Your FreeStyle Libre 14 day System

IN-SERVICE GUIDE

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Abbott

See inside for Indications and Important Safety Information.

Important Safety Information

Indications For Use

The FreeStyle Libre 14 day Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device indicated for the management of diabetes in persons age 18 and older. It is designed to replace blood glucose testing for diabetes treatment decisions.

The System detects trends and tracks patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time. The System is intended for single patient use and requires a prescription.

Contraindications

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

WARNINGS:

- **Do not ignore symptoms that may be due to low or high blood glucose:** if you are experiencing symptoms that are not consistent with your glucose readings, consult your health care professional.

- **Check Sensor glucose readings by conducting a fingerstick test with a blood glucose meter under the following conditions, when Sensor glucose readings may not be accurate and should not be used to make a diabetes treatment decision:**

  o If you suspect that your reading may be inaccurate for any reason

  o When you are experiencing symptoms that may be due to low or high blood glucose

  o When you are experiencing symptoms that do not match the Sensor glucose readings

  o During the first 12 hours of wearing a FreeStyle Libre 14 day Sensor

  o During times of rapidly changing glucose (more than 2 mg/dL per minute)

  o When the Sensor glucose reading does not include a Current Glucose number or Glucose Trend Arrow

  o In order to confirm hypoglycemia or impending hypoglycemia as reported by the Sensor

  o 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.

  o 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.

Important Safety Information

⚠️ **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.
- The System uses all available glucose data to give you readings so you should scan your Sensor at least once every 8 hours for the most accurate performance. Scanning less frequently may result in decreased performance. If you are using both the App and Reader with the same Sensor, be sure to scan frequently with both devices.
- 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.

Important Safety Information

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 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.

Important Safety Information

⚠️ **What to do if you are dehydrated:**

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

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

- The FreeStyle Libre 14 day Reader has a built-in blood glucose meter that is designed to be used only with FreeStyle Precision Neo blood glucose test strips and MediSense Glucose and Ketone Control Solution. Using other test strips with the Reader's built-in meter will produce an error or cause the Reader's built-in meter to not turn on or start a test. The Reader's built-in meter does not have ketone testing functionality.

- The Reader's built-in meter is not for use on people who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.

- The Reader's built-in meter is not for use on neonates, in critically-ill patients, or for diagnosis or screening of diabetes.

- See Using the Reader's Built-in meter section 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 14 day 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.

Getting to Know Your System

- The reader or app* scans the sensor for glucose readings and stores up to 90 days of glucose history
- The reader or app† activates the sensor and initiates the 1-hour warm up period
- The reader is rechargeable

- The sensor is worn on the back of the upper arm and stores glucose readings every 15 minutes
- Follow the instructions to prepare and apply the sensor
- The sensor may be worn for up to 14 days with no fingersticks for calibration or insulin dosing‡

FreeStyle LibreLink App

Reader

Touch Screen

Sensor Applicator

Sensor Pack

Codes on labels must match

USB Port

Home Button
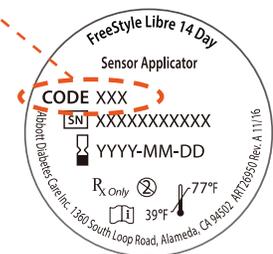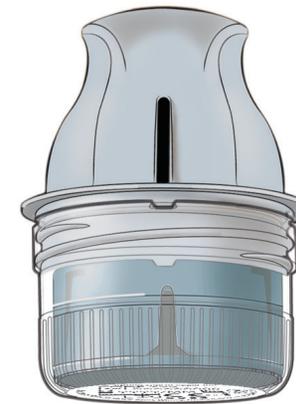
See User's Manual for instruction on setting up the reader for the first time.

*The FreeStyle LibreLink app and the FreeStyle Libre 14 Day reader have similar but not identical features. Fingersticks are required for treatment decisions when you see Check Blood Glucose symbol, when symptoms do not match system readings, when you suspect readings may be inaccurate, or when you experience symptoms that may be due to high or low blood glucose.

†The FreeStyle LibreLink app is only compatible with certain mobile devices and operating systems. Please check our website for more information about device compatibility before using the app. Use of the FreeStyle LibreLink app requires registration with LibreView.
‡Lancing is not required except when symptoms do not match glucose reading, when reader prompts a blood glucose test, or when glucose readings are not available with system.

Sensor Application

1 Assemble sensor and apply it to your body

Get Ready

STEP 1

Select site on **back of your upper arm.** Do not use other sites as these are not approved and may result in inaccurate glucose readings.

Note: Avoid scars, moles, stretch marks, lumps, and insulin injection sites. To prevent skin irritation, rotate sites between applications.

