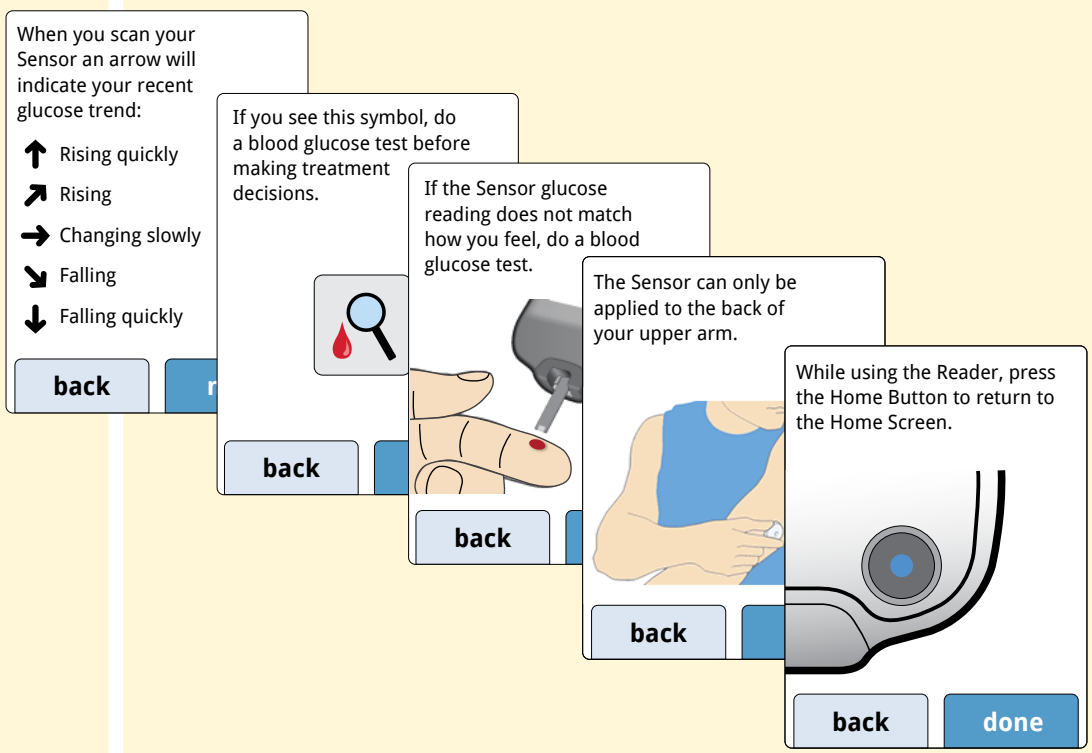
Setting up Your Reader for the First Time

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

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

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

Step	Action
6	The Reader now displays important information about key topics to help you use the System: • How to understand the Glucose Trend Arrow included on the Glucose Reading screen. • When to do a blood glucose test. • Where to apply the Sensor. • How to return to the Home Screen from any other screen.



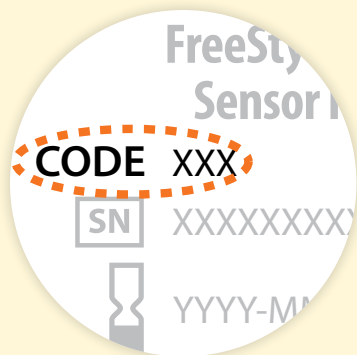
Touch **next** to move to the next topic. At the end of the Reader setup, touch **done** to go to the Home Screen.

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

Using Your Sensor

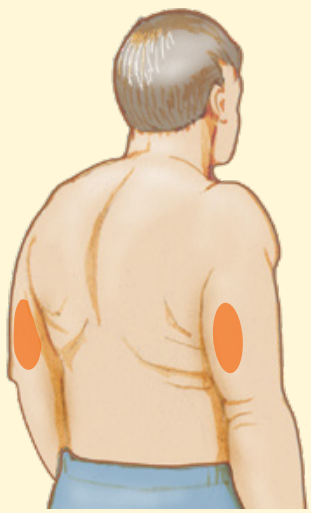
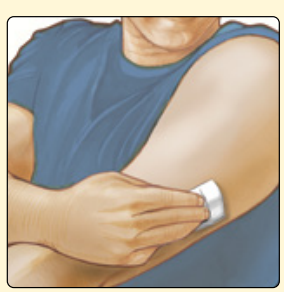
CAUTIONS:

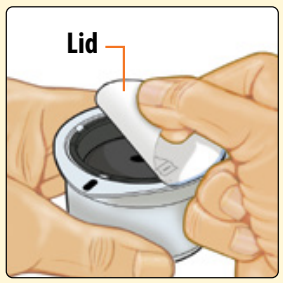
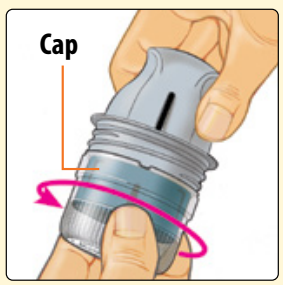
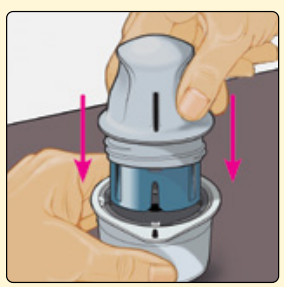
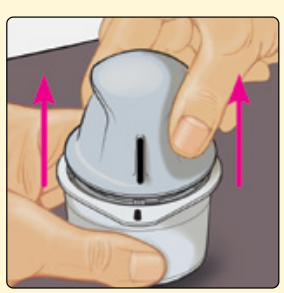
- The Sensor Pack and Sensor Applicator are packaged as a set (separately from the Reader) and have the same Sensor code. Check that the Sensor codes match before using your Sensor Pack and Sensor Applicator. Do not use Sensor Packs and Sensor Applicators with different Sensor codes together as this will result in incorrect glucose readings.

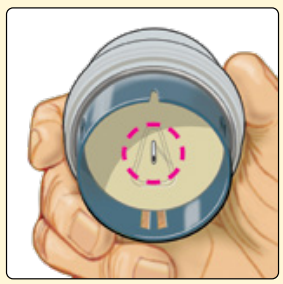
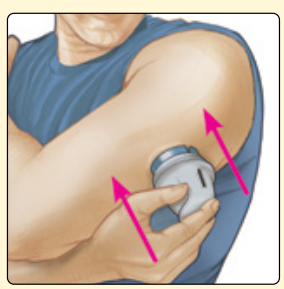


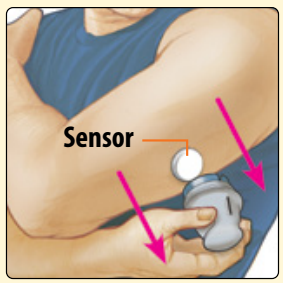
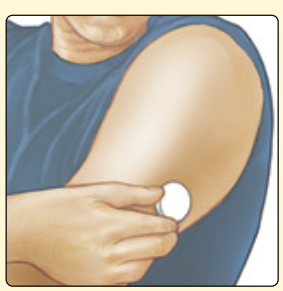
- Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. Remove and replace your Sensor if it starts to loosen and follow the instructions to select an appropriate application site.

Applying Your Sensor

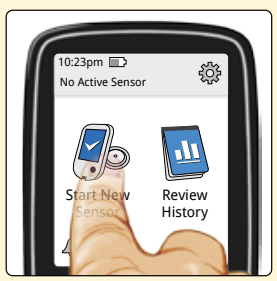
Step	Action
1	 Apply Sensors only on the back of your upper arm. If placed in other areas, the Sensor may not function properly and could give inaccurate readings. The application of the Sensor is not approved for other sites. Avoid areas with scars, moles, stretch marks, or lumps. Select an area of 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	 Clean application site with an alcohol wipe and allow site to dry before proceeding. This helps the Sensor stay attached to your body. **Note:** The area **MUST** be clean and dry, or the Sensor may not stick to the site.

