



FreeStyle
LibreLink

English

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Direction your glucose is going. See [Understanding Your Glucose Readings](#) for more information.



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Important Information

Indications for Use

FreeStyle LibreLink app ('App') when used with a FreeStyle Libre Flash Glucose Monitoring System Sensor ('Sensor') is indicated for measuring interstitial fluid glucose levels in people (age 4 and older) with diabetes mellitus. The App and Sensor are designed to replace blood glucose testing in the self-management of diabetes, including dosing of insulin.

The indication for children (age 4 – 17) is limited to those who are supervised by a carer who is at least 18 years of age. The carer is responsible for managing or assisting the child to manage the App and Sensor and also for interpreting or assisting the child to interpret Sensor glucose readings.

WARNING: If you are using FreeStyle LibreLink, you must also have access to a blood glucose monitoring system as the App does not provide one.

CAUTION: 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.

Additional Safety Information

- FreeStyle LibreLink does not share data with the FreeStyle Libre Flash Glucose Monitoring System Readers ('Readers').
- 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.

Security Information

- You are responsible for properly securing and managing your smartphone. If you suspect an adverse cybersecurity event related to FreeStyle LibreLink, contact Customer Service.
- Make sure that your phone and Sensor kit are kept in a safe place, under your control. This is important to help prevent anyone from accessing or tampering with the System.
- FreeStyle LibreLink is not intended for use on a smartphone that has been altered or customised to remove, replace or circumvent the manufacturer's approved configuration or use restriction, or that otherwise violates the manufacturer's warranty.

The following Contraindication, Warnings, and other safety information apply to the Sensor, when used with FreeStyle LibreLink.

CONTRAINDICATION: The Sensor must be removed prior to Magnetic Resonance Imaging (MRI).

WARNING:

- The Sensor contains small parts that may be dangerous if swallowed.
- Do not ignore symptoms that may be due to low or high blood glucose. If you have symptoms that do not match the Sensor glucose reading, or suspect your reading may be inaccurate, check the reading by conducting a fingerstick test using a blood glucose meter. If you are experiencing symptoms that are not consistent with your glucose readings, consult your healthcare professional.

CAUTION:

- On rare occasions, you may get inaccurate Sensor glucose readings. If you believe your readings are not correct or are inconsistent with how you feel, perform a blood glucose test on your finger to confirm your glucose and check to make sure your Sensor has not come loose. If the problem continues or if your Sensor is coming loose, remove the current Sensor and apply a new one.
- Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. If your Sensor comes loose, you may get no readings or unreliable readings, which may not match how you feel. Follow the instructions to select an appropriate application site.
- The Sensor 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 two devices with the

same Sensor, be sure to scan frequently with both devices.

- 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 Sensor. Contact your healthcare professional before continuing to use the Sensor.
- Performance of the Sensor when used with other implanted medical devices, such as pacemakers, has not been evaluated.
- 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-sterilisation. Further exposure to irradiation may cause inaccurate results.
- The Sensor Pack and Sensor Applicator are packaged as a set and have the same Sensor code. Check that the Sensor codes match before using your Sensor Pack and Sensor Applicator. Sensor Packs and Sensor Applicators with the same Sensor code should be used together or your Sensor glucose readings may be incorrect.

Additional Safety Information

- Physiological differences between the interstitial fluid and capillary blood may result in differences in glucose readings. Differences in Sensor 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.
- Store the Sensor Kit between 4°C and 25°C. While you don't need to keep your Sensor Kit in a refrigerator, you can as long as the refrigerator is between 4°C and 25°C.
- If you have a medical appointment that includes strong magnetic or electromagnetic radiation, for example an X-ray, MRI (Magnetic Resonance Imaging) or CT (Computed Tomography) scan, remove the Sensor that you are wearing and apply a new one after the appointment. The effect of these types of procedures on the performance of the Sensor has not been evaluated.
- The Sensor has not been evaluated for use in pregnant women, persons on dialysis or people younger than 4 years of age.
- The Sensor Pack is sterile unless opened or damaged.
- Your Sensor has been tested to withstand immersion into 1 metre (3 ft) of water for up to 30 minutes. It is also protected against insertion of objects > 12 mm diameter. (IP27)
- Do not freeze the Sensor. Do not use if expiry date has passed.

FreeStyle LibreLink Overview

IMPORTANT: Read all of the information in this User's Manual before using FreeStyle LibreLink with a Sensor. Refer to your smartphone's instructions for use for how to use your smartphone. If you are using a Reader, refer to the User's Manual in the Reader Kit.

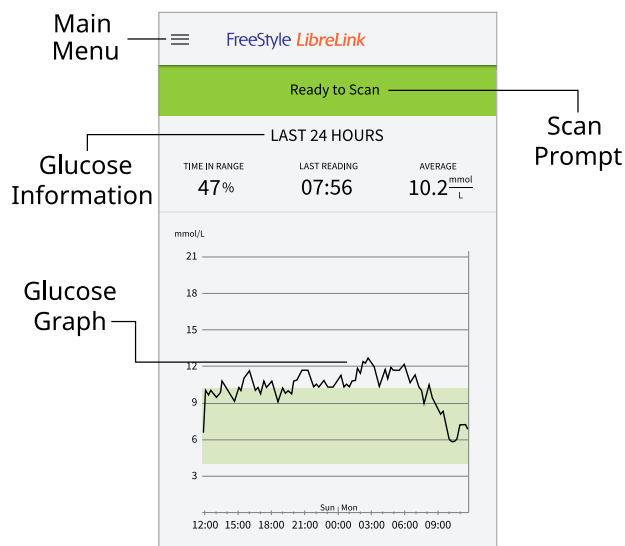
FreeStyle LibreLink is available for download from the Google Play Store. When you're ready to start using FreeStyle LibreLink, you'll prepare and apply a Sensor to the back of your upper arm. You can then use the App to get glucose readings from the Sensor and store your glucose history and notes. The Sensor can be worn on your body for up to 14 days.

Note:

- The Sensor comes in the FreeStyle Libre Sensor kit. See [Sensor Kit](#).
- Go to www.FreeStyleLibre.com for smartphone requirements and compatibility. Please keep in mind that the ease of scanning a Sensor may vary between devices.

