Operator's Manual

FreeStyle Libre Pro

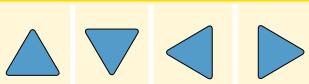
FLASH GLUCOSE MONITORING SYSTEM

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

Abbott

Contents

Reader Symbols

Symbol	What It Means
	View previous/next screen
	Options
	Low battery
	Battery charging
	Confirm Sensor reminder
	Communication strength
	Data to report

Important Safety Information

Indications for Use

The FreeStyle Libre Pro Flash Glucose Monitoring System is a professional continuous glucose monitoring (CGM) device indicated for detecting trends and tracking patterns in persons (age 18 and older) with diabetes. The System is intended for use by health care professionals and requires a prescription. Readings from the FreeStyle Libre Pro Sensor are only made available to patients through consultation with a health care professional. The System does not require user calibration with blood glucose values.

The FreeStyle Libre Pro System aids in the detection of glucose level excursions above or below the desired range, facilitating therapy adjustments. Interpretation of the FreeStyle Libre Pro Flash Glucose Monitoring System readings should be based on the trends and patterns analyzed through time using the reports available.

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

The FreeStyle Libre Pro Flash Glucose Monitoring 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 to detect trends and track patterns in the user's glucose values during the wear period.

WARNING: The FreeStyle Libre Pro Flash Glucose Monitoring System contains small parts that may be dangerous if swallowed.

CAUTION:

- Performance of the System when used with other implanted medical devices, such as pacemakers, has not been evaluated.
- Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If your patient notices significant skin irritation around or under their Sensor, they should remove the Sensor and stop using the FreeStyle Libre Pro System. Follow your facility's procedures for handling skin reactions.

Warnings/Limitations

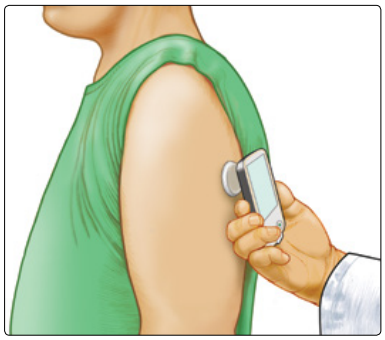
- Review all product information before use.
- Physiologic differences between the interstitial fluid and capillary blood may result in differences in glucose readings. Differences in glucose readings between interstitial fluid and capillary blood may be observed during times of rapid change in blood glucose, such as after eating, dosing insulin, or exercising.
- Severe dehydration and excessive water loss may cause inaccurate results.
- 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.
- Interfering Substances: 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.

- Take standard precautions for transmission of blood borne pathogens to avoid contamination.
- The Reader should be cleaned between patients.
- If a Sensor breaks inside a patient, remove with tweezers, treat any medical complications and call Customer Service.
- Use of the System is not recommended in the critically ill population since performance is unknown due to different conditions and medications.
- 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.
- If the Sensor Kit package or contents or the Reader appear to be damaged, do not use as there may be a risk of electric shock, no results, and/or infection.
- Store the Sensor Kit between 39°F-77°F. While you don't need to keep the Sensor Kit in a refrigerator, you can as long as the refrigerator is between 39°F-77°F.
- Store the Sensor Kit between 10-90% non-condensing humidity.
- The System does not provide real-time results. Patients need to rely on blood glucose readings for monitoring glucose during System use.
- Clean hands prior to Sensor handling/insertion to help prevent infection.
- Clean the application site and ensure that it is dry prior to Sensor insertion. This helps the Sensor stay attached to the body.

- Change the application site for the next Sensor application to prevent discomfort or skin irritation.
- 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.
- The Sensor should not be worn more than 14 days. Readings are not obtained after 14 days.
- 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 the user's glucose values during the wear period.
- The FreeStyle Libre Pro Flash Glucose Monitoring System has not been evaluated for use in pregnant women, persons on dialysis, or people less than 18 years of age.

Getting to Know the System

The FreeStyle Libre Pro Flash Glucose Monitoring System has three main parts: a handheld Reader, a disposable Sensor, and FreeStyle Libre Pro software. A single FreeStyle Libre Pro Reader can be used to gather data from FreeStyle Libre Pro Sensors on multiple patients.



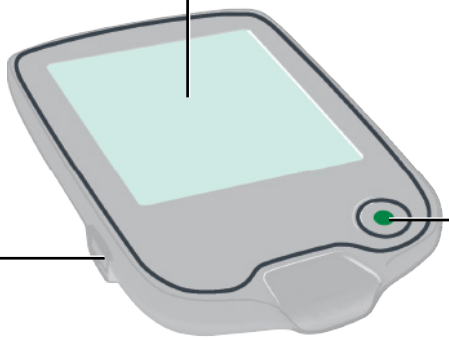
IMPORTANT: Safety information about the System is in this Operator's Manual. Read all of the information in the Operator's Manual before using the System.

When opening the **Reader Kit** and **Sensor Kit**, check that the contents are undamaged and that you have all parts listed. If any parts are missing or damaged, contact Customer Service.

Reader Kit

The Reader Kit includes:

- FreeStyle Libre Pro Reader
- USB Cable
- Power Adapter
- Operator's Manual
- Quick Start Guide



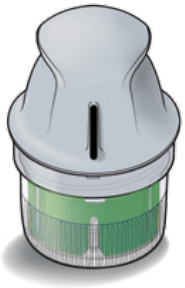
The Reader is used to start the Sensor on a patient and gather their glucose readings. Multiple patients can have their Sensor started by the same Reader.

