## Contents

**Important Safety Information** ............................................ 1  
Indications For Use ......................................................... 1  
Contraindications .............................................................. 1  
Warnings .............................................................................. 2  
Cautions and Limitations ..................................................... 3  

**Reader Symbols** .............................................................. 10  

**Getting to Know Your System** ........................................... 12  
Reader Kit ........................................................................... 13  
Sensor Kit ........................................................................... 14  
FreeStyle Libre Software .................................................... 17  

**Setting up Your Reader for the First Time** ........................ 18  

**Using Your Sensor** .......................................................... 21  
Applying Your Sensor .......................................................... 22  
Starting Your Sensor ........................................................... 26  
Checking Your Glucose ........................................................ 27  

**Making Treatment Decisions** ............................................ 33  
Making Treatment Decisions – Getting Started ..................... 34  
Making Treatment Decisions – Advanced ............................. 39
Important Safety Information

Indications For Use

The FreeStyle Libre 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 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.

• Checking Sensor glucose readings with a blood glucose meter: Under the following conditions, Sensor glucose readings may not be accurate and you should conduct a fingerstick test using a blood glucose meter. You should not use Sensor glucose readings 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 FreeStyle Libre System readings
  • During times of rapidly changing glucose (more than 2 mg/dL per minute), when interstitial fluid glucose levels as measured by the Sensor may not accurately reflect blood glucose levels
  • 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.
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.

WARNINGS (cont.)
• Hypoglycemic unawareness: The FreeStyle Libre 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 FreeStyle Libre 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 FreeStyle Libre System contains small parts that may be dangerous if swallowed.

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:
• Take standard precautions for transmission of blood borne pathogens to avoid contamination.
• After the 12 hour start-up period, the Sensor can be worn for up to 10 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 FreeStyle Libre System. Contact your health care professional before continuing to use the FreeStyle Libre 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.
- 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.

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

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

Reader Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>What It Means</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image.png" alt="Icon" /></td>
<td>Sensor may be inaccurate. Check blood glucose with a test strip before making any treatment decisions</td>
</tr>
<tr>
<td><img src="image.png" alt="Icon" /></td>
<td>Active Sensor</td>
</tr>
<tr>
<td><img src="image.png" alt="Icon" /></td>
<td>Direction your glucose is going. See Checking Your Glucose section for more information</td>
</tr>
<tr>
<td><img src="image.png" alt="Icon" /></td>
<td>Caution</td>
</tr>
<tr>
<td><img src="image.png" alt="Icon" /></td>
<td>View previous/next screen</td>
</tr>
<tr>
<td><img src="image.png" alt="Icon" /></td>
<td>Notes</td>
</tr>
<tr>
<td><img src="image.png" alt="Icon" /></td>
<td>Add more information to notes</td>
</tr>
<tr>
<td><img src="image.png" alt="Icon" /></td>
<td>Food note</td>
</tr>
<tr>
<td><img src="image.png" alt="Icon" /></td>
<td>Rapid-acting insulin note</td>
</tr>
<tr>
<td>Symbol</td>
<td>What It Means</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>🕒</td>
<td>Time changed on Reader</td>
</tr>
<tr>
<td>⌚️</td>
<td>Reminders</td>
</tr>
<tr>
<td>⚪️</td>
<td>Blood glucose test</td>
</tr>
<tr>
<td>🛠️</td>
<td>Settings</td>
</tr>
<tr>
<td>🔥</td>
<td>Control solution test result</td>
</tr>
<tr>
<td>⚠️</td>
<td>Low battery</td>
</tr>
<tr>
<td>🚄</td>
<td>Battery charging</td>
</tr>
<tr>
<td>⥣</td>
<td>Sensor too cold</td>
</tr>
<tr>
<td>⏰</td>
<td>Sensor too hot</td>
</tr>
</tbody>
</table>

### Getting to Know Your System

The FreeStyle Libre 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.
- 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 Reader
- USB Cable
- Interactive Tutorial on USB
- Power Adapter
- 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.

Sensor Kit

The Sensor Kit includes:

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

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

Sensor Applicator
Applies the Sensor to your body.

The Sensor measures and stores glucose readings when worn on your body. It initially comes in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. By following the instructions, you prepare and apply the Sensor on the back of your upper arm. The Sensor has a small, flexible tip that is inserted just under the skin. After the 12 hour start-up period, the Sensor can be worn for up to 10 days.

Sensor
Measures your glucose while on your body (only visible after applied).
The Reader Home Screen provides access to information about your glucose and the System. You can press the Home Button to get to the Home Screen.

**Home Screen**

- **Time**: Current time set on the Reader.
- **Battery Level**: Battery charge remaining.
- **Sensor Status**: Information about your current Sensor.
- **Check Glucose**: Touch to check your Sensor glucose.
- **Reminder**: Touch to set or change reminders.
- **Review History**: Touch to review information about your past glucose readings.
- **Settings**: Touch to change the Reader’s settings.

**Sensor Glucose Readings**

- **Message**: Touch for more information.
- **Current Glucose**: Glucose from your latest scan.
- **Glucose Trend Arrow**: Direction your glucose is going.
- **Check Blood Glucose symbol**: Touch for more information.
- **Food Note**: Touch to add notes to the glucose reading.
- **Glucose Graph**: Graph of your current and stored glucose readings.
- **Add Notes**: Touch to add notes to the glucose reading.
- **Rapid-Acting Insulin Note**: Graph of your current and stored glucose readings.
FreeStyle Libre Software

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

INTENDED USE

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

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

Setting up Your Reader for the First Time

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

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Press the Home Button to turn on the Reader.</td>
</tr>
<tr>
<td>2</td>
<td>If prompted, use the touchscreen to select your preferred language for the Reader. Touch OK to continue. &lt;br&gt;Note: Use the pad of your finger. Do NOT use your fingernail or any other object on the screen.</td>
</tr>
<tr>
<td>3</td>
<td>Set the Current Date using the arrows on the touchscreen. Touch next to continue.</td>
</tr>
</tbody>
</table>
### Step 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.

### Step 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 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.

**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

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>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.</td>
</tr>
<tr>
<td>2</td>
<td>Clean application site with an alcohol wipe and allow site to dry before proceeding. This helps the Sensor stay attached to your body. <strong>Note:</strong> The area MUST be clean and dry, or the Sensor may not stick to the site.</td>
</tr>
<tr>
<td>Step</td>
<td>Action</td>
</tr>
<tr>
<td>------</td>
<td>--------</td>
</tr>
<tr>
<td>3</td>
<td><strong>Open the Sensor Pack by peeling the lid off completely. Unscrew the cap from the Sensor Applicator and set the cap aside.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>CAUTION:</strong> 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.</td>
</tr>
<tr>
<td>4</td>
<td>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.</td>
</tr>
<tr>
<td>5</td>
<td>Lift the Sensor Applicator out of the Sensor Pack.</td>
</tr>
<tr>
<td>6</td>
<td>The Sensor Applicator is prepared and ready to apply the Sensor.</td>
</tr>
<tr>
<td></td>
<td><strong>CAUTION:</strong> The Sensor Applicator now contains a needle. Do NOT touch inside the Sensor Applicator or put it back into the Sensor Pack.</td>
</tr>
<tr>
<td>7</td>
<td>Place the Sensor Applicator over the prepared site and push down firmly to apply the Sensor to your body.</td>
</tr>
<tr>
<td></td>
<td><strong>CAUTION:</strong> Do NOT push down on the Sensor Applicator until placed over prepared site to prevent unintended results or injury.</td>
</tr>
</tbody>
</table>
### Step 8

