FreeStyle Libre

FLASH GLUCOSE MONITORING SYSTEM

FreeStyle LibreLink app
A FreeStyle Libre product

FreeStyle

DOC39658 Rev. B 09/18

Interactive Tutorial

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Important information about the FreeStyle Libre System

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 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 the Sensor glucose 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.
- If you are using the FreeStyle LibreLink app, you must also have access to a blood glucose monitoring system as the App does not provide one.
- **Hypoglycemic unawareness:** The System has not been evaluated for use in patients with hypoglycemic unawareness and will not automatically alert you of a hypoglycemic event without you scanning your Sensor.
- **No alarms without a Sensor scan:** The System does not have alarms that will automatically notify you when you are having a severe low (hypoglycemic) or high (hyperglycemic) glucose event unless you scan your Sensor. For example, the System does not have an alarm that can alert or wake you when you are sleeping in the case of low or high glucose.
- **Choking hazard:** The System contains small parts that may be dangerous if swallowed.

Cautions and Limitations

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

 What to know about Alarms/Alerts:

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

 What to know before using the System:

- Review all product information before use.
- Take standard precautions for transmission of blood borne pathogens to avoid contamination.

 Who should not use the System:

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

 What should you know about wearing a Sensor:

- After the start-up period, the Sensor can be worn for up to the wear duration specified in your Sensor Kit's product insert.
- Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If you notice significant skin irritation around or under your Sensor, remove the Sensor and stop using the System. Contact your health care professional before continuing to use the System.
- Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. Remove and replace your Sensor if it starts to loosen and follow the instructions to select an appropriate application site.
- 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 Reader has a built-in blood glucose meter that is designed to be used only with FreeStyle Precision Neo blood glucose test strips and MediSense Glucose and Ketone Control Solution. Using other test strips with the Reader's built-in meter will produce an error or cause the Reader's built-in meter to not turn on or start a test. The Reader's built-in meter does not have ketone testing functionality.
- The Reader's built-in meter is not for use on people who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.
- The Reader's built-in meter is not for use on neonates, in critically-ill patients, or for diagnosis or screening of diabetes.
- See Using the Reader's Built-in meter section of the Reader Kit 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.

What to know about FreeStyle LibreLink:

- FreeStyle LibreLink installed on a smartphone is intended for use by a single person. It must not be used by more than one person due to the risk of misinterpreting glucose information.
- FreeStyle LibreLink and FreeStyle Libre Readers do not share data. For complete information on a device, be sure to scan your Sensor every 8 hours with that device; otherwise, your reports will not include all your data.

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Welcome to Your System!

The FreeStyle Libre System is a continuous glucose monitoring (CGM) System designed to replace blood glucose testing for diabetes treatment decisions. This Interactive Tutorial will help you learn how to set up and use your new System. Topics include:

- Product overview
- Reader setup & use
- App setup & use
- Sensor application & start up
- Product use & treatment decisions guide

Pay special attention to ⚠ and ⓘ throughout this tutorial. Click the icons to view important considerations about using the System.

For more details, refer to the User's Manual and the Quick Reference Guide.

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IMPORTANT: Safety information about the System is in the User's Manual and the Quick Reference Guide. Read all of the information in the User's Manual, the Quick Reference Guide and the FreeStyle Precision Neo blood glucose test strip instructions for use before using your System.

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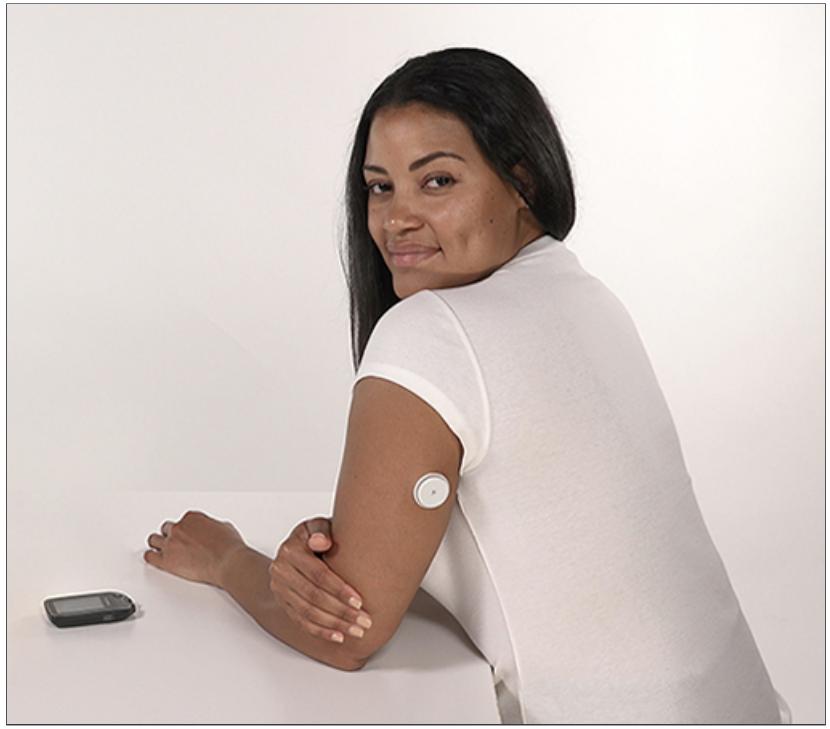
System Overview

The System has two main parts: a disposable Sensor and either a handheld Reader or mobile app. The Sensor is worn on the back of the upper arm and does not need to be calibrated with blood glucose values. The Reader or mobile app is used to wirelessly scan the Sensor and get glucose readings. The Reader also has a built-in blood glucose meter, which works with FreeStyle Precision Neo blood glucose test strips.

IMPORTANT: Safety information about the System is in the User's Manual and the Quick Reference Guide. Read all of the information in the User's Manual, the Quick Reference Guide and the FreeStyle Precision Neo blood glucose test strip instructions for use before using your System.



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Getting to Know the Reader

The Reader scans the Sensor and provides glucose readings. It can store approximately 90-days of glucose history as well as notes about activities, insulin, meals, and exercising. When scanning, the Sensor automatically transmits data to the Reader.

The Reader is compact, lightweight, and easy to hold. It has a backlit color touchscreen and uses a rechargeable battery. The Reader is not waterproof.

Touch Screen

USB Port

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

Home Button

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

Test Strip Port

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

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Getting to Know FreeStyle LibreLink App

The App performs some similar functions to the Reader. You can use it to start a Sensor, get glucose readings from the Sensor, and store your glucose history and notes you enter.

FreeStyle LibreLink app is available for download from the App Store.

The App is not compatible with all smartphones. Before upgrading your smartphone or its operating system, check www.FreeStyleLibre.com.

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Sensor Kit

The Sensor automatically measures and continuously stores glucose readings for 8 hours. The Sensor Kit has two parts: a Sensor Pack and a Sensor Applicator. Once you have assembled the Sensor, you will apply it to the back of your upper arm. It has a small, flexible, 5mm-long filament that is inserted just under the skin. After the start-up period, the Sensor can be worn for up to the wear duration specified in your Sensor Kit's product insert.

IMPORTANT: The Sensor is water-resistant in up to 3 feet (1 meter) of water. Do not immerse longer than 30 minutes.

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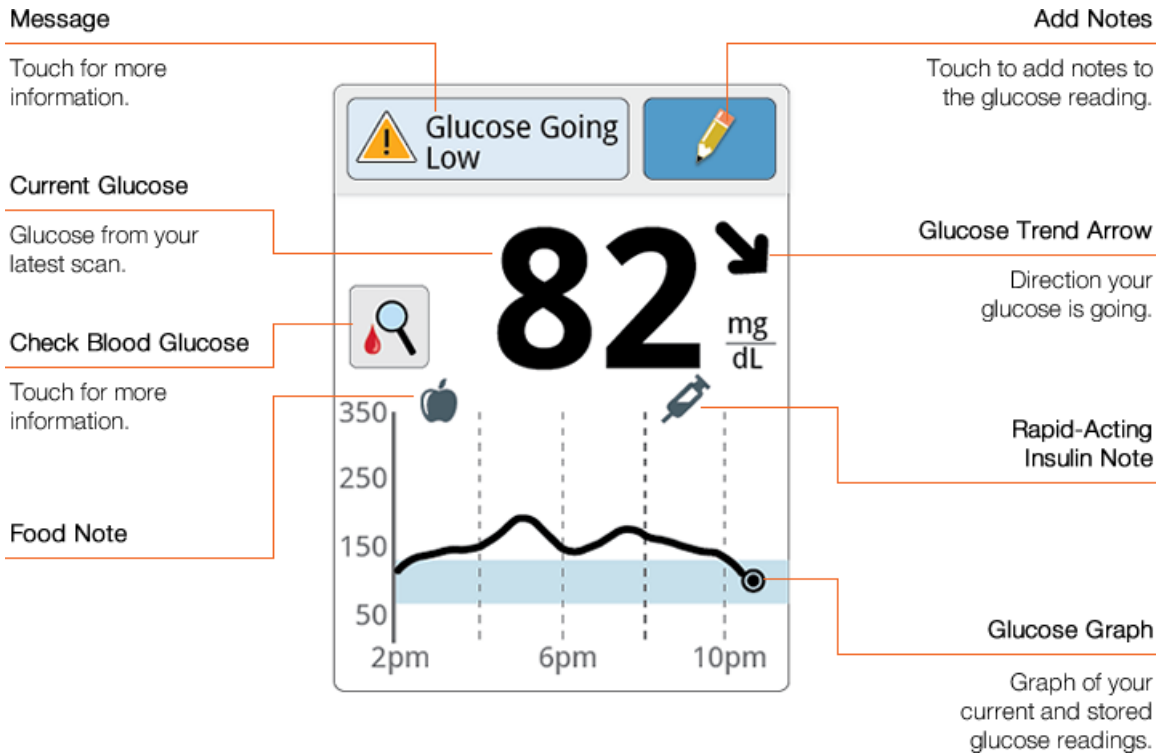
Sensor Glucose Readings

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

What you see on the Reader



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Sensor Glucose Readings

What you see on the App

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Set the **Current Date** using the arrows on the touchscreen. Touch **next** to continue.

Set the **Current Time**. Touch **next** to continue.

Touch + or - to set your **Target Glucose Range**. Work with your health care professional to determine your Target Glucose Range. Touch **next** to continue.

The Reader now displays important information about how to understand the **Glucose Trend Arrow**. Touch **next** to move through the next topics.

When the setup is complete, touch **done** to return to the Home screen.

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First Time Reader Setup

Complete the setup to use the Reader to check your Sensor glucose readings or use the Reader's built-in meter.

How to do it:

Press the Home Button to tum on the Reader.

If prompted, use the touchscreen to select your preferred language for the Reader. Touch **OK** to continue.

Set the **Current Date** using the arrows on the touchscreen. Touch **next** to continue.

Set the **Current Time**. Touch **next** to continue.

Touch + or - to set your **Target Glucose Range**. Work with your health care professional to determine your Target Glucose Range. Touch **next** to continue.

The Reader now displays important information about how to understand the **Glucose Trend Arrow**. Touch **next** to move through the next topics.

When the setup is complete, touch **done** to return to the Home screen.

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First Time Reade

Complete the setup to use the
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How to do it:

Press the Home Button to tum on the Reader.

If prompted, use the touchscreen to select your preferred language for the Reader. Touch **OK** to continue.

Set the **Current Date** using the arrows on the touchscreen. Touch **next** to continue.

Set the **Current Time**. Touch **next** to continue.

Touch + or - to set your **Target Glucose Range**. Work with your health care professional to determine your Target Glucose Range. Touch **next** to continue.

The Reader now displays important information about how to understand the **Glucose Trend Arrow**. Touch **next** to move through the next topics.

When the setup is complete, touch **done** to return to the Home screen.

Note

Use the pad of your finger. Do NOT use your fingernail or any other object on the screen.

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The Reader now displays important information about how to understand the **Glucose Trend Arrow**. Touch **next** to move through the next topics.

When the setup is complete, touch **done** to return to the Home screen.

Caution

It is very important to set the time and date correctly. These values affect the Reader data and settings.

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The Reader now displays important information about how to understand the **Glucose Trend Arrow**. Touch **next** to move through the next topics.

When the setup is complete, touch **done** to return to the Home screen.

Note

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

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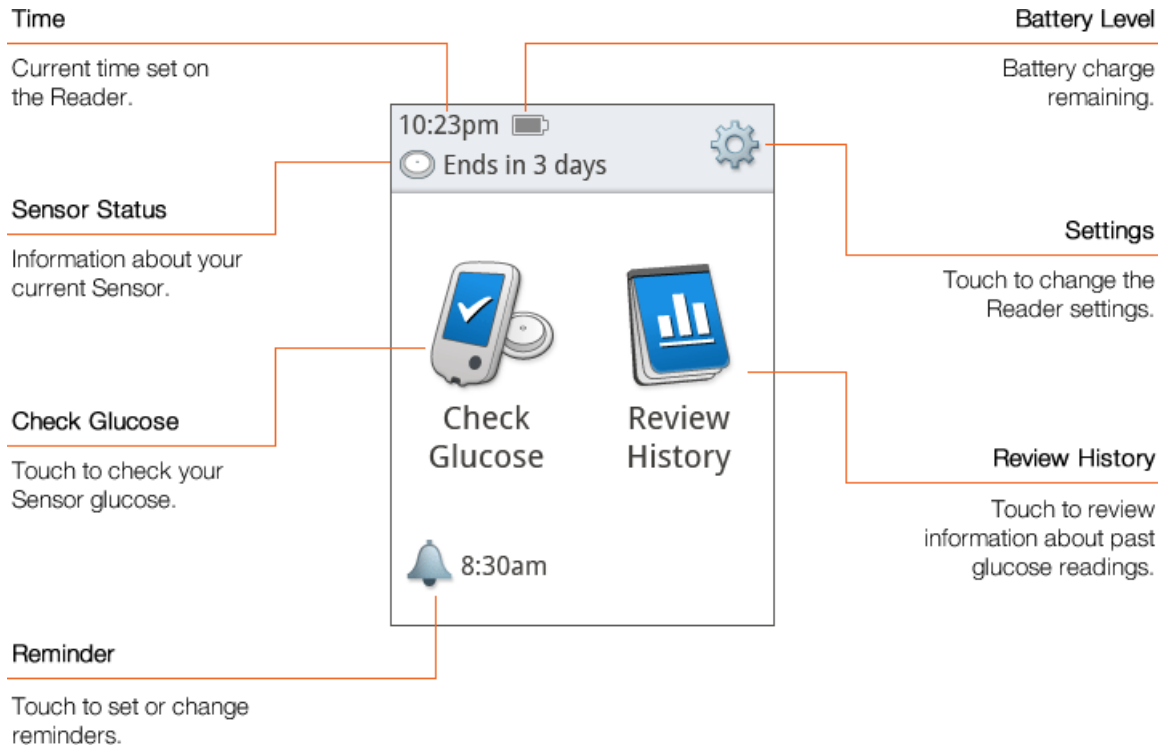
Reader Home Screen

The Reader Home Screen provides access to information about glucose readings and the System. Press the Home Button to go to the Home Screen from any other screen.



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Setting Reminders

Use Reminders to remember when to check glucose, take insulin, or as a general alarm.

How to do it:

Touch the symbol on the Home Screen.

Touch to select which **Type** of reminder to set: Check Glucose, Take Insulin, or Alarm.

Touch to select how often the Reminder needs to **Repeat**: Daily, Once, or Timer.

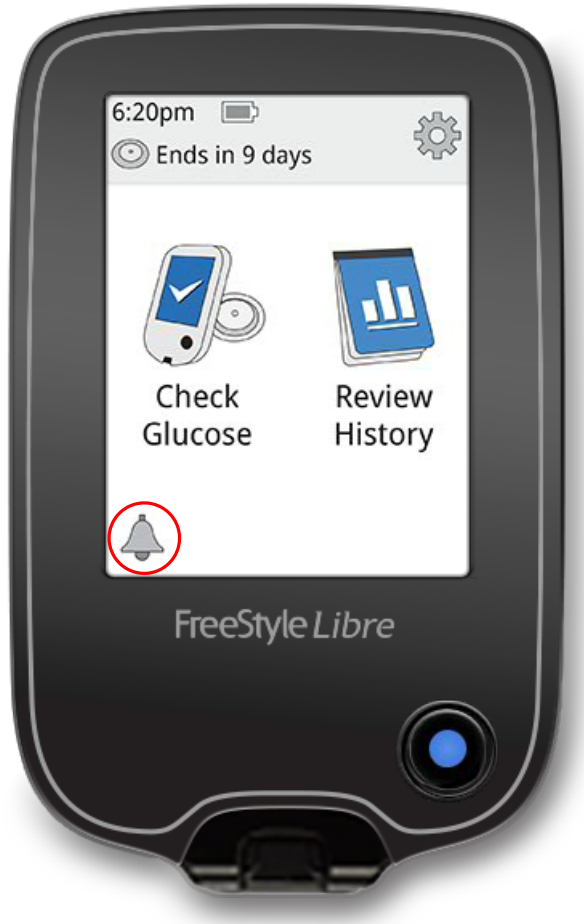
Select the Reminder **Time**, using the arrows on the touchscreen.

Touch **save** to save all Reminder settings.

From the Reminders screen, you can turn the reminder **On/Off** or **add new** reminders.

Touch **done** to return to the Home Screen.

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



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Touch **done** to return to the Home Screen.

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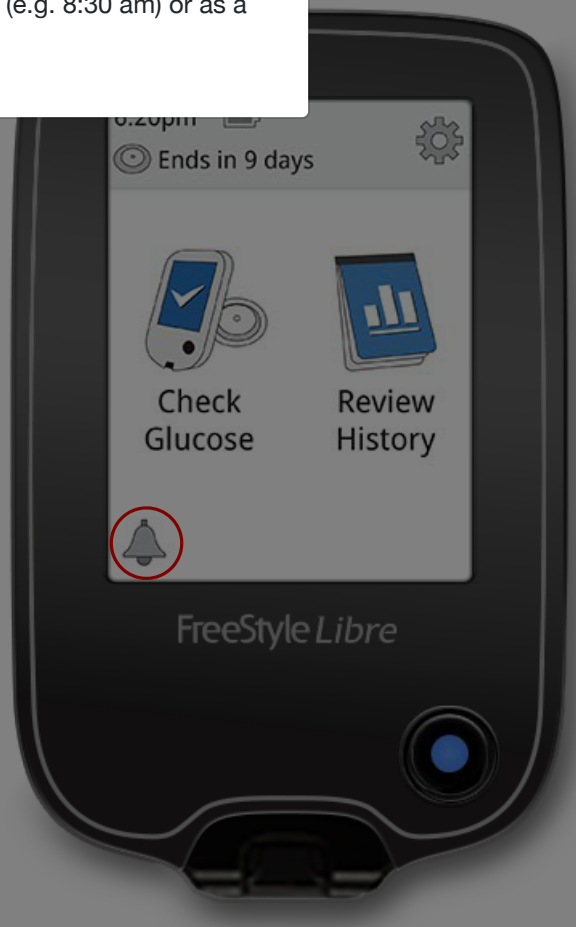
Note

You can set reminders for a specific time (e.g. 8:30 am) or as a timer (e.g. 3 hours from the current time).