Sensor Kit

The Sensor Kit includes:

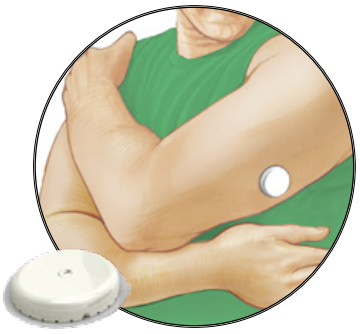
- Sensor Pack
- Sensor Applicator
- Alcohol wipe
- Product insert

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



Sensor Applicator
Applies the Sensor to the patient's body.

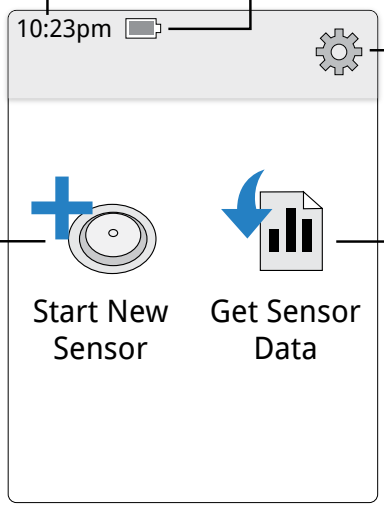
The Sensor measures and stores glucose readings when worn on the body. It initially comes in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. By following the instructions, prepare and apply the Sensor on the back of the patient's upper arm. The Sensor has a small, flexible tip that is inserted just under the skin. The Sensor can be worn for up to 14 days.



Sensor
Measures glucose while on body (only visible after applied).

The Reader Home Screen provides access to starting a new Sensor, getting Sensor data, and information about the System.

Home Screen



Time

Current time set on the Reader.

Battery Level

Battery charge remaining.

Options

Touch to view or change the Reader's options.

Start New Sensor

Touch to start a new Sensor.

Get Sensor Data

Touch to download all glucose readings from the Sensor into the Reader.

FreeStyle Libre Pro Software

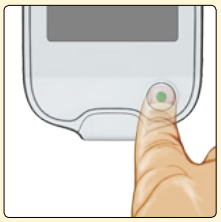
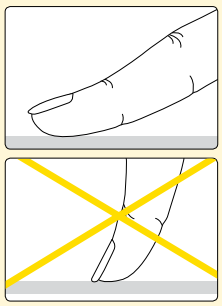
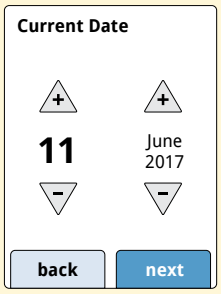
FreeStyle Libre Pro software can be used to create reports based on glucose readings from the most recently downloaded Sensor. The software is compatible with most Windows and Mac operating systems. Go to www.FreeStyleLibrePro.com and follow onscreen instructions to download and install the software.

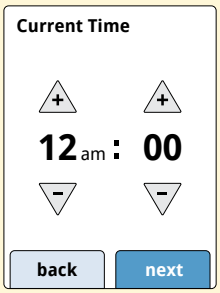
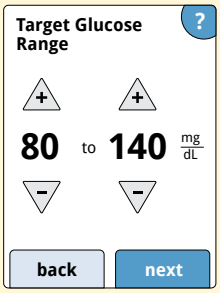
INTENDED USE

The FreeStyle Libre Pro software is intended for use by health care professionals to aid in the review, analysis and evaluation of a patient's glucose readings uploaded from the FreeStyle Libre Pro Flash Glucose Monitoring System in support of an effective diabetes health management program.

Setting up the Reader for the First Time

Before using the System for the first time, the Reader must be set up.

Step	Action
1	 Press the Home Button to turn on the Reader.
2	 If prompted, use the touchscreen to select your preferred language for the Reader. Touch **OK** to continue. **Note:** Use the pad of your finger. Do NOT use your fingernail or any other object on the screen.
3	 Set the **Current Date** using the arrows on the touchscreen. Touch **next** to continue.

Step	Action
4	 Set the **Current Time**. Touch **next** to continue. **CAUTION:** It is very important to set the time and date correctly for correct interpretation of Sensor data.
5	 Set the **Target Glucose Range**. Touch **next** to continue. **Note:** The Target Glucose Range is displayed on the Daily Graph on the Reader once Sensor data has been downloaded. While the glucose data are gathered in the System range of 40-500 mg/dL, the Daily Graph display range is 0-350 mg/dL for ease of review on screen.
6	 The Reader now indicates how to return to the Home Screen from any other screen. Touch **done** to go to the Home Screen.

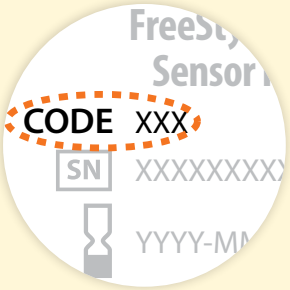
Note: Charge the Reader if the battery level is low. Only use the USB cable and power adapter included with the System.

Using the Sensor

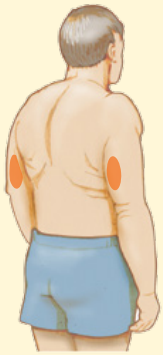
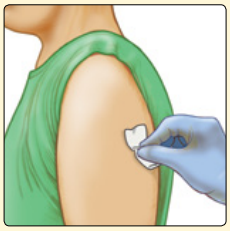
After you assemble and apply the Sensor to your patient's body, start the Sensor with the Reader and confirm it is working. The Sensor stores glucose readings every 15 minutes for up to 14 days. The first reading is stored 1 hour after the Sensor is successfully started.