<table>
<thead>
<tr>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gently pull the Sensor Applicator away from your body. The Sensor should now be attached to your skin. <strong>Note:</strong> 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.</td>
</tr>
</tbody>
</table>

### Step 9

<table>
<thead>
<tr>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

### Starting Your Sensor

#### Step 1

<table>
<thead>
<tr>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Press the Home Button to turn on the Reader.</td>
</tr>
</tbody>
</table>

#### Step 2

<table>
<thead>
<tr>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Touch <strong>Start New Sensor.</strong></td>
</tr>
</tbody>
</table>

#### Step 3

<table>
<thead>
<tr>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>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 12 hours. During the 12 hour period, you can scan the Sensor to check its status. <strong>Note:</strong> If the Sensor is not successfully scanned within 15 seconds, the Reader displays a prompt to scan the Sensor again. Touch <strong>OK</strong> to return to the Home Screen and touch <strong>Start New Sensor</strong> to scan your Sensor.</td>
</tr>
</tbody>
</table>
### Checking Your Glucose

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Turn the Reader on by pressing the Home Button or touch Check Glucose from the Home Screen. OR</td>
</tr>
<tr>
<td></td>
<td>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. <strong>Note:</strong> 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.</td>
</tr>
<tr>
<td>3</td>
<td>The Reader displays your current glucose reading along with your glucose graph and an arrow indicating the direction your glucose is going.</td>
</tr>
</tbody>
</table>
**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.

**Check Blood Glucose**
When you see this symbol, do a blood glucose test before making treatment decisions.

**Current Glucose**

**Target Glucose Range**

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.

<table>
<thead>
<tr>
<th>Display</th>
<th>What To Do</th>
</tr>
</thead>
<tbody>
<tr>
<td>LO</td>
<td>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.</td>
</tr>
<tr>
<td>63</td>
<td>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.</td>
</tr>
<tr>
<td>289</td>
<td>If your glucose reading is less than 70 mg/dL, projected to be less than 70 mg/dL, rapidly changing, or there is no number or trend arrow, you will see this symbol . You can touch the symbol for more information. Check your blood glucose on your finger with a test strip before making treatment decisions.</td>
</tr>
</tbody>
</table>

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 FreeStyle Libre System information for making treatment decisions.

**WARNING:** The FreeStyle Libre 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 FreeStyle Libre 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 FreeStyle Libre 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 FreeStyle Libre 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 FreeStyle Libre 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 not 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 \( \text{ tệ} \) symbol. Whenever you see the \( \text{ tệ} \) 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 \( \text{ tệ} \) symbol. Whenever you see the \( \text{ tệ} \) 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 \( \text{ tệ} \) symbol. Whenever you see the \( \text{ tệ} \) 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 \( \text{ tệ} \) 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.

Check Blood Glucose
When you see this symbol, do a blood glucose test before making a treatment decision.

Current Glucose
When you see this symbol, do a blood glucose test before making a treatment decision.

Glucose Trend Arrow
Direction your glucose is going
What it means
↑ Glucose rising quickly
↑ Glucose rising
↑ Glucose changing slowly
↓ Glucose falling slowly
↓ Glucose falling quickly

Glucose Graph
Graph of your current and stored glucose readings

Message

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.

<table>
<thead>
<tr>
<th>Glucose Trend Arrow</th>
<th>Treatment Decision Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Glucose (&lt; 70 mg/dL)</td>
<td>No Arrow or No Number</td>
</tr>
<tr>
<td>Glucose in Target Range</td>
<td>You will see the symbol. Do not treat based on Sensor glucose reading. Do a blood glucose test.</td>
</tr>
<tr>
<td>High Glucose (&gt; 240 mg/dL)</td>
<td>You will see the symbol. Do not treat based on Sensor glucose reading. Do a blood glucose test.</td>
</tr>
</tbody>
</table>

Glucose Trend Arrow

<table>
<thead>
<tr>
<th>Arrow</th>
<th>Treatment Decision Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Glucose (&lt; 70 mg/dL)</td>
<td>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”.</td>
</tr>
<tr>
<td>Glucose in Target Range</td>
<td>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”.</td>
</tr>
<tr>
<td>High Glucose (&gt; 240 mg/dL)</td>
<td>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”.</td>
</tr>
<tr>
<td>Glucose Trend Arrow</td>
<td>Treatment Decision Considerations</td>
</tr>
<tr>
<td>---------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td><strong>Low Glucose</strong> (&lt; 70 mg/dL)</td>
<td>If you are about to eat, take insulin to cover your meal. If this is between meals, do nothing and scan again later.</td>
</tr>
<tr>
<td><strong>Glucose in Target Range</strong></td>
<td>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”.</td>
</tr>
<tr>
<td><strong>High Glucose</strong> (&gt; 240 mg/dL)</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Glucose Trend Arrow</strong></td>
<td>If you are about to eat, take insulin to cover your meal. If this is between meals, do nothing and scan again later.</td>
</tr>
<tr>
<td><strong>Glucose in Target Range</strong></td>
<td>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”.</td>
</tr>
<tr>
<td><strong>High Glucose</strong> (&gt; 240 mg/dL)</td>
<td>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”.</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>What you see</th>
<th>What it means</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>When you wake-up:</strong></td>
<td>When you wake up, your current glucose is 65 mg/dL and the trend arrow shows it is changing slowly. There is also a 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.</td>
</tr>
</tbody>
</table>

**Before breakfast:**

- **What you see**
  - 115 mg/dL

- **What it means**
  - 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:**

- **What you see**
  - 108 mg/dL

- **What it means**
  - After breakfast, your current glucose is 108 mg/dL. The trend arrow shows it is going down quickly. There is also a 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.
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 🗿.

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.

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, 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.

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### 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.

**Logbook**

Entries for each time you scanned your Sensor or performed a blood glucose test. If you entered Notes with a glucose reading, the 📊 symbol appears in that row. For more information about the symbols, see Reader Symbols section.

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

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

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.

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

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
</table>
| 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 10 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.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>From the Home Screen, touch the symbol.</td>
</tr>
<tr>
<td>2</td>
<td>Touch to select which Type of reminder you want to set: Check Glucose, Take Insulin, or Alarm.</td>
</tr>
<tr>
<td>3</td>
<td>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).</td>
</tr>
<tr>
<td>Step</td>
<td>Action</td>
</tr>
<tr>
<td>------</td>
<td>--------</td>
</tr>
<tr>
<td>4</td>
<td>Set the reminder <strong>Time</strong> using the arrows on the touchscreen. Touch <strong>save</strong>.</td>
</tr>
<tr>
<td>5</td>
<td>From the Reminders screen, you can turn the reminder <strong>On/Off</strong> or <strong>add new</strong> reminders. Touch <strong>done</strong> to return to the Home Screen.</td>
</tr>
</tbody>
</table>

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.