TIP: Select an area on the back of the upper arm that generally stays flat during normal daily activities (no bending or folding).

STEP 2

Clean application site with an alcohol wipe. **Allow site to dry completely before proceeding.**

TIP: The area MUST be clean and dry or the sensor may not stick to the site.

STEP 3
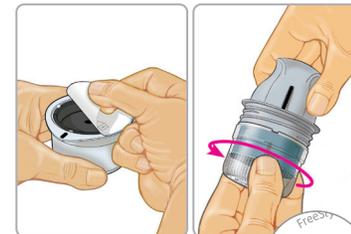
Peel lid completely off sensor pack. Unscrew cap from sensor applicator.

CAUTION: *Sensor codes must match on sensor pack and sensor applicator or glucose readings will be incorrect.*

CODE XXX
SN XXXXXX
YYYY

Prepare Sensor Applicator

STEP 4

Line up dark mark on sensor applicator with dark mark on sensor pack. On a hard surface, press down firmly on sensor applicator until it comes to a stop and you hear an audible click.

TIP: Assemble on a hard surface, such as a table.

STEP 5

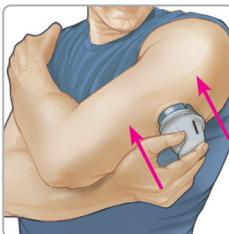Lift sensor applicator straight out of sensor pack.

STEP 6

Sensor applicator is ready to apply sensor.

CAUTION: *Sensor applicator now contains a needle. Do not touch inside sensor applicator or put it back into sensor pack.*
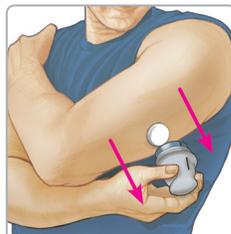
Apply Sensor

STEP 7

Place sensor applicator over site and push down firmly to apply sensor.

CAUTION: *Do not push down on sensor applicator until placed over prepared site to prevent unintended results or injury.*

TIP: For video of sensor application, visit **https://www.MyFreeStyle.com/provider/resources**

STEP 8

Gently pull back applicator to remove, leaving sensor on body.

STEP 9

Make sure sensor is secure by gently pressing adhesive to the skin. Discard used sensor applicator and sensor pack according to local regulations.

Start New Sensor

2 Start new sensor with reader

STEP 1

Press Home Button to turn on reader.

NOTE: If using reader for the first time, follow the prompts to set date, time, and target glucose range.

STEP 2

Touch Start New Sensor.

STEP 3

Hold reader within 1.5 inches (4 cm) of sensor to scan it.

Sensor can be used to check your glucose after 1 hour.

3 Start new sensor with app

STEP 1

Tap the scan button.

STEP 2

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.

STEP 3

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

If you would like to use both your reader and your app during your sensor wear, scan the sensor first with your reader and then with your app.

After the 1-hour warm up period, the sensor can be worn for up to 14 days. Your sensor automatically stops working after 14 days of data and must be replaced.

Work with your healthcare provider to choose and enter a custom target range on your reader.

Start New Sensor

If you would like to use both your reader and your app during your sensor wear, scan the sensor first with your reader and then with your app.

After the 1-hour warm up period, the sensor can be worn for up to 14 days. Your sensor automatically stops working after 14 days of data and must be replaced.

Work with your healthcare provider to choose and enter a custom target range on your reader.

First Time App Setup

How to do it:

Check that your smartphone is connected to a network (WiFi or cellular). Download FreeStyle LibreLink from the App Store or Google Play. Open the App.

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

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.

The LibreView data management software is intended for use by both patients and healthcare professionals to assist people with diabetes and their healthcare professionals in the review, analysis and evaluation of historical glucose meter data to support effective diabetes management. The LibreView software is not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

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.

Carrier 10:37 PM

FreeStyle
LibreLink

● ○ ○ ○ ○

Already have a LibreView account? Sign In

GET STARTED NOW

Accessing Your Glucose Data

You can scan to get a real-time glucose reading anytime. The reader stores up to 90 days of data.

Check your glucose

STEP 1

Press Home Button to turn on reader **OR** touch Check Glucose from the Home Screen. For app use, press main menu and tap home to return to the App Home Screen. Tap "Check Glucose" at the bottom of your screen when you are ready to scan.

STEP 2

Hold reader within 1.5 inches (4 cm) of sensor to scan it.

NOTE: If the sensor is not successfully scanned within 15 seconds, the reader displays a prompt to scan the sensor again. Touch OK to return to the Home Screen and touch Check Glucose to scan your sensor.