Home Screen

The Home Screen gives you access to information about your glucose 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 Connected Apps. You can also access Settings, Help, and other information.

Glucose Graph - Graph of your stored Sensor glucose readings.

Scan Prompt - Indicates if the App is ready to scan a Sensor.

Glucose Information - Your Time In Range, information about your last reading and

average glucose for the last 24 hours.

Sensor Kit



The Sensor Kit includes:

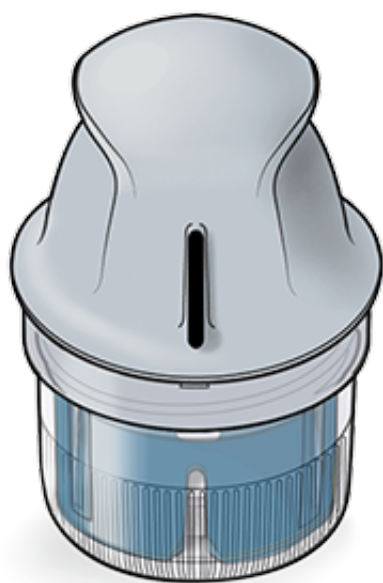
- Sensor Pack
- Sensor Applicator
- Product insert

When opening your kit, check that the contents are undamaged and that you have all parts listed. If any parts are missing or damaged, contact Customer Service. The Sensor (only visible after applied) is initially in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. Once prepared and applied to your body, the Sensor measures your glucose using a small, flexible tip that inserts just under the skin.

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



Sensor Applicator. Applies the Sensor to your body.



App Setup

Before using the App for the first time, you must complete the setup.

1. Check that your smartphone is connected to a network (Wi-Fi or mobile). You can then install FreeStyle LibreLink from the Google Play Store. Tap the App icon to open the App.
Note: You only need to be connected to a network for setup, using LibreView, and sharing with other apps. You do not need to be connected to scan a Sensor, add notes or review your history in the App.
2. Swipe left to view some helpful tips or tap **GET STARTED NOW** at any point.

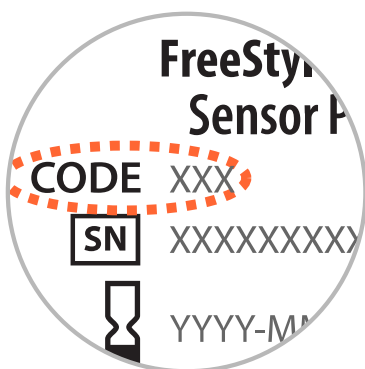
3. Confirm your country/region and tap **NEXT**.
4. You need a LibreView account to use the App. Follow onscreen instructions to review legal information and create a new account or log in to your existing account.
5. Confirm your glucose unit of measure and tap **NEXT**.
6. Set your Target Glucose Range and tap **NEXT**. Work with your health care professional to determine your Target Glucose Range. Your Target Glucose Range is displayed on glucose graphs in the App and is used to calculate your Time In Range.
7. Select how you count carbohydrates (in grams or portions) and tap **NEXT**. The carbohydrate unit will be used in any food notes that you enter in the App.
8. Select whether you want sound and vibration OR vibration only when you scan your Sensor. Tap **NEXT**.
9. The App now displays useful information about the My Glucose screen. Tap **NEXT** to view information about the Glucose Trend Arrow. Tap **NEXT** again.
10. Accept required permissions.
11. Apply a new Sensor and then tap **NEXT**. Go to [Starting Your Sensor](#).

Note: If you need help applying your Sensor, tap **HOW TO APPLY A SENSOR** or go to [Applying Your Sensor](#).

Applying Your Sensor

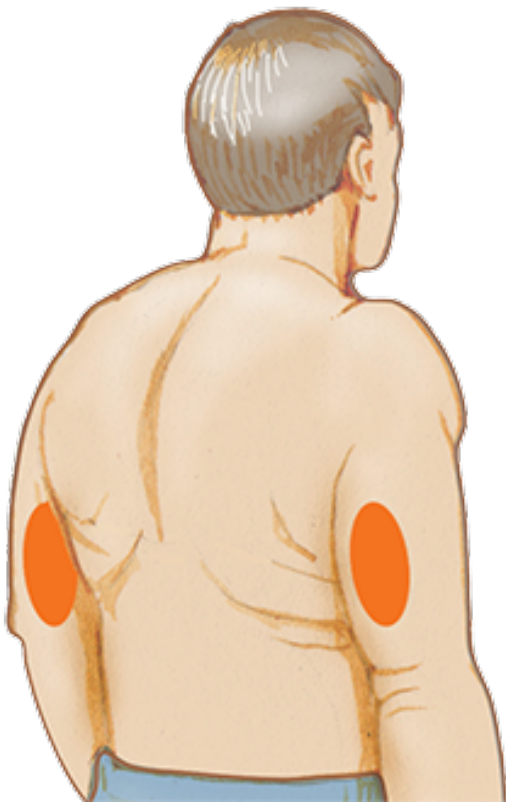
CAUTION:

- The Sensor Pack and Sensor Applicator are packaged together as a set and have the same Sensor code. Check that the Sensor codes match before using your Sensor Pack and Sensor Applicator. Sensor Packs and Sensor Applicators with the same Sensor code should be used together or your Sensor glucose readings may be incorrect.



- Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. If your Sensor comes loose, you may get no readings or unreliable readings, which may not match how you feel. Follow the instructions to select an appropriate application site.
-

1. Apply Sensors 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 your 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.



2. Wash application site using a plain soap, dry and then clean with an alcohol wipe. This will help to remove any oily residue that may prevent the Sensor from sticking properly. Allow site to air dry before proceeding.

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

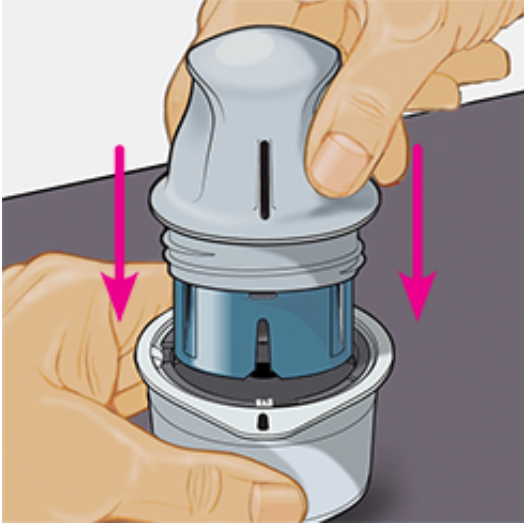


3. Open the Sensor Pack by peeling the lid off completely. Unscrew the cap from the Sensor Applicator and set the cap aside.