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**Using the Reader’s Built-in Meter**

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

**WARNING:** Do NOT use the built-in meter while the Reader is connected to an electrical outlet or a computer due to the potential risk of electrical shock.

**Intended Use**

The FreeStyle Libre 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 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 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.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
</table>
| 1    | Wash your hands with warm soapy water for accurate results. Thoroughly dry your hands. To warm the site, apply a warm dry pad or rub vigorously for a few seconds.  
**Note:** 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. |
| 2    | Check the test strip expiration date. Do not use expired test strips as they may give inaccurate results.  
**CAUTION:** Test on your fingers in accordance with the Intended Use in this section. |
| 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. |
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.

**Important:**
After performing a blood glucose test, wash your hands with soap and water and thoroughly dry them.

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

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

**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.
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. Consult your healthcare professional to determine the range that is appropriate for you.

<table>
<thead>
<tr>
<th>Display</th>
<th>What To Do</th>
</tr>
</thead>
<tbody>
<tr>
<td>LO</td>
<td>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.</td>
</tr>
<tr>
<td>HI</td>
<td>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.</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>From the Home Screen, touch the Settings symbol (\text{Settings}). Touch Control Solution Test to do a control solution test.</td>
</tr>
<tr>
<td>2</td>
<td>Check the test strip expiration date.</td>
</tr>
<tr>
<td>3</td>
<td>Open the foil test strip packet at the notch and tear down to remove the test strip.</td>
</tr>
<tr>
<td>Step</td>
<td>Action</td>
</tr>
<tr>
<td>------</td>
<td>--------</td>
</tr>
<tr>
<td>4</td>
<td>Insert the test strip with the three black lines facing up. Push the strip until it stops. <strong>Note:</strong> 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.</td>
</tr>
</tbody>
</table>
| 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. |

**Note:** 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.
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.

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

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

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

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

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>To get to the Settings menu, touch the Settings symbol 🛠 on the Home Screen.</td>
</tr>
</tbody>
</table>

**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 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**

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
</table>
| 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 FreeStyle Libre System**

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

<table>
<thead>
<tr>
<th>Activity</th>
<th>What You Need To Know</th>
</tr>
</thead>
</table>
| **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. |
<p>| <strong>Sleeping</strong> | 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. |</p>
<table>
<thead>
<tr>
<th>Activity</th>
<th>What You Need To Know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traveling by Air</td>
<td>You can safely use your System at all times while on an aircraft.</td>
</tr>
<tr>
<td></td>
<td>• 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.</td>
</tr>
<tr>
<td></td>
<td>• 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.</td>
</tr>
<tr>
<td></td>
<td>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 &amp; Date. Changing the time and date affects the graphs and statistics. The clock 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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Activity</th>
<th>What You Need To Know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traveling by Air (cont.)</td>
<td>• 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 &amp; Date. Changing the time and date affects the graphs and statistics. The clock 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.</td>
</tr>
</tbody>
</table>
**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.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Turn off the Reader before you clean and disinfect it.</td>
</tr>
<tr>
<td>2</td>
<td>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.</td>
</tr>
<tr>
<td>3</td>
<td>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.</td>
</tr>
<tr>
<td>4</td>
<td>Dry with clean paper towel to remove any residual moisture.</td>
</tr>
<tr>
<td>5</td>
<td>When finished, thoroughly wash your hands with soap and water.</td>
</tr>
</tbody>
</table>
IMPORTANT: If you require assistance or if you notice any signs of deterioration on the Reader (such as clouding or crazing on the display of the Reader, corroding or eroding of the plastic housing, or cracking of plastic housing or display) or if the Reader does not turn on, discontinue use of the Reader and contact Customer Service at 1-855-632-8658.

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

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

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

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

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

Reader Does Not Power On

<table>
<thead>
<tr>
<th>Problem</th>
<th>What It May Mean</th>
<th>What To Do</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reader does not power on after you press the Home Button or insert a test strip.</td>
<td>Reader battery is too low.</td>
<td>Charge the Reader.</td>
</tr>
<tr>
<td></td>
<td>Reader is outside of its operating temperature range.</td>
<td>Move the Reader to a temperature between 50 °F and 113 °F and then try to power it on.</td>
</tr>
</tbody>
</table>

If the Reader still does not power on after trying these steps, contact Customer Service.
### Problems at the Sensor Application Site

<table>
<thead>
<tr>
<th>Problem</th>
<th>What It May Mean</th>
<th>What To Do</th>
</tr>
</thead>
</table>
| 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

<table>
<thead>
<tr>
<th>Display</th>
<th>What It May Mean</th>
<th>What To Do</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Sensor Starting Up</td>
<td>Sensor is not ready to read glucose.</td>
<td>Wait until the 12 hour Sensor start-up period has completed.</td>
</tr>
<tr>
<td>Scan Timeout</td>
<td>The Reader is not held close enough to the Sensor.</td>
<td>Hold the Reader within 1.5 inches (4 cm) of the Sensor. Bring the screen of the Reader close to the Sensor.</td>
</tr>
<tr>
<td>Sensor Ended</td>
<td>The Sensor life has ended.</td>
<td>Apply and start a new Sensor.</td>
</tr>
<tr>
<td>Display</td>
<td>What It May Mean</td>
<td>What To Do</td>
</tr>
<tr>
<td>-------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>New Sensor Found</td>
<td>You scanned a new Sensor before your previous Sensor ended.</td>
<td>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”.</td>
</tr>
<tr>
<td>Scan Error</td>
<td>The Reader was unable to communicate with the Sensor.</td>
<td>Try scanning again. <strong>Note:</strong> You may need to move away from potential sources of electromagnetic interference.</td>
</tr>
<tr>
<td>Sensor Error</td>
<td>The System is unable to provide a glucose reading.</td>
<td>Scan again in 10 minutes.</td>
</tr>
<tr>
<td>Glucose Reading Unavailable</td>
<td>Your Sensor is too hot or too cold.</td>
<td>Move to a location where the temperature is appropriate and scan again in a few minutes.</td>
</tr>
<tr>
<td>Sensor Already in Use</td>
<td>The Sensor was started by another Reader.</td>
<td>A Sensor can only be scanned by the Reader that started it. Scan the Sensor again with the Reader that started it. Or, apply and start a new Sensor.</td>
</tr>
<tr>
<td>Check Sensor</td>
<td>The Sensor tip may not be under your skin.</td>
<td>Try to start your Sensor again. If Reader displays “Check Sensor” again, your Sensor was not applied properly. Apply and start a new Sensor.</td>
</tr>
<tr>
<td>Replace Sensor</td>
<td>The System has detected a problem with your Sensor.</td>
<td>Apply and start a new Sensor.</td>
</tr>
</tbody>
</table>
### Blood Glucose Error Messages