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Changing the Reader Settings

Many System features can be customized from the Settings menu.

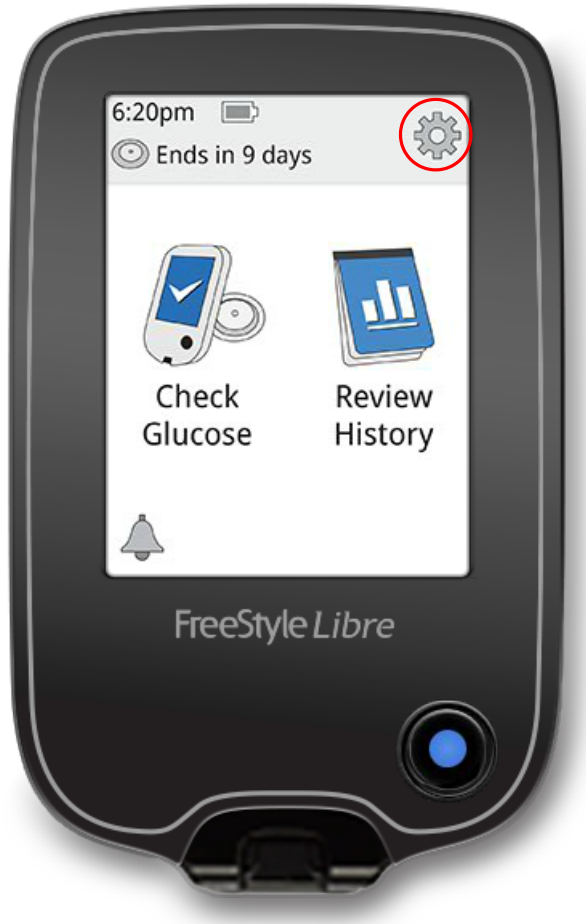
How to do it:

Touch the Settings Symbol on the Home Screen.

Touch the arrows to scroll up or down. Touch the setting you want to change: Sounds, Target Range, Control Solution Test, Time & Date, Language, System Status, Reader Basics and Dose Increment. Touch **OK** to save.

Touch **System Status** to view System information including current Sensor end date, serial numbers for Sensor and Reader, number of Sensors used, number of tests performed using test strips, Event Logs which may be used by Customer Service to help troubleshoot your System, and perform a Reader Test.

Touch **Reader Basics** to access important information about the Reader.



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Confirm your country and tap **NEXT**.

You need a LibreView account to use the App. Follow onscreen instructions to review legal information and create a new account or login to your existing account.

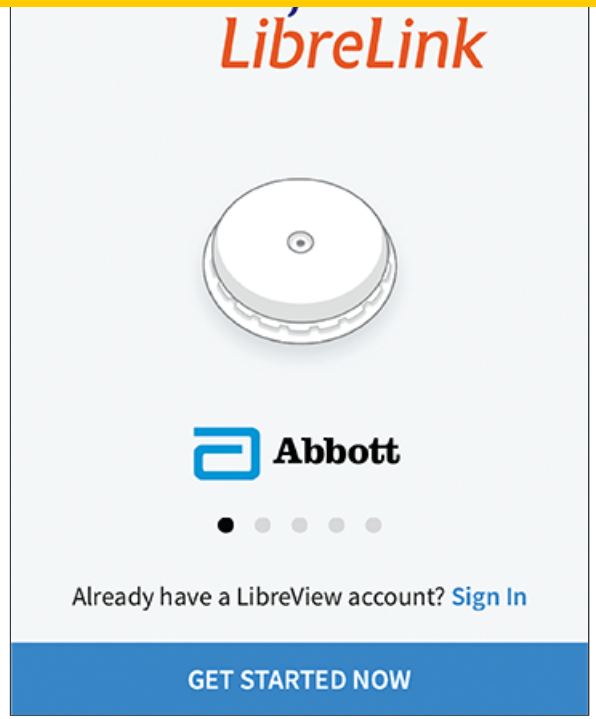
LibreView Data Management Software is developed and distributed by Newyu, Inc. Use of FreeStyle LibreLink requires registration with LibreView, a service provided by Abbott and Newyu, Inc.

Confirm your glucose unit of measure and tap **NEXT**.

Set your Target Glucose Range and tap **NEXT**. Work with your health care professional to determine your Target Glucose Range.

Select how you count carbohydrates and tap **NEXT**.

The App now displays some important information. Tap **NEXT** to move through the screens.



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First Time App Setup

How to do it:

Check that your smartphone is connected to a network (WiFi or cellular). Install FreeStyle LibreLink from the App store and open the App.

Swipe left to view some helpful tips or tap **GET STARTED NOW**.

Confirm your country and tap **NEXT**.

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Select how you count carbohydrates and tap **NEXT**.

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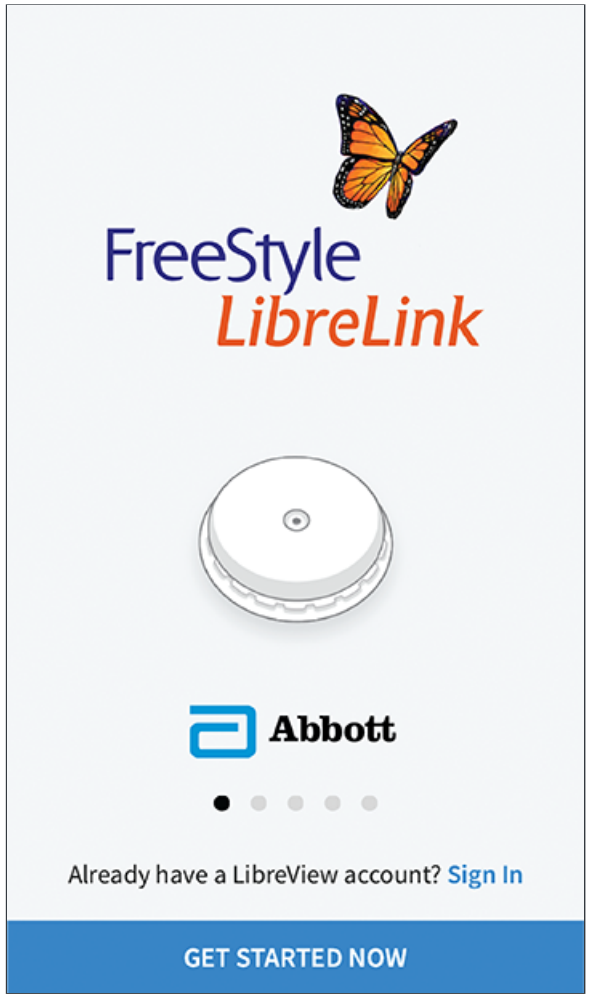

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FLASH GLUCOSE MONITORING SYSTEM

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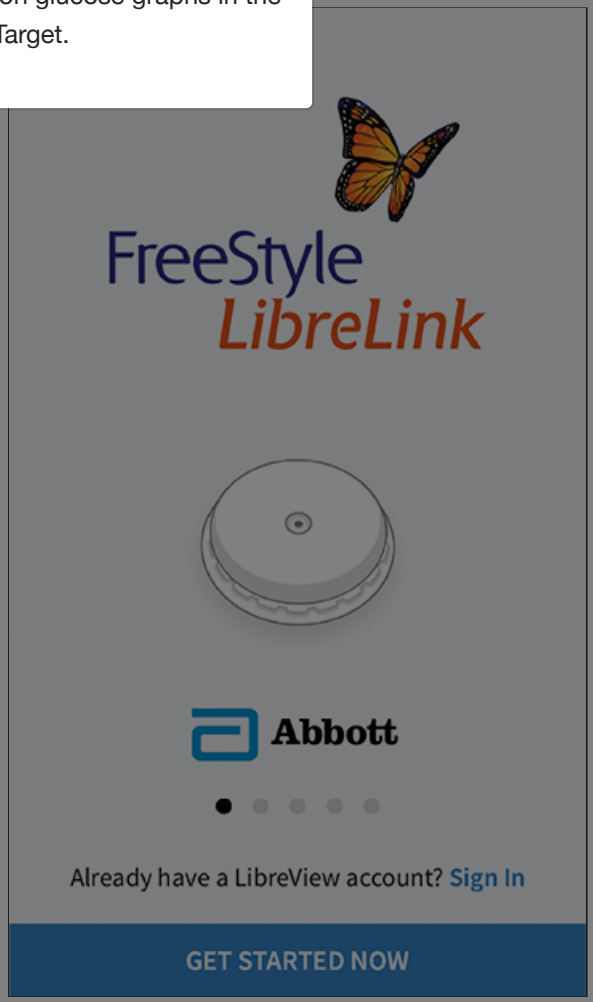
Note

Your Target Glucose Range is displayed on glucose graphs in the App and used to calculate your Time in Target.



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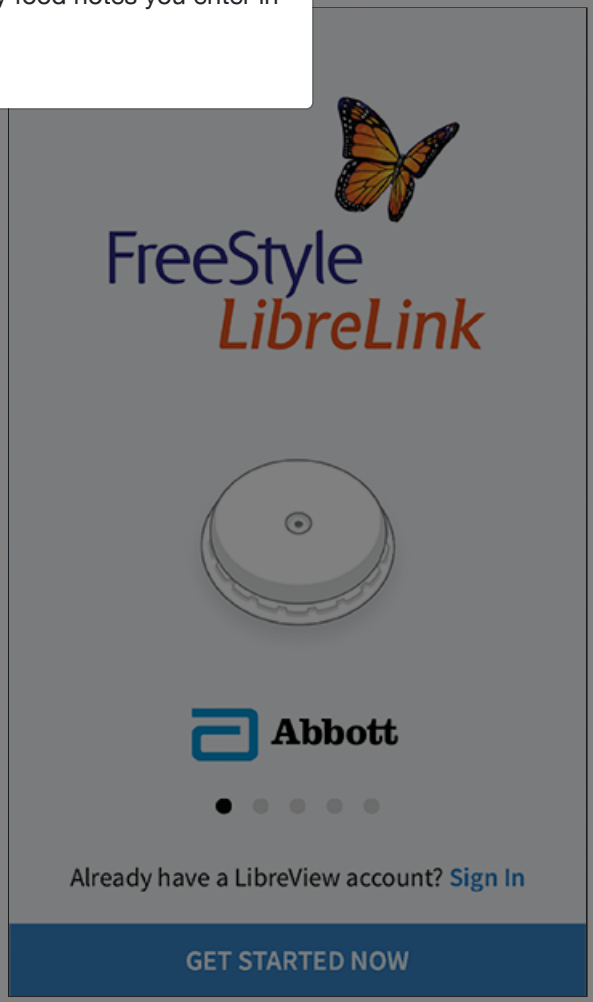
Set your Target Glucose Range and tap **NEXT**. Work with your health care professional to determine your Target Glucose Range.

Select how you count carbohydrates and tap **NEXT**.

The App now displays some important information. Tap **NEXT** to move through the screens.

Note

The carbohydrate unit will be used in any food notes you enter in the App.



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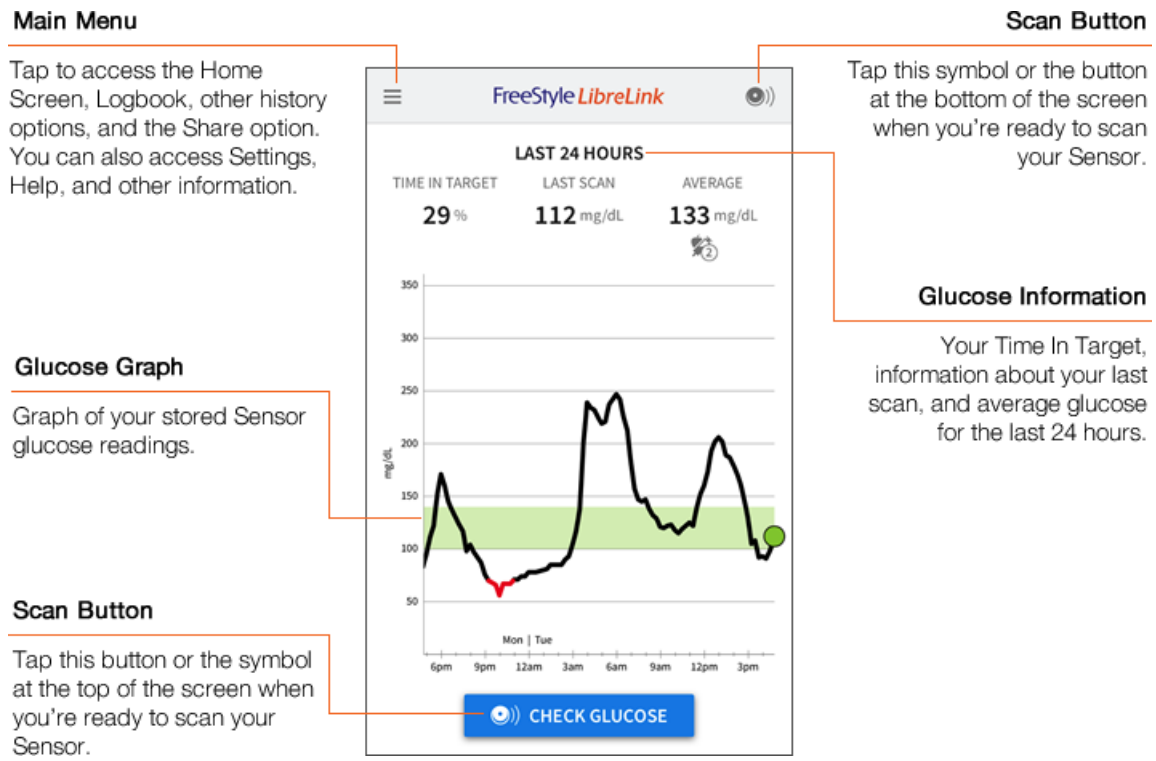
App Home Screen

The App Home Screen provides access to information about glucose readings and the App. To return to the Home Screen from another screen, go to the Main Menu and tap **Home**.



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Setting Reminders

Use Reminders to remember when to check glucose, take insulin, or as a general alarm.

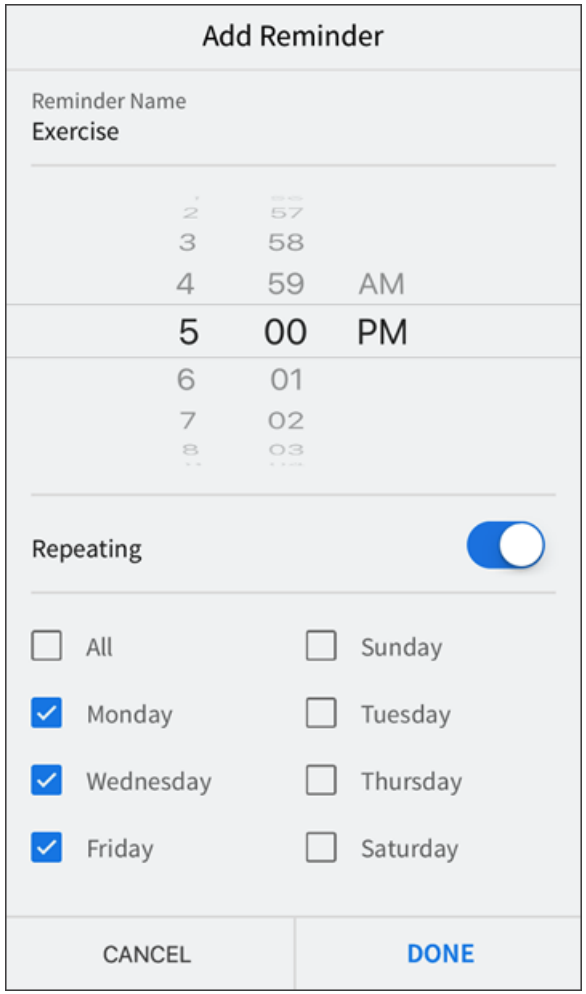
How to do it:

Go to the Main Menu and tap Reminders. Tap **ADD REMINDER**.

Name your reminder.

Tap the time fields to set the time for the reminder.

Tap **DONE**. You will now see your reminder on the list along with the time you will receive it.



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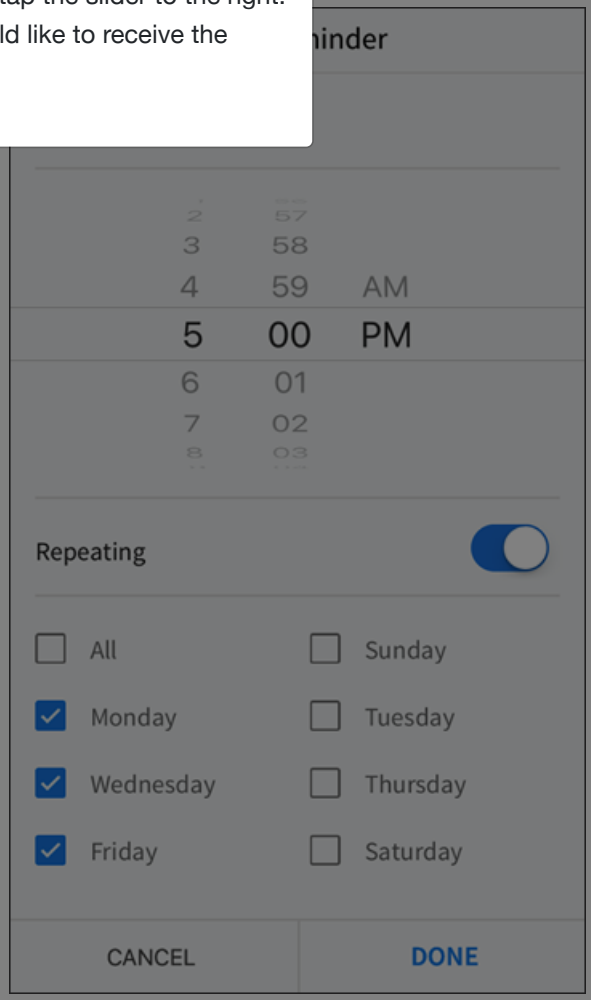
Tap **DONE**. You will now see your reminder on the list along with the time you will receive it.