STEP 3

Both reader and app show your glucose reading along with your glucose graph and an arrow indicating the direction your glucose is going.
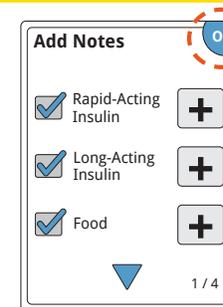
Adding notes
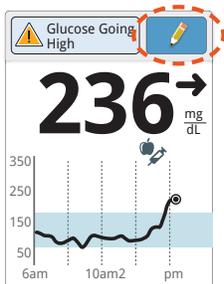
From the Glucose Reading screen, add a note by touching the ✏ in the upper right corner of the screen.
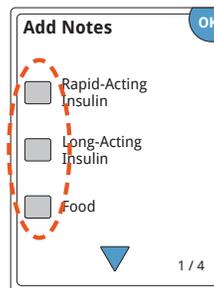
Select the checkbox next to the information you'd like to add. Options include insulin, food, exercise, and any medication you take.

Touch OK to save your notes. Notes are viewable in the logbook.

Accessing Your Glucose Data

You can scan to get a real-time glucose reading anytime. The reader stores up to 90 days of data.
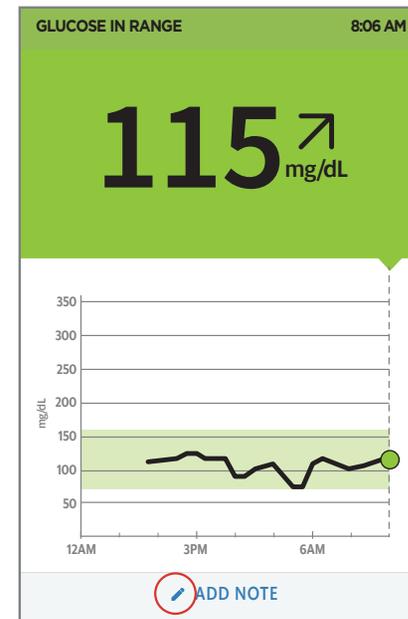
Adding notes
How to do it with the App:

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.

GLUCOSE IN RANGE   8:06 AM

115 ↗
mg/dL

350
300
250
200
150
100
50

mg/dL

12AM   3PM   6AM

✏ ADD NOTE

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**.
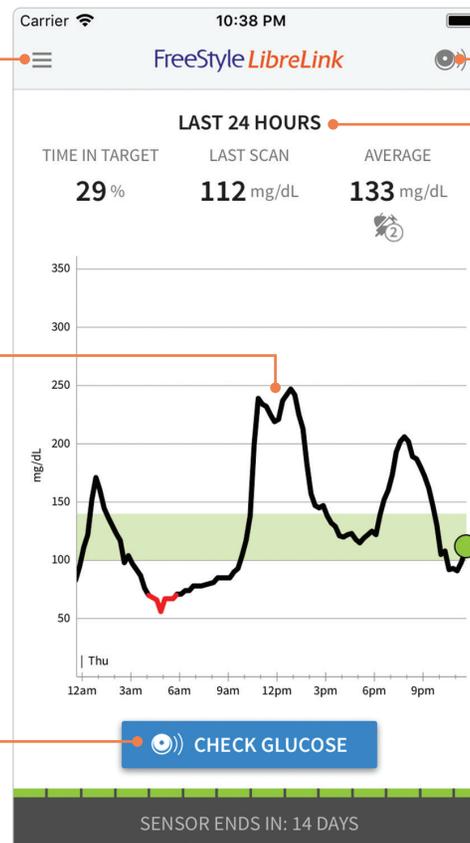
Main Menu

Tap to access the Home Screen, Logbook, other history options, and the Share option. You can also access Settings, Help, and other information.

Glucose Graph

Graph of your stored Sensor glucose readings.

Scan Button

Tap this button or the symbol at the top of the screen when you're ready to scan your Sensor.

Scan Button

Tap this symbol or the button at the bottom of the screen when you're ready to scan your Sensor.

Glucose Information

Your Time in Target, information about your last scan, and average glucose for the last 24 hours.

Carrier — 10:38 PM

FreeStyle *LibreLink*

LAST 24 HOURS

TIME IN TARGET	LAST SCAN	AVERAGE
29 %	**112** mg/dL	**133** mg/dL

CHECK GLUCOSE

SENSOR ENDS IN: 14 DAYS

Review Your History

The system provides insightful information to identify 7-, 14-, 30-, and 90-day trends.
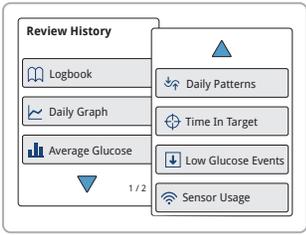
STEP 1
Press Home Button to turn on the reader and go to Home Screen.
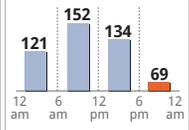
STEP 2
Touch Review History.