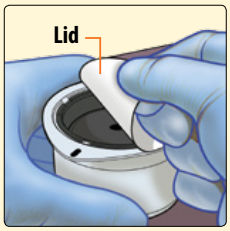
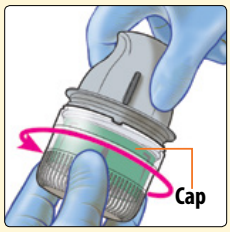
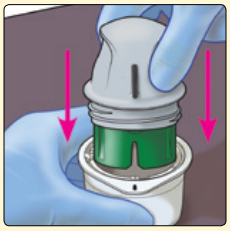
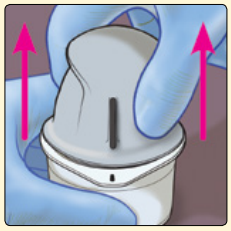
CAUTION:

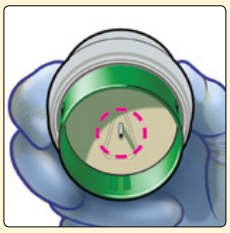
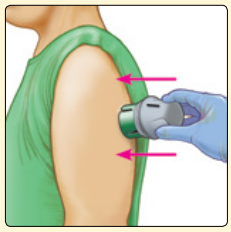
The Sensor Pack and Sensor Applicator are packaged as a set (separately from the Reader) and have the same Sensor code. Check that the Sensor codes match before using the Sensor Pack and Sensor Applicator. Sensor Packs and Sensor Applicators with the same Sensor code should be used together or Sensor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

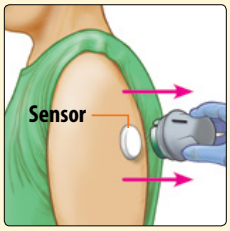
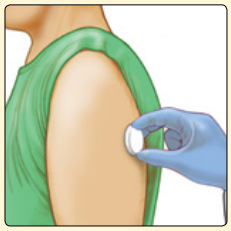


Applying the Sensor

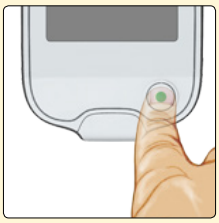
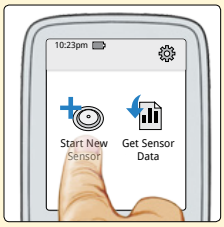
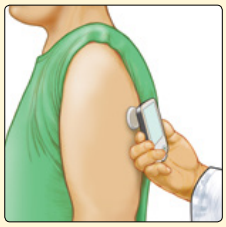
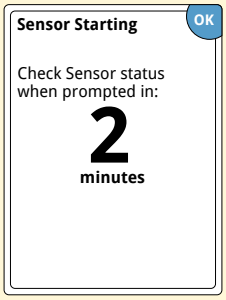
Step	Action
1	 Apply Sensors only on the back of your patient's upper arm. Avoid areas with scars, moles, stretch marks, or lumps. Select an area of skin that generally stays flat during normal daily activities (no bending or folding). Choose a site that is at least 1 inch (2.5 cm) away from an insulin injection site. To prevent discomfort or skin irritation, you should select a different site other than the one most recently used.
2	 Clean application site with an alcohol wipe and allow site to dry before proceeding. This helps the Sensor stay attached to the body. **Note:** The area **MUST** be clean and dry, or the Sensor may not stick to the site.

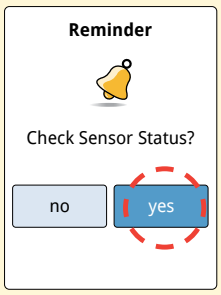
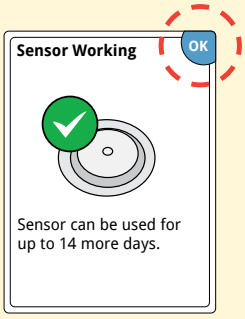
Step	Action
3	  Open the Sensor Pack by peeling the lid off completely. Unscrew cap from the Sensor Applicator and set the cap aside. **CAUTION:** Do NOT use if the Sensor Pack or the Sensor Applicator seem to be damaged or already opened. Do NOT use if past expiration date.
4	 Line up the dark mark on the Sensor Applicator with the dark mark on the Sensor Pack. Press firmly down on the Sensor Applicator until it comes to a stop.
5	 Lift the Sensor Applicator out of the Sensor Pack.

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

Step	Action
8	 Gently pull the Sensor Applicator away from the 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.
9	 Make sure the Sensor is secure after application. Put the cap back on the Sensor Applicator. Discard the used Sensor Pack and Sensor Applicator according to your facility's procedures.

Starting the Sensor

Step	Action
1	 Press the Home Button to turn on the Reader.
2	 Touch **Start New Sensor**.
3	 Hold the Reader within 1.5 inches (4 cm) of the Sensor to start it. If sounds are turned on, the Reader beeps when the Sensor has been started. You can check the Sensor has successfully started in 2 minutes.  **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 **Start New Sensor** to start the Sensor.

Step	Action
4	 When prompted, touch **yes** to check the Sensor status. Hold the Reader within 1.5 inches (4 cm) of the Sensor to verify Sensor is working.
5	 Touch **OK** to go to the Home Screen.

Patient Wear

The Sensor stores your patient's glucose readings every 15 minutes for up to 14 days. The first reading is stored 1 hour after the Sensor is successfully started.