<table>
<thead>
<tr>
<th>Error Message</th>
<th>What It May Mean</th>
<th>What To Do</th>
</tr>
</thead>
</table>
| 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. |
| 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. |
<table>
<thead>
<tr>
<th>Error Message</th>
<th>What It May Mean</th>
<th>What To Do</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-5</td>
<td>Blood was applied to the test strip too soon.</td>
<td>1. Review the testing instructions. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Service.</td>
</tr>
<tr>
<td>E-6</td>
<td>The test strip may not be compatible with the Reader.</td>
<td>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.</td>
</tr>
<tr>
<td>E-7</td>
<td>Test strip may be damaged, used, or the Reader does not recognize it.</td>
<td>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.</td>
</tr>
<tr>
<td>E-9</td>
<td>Reader error.</td>
<td>1. Turn off the Reader. 2. Repeat the test using a new test strip. 3. If the error reappears, contact Customer Service.</td>
</tr>
</tbody>
</table>
## Problems Checking Your Blood Glucose

<table>
<thead>
<tr>
<th>Problem</th>
<th>What It May Mean</th>
<th>What To Do</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Reader does not start a test after inserting a test strip.</td>
<td>Test strip is not inserted correctly or not inserted fully into the strip port.</td>
<td>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.</td>
</tr>
<tr>
<td>Reader battery is too low.</td>
<td></td>
<td>Charge the Reader.</td>
</tr>
<tr>
<td>The test strip is damaged, used, or unrecognizable by the Reader.</td>
<td></td>
<td>Insert a new FreeStyle Precision Neo test strip.</td>
</tr>
<tr>
<td>Reader is outside of its operating temperature range.</td>
<td></td>
<td>Move the Reader to a temperature between 50 °F and 113 °F and then try to power it on.</td>
</tr>
<tr>
<td>Reader is in a power saving mode.</td>
<td></td>
<td>Press the Home Button then insert a test strip.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Problem</th>
<th>What It May Mean</th>
<th>What To Do</th>
</tr>
</thead>
<tbody>
<tr>
<td>The test does not start after applying the blood sample.</td>
<td>Blood sample is too small.</td>
<td>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.</td>
</tr>
<tr>
<td>Sample applied after the Reader turned off.</td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>Problem with Reader or test strip.</td>
<td></td>
<td>1. Repeat the test using a new test strip. 2. If the test still does not start, contact Customer Service.</td>
</tr>
</tbody>
</table>
Perform a Reader Test

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

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

Customer Service

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

System Specifications

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

Sensor Specifications

<table>
<thead>
<tr>
<th>Sensor glucose assay method</th>
<th>Amperometric electrochemical sensor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensor glucose reading range</td>
<td>40 to 500 mg/dL</td>
</tr>
<tr>
<td>Sensor size</td>
<td>5 mm height and 35 mm diameter</td>
</tr>
<tr>
<td>Sensor weight</td>
<td>5 grams</td>
</tr>
<tr>
<td>Sensor power source</td>
<td>One silver oxide battery</td>
</tr>
</tbody>
</table>
### Sensor data
- **Up to 10 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

<table>
<thead>
<tr>
<th>Blood glucose assay range</th>
<th>20 to 500 mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reader size</td>
<td>95 mm x 60 mm x 16 mm</td>
</tr>
<tr>
<td>Reader weight</td>
<td>65 grams</td>
</tr>
<tr>
<td>Reader power source</td>
<td>One lithium-ion rechargeable battery</td>
</tr>
<tr>
<td>Reader battery life</td>
<td>7 days of typical use</td>
</tr>
<tr>
<td>Reader memory</td>
<td>90 days of typical use</td>
</tr>
<tr>
<td>Reader operating temperature</td>
<td>50 °F to 113 °F</td>
</tr>
<tr>
<td>Reader storage temperature</td>
<td>-4 °F to 140 °F</td>
</tr>
<tr>
<td>Operating and storage relative humidity</td>
<td>10-90%, non-condensing</td>
</tr>
<tr>
<td><strong>Reader moisture protection</strong></td>
<td>Keep dry</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td><strong>Operating and storage altitude</strong></td>
<td>-1,250 ft (-381 meters) to 10,000 ft (3,048 meters)</td>
</tr>
<tr>
<td><strong>Reader display timeout</strong></td>
<td>60 seconds (120 seconds when test strip is inserted)</td>
</tr>
<tr>
<td><strong>Radio Frequency</strong></td>
<td>Near Field Communication* (13.56 MHz RFID); ASK Modulation; 124 dBuV/m; 1.5 inch communication range</td>
</tr>
<tr>
<td><strong>Data port</strong></td>
<td>Micro USB</td>
</tr>
<tr>
<td><strong>Minimum Computer Requirements</strong></td>
<td>System must only be used with EN60950-1 rated computers</td>
</tr>
<tr>
<td><strong>Mean use life</strong></td>
<td>3 years of typical use</td>
</tr>
<tr>
<td><strong>Reader cleaning and disinfection</strong></td>
<td>The Reader has a mean use life of 3 years, which is 156 cleaning and disinfection cycles (1 cycle per week for 3 years).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Power Adapter</strong></th>
<th>Abbott Diabetes Care PRT25611</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operating temperature</strong></td>
<td>50 °F to 104 °F</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>USB Cable</strong></th>
<th>Abbott Diabetes Care PRT21373</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Length</strong></td>
<td>37 inches (94 cm)</td>
</tr>
</tbody>
</table>

* 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 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
- Catalog number
- Manufacturer
- Serial number
- Batch code
- Keep dry
- Type BF applied part
- Non-ionizing radiation
- Sensor code
- Caution
- Do not re-use
- Sterilized using irradiation
- MR unsafe
- Humidity limitation
- FCC Declaration of Conformity mark
- Do not use if package is damaged
- Not made with natural rubber latex

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 Flash Glucose Monitoring System (the System) was evaluated in a clinical study. The study was conducted at 4 centers with a total of 48 subjects with diabetes (95.8% Type 1, 4.2% Type 2). Subjects in the study required insulin to manage their diabetes. Each subject wore up to two FreeStyle Libre 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 FreeStyle Libre reader. Additionally, subjects had their venous blood glucose analyzed up to 128 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 FreeStyle Libre 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. The results are presented in Table 1 for YSI reference. Overall 91.0% of results were within ±20 mg/dL / 20% of YSI reference.

<table>
<thead>
<tr>
<th>CGM Glucose Level (mg/dL)</th>
<th>Number of CGM-Reference Pairs</th>
<th>Within ±15% / ±15mg/dL</th>
<th>Within ±20% / ±20mg/dL</th>
<th>Within ±30% / ±30mg/dL</th>
<th>Within ±40% / ±40mg/dL</th>
<th>Outside ±40% / ±40mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>5772</td>
<td>82.1</td>
<td>91.0</td>
<td>97.8</td>
<td>99.3</td>
<td>0.7</td>
</tr>
<tr>
<td>40-50</td>
<td>38</td>
<td>44.7</td>
<td>57.9</td>
<td>81.6</td>
<td>94.7</td>
<td>5.3</td>
</tr>
<tr>
<td>51-80</td>
<td>461</td>
<td>72.2</td>
<td>81.1</td>
<td>92.0</td>
<td>97.6</td>
<td>2.4</td>
</tr>
<tr>
<td>81-180</td>
<td>3236</td>
<td>82.9</td>
<td>91.2</td>
<td>97.9</td>
<td>99.3</td>
<td>0.7</td>
</tr>
<tr>
<td>181-300</td>
<td>1799</td>
<td>84.9</td>
<td>93.6</td>
<td>99.2</td>
<td>99.7</td>
<td>0.3</td>
</tr>
<tr>
<td>301-400</td>
<td>226</td>
<td>77.0</td>
<td>95.1</td>
<td>99.6</td>
<td>99.6</td>
<td>0.4</td>
</tr>
<tr>
<td>401-500</td>
<td>12</td>
<td>58.3</td>
<td>75.0</td>
<td>100.0</td>
<td>100.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>
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 above 80 mg/dL, 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