10:23pm
Ends in 10 days
Check Glucose
Review History

STEP 3
Use the arrows to view the available options.

Review History
- Logbook
- Daily Graph
- Average Glucose

- Daily Patterns
- Time In Target
- Low Glucose Events
- Sensor Usage

1 / 2

Average Glucose

Average Glucose OK

Average: **119** mg/dL

121 | 152 | 134 | | 69

12 am | 6 am | 12 pm | 6 pm | 12 am

◀ Last 7 Days

Information about the average sensor glucose readings[1]

Daily Graph

Daily Graph (mg/dL) OK

350
250
150
50

12 am | 6 am | 12 pm | 6 pm | 12 am
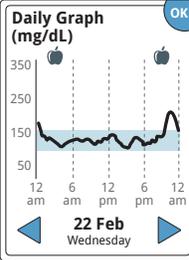
◀ **22 Feb** Wednesday ▶

Sensor glucose readings by day[2]

Daily Patterns

Daily Patterns (mg/dL) OK

350
250
150
50

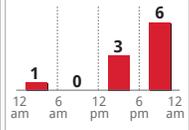12 am | 6 am | 12 pm | 6 pm | 12 am
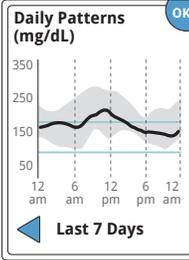
◀ Last 7 Days

The pattern and variability of your sensor glucose over a typical day[2,3,4]

Low Glucose Events

Low Glucose Events OK

Total Events: **10**

1 | 0 | 3 | 6

12 am | 6 am | 12 pm | 6 pm | 12 am

◀ Last 7 Days

The number of low glucose events measured
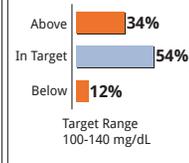

Sensor Usage

Sensor Usage OK

Scans Per Day **3**

Sensor data captured **81%**

◀ Last 7 Days

Report on how often you scan the sensor

Time in Target Range

Time In Target OK

Above **34%**
In Target **54%**
Below **12%**

Target Range 100-140 mg/dL

◀ Last 7 Days

The percentage of time glucose readings were above, below, or within Target Glucose Range[1]

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1. Readings above or below your Target Glucose Range are orange, while readings in range are blue.
2. The thick black line shows the median (midpoint) of your glucose readings.
3. The gray shading represents a range (10-90 percentiles) of your sensor readings. This is not the Ambulatory Glucose Profile.
4. Daily Patterns needs at least 5 days of glucose data.
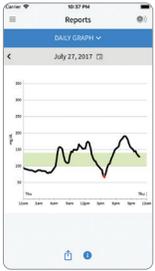
Review Your History

The system provides insightful information to identify 7-, 14-, 30-, and 90-day trends.
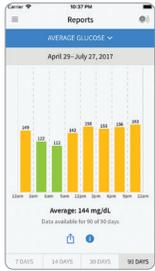
Logbook

Sensor scan results from each day. You can also use the Logbook to manually enter your blood glucose test results.
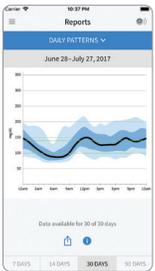
Daily Graph

Sensor glucose readings from each day.

Average Glucose

Sensor glucose readings collected in the last 7, 14, 30, and 90 days.
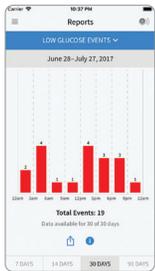
Daily Patterns

Sensor glucose readings collected in the last 7, 14, 30, and 90 days.
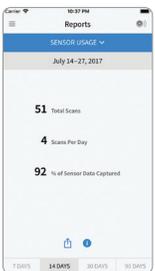
Time in Target

Sensor glucose readings collected in the last 7, 14, 30, and 90 days.

Low Glucose Events

Sensor glucose readings collected in the last 7, 14, 30, and 90 days.

Sensor Usage

Sensor glucose readings collected in the last 7, 14, 30, and 90 days.

Maintenance and Disposal

Your sensor automatically stops working after 14 days of data is collected and must be replaced. You should also replace your sensor if you notice any irritation or discomfort at the application site or if the reader reports a problem with the sensor currently in use.

Sensor Removal

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

If you removed your last sensor before it ended, you will be prompted to confirm that you would like to start a new sensor when you first scan it.

When you are ready to apply a new sensor, follow the instructions previously outlined.

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

Reader Cleaning & Disinfection

You should clean and disinfect the reader once a week. Use Clorox Healthcare Bleach Germicidal Wipes.*

NOTE: Turn off the reader before you clean and disinfect it.