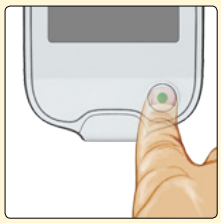
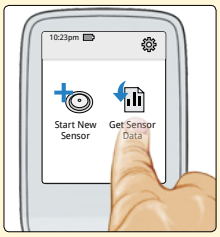
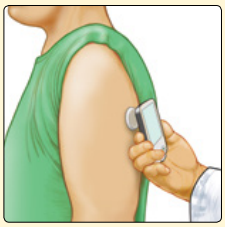
IMPORTANT:

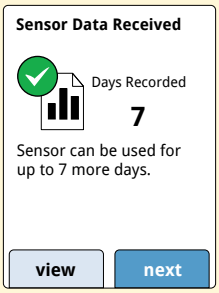
- The Sensor should not be worn for more than 14 days.
- Data can be downloaded at anytime from Sensors that are on or off the body.
- Before your patient goes home, review and give them the "Living with Your FreeStyle Libre Pro Sensor" section of the insert in the Sensor Kit.

CAUTION: Intense exercise may cause the Sensor to loosen due to sweat or movement of the Sensor. If the Sensor becomes loose, the Sensor readings may be unavailable or unreliable. Your patient should return to your facility for application of a new Sensor.

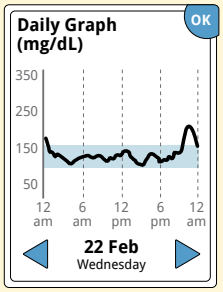
Getting Sensor Data

Data can be downloaded at anytime from Sensors that are on or off the body.

Step	Action	
1		Press the Home Button to turn on the Reader.
2		Touch **Get Sensor Data**.
3		Hold the Reader within 1.5 inches (4 cm) 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	Action
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.
5	 To create reports, connect the Reader to a computer. See *Creating Reports* section in the FreeStyle Libre Pro software User's Manual. The User's Manual can be found in the Help Menu of the software. Touch **done** to return to the Home Screen. **Note:** The Home Screen will show this symbol  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.

Daily Graph



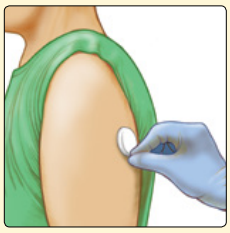
The Daily Graph shows the Sensor glucose readings by day and the Target Glucose Range that is set on the Reader. You can change the target glucose range by touching the Options symbol on the Home Screen and selecting **Target Range**.

Notes:

- If you want the graph to show the current patient's target range, set their target range before downloading their data.
- The graph displays glucose readings up to 350 mg/dL. Glucose readings above 350 mg/dL are displayed at 350 mg/dL. For sequential readings above 350 mg/dL, a line is displayed at 350 mg/dL.

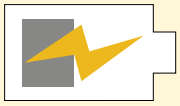
Removing the Sensor

The Sensor automatically stops working and should be removed 14 days after being started. You should also replace the Sensor if there is any irritation or discomfort at the application site or if the Reader reports a problem with the Sensor currently in use.

Step	Action
1	 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.
2	Discard the used Sensor according to your facility's procedures. See *Maintenance and Disposal* section.

Charging the Reader

A fully charged Reader battery should last up to 2 weeks. The battery life may vary depending on your usage.



Charging

Plug the included USB cable into an electrical outlet using the included power adapter. Then, plug the other end of the USB cable into the USB port on the Reader.

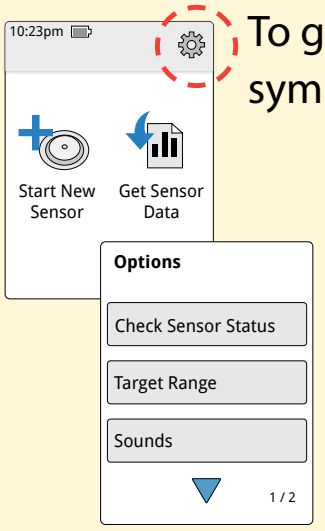
CAUTION: Be sure to select a location for charging that allows the power adapter to be easily unplugged.

Notes:

- You must charge the Reader when the battery is low  to keep using the Reader.
- To fully charge the battery, charge the Reader for at least 3 hours.
- Only use the USB cable and power adapter included with the system.
- Fully charge the Reader before storing it for more than 3 months.

Reader Options

You can go to the Options menu to check Sensor or System Status or change settings on the Reader, like Time & Date or Sounds.

Step	Action
1	 To get to the Options menu, touch the Options symbol on the Home Screen.

Step	Action
2	Touch the option you want to view or change: **Check Sensor Status** – Check if a Sensor is working or has ended **Target Range** – Set range displayed on Reader Daily Glucose graph **Sounds** – Set tones and vibrations **Time & Date** – Change the Time or Date **Language** – Change the language on the Reader (option only available on Readers with multiple languages) **System Status** – Check Reader information and performance • View System Information: The Reader will display information about the system including: - Reader serial and version numbers - Sensor serial number for most recently downloaded Sensor - Sensor version for most recently downloaded Sensor - Sensor start date and time for most recently downloaded Sensor - Sensor download date and time for most recently downloaded Sensor - Amount of data downloaded from Sensor

Step	Action
2 ***(cont.)***	• Perform a Reader Test: The Reader Test will perform internal diagnostics and allow you to check that the display is showing all pixels, sounds (including both tones and vibrations) are working, and the touchscreen is responding when touched • View Event Logs: A list of events recorded by the Reader, which may be used by Customer Service to help troubleshoot the System Touch **OK** when you are done.

Maintenance and Disposal

Cleaning

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 substance in the USB port.

Maintenance

The FreeStyle Libre Pro Flash Glucose Monitoring System has no serviceable parts.

Disposal

This product 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.

Troubleshooting

This section lists problems or observations that may occur, the possible cause(s), and recommended actions. If the Reader experiences an error, a message will appear on the screen with directions to resolve the error.

Reader Does Not Power On

Problem	What It May Mean	What To Do
Reader does not power on after you press the Home Button.	Reader battery is too low.	Charge the Reader.
	Reader is outside of its operating temperature range.	Move the Reader to a temperature between 50 °F and 113 °F and then try to power it on.