Note

If you would like the reminder to repeat, tap the slider to the right. You can also select which days you would like to receive the reminder.



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FLASH GLUCOSE MONITORING SYSTEM

Setting Reminde

Use Reminders to remember v
insulin, or as a general alarm.

How to do it:

Go to the Main Menu and tap
REMINDER.

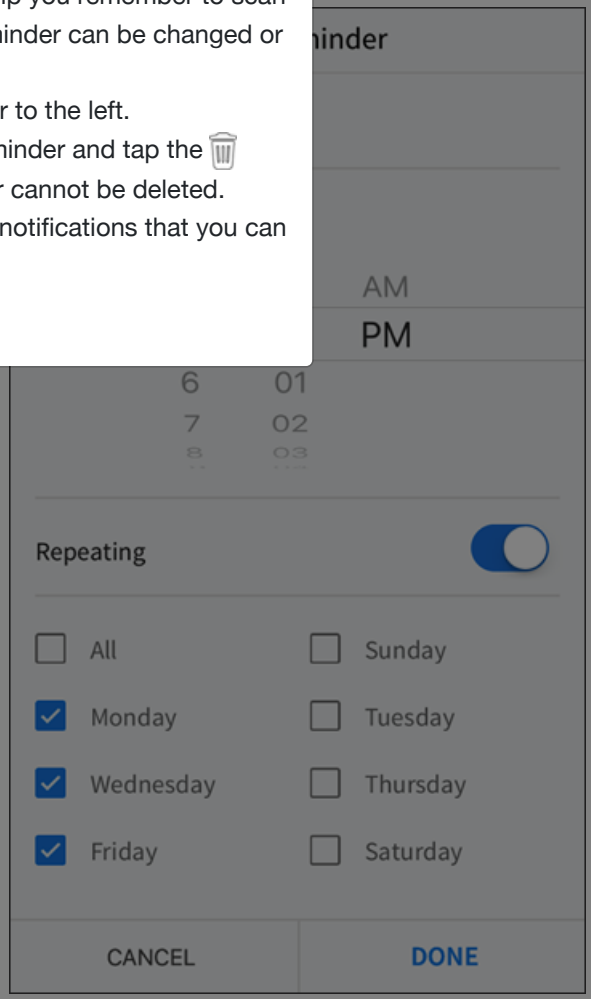
Name your reminder.

Tap the time fields to set the ti

Tap **DONE**. You will now see your reminder on the list along with the time you will receive it.

Note

- There is one default reminder to help you remember to scan your Sensor. This Scan Sensor reminder can be changed or disabled but cannot be deleted.
- To turn off a reminder, tap the slider to the left.
- To delete a reminder, swipe the reminder and tap the symbol. The Scan Sensor reminder cannot be deleted.
- Your reminders will be received as notifications that you can swipe or tap to dismiss.



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Changing App Settings

How to do it:

Go to the Main Menu to access the App settings.

Unit of Measurement - View the glucose unit of measure used in the App.
Target Glucose Range - Set the target range you want to be displayed on the App glucose graph. It is also used to calculate your Time In Target. Tap **SAVE** when you are done.
Carbohydrate Units - Choose grams or servings for food notes that you enter. Tap **SAVE** when you are done.
Text to Speech - Turn on Text to Speech to have the glucose reading read aloud when you scan the Sensor. You will hear only your current glucose value and trend arrow direction along with whether you need to do a blood glucose test before making treatment decisions. Additional information, such as the glucose graph and any message, is available on your My Glucose screen. Always review your My Glucose screen to get complete information. Tap **SAVE** when you are done.

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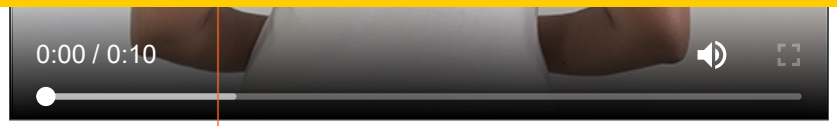
FLASH GLUCOSE MONITORING SYSTEM

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.



Only apply Sensor to the back of your upper arm.

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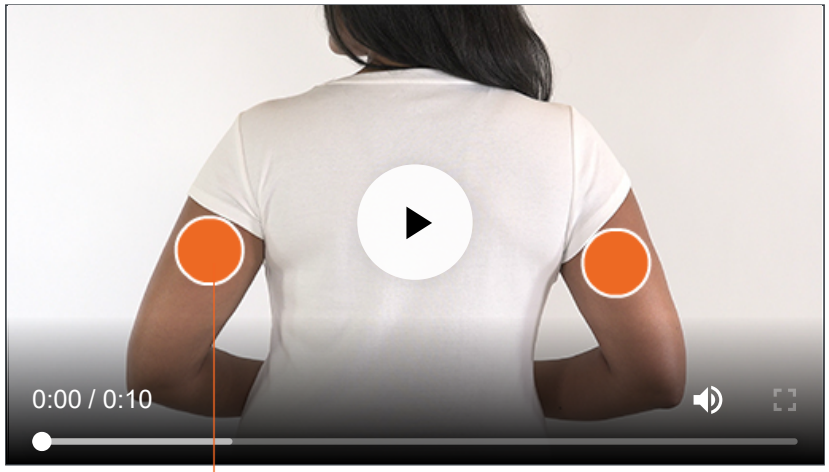
Application Site Selection

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.



Only apply Sensor to the back of your upper arm.

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Application Site

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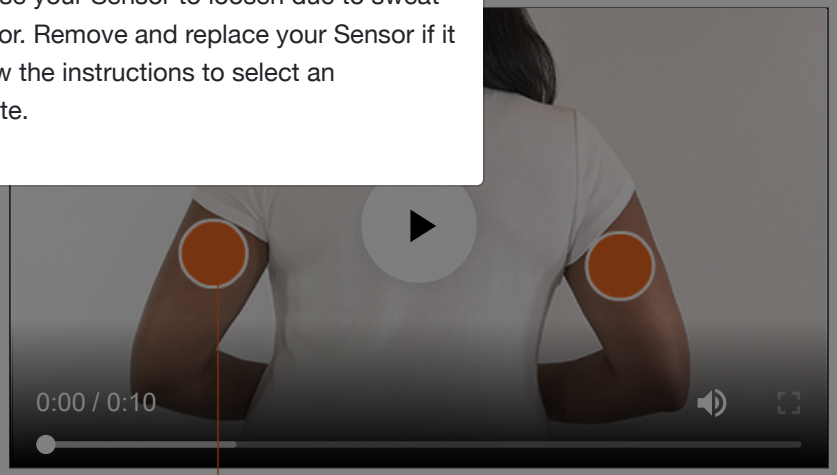
moles, stretch marks, or lumps.

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.

Caution

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.



Only apply Sensor to the back of your upper arm.

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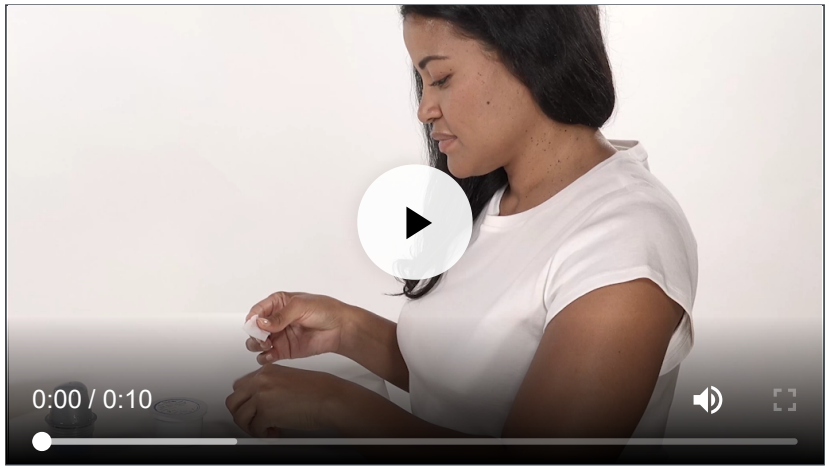
Preparing the Application Site

Clean application site with an alcohol wipe and allow site to dry before proceeding. This helps the Sensor stay attached to your body.



FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

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Preparing the Ap

Clean application site with an
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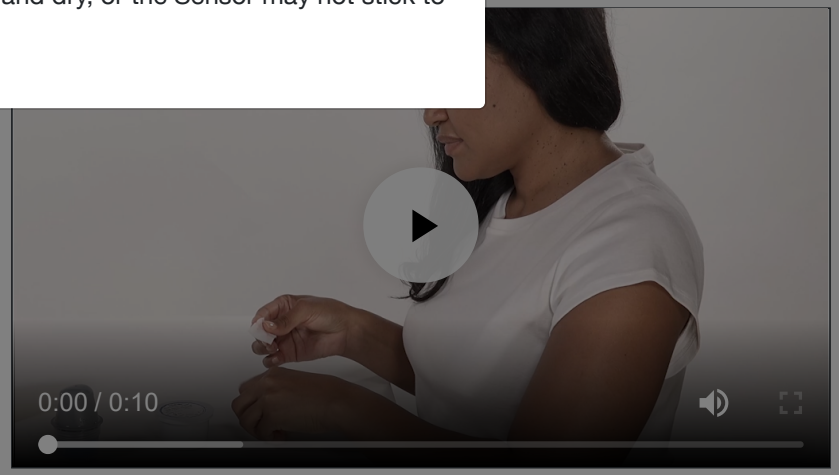
the Sensor stay attached to yo

Note

The area **MUST** be clean and dry, or the Sensor may not stick to the site.



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FLASH GLUCOSE MONITORING SYSTEM

Preparing the Sensor Applicator

To ensure glucose readings are accurate, make certain the Sensor Pack and Sensor Applicator codes match.

How to do it:

Open the Sensor Pack by peeling the lid off completely.

Unscrew the cap from the Sensor Applicator and set the cap aside.

Place the Sensor Pack on a flat hard surface and line up the dark mark on the Sensor Applicator with the dark mark on the Sensor Pack. Press firmly down on the Sensor Applicator until it comes to a stop.

Lift the Sensor Applicator out of the Sensor Pack.

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

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FLASH GLUCOSE MONITORING SYSTEM

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Preparing the Se

To ensure glucose readings are
certain the Sensor Pack and S
match.

How to do it:

Open the Sensor Pack by peel
completely.

Unscrew the cap from the Sensor Applicator and set the cap aside.

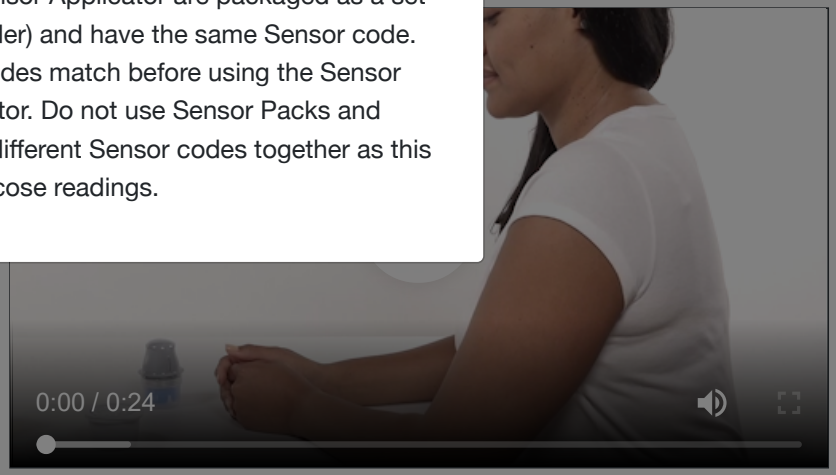
Place the Sensor Pack on a flat hard surface and line up the dark mark on the Sensor Applicator with the dark mark on the Sensor Pack. Press firmly down on the Sensor Applicator until it comes to a stop.

Lift the Sensor Applicator out of the Sensor Pack.

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

Caution

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 the 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.



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FLASH GLUCOSE MONITORING SYSTEM

Preparing the Se

To ensure glucose readings are
certain the Sensor Pack and S
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How to do it:

Open the Sensor Pack by peeling the lid off completely.

Unscrew the cap from the Sensor Applicator and set the cap aside.

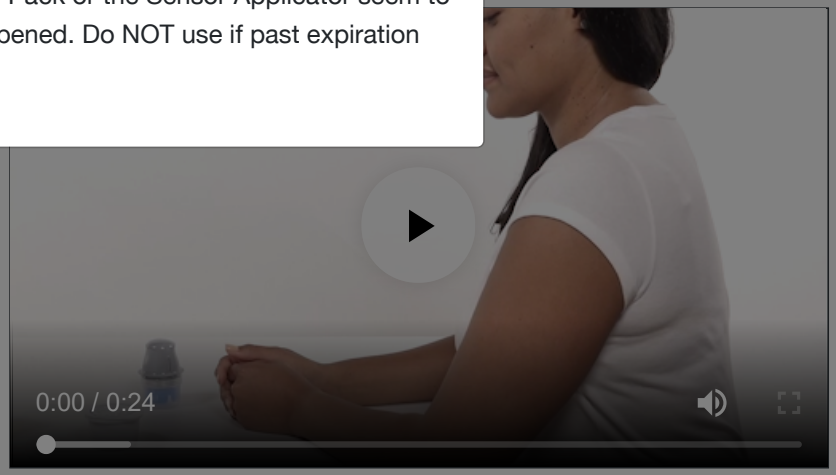
Place the Sensor Pack on a flat hard surface and line up the dark mark on the Sensor Applicator with the dark mark on the Sensor Pack. Press firmly down on the Sensor Applicator until it comes to a stop.

Lift the Sensor Applicator out of the Sensor Pack.

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

Caution

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



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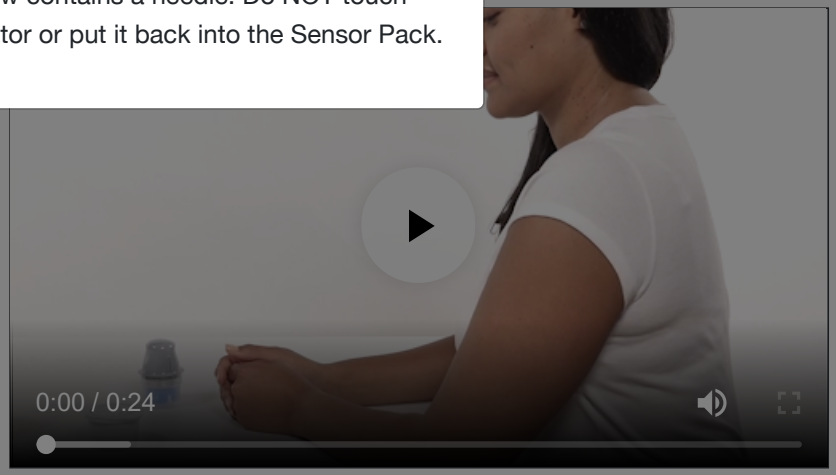
FLASH GLUCOSE MONITORING SYSTEM

Preparing the Se

To ensure glucose readings are
certain the Sensor Pack and S
match.

Caution

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



How to do it:

Open the Sensor Pack by peeling the lid off completely.

Unscrew the cap from the Sensor Applicator and set the cap aside.

Place the Sensor Pack on a flat hard surface and line up the dark mark on the Sensor Applicator with the dark mark on the Sensor Pack. Press firmly down on the Sensor Applicator until it comes to a stop.

Lift the Sensor Applicator out of the Sensor Pack.

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

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FLASH GLUCOSE MONITORING SYSTEM

Applying Your Sensor

How to do it:

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

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

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.

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FLASH GLUCOSE MONITORING SYSTEM

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Applying Your S

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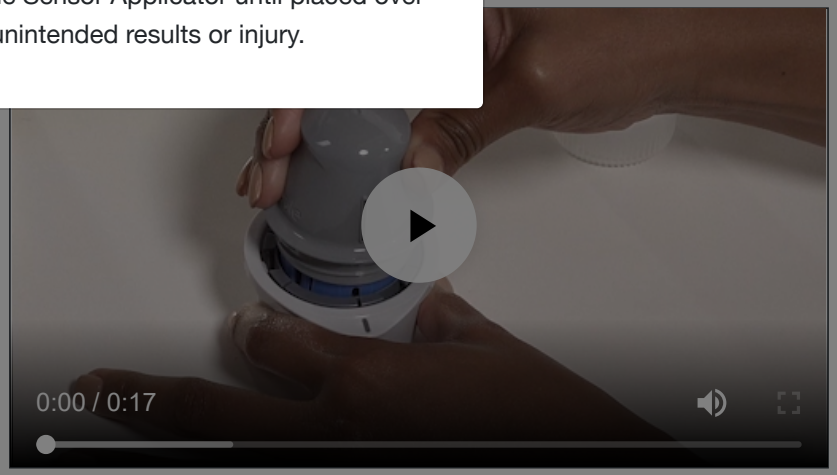
Gently pull the Sensor Applicator away from your body. The Sensor should now be attached to your skin.

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.

Caution

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



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FLASH GLUCOSE MONITORING SYSTEM

Applying Your S

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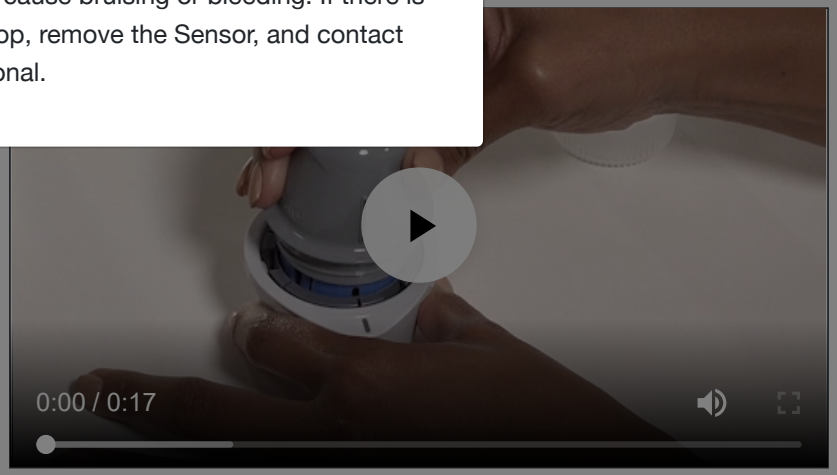
Gently pull the Sensor Applicator away from your body. The Sensor should now be attached to your skin.