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



4. Line up the dark mark on the Sensor Applicator with the dark mark on the Sensor Pack. On a hard surface, press down firmly on the Sensor Applicator until it comes to a stop.

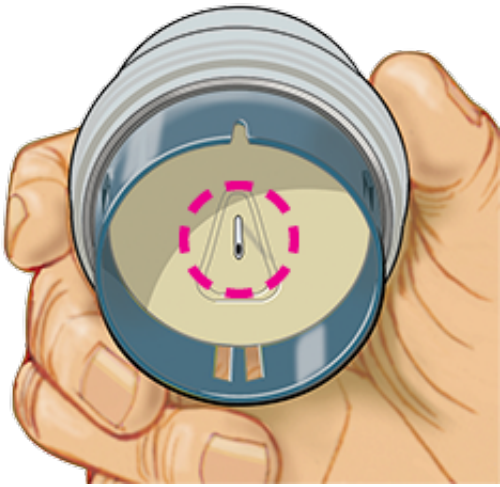


5. Lift the Sensor Applicator out of the Sensor Pack.



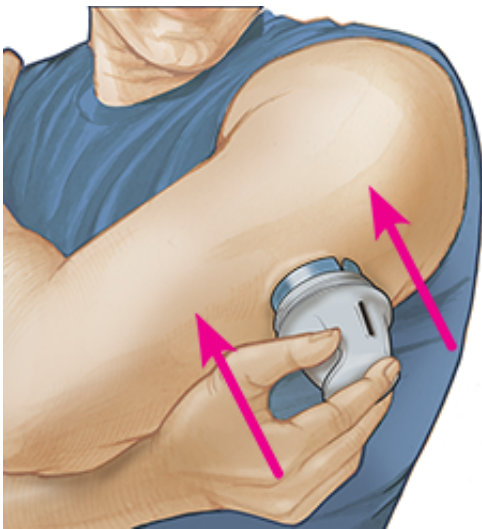
6. The Sensor Applicator is prepared and ready to apply the Sensor.

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



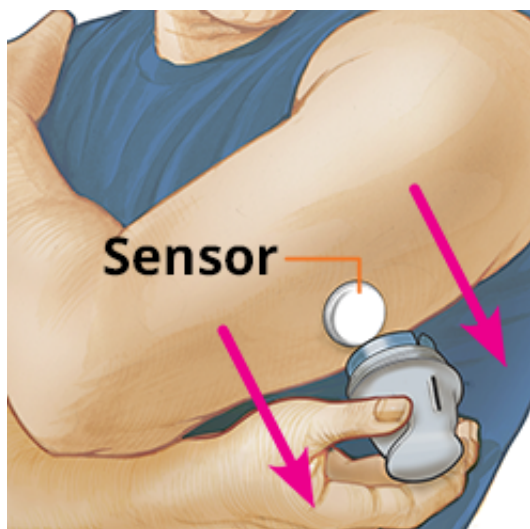
7. Place the Sensor Applicator over the prepared site and push down firmly to apply the Sensor to your body.

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



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

Note: Applying the Sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the Sensor and apply a new one at a different site.



9. Make sure Sensor is secure after application. Put the cap back on the Sensor Applicator. Discard the used Sensor Applicator and Sensor Pack. See [Disposal](#).

Note: Tap **Help** in the Main Menu to access an in-app tutorial on applying a Sensor.



Starting Your Sensor

IMPORTANT:

- Keep in mind that the ease of scanning a Sensor may vary between devices. Once you determine the location of the NFC (Near Field Communication) antenna on your smartphone, you should be able to reliably scan your Sensor by holding that area near your Sensor. You may need to adjust your scan distance based on what clothing you are wearing. In addition to proximity and orientation, other factors can affect NFC performance. For example, a bulky or metallic case can interfere with the NFC signal.
- The App requires that your smartphone be set to network time. This is the default time setting for most smartphones.

- When using the App, you should keep your smartphone well-charged and be sure you have access to a blood glucose meter.
 - Make sure your smartphone's sound is set so you can hear scan sounds if you turned those on.
-

1. Hold the back of your smartphone near the Sensor (this can be done over clothing) and position the NFC antenna over the Sensor. Do not move the smartphone until you hear the first tone and/or feel a vibration. This indicates your smartphone and Sensor have established an NFC connection.
2. Continue holding your smartphone near the Sensor until you hear a second tone and/or feel a vibration. This completes the scan.

Note:

- If you need help, tap **HOW TO SCAN A SENSOR** to view an in-app tutorial. You can also access this later by going to the Main Menu and then tapping **Help**.
- If your Sensor is not successfully scanned, you may receive a scan error.

See [Troubleshooting](#) for additional error messages.

3. The Sensor can be used to check your glucose after 60 minutes. While the Sensor is starting up, you can navigate away from the App. You will see a notification when the Sensor is ready.

Note:

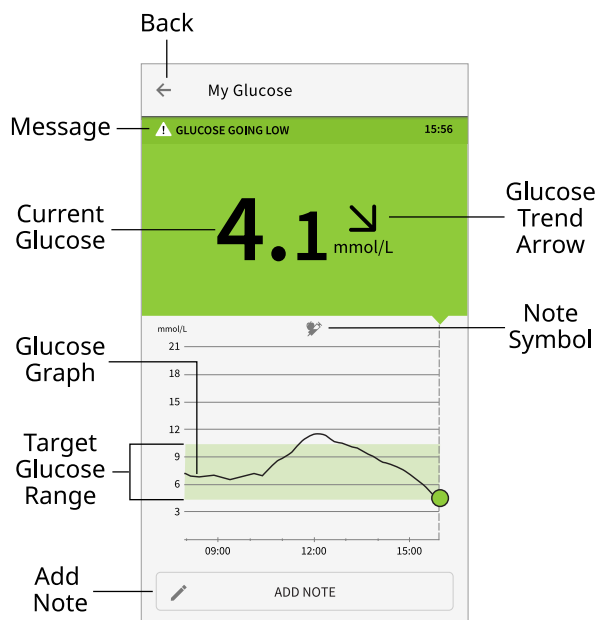
- If you want to use both the FreeStyle LibreLink app and the Reader, you must start the Sensor with the Reader first then scan with the FreeStyle LibreLink app.
- Performance between the Reader and App may vary depending on your Reader's software version. Please refer to the performance data insert that's included in the Reader Kit for Reader performance information.
- FreeStyle LibreLink does not share data with FreeStyle Libre Reader.
- 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.