If the Reader still does not power on after trying these steps, contact Customer Service.

Problems at the Sensor Application Site

Problem	What It May Mean	What To Do
The Sensor is not sticking to the patient's skin.	The site is not free of dirt, oil, hair, or sweat.	1. Remove the Sensor. 2. Consider shaving and/or cleaning the site with soap and water. 3. Follow the instructions in *Applying and Starting the Sensor* sections.
Skin irritation at the Sensor application site.	Seams or other constrictive clothing or accessories causing friction at the site.	Ensure that nothing rubs on the site.
	The patient may be sensitive to the adhesive material.	Follow your facility's procedures for handling skin reactions.

Problems Starting the Sensor

Display	What It May Mean	What To Do
Sensor Ended	You may be trying to start a used Sensor.	If you need to start a Sensor, then apply and start a new one. Otherwise, return to the Home Screen to get Sensor data.
Communication Error	The Reader was unable to communicate with the Sensor.	Hold the Reader within 1.5 inches (4 cm) of the Sensor. **Note:** You may need to move away from potential sources of electromagnetic interference.
Replace Sensor	The System has detected a problem with the Sensor.	Apply and start a new Sensor.

Problems Getting Sensor Data

Display	What It May Mean	What To Do
Data Transfer Error	The Reader is not held close enough or long enough to the Sensor.	Hold the Reader within 1.5 inches (4 cm) of the Sensor for up to 5 seconds.
New Sensor Found	The Sensor was never started.	If you would like to begin using this Sensor, touch **Yes**.
Communication Error	The Reader was unable to communicate with the Sensor.	Hold the Reader within 1.5 inches (4 cm) of the Sensor. **Note:** You may need to move away from potential sources of electromagnetic interference.

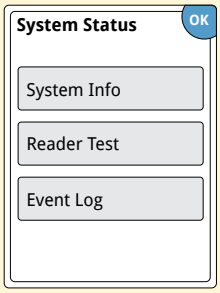
Display	What It May Mean	What To Do
Sensor Starting	The Sensor has not completed starting.	Wait for the reminder to check Sensor status. This will take approximately 2 minutes.
No Data Available	There is no data available to download.	Sensor data is usually available for download 80 minutes after a Sensor was started. Try again after this time.
Sensor Error	There is no data available from this Sensor. The Sensor may not be working.	If the Sensor was recently applied, wait 1 hour and try again. If this doesn't work, contact Customer Service.

Display	What It May Mean	What To Do
Data to Report	You have not yet generated reports from the data already on the Reader.	To create reports from the data already on the Reader, connect the Reader to a computer. Or, to overwrite with data from the current Sensor, touch **yes**.

Reader Error Messages

Display	What It May Mean	What To Do
E-2	Reader error.	Turn off the Reader and try again. If the error reappears, contact Customer Service.
E-9	Reader error.	Turn off the Reader and try again. If the error reappears, contact Customer Service.

Perform a Reader Test



If you think the Reader is not working properly, you can check the Reader by performing a Reader Test.

Touch the Options symbol from the Home Screen, select **System Status** and then select **Reader Test**.

Note: The Reader Test will perform internal diagnostics and will allow you to check that the display, sounds, and touchscreen are working properly.

Customer Service

Customer Service is available to answer any questions you may have about the FreeStyle Libre Pro Flash Glucose Monitoring System. Please go to the back cover of this manual for your Customer Service phone number.

System Specifications

Sensor Specifications

Sensor glucose assay method	Amperometric electrochemical sensor
Sensor glucose reading range	40 to 500 mg/dL
Sensor size	5 mm height and 35 mm diameter
Sensor weight	5 grams
Sensor power source	One silver oxide battery
Sensor wear period	Up to 14 days

Sensor memory	Up to 14 days (glucose readings stored every 15 minutes)
Operating temperature	50 °F to 113 °F
Sensor Applicator and Sensor Pack storage temperature	39 °F to 77 °F
Operating and storage relative humidity	10-90%, non-condensing
Sensor water resistance	IP27: Can withstand immersion into 3 ft (one meter) of water for up to 30 minutes
Operating and storage altitude	-1,250 ft (-381 meters) to 10,000 ft (3,048 meters)

Reader Specifications

Reader size	95 mm x 60 mm x 16 mm
Reader weight	65 grams
Reader power source	One lithium-ion rechargeable battery
Reader battery life	2 weeks of typical use
Reader Sensor memory	1 Sensor
Reader operating temperature	50 °F to 113 °F
Reader storage temperature	-4 °F to 140 °F
Operating and storage relative humidity	10-90%, non-condensing
Reader moisture protection	Keep dry

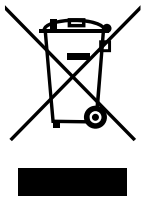
Operating and storage altitude	-1,250 ft (-381 meters) to 10,000 ft (3,048 meters)
Reader display timeout	60 seconds
Radio Frequency	Near Field Communication* (13.56 MHz RFID); ASK Modulation; 124 dBuV/m; 1.5 inch communication range
Data port	Micro USB
Minimum Computer Requirements	System must only be used with EN60950-1 rated computers
Mean service life	3 years of typical use
Power Adapter	Abbott Diabetes Care PRT25611 Operating temperature: 50 °F to 104 °F
USB Cable	Abbott Diabetes Care PRT21373 Length: 37 inches (94 cm)

* Security measures: The communication between Reader and Sensor is a short range near field communication method making it difficult to interfere with or intercept data that is being transferred. The Sensor and Reader are protected by proprietary data format, memory mapping, and cyclic redundancy check (CRC) generation and verification of data.