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.

Note

Applying the Sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the Sensor, and contact your health care professional.



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FLASH GLUCOSE MONITORING SYSTEM

Starting Your Sensor

Start your Sensor with the Reader if you would like to use the Reader to check your glucose. If you want to also use the App with the Sensor, scan the Sensor with the App after starting it with the Reader.

How to do it with the Reader:

Press the Home Button to turn on the Reader.

Touch **Start New Sensor**.

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 the start-up period. During the start-up period, you can scan the Sensor to check its status.

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FLASH GLUCOSE MONITORING SYSTEM

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Starting Your Se

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also use the App with the Sens
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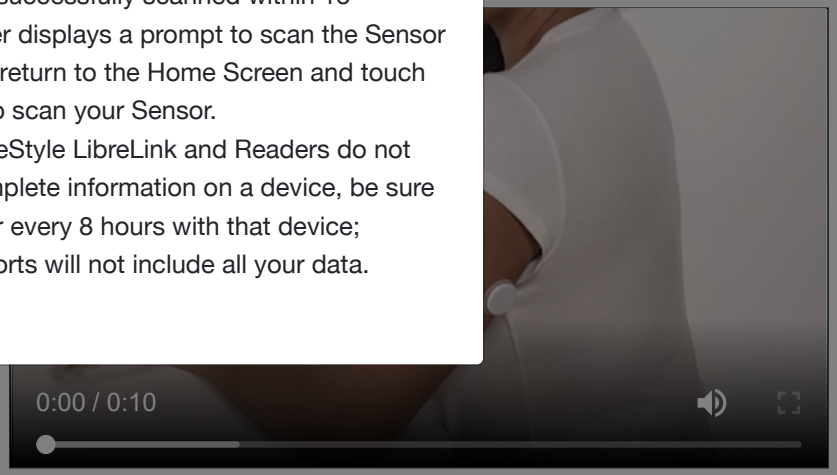
Note

- If the Sensor is not successfully scanned within 15 seconds, the Reader displays a prompt to scan the Sensor again. Touch **OK** to return to the Home Screen and touch **Start New Sensor** to scan your Sensor.
- Remember that FreeStyle LibreLink and Readers do not share data. For complete information on a device, be sure to scan your Sensor every 8 hours with that device; otherwise, your reports will not include all your data.



FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Starting Your Sensor

Start the Sensor with the App if you would like to only use the App to check your glucose. If you want to use both the Reader and the App to check your glucose, you must start the Sensor with the Reader first.

How to do it with the App:

Tap the scan button .

Hold the top of your iPhone near the Sensor. Hold still until you hear a tone and/or feel a vibration. This completes the scan.

The Sensor can be used to check your glucose after the start-up period. While the Sensor is starting up, you can navigate away from the App.

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Starting Your Se

Start the Sensor with the App
App to check your glucose. If
and the App to check your glu
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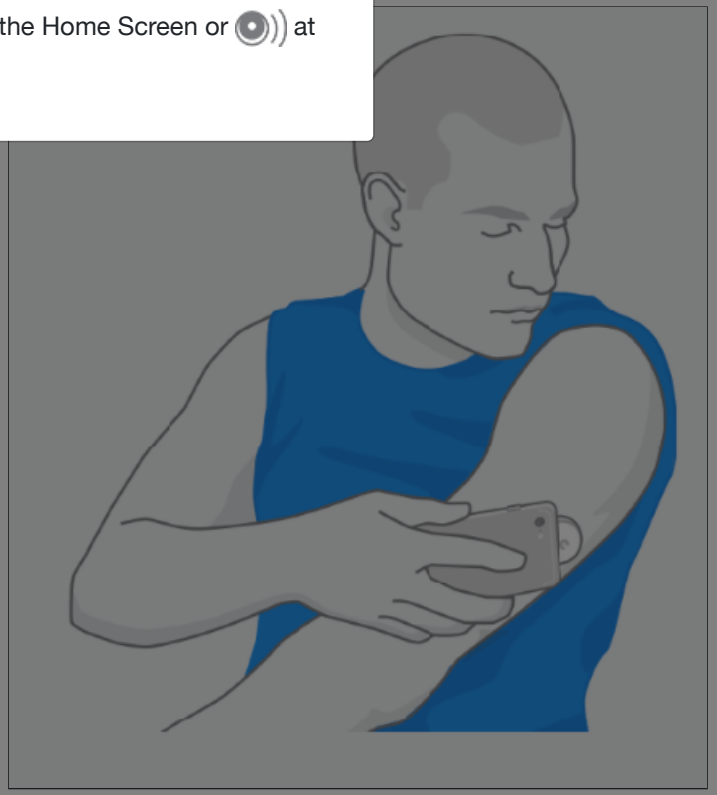
Tap the scan button .

Hold the top of your iPhone near the Sensor. Hold still until you hear a tone and/or feel a vibration. This completes the scan.

The Sensor can be used to check your glucose after the start-up period. While the Sensor is starting up, you can navigate away from the App.

Note

You can either tap the blue box on the Home Screen or at the top right.



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FLASH GLUCOSE MONITORING SYSTEM

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The Sensor can be used to check your glucose after the start-up period. While the Sensor is starting up, you can navigate away from the App.

Note

- If your Sensor is not successfully scanned, you may receive a Scan Error. Tap the scan button and scan again.
- Remember that FreeStyle LibreLink and Readers do not share data. For complete information on a device, be sure to scan your Sensor every 8 hours with that device; otherwise, your reports will not include all your data.

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Removing Your Sensor

The Sensor automatically stops working after the wear duration specified in the Sensor Kit's product insert and must be replaced. Replace the Sensor if you notice any irritation or discomfort at the application site or if your device reports a problem with the Sensor currently in use. Taking action early can keep small problems from turning into larger ones.

How to do it:

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

Discard the used Sensor following directions from your health care professional. See the Maintenance and Disposal section of the Reader Kit User's Manual.

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Removing Your S

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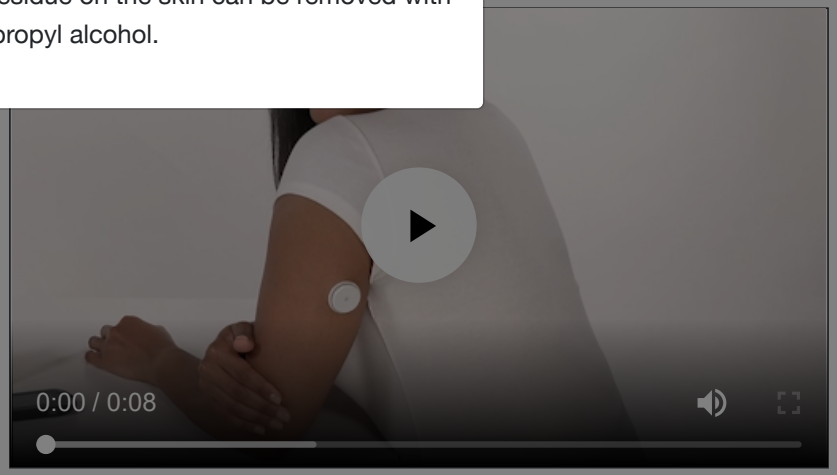
How to do it:

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

Discard the used Sensor following directions from your health care professional. See the Maintenance and Disposal section of the Reader Kit User's Manual.

Note

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



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Product Use

- Checking Glucose with a Sensor
- Understanding Sensor Readings - Reader
- Understanding Sensor Readings - App
- Treatment Decisions Guide
- Treatment Decisions Guide - Knowledge Check
- Checking Glucose with a Test Strip
- Adding Notes
- Reviewing History

Play

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Checking Glucose with a Sensor

How to do it with the Reader:

Press the Home Button to turn on the Reader or touch **Check Glucose** on the Home Screen.

Hold the Reader within 1.5 inches (4 cm) of the Sensor to scan it. The Sensor wirelessly sends glucose readings to the Reader. If sounds are turned on, the Reader beeps when the Sensor has been successfully scanned.

The Reader displays the current glucose reading along with a glucose graph and an arrow indicating the direction the glucose is going.

Play

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Checking Gluco

How to do it with the Reader:

Press the Home Button to turn
Glucose on the Home Screen.

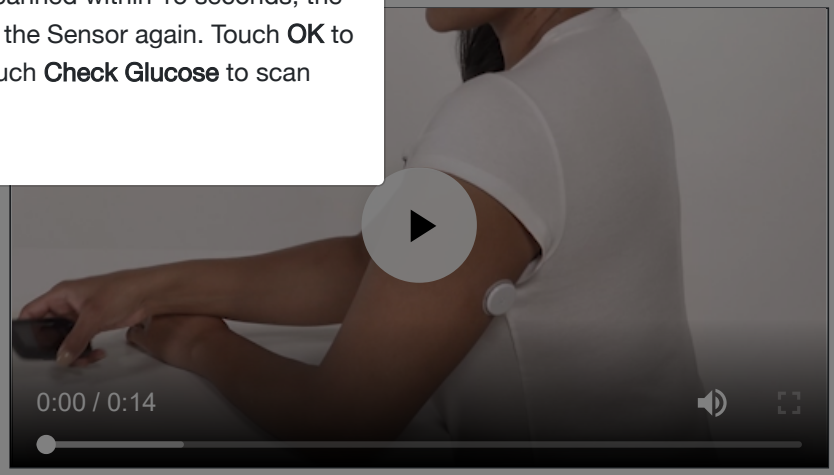
Hold the Reader within 1.5 inches (4 cm) of the Sensor to scan it. The Sensor wirelessly sends glucose readings to the Reader. If sounds are turned on, the Reader beeps when the Sensor has been successfully scanned.

The Reader displays the current glucose reading along with a glucose graph and an arrow indicating the direction the glucose is going.

Play

Note

If the Sensor is not successfully scanned within 15 seconds, the Reader displays a prompt to scan the Sensor again. Touch **OK** to return to the Home Screen and touch **Check Glucose** to scan your Sensor.



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Checking Glucose with a Sensor

How to do it with the Reader:

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The Reader displays the current glucose reading along with a glucose graph and an arrow indicating the direction the glucose is going.

Play

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Checking Glucose with a Sensor

How to do it with the App:

Tap the scan button .

Hold the top of your iPhone near the Sensor. Hold still until you hear a tone and/or feel a vibration. This completes the scan.

The App displays the current glucose reading along with a glucose graph and an arrow indicating the direction the glucose is going.

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Checking Gluco

How to do it with the App:

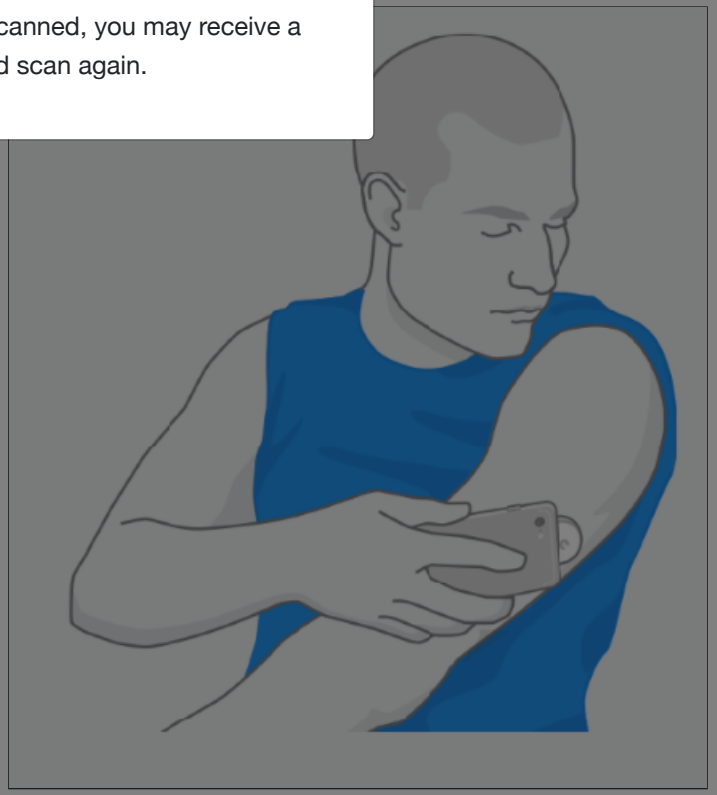
Tap the scan button .

Hold the top of your iPhone near the Sensor. Hold still until you hear a tone and/or feel a vibration. This completes the scan.

The App displays the current glucose reading along with a glucose graph and an arrow indicating the direction the glucose is going.

Note

If your Sensor is not successfully scanned, you may receive a Scan Error. Tap the scan button and scan again.



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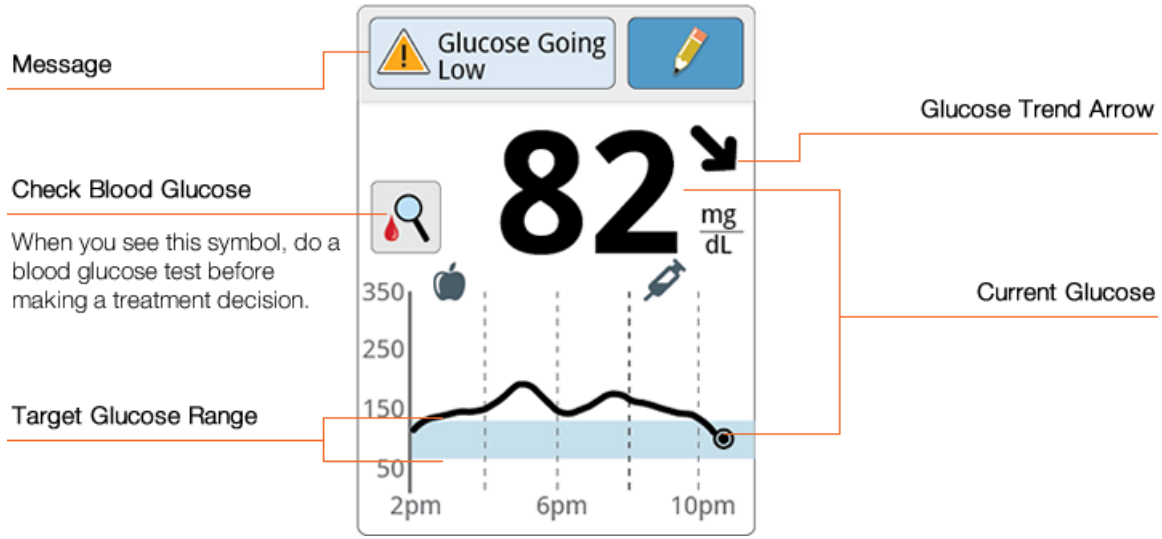
Understanding Sensor Readings - Reader

Note: 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.

Note: The symbol may appear, indicating the Reader time was changed. Gaps in the graph may result or glucose readings may be hidden.



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Understanding Sensor Readings - Reader

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

Note: The **Glucose Trend Arrow** may not always appear with your reading. When there is no Glucose Trend Arrow, you will see a  symbol, telling you to do a blood glucose test before making treatment decisions.

↑	**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 fallling** (between 1 and 2 mg/dL per minute)
↓	**Glucose is falling quickly** (more than 2 mg/dL per minute)

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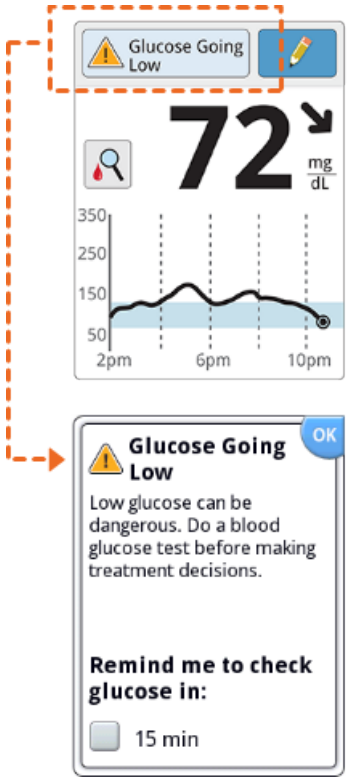
Understanding Sensor Readings - Reader

If your glucose is projected to be higher than 240 mg/dL or lower than 70 mg/dL within 15 minutes, you will see a Glucose Going High or a Glucose Going Low message on the screen. You can touch the message button for more information and set a reminder to check your glucose.

When there is a Glucose Going Low message, you will see a symbol, telling you to do a blood glucose test before making treatment decisions.

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



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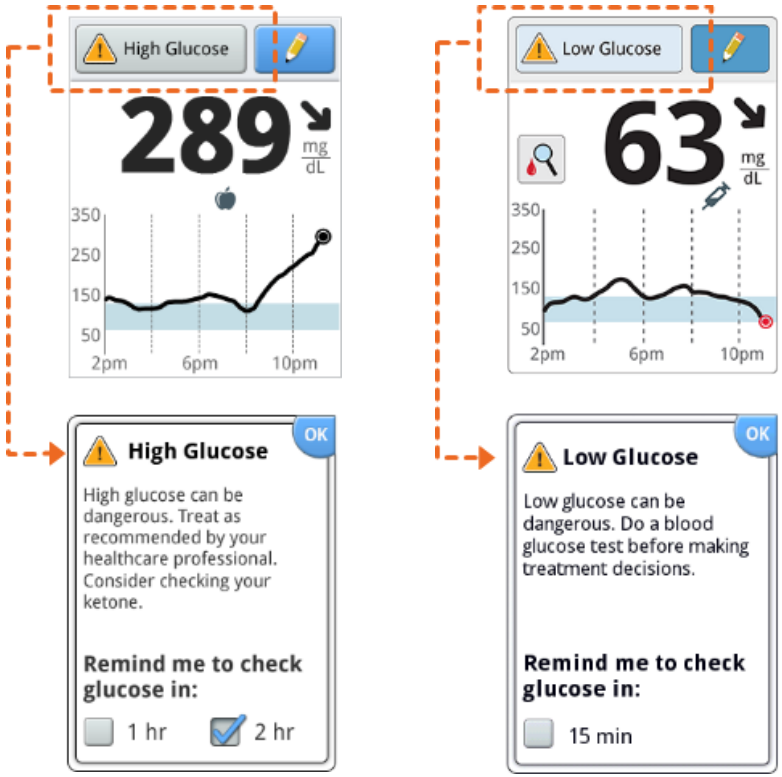
FLASH GLUCOSE MONITORING SYSTEM

Understanding Sensor Readings - Reader

If your glucose is higher than 240 mg/dL or lower than 70 mg/dL, you will see a High Glucose or Low Glucose message on the screen. You can touch the message button for more information and set a reminder to check your glucose.

