Welcome to your FreeStyle Libre Pro System

IN-SERVICE GUIDE

For Healthcare Professional Use Only



See inside for Indications and Important Safety Information.

Important Safety Information

Important Safety Information

The FreeStyle Libre Pro Flash Glucose Monitoring System is a professional continuous glucose monitoring (CGM) device indicated for detecting trends and tracking patterns and glucose level excursions above or below the desired range, facilitating therapy adjustments in persons (age 18 and older) with diabetes. The system is intended for use by health care professionals and requires a prescription.

IMPORTANT: The device may inaccurately indicate hypoglycemia. The results of the clinical study conducted for this device showed that 40% of the time when the device indicated that user sensor glucose values were at or below 60 mg/dL, user glucose values were actually in the range of 81-160 mg/dL. Therefore, interpretation of the FreeStyle Libre Pro Flash Glucose Monitoring System readings should only be based on the trends and patterns analyzed through time using the reports available per the intended use.

CONTRAINDICATIONS: Remove the Sensor before MRI, CT scan, X-ray, or diathermy treatment.

WARNINGS/LIMITATIONS: The FreeStyle Libre Pro System does not provide real-time results and patients should adhere to their blood glucose monitoring routine while using the system. If a sensor breaks, contact physician and call Customer Service. Patients with high levels of ascorbic acid (Vitamin C) or salicylic acid (used in Aspirin) or severe dehydration or excessive water loss may experience inaccurate results with this system. The FreeStyle Libre Pro System is not approved for pregnant women, persons on dialysis, or recommended for critically ill population. Sensor placement is not approved for sites other than the back of the arm and standard precautions for transmission of blood borne pathogens should be taken.

Review all product information before use or contact Abbott toll-free 855-632-5297 or visit https://www.freestyleprovider.abbott/us-en/safety-information.html for detailed indications for use and safety information.

Getting to Know your System

- The Reader is used to start the Sensor on your patient and gather his or her glucose readings
- Multiple patients can have their Sensor started by the same Reader

- The Sensor measures and stores glucose readings when worn on the body
- By following the instructions, prepare and apply the Sensor on the back of the patient's upper arm
- The Sensor may be worn for up to 14 days



See Operator's Manual for instruction on setting up the Reader for the first time.

YOUR SYSTEM

3

Sensor Application

Assemble Sensor and apply it to your patient's body

STEP 1



Ready

Get

Prepare Sensor Applicator

Select area on **back of patient's** upper arm.

Note: Avoid areas with 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



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:** Do NOT use if the Sensor Pack or the Sensor Applicator seem to be damaged or already opened. Do NOT use if past expiration date. Sensor codes must match on Sensor Pack and Sensor Applicator.

STEP 4



Line up dark mark on Sensor Applicator with dark mark on Sensor Pack. 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 out of Sensor Pack.

STEP 6

CODE XXX



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



With one hand holding the front of the patient's arm in place, use your other hand to place the Sensor Applicator over the prepared site and push down firmly to apply Sensor. **CAUTION**: *Do NOT push down on*

the Sensor Applicator until placed over prepared site to prevent unintended results or injury.

STEP 8



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

STEP 9



Make sure Sensor is secure. Gently press adhesive to the skin Discard used Sensor Applicator and Sensor Pack according to your facility's procedures.



Start New Sensor

2 Start Sensor with Reader

STEP 1



Press Home Button to turn on Reader and touch **Start New Sensor**. **Note:** If using Reader for the first time, follow the prompts to set date, time, and target glucose range.



STEP 2

Hold Reader within 1.5 inches (4 cm) of Sensor to start it.

> You will be prompted to check Sensor status after 2 minutes.



STEP 3

When prompted, touch **yes** to check the Sensor status. Hold the Reader within 1.5 inches (4 cm) of Sensor to verify Sensor is working. Then touch **OK**. Your patient can now go home and wear his or her Sensor for up to 14 days.

The Sensor should not be worn for more than 14 days. The Sensor automatically stops collecting glucose readings after 14 days.