Quality of Service (QoS): QoS for the FreeStyle Libre Pro Reader and Sensor wireless communications using the near field communications is assured within the effective range of 4 cm between the Sensor and Reader that is specified to occur within 15 seconds.

Labeling Symbols

	Consult instructions for use		Use-by date
	Temperature limit	REF	Catalog number
	Manufacturer	SN	Serial number
LOT	Batch code		Do not use if package is damaged
	Type BF applied part		Keep dry
CODE	Sensor code		Non-ionizing radiation
	Do not re-use		Caution
	MR unsafe		Humidity limitation
	FCC Declaration of Conformity mark	STERILE R	Sterilized using irradiation
	Not made with natural rubber latex		

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

Performance Characteristics

Clinical Study Overview

Performance of the FreeStyle Libre Pro Flash Glucose Monitoring System (the System) was evaluated in a clinical study. The study was conducted in 4 centers; a total of 72 subjects with diabetes (81.9% Type 1, 18.1% Type 2) aged eighteen and older were included in the study; all subjects required insulin administration either by an insulin pump or via multiple daily injections to manage their diabetes. Each subject wore two sensors for up to 14 days, one on the back of each upper arm. During the study, subjects tested their blood glucose using fingerstick capillary samples using a FreeStyle Precision blood glucose meter. Additionally, subjects had their venous blood glucose analyzed approximately 96 times over three separate visits to the clinical center using the Yellow Spring Instrument Life Sciences 2300 STAT Plus™ Glucose & Lactate Analyzer (YSI). YSI is a laboratory-grade glucose and lactate analyzer of whole blood and plasma and is a widely recognized standard in laboratory analysis of blood glucose. Glucose readings obtained from the System were compared to glucose readings obtained from the YSI to evaluate the performance of the System. Three lots of sensors were evaluated in the study.

Agreement with YSI Levels

Agreement between GM and venous blood was characterized by using paired GM and plasma equivalent Yellow Springs Instrument measurements (YSI).

The accuracy of GM versus YSI reference was assessed by calculating the percentage of System readings that were within 15%, 20%, 30% and 40% for reference values 80 mg/dL and above, and 15 mg/dL, 20 mg/dL, 30 mg/dL and 40 mg/dL for values below 80 mg/dL when glucose levels are assigned using the YSI values. The results are presented in **Table 1**. Overall 83.8% of results were within ±20 mg/dL / 20% of YSI reference.

Table 1: Number and Percent of Results within YSI Reference

YSI Glucose Level (mg/dL)	Number of GM-Reference Pairs	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±30% / ±30 mg/dL	Within ±40% / ±40 mg/dL	Outside ±40% / ±40 mg/dL
Overall	12323	71.8	83.8	95.2	98.5	1.5
40-50	30	53.3	83.3	93.3	100.0	0.0
51-80	505	58.4	73.3	89.1	96.0	4.0
81-180	7373	68.3	80.2	93.7	98.0	2.0
181-300	4115	79.0	90.4	98.3	99.5	0.5
301-400	286	84.6	96.5	99.7	100.0	0.0
401-500	14	85.7	100.0	100.0	100.0	0.0

Agreement with GM Glucose Levels

The accuracy of GM versus YSI reference was also assessed by calculating the percentage of System readings that were within 15%, 20%, 30% and 40% for reference values 80 mg/dL and above, and 15 mg/dL, 20 mg/dL, 30 mg/dL and 40 mg/dL for values below 80 mg/dL when glucose levels are assigned using the GM readings. The results are presented in **Table 2**. Overall 83.6% of results were within ±20 mg/dL / 20% of the YSI reference.

Table 2: Number and Percent of Results within YSI Reference

GM Glucose Level (mg/dL)	Number of GM-Reference Pairs	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±30% / ±30 mg/dL	Within ±40% / ±40 mg/dL	Outside ±40% / ±40 mg/dL
Overall	12323	71.7	83.6	94.9	98.2	1.8
40-50	28	17.9	28.6	50.0	71.4	28.6
51-80	586	54.1	70.6	88.2	94.2	5.8
81-180	6685	72.2	83.0	94.2	97.9	2.1
181-300	4449	73.9	86.2	96.9	99.2	0.8
301-400	541	70.1	86.7	97.2	98.9	1.1
401-500	34	55.9	88.2	97.1	100.0	0.0

Agreement on Day 1 against YSI Reference

The accuracy of GM versus YSI reference on the first day of sensor wear was assessed by calculating the percentage of System readings that were within 15%, 20%, 30% and 40% for reference values 80 mg/dL and above, and 15 mg/dL, 20 mg/dL, 30 mg/dL and 40 mg/dL for values below 80 mg/dL by hourly intervals. The results are presented in **Table 3**.

Table 3: Number and Percent of Results within YSI Reference

Time Interval (hour)	Number of GM-Reference Pairs	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±30% / ±30 mg/dL	Within ±40% / ±40 mg/dL	Outside ±40% / ±40 mg/dL
(0-2)	235	60.9	73.2	92.8	98.3	1.7
(2-4)	552	67.4	77.7	90.4	96.4	3.6
(4-6]	557	61.4	74.3	89.2	95.9	4.1
(6-8]	534	65.5	80.5	94.0	98.3	1.7
(8-12]	239	66.1	83.3	97.9	99.2	0.8
(12-24]	436	59.9	77.1	93.6	97.7	2.3

Overall Accuracy against YSI Reference

Accuracy was measured by comparing the absolute relative difference between the System and reference YSI glucose values. The absolute relative difference measures the level of disagreement between the System and the reference value, but does not tell you whether the System glucose value was, on average, higher or lower than the reference glucose value. The Mean Absolute Relative Difference gives an indication of the average percent disagreement between the GM and the reference. **Table 4** shows the absolute difference measures by glucose level. Overall the Mean Absolute Relative Difference was 12.3% for the comparison with YSI reference. The Median Absolute Relative Difference shows that half of the time the System was within 10.1% of the YSI reference.