Checking Your Glucose

1. Open the App and hold the back of your smartphone near the Sensor. If scan sounds are turned on, you will get two separate tones along with the vibrations when your Sensor

has been scanned.

- Your glucose 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.



Message – Tap for more information.

Back – Tap to return to Home screen.

Current Glucose – Glucose value from your latest scan.

Add Note – Tap to add notes to the glucose reading.

Glucose Trend Arrow - Direction your glucose is going.

Note Symbol – Tap to review notes that you've entered.

Glucose Graph – Graph of your current and stored glucose readings.

Target Glucose Range - The graph shows your target glucose range.

Note:

- A Sensor can store up to 8 hours of glucose data, so scan it at least once every 8 hours to capture all of your available glucose data.
- The graph will scale to 27.8 mmol/L to accommodate glucose readings above 21 mmol/L.
- The ⌚ symbol may appear, indicating the smartphone's time was changed. Gaps in

the graph may result or glucose readings may be hidden.

- Your current glucose value determines the background colour on your glucose reading display:

Orange - High glucose (above 13.3 mmol/L)

Yellow - Between the Target Glucose Range and high or low glucose level

Green - Within the Target Glucose Range

Red - Low glucose (below 3.9 mmol/L)

Understanding Your Glucose Readings

Glucose Trend Arrow

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



Glucose is rising quickly (more than 0.1 mmol/L per minute)



Glucose is rising (between 0.06 and 0.1 mmol/L per minute)



Glucose is changing slowly (less than 0.06 mmol/L per minute)




Glucose is falling (between 0.06 and 0.1 mmol/L per minute)

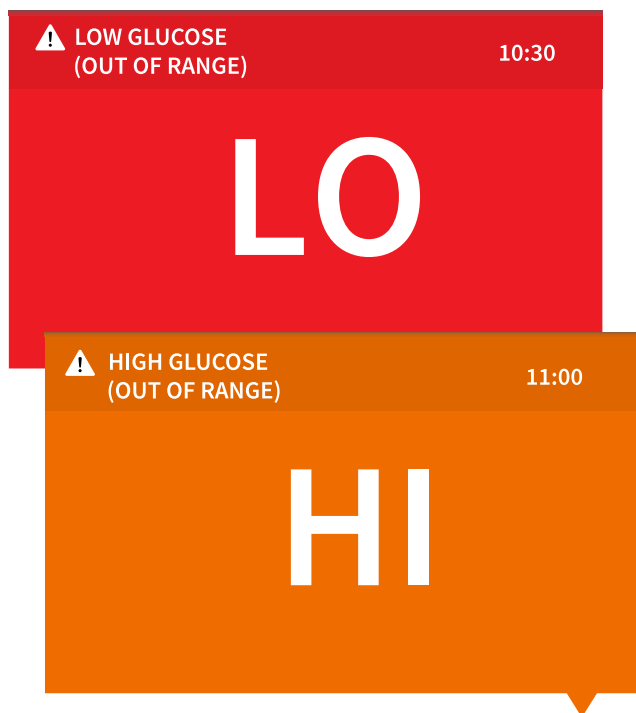



Glucose is falling quickly (more than 0.1 mmol/L per minute)

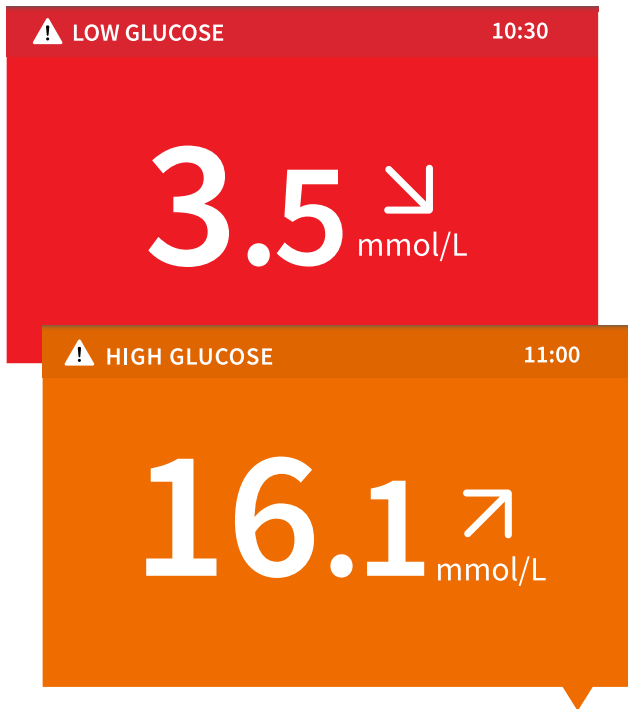
Messages


Below are messages you may see with your glucose readings.