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

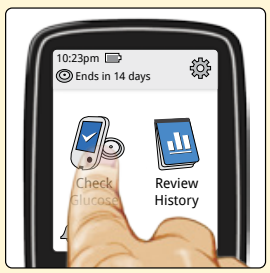
Step	Action
6	 The Sensor Applicator is prepared and ready to apply the Sensor. **CAUTION:** The Sensor Applicator now contains a needle. Do NOT touch inside the Sensor Applicator or put it back into the Sensor Pack.
7	 Place the Sensor Applicator over the prepared site and push down firmly to apply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

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

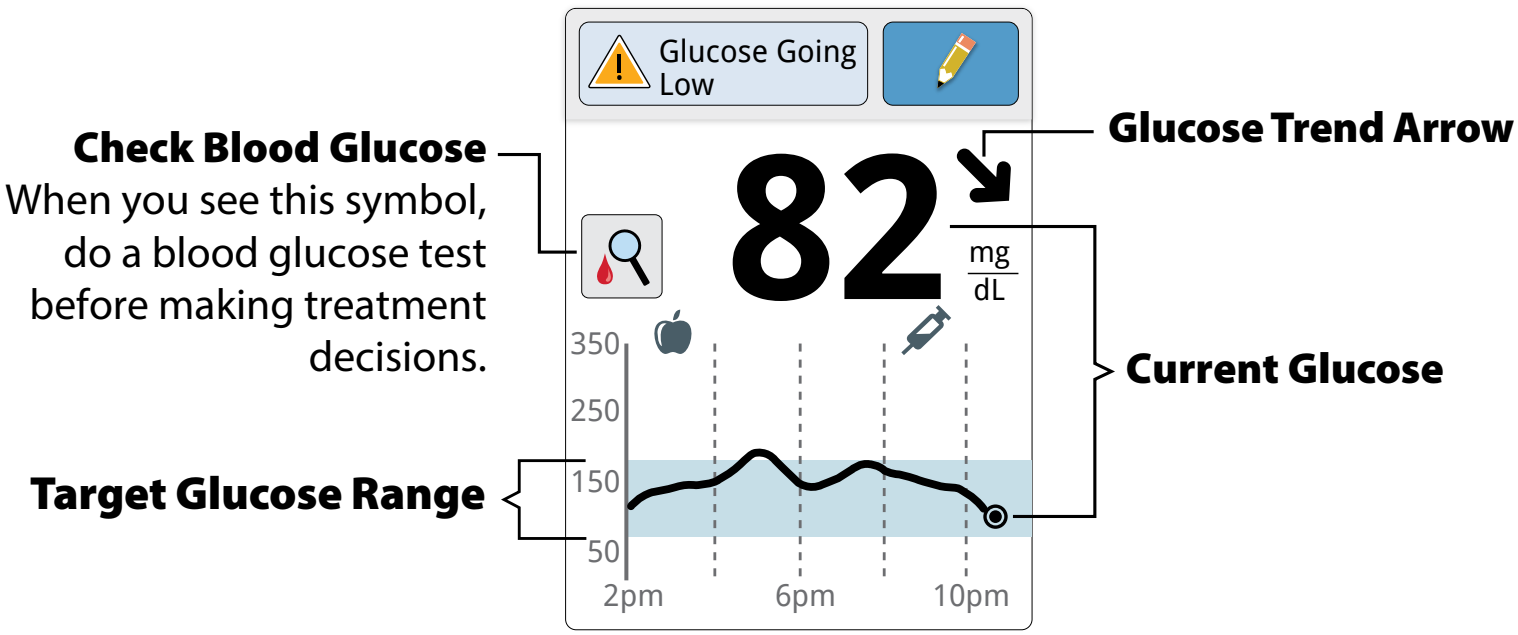
Step	Action
1	 Press the Home Button to turn on the Reader.
2	 Touch **Start New Sensor**.
3	 Hold the Reader within 1.5 inches (4 cm) of the Sensor to scan it. This starts your Sensor. If sounds are turned on, the Reader beeps when the Sensor has been successfully activated. The Sensor can be used to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

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.

Sensor Glucose Readings



Notes:

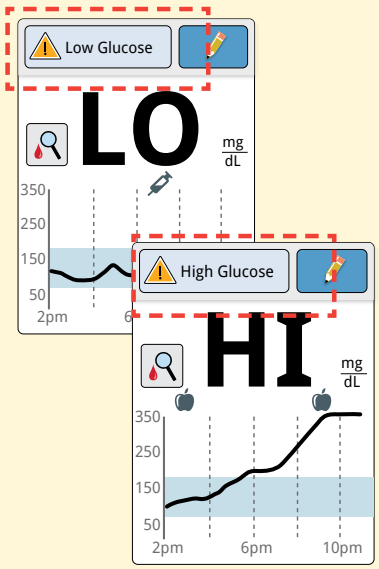
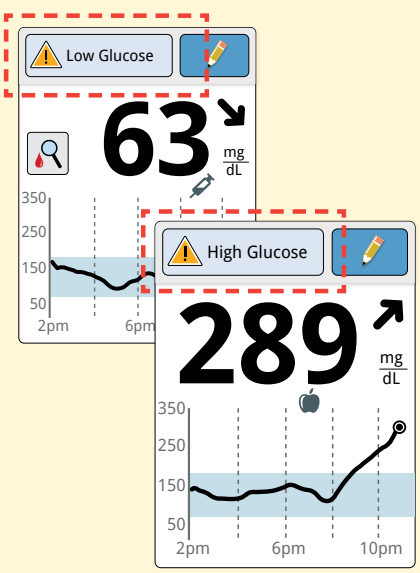
- While Sensor glucose readings are gathered in the System range of 40-500 mg/dL, the graph display range is 0-350 mg/dL for ease of review on screen. Glucose readings above 350 mg/dL are displayed at 350 mg/dL. For sequential readings above 350 mg/dL, a line is displayed at 350 mg/dL.
- The ◷ symbol may appear, indicating the Reader time was changed. Gaps in the graph may result or glucose readings may be hidden.

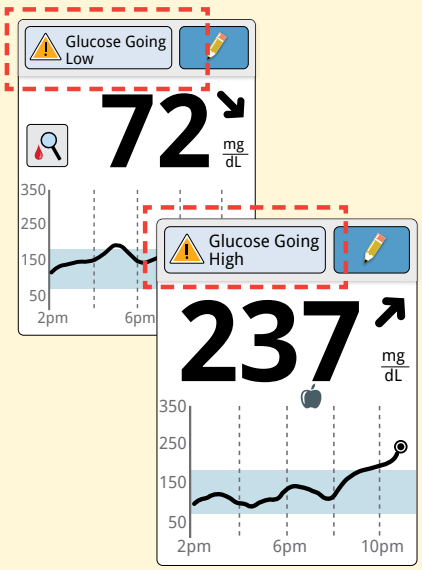
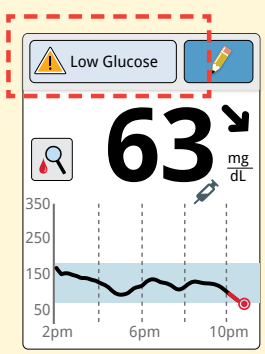
The Glucose Trend Arrow gives you an indication of the direction your glucose is going.

	**Glucose is rising quickly** (more than 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)

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

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

Display	What To Do
	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 500 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, 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.

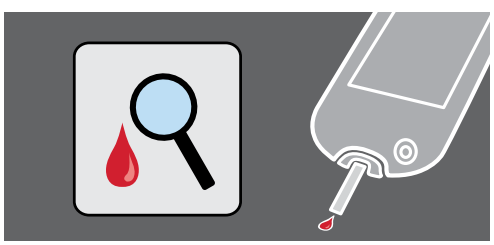
Display	What To Do
	If your glucose is projected to be higher than 240 mg/dL or lower than 70 mg/dL within 15 minutes, you will see a message on the screen. You can touch the message button for more information and set a reminder to check your glucose.
	You will see this symbol if your glucose reading is less than 70 mg/dL, projected to be less than 70 mg/dL, rapidly changing, has no number or trend arrow, or it is in the first 12 hours after inserting the Sensor. You can touch the symbol for more information. Check your blood glucose on your finger with a test strip before making treatment decisions.

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

Making Treatment Decisions

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

WARNING: The System can replace blood glucose testing except in a few 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 see the Check Blood Glucose symbol. The symbol means your Sensor glucose reading may not be accurate. For example, there may be times when you get a low glucose reading but you do not actually have low glucose.

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.

Note: The symbol will **NOT** appear in this situation.

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, and in different situations.

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

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

Helpful Tips

- Confirm your Sensor glucose readings with a blood glucose meter until you understand:
  - Sensor accuracy may vary between Sensors.
  - Sensor accuracy may vary during a Sensor wear session.
  - Sensor accuracy may vary in different situations (meals, exercise, first day of use, etc.).
  - Scan your Sensor often to see how carbs, medication, exercise, illness, or stress levels impact your Sensor glucose readings. The information you get can help you figure out why your glucose sometimes goes too high or too low, and how to prevent it from doing so in the future.