<table>
<thead>
<tr>
<th>Time Interval (hours)</th>
<th>Number of CGM-Reference Pairs</th>
<th>Within ±15% / ±15mg/dL</th>
<th>Within ±20% / ±20mg/dL</th>
<th>Within ±30% / ±30mg/dL</th>
<th>Within ±40% / ±40mg/dL</th>
<th>Outside ±40% / ±40mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>(0-2)</td>
<td>81</td>
<td>69.1</td>
<td>87.7</td>
<td>100.0</td>
<td>100.0</td>
<td>0.0</td>
</tr>
<tr>
<td>(2-4)</td>
<td>318</td>
<td>73.9</td>
<td>84.6</td>
<td>97.2</td>
<td>99.7</td>
<td>0.3</td>
</tr>
<tr>
<td>(4-6)</td>
<td>374</td>
<td>76.7</td>
<td>88.0</td>
<td>97.3</td>
<td>99.7</td>
<td>0.3</td>
</tr>
<tr>
<td>(6-8)</td>
<td>369</td>
<td>79.9</td>
<td>90.8</td>
<td>99.2</td>
<td>100.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

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 9.7% for the comparison with YSI reference. The Median Absolute Relative Difference shows that half of the time the System was within 7.7% of the YSI reference. Overall 84.3% of results were within ±20 mg/dL / 20% of YSI values.

### Table 3: Difference Measures with YSI Reference

<table>
<thead>
<tr>
<th>Number of CGM-Reference Pairs</th>
<th>Median Absolute Relative Difference</th>
<th>Mean Absolute Relative Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>5772</td>
<td>7.7%</td>
<td>9.7%</td>
</tr>
</tbody>
</table>

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 values above 80 mg/dL, 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.

### Table 4: Difference Measures with YSI Reference

<table>
<thead>
<tr>
<th>Mean Absolute Relative Difference</th>
<th>7%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>84.3%</td>
</tr>
</tbody>
</table>
Table 4: Number and Percent of Results within BG Values*

<table>
<thead>
<tr>
<th>CGM Glucose Level (mg/dL)</th>
<th>Number of CGM-Reference Pairs</th>
<th>Within ±15% / ±15mg/dL</th>
<th>Within ±20% / ±20mg/dL</th>
<th>Within ±30% / ±30mg/dL</th>
<th>Within ±40% / ±40mg/dL</th>
<th>Outside ±40% / ±40mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>3680</td>
<td>72.8</td>
<td>84.3</td>
<td>95.0</td>
<td>98.0</td>
<td>2.0</td>
</tr>
<tr>
<td>40-50</td>
<td>23</td>
<td>47.8</td>
<td>73.9</td>
<td>87.0</td>
<td>95.7</td>
<td>4.3</td>
</tr>
<tr>
<td>51-80</td>
<td>288</td>
<td>65.6</td>
<td>77.1</td>
<td>89.6</td>
<td>97.6</td>
<td>2.4</td>
</tr>
<tr>
<td>81-180</td>
<td>1722</td>
<td>71.7</td>
<td>82.9</td>
<td>94.7</td>
<td>97.4</td>
<td>2.6</td>
</tr>
<tr>
<td>181-300</td>
<td>1193</td>
<td>75.0</td>
<td>87.3</td>
<td>96.2</td>
<td>98.4</td>
<td>1.6</td>
</tr>
<tr>
<td>301-400</td>
<td>362</td>
<td>76.8</td>
<td>87.8</td>
<td>97.2</td>
<td>99.2</td>
<td>0.8</td>
</tr>
<tr>
<td>401-500</td>
<td>92</td>
<td>78.3</td>
<td>85.9</td>
<td>95.7</td>
<td>98.9</td>
<td>1.1</td>
</tr>
</tbody>
</table>

* Comparison to BG was performed using the FreeStyle Libre 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 glucose 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 12.1% for the comparison with BG value. The Median Absolute Relative Difference shows that half of the time the System was within 9.4% of the BG value.

Table 5: Difference Measures with BG Value *

<table>
<thead>
<tr>
<th>Number of CGM-Reference Pairs</th>
<th>Median Absolute Relative Difference</th>
<th>Mean Absolute Relative Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>3680</td>
<td>9.4%</td>
<td>12.1%</td>
</tr>
</tbody>
</table>

* Comparison to BG was performed using the FreeStyle Libre 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 0.2% of the time, between 61 and 80 mg/dL 5.6% of the time, between 81 and 120 mg/dL 75.9% of the time, between 121 and 160 mg/dL 17.6% of the time, between 161 and 200 mg/dL 0.6% 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

<table>
<thead>
<tr>
<th>CGM (mg/dL)</th>
<th>YSI Glucose Level (mg/dL)</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;40</td>
<td>&lt;40</td>
<td>21</td>
</tr>
<tr>
<td>40-60</td>
<td>40-60</td>
<td>143</td>
</tr>
<tr>
<td>61-80</td>
<td>61-80</td>
<td>356</td>
</tr>
<tr>
<td>81-120</td>
<td>81-120</td>
<td>1223</td>
</tr>
<tr>
<td>121-160</td>
<td>121-160</td>
<td>1435</td>
</tr>
<tr>
<td>161-200</td>
<td>161-200</td>
<td>1087</td>
</tr>
<tr>
<td>201-250</td>
<td>201-250</td>
<td>905</td>
</tr>
<tr>
<td>251-300</td>
<td>251-300</td>
<td>386</td>
</tr>
<tr>
<td>301-350</td>
<td>301-350</td>
<td>170</td>
</tr>
<tr>
<td>351-400</td>
<td>351-400</td>
<td>56</td>
</tr>
<tr>
<td>401-500</td>
<td>401-500</td>
<td>12</td>
</tr>
<tr>
<td>&gt;500</td>
<td>&gt;500</td>
<td>0</td>
</tr>
</tbody>
</table>

* 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 ( ) 0.3% of the time, falling ( ) 3.7% of the time, changing slowly ( ) 83.0% of the time, rising ( ) 3.9% of the time, and rising quickly ( ) 0.5% of the time.