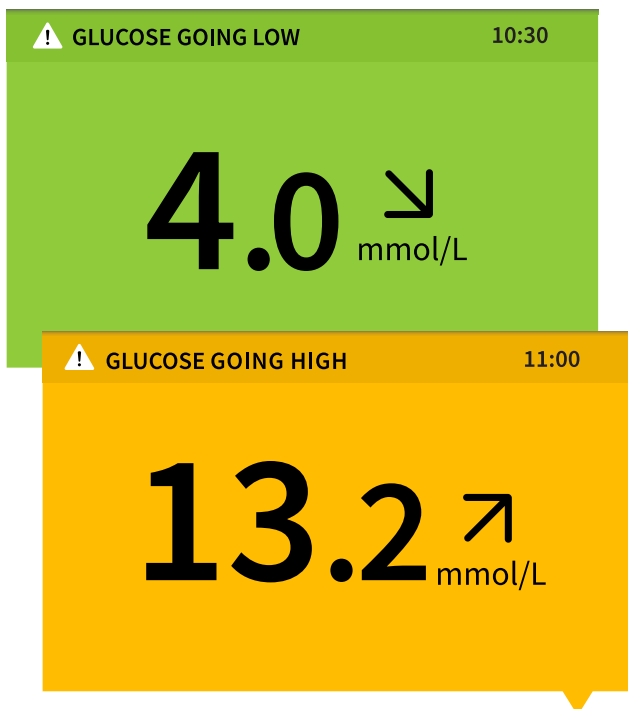
LO | HI: If **LO** appears, your reading is lower than 2.2 mmol/L. If **HI** appears, your reading is higher than 27.8 mmol/L. You can tap the  symbol for more information. Check your blood glucose on your finger with a test strip. If you get a second **LO** or **HI** result, contact your healthcare professional IMMEDIATELY.



Low Glucose | High Glucose: If your glucose is higher than 13.3 mmol/L or lower than 3.9 mmol/L, you will see a message on the screen. You can tap the  symbol for more information and set a reminder to check your glucose.



Glucose Going Low | Glucose Going High: If your glucose is projected to be higher than 13.3 mmol/L or lower than 3.9 mmol/L within 15 minutes, you will see a message on the screen. The background colour corresponds to your current glucose value. You can tap the  symbol for more information and set a reminder to check your glucose.




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

for information.

Adding Notes

Notes can be saved with your glucose readings to help you track food, insulin and exercise. You can also add your own comment.

1. Tap  on your glucose reading screen.
2. Select the tick box next to the notes you would like to add. After you tick the box, you can add more specific information to your note.
 - Food notes: Enter meal type and grams or portion information
 - Insulin notes: Enter the number of units taken
 - Exercise notes: Enter intensity and duration
3. Tap **DONE** to save your note.

Notes you add are shown on your glucose graph and in your Logbook as symbols. You can review a note by tapping its symbol on your glucose graph or by going to the Logbook. See [Reviewing Your History](#) for more information about the Logbook. To edit a note from the glucose graph, tap the symbol and then tap on the information you would like to change. Tap **DONE** when you are finished.



Food



Insulin



Exercise



Food + insulin



Multiple/Custom notes – indicates different types of notes entered together or notes entered within a short period of time. A numbered badge next to the symbol indicates the number of notes.



Reviewing Your History



Reviewing and understanding your glucose history can be an important tool for improving your glucose control. The App stores about 90 days of information and has several ways to review your past glucose readings and notes. From the Main Menu, tap **Logbook** to view the Logbook or tap on one of the other history options under **Reports**.

IMPORTANT:

- Work with your healthcare professional to understand your glucose history.
- FreeStyle LibreLink does not share data with the FreeStyle Libre Reader.
- For complete information on a device, ensure that you scan your Sensor every 8 hours with that device; otherwise, your reports will not include all your data.

Logbook

The **Logbook** contains entries for each time that you scanned your Sensor as well as notes that you added. If you would like to view a different day, tap the  symbol or use the arrows. To add a note to a Logbook entry, tap on the entry and then tap . Select your note information and tap **DONE**.

To add a note that is independent of a Logbook entry, tap  on the main Logbook screen. Tap  if you want to add a note on a different date.

Other History Options

Daily Patterns: A graph showing the pattern and variability of your Sensor glucose readings over a typical day. The thick black line shows the median (midpoint) of your glucose readings. The light blue shading represents the 10th – 90th percentile range of your glucose readings. Dark blue shading represents the 25th – 75th percentile range.


Note: This report needs at least 5 days of glucose data.

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

Low Glucose Events: Information about the number of low glucose events measured by your Sensor. A low glucose event is recorded when your Sensor glucose reading is lower than 3.9 mmol/L for 15 minutes or longer. The total number of events is displayed below the graph. The bar graph displays the low glucose events in different periods of the day.

Average Glucose: Information about the average of your Sensor glucose readings. The overall average for the selected time period is displayed below the graph. The average is also shown for different periods of the day. Readings above or below your Target Glucose Range are yellow, orange or red. Readings in range are green.

Daily Graph: A graph of your Sensor glucose readings by day. The graph shows your Target Glucose Range and symbols for notes you have entered.

- The graph will scale to 27.8 mmol/L to accommodate glucose readings above 21 mmol/L.
- You might see gaps in the graph during times when you have not scanned at least once in 8 hours.
- The  symbol may appear indicating a time change. Gaps in the graph may result or glucose readings may be hidden.

Estimated A1c: Your estimated A1c level (also called HbA1c) is based on available Sensor glucose data from the last 90 days. The more data available, the better your estimation will be. However, the estimated level may not match your A1c measured in a laboratory*. A1c can be used as an indicator of how well your glucose levels have been controlled and may be used to monitor your diabetes treatment regimen.

* The formula is based on the published reference, which compared average Sensor glucose and laboratory-measured A1c:



$$A1c_{\%} = (\text{Avg } SG_{\text{mg/dL}} + 46.7)/28.7$$

$$A1c_{\%} = (\text{Avg } SG_{\text{mmol/L}} + 2.59)/1.59$$

Reference: Nathan DM, Kuenen J, Borg R, Zheng H, Schoenfeld D, Heine RJ for the A1c-Derived Average Glucose (ADAG). Study Group: Translating the hemoglobin A1c assay into estimated average glucose values. Diabetes Care 2008, 31:1473-8.

Sensor Usage: Information about how often you scanned your Sensor or viewed your Sensor glucose readings in the App and how much information has been captured from your Sensor.

Note:

- Tap the  symbol on any report to share a screenshot of the report.
- Tap the  symbol to view a description of the report.
- From any report screen, swipe left or right to view the next or previous report.
- On all reports except the **Daily Graph** and **Estimated A1c**, you can select to show information about your last 7, 14, 30 or 90 days.

Removing Your Sensor

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

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



2. Discard the used Sensor. See [Disposal](#). When you are ready to apply a new Sensor, follow the instructions in [Applying Your Sensor](#) and [Starting Your Sensor](#).

Replacing Your Sensor

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

CAUTION: If the glucose readings from the Sensor do NOT seem to match with how you feel, check to make sure that your Sensor has not come loose. If the Sensor tip has come out of your skin, or your Sensor is coming loose, remove the Sensor and apply a new one.