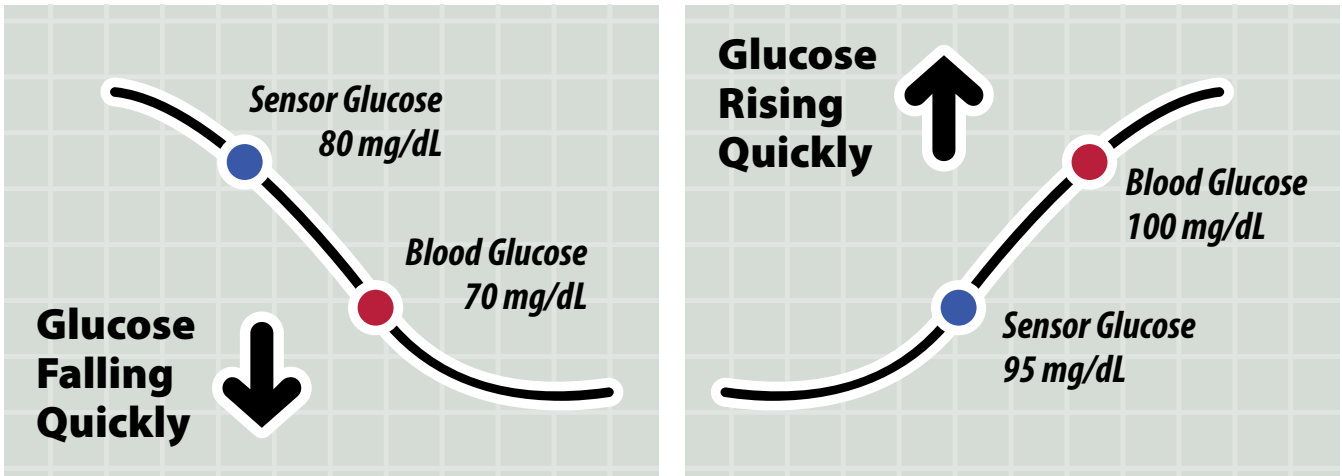
- Talk to your health care professional about how your insulin works. The more you understand about your insulin, including how long it takes to start working and how long it lasts in your body, the more likely you will be to make better treatment decisions.
- Making a treatment decision doesn't just mean taking insulin. Treatment decisions can also include things like taking fast-acting carbs, eating, or even doing nothing and scanning again later.
- Your health care professional can also help you to understand when doing nothing and scanning again later is the right treatment decision. For example, if your glucose is high and going up, your first instinct may be to take more insulin to lower your glucose, however depending on when you last took insulin or your recent activity, the right treatment decision may be to do nothing and scan again later. Avoid "insulin stacking".

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

Glucose is Falling Quickly or Rising Quickly

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. For example after eating, taking insulin, or exercising. When glucose levels are falling quickly, glucose readings from the Sensor may be higher than blood glucose levels. On the other hand, when glucose levels are rising quickly, glucose readings from the Sensor may be lower than blood glucose levels.

If glucose is rising quickly or falling quickly, you will see the symbol. Whenever you see the symbol, do a blood glucose test and treat based on that result.



Low Glucose or Glucose Going Low message

The System lets you know about hypoglycemia or impending hypoglycemia with a Low Glucose or Glucose Going Low message. These messages may not accurately reflect blood glucose. When there is a Low Glucose or Glucose Going Low message, you will also see the symbol. Whenever you see the symbol, do a blood glucose test and treat based on that result.

No Glucose Trend Arrow

When there is no Glucose Trend Arrow, the System can't tell if your glucose is rising quickly or falling quickly and will display the symbol. Whenever you see the symbol, you should do a blood glucose test and treat based on that result.

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. When there is no Current Glucose you will see the  symbol. Whenever you see the  symbol, do a blood glucose test and treat based on that result.

During the first 12 hours of wearing a Sensor

During the first 12 hours of wearing a Sensor, you should not use glucose readings from the Sensor to make treatment decisions. You will see the  symbol displayed during this time, and whenever you see the  symbol, do a blood glucose test and treat based on that result.

Think Your Readings are Incorrect?

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

You Have Low or High Blood Glucose Symptoms

Don't ignore symptoms that may be due to low or high blood glucose. 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.

Note: The  symbol will **NOT** display in these situations.

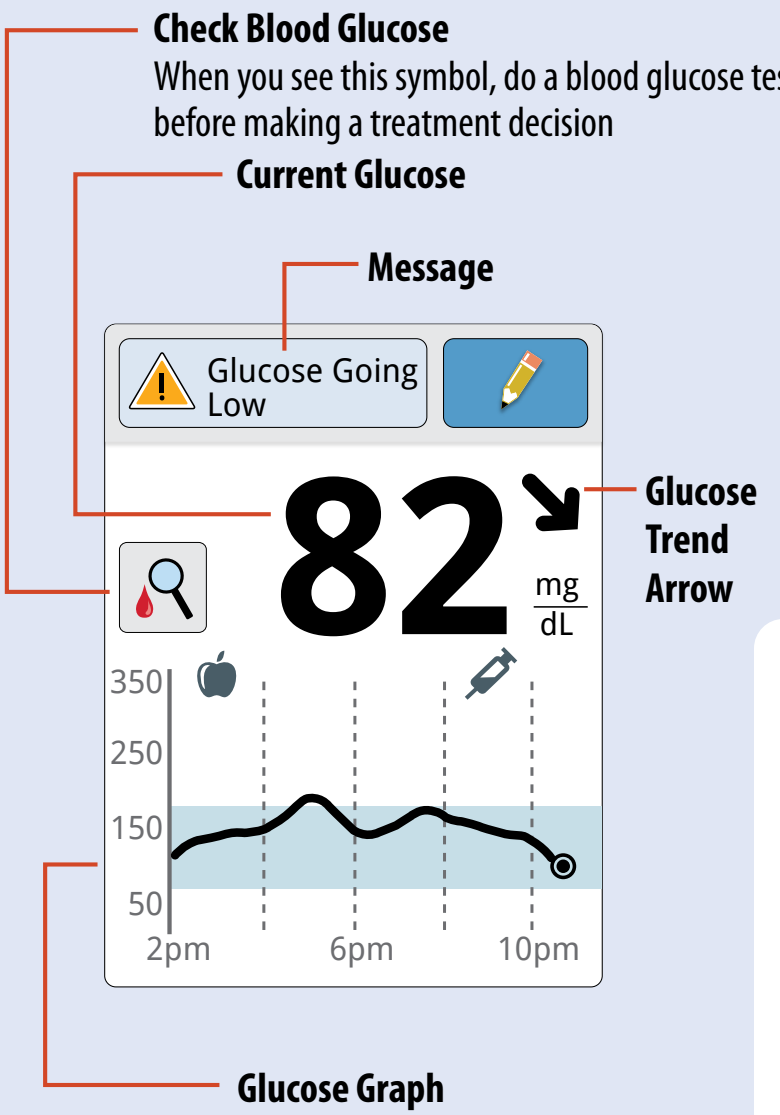
When to do Nothing and Scan Again Later

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.

Making Treatment Decisions – Advanced

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



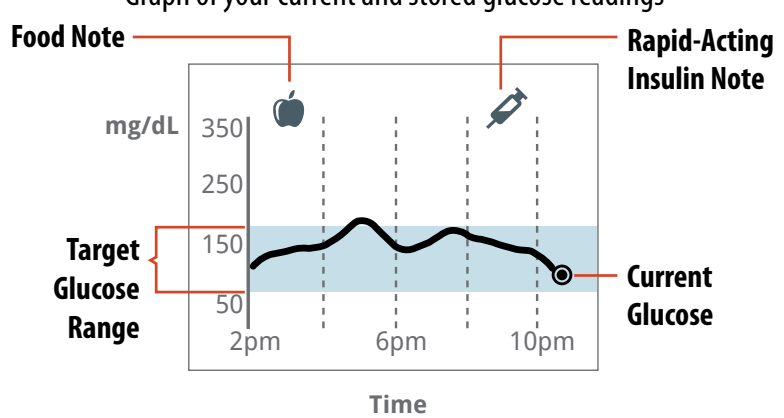
Glucose Trend Arrow

Direction your glucose is going

Arrow	What it means
↑	Glucose rising quickly
↗	Glucose rising
→	Glucose changing slowly
↘	Glucose falling
↓	Glucose falling quickly

Glucose Graph

Graph of your current and stored glucose readings



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.

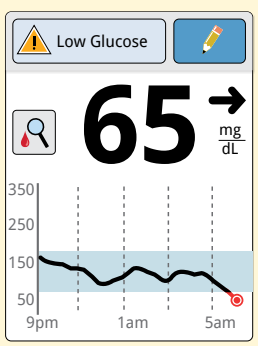
Glucose Trend Arrow	Treatment Decision Considerations		
	Low Glucose (< 70 mg/dL)	**Glucose in Target Range**	**High Glucose (> 240 mg/dL)**
No Arrow or No Number	You will see the symbol. Do not treat based on Sensor glucose reading. Do a blood glucose test.		
↑	You will see the symbol. Do not treat based on Sensor glucose reading. Do a blood glucose test.		
↗	You will see the symbol. Do not treat based on Sensor glucose reading. Do a blood glucose test.	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".

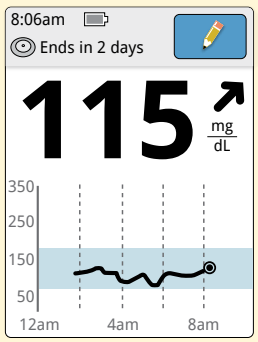
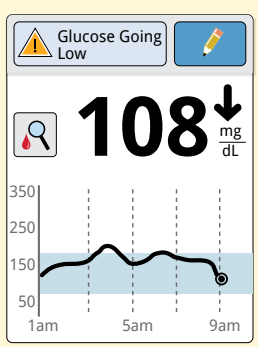
Glucose Trend Arrow	Treatment Decision Considerations		
	Low Glucose (< 70 mg/dL)	**Glucose in Target Range**	**High Glucose (> 240 mg/dL)**
→	You will see the  symbol. Do not treat based on Sensor glucose reading. Do a blood glucose test.	If you are about to eat, take insulin to cover your meal. If 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".