Table 7: Concurrence Analysis by Glucose Trend Arrow

<table>
<thead>
<tr>
<th>CGM (mg/dL/min)</th>
<th>YSI (mg/dL/min)</th>
<th>&lt; -2</th>
<th>[-2, -1]</th>
<th>[-1, 0]</th>
<th>[0, 1]</th>
<th>[1, 2]</th>
<th>&gt; 2</th>
<th>N</th>
<th>N*</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; -2 ( )</td>
<td></td>
<td>26.3</td>
<td>45.5</td>
<td>10.3</td>
<td>1.3</td>
<td>0.0</td>
<td>0.0</td>
<td>16.7</td>
<td>156</td>
</tr>
<tr>
<td>-2 to -1 ( )</td>
<td></td>
<td>4.3</td>
<td>27.0</td>
<td>54.6</td>
<td>3.8</td>
<td>0.6</td>
<td>0.0</td>
<td>9.7</td>
<td>652</td>
</tr>
<tr>
<td>-1 to 1 ( )</td>
<td></td>
<td>0.3</td>
<td>3.7</td>
<td>49.4</td>
<td>33.6</td>
<td>3.9</td>
<td>0.5</td>
<td>8.6</td>
<td>4175</td>
</tr>
<tr>
<td>1 to 2 ( )</td>
<td></td>
<td>0.0</td>
<td>0.6</td>
<td>8.8</td>
<td>38.6</td>
<td>33.3</td>
<td>9.2</td>
<td>9.4</td>
<td>477</td>
</tr>
<tr>
<td>&gt; 2 ( )</td>
<td></td>
<td>0.0</td>
<td>0.0</td>
<td>2.8</td>
<td>14.6</td>
<td>34.9</td>
<td>40.6</td>
<td>7.1</td>
<td>212</td>
</tr>
<tr>
<td>NA†</td>
<td></td>
<td>2.5</td>
<td>9.1</td>
<td>33.1</td>
<td>20.7</td>
<td>14.0</td>
<td>9.1</td>
<td>11.6</td>
<td>121</td>
</tr>
</tbody>
</table>

* Glucose rate of change not available due to the time difference between glucose readings exceeding 10 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’. No measurements were obtained above 500 mg/dL in the clinical study. 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, above 40 mg/dL 100.0% of the time, above 50 mg/dL 95.2% of the time, above 60 mg/dL 80.9% of the time, above 70 mg/dL 42.8% of the time, and above 80 mg/dL 19.0% of the time.

Table 8: Concurrence Analysis with ‘LO’ CGM Reading

<table>
<thead>
<tr>
<th>YSI (mg/dL)</th>
<th>&lt; 40</th>
<th>&gt; 40</th>
<th>&gt; 50</th>
<th>&gt; 60</th>
<th>&gt; 70</th>
<th>&gt; 80</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of CGM points in YSI range</td>
<td>0.0</td>
<td>100.0</td>
<td>95.2</td>
<td>80.9</td>
<td>42.8</td>
<td>19.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Number of CGM points in YSI range</td>
<td>0</td>
<td>21</td>
<td>20</td>
<td>17</td>
<td>9</td>
<td>4</td>
<td>21</td>
</tr>
</tbody>
</table>
Accuracy by Day of Wear

After the 12 hour start-up period, the sensor can be worn for up to 10 days. To show sensor performance over time, the absolute relative difference between the System and reference YSI glucose values over the wear is presented in Table 9.

Table 9: Difference Measures by Day (YSI Reference)

<table>
<thead>
<tr>
<th>Day</th>
<th>Number of CGM-Reference Pairs</th>
<th>Median Absolute Relative Difference (%)</th>
<th>Mean Absolute Relative Difference (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1497</td>
<td>8.7</td>
<td>10.7</td>
</tr>
<tr>
<td>4</td>
<td>1470</td>
<td>7.4</td>
<td>9.6</td>
</tr>
<tr>
<td>7</td>
<td>1394</td>
<td>7.4</td>
<td>9.1</td>
</tr>
<tr>
<td>10</td>
<td>1411</td>
<td>7.5</td>
<td>9.3</td>
</tr>
</tbody>
</table>

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 10.

Table 10: Number and Percent of Results within YSI Reference

<table>
<thead>
<tr>
<th>Day</th>
<th>Number of CGM-Reference Pairs</th>
<th>Within ±15% / ±15mg/dL</th>
<th>Within ±20% / ±20mg/dL</th>
<th>Within ±30% / ±30mg/dL</th>
<th>Within ±40% / ±40mg/dL</th>
<th>Outside ±40% / ±40mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1497</td>
<td>76.2</td>
<td>87.4</td>
<td>97.9</td>
<td>99.5</td>
<td>0.5</td>
</tr>
<tr>
<td>4</td>
<td>1470</td>
<td>82.3</td>
<td>91.4</td>
<td>97.6</td>
<td>99.3</td>
<td>0.7</td>
</tr>
<tr>
<td>7</td>
<td>1394</td>
<td>85.0</td>
<td>93.5</td>
<td>98.6</td>
<td>99.1</td>
<td>0.7</td>
</tr>
<tr>
<td>10</td>
<td>1411</td>
<td>85.3</td>
<td>92.3</td>
<td>97.9</td>
<td>99.4</td>
<td>0.6</td>
</tr>
</tbody>
</table>
System Glucose Availability
The System is designed to produce a glucose reading after each user initiated scan that is performed after the start-up time, through the wear period. Table 11 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, 99.5% of CGM readings (9,228 CGM readings out of an expected 9,272) were available.

Table 11: CGM Availability

<table>
<thead>
<tr>
<th>No. CGM</th>
<th>No. Scan</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>9228</td>
<td>9272</td>
<td>99.5</td>
</tr>
</tbody>
</table>

Detection of Hypoglycemic and Hyperglycemic Events
Table 12 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 85.4% of actual low glucose events (detection rate), but 39.9% of the time a Low Glucose message was displayed in error (false notification rate) and 14.6% of the time a Low Glucose message was not displayed when it should have been (missed detection rate).
Table 12: Detection of Hypoglycemic and Hyperglycemic Events

<table>
<thead>
<tr>
<th>Type of Notification</th>
<th>Notification Status</th>
<th>15 Minute Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notification of Hypoglycemic Events (Low Glucose message)</td>
<td>Detection Rate (%)</td>
<td>85.4</td>
</tr>
<tr>
<td></td>
<td>Missed Detection Rate (%)</td>
<td>14.6</td>
</tr>
<tr>
<td></td>
<td>False Notification Rate (%)</td>
<td>39.9</td>
</tr>
<tr>
<td>Notification of Hyperglycemic Events (High Glucose message)</td>
<td>Detection Rate (%)</td>
<td>95.1</td>
</tr>
<tr>
<td></td>
<td>Missed Detection Rate (%)</td>
<td>4.9</td>
</tr>
<tr>
<td></td>
<td>False Notification Rate (%)</td>
<td>22.1</td>
</tr>
<tr>
<td>Impending Notification of Hypoglycemic Events (Glucose Going Low message)</td>
<td>Detection Rate (%)</td>
<td>95.0</td>
</tr>
<tr>
<td></td>
<td>Missed Detection Rate (%)</td>
<td>5.0</td>
</tr>
<tr>
<td></td>
<td>False Notification Rate (%)</td>
<td>46.8</td>
</tr>
<tr>
<td>Impending Notification of Hyperglycemic Events (Glucose Going High message)</td>
<td>Detection Rate (%)</td>
<td>97.2</td>
</tr>
<tr>
<td></td>
<td>Missed Detection Rate (%)</td>
<td>2.8</td>
</tr>
<tr>
<td></td>
<td>False Notification Rate (%)</td>
<td>28.4</td>
</tr>
</tbody>
</table>

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 13 provides data from two separate sensors worn on 47 subjects at the same time, providing 7,319 real-time pairs of CGM measurements, with a mean CV of 6.0%.