For cleaning, wipe outside surfaces of the reader with one bleach wipe.

For disinfection, use a second bleach wipe to wipe outside surfaces of the reader until surfaces are wet.

NOTE: Make sure liquid does not get into the test strip and USB ports.

Allow the reader surfaces to remain wet for 60 seconds. After 1 full minute, immediately dry with a clean paper towel to remove any residual moisture. When finished, thoroughly wash your hands with soap and water.

Discard the used sensor in accordance with all applicable local regulations related to the disposal of electronic equipment, batteries, and materials potentially exposed to body fluids.

*Clorox Healthcare Bleach Germicidal Wipes may be purchased at major online retailers, such as Walmart.com, Amazon.com, and OfficeDepot.com.

Interpreting Sensor Readings

Sensor glucose readings appear after scanning your sensor. Before making treatment decisions, it is important to understand your sensor readings. **Use all of the information on the screen** when deciding what to do or what treatment decision to make.

What you see in the App

Message
Tap for more information.

Current Glucose
Glucose from your latest scan.

Check Blood Glucose symbol
Tap for more information.

Food Note

Glucose Trend Arrow
Direction your glucose is going.

Rapid-Acting Insulin Note

Glucose Graph
Graph of your current and stored glucose readings.

Add Notes
Tap to add notes to your glucose reading.

⚠ GLUCOSE GOING LOW
82 mg/dL
350
300
250
200
150
100
50
3PM   6PM   9PM
✎ ADD NOTE

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

Target Glucose Range

⚠ Glucose Going Low
82 mg/dL
350
250
150
50
2pm   6pm   10pm

Glucose Trend Arrow

Current Glucose

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.

NOTE: The 🕐 symbol may appear, indicating the reader time was changed. Gaps in the graph may result or glucose readings may be hidden.
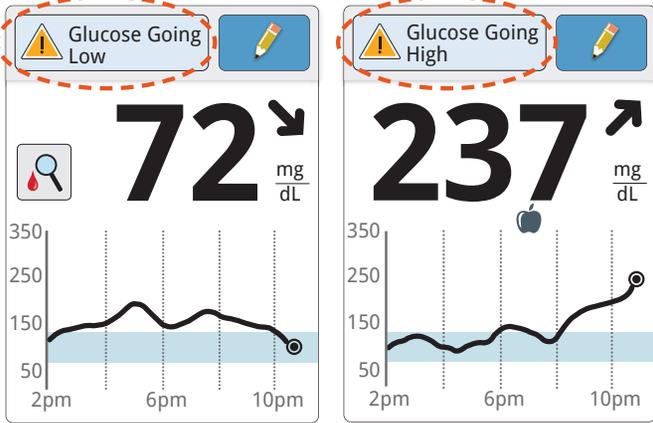
Trend Arrows

The Glucose Trend Arrow indicates which direction your glucose is going.

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

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

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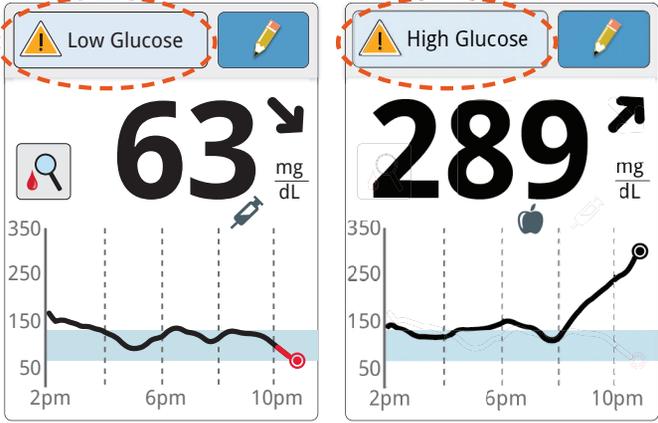
Going High/Low Reading

Messages will appear on the Reader when glucose readings are trending.

DISPLAY	WHAT TO DO
	If your glucose is projected to be higher than 240 mg/dL or lower than 70 mg/dL within 15 minutes, a message will appear on the screen. **Touch the message button for more information and set a reminder to check your glucose again.**

If your glucose reading is less than 70 mg/dL, projected to be less than 70 mg/dL, rapidly changing, or there is no number or trend arrow, you will see this symbol. You can touch the symbol for more information. Check your blood glucose on your finger with a test strip before making treatment decisions. |

High/Low Reading

Messages will appear on the Reader when the glucose reading is high or low.

DISPLAY

WHAT TO DO

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

You will see this symbol 🔍. Check your blood glucose on your finger with a test strip before making treatment decisions.

HI/LO Reading

Current Glucose will display HI or LO when glucose readings are outside measuring range.

