

Front

2nd fold

2.2"

2.25"

3rd fold

2.25"

1st fold (to half)

2.25"

2.25"

2.2"

STEP 1: Select site on back of upper arm.

STEP 2: Wash site using a plain soap, dry, and then clean with alcohol wipe. Allow site to air dry before proceeding.

STEP 3: Peel lid completely off Sensor Pack. Unscrew cap from Sensor Applicator.

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

STEP 4: Line up dark marks on Sensor Applicator and Sensor Pack. On a hard surface, press down firmly on Sensor Applicator until it comes to a stop.

STEP 5: Lift Sensor Applicator out of Sensor Pack.

STEP 6: Sensor Applicator is ready to apply Sensor.

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

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

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

STEP 8: Gently pull Sensor Applicator away.

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

To use your System, refer to the User's Manual included in the Reader Kit.

FreeStyle Libre 2 Sensor - FCC ID: QXS-LIB02S

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION: Changes or modifications not approved by Abbott could void the user's authority to operate the equipment.

Language 2



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Final Facing Fold

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Back

2.2"

2.25"

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2.2"

FreeStyle Libre 2 Flash Glucose Monitoring System

READ THIS INSERT AND THE READER KIT USER'S MANUAL BEFORE HANDLING THE SENSOR KIT PARTS.

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

Indications for Use

The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.

The System also detects trends and tracks patterns and aids 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 also intended to autonomously communicate with digitally connected devices. The System can be used alone or in conjunction with these digitally connected devices where the user manually controls actions for therapy decisions.

Compatible Devices, Apps, and Software

For a list of compatible devices, apps, and software that can be used with the FreeStyle Libre 2 Sensor, please go to: <https://freestylelibre.us/support/overview.html>

Use of the Sensor with devices, apps, and software that are not listed may cause inaccurate glucose readings.

CONTRAINDICATIONS

Automated Insulin Dosing: The System must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems.

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.

WARNING:

- **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.
- Use your blood glucose meter to make diabetes treatment decisions when you see the  symbol during the first 12 hours of wearing a Sensor, if your Sensor glucose reading does not match how you feel, or if the reading does not include a number.
- **Choking hazard:** The System contains small parts that may be dangerous if swallowed.

CAUTION:

- For you to receive alarms, they must be on and your device should be within 20 feet of you at all times. The transmission range is 20 feet unobstructed. If you are out of range, you may not receive glucose alarms.
- 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, apply a new one, and contact Customer Service.
- Intense exercise may cause your Sensor to loosen due to sweat or movement of 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 low readings. Remove and replace your Sensor if it starts to loosen and follow the instructions to select an appropriate application site. Do not attempt to reinsert the Sensor. Contact Customer Service if your Sensor becomes loose

or falls off before the end of the wear period. Customer Service is available at 1-855-632-8658 7 Days a Week from 8AM to 8PM Eastern Standard Time.

- 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 unreliable low 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. Do not use Sensor Packs and Sensor Applicators with different Sensor codes together as this will result in incorrect glucose readings.
- 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.

Description

The Sensor initially comes in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. Follow the instructions to prepare and apply the Sensor on the back of your upper arm. The Sensor has a small, flexible tip that is inserted just under the skin. The Sensor can be worn for up to 14 days. The Sensor does not need to be calibrated with blood glucose values.

Sensor Kit Parts



Sensor Pack

Used with Sensor Applicator to prepare Sensor for use.



Sensor Applicator

Applies Sensor to body.



Alcohol Wipe

Used to prepare skin before Sensor application.

User Safety, Storage, and Handling

- The Sensor Pack is sterile and non-pyrogenic unless opened or damaged. Using a non-sterile or pyrogenic Sensor might cause infection.
- Store the Sensor Kit between 36°F and 82°F. Storage outside of this range may cause inaccurate Sensor glucose readings.
- If you suspect that the temperature may exceed 82°F (for example, in an un-airconditioned home in summer), you should refrigerate your Sensor Kit. Do not freeze your Sensor Kit.
- Store your Sensor Kit in a cool, dry place. Do not store your Sensor Kit in a parked car on a hot day.
- Your Sensor has been tested to withstand immersion into 3 feet (1 meter) of water for up to 30 minutes. It is also protected against insertion of objects > 12mm diameter. (IP27)
- Do NOT use if Sensor Kit contents are past expiration date.
- Interfering Substances: Taking ascorbic acid (vitamin C) supplements while wearing the Sensor may falsely raise Sensor glucose readings. Taking more than 500 mg of ascorbic acid per day may affect the Sensor readings which could cause you to miss a severe low glucose event. Ascorbic acid can be found in supplements including multivitamins. Some supplements, including cold remedies such as Airborne® and Emergen-C®, may contain high doses of 1000 mg of ascorbic acid and should not be taken while using the Sensor. See your health care professional to understand how long ascorbic acid is active in your body.
- The alcohol wipe is labeled as follows: Saturated with 70% Isopropyl alcohol; For External Use only; Single use; Do not use if package is opened or damaged; Sterilized using irradiation; Not made with natural rubber latex. Covidien Ilc, 15 Hampshire St., Mansfield, MA 02048 www.covidien.com

Language 2

To the extent allowed by law, the FreeStyle Libre 2 Sensor is provided to you “as is.” Abbott hereby disclaims all warranties (express, implied, and statutory) with respect to the Sensor, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. There are no warranties which extend beyond the description on the face hereof. | To the extent allowed by law, the FreeStyle Libre 2 Sensor is provided to you “as is.” Abbott hereby disclaims all warranties (express, implied, and statutory) with respect to the Sensor, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. There are no warranties which extend beyond the description on the face hereof.

Distributed by | Distributed by:

Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502 USA
1-855-632-8658

Customer Service | Customer Service:

7 Days a Week from 8AM to 8PM Eastern Standard Time |
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Placeholder for copyright date

Labeling Symbols | Labeling Symbols

CODE	Sensor code Sensor code
	Do not re-use Do not re-use
	Sterilized using irradiation Sterilized using irradiation
	Use-by date Use-by date
	Serial number Serial number
	Caution Caution
	Temperature limit Temperature limit
	Do not use if package is damaged Do not use if package is damaged
	Type BF applied part Type BF applied part
	Manufacturer Manufacturer
	Consult instructions for use Consult instructions for use
	Batch code Batch code
	Catalog number Catalog number
	CAUTION: Federal law restricts this device to sale by or on the order of a physician. CAUTION: Federal law restricts this device to sale by or on the order of a physician.
	Humidity limitation Humidity limitation
	MR unsafe MR unsafe
	Not made with natural rubber latex Not made with natural rubber latex
	This product contains electronic equipment, batteries, sharps and materials that may contact bodily fluids during use. Dispose of product in accordance with all applicable local regulations. This product contains electronic equipment, batteries, sharps and materials that may contact bodily fluids during use. Dispose of product in accordance with all applicable local regulations.

Manufacturer | Manufacturer

Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502 USA