Table 13: Overall between Sensor Precision

<table>
<thead>
<tr>
<th>Mean Glucose (mg/dL)</th>
<th>Median CV</th>
<th>Mean CV</th>
<th>Number of Subjects</th>
<th>Number of Paired Readings</th>
</tr>
</thead>
<tbody>
<tr>
<td>175.3</td>
<td>4.6</td>
<td>6.0</td>
<td>47</td>
<td>7319</td>
</tr>
</tbody>
</table>

Sensor Wear Duration

After the 12 hour start-up period, the Sensor can be worn for up to 10 days. To estimate how long a Sensor will work over the wear duration, 97 Sensors were evaluated in the clinical study to determine how many days of readings each Sensor provided. Of these 97 sensors, 75 (77.3%) lasted until the final day of use. 84 sensors (86.6%) lasted more than 5 days. There were 22 (22.7%) sensors that failed early, of which 11 (11.3%) failed on or before the fifth day of wear.

Adverse Events

No device related serious adverse events occurred during the study. Mild skin irritations, such as erythema, edema, rash, bleeding, itching, induration, and infection were reported around the insertion site and adhesive area by a moderate frequency of subjects (5 out of 48 or 10.4%). Pain was mostly reported as none with only one instance of mild pain.
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.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>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.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
<td>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.</td>
</tr>
<tr>
<td>Voltage fluctuations / Flicker emissions IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

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.
### 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.

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

### IMMUNITY test

<table>
<thead>
<tr>
<th>IMMUNITY test</th>
<th>IEC 60601 test level</th>
<th>Compliance Level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>Mains power quality should be that of a typical domestic, commercial, or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>&lt;5 % U&lt;sub&gt;1&lt;/sub&gt; (&gt;95 % dip in U&lt;sub&gt;1&lt;/sub&gt;) for 0.5 cycle 40 % U&lt;sub&gt;1&lt;/sub&gt; (60 % dip in U&lt;sub&gt;1&lt;/sub&gt;) for 5 cycles 70 % U&lt;sub&gt;1&lt;/sub&gt; (30 % dip in U&lt;sub&gt;1&lt;/sub&gt;) for 25 cycles &lt;5 % U&lt;sub&gt;1&lt;/sub&gt; (&gt;95 % dip in U&lt;sub&gt;1&lt;/sub&gt;) for 5 seconds</td>
<td>&lt;5 % U&lt;sub&gt;1&lt;/sub&gt; (&gt;95 % dip in U&lt;sub&gt;1&lt;/sub&gt;) for 0.5 cycle 40 % U&lt;sub&gt;1&lt;/sub&gt; (60 % dip in U&lt;sub&gt;1&lt;/sub&gt;) for 5 cycles 70 % U&lt;sub&gt;1&lt;/sub&gt; (30 % dip in U&lt;sub&gt;1&lt;/sub&gt;) for 25 cycles &lt;5 % U&lt;sub&gt;1&lt;/sub&gt; (&gt;95 % dip in U&lt;sub&gt;1&lt;/sub&gt;) for 5 seconds</td>
<td>Mains power quality should be that of a typical domestic, commercial, or hospital environment.</td>
</tr>
</tbody>
</table>
### Electromagnetic environment – guidance

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

**NOTE**: UT is the a.c. mains voltage prior to application of the test level.

<table>
<thead>
<tr>
<th>IMMUNITY test</th>
<th>IEC 60601 test level</th>
<th>Compliance Level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
</table>
| Conducted RF IEC 61000-4-6 | 6 Vrms | 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: 

\[
d = 1.2 \sqrt{F}
\]
**IMMUNITY**

<table>
<thead>
<tr>
<th>IMMUNITY test</th>
<th>IEC 60601 test level</th>
<th>Compliance Level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiated RF</td>
<td>10 V/m 80 MHz to 2.7 GHz</td>
<td>10 V/m</td>
<td>Recommended separation distance</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = 1.2 \sqrt{P}$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$d = 2.3 \sqrt{P}$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>800 MHz to 2.5 GHz</td>
</tr>
</tbody>
</table>

*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, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol: ![Interference Symbol](image)

**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.

---

* 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.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>$d = 1.2 \sqrt{P}$</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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.
Limited Warranty

We hope that you are happy with your FreeStyle Libre system. Please refer to the User’s Manual before using your Reader for the first time.

Abbott Diabetes Care (“Abbott”) warrants that the FreeStyle Libre reader (“Reader”) shall be free from defects in material and workmanship for a period of one (1) year from the date of manufacture or one (1) year from the original date of purchase with proof of purchase (whichever is later). This Limited Warranty is invalid if the Reader is modified, altered, damaged, misused or used other than in accordance with the User’s Manual, applicable labeling, and/or inserts. Abbott’s sole obligation is to replace the Reader, free of charge, with the same or an alternative reader as determined by Abbott in its sole discretion. Your replacement may be a different model or type. Abbott may require, as a condition of obtaining limited warranty service, that you return the Reader postage prepaid, with proof of purchase to an address specified by Abbott. The Limited Warranty on the replacement Reader will expire on the date of the original Limited Warranty expiration or 90 days after the shipment of a replacement Reader, whichever period is longer. This Limited Warranty covers only the Reader, does not cover the sensor or disposable accessories, extends only to the original purchaser, and is not assignable or transferable.

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Your Rights Under State Law: This Limited Warranty gives you specific legal rights, and you may also have other rights that vary from state to state.

FreeStyle, Libre and related brand marks are trademarks of Abbott Diabetes Care Inc. in various jurisdictions.

LIMITED WARRANTY SERVICES
For questions or warranty service, contact Customer Service at 1-855-632-8658.

ABBOTT MAY MODIFY OR DISCONTINUE THIS PROGRAM AT ANY TIME WITHOUT NOTICE.

References:
FLASH GLUCOSE MONITORING SYSTEM

IMPORTANT USER INFORMATION

• 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.

• Talk to your health care professional about how you should use your Sensor glucose information to help manage your diabetes.
**INDICATIONS FOR USE**

The FreeStyle Libre 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.

**What you need to understand in the Indications For Use:**

You can use the FreeStyle Libre System if you're 18 or older.

**IMPORTANT:**

- After you scan the Sensor, consider all the information on your screen before deciding what to do or what treatment decision to make.
- Don't take a correction dose within 2 hours of your meal dose. This may result in “insulin stacking” and low glucose.

**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 be inaccurate. 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.

- **Do a blood glucose test** 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.

**WARNING:**

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.
CONTRAINDICATIONS:

MRI/CT/Diathermy: The FreeStyle Libre 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.
- Checking Sensor glucose readings with a blood glucose meter: Under the following conditions, Sensor glucose readings may not be accurate and you should conduct a fingerstick test using a blood glucose meter. You should not use Sensor glucose readings 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 FreeStyle Libre System readings
  - During times of rapidly changing glucose (more than 2 mg/dL per minute), when interstitial fluid glucose levels as measured by the Sensor may not accurately reflect blood glucose levels
  - 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.
- Hypoglycemic unawareness: The FreeStyle Libre 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 FreeStyle Libre 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 FreeStyle Libre 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:

- After the 12 hour start-up period, the Sensor can be worn for up to 10 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 FreeStyle Libre System. Contact your health care professional before continuing to use the FreeStyle Libre 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.
- 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.