When there is a Low Glucose message, you will see a symbol, telling you to do a blood glucose test before making treatment decisions.

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



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FLASH GLUCOSE MONITORING SYSTEM

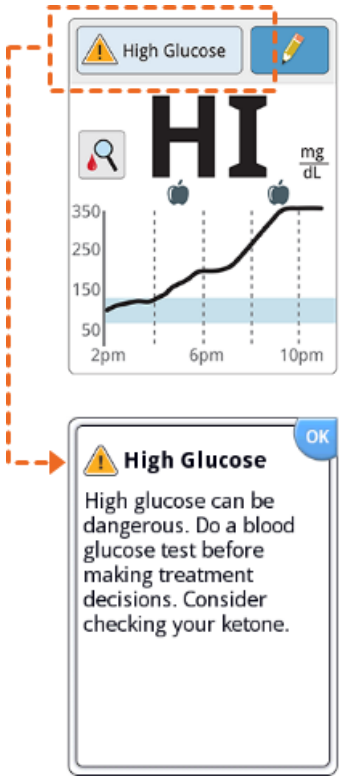
Understanding Sensor Readings - Reader

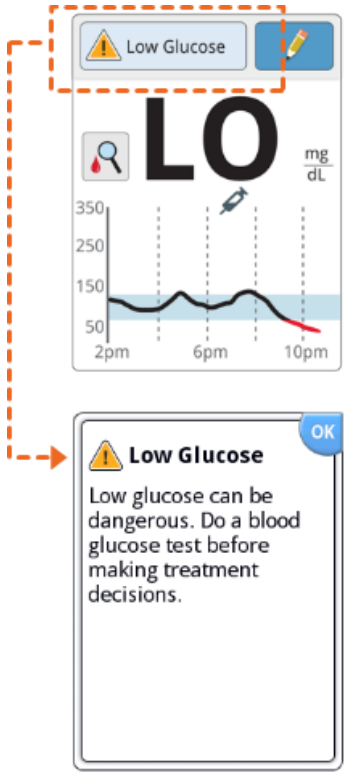
If **LO** appears on the Reader, your reading is lower than 40 mg/dL.

If **HI** appears on the Reader, your reading is higher than 500 mg/dL.

You can touch the message button for more information. If you get a **LO** or **HI** result on the Reader you will see a symbol, teling you to do a blood glucose test before making treatment decisions.

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





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FLASH GLUCOSE MONITORING SYSTEM

Understanding Sensor Readings - App

Sensor Glucose Reading | Trend Arrows | Going High/Low Reading | High/Low Reading | HI/LO Reading

Note: The glucose graph in the App will scale to 500 mg/dL to accommodate glucose readings above 350 mg/dL.

Note: The symbol may appear, indicating the smartphone's time was changed. Gaps in the graph may result or glucose readings may be hidden.

Note: Your current glucose value determines the background color on the My Glucose screen:

- Orange — High glucose (above 240 mg/dL)
- Yellow — Between the Target Glucose Range and high or low glucose level
- Green — Within the Target Glucose Range
- Red — Low glucose (below 70 mg/dL)

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FLASH GLUCOSE MONITORING SYSTEM

Understanding Sensor Readings - App

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

Note: The **Glucose Trend Arrow** may not always appear with your reading. When there is no Glucose Trend Arrow, you will see a  symbol, telling you to do a blood glucose test before making treatment decisions.

	**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 fallling** (between 1 and 2 mg/dL per minute)
	**Glucose is falling quickly** (more than 2 mg/dL per minute)

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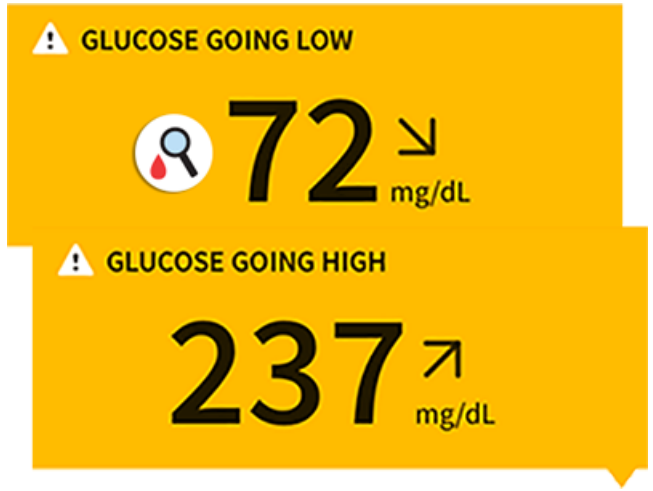
Understanding Sensor Readings - App

If your glucose is projected to be higher than 240 mg/dL or lower than 70 mg/dL within 15 minutes, you will see a GLUCOSE GOING HIGH or a GLUCOSE GOING LOW message on the screen. You can touch the ⚠ symbol for more information and set a reminder to check your glucose.

When there is a GLUCOSE GOING LOW message, you will see a symbol, telling you to do a blood glucose test before making treatment decisions.

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



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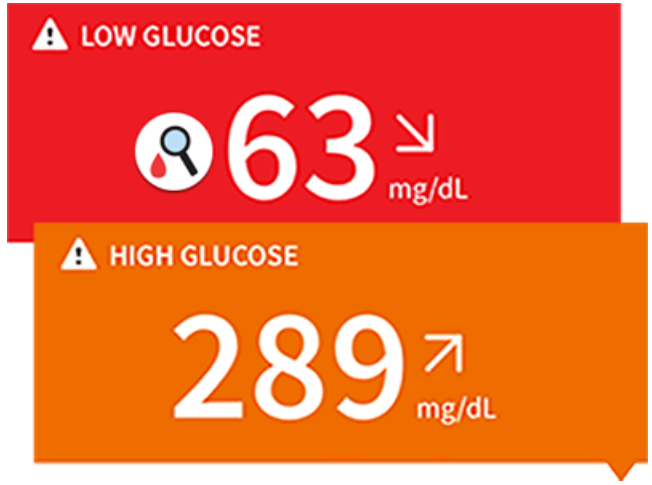
Understanding Sensor Readings - App

If your glucose is higher than 240 mg/dL or lower than 70 mg/dL, you will see a HIGH GLUCOSE or LOW GLUCOSE message on the screen. You can touch the ⚠ symbol for more information and set a reminder to check your glucose.

When there is a LOW GLUCOSE message, you will see a 🔍 symbol, telling you to do a blood glucose test before making treatment decisions.

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



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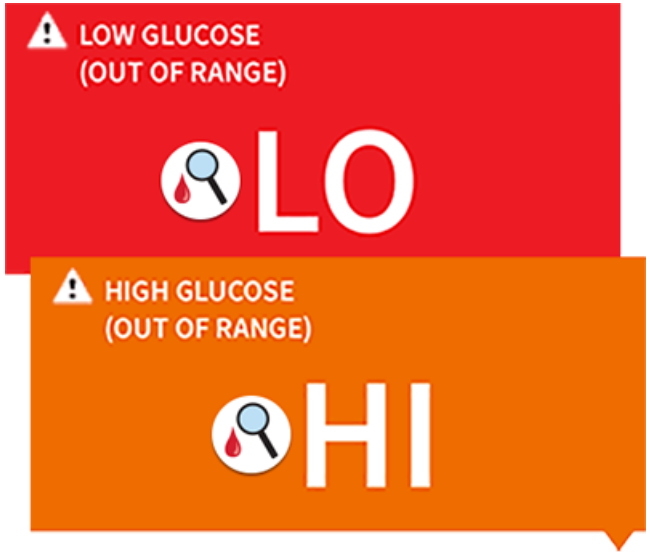
Understanding Sensor Readings - App

If **LO** appears, your reading is lower than 40 mg/dL.

If **HI** appears, your reading is higher than 500 mg/dL.

You can touch the ⚠ symbol for more information. If you get a **LO** or **HI** result you will see a symbol, telling you to do a blood glucose test before making treatment decisions.

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



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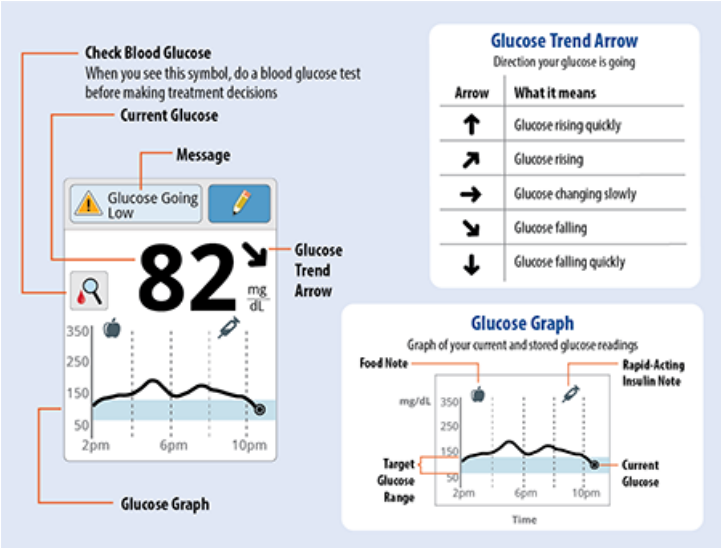
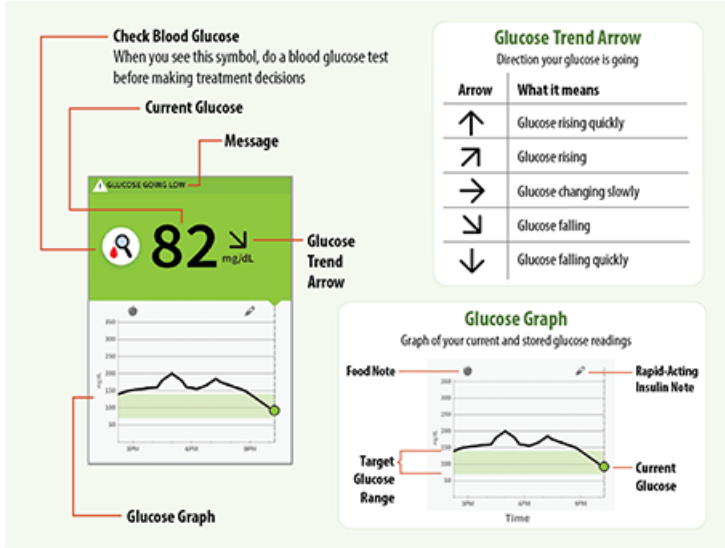
Treatment Decisions Guide

Using Sensor Glucose Readings for treatment decisions

Reader



App



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Treatment Decisions Guide

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.

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FLASH GLUCOSE MONITORING SYSTEM

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Treatment Decisions Guide – Example Scenarios

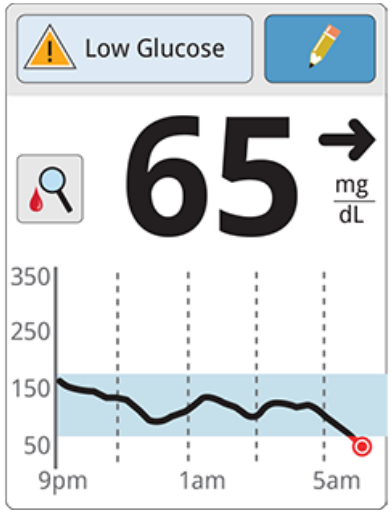
What you see:

When you wake-up, your current glucose is 65 mg/dL and the trend arrow shows it is changing slowly ➔ . There is a Low Glucose (Reader) / LOW GLUCOSE (App) message at the top of the screen and the symbol.

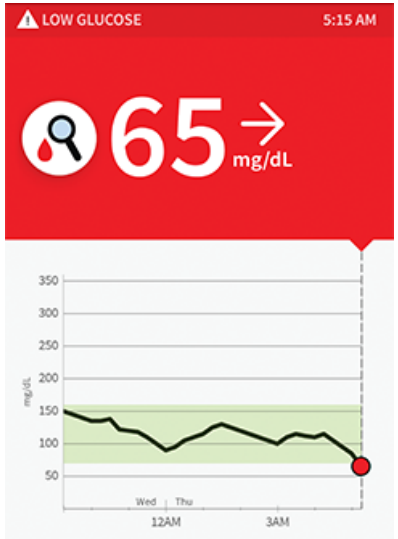
What it means:

Anytime you see the symbol, you should do a blood glucose test before deciding what to do.

Reader



App



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Treatment Decisions Guide – Example Scenarios

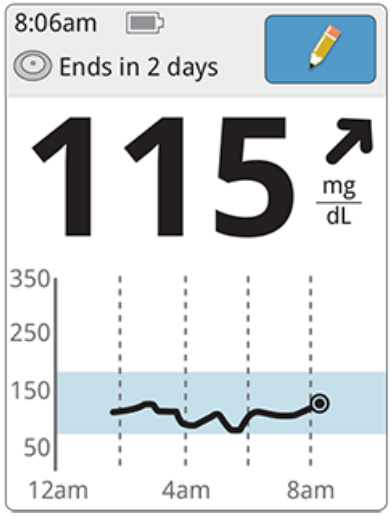
What you see: Before breakfast, your current glucose is 115 mg/dL. The graph shows that your glucose is going up and so does the trend arrow ↗.

What it means:
Consider what might be causing your glucose to go up and what you might do to prevent a high glucose.

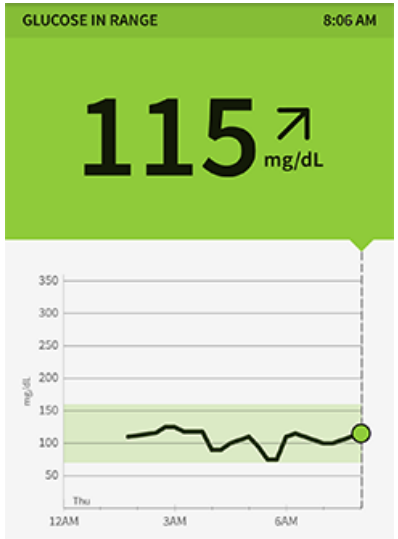
For example:

- How much insulin should you take before your meal?
- Since you see ↗, should you consider taking a little more insulin?

Reader



App



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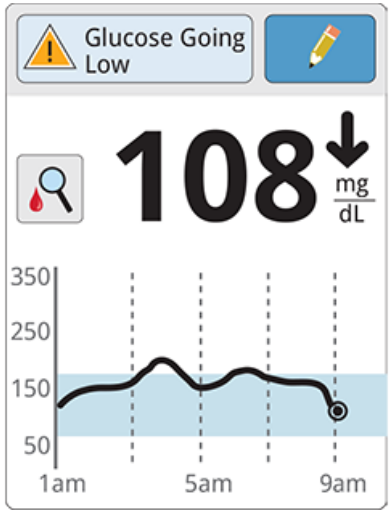
FLASH GLUCOSE MONITORING SYSTEM

Treatment Decisions Guide – Example Scenarios

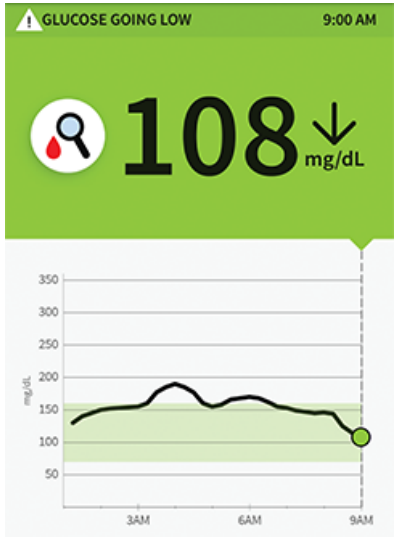
What you see: After breakfast, your current glucose is 108 mg/dL. The trend arrow shows it is going down quickly ↓ . There is a Glucose Going Low (Reader) / GLUCOSE GOING LOW (App) message at the top of the screen and the symbol.

What it means:
Anytime you see the symbol, you should do a blood glucose test before deciding what to do.

Reader



App



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FLASH GLUCOSE MONITORING SYSTEM

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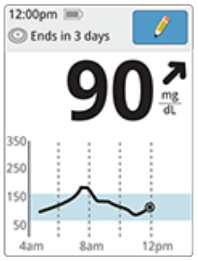
Treatment Decisions Guide – Example Scenarios

What you see:

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 ↗ .

Before Lunch

Reader

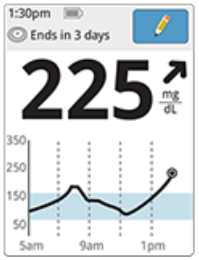


App

90 minutes after lunch, your current glucose is 225 mg/dL. The graph shows that your glucose is still going up, and so does the trend arrow ↗ .

After Lunch

Reader



App

What it means:

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.

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FLASH GLUCOSE MONITORING SYSTEM

Treatment Decisions Guide – Example Scenarios

When You Wake-Up | Before Breakfast | After Breakfast | Lunch | **After Exercising** | Before Dinner | After Dinner

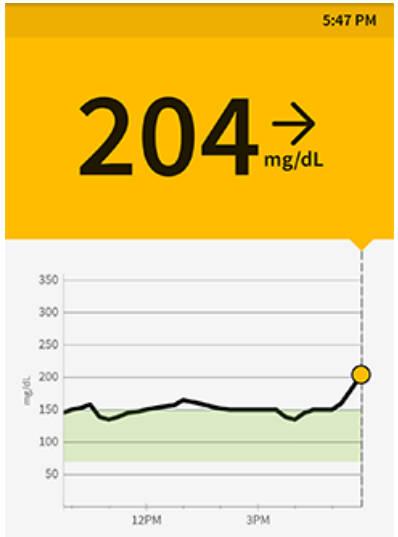
What you see: After exercising, you are feeling shaky, sweaty, and dizzy – symptoms you generally get when you have low glucose. But, your current glucose is 204 mg/dL.