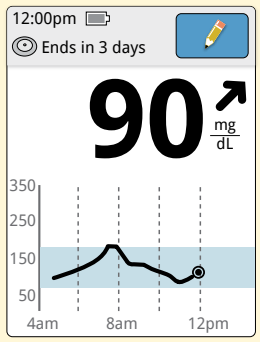
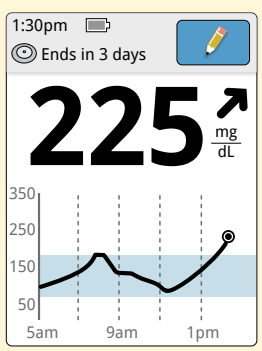
Glucose Trend Arrow	Treatment Decision Considerations		
	Low Glucose (< 70 mg/dL)	**Glucose in Target Range**	**High Glucose (> 240 mg/dL)**
↘	You will see the symbol. Do not treat based on Sensor glucose reading. Do a blood glucose test.	If you are about to eat, take insulin to cover your meal. Consider 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".
↓	You will see the symbol. Do not treat based on Sensor glucose reading. Do a blood glucose test.		

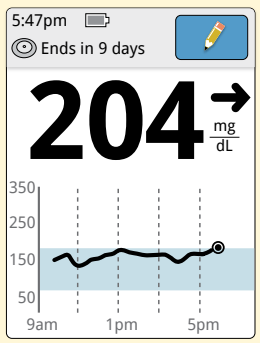
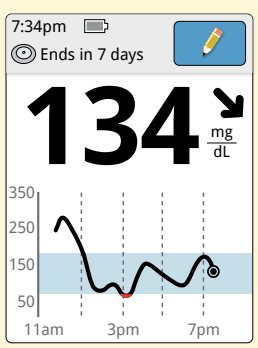
Example Scenarios

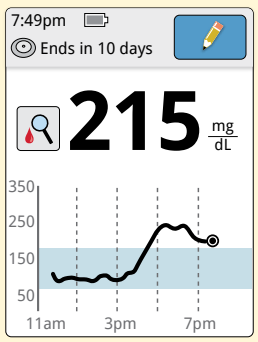
Next are some example scenarios to help you understand how to use the information on your screen. Always use all of the information on the screen before deciding what to do or what treatment decision to make. If you are not sure about what to do, consult your health care professional.

What you see	What it means
When you wake-up: 	When you wake up, your current glucose is 65 mg/dL and the trend arrow shows it is changing slowly ➜. There is also a Low Glucose message at the top of the screen and the symbol. Anytime you see the symbol, you should do a blood glucose test before deciding what to do.

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?
After breakfast: 	After breakfast, your current glucose is 108 mg/dL. The trend arrow shows it is going down quickly ↓. There is also a Glucose Going Low message at the top of the screen and the symbol. Anytime you see the symbol, you should do a blood glucose test before deciding what to do.

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
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. **Note:** The Check Blood Glucose symbol will **NOT** appear in this situation.
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?

What you see	What it means
After dinner: 	After dinner, your current glucose is 215 mg/dL but there is no trend arrow. There is also the  symbol on the screen. Anytime you see the  symbol, you should do a blood glucose test before deciding what to do.

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?

Bedtime

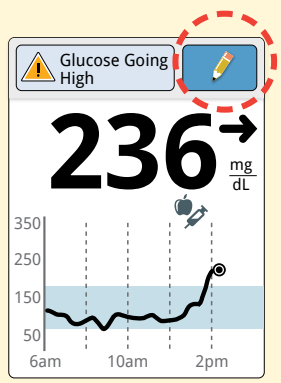
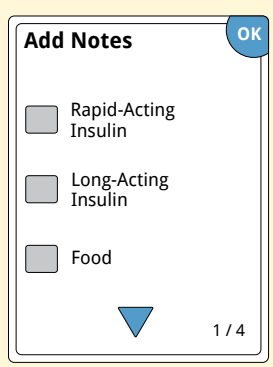
- How often do you check your glucose before bed?
- What do you consider a safe bedtime glucose?
- What do you do if your bedtime glucose is high?
- What do you do if your bedtime glucose is low?
- When should you eat a bedtime snack?
- What do you do if your before meal glucose is high?
- What do you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

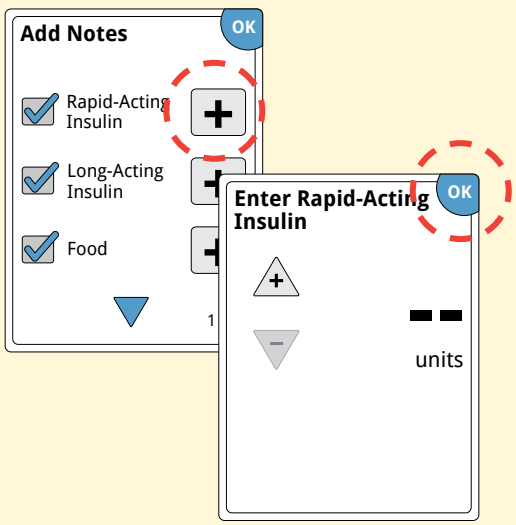
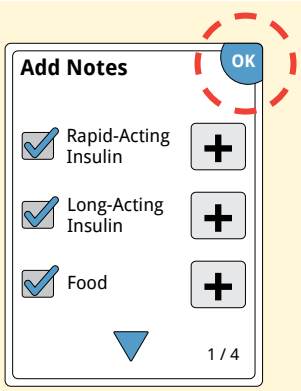
Other factors

- 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?

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.

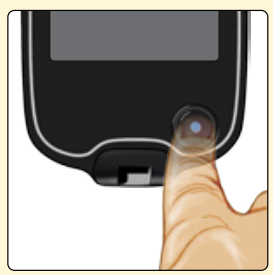
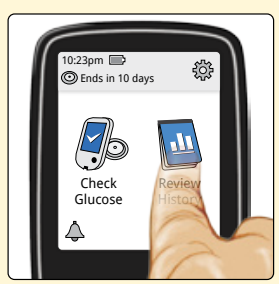
Step	Action
1	 From the Glucose Reading screen, add notes by touching the symbol in the upper right corner of the touchscreen. If you do not want to add notes, you can press the Home Button to go to the Home Screen or hold the Home Button to turn the Reader off.
2	 Select the checkbox next to the notes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

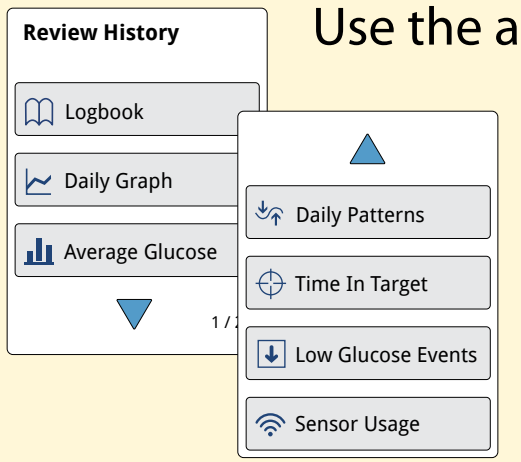
Step	Action
3	 After you check the box for food and insulin notes, the + symbol appears to the right of the note. You can touch it to add more specific information to your note. Then touch **OK**. • Insulin notes: Enter the number of units taken. • Food notes: Enter grams or serving information. **Note:** 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.

Reviewing Your History

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

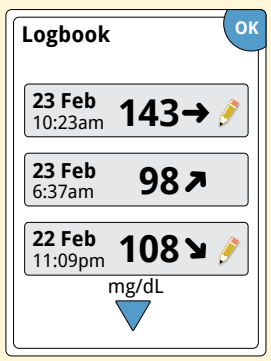
Step	Action
1	  Press the Home Button to turn on the Reader. Press the Home Button again to go to the Home Screen.
2	 Touch the **Review History** icon.

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

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

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

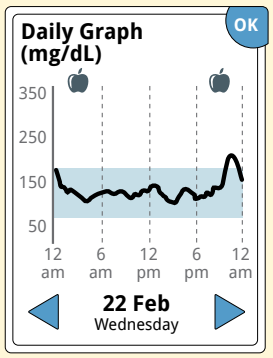
Logbook



Entries for each time you scanned your Sensor or performed a blood glucose 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 reporting software to create reports.

Daily Graph



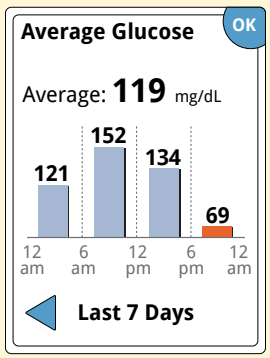
A graph of your Sensor glucose readings by day. The graph shows your Target Glucose Range and symbols for food or rapid-acting insulin notes you have entered.

Notes:

- While Sensor glucose readings are gathered in the System range of 40-500 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.