Setting Reminders

You can create single or repeating reminders to help you remember things like checking your glucose or taking insulin. There is one default reminder to help you remember to check your glucose. This reminder can be changed or disabled but cannot be deleted.


Note:

- If you want to receive a sound/vibration with your reminder, ensure that sound/vibration on your smartphone is turned on, sound is set at a level you can hear and your smartphone's Do Not Disturb feature is turned off. If Do Not Disturb is on, you will only

see your reminder on the screen.

- Allow Alarms & reminders permission for the App. This permission is required for Android 12 and above.
1. To add a new reminder, go to the Main Menu and tap **Reminders**. Tap **ADD REMINDER**.
 2. Name your reminder.
 3. Tap the time fields to set the time for the reminder.
 4. Tap **DONE**. You will now see your reminder on the list along with the time you will receive it.

Note:

- To delete a reminder, swipe the reminder and tap the  symbol. The reminder to check your glucose cannot be deleted.
- Your reminders will be received as notifications that you can swipe or tap to dismiss.

Settings and Other Options in the Main Menu

Settings

App Settings:

Unit of Measurement – View the glucose unit of measure used in the App.

Report Settings - Set the target range you want to be displayed on the App glucose graph. It is also used to calculate your Time In Range. Tap **SAVE** when you are done.

Carbohydrate Units – Choose grams or portions for food notes that you enter. Tap **SAVE** when you are done.

Scan Sounds – Select whether you would like to hear a sound in addition to a vibration when you scan the Sensor. Remember that Scan Sounds inherit the volume settings on your smartphone. If your smartphone volume is turned off, you will not hear a scan sound. Tap **SAVE** when you are done.

Text to Speech – Turn on to have the glucose reading read aloud when you scan the Sensor. You will hear only your current glucose value and trend arrow direction. Additional information, such as the glucose graph and any message, are available on your glucose reading screen. Always review your glucose reading to get complete information. Remember that this feature inherits the volume settings on your phone. If your phone

volume is turned off, you will not hear the glucose reading read aloud. Tap **SAVE** when you are done.

Account Settings:

Account Details – View/change your LibreView account information.

Account Password – Change your LibreView account password.

Account Options – Delete your LibreView account. Deleting your account means you will no longer be able to:

- Use your current Sensor.
- Access your account and all related data. Data will be deleted and cannot be recovered for future use.
- Use the account with the FreeStyle LibreLink app.
- Use the Connected Apps or Account Settings features.

Connected Apps

The **Connected Apps** option in the Main menu opens a web browser within the App. It lists different apps you can connect with to share your data. The available apps may vary based on your country/region. To connect your data with apps listed in this option, select them from the list of apps and follow the onscreen instructions.

Help

View in-app tutorials, access this User's Manual and review the App's legal information. You can also view a list of events recorded by the App, which may be used by Customer Service to help troubleshoot.

About

View App software version and other information.

Living with your Sensor

Activities

Bathing, Showering and Swimming: Your Sensor is water-resistant and can be worn while bathing, showering or swimming. Do NOT take your Sensor deeper than 1 metre (3 ft) or

immerse it longer than 30 minutes in water.

Sleeping: Your Sensor should not interfere with your sleep. It is recommended that you scan your Sensor before going to sleep and when you wake up because your Sensor holds 8 hours of data at a time. If you have reminders set to go off while you are sleeping, place your smartphone nearby.

Travelling by Air: You may use your Sensor while on an aircraft, following any requests from the flight crew.

- You can continue to scan your Sensor to get glucose readings after you put your phone in aeroplane mode. Confirm NFC is turned on.
- Some airport full-body scanners include X-ray or millimetre radio-wave, which you cannot expose your Sensor to. The effect of these scanners has not been evaluated and the exposure may damage the Sensor or cause inaccurate results. To avoid removing your Sensor, you may request another type of screening. If you do choose to go through a full-body scanner, you must remove your Sensor.
- The Sensor can be exposed to common electrostatic (ESD) and electromagnetic interference (EMI), including airport metal detectors.

Note: Changing the time affects the graphs and statistics. The ⌚ symbol may appear on your glucose graph indicating a time change. Gaps in the graph may result or glucose readings may be hidden.

Maintenance

The Sensor has no serviceable parts.

Disposal

Reader and Sensor: These devices must not be disposed of via municipal waste collection. Contact the manufacturer for details.

As Readers and Sensors may have been exposed to bodily fluids, you may wipe prior to disposing, such as by using a cloth dampened with a mixture of one part household bleach and nine parts water.

Note: Readers and Sensors contain non-removable batteries and must not be incinerated. Batteries may explode upon incineration.

Sensor Applicator: Please consult your local waste management authority for instructions on how to dispose of Sensor Applicators at a designated sharps collection site. Ensure the cap is on the Sensor Applicator as it contains a needle.

Sensor Pack: Used Sensor Packs may be disposed of via municipal waste collection.

Troubleshooting

This section lists problems that you may experience, the possible cause(s) and recommended actions. If there is an error, a message will appear on the screen with directions to resolve the error.

IMPORTANT: If you are having issues with the App, please keep in mind that uninstalling the App and/or clearing data will cause you to lose all historical data and end the Sensor currently in use. Please call Customer Service if you have any questions.

Problems at the Sensor Application Site

Problem: **The Sensor is not sticking to your skin.**

What it may mean: The site is not free of dirt, oil, hair or sweat.

What to do: 1. Remove the Sensor. 2. Clean the site with a plain soap and water and consider shaving. 3. Follow the instructions in [Applying Your Sensor](#) and [Starting Your Sensor](#).

Problem: **Skin irritation at the Sensor application site.**

What it may mean: Seams or other constrictive clothing or accessories causing friction at the site **OR** you may be sensitive to the adhesive material.

What to do: Ensure that nothing rubs on the site. If the irritation is where the adhesive touches skin, contact your healthcare professional to identify the best solution.

Problems Starting Your Sensor or Receiving Sensor Readings

Display: **Sensor Starting Up**

What it may mean: Sensor is not ready to read glucose.

What to do: Wait until the 60 minute Sensor start-up period has completed.