DISPLAY

⚠ Low Glucose

LO mg/dL

350
250
150
50

2pm 6pm 10pm

⚠ High Glucose

HI mg/dL

350
250
150
50

2pm 6pm 10pm

WHAT TO DO

If **LO** appears on the reader, your reading is lower than 40 mg/dL. If **HI** appears on the reader, your reading is higher than 500 mg/dL. You can touch the message button for more information. Check your blood glucose on your finger with a test strip. **If you get a second LO or HI result, contact your healthcare professional immediately.**

You will see this symbol. Check your blood glucose on your finger with a test strip before making treatment decisions.

Treatment Decisions–Getting Started
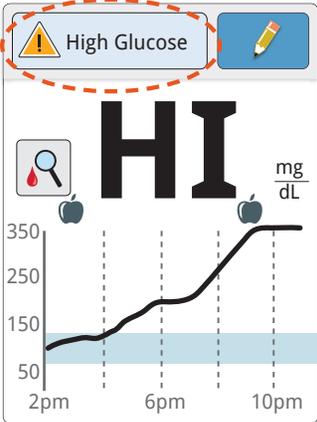
Before you start using the FreeStyle Libre 14 day System for treatment decisions, make sure you have a good understanding of how the system works for your body.

- Continue to use your blood glucose meter for treatment decisions until you are comfortable with the information you receive
- Getting familiar with the system could take days, weeks, or even months
- Work with your healthcare professional to put together a plan for making treatment decisions
- Scan often to see how carbs, medication, exercise, illness, or stress levels impact your sensor glucose readings

HELPFUL TIPS
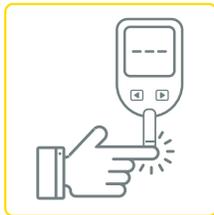
CONFIRM SENSOR GLUCOSE READINGS

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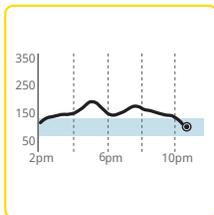
UNDERSTAND YOUR INSULIN

Understand how your insulin works, including how long it takes to start working and how long it lasts in your body.

NOTE: Making a treatment decision doesn't just mean taking insulin. Treatment decisions can include taking fast-acting carbs, eating, or doing nothing and scanning again later.

AVOID "INSULIN STACKING"

If your glucose is high and going up, your first instinct may be to take more insulin to lower your glucose. However, depending on when you last took insulin or your recent activity, the right treatment decision may be to do nothing and scan again later.

Treatment Decisions–When Not to Use Sensor Readings

Whenever you see this symbol,

do a blood glucose test and treat based on that result!

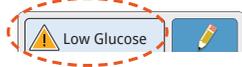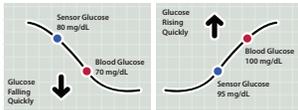|	
Sensor Glucose 80 mg/dL — Blood Glucose 70 mg/dL — Glucose Falling Quickly / Glucose Rising Quickly — Blood Glucose 100 mg/dL — Sensor Glucose 95 mg/dL	**Glucose is Falling Quickly or Rising Quickly** Interstitial fluid can be different from blood glucose levels, particularly during times when your blood glucose is changing quickly, for example, after eating, taking insulin, or exercising.
⚠ Low Glucose	**Low Glucose or Glucose Going Low Message** Low sensor glucose readings may not accurately reflect blood glucose.
	No Glucose Trend Arrow When there is no Glucose Trend Arrow, the system can't tell if your glucose is rising quickly or falling quickly.
⚠ Low Glucose / **LO** mg/dL	**No Current Glucose Number** When there is no Current Glucose number, such as when you receive an error message or a LO or HI result, you don't have enough information to make a treatment decision.
	During the first 12 hours of wearing a FreeStyle Libre 14 day Sensor During the first 12 hours, you should not use glucose readings from the Sensor to make treatment decisions.

You Think Your Readings Are Incorrect
Don't trust sensor glucose readings that you think may be incorrect or that don't match what you would expect based on your recent activity. For example, if you ate dinner but forgot to take insulin before eating, you would expect your glucose to be high. If your glucose reading is low, then it doesn't match your recent activity. Don't make treatment decisions if you think your sensor glucose readings are incorrect.

NOTE: The 🔍 symbol will NOT display in these situations.

You Have Low or High Blood Glucose Symptoms
Don't ignore symptoms that may be due to low or high blood glucose. Do a blood glucose test and treat based on that result.

Symptoms Don't Match Reading
There may be times when your symptoms don't match your sensor glucose readings. You may feel shaky, sweaty, and dizzy—symptoms you generally get when you have low glucose—but your glucose is within your target range. Don't ignore symptoms that may be due to low or high blood glucose.