Other History Options

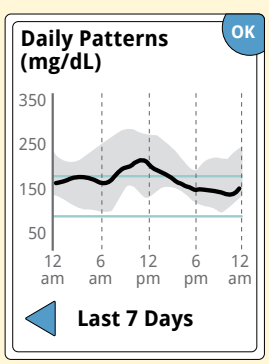
Use the arrows to view information about your last 7, 14, 30, or 90 days.



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.

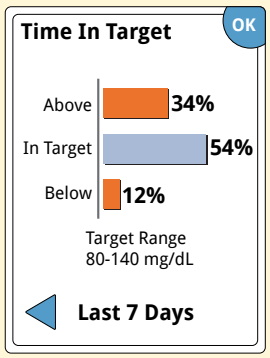
Readings above or below your Target Glucose Range are orange, while readings in range are blue.



Daily Patterns

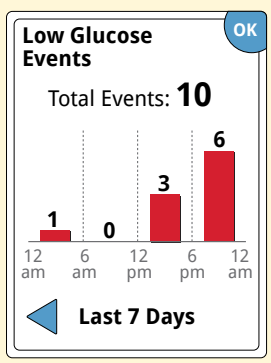
A graph showing the pattern and variability of your Sensor glucose over a typical day. The thick black line shows the median (midpoint) of your glucose readings. The gray shading represents a range (10-90 percentiles) of your Sensor readings.

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



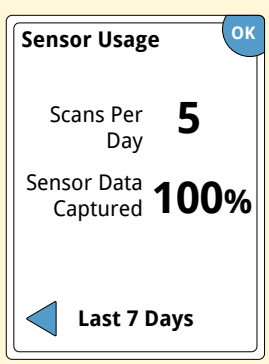
Time In Target

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



Low Glucose Events

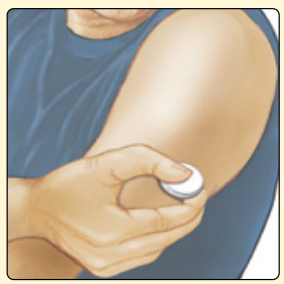
Information about the number of low glucose events measured by your Sensor. A low glucose event is recorded when your Sensor glucose reading is lower than 70 mg/dL for 15 minutes or longer. The total number of events is displayed above the graph. The bar graph displays the low glucose events in four 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.

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.

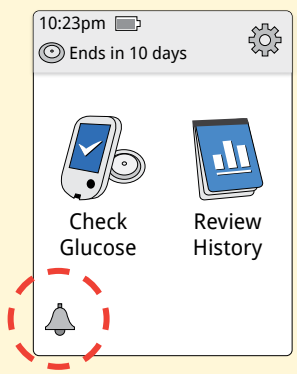
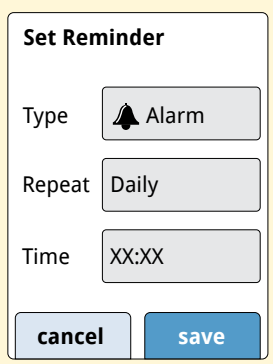
Replacing Your Sensor

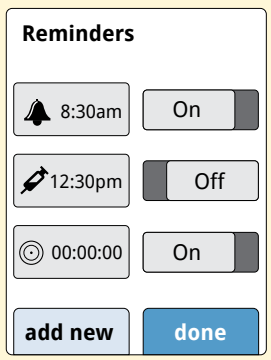
Your Sensor automatically stops working after 14 days of data and must be replaced. You should also replace your Sensor if you notice any irritation or discomfort at the application site or if the Reader reports a problem with the Sensor currently in use. Taking action early can keep small problems from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

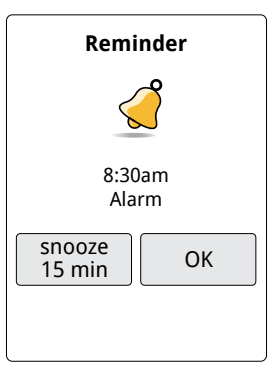
CAUTION: If the Sensor is becoming loose or if the Sensor tip is coming out of your skin, you may get no readings or unreliable readings, which may not match how you feel. Check to make sure your Sensor has not come loose. If it has come loose, remove it and apply a new one.

Using Reminders

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

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

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



When reminders are On, the next reminder time appears next to the reminder symbol on the Home Screen.
For example, 8:30am

Your reminder comes on even if the Reader is turned off. Touch **OK** to dismiss your reminder or **snooze** to be reminded again in 15 minutes.
Note: Reminders will not appear if the Reader is connected to a computer.

Using the 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 14 day 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 14 day 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 14 day Reader's built-in meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

IMPORTANT:

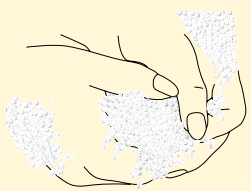
- Use only FreeStyle Precision Neo test strips. Other test strips may produce inaccurate results.
- Read all the instructions in this section. Failure to follow instructions may cause incorrect blood glucose results. Practice the testing procedures before using the Reader's built-in meter.
- Read the 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.
- 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.

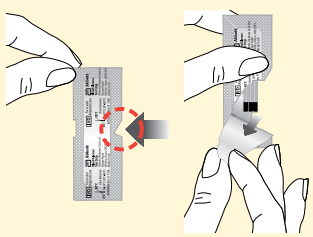
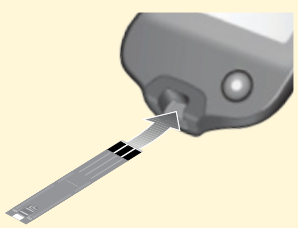
IMPORTANT: ***(cont.)***

- 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 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.
- Do not put urine on the test strip.
- Do not use expired test strips as they may cause inaccurate results.
- Do not use a wet, bent, scratched, or damaged test strip.
- Do not use the test strip if the foil packet has a hole or is torn.
- Results from the built-in meter are shown only in your Logbook and not in other history options.
- Refer to your lancing device instructions for use for how to use your lancing device.

Blood Glucose Testing

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

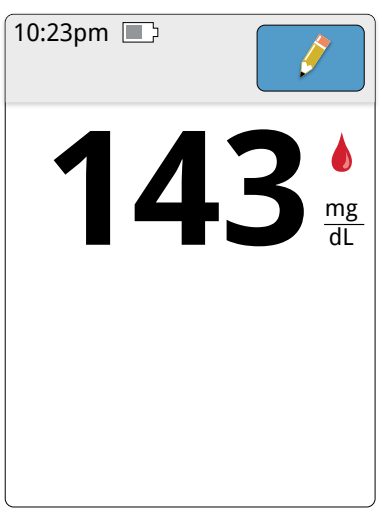
Step	Action
1	 **CAUTION:** Test on your fingers in accordance with the Intended Use in this section. Wash your hands with warm soapy water for accurate results. Thoroughly dry your hands. To warm the site, apply a warm dry pad or rub vigorously for a few seconds. **Note:** Do not use lotion or cream 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. Remove and reinsert the unused test strip to restart the built-in meter.

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

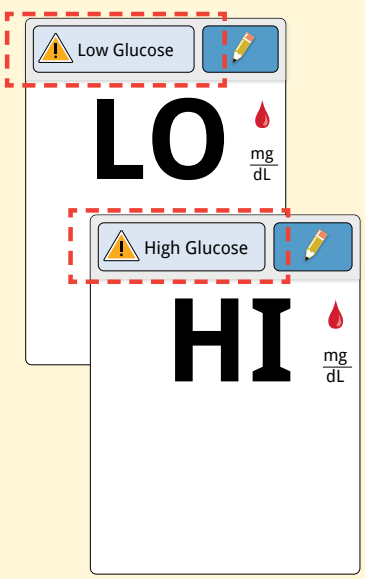
Your Blood Glucose Results

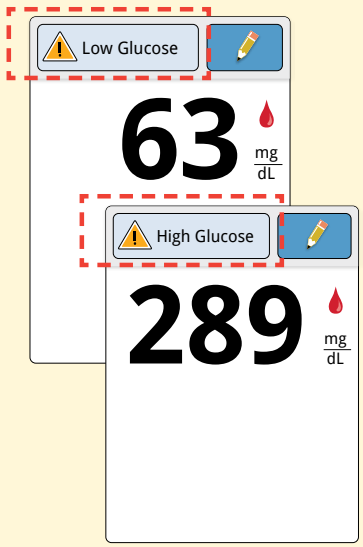
Blood glucose results are marked on the results screen and in the Logbook with the symbol.

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

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 expected glucose range for a non-diabetic, non-pregnant fasting adult is under 100 mg/dL. Two hours after meals, levels should be less than 140 mg/dL.[3] Consult your healthcare 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.