What it means:
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.

Reader

App



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Treatment Decisions Guide – Example Scenarios

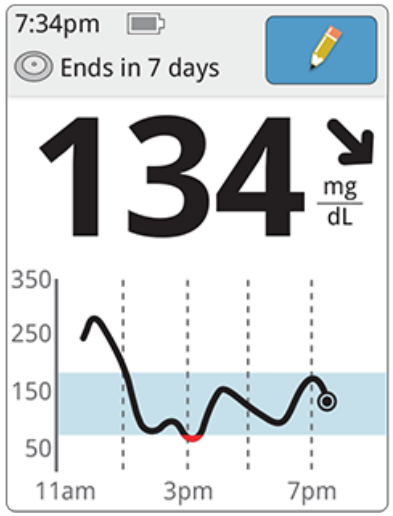
What you see: Before dinner, your current glucose is 134 mg/dL. The graph shows that your glucose is going down and so does the trend arrow ↘ .

What it means:
Consider what might be causing your glucose to go down and what you might do to prevent a low glucose.

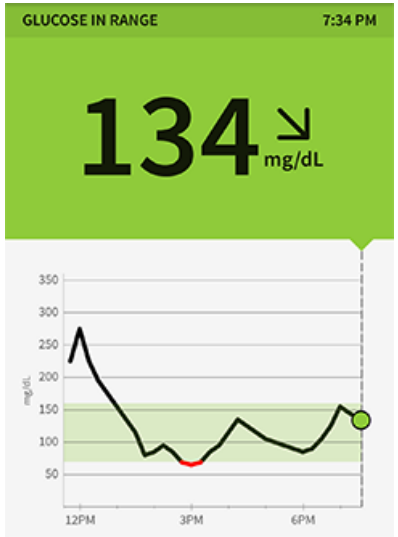
For example:

- How much insulin should you take before your meal?
- Since you see ↘ , should you consider taking a little less insulin?

Reader



App



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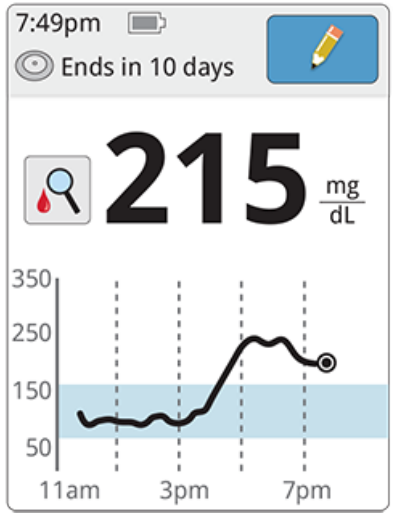
Treatment Decisions Guide – Example Scenarios

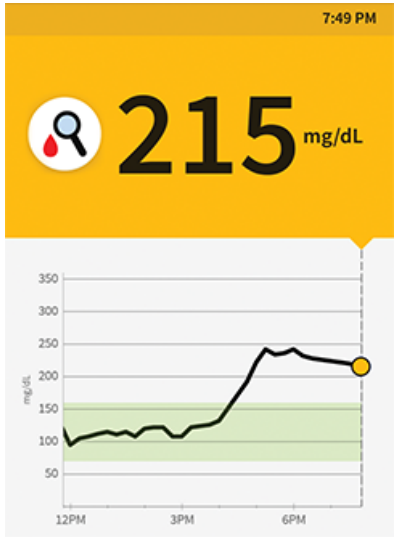
What you see: After dinner, your current glucose is 215 mg/dL but there is no trend arrow. There is also the symbol on the screen.

What it means:
Anytime you see the symbol, you should do a blood glucose test before deciding what to do.

Reader



App



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Treatment Decisions Guide – Knowledge Check

1. What would you do if you scanned your Sensor and saw this  symbol with your reading?

- ○ Do not treat based on this reading – check my blood glucose with a test strip
- ○ Make a treatment decision

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FLASH GLUCOSE MONITORING SYSTEM

Treatment Decisions Guide – Knowledge Check

1. What would you do if you scanned your Sensor and saw this symbol with your reading?

- ○ Do not treat based on this reading – check my blood glucose with a test strip
- ☒ ◉ Make a treatment decision

Incorrect. Don't make treatment decisions based on a Sensor glucose reading that includes this symbol. The symbol means your Sensor glucose reading may not be accurate.

Please click Previous and try again.

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Treatment Decisions Guide – Knowledge Check

1. What would you do if you scanned your Sensor and saw this  symbol with your reading?

- [x] Do not treat based on this reading – check my blood glucose with a test strip
- [ ] Make a treatment decision

Correct! Anytime you see this  symbol, check your blood glucose with a test strip before making treatment decisions. The  symbol means your Sensor glucose reading may not be accurate.

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FLASH GLUCOSE MONITORING SYSTEM

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Treatment Decisions Guide – Knowledge Check

2. What would you do if you are getting ready to eat lunch, you scan your Sensor and you get a reading that your glucose level is above your target range and changing slowly ➜ .

- ○ Do not treat based on this reading – check my blood glucose with a test strip
- ○ Make a treatment decision, such as take insulin

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Treatment Decisions Guide – Knowledge Check

2. What would you do if you are getting ready to eat lunch, you scan your Sensor and you get a reading that your glucose level is above your target range and changing slowly ➔ .

- [x] Do not treat based on this reading – check my blood glucose with a test strip
- [ ] Make a treatment decision, such as take insulin

Incorrect. You could check your blood glucose with a test strip, but you don't have to, unless you have symptoms that don't match your reading.

Please click Previous and try again.

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FLASH GLUCOSE MONITORING SYSTEM

Treatment Decisions Guide – Knowledge Check

2. What would you do if you are getting ready to eat lunch, you scan your Sensor and you get a reading that your glucose level is above your target range and changing slowly ➜ .

- ○ Do not treat based on this reading – check my blood glucose with a test strip
- ☑ ◉ Make a treatment decision, such as take insulin

Correct! Based on your reading and what you are about to eat, consider how much insulin you should take.

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Treatment Decisions Guide – Knowledge Check

3. What would you do if your body was telling you that your glucose was low, but when you scanned your Sensor your reading was high?

- ○ Do not treat based on this reading – check my blood glucose with a test strip
- ○ Do something to lower glucose, such as take insulin

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FLASH GLUCOSE MONITORING SYSTEM

Treatment Decisions Guide – Knowledge Check

3. What would you do if your body was telling you that your glucose was low, but when you scanned your Sensor your reading was high?

- ○ Do not treat based on this reading – check my blood glucose with a test strip
- ☒ ◉ Do something to lower glucose, such as take insulin

Incorrect. If you feel low, trust your symptoms. Check your blood glucose with a test strip and treat accordingly. The Sensor may be inaccurate sometimes. Remember the symbol will **NOT** appear in this situation.

Please click Previous and try again.

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FLASH GLUCOSE MONITORING SYSTEM

Treatment Decisions Guide – Knowledge Check

3. What would you do if your body was telling you that your glucose was low, but when you scanned your Sensor your reading was high?

- [x] Do not treat based on this reading – check my blood glucose with a test strip
- [ ] Do something to lower glucose, such as take insulin

You're right! Anytime you get a reading that doesn't match how you feel, check your blood glucose with a test strip before you make a treatment decision. Remember the symbol will **NOT** appear in this situation.

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Treatment Decisions Guide – Knowledge Check

4. "Insulin stacking" is when you take two or more doses of rapid-acting insulin too close together. Which of the following scenarios would avoid "insulin stacking"?

- ○ You took your full breakfast insulin dose and ate breakfast. 75 minutes later your glucose was high, so you took a correction insulin dose.
- ○ You took your full breakfast insulin dose and ate breakfast. 75 minutes later your glucose was high. You know insulin takes some time to work, so you decided to do nothing and scan again later.

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FLASH GLUCOSE MONITORING SYSTEM

Treatment Decisions Guide – Knowledge Check

4. “Insulin stacking” is when you take two or more doses of rapid-acting insulin too close together. Which of the following scenarios would avoid “insulin stacking”?

- [x] You took your full breakfast insulin dose and ate breakfast. 75 minutes later your glucose was high, so you took a correction insulin dose.

- [ ] You took your full breakfast insulin dose and ate breakfast. 75 minutes later your glucose was high. You know insulin takes some time to work, so you decided to do nothing and scan again later.

Incorrect. Taking multiple doses of rapid-acting insulin too close together may lead to "insulin stacking" and low glucose. Don't take a correction dose within 2 hours of your meal dose.

Please click Previous and try again.

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FLASH GLUCOSE MONITORING SYSTEM

Treatment Decisions Guide – Knowledge Check

4. “Insulin stacking” is when you take two or more doses of rapid-acting insulin too close together. Which of the following scenarios would avoid “insulin stacking”?

- ( ) You took your full breakfast insulin dose and ate breakfast. 75 minutes later your glucose was high, so you took a correction insulin dose.
- (•) ☑ You took your full breakfast insulin dose and ate breakfast. 75 minutes later your glucose was high. You know insulin takes some time to work, so you decided to do nothing and scan again later.

That's correct! Since you did not take multiple doses of rapid-acting insulin too close together, you avoided "insulin stacking" and low glucose. Don't take a correction dose within 2 hours of your meal dose.

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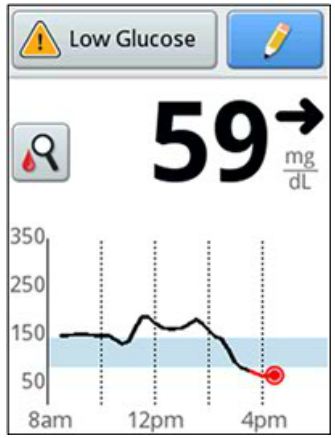
FLASH GLUCOSE MONITORING SYSTEM

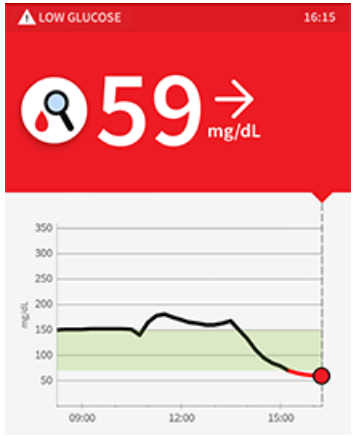
Treatment Decisions Guide – Knowledge Check

5. What would you do if you scanned your Sensor before exercise, and you got this Reading?

Reader



App



- ○ Do not treat based on this result – check my blood glucose with a test strip.
- ○ Do something to bring my glucose up, like eat or take glucose tablets.

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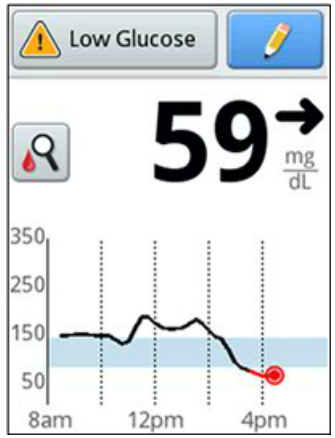
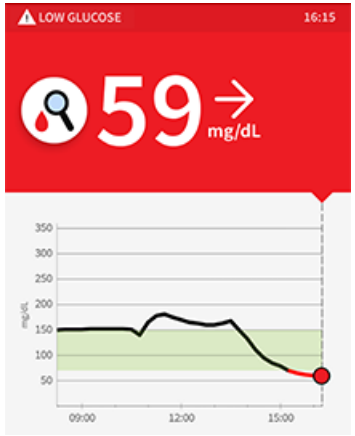
Treatment Decisions Guide – Knowledge Check

5. What would you do if you scanned your Sensor before exercise, and you got this Reading?

Reader



App



- ○ Do not treat based on this result – check my blood glucose with a test strip.
- ☒ ◉ Do something to bring my glucose up, like eat or take glucose tablets.

Incorrect! Although your glucose reading is low, anytime you see this symbol, check your blood glucose with a test strip before making treatment decisions. The symbol means your Sensor glucose reading may not be accurate.

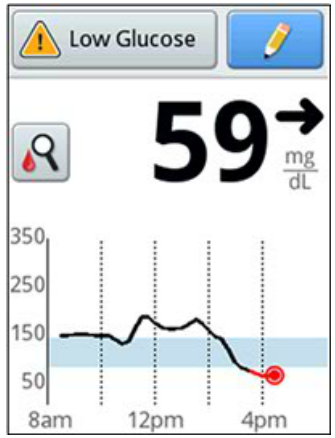
Please click Previous and try again.

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

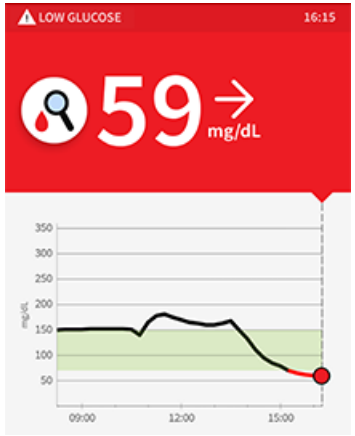
Treatment Decisions Guide – Knowledge Check

5. What would you do if you scanned your Sensor before exercise, and you got this Reading?

Reader



App



- [x] Do not treat based on this result – check my blood glucose with a test strip.

- [ ] Do something to bring my glucose up, like eat or take glucose tablets.

That's right! Anytime you see this symbol, check your blood glucose with a test strip before making treatment decisions.

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FLASH GLUCOSE MONITORING SYSTEM

Treatment Decisions Guide – Knowledge Check

Congratulations – you have finished the knowledge assessment. Click Next to learn more about the System.

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

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Checking Glucose with a Test Strip

You can use the Reader's 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.

How to do it:

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.

Check the FreeStyle Precision Neo test strip expiration date. Do not use expired test strips as they may give inaccurate results.

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.

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

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FLASH GLUCOSE MONITORING SYSTEM

Checking Gluco

You can use the Reader's built sor or not. Be sure to read the test strip instructions for us

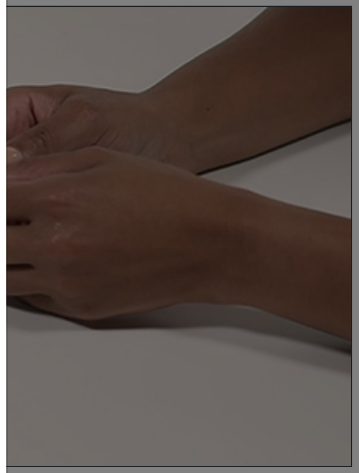
How to do it:

Wash your hands with warm s accurate results. Thoroughly d warm the site, apply a warm d vigorously for a few seconds.

Check the FreeStyle Precision expiration date. Do not use ex may give inaccurate results.

Open the foil test strip packet down to remove the test strip. immediately after removing fro

Insert the test strip with the th the end facing up. Push the st



Caution

Test on your fingers in accordance with the Intended Use.

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.

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FLASH GLUCOSE MONITORING SYSTEM

Checking Gluco

You can use the Reader's built ...nsor or not. Be sure to read the test strip instructions for us...

How to do it:

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.

Check the FreeStyle Precision Neo test strip expiration date. Do not use expired test strips as they may give inaccurate results.

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.

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

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.

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Checking Gluco

You can use the Reader's built sor or not. Be sure to read the test strip instructions for us

How to do it:

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.

Check the FreeStyle Precision Neo test strip expiration date. Do not use expired test strips as they may give inaccurate results.

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.

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.

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Checking Glucose with a Test Strip

How to do it:

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.

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

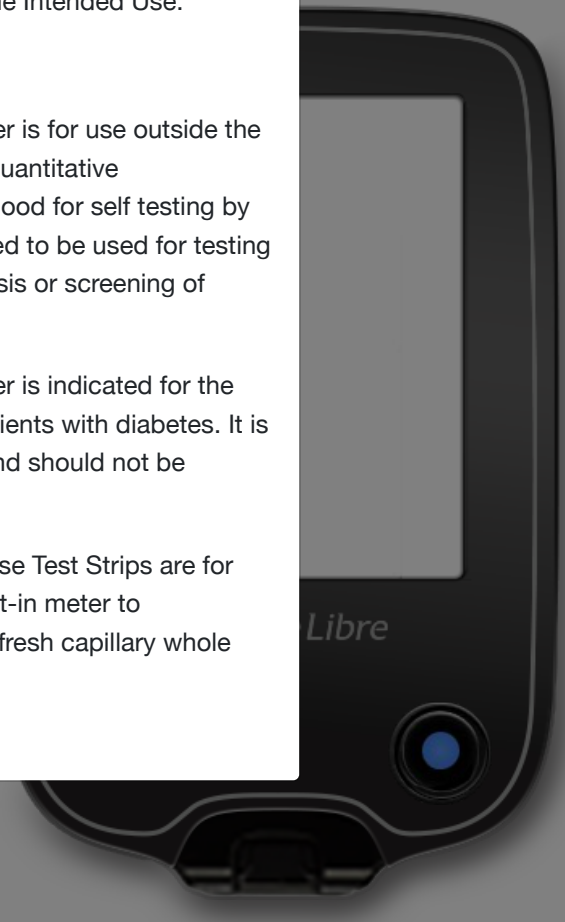
Checking Gluco

How to do it:

Use your lancing device to obt
blood to the white area at the
your lancing device instruction
your lancing device. If sounds
once to let you know you have

You will see a butterfly on the
your result. Do not remove the
butterfly is on the screen. If so
Reader beeps once when your

If the butterfly does not appea
applied enough blood to the te
drop of blood to the test strip
first drop. If the butterfly still d
than 5 seconds have passed,
off the Reader and repeat the
new test strip.



Caution

Test on your fingers in accordance with the Intended Use.

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.