NOTE: The 🔍 symbol will NOT display in these situations.

When checking blood glucose, you can use the reader's built-in meter to check your blood glucose with FreeStyle Precision Neo test strips. Precision Neo Test Strips are available in the diabetes supply section of your major retail pharmacy. Check for participating locations.
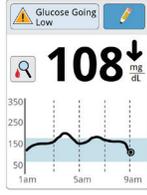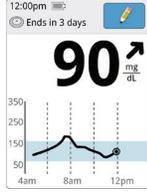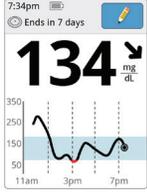
Treatment Decisions–Glucose Trend Arrows

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

Glucose Trend Arrow	TREATMENT DECISION CONSIDERATIONS		
	Low Glucose (< 70 mg/dL)	Glucose in Target Range	High Glucose (> 240 mg/dL)
No Arrow or No Number	You will see the 🩸 symbol. Do not treat based on sensor glucose reading. Do a blood glucose test.		
↑	You will see the 🩸 symbol. Do not treat based on sensor glucose reading. Do a blood glucose test.		
↗	You will see the 🩸 symbol. Do not treat based on sensor glucose reading. Do a blood glucose test.	If you are about to eat, take insulin to cover your meal. Consider taking a little more since glucose is rising. If you have taken insulin recently, do nothing and scan again later. Avoid "insulin stacking."	If you are about to eat, take insulin to cover your meal. Consider taking a little more since glucose is high and rising. If this is between meals, consider taking an insulin correction dose, unless you have taken insulin recently. If you have taken insulin recently, do nothing and scan again later. Avoid "insulin stacking."
→	You will see the 🩸 symbol. Do not treat based on sensor glucose reading. Do a blood glucose test.	If you are about to eat, take insulin to cover your meal. If this is between meals, do nothing and scan again later.	If you are about to eat, take insulin to cover your meal. Consider taking a little more since glucose is high. If this is between meals, consider taking an insulin correction dose, unless you have taken insulin recently. If you have taken insulin recently, do nothing and scan again later. Avoid "insulin stacking."
↘	You will see the 🩸 symbol. Do not treat based on sensor glucose reading. Do a blood glucose test.	If you are about to eat, take insulin to cover your meal. Consider taking a little less since glucose is falling. If this is between meals, consider eating a snack or fast-acting carbohydrates to stay within target and scan again later.	If you are about to eat, take insulin to cover your meal. Consider taking a little less since glucose is falling. If this is between meals, consider doing nothing and scan again later. Avoid "insulin stacking."
↓	You will see the 🩸 symbol. Do not treat based on sensor glucose reading. Do a blood glucose test.		

Consult with your healthcare provider about how to incorporate trend arrow information into treatment decisions.

Treatment Decisions

Treatment Decisions–Example Scenarios

Example scenarios to help you understand how to use all of the information on the screen. The recommendations below are based on a clinical article published in a peer reviewed journal.

ANNE	WHAT ANNE SEES	WHAT ANNE DOES
Anne has a target of <180 mg/dL and a correction factor of 1:50. This means she would take 1 unit of rapid-acting insulin to lower her glucose about 50 mg/dL.	**After breakfast** After breakfast, Anne sees her glucose is 108 mg/dL. The trend arrow shows it is going down quickly. There is also a Glucose Going Low message at the top of the screen and the symbol.	Anytime Anne sees the symbol, she does a blood glucose test before deciding what to do.
	Before lunch Anne sees her glucose is 90 mg/dL and rising.	Before eating lunch, Anne takes enough insulin to cover the meal and a little more since her trend arrow was rising ↗.
	After lunch Ninety minutes later, Anne's glucose is still 225 mg/dL.	Anne does not take a correction dose as it is within 2 hours of her meal dose. This could result in "insulin stacking" and low glucose. The insulin she took for her meal may not have reached its full effect. Anne decides to wait and scan again later.
For more scenarios, consult your FreeStyle Libre 14 day System User's Manual.	**Before dinner** Anne sees her current glucose is 134 mg/dL. The graph shows that her glucose is going down and so does the trend arrow ↘.	Anne considers what might be causing her glucose to go down and what she might do to prevent a low glucose. She considers how much insulin she should take before her meal. Because she sees ↘ she considers taking a little less insulin.

*FreeStyle Libre 14 day System User's Manual

Ambulatory Glucose Profile (AGP) Report

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occuring in a single day.

AGP Report
January 16, 2020 - January 29, 2020 (14 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

January 16, 2020 - January 29, 2020	14 Days
% Time CGM is Active	100%

Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges Target Range 70-180 mg/dL	Targets % of Readings (Time/Day) Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.