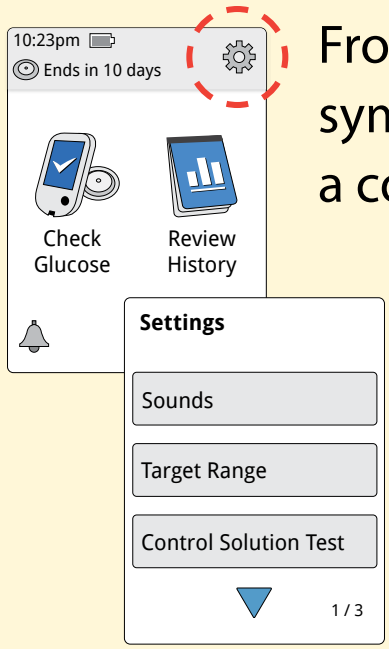
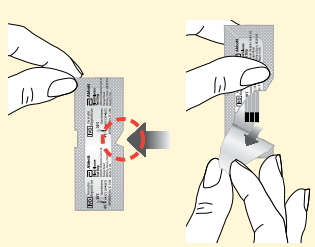
IMPORTANT: You should clean and disinfect your Reader once per week. Refer to the *Maintenance and Disposal* section for instructions.

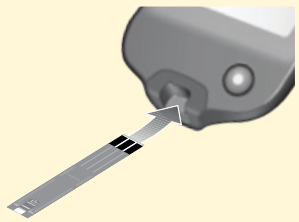
Control Solution Testing

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.

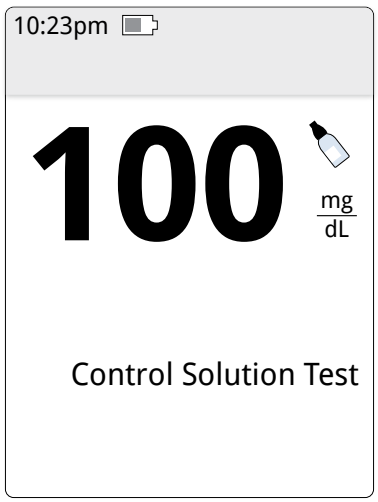
IMPORTANT:

- 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 Customer Service (1-855-632-8658) for information on how to obtain control solution.

Step	Action
1	 From the Home Screen, touch the Settings symbol ⚙. Touch **Control Solution Test** to do a control solution test.
2	Check the test strip 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. Remove and reinsert the unused test strip to restart the built-in meter.
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.

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.

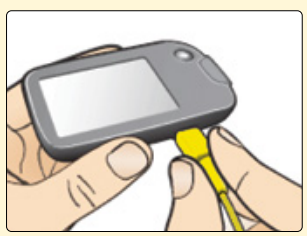
Note: Repeat the control solution test if the results are outside of the range printed on the test strip instructions for use. Stop using the built-in meter if the control solution results are repeatedly outside of the printed range. Contact Customer Service.

Charging the Reader

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

CAUTION:

- Always use the Abbott provided power adapter and yellow USB cable that came with your Reader to minimize the risk of fire or burns. Take care when plugging and unplugging your USB cable. Do not force or bend the end of the USB cable into the Reader's USB port.
- Choose a location for charging where you can easily access the power adapter and quickly disconnect to prevent the potential risk of electrical shock.
- The maximum surface temperature of the Reader and/or the power adapter could go as warm as 120°F when it's charging or 118°F during normal use. Under these conditions, do not hold the Reader or the power adapter for five minutes or more. People with disorders of peripheral circulation or sensation should use caution at this temperature.
- Do NOT expose the USB cable or power adapter to water or other liquids as this may cause them to not function properly and may lead to risk of fire or burns.

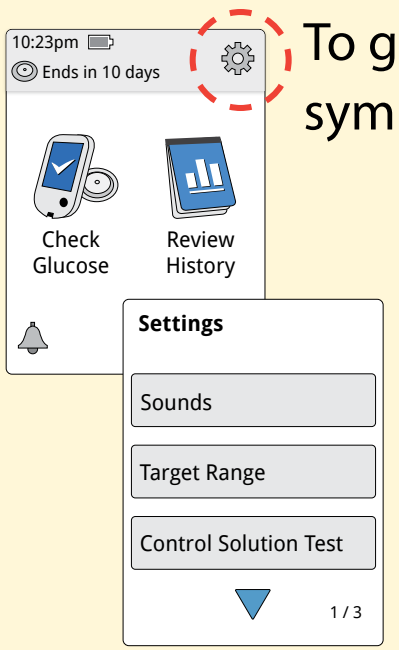
Step	Action
1	Before charging, to minimize the risk of fire or burns: • Check the provided power adapter and yellow USB cable to make sure they are not damaged. • Check the Reader's USB port and make sure it is dry and free of debris.
2	 Plug the yellow USB cable into an electrical outlet using the power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

Note:

- You must charge the Reader when the battery is low  to keep using the Reader.
- To fully charge the battery, charge the Reader for at least 3 hours.
- If the Reader does not turn on after being charged or you notice a significant deterioration in battery life, contact Customer Service about replacing your Reader, yellow USB cable, and power adapter. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.
- Fully charge your Reader before storing it for more than 3 months.

Changing the Reader Settings

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

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

Step	Action
2	Touch the setting you want to change: **Sounds** – Set tones and vibrations **Target Range** – Set range displayed on Reader glucose graphs **Control Solution Test** – Perform a Control Solution test **Time & Date** – Change the Time or Date **Language** – Change the language on the Reader **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 (including both tones and vibrations) are working, and the Touchscreen is responding when touched **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 Touch **OK** when you are done.

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 have reminders set to go off while you are sleeping, place the Reader nearby.

Activity	What You Need To Know
Traveling by Air	You can safely use your System at all times while on an aircraft. • 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. Please note though that you must still comply with any requests from the flight crew to not scan your Sensor due to the wireless connection between the Reader and the Sensor. You will still be able to do a blood glucose test by inserting a strip into the Reader as this does not turn on the wireless connection. • 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.

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.

This device is not intended for use in healthcare 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.
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.

Step	Action
4	Dry with clean paper towel to remove any residual moisture.
5	When finished, thoroughly wash your hands with soap and water.

IMPORTANT: Do NOT use the Reader if you notice any signs of deterioration on the Reader (such as clouding or crazing on the display of the Reader, corroding, eroding or swelling of the plastic housing, or cracking of plastic housing or display) or if the Reader does not turn on. Contact Customer Service about replacing your Reader. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays.

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 port as this may cause the Reader to not function properly and may lead to risk of fire or burns.

Maintenance

The System has no serviceable parts.

Disposal

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

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

Troubleshooting

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

Reader Does Not Power On

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

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. Consider shaving and/or cleaning the site with soap and water. 3. Follow the instructions in *Applying and Starting Your Sensor* sections.
Skin irritation at the Sensor application site.	Seams or other constrictive clothing or accessories causing friction at the site.	Ensure that nothing rubs on the site.
	You may be sensitive to the adhesive material.	If the irritation is where the adhesive touches skin, contact your health care professional to identify the best solution.

Problems Starting Your Sensor or Receiving Sensor Readings

Display	What It May Mean	What To Do
New Sensor Starting Up	Sensor is not ready to read glucose.	Wait until the 60 minute Sensor start-up period has completed.
Scan Timeout	The Reader is not held close enough to the Sensor.	Hold the Reader within 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.
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”.

Display	What It May Mean	What To Do
Scan Error	The Reader was unable to communicate with the Sensor.	Try scanning again. **Note:** You may need to move away from potential sources of electromagnetic interference.
Sensor Error	The System is unable to provide a glucose reading.	Scan again 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.

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

Blood Glucose Error Messages

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

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

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

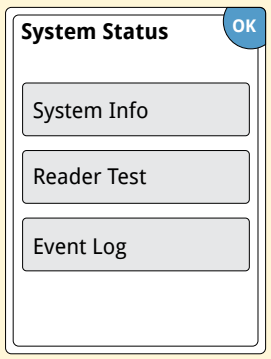
Error Message	What It May Mean	What To Do
E-7	Test strip may be damaged, used, or the Reader does not recognize it.	1. Check that you are using the correct test strip for the Reader. (See test strip instructions for use to verify your strip is compatible with the Reader). 2. Repeat the test using a test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

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.
	Reader is in a power saving mode.	Press the Home Button then insert a test strip.

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

Perform a Reader Test



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

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

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

Customer Service

Customer Service is available to answer any questions you may have about your System. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Time; excluding holidays. A printed copy of the User's Manual is available upon request. The latest version of the User's Manual is available at www.FreeStyleLibre.us/support/overview.html.

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 500 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
Sensor memory	8 hours (glucose readings stored every 15 minutes)
Operating temperature	50°F to 113°F
Sensor Applicator and Sensor Pack storage temperature	39°F to 77°F
Operating and storage relative humidity	10-90%, non-condensing
Sensor water resistance	IP27: Can withstand immersion into 3 ft (one meter) of water for up to 30 minutes. Protected against insertion of objects > 12mm diameter.
Operating and storage altitude	-1,250 ft (-381 meters) to 10,000 ft (3,048 meters)

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	7 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

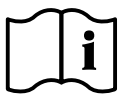
Reader moisture protection	Keep dry
Operating and storage altitude	-1,250 ft (-381 meters) to 10,000 ft (3,048 meters)
Reader display timeout	60 seconds (120 seconds when test strip is inserted)
Radio Frequency	Near Field Communication* (13.56 MHz RFID); ASK Modulation; 124 dBuV/m; 1.5 inch communication range
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).