Display: **Sensor Ended**

What it may mean: The Sensor life has ended.

What to do: Apply and start a new Sensor.

Display: New Sensor Found

What it may mean: You scanned a new Sensor before your previous Sensor ended.

What to do: Your smartphone can only be used with one Sensor at a time. If you start a new Sensor, you will no longer be able to use your old Sensor. If you would like to begin using the new Sensor, select **Yes**.

Display: Sensor Error

What it may mean: The Sensor is unable to provide a glucose reading.

What to do: Check again after the duration specified in the message.

Display: Glucose Reading Is Unavailable

What it may mean: The Sensor is unable to provide a glucose reading.

What to do: Check again after the duration specified in the message.

Display: Sensor Too Hot

What it may mean: Your Sensor is too hot to provide a glucose reading.

What to do: Move to a location where the temperature is appropriate and check again in a few minutes.

Display: Sensor Too Cold

What it may mean: Your Sensor is too cold to provide a glucose reading.

What to do: Move to a location where the temperature is appropriate and check again in a few minutes.

Display: Check Sensor

What it may mean: The Sensor tip may not be under your skin.

What to do: Try to start your Sensor again. If you see **Check Sensor** again on the screen, your Sensor was not applied properly. Apply and start a new Sensor.

Display: Replace Sensor

What it may mean: The App has detected a problem with your Sensor.

What to do: Apply and start a new Sensor.

Display: Unexpected Application Error

What it may mean: The App has detected an unexpected error.

What to do: Shut down the App completely and restart.

Display: Incompatible Sensor

What it may mean: The Sensor cannot be used with the App.

What to do: Call Customer Service.

Display: Scan Error

What it may mean: The smartphone was unable to scan the Sensor **OR** another NFC app is competing for your smartphone's NFC.

What to do: Try scanning the Sensor again. Make sure to hold your smartphone still once you get the first tone and/or vibration. Wait until you get the second tone and/or vibration to move it away from the Sensor. Make sure you are not touching any buttons on the smartphone or the screen. **OR** open the App to scan your Sensor because another app that uses NFC was detected.

Display: App Permission Required

What it may mean: A required App permission is turned off.

What to do: Follow the instructions on the screen to turn the permission on.

Customer Service

Customer service is available to answer any questions you may have about FreeStyle LibreLink. Please go to www.FreeStyleLibre.com or refer to the product insert in your Sensor Kit for your Customer Service phone number. A printed copy of this User's Manual is available upon request.

Sensor Specifications

Sensor glucose assay method: Amperometric electrochemical sensor

Sensor glucose reading range: 2.2 to 27.8 mmol/L

Sensor size: 5 mm height and 35 mm diameter

Sensor weight: 5 grams

Sensor power source: One silver oxide battery

Sensor life: Up to 14 days

Sensor memory: 8 hours (glucose readings stored every 15 minutes)

Operating temperature: 10°C to 45°C

Sensor Applicator and Sensor Pack storage temperature: 4°C to 25°C

Operating and storage relative humidity: 10 – 90%, non-condensing

Sensor water resistance and ingress protection: IP27: Can withstand immersion into 1 metre (3 ft) of water for up to 30 minutes. Protected against insertion of objects > 12 mm diameter.

Operating and storage altitude: -381 metres (-1,250 ft) to 3,048 metres (10,000 ft)

Labelling Symbols and Definitions



Consult instructions for use



Temperature limit



Manufacturer



Single sterile barrier system



Batch code



Unique Device Identifier



Type BF applied part

CODE

Sensor code




Do not re-use



Use-by date

REF Catalogue number


SN Serial number

 Caution


STERILE R Sterilised by irradiation




Sterile Barrier. Refer to Instructions for Use if opened or damaged.

 Humidity limitation

Do not use if package is damaged.

 **For Sterile Barrier:** Do not use if the product sterile barrier system or its packaging is compromised.

 This product must not be disposed of via municipal waste collection. Contact the manufacturer for details.

Electromagnetic Compatibility

- The Sensor needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect the Sensor.
- The use of accessories, transducers and cables other than those specified by Abbott Diabetes Care may result in increased EMISSIONS or decreased IMMUNITY of the Sensor.
- The Sensor should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Sensor should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic emissions

The Sensor is intended for use in the electromagnetic environment specified below. The

customer or the user of the Sensor should ensure that it is used in such an environment.

Emissions test: RF emissions; CISPR 11

Compliance: Group 1

Electromagnetic environment – guidance: The Sensor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Emissions test: RF emissions; CISPR 11

Compliance: Class B

Electromagnetic environment – guidance: The Sensor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test: Electrostatic discharge (ESD); IEC 61000-4-2

IEC 60601 test level: ± 8 kV contact; ± 15 kV air

Compliance level: ± 8 kV contact; ± 15 kV air

Electromagnetic environment – guidance: Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Immunity test: Power frequency (50/60 Hz); magnetic field; IEC 61000-4-8

IEC 60601 test level: 30 A/m

Compliance level: 30 A/m

Electromagnetic environment – guidance: Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.

Immunity test: Radiated RF; IEC 61000-4-3

IEC 60601 test level: 10 V/m; 80 MHz to 2.7 GHz

Compliance level: 10 V/m

Electromagnetic environment – guidance:

Recommended separation distance

$$d = 1.2 \sqrt{P}$$

80 MHz to 800 MHz

$$d = 2.3 \sqrt{P}$$

800 MHz to 2.5 GHz

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

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b

Interference may occur in the vicinity of equipment marked with the following symbol:



NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

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

Recommended separation distances between portable and mobile RF communications equipment and the Sensor

The Sensor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sensor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sensor as recommended

below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Performance Characteristics

Note: Please consult your healthcare team on how to use the information in this section.

Performance Characteristics

Performance of the Sensor was evaluated in a controlled clinical study. The study was conducted in 5 centres and a total of 146 subjects with diabetes were included in the effectiveness analysis. Each subject wore up to two Sensors for up to 14 days on the back of the upper arm. During the study, subjects had their venous blood glucose analysed over three separate visits to the clinical centre using the Yellow Springs Instrument Life Sciences 2300 STAT Plus™. Three lots of Sensors were evaluated in the study.

Figure 1. Comparison of the Sensors vs. YSI reference.