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Checking Gluco

How to do it:

Use your lancing device to obt
blood to the white area at the
your lancing device instruction
your lancing device. If sounds
once to let you know you have

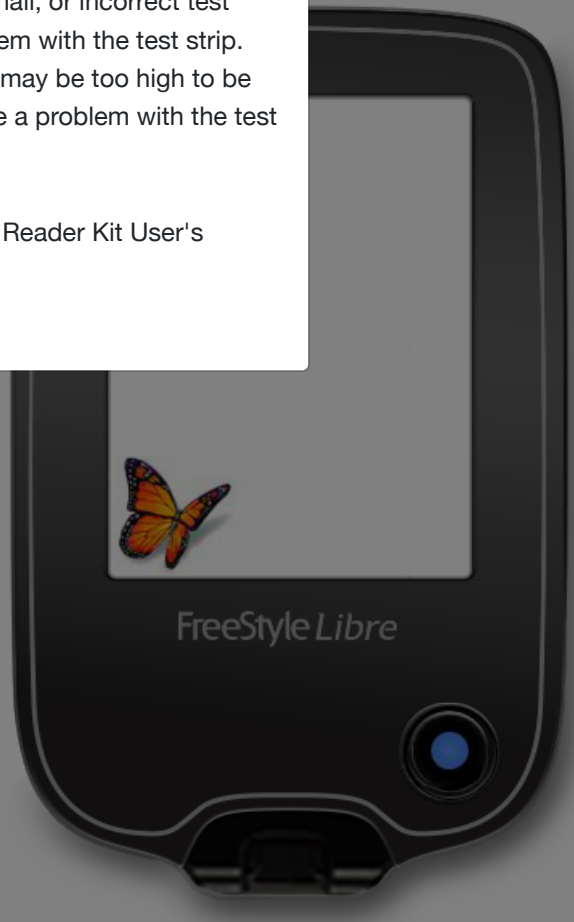
You will see a butterfly on the
your result. Do not remove the
butterfly is on the screen. If sounds are turned on, the Reader beeps once when your result is ready.

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.

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 of the Reader Kit User's Manual for more information.



FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Checking Glucose with a Test Strip

How to do it:

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

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

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

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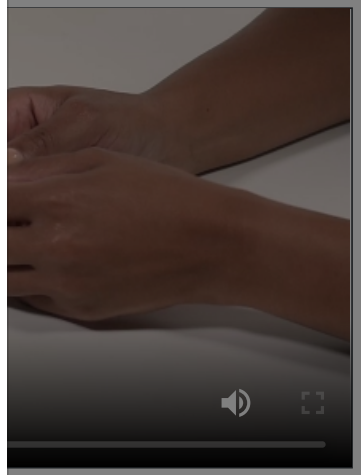
Checking Gluco

How to do it:

After reviewing your result, ren
the used test strip according t
regulations.

Blood glucose results are mark
screen and in the Reader's Lo
symbol.



Caution

Test on your fingers in accordance with the Intended Use.

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.

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

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After revi
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regulatior

Blood glu
screen ar
symbol.

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. Refer to the Maintenance and Disposal section of the Reader Kit User's manual for instructions.
- 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.
- 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 Reader's Logbook and not in other history options.
- Refer to your lancing device instructions for use for how to use your lancing device.
- After performing a blood glucose test, wash your hands with soap and water and thoroughly dry them.
- The built-in meter displays results from 20 - 500 mg/dL. Low or high blood glucose results can indicate a potentially serious medical condition.

Checking Gluco

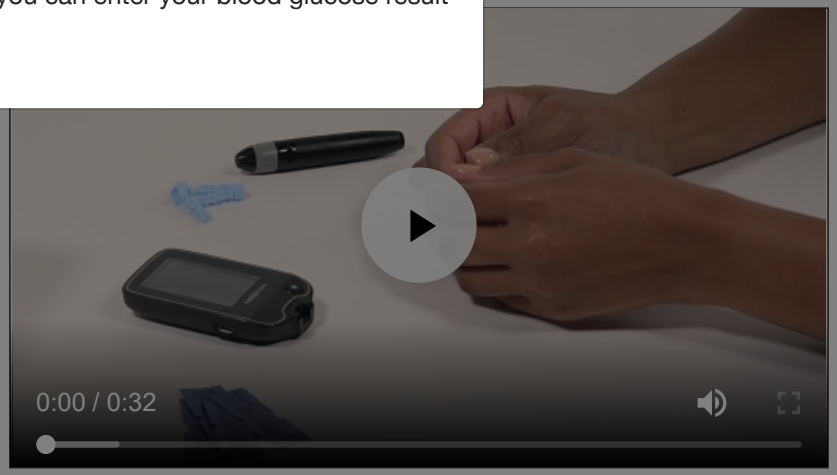
How to do it:

After reviewing your result, rem
the used test strip according to local
regulations.

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

Note

If you are using the App, you can enter your blood glucose result into the App's Logbook.



FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Adding Notes

Both the Reader and the App let you track food, insulin and exercise.

How to do it with the Reader:

Press the Home Button to turn on the Reader. Check your glucose.

From the Glucose Reading screen, add notes by touching the symbol.

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

After checking the box for food and insulin notes, the + symbol appears to the right of the note. Touch + to add more specific information to the note. Then touch **OK**.

Touch **OK** to save notes.

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Adding Notes

Both the Reader and the App l

How to do it with the Reader:

Press the Home Button to turn
glucose.

From the Glucose Reading screen, add notes by touching the
symbol.

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

After checking the box for food and insulin notes, the + symbol appears to the right of the note. Touch + to add more specific information to the note. Then touch **OK**.

Touch **OK** to save notes.

Note

- You can add a note at the time of your glucose reading or within 15 minutes after your reading was obtained.
- Food and rapid-acting insulin notes are shown on your glucose graphs and in your Logbook as symbols.

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Adding Notes

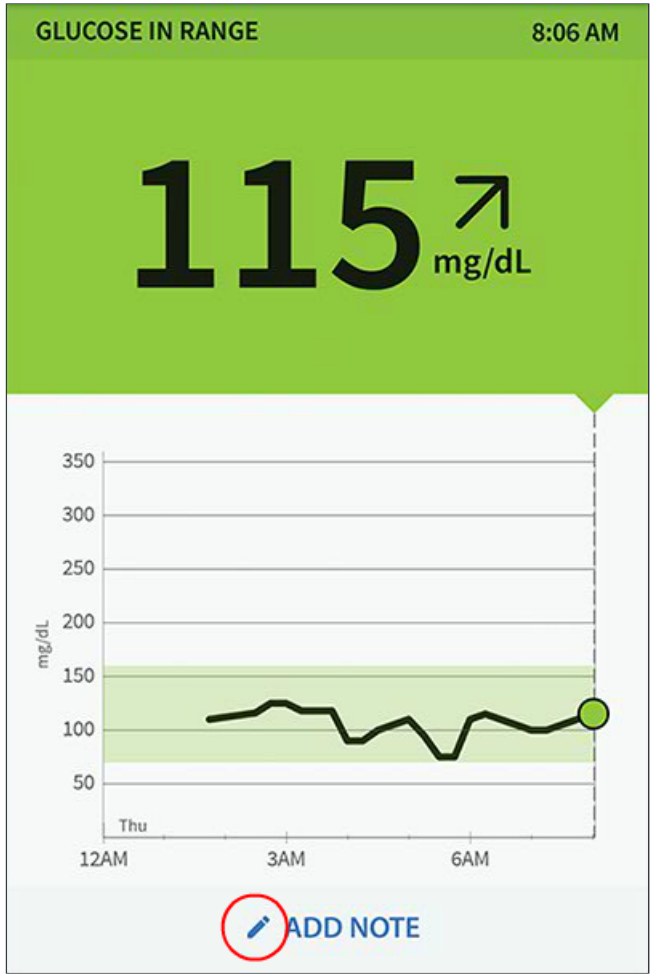
How to do it with the App:

Tap the symbol on the My Glucose screen.

Select the checkbox next to the note you would like to add.

After you check the box, you can add more specific information to your note.

Tap **DONE** to save your note.



FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Adding Notes

How to do it with the App:

Tap the symbol on the My

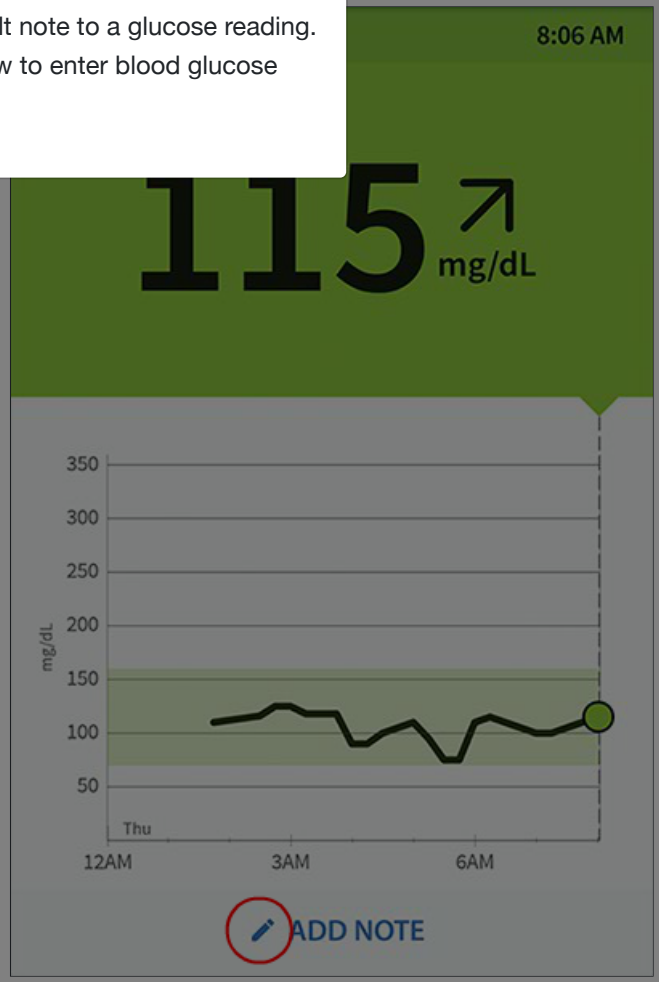
Select the checkbox next to the note you would like to add.

After you check the box, you can add more specific information to your note.

Tap **DONE** to save your note.

Note

You cannot add a blood glucose result note to a glucose reading. See Reviewing History section for how to enter blood glucose results in the App's Logbook.



FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Adding Notes

How to do it with the App:

Tap the symbol on the My

Select the checkbox next to the note you would like to add.

After you check the box, you can add more specific information to your note.

Tap **DONE** to save your note.

Note

Notes are shown on your glucose graphs and in your Logbook as symbols. See App Symbols section for more information.

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

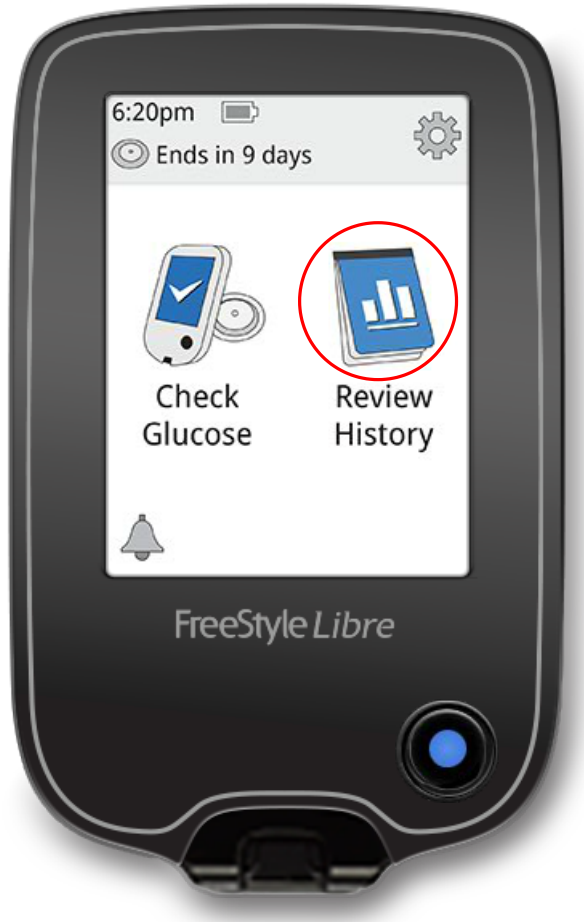
Reviewing History

Reviewing and understanding your glucose history can be an important tool for improving your glucose control. Both the Reader and App store about 90 days of information and have several ways to review your past glucose readings, notes, and other information.

How to do it with the Reader:

Touch the **Review History** icon on the Home Screen.

Use the arrows to view the available options.



FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Reviewing Histo

Reviewing and understanding
important tool for improving yo
Reader and App store about 9
several ways to review your past glucose readings, notes, and other information.

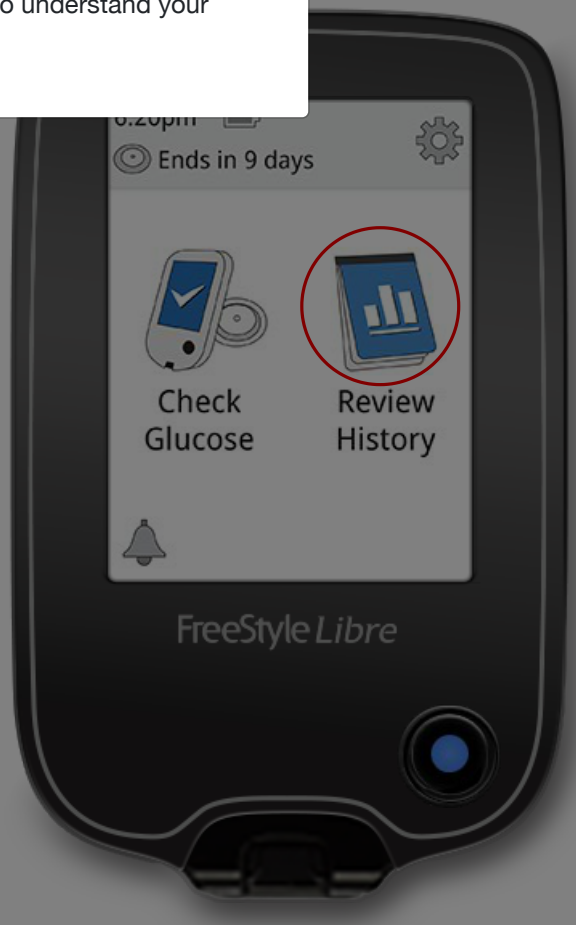
Important

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

How to do it with the Reader:

Touch the **Review History** icon on the Home Screen.

Use the arrows to view the available options.

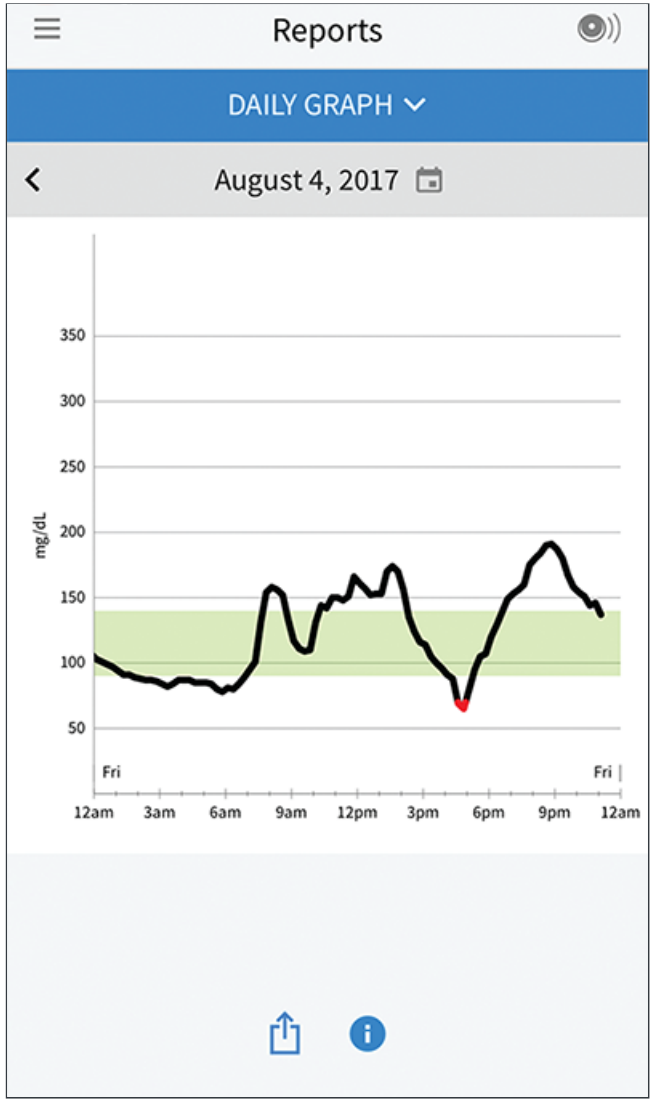


FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Reviewing History

How to do it with the App:

From the Main Menu, tap Logbook to view the **Logbook** or tap on one of the other history options under **Reports**.



FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

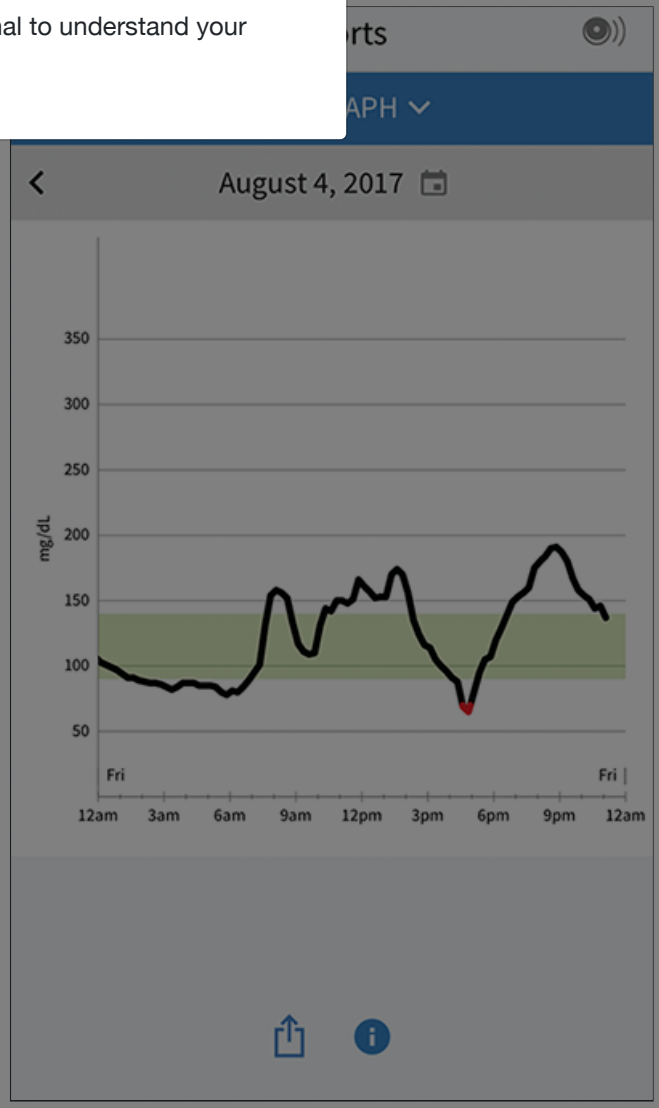
Reviewing Histo

How to do it with the App:

From the Main Menu, tap Logb
or tap on one of the other history options under **Reports**.