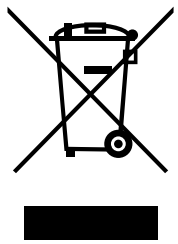
Power Adapter	Abbott Diabetes Care PRT25611 Operating temperature: 50°F to 104°F
USB Cable	Abbott Diabetes Care PRT21373 Length: 37 inches (94 cm) Color: Yellow

* Security measures: The communication between Reader and Sensor is a short range near field communication method making it difficult to interfere with or intercept data that is being transferred. The Sensor and Reader are protected by proprietary data format, memory mapping, and cyclic redundancy check (CRC) generation and verification of data.

  Quality of Service (QoS): QoS for the FreeStyle Libre 14 day Reader and Sensor wireless communications using the near field communications is assured within the effective range of 4 cm between the Sensor and Reader that is specified to occur within 15 seconds.

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 unsafe		Humidity limitation
	FCC Declaration of Conformity mark		Do not use if package is damaged

R_X *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

Clinical Study Overview

Performance of the FreeStyle Libre 14 day Flash Glucose Monitoring System (the System) was evaluated in a clinical study. The study was conducted at 4 centers with a total of 95 subjects with diabetes (84.2% Type 1, 15.8% Type 2). All subjects were aged eighteen and older. Subjects in the study required insulin to manage their diabetes. Each subject wore up to two Sensors on the back of the upper arm. During the study, subjects tested their blood glucose using fingerstick capillary samples at least eight times during each day of the study. Subjects used the blood glucose meter built into the Reader. Additionally, subjects had their venous blood glucose analyzed up to 112 times over four separate visits to the clinical center. Venous blood was analyzed using the Yellow Springs Instrument Life Sciences 2300 STAT Plus™ Glucose & Lactate Analyzer (YSI). YSI is a laboratory glucose and lactate analyzer of whole blood and plasma and is a widely recognized standard in laboratory analysis of blood glucose. Glucose readings obtained from the System were compared to glucose readings obtained from the YSI to evaluate the performance of the System. Three lots of Sensors were evaluated in the study.

Agreement with YSI Levels

Agreement between the System Glucose Measurement (CGM) and venous blood was characterized by using paired CGM and Yellow Springs Instrument measurements (YSI). The accuracy of CGM versus YSI reference was assessed by calculating the percentage of System readings that were within 15%, 20%, 30% and 40% for reference values 80 mg/dL and above, and 15 mg/dL, 20 mg/dL, 30 mg/dL and 40 mg/dL for values below 80 mg/dL when glucose levels are assigned using the YSI values. Overall 90.7% of results were within ±20 mg/dL / 20% of YSI reference.

Agreement with CGM Glucose Levels

Agreement between CGM and venous blood was characterized by using paired CGM and Yellow Springs Instrument measurements (YSI). The accuracy of CGM versus YSI reference was assessed by calculating the percentage of System readings that were within 15%, 20%, 30% and 40% for reference values 80 mg/dL and above, and 15 mg/dL, 20 mg/dL, 30 mg/dL and 40 mg/dL for values below 80 mg/dL. The results are presented in **Table 1** for YSI reference. Overall 90.9% of results were within ±20 mg/dL / 20% of YSI reference.

Table 1: Number and Percent of Results within YSI Reference

CGM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Within ±15% / ±15mg/dL	Within ±20% / ±20mg/dL	Within ±30% / ±30mg/dL	Within ±40% / ±40mg/dL	Outside ±40% / ±40mg/dL
Overall	9725	83.0	90.9	97.3	99.1	0.9
40-50	40	52.5	60.0	80.0	85.0	15.0
51-80	741	58.2	70.9	87.9	94.6	5.4
81-180	6112	82.2	90.9	97.5	99.4	0.6
181-300	2513	91.7	96.9	99.4	99.8	0.2
301-400	291	89.0	95.2	99.7	99.7	0.3
401-500	28	100.0	100.0	100.0	100.0	0.0

Agreement on Day 1 against YSI Reference

The accuracy of CGM versus YSI reference on the first day of Sensor wear was assessed by calculating the percentage of System readings that were within 15%, 20%, 30% and 40% for reference values 80 mg/dL and above, and within 15 mg/dL, 20 mg/dL, 30 mg/dL and 40 mg/dL for values below 80 mg/dL by hourly intervals. The results are presented in **Table 2**.

Table 2: Number and Percent of Results within YSI Reference

Time Interval (hours)	Number of CGM-Reference Pairs	Within ±15% / ±15mg/dL	Within ±20% / ±20mg/dL	Within ±30% / ±30mg/dL	Within ±40% / ±40mg/dL	Outside ±40% / ±40mg/dL
(0-2] *	182	77.5	87.9	95.6	99.5	0.5
(2-4]	385	71.2	83.1	94.8	98.4	1.6
(4-6]	375	77.6	86.4	91.7	96.3	3.7
(6-8]	373	78.0	87.9	97.3	99.5	0.5
(8-16]†	106	74.5	83.0	97.2	100.0	0.0
(16-18]	303	80.2	89.1	96.7	99.7	0.3
(18-20]	344	80.2	86.6	94.8	98.8	1.2
(20-22]	336	81.3	87.8	97.9	98.8	1.2
(22-24)	155	86.5	93.5	96.1	98.7	1.3

* (0-2] interval includes the 1 hour start-up time.

† Time interval is not divided to smaller segments due to small number of data pairs.

Overall Accuracy against YSI reference

Accuracy was measured by comparing the absolute relative difference between the System and reference YSI glucose values. The absolute relative difference measures the level of disagreement between the System and the reference value, but does not tell you whether the System glucose value was, on average, higher or lower than the reference glucose value. The Mean Absolute Relative Difference gives an indication of the average percent disagreement between the CGM and the reference. **Table 3** shows the overall absolute difference measure. Overall the Mean Absolute Relative Difference was 9.4% for the comparison with YSI reference. The Median Absolute Relative Difference shows that half of the time the System was within 7.4% of the YSI reference.

Table 3: Difference Measures with YSI Reference

Number of CGM-Reference Pairs	Median Absolute Relative Difference (%)	Mean Absolute Relative Difference (%)
9725	7.4	9.4

Agreement with BG Levels

Agreement between the System and capillary blood glucose values (BG) as measured by the Reader's built-in meter was characterized by using paired System CGM and BG value. The accuracy of CGM versus BG value was assessed by calculating the percentage of System readings that were within 15%, 20%, 30% and 40% for BG values 80 mg/dL and above, and within 15 mg/dL, 20 mg/dL, 30 mg/dL and 40 mg/dL for values below 80 mg/dL. The results are presented in **Table 4** for BG values. Overall 87.0% of results were within ±20 mg/dL / 20% of BG values.

Table 4: Number and Percent of Results within BG Values*

CGM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Within ±15% / ±15mg/dL	Within ±20% / ±20mg/dL	Within ±30% / ±30mg/dL	Within ±40% / ±40mg/dL	Outside ±40% / ±40mg/dL
Overall	9234	75.8	87.0	96.1	98.6	1.4
40-50	123	52.0	62.6	78.0	89.4	10.6
51-80	795	60.5	71.9	88.2	95.0	5.0
81-180	4839	73.3	85.9	96.4	98.9	1.1
181-300	2800	83.8	92.8	98.4	99.4	0.6
301-400	563	82.4	93.6	98.0	99.3	0.7
401-500	114	80.7	93.0	97.4	98.2	1.8

* Comparison to BG was performed using the Reader's built-in blood glucose meter. Different performance may be expected when compared to other models of blood glucose meters.

Overall Accuracy against BG values

Accuracy was measured by comparing the absolute relative difference between the System and BG values. The absolute relative difference measures the level of disagreement between the System and the BG value, but does not tell you whether the System glucose value was, on average, higher or lower than the BG value. The Mean Absolute Relative Difference gives an indication of the average percent disagreement between the CGM and the BG value. **Table 5** shows the overall absolute difference measure. Overall the Mean Absolute Relative Difference was 11.4% for the comparison with BG value. The Median Absolute Relative Difference shows that half of the time the System was within 9.1% of the BG value.

Table 5: Difference Measures with BG Value *

Number of CGM-Reference Pairs	Median Absolute Relative Difference (%)	Mean Absolute Relative Difference (%)
9234	9.1	11.4

* Comparison to BG was performed using the Reader's built-in blood glucose meter. Different performance may be expected when compared to other models of blood glucose meters.

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 **Table 6**. For example, in the clinical study, when the System glucose results were within the 81 to 120 mg/dL range, actual blood glucose values were less than 40 mg/dL 0% of the time, between 40 and 60 mg/dL 0.1% of the time, between 61 and 80 mg/dL 2.7% of the time, between 81 and 120 mg/dL 68.1% of the time, between 121 and 160 mg/dL 27.7% of the time, between 161 and 200 mg/dL 1.2% of the time, between 201 and 250 mg/dL 0.1% of the time and above 250 mg/dL 0% of the time.