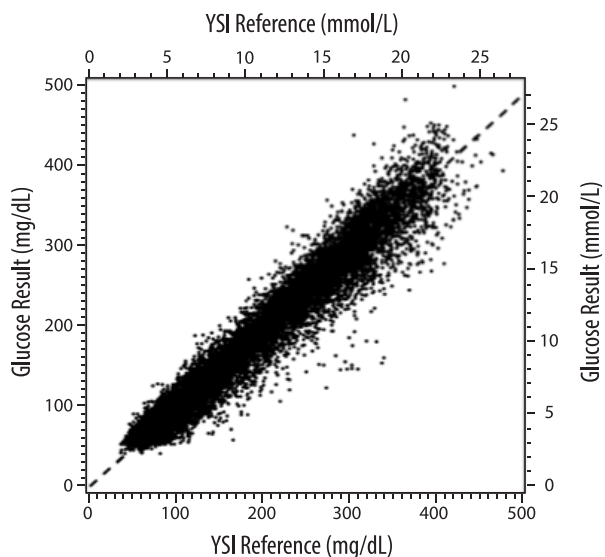


Table 1. Regression analysis of the Sensors vs. YSI reference

Slope	0.97
Intercept	-1.3 mg/dL (-0.1 mmol/L)
Correlation	0.98
N	18926
Range	37 - 479 mg/dL (2.0 - 26.6 mmol/L)
Overall mean bias	-5.6 mg/dL (-0.3 mmol/L)
Mean Absolute Relative Difference (MARD)	9.2%

Table 2. Sensor accuracy for all results vs. YSI reference

	Within ±15 mg/dL (within ±0.83 mmol/L)	Within ±20 mg/dL (within ±1.11 mmol/L)	Within ±30 mg/dL (within ±1.67 mmol/L)
Sensor accuracy results for glucose concentrations <80 mg/dL (4.4 mmol/L)	4199 / 4595 (91.4%)	4482 / 4595 (97.5%)	4583 / 4595 (99.7%)
Sensor accuracy results for glucose concentrations ≥80 mg/dL (4.4 mmol/L)	Within ±15%	Within ±20%	Within ±30%
	12143 / 14331 (84.7%)	13153 / 14331 (91.8%)	14012 / 14331 (97.8%)
Sensor accuracy for all results	Within ±20 mg/dL (±1.11 mmol/L) and within ±20% of reference		
	17635 / 18926 (93.2%)		

Table 3. Sensor performance relative to YSI reference at different glucose levels

Glucose	Mean Absolute Relative Difference
≤50 mg/dL (2.8 mmol/L)	9.1 mg/dL (0.5 mmol/L)*
51-80 mg/dL	7.0 mg/dL

(2.8-4.4 mmol/L)	(0.4 mmol/L)*
81-180 mg/dL (4.5-10.0 mmol/L)	10.1%
181-300 mg/dL (10.0-16.7 mmol/L)	7.5%
301-400 mg/dL (16.7-22.2 mmol/L)	7.1%
>400 mg/dL (22.2 mmol/L)	10.2%

* For glucose ≤ 80 mg/dL (4.4 mmol/L), the differences in mg/dL (mmol/L) are presented instead of relative differences (%).

Table 4. Sensor accuracy over wear duration vs. YSI reference

	Beginning	Early middle	Late middle	End
Within ± 20 mg/dL (± 1.11 mmol/L) and within $\pm 20\%$ of reference	91.2%	95.1%	94.2%	93.7%
Mean Absolute Relative Difference (%)	10.0	8.5	8.8	9.1

Skin Interaction

Based on the examination of 146 study participants, the following incidence of skin issues were observed. Four occurrences of erythema were reported to be moderate in intensity. All other skin issues were reported to be mild in intensity.

Bleeding – 0.7% of the time

Bruising – 0.7% of the time

Erythema – 2.7% of the time

Pain – 0.7% of the time

Scabbing – 2.7% of the time

Expected Clinical Benefits

Complications as a result of diabetes mellitus (including, but not limited to: diabetic retinopathy, diabetic nephropathy) are well documented.¹ Self-monitoring of blood glucose (SMBG) by patients has revolutionised management of diabetes.² Using glucose monitoring devices patients with diabetes can work to achieve and maintain specific glycaemic goals. Given the results of the Diabetes Control and Complications Trial (DCCT)³ and other studies,

there is broad consensus on the health benefits of normal or near-normal blood glucose levels and on the importance, especially in insulin-treated patients, of glucose monitoring devices in treatment efforts designed to achieve these glycaemic goals. Based principally on the DCCT results, experts recommend that most individuals with diabetes should attempt to achieve and maintain blood glucose levels as close to normal as is safely possible. Most patients with diabetes, especially insulin treated patients, can achieve this goal only by using glucose monitoring devices.

¹ Textbook of Diabetes, Volumes 1 & 2; Pickup and Williams, 1999.

² ADA Position Statement. Test of glycemia in diabetes. Diabetes Care 2003; 26 (Suppl.1) S106-108.

³ Diabetes Control and Complications Trial Research Group (DCCT): The effect of intensive treatment of diabetes on the development and progression of long term complications in insulin dependent diabetes mellitus. New Engl J Med, 329: 977-86; 1993.

*** Additional labelling: For Use in Singapore Only – Not relevant for European Market**

WARNING:

FreeStyle Libre Flash Glucose Monitoring System is designed to replace blood glucose testing in the self-management of diabetes with the exceptions listed below. Under the following circumstances, use a blood glucose meter to check the current glucose readings from the FreeStyle Libre Flash Glucose Monitoring System Sensor:

- During times of rapidly changing glucose levels, interstitial glucose levels as measured by the Sensor and reported as current may not accurately reflect blood glucose levels. When glucose levels are falling rapidly, glucose readings from the Sensor may be higher than blood glucose levels. Conversely, when glucose levels are rising rapidly, glucose readings from the Sensor may be lower than blood glucose levels.
- In order to confirm hypoglycaemia or impending hypoglycaemia as reported by the Sensor.
- If symptoms do not match the FreeStyle Libre Flash Glucose Monitoring System reading. Do not ignore symptoms that may be due to low blood glucose or high blood glucose.

Customer Service: www.FreeStyleLibre.com

Patent: www.abbott.com/patents

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