Table 4: Difference Measures by YSI Reference Glucose Levels

	YSI Reference		
Reference Glucose Level (mg/dL)	**Number of GM-Reference Pairs**	**Median Absolute Relative Difference (%)**	**Mean Absolute Relative Difference (%)**
Overall	12323	10.1	12.3
40-50*	30	14.2	15.8
51-80*	505	12.5	15.5
81-180	7373	10.7	12.9
181-300	4115	8.7	10.1
301-400	286	7.8	8.8
401-500	14	4.2	7.2

* For reference values ≤ 80 mg/dL, the mean and median absolute differences (mg/dL) are presented instead of mean and median absolute relative differences (%).

Agreement with BG Levels

Agreement between the System and capillary FreeStyle Precision blood glucose values (BG) was characterized by using paired System Glucose Measurements (GM) and BG reference.

The accuracy of GM versus BG reference was assessed by calculating the percentage of System readings that were within 15%, 20%, 30% and 40% for reference values 80 mg/dL and above, and 15 mg/dL, 20 mg/dL, 30 mg/dL and 40 mg/dL for values below 80 mg/dL. The results are presented in **Table 5**. Overall 79.4% of results were within ±20 mg/dL / 20% of BG reference. Please note that different blood glucose meters have different levels of performance compared to the meter used in this study. The performance presented here is not representative of a comparison to all blood glucose meters.

Table 5: Number and Percent of Results within BG Reference*

BG Glucose Level (mg/dL)	Number of GM-Reference Pairs	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±30% / ±30 mg/dL	Within ±40% / ±40 mg/dL	Outside ±40% / ±40 mg/dL
Overall	11918	66.5	79.4	93.4	97.9	2.1
40-50	152	57.2	66.4	86.8	92.8	7.2
51-80	841	68.4	80.6	93.6	98.1	1.9
81-180	6397	65.7	78.5	92.6	97.4	2.6
181-300	3719	66.5	80.2	94.1	98.7	1.3
301-400	695	71.7	83.5	97.3	99.3	0.7
401-500	114	81.6	90.4	97.4	99.1	0.9

* Comparison to BG was performed using the FreeStyle Precision blood glucose meter. Different performance may be expected when compared to other models of blood glucose meters.

Overall Accuracy against BG Reference

Accuracy was measured by comparing the absolute relative difference between the System and reference BG values. The absolute relative difference measures the level of disagreement between the System and the reference value, but does not tell you whether the System glucose value was, on average, higher or lower than the reference glucose value. The Mean Absolute Relative Difference gives an indication of the average percent disagreement between the GM and the reference. **Table 6** shows the absolute difference measures by glucose level. Overall the Mean Absolute Relative Difference was 13.9% for the comparison with BG reference. The Median Absolute Relative Difference shows that half of the time the System was within 11.1% of the BG reference.

Table 6: Difference Measures by BG Reference Levels*

	BG Reference		
Reference Glucose Level (mg/dL)	**Number of GM-Reference Pairs**	**Median Absolute Relative Difference (%)**	**Mean Absolute Relative Difference (%)**
Overall	11918	11.1	13.9
40-50**	152	13.5	19.1
51-80**	841	10.0	12.6
81-180	6397	10.9	13.5
181-300	3719	10.9	12.9
301-400	695	9.1	11.3
401-500	114	7.1	9.2

* Comparison to BG was performed using the FreeStyle Precision blood glucose meter. Different performance may be expected when compared to other models of blood glucose meters.

** For reference values ≤ 80 mg/dL, the mean and median absolute differences (mg/dL) are presented instead of mean and median absolute relative differences (%).

Concurrence of System and Reference (YSI vs. GM)

The percentage of concurring glucose values (YSI vs. GM) in each glucose reference range is presented for each YSI range in **Table 7**. For example, when the YSI glucose results are within the 81 to 120 mg/dL range, you can expect the GM values were less than 40 mg/dL 0.2% of the time, between 40 and 60 mg/dL 1.8% of the time, between 61 and 80 mg/dL 9.0% of the time, between 81 and 120 mg/dL 61.4% of the time, between 121 and 160 mg/dL 26.7% of the time, between 161 and 200 mg/dL 0.8% of the time, and above 201 mg/dL 0.0% of the time.

Table 7: Concurrence Analysis by Glucose Level

YSI (mg/dL)	GM Glucose Level (mg/dL)												N
	<40*	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	401-500	>500*	
<40	20.0	80.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	5
40-60	0.0	26.4	60.0	11.8	1.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	110
61-80	0.2	11.1	42.9	43.6	1.7	0.2	0.2	0.0	0.0	0.0	0.0	0.0	422
81-120	0.2	1.8	9.0	61.4	26.7	0.8	0.0	0.0	0.0	0.0	0.0	0.0	2472
121-160	0.0	0.1	0.4	12.4	60.8	25.0	1.2	0.0	0.0	0.0	0.0	0.0	3338
161-200	0.0	0.0	0.1	1.1	16.8	49.8	31.5	0.6	0.1	0.0	0.0	0.0	2853
201-250	0.0	0.0	0.0	0.1	0.8	9.6	62.0	26.6	0.8	0.0	0.0	0.0	1937
251-300	0.0	0.0	0.0	0.0	0.0	0.1	11.3	56.6	29.8	2.1	0.0	0.0	892
301-350	0.0	0.0	0.0	0.0	0.0	0.0	0.0	12.4	53.1	33.2	1.3	0.0	226
351-400	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	35.0	35.0	30.0	0.0	60
401-500	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	6.3	81.3	12.5	16
>500	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0

* Levels outside of system dynamic range.