Table 6: Concurrence Analysis by Glucose Level

CGM (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	401-500	>500*	
<40	0.0	44.4	33.3	22.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	18
40-60	2.8	31.0	48.3	17.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	145
61-80	0.2	4.9	34.0	59.0	2.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	636
81-120	0.0	0.1	2.7	68.1	27.7	1.2	0.1	0.0	0.0	0.0	0.0	0.0	2498
121-160	0.0	0.0	0.0	7.0	71.2	20.7	1.0	0.2	0.0	0.0	0.0	0.0	2625
161-200	0.0	0.0	0.0	0.2	11.1	68.8	18.5	1.1	0.3	0.0	0.0	0.0	1762
201-250	0.0	0.0	0.0	0.0	0.3	15.0	72.8	11.6	0.3	0.0	0.0	0.0	1186
251-300	0.0	0.0	0.0	0.0	0.0	0.5	23.5	65.3	10.6	0.0	0.0	0.0	554
301-350	0.0	0.0	0.0	0.0	0.0	0.0	2.7	33.3	56.6	7.3	0.0	0.0	219
351-400	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.4	20.8	66.7	11.1	0.0	72
401-500	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	21.4	78.6	0.0	28
>500	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	92.3	7.7	13

* Levels out of system dynamic range.

Concurrence Analysis by Glucose Trend Arrow

Trend Arrow accuracy of the System, as assessed by concurrence analysis, is presented in **Table 7**. For example, in the clinical study, when the trend arrow indicated that glucose was changing slowly (-1 to 1 mg/dL/min (→)), actual glucose levels in the body were falling quickly (↓) 0.2% of the time, falling (↘) 2.6% of the time, changing slowly (→) 86.6% of the time, rising (↗) 4.2% of the time, and rising quickly (↑) 0.6% of the time.

Table 7: Concurrence Analysis by Glucose Trend Arrow

CGM (mg/dL/min)	YSI (mg/dL/min)							N
	<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2	NA*	
<-2 (↓)	39.9	42.7	8.4	0.7	0.0	0.0	8.4	143
-2 to -1 (↘)	4.7	27.2	56.1	5.5	0.3	0.0	6.2	695
-1 to 1 (→)	0.2	2.6	50.2	36.4	4.2	0.6	5.8	7786
1 to 2 (↗)	0.0	0.6	5.6	43.4	36.3	9.8	4.5	717
>2 (↑)	0.0	0.0	1.6	12.6	37.2	43.3	5.3	247
NA†	0.6	8.3	27.4	37.5	13.1	4.2	8.9	168

* Glucose rate of change not available due to the time difference between glucose readings exceeding 30 minutes.

† Glucose Trend Arrow not available.

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

The System reports glucose concentrations between 40 and 500 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 500 mg/dL, it will report as 'HI'. **Table 8** displays the concurrence between the CGM and YSI reference glucose when CGM reads 'LO'. For example, in the clinical study, when CGM reading was 'LO', YSI glucose values were less than 40 mg/dL 0.0% of the time, equal to or above 40 mg/dL 100.0% of the time, above 50 mg/dL 83.3% of the time, above 60 mg/dL 55.6% of the time, above 70 mg/dL 33.3% of the time, and above 80 mg/dL 22.2% of the time.

Table 8: Concurrence Analysis with 'LO' CGM Reading

	YSI (mg/dL)						N
	<40	≥40	>50	>60	>70	>80	
% of CGM points in YSI range	0.0	100.0	83.3	55.6	33.3	22.2	
Number of CGM points in YSI range	0	18	15	10	6	4	18

Table 9 displays the concurrence between the CGM and YSI reference glucose when CGM reads 'HI'. For example, in the clinical study, when CGM reading was 'HI', YSI glucose values were less than or equal to 200 mg/dL 0% of the time, above 200 mg/dL 100% of the time, above 300 mg/dL 100% of the time, above 400 mg/dL 100% of the time, and above 500 mg/dL 7.7% of the time.

Table 9: Concurrence Analysis with 'HI' CGM Reading

	YSI (mg/dL)					N
	≤200	>200	>300	>400	>500	
% of CGM points in YSI range	0.0	100.0	100.0	100.0	7.7	
Number of CGM points in YSI range	0	13	13	13	1	13

Accuracy by Day of Wear

The Sensor can be worn for up to 14 days. To show Sensor performance over time, the absolute relative difference between the System and reference YSI glucose values over the wear duration is presented in **Table 10**.

Table 10: Difference Measures by Day (YSI Reference)

Day	Number of CGM-Reference Pairs	Median Absolute Relative Difference (%)	Mean Absolute Relative Difference (%)
1	2563	8.3	10.8
6	2545	7.1	8.5
11	2419	7.4	9.3
14	2198	6.6	9.1

The accuracy of CGM versus YSI reference and BG reference was assessed by calculating the percentage of System readings that were within 15%, 20%, 30% and 40% for reference values 80 mg/dL and above, and 15 mg/dL, 20 mg/dL, 30 mg/dL and 40 mg/dL for values below 80 mg/dL. The results for CGM vs. YSI reference are presented in **Table 11**.

Table 11: Number and Percent of Results within YSI Reference

Day	Number of CGM-Reference Pairs	Within ±15% / ±15mg/dL	Within ±20% / ±20mg/dL	Within ±30% / ±30mg/dL	Within ±40% / ±40mg/dL	Outside ±40% / ±40mg/dL
1	2563	78.2	87.0	95.6	98.7	1.3
6	2545	87.0	94.5	99.4	99.8	0.2
11	2419	82.3	90.0	98.2	99.9	0.1
14	2198	83.9	91.3	96.2	99.0	1.0

System Glucose Availability

The System is designed to produce a glucose reading after each user initiated scan that is performed throughout the wear period after the start-up time. **Table 12** shows the number of available glucose readings reported by all Sensors and the expected number based on the total number of scan attempts. Results are shown for Sensors which produced at least one CGM reading during the clinical study over the total wear period. The percentage of available CGM readings is presented in comparison to the number of expected CGM readings. Overall, 99.6% (18,488 CGM readings out of an expected 18,562) were available.

Table 12: CGM Availability

No. CGM	No. Scan	%
18488	18562	99.6

Detection of Hypoglycemic and Hyperglycemic Events

Table 13 shows the accuracy of the System's Glucose Messages in informing the user of low or high glucose events within 15 minutes before or after the true low or high blood glucose value. Percentages are displayed for three different parameters:

- Detection Rate – amount of time the System displays a Glucose Message correctly.
- Missed Detection Rate – amount of time the System did not display a Glucose Message when it should have.
- False Notification Rate – amount of time the System displays a Glucose Message when it shouldn't have.

For example, in the clinical study, the System was able to detect 77.6% of actual low glucose events (detection rate), but 52.5% of the time a Low Glucose message was displayed in error (false notification rate) and 22.4% of the time a Low Glucose message was not displayed when it should have been (missed detection rate).

Table 13: Detection of Hypoglycemic and Hyperglycemic Events

Type of Notification	Notification Status	15 Minute Interval
Notification of Hypoglycemic Events (Low Glucose message)	Detection Rate (%)	77.6
	Missed Detection Rate (%)	22.4
	False Notification Rate (%)	52.5
Notification of Hyperglycemic Events (High Glucose message)	Detection Rate (%)	84.7
	Missed Detection Rate (%)	15.3
	False Notification Rate (%)	10.6
Impending Notification of Hypoglycemic Events (Glucose Going Low message)	Detection Rate (%)	91.6
	Missed Detection Rate (%)	8.4
	False Notification Rate (%)	58.8
Impending Notification of Hyperglycemic Events (Glucose Going High message)	Detection Rate (%)	88.8
	Missed Detection Rate (%)	11.2
	False Notification Rate (%)	15.5

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 14** provides data from two separate Sensors worn on 95 subjects at the same time, providing 15,283 real-time pairs of CGM measurements, with a mean CV of 5.6%.

Table 14: Overall between Sensor Precision

Mean Glucose (mg/dL)	Median CV	Mean CV	Number of Subjects	Number of Paired Readings
164.2	4.2	5.6	95	15283

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, 190 Sensors were evaluated in the clinical study to determine how many days of readings each Sensor provided. Of these 190 Sensors, 136 (71.6%) lasted until the final day of use. 168 Sensors (88.4%) lasted at least 7 days. There were 54 (28.4%) Sensors that failed early, of which 22 (11.6%) failed on or before the seventh day of wear.

Adverse Events

No device related serious adverse events occurred during the study. Mild skin irritations, such as erythema, bruising, bleeding, infection and papule were reported around the insertion site and adhesive area by a small number of subjects (8 out of 95 or 8.4%).

Electromagnetic Compatibility (EMC)

- 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.

Guidance and manufacturer's declaration – electromagnetic emissions

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

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

Guidance and manufacturer's declaration – electromagnetic immunity

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

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

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

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

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

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

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.

[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

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://wayback.archive-it.org/7993/20170111013014/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

[3] American Diabetes Association, Classification and Diagnosis of Diabetes, 2017. Diabetes Care 40(Suppl. 1):S11–S2

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