No separate receiver, transmitter, or recorder for patients to wear or carry



Get your Patient's Sensor Data

The patient returns to the office after 14 days of wear. Data can be downloaded at anytime from Sensors that are on or off the body.

STEP 1



Press the Home Button to turn on the Reader.

STEP 2

tart New



STEP 3



Hold the Reader within 1.5 inches (4cm) of the Sensor. If sounds are turned on, the Reader will beep when all the data has been successfully downloaded from the Sensor. This may take up to 5 seconds.

Note: If communication is not established within 15 seconds, the Reader displays a prompt to try again. Touch **OK** to return to the Home Screen and touch **Get Sensor Data** again.

STEP 4



The Reader will indicate how many days of Sensor wear are left, if any. Touch view to view the daily graph. Touch **next**. For more information about the daily graph, see Daily Graph section in your FreeStyle Libre Pro System Operator's Manual.

STEP 5

To create reports, connect Reader to a computer.



To create reports, connect the Reader to a computer.

Note: the Home Screen will show this symbol in near the top of the screen when there is new Sensor data in the Reader that has not been transferred to a computer. A report should be generated from this data before the next Sensor is downloaded.



There are two ways to get the reports:

LibreView

Visit **LibreView.com** to create your account today. The LibreView system is a secure, free, cloud-based diabetes management system.

FreeStyle Libre Pro desktop reporting software. Visit **FreeStyleLibrePro.us** to download.

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.

GETTING DATA

Sensor Removal and Disposal



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.



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

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



You may clean the Reader using a damp cloth. Gently wipe the exterior of the Reader and allow to air dry.

CAUTION: Do NOT place the Reader in water or other liquids. Avoid getting dust, dirt, water, or any other substances in the USB port.

The Sensor and Sensor Applicator are intended for single use and do not require disinfection



FreeStyle Libre Pro System Reports

Comprehensive and simple reports illustrate glucose patterns to detect hypoglycemia, hyperglycemia, and glucose variability



Daily Glucose Summary (14 Days)

Snapshot Report

Not pictured, Glucose Pattern Insights report.

Images are for illustrative purposes only. No actual patient data.

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AGP Report

A standardized, single-page report for easy, quick interpretation



- **Glucose Statistics and Targets** are the recommended Time In Ranges for patients¹.
- Time In Range bar graph shows % of patient's glucose readings above, in and below target range.
- Ambulatory Glucose Profile (AGP) displays several days of glucose data, one on top of the other, as if they occurred over the same 24-hour period.

Daily Glucose Profiles underline specific daily glucose activity, which could help identify causes for deviations from Time In Range.

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Daily Pattern Report with Glucose Traces

14 daily traces to track patterns of hypoglycemia, hyperglycemia, and glucose variability



Glucose averages for each 2-hour increment over 14-day wear.

2 Percentage of time in target during 14-day wear.

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DAILY TRACES

Daily Patterns Report

Report collapses up to 14 days of glucose readings into a single 24-hour period to view a patient's typical day



- 1 Are the readings within target range?
- 2 Are there patterns of hypoglycemia?
- 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.
- 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.

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DAILY PATTERNS

Daily Glucose Summary Report

Daily glucose results at a glance



Identifies Highs/Lows for each day's glucose tracings with highs and lows highlighted.

2 Glucose Target Assessment of daily glucose results with time in target, time below target, and time above target.

Images are for illustrative purposes only. No actual patient data.

Daily Log Name I need to test my blood sugar times per day Continue your regular self-testing routine per Tarnet rannes: Pre-meal Post-mea your healthcare provider's recommendation. Next appointment Day & Date Breakfast Lunch Dinne Bedtime After 💥 After 📆 🍎 Before Insulin 🎜 (Before Before After 🛱 (Before After 🚆 Before 2 After 🕅 🍎 Before 🛛 After 🎽 Insulin 🖌 (Before After 3 Ó 🍎 Before 🛛 After 💥 (Before After 🛱 Insulin 🖨 (Before After 17 Insulin 🖌 🍎 Before 🛛 After 🚆 5 After 🛱 Insulin D Before After 57 Insulin 🖌 6 Ó Ť (Before Insulin 🆌 Ó Ó Ť (Before Insulin 🆌 Abbott

FreeStyle Libre Pro patient Daily Log sheet

TIP: View Daily Glucose Summary Report side-by-side with your patient's Daily Log to better understand glucose patterns and trends.