Average Glucose	**143** mg/dL
Glucose Management Indicator (GMI)	**6.7 %**
Glucose Variability	**35.5%**

Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES

Very High >250 mg/dL	2%	(29min)
High 181-250 mg/dL	23%	(5h 31min)
Target Range 70-180 mg/dL	71%	(17h 2min)
Low 54-69 mg/dL	4%	(58min)
Very Low <54 mg/dL	0%	(0min)

AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.

Average Glucose mg/dL

190 mg/dL — Average Glucose

48% — Percent in Target

Hyperglycemia — Median — Variability — Target Range — Hypoglycemia

DAILY GLUCOSE PROFILES

Each daily profile represents a midnight to midnight period with the date displayed in the upper left corner.

Thursday 16 | Friday 17 | Saturday 18 | Sunday 19 | Monday 20 | Tuesday 21 | Wednesday 22

23 | 24 | 25 | 26 | 27 | 28 | 29

Source: Battelino, Tadej, et al. "Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range." Diabetes Care, American Diabetes Association, 7 June 2019, https://doi.org/10.2337/dci19-0028.

1. Are there patterns of hypoglycemia?

2. Are the readings within target range?

3. Identify glucose variability by the shape of the Median curve. The Median curve shows the median glucose value for every time point. Median curve is not flat, indicating glucose variability.

4. Identify glucose variability by the width of the Interquartile Range (IQR). The IQR is the middle 50 percent of the data. The IQR is wide-spread, indicating glucose variability.

When to Contact your Healthcare Professional

As instructed by the FreeStyle Libre 14 day labeling.

Symptoms
- If you are experiencing symptoms that are not consistent with your glucose readings
- If you have significant skin irritation around the sensor
- If the sensor breaks in your body
- If you are suffering from dehydration
- If bleeding does not stop after removing sensor

Treatment Decisions
- To determine how you should use your sensor glucose information to help manage your diabetes
- To determine and set your target glucose range
- To understand how insulin works
- To determine when to do nothing/scan again later
- To determine how to use your blood glucose results
- To discuss what to do if symptoms don't match your blood glucose results

Sensor Readings
- If you get a LO or HI sensor reading followed by a LO or HI blood glucose result
- If you are not sure about the reader message or the glucose reading

Maintenance and Disposal
- How to discard a used sensor

Contact HCP

Frequently Asked Questions

Sensor Application

How is the sensor applied to the body?

The sensor is applied to the back of the upper arm with a simple, disposable device called an applicator. When the sensor is applied, a small (5mm) filament is inserted just under the skin, and held in place with a small adhesive pad. Most patients don't feel pain when applying the FreeStyle Libre 14 day sensor.*

Is it necessary to apply a sensor in a different location if I feel discomfort or in case of a mis-application?

To prevent discomfort or skin irritation, you should select a different site other than the one most recently used.

When applying the sensor to my arm, do I need to stretch or pinch the skin?

No, there is no need to stretch or pinch the skin to apply the sensor. The sensor should be applied only on the back of your upper arm. 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 2.5 cm (1 inch) away from an insulin injection site. To prevent discomfort or skin irritation, you should select a different site other than the one most recently used. For more information please refer to the FreeStyle Libre 14 day User's Manual.

Patient Wear

Will the user feel the sensor while wearing it?

The portion of the sensor that gets inserted under the skin is less than 0.4 millimeter wide (1mm is about the thickness of a few strands of human hair) and it's inserted only about 5mm under the skin, so most people will not feel the sensor while it is being worn.*

Can users bathe, shower, swim or exercise while wearing a sensor?

Yes. The sensor can be worn while bathing, showering, swimming or exercise. The sensor should not be taken below 1 meter of water (3 feet), and should not be submerged in water for more than 30 minutes. The adhesive is designed to keep the sensor securely and comfortably in place for up to 14 days after the warm up period.

How long can the sensor be worn?

The disposable sensor is designed to adhere to the back of the upper arm and provide accurate glucose readings for up to 14 days after the warm up period. After the 14 days, the user removes the sensor by peeling off the adhesive pad.

How do you remove the sensor?

Pull up the edge of the adhesive that keeps the sensor attached to the skin. Slowly peel away from the skin in one motion. Note: Any remaining adhesive residue on the skin can be removed with warm soapy water or isopropyl alcohol.

What if the user needs to remove the sensor before 14 days (or if it falls off)?

Users should remove the sensor and start a new sensor. The reader will identify that it is a new sensor and ask users if they want to start it. If a sensor falls off before 10 days have completed, then the user should call Customer Service at 1-855-632-8658.

*Data on file. Abbott Diabetes Care.

FreeStyle Libre 14 day

life. *to the fullest.*®

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