Important

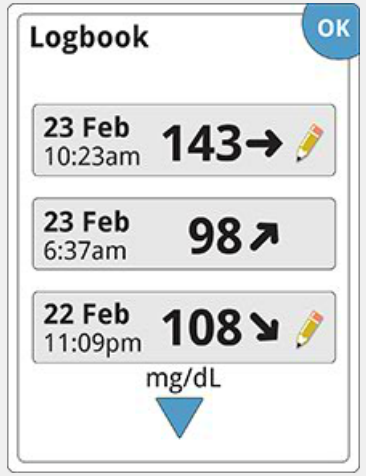
Work with your health care professional to understand your glucose history.



FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Reviewing History

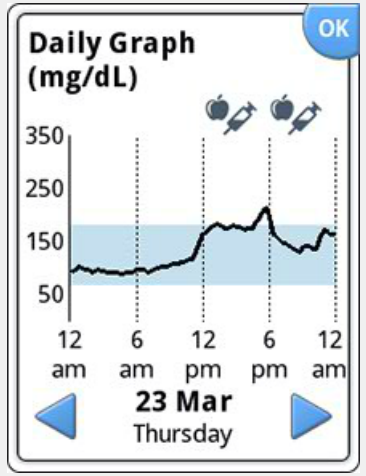
Summary of History Options - Reader

	What data is used?	What does this show?	Example
Logbook	Sensor scan results and blood glucose test results from each day.	Shows 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. Touch the entry to review detailed information including any notes you entered.	
Daily Graph			
Average Glucose			
Daily Patterns			
Time In Target			
Low Glucose Events			
Sensor Usage			

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Reviewing History

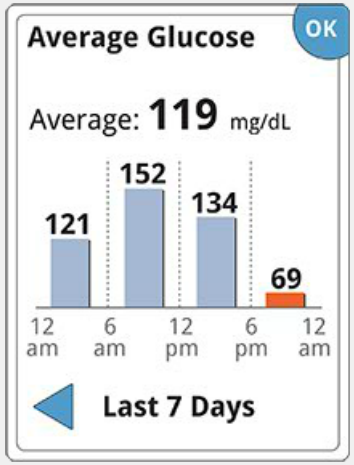
Summary of History Options - Reader

	What data is used?	What does this show?	Example
Logbook	Sensor glucose readings from each day.	Shows a graph of your Sensor glucose readings by day. The blue bar indicates your Target Glucose Range. Symbols indicate any food or rapid-acting insulin notes you have entered.	
Daily Graph			
Average Glucose			
Daily Patterns			
Time In Target			
Low Glucose Events			
Sensor Usage			

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Reviewing History

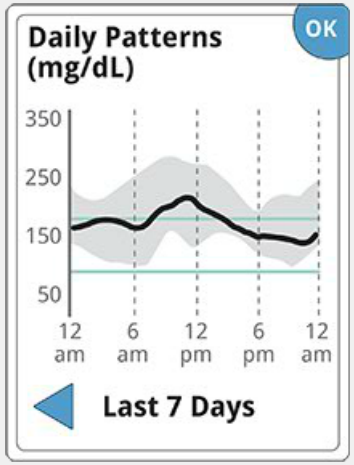
Summary of History Options - Reader

	What data is used?	What does this show?	Example
Logbook	Sensor glucose readings collected in the last 7, 14, 30, and 90 days.	Shows information about the average of your Sensor glucose readings. It includes the overall average and the average for four different 6-hour periods of the day.	
Daily Graph			
Average Glucose			
Daily Patterns			
Time In Target			
Low Glucose Events			
Sensor Usage			

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Reviewing History

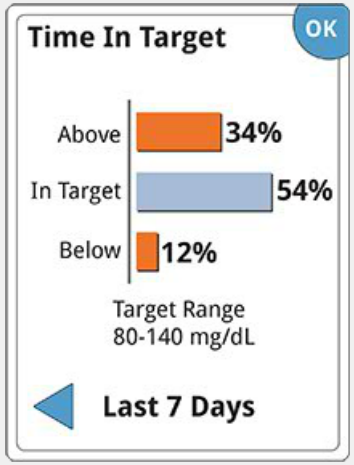
Summary of History Options - Reader

	What data is used?	What does this show?	Example
Logbook	Sensor glucose readings collected in the last 7, 14, 30, and 90 days.	Shows the pattern and variability of your Sensor glucose over a typical day.	
Daily Graph			
Average Glucose			
Daily Patterns			
Time In Target			
Low Glucose Events			
Sensor Usage			

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Reviewing History

Summary of History Options - Reader

	What data is used?	What does this show?	Example
Logbook	Sensor glucose readings collected in the last 7, 14, 30, and 90 days.	Shows the percentage of time your Sensor glucose readings were above, below, or within your Target Glucose Range.	
Daily Graph			
Average Glucose			
Daily Patterns			
Time In Target			
Low Glucose Events			
Sensor Usage			

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Reviewing History

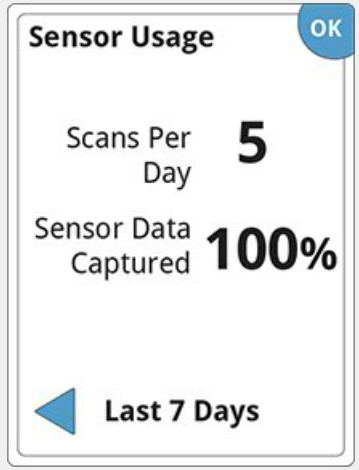
Summary of History Options - Reader

	What data is used?	What does this show?	Example
Logbook	Sensor glucose readings collected in the last 7, 14, 30, and 90 days.	Shows the number of low glucose events measured by your Sensor. It includes the total number of events and the events in four different 6-hour periods of the day.	
Daily Graph			
Average Glucose			
Daily Patterns			
Time In Target			
Low Glucose Events			
Sensor Usage			

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Reviewing History

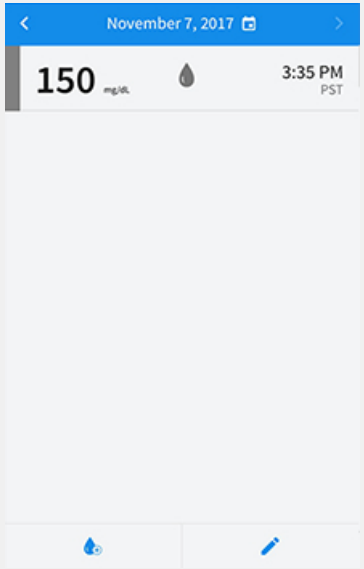
Summary of History Options - Reader

	What data is used?	What does this show?	Example
Logbook	Sensor glucose readings collected in the last 7, 14, 30, and 90 days.	Shows how often you scan your Sensor. It includes 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.	
Daily Graph			
Average Glucose			
Daily Patterns			
Time In Target			
Low Glucose Events			
Sensor Usage			

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Reviewing History

Summary of History Options - App

	What data is used?	What does this show?	Example
Logbook	Sensor scan results from each day. You can also use the Logbook to manually enter your blood glucose test results.	Shows entries for each time you scanned your Sensor as well as notes you added. The Logbook also lets you record a blood glucose test you performed. To do this, tap the symbol and enter your result.	
Daily Graph			
Average Glucose			
Daily Patterns			
Time In Target			
Low Glucose Events			
Sensor Usage			

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Reviewing History

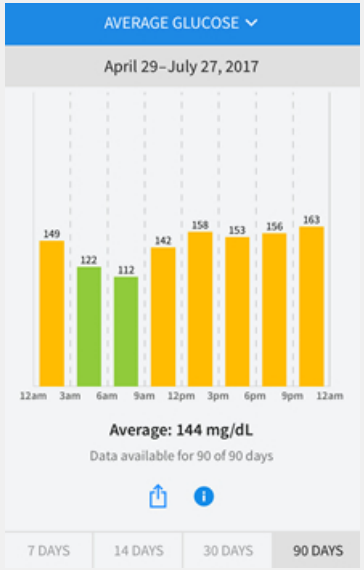
Summary of History Options - App

	What data is used?	What does this show?	Example
Logbook	Sensor glucose readings from each day.	Shows a graph of your Sensor glucose readings by day. The green bar indicates your Target Glucose Range. Symbols indicate any notes you have entered.	
Daily Graph			
Average Glucose			
Daily Patterns			
Time In Target			
Low Glucose Events			
Sensor Usage			

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Reviewing History

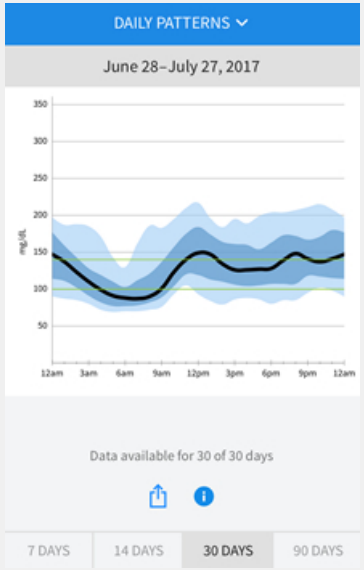
Summary of History Options - App

	What data is used?	What does this show?	Example
Logbook	Sensor glucose readings collected in the last 7, 14, 30, and 90 days.	Shows information about the average of your Sensor glucose readings. It includes the overall average and the average for different periods of the day.	
Daily Graph			
Average Glucose			
Daily Patterns			
Time In Target			
Low Glucose Events			
Sensor Usage			

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Reviewing History

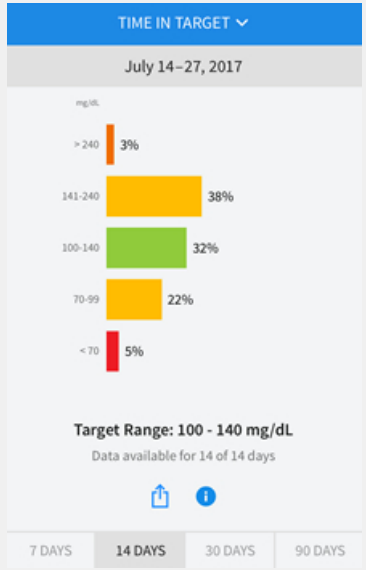
Summary of History Options - App

	What data is used?	What does this show?	Example
Logbook	Sensor glucose readings collected in the last 7, 14, 30, and 90 days.	Shows the pattern and variability of your Sensor glucose over a typical day.	
Daily Graph			
Average Glucose			
Daily Patterns			
Time In Target			
Low Glucose Events			
Sensor Usage			

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Reviewing History

Summary of History Options - App

	What data is used?	What does this show?	Example
Logbook	Sensor glucose readings collected in the last 7, 14, 30, and 90 days.	Shows the percentage of time your Sensor glucose readings were above, below, or within your Target Glucose Range.	
Daily Graph			
Average Glucose			
Daily Patterns			
Time In Target			
Low Glucose Events			
Sensor Usage			

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Reviewing History

Summary of History Options - App

	What data is used?	What does this show?	Example
Logbook	Sensor glucose readings collected in the last 7, 14, 30, and 90 days.	Shows the number of low glucose events measured by your Sensor. It includes the total number of events and the events in different periods of the day.	
Daily Graph			
Average Glucose			
Daily Patterns			
Time In Target			
Low Glucose Events			
Sensor Usage			

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

Reviewing History

Summary of History Options - App

	What data is used?	What does this show?	Example
Logbook	Sensor glucose readings collected in the last 7, 14, 30, and 90 days.	Shows how often you scan your Sensor. It includes the total number of scans, an average of how many times you scanned your Sensor each day, and the percentage of possible Sensor data the App recorded from your scans.	
Daily Graph			
Average Glucose			
Daily Patterns			
Time In Target			
Low Glucose Events			
Sensor Usage			

FreeStyle Libre
FLASH GLUCOSE MONITORING SYSTEM

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several sequential readings over time. The System is intended for single patient use and requires a prescription.

Contraindications

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

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 the Sensor glucose 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.
- If you are using the FreeStyle LibreLink app, you must also have access to a blood glucose monitoring system as the App does not provide one.
- **Hypoglycemic unawareness:** The System has not been evaluated for use in patients with hypoglycemic unawareness and will not automatically alert you of a hypoglycemic event without you scanning your Sensor.
- **No alarms without a Sensor scan:** The System does not have alarms that will automatically notify you when you are having a severe low (hypoglycemic) or high (hyperglycemic) glucose event unless you scan your Sensor. For example, the System does not have an alarm that can alert or wake you when you are sleeping in the case of low or high glucose.
- **Choking hazard:** The System contains small parts that may be dangerous if swallowed.

Cautions and Limitations

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

 What to know about Alarms/Alerts:

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

 What to know before using the System:

- Review all product information before use.
- Take standard precautions for transmission of blood borne pathogens to avoid contamination.

 Who should not use the System:

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

 What should you know about wearing a Sensor:

- After the start-up period, the Sensor can be worn for up to the wear duration specified in your Sensor Kit's product insert.
- Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If you notice significant skin irritation around or under your Sensor, remove the Sensor and stop using the System. Contact your health care professional before continuing to use the System.
- Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. Remove and replace your Sensor if it starts to loosen and follow the instructions to select an appropriate application site.
- 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 Reader has a built-in blood glucose meter that is designed to be used only with FreeStyle Precision Neo blood glucose test strips and MediSense Glucose and Ketone Control Solution. Using other test strips with the Reader's built-in meter will produce an error or cause the Reader's built-in meter to not turn on or start a test. The Reader's built-in meter does not have ketone testing functionality.
- The Reader's built-in meter is not for use on people who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.
- The Reader's built-in meter is not for use on neonates, in critically-ill patients, or for diagnosis or screening of diabetes.
- See Using the Reader's Built-in meter section of the Reader Kit 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.

What to know about FreeStyle LibreLink:

- FreeStyle LibreLink installed on a smartphone is intended for use by a single person. It must not be used by more than one person due to the risk of misinterpreting glucose information.
- FreeStyle LibreLink and FreeStyle Libre Readers do not share data. For complete information on a device, be sure to scan your Sensor every 8 hours with that device; otherwise, your reports will not include all your data.

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FLASH GLUCOSE MONITORING SYSTEM

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Important information about the FreeStyle Libre System

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 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 the Sensor glucose 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.
- If you are using the FreeStyle LibreLink app, you must also have access to a blood glucose monitoring system as the App does not provide one.
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⚠ What to know about the Reader's Built-in Meter:

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- 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 Reader Kit 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.

What to know about FreeStyle LibreLink:

- FreeStyle LibreLink installed on a smartphone is intended for use by a single person. It must not be used by more than one person due to the risk of misinterpreting glucose information.
- FreeStyle LibreLink and FreeStyle Libre Readers do not share data. For complete information on a device, be sure to scan your Sensor every 8 hours with that device; otherwise, your reports will not include all your data.

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Reader Symbols

	Sensor may be inaccurate. Check blood glucose with a test strip before making any treatment decisions
	Sensor
	Direction glucose is going
	Caution
	View previous/next screen
	Notes
	Add more information to notes
	Food note

	Rapid-acting insulin note
	Time changed on Reader
	Reminders
	Blood glucose test
	Settings
	Control solution test result
	Low battery
	Battery charging
	Sensor too cold
	Sensor too hot

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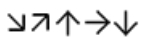
App Symbols

	App icon
	Sensor may be inaccurate. Check blood glucose with a test strip before making any treatment decisions
	Scan button
	Direction glucose is going
	Caution
	Add/edit notes
	Manually entered blood glucose result note
	Add blood glucose result note
	Food note
	Insulin (Rapid or Long-acting) note
	Exercise note
	Time change
	Main menu
	Multiple/Custom notes
	Share report
	Additional information
	Calendar
	Sensor too cold
	Sensor too hot

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System Specifications

Sensor Specifications | Reader Specifications

Sensor glucose assay method	Amperometric electrochemical sensor
Sensor glucose reading range	40 to 500 mg/dL
Sensor size	5 mm height and 35 mm diameter
Sensor weight	5 grams
Sensor power source	One silver oxide battery
Sensor data	Up to the wear duration specified in your Sensor Kit's product insert
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 > 12 mm diameter
Operating and storage altitude	-1,250 ft (-381 meters) to 10,000 ft (3,048 meters)

Please refer to the Reader Kit User's Manual for updates to the information.

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System Specifications

Sensor Specifications | Reader Specifications

Blood glucose assay range	20 to 500 mg/dL
Reader size	95 mm x 60 mm x 16 mm
Reader weight	65 grams
Reader power source	One lithium-ion rechargeable battery
Reader battery life	7 days of typical use
Reader memory	90 days of typical use
Reader operating temperature	50 °F to 113 °F
Reader storage temperature	-4 °F to 140 °F
Operating and storage relative humidity	10-90%, non-condensing
Reader moisture protection	Keep dry
Operating and storage altitude	-1,250 ft (-381 meters) to 10,000 ft (3,048 meters)

Reader display timeout	60 seconds (120 seconds when test strip is inserted)
Radio Frequency	Near Field Communication* (13.56 MHz RFID); ASK Modulation; 124 dBuV/m; 1.5 inch communication range
Data port	Micro USB
Minimum Computer Requirements	System must only be used with EN60950-1 rated computers
Mean service life	3 years of typical use
Reader cleaning and disinfection	The Reader has a mean use life of 3 years, which is 156 cleaning and disinfection cycles (1 cycle per week for 3 years).
Power Adapter	Abbott Diabetes Care PRT25611 Operating temperature: 50 °F to 104 °F
USB Cable	Abbott Diabetes Care PRT21373 Length: 37 inches (94 cm)

Please refer to the Reader Kit User's Manual for updates to the information.

*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.

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