⚠️ 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 methylldopa (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 Flash Glucose Monitoring System 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 of the User’s Manual for additional important information on the use of the Reader’s built-in meter.

⚠️ Where to charge your Reader:
• Be sure to select a location for charging that allows the power adapter to be easily unplugged. Do NOT block access to the charger due to the potential risk of electrical shock.
Using Sensor Glucose Readings for Treatment Decisions

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

**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.

---

### Example Scenarios

Here are some example scenarios to help you understand how to use the information on your screen. If you are not sure about what to do, consult your health care professional.

<table>
<thead>
<tr>
<th>When you wake-up:</th>
<th>What it means</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Grocery Graph" /></td>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Before breakfast:</th>
<th>What it means</th>
</tr>
</thead>
</table>
| ![Grocery Graph](image) | 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? |

<table>
<thead>
<tr>
<th>After breakfast:</th>
<th>What it means</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Grocery Graph" /></td>
<td>After breakfast, your current glucose is 108 mg/dL. The trend arrow shows it is going down quickly. There is also a 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.</td>
</tr>
<tr>
<td>Time</td>
<td>Glucose Level</td>
</tr>
<tr>
<td>------</td>
<td>--------------</td>
</tr>
<tr>
<td><strong>Before lunch:</strong></td>
<td></td>
</tr>
<tr>
<td>12:00pm</td>
<td>90 mg/dL</td>
</tr>
</tbody>
</table>
| 90 minutes later | 225 mg/dL | 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 \( \uparrow \). **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. |
| **After exercising:** | | |
| 5:47pm | 204 mg/dL | 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 \( \text{A} \) symbol will **NOT** appear in this situation. |
| **Before dinner:** | | |
| 7:34pm | 134 mg/dL | Before dinner, your current glucose is 134 mg/dL. The graph shows that your glucose is going down and so does the trend arrow \( \downarrow \). 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 \( \downarrow \), should you consider taking a little less insulin? |
| **After dinner:** | | |
| 7:49pm | 215 mg/dL | After dinner, your current glucose is 215 mg/dL but there is no trend arrow. There is also the \( \text{A} \) symbol on the screen. Anytime you see the \( \text{A} \) symbol, you should do a blood glucose test before deciding what to do. |
## Setup Overview

Refer to your User's Manual for full system instructions and information.

### 1. Assemble and Apply Sensor to the back of your upper arm

#### STEP 1
Get Ready
- Select site on back of upper arm.
- Do not use other sites as these are not approved and may result in inaccurate glucose readings.
- **Note:** Avoid scars, moles, stretch marks, lumps, and insulin injection sites. To prevent skin irritation, rotate sites between applications.

#### STEP 2
Clean site with alcohol wipe. Allow site to dry before proceeding.

#### STEP 3
- Peel lid completely off Sensor Pack.
- Unscrew cap from Sensor Applicator.
- **CAUTION:** Sensor codes must match on Sensor Pack and Sensor Applicator or glucose readings will be incorrect.
- Select site on back of upper arm.
- Do not use other sites as these are not approved and may result in inaccurate glucose readings.
- **Note:** Avoid scars, moles, stretch marks, lumps, and insulin injection sites. To prevent skin irritation, rotate sites between applications.

#### STEP 4
- Lift Sensor Applicator out of Sensor Pack.
- Sensor Applicator is ready to apply Sensor.
- **CAUTION:** Sensor Applicator now contains a needle. Do not touch inside Sensor Applicator or put it back into Sensor Pack.

#### STEP 5
- Line up dark mark on Sensor Applicator with dark mark on Sensor Pack. On a hard surface, press down firmly on Sensor Applicator until it comes to a stop.

#### STEP 6
- Gently pull Sensor Applicator away from your body.

#### STEP 7
- Place Sensor Applicator over site and push down firmly to apply Sensor.
- **CAUTION:** Do not push down on Sensor Applicator until placed over prepared site to prevent unintended results or injury.

#### STEP 8
- Make sure Sensor is secure. Discard used Sensor Applicator and Sensor Pack according to local regulations.
2 Start new Sensor with Reader

**STEP 1**
Press Home Button to turn on Reader.

**STEP 2**
Touch Start New Sensor.

**STEP 3**
Hold Reader within 1.5 inches (4 cm) of Sensor to scan it.

Sensor can be used to check your glucose after 12 hours.

3 Check your glucose

**STEP 1**
Press Home Button to turn on Reader.

**STEP 2**
Hold Reader within 1.5 inches (4 cm) of Sensor to scan it.

**STEP 3**
Reader shows your glucose readings.

Understanding your glucose readings

**Glucose Graph**
Graph of your current and stored glucose readings

**Food Note**
mg/dL

**Rapid Acting Insulin Note**
mg/dL

**Target Glucose Range**
-50 to +50

**Current Glucose**
mg/dL

**Message**
Touch for more information

**Glucose Trend Arrow**
Direction your glucose is going

**What it means**

- Glucose rising quickly
- Glucose rising
- Glucose changing slowly
- Glucose falling
- Glucose falling quickly

**WARNING:** 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.

4 Review your history

**STEP 1**
Press Home Button to turn on Reader. Press Home Button again to go to Home Screen.

**STEP 2**
Touch Review History.

**STEP 3**
Select option to view.

If you have followed the instructions described in the User’s Manual and are still having difficulty setting up your System or if you are experiencing symptoms that are not consistent with your glucose monitoring, contact your health care professional.
STEP 1: Select site on back of upper arm.
STEP 2: Clean site with alcohol wipe and allow site to dry.

CAUTION: Sensor codes must match on Sensor Pack and Sensor Applicator. Do NOT use if damaged or already opened.

STEP 4: Line up dark marks on Sensor Applicator and Sensor Pack. On a hard surface, press down firmly on Sensor Applicator until it comes to a stop.
STEP 5: Lift Sensor Applicator out of Sensor Pack.
STEP 6: Sensor Applicator is ready to apply Sensor.

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

STEP 7: Place Sensor Applicator over site. Push down firmly to apply Sensor.

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

STEP 8: Gently pull Sensor Applicator away.
STEP 9: Make sure Sensor is secure. Discard used Sensor Applicator and Sensor Pack according to local regulations.

To use your System, refer to the User’s Manual included in the Reader Kit.
• The System detects trends and tracks patterns aiding in the interpretation of System readings.

Interpretation of the System readings should be based on the glucose results and should include consideration of how you feel, performance of the System has not been evaluated. The FreeStyle Libre System has been evaluated under normal use conditions and may not be accurate and you should conduct a fingerstick test with a blood glucose meter before making any treatment decision.

The System is intended for single patient use and requires a prescription. The FreeStyle Libre 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 monitoring (BG) procedures for diabetes treatment decisions. The System detects trends and tracks patterns aiding in the interpretation of System readings. The System is intended for single patient use and requires a prescription.

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