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DAILY GLUCOSE SUMMARY

Snapshot Report

A quick overview of patients' average glucose and hypoglycemic events



Average Glucose

Overall glucose average for up to 14 days.

Time in Target

- % of time above Target
- % of time in Target
- % of time below Target

3 Low Glucose Events

- number of low glucose events
- average duration of low glucose events

TIP: The Snapshot report is only available on LibreView.

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SNAPSHOT

Frequently Asked Questions

Sensor Application

What third-party products can be used to help with sensor adhesion?

Several products help with sensor adhesion*

Torbot Skin Tac™	A hypoallergenic and latex-free "tacky" skin barrier
Skin-Prep™ Protective Barrier Wipe	Protective liquid dressing that allows skin to breathe so tapes and films adhere better
Mastisol® Liquid Adhesive	Clear, non irritating, non water-soluble liquid adhesive that secures dressings even in moist areas

What if my patient has a hairy arm?

The site selected on the back of the upper arm should be clean-shaven.

Patient Wear

Will the user feel the sensor while wearing it?

The sensor filament is less than 0.4 millimeters thick and is inserted 5 millimeters under the skin surface. In a study conducted by Abbott Diabetes Care, 93.4% of patients surveyed (n=30) did not feel discomfort under the skin while wearing the sensor¹.

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

Yes. The sensor can be worn while bathing, showering, swimming or exercising. 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.

How does the patient remove the sensor in the event he or she needs to do so prior to 14 days?

The patient should pull up the edge of the adhesive that keeps the sensor attached to the skin, then 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.

Were there any skin reactions reported by patients wearing FreeStyle Libre Pro sensors?

In the clinical study, the incidence of skin issues observed was¹:

- 93.4% No feeling of discomfort under the skin while wearing the sensor
- 0% Moderate pain
- 1% Moderate to severe itching
- 4% Erythema
- Note: The rate of moderate incidences for any individual category of skin issues, including induration, rash, bleeding, itching, and scaling of the skin, was no more than 1%.

*Abbott Diabetes Care ("ADC") is not affiliated with the manufacturers of the products listed. Reference to third-party products does not constitute or imply an endorsement, recommendation, sponsorship or favoring of any product or manufacturer. ADC is not responsible for the completeness or accuracy of any information regarding third-party products. ADC makes no representations, expressed or implied, regarding third-party products or their manufacturers, quality or suitability for you. Manufacturers' instructions for use of each product should be followed. **1.** FreeStyle Libre Pro System Operator's Manual.

Frequently Asked Questions

Patient Wear (continued)

What if the sensor falls off before day 14?

Patients: call your healthcare professional for instructions.

HCPs: call Abbott Customer Service at 855-632-5297.

How frequently did the sensor fall off before the end of the 14-day wear period?

85.3% of sensors lasted for the intended 14-day wear duration¹.

Do patients have to remove the sensor during MRI/CT scan?

Yes. The sensor should be removed prior to exposing it to strong magnetic or electromagnetic radiation, such as with an MRI (magnetic resonance imaging)

or CT (computed tomography) scan. The effect of these types of procedures on the performance of the system has not been evaluated.

Re-Order the FreeStyle Libre Pro System

Visit FreeStyleLibrePro.us and click "How to Purchase"

or place your order online at eAbbott.com All e-Abbott ordering requires a customer account number and complete registration.

Please contact customer service for assistance.

Customer Service 8AM-8PM EST Tel 800-537-3575 Fax 847-785-8839 adc.customerservice@abbott.com

Item numbers for ordering the FreeStyle Libre Pro system

DESCRIPTION	ITEM
Sensor Kit (1 sensor) (must be purchased in increments of 4)	71562-01
Reader Kit (1 reader)	71687-01
Cable and Adapter	71613-01
Sensor Mailer Kit (10/pack)	71688-01
Software CD	75170-01