Agreement with 'LO' or 'HI' GM Reading against YSI Reference

The system reports glucose concentrations between 40 and 500 mg/dL. When the system determines that glucose level is below 40 mg/dL, it will report as 'LO'. When the system determines that glucose level is above 500 mg/dL, it will report as 'HI'. **Table 8** displays the concurrence between the GM and YSI reference glucose when GM reads 'LO'. For example, when GM reads 'LO' you can expect that YSI glucose values were less than 40 mg/dL 16.7% of the time, between 40 and 50 mg/dL 0.0% of the time, between 51 and 60 mg/dL 0.0% of the time, between 61 and 70 mg/dL 16.7% of the time, between 71 and 80 mg/dL 0.0% of the time, and above 80 mg/dL 66.7% of the time.

Table 8: Concurrence Analysis with LO GM Reading

GM Glucose Level (mg/dL)	YSI (mg/dL)						N
	<40	40-50	51-60	61-70	71-80	>80	
<40 (LO)	16.7	0.0	0.0	16.7	0.0	66.7	6

Table 9 displays the concurrence between the GM and YSI reference glucose when GM reads 'HI'. For example, when GM reads 'HI' you can expect that YSI glucose values were less than 200 mg/dL 0.0% of the time, between 200 and 300 mg/dL 0.0% of the time, between 301 and 400 mg/dL 0.0% of the time, between 401 and 500 mg/dL 100% of the time, and above 500 mg/dL 0.0% of the time.

Table 9: Concurrence Analysis with HI GM Reading

GM Glucose Level (mg/dL)	YSI (mg/dL)					N
	<200	200-300	301-400	401-500	>500	
>500 (HI)	0.0	0.0	0.0	100.0	0.0	2

Accuracy by Day of Wear

The sensor can be worn for up to 14 days. To show sensor performance over time, the absolute relative difference between the System and reference YSI glucose and capillary blood glucose values (BG) over the 14 day wear is presented in **Table 10** and **Table 11**. The accuracy of GM versus YSI reference and BG reference was assessed by calculating the percentage of System readings that were within 15%, 20%, 30% and 40% for reference values 80 mg/dL and above, and 15 mg/dL, 20 mg/dL, 30 mg/dL and 40 mg/dL for values below 80 mg/dL. The results are presented in **Table 12** for GM vs. YSI reference and in **Table 13** for GM vs. BG reference.

Table 10: Difference Measures by Day (YSI Reference)

	YSI Reference		
Day	**Number of GM-Reference Pairs**	**Median Absolute Relative Difference (%)**	**Mean Absolute Relative Difference (%)**
1	2117	11.4	13.8
2-5	4036	11.0	13.3
6-9	2919	10.2	12.3
10-13	2214	8.4	10.4
14	1037	7.3	9.6

Table 11: Difference Measures by Day (BG Reference*)

	BG Reference		
Day	**Number of GM-Reference Pairs**	**Median Absolute Relative Difference (%)**	**Mean Absolute Relative Difference (%)**
1	1087	11.9	15.0
2-5	4005	11.9	14.6
6-9	3432	11.7	14.5
10-13	2841	9.8	12.5
14	553	8.3	10.6

* Comparison to BG was performed using the FreeStyle Precision blood glucose meter. Different performance may be expected when compared to other models of blood glucose meters.

Table 12: Number and Percent of Results within YSI Reference

Day	Number of GM-Reference Pairs	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±30% / ±30 mg/dL	Within ±40% / ±40 mg/dL	Outside ±40% / ±40 mg/dL
1	2117	64.5	77.7	92.1	97.3	2.7
2-5	4036	68.0	80.9	94.2	98.2	1.8
6-9	2919	71.5	84.3	95.7	99.0	1.0
10-13	2214	80.4	90.4	97.9	99.1	0.9
14	1037	84.7	91.3	98.0	99.3	0.7

Table 13: Number and Percent of Results within BG Reference*

Day	Number of GM-Reference Pairs	Within ±15% / ±15 mg/dL	Within ±20% / ±20 mg/dL	Within ±30% / ±30 mg/dL	Within ±40% / ±40 mg/dL	Outside ±40% / ±40 mg/dL
1	1087	61.8	74.1	91.5	96.9	3.1
2-5	4005	64.4	77.6	92.2	97.7	2.3
6-9	3432	64.4	78.2	92.9	97.4	2.6
10-13	2841	71.0	83.4	95.7	98.8	1.2
14	553	80.7	90.2	96.9	99.6	0.4

* Comparison to BG was performed using the FreeStyle Precision blood glucose meter. Different performance may be expected when compared to other models of blood glucose meters.

System Glucose Availability

The System is designed to generate a GM value every 15 minutes throughout the sensor wear time. Overall, 202 sensors were inserted. 167 sensors produced glucose readings and are included in the analysis. There were 35 sensors that failed at insertion (i.e. no glucose reading generated) and are not included in the analysis. There were 62.5% of primary sensors that worked for 14 days. The mean sensor duration for all primary sensors was determined to be 258 hours, and the median duration of was 327 hours.

Table 14 shows the number of available glucose readings reported by all sensors (by sensor operational hour) that produced at least one GM reading during the clinical study over the 14-day wear period. The percentage of available GM readings is presented in comparison to the number of expected GM readings based on the number of hours of sensor wear. Overall, 96.9% (153,169 GM readings out of expected 158,052) of GM readings were available.

Table 14: GM Availability

Operational Hour	No. Historic GM	Expected No.	%
0 - 24	81	83	97.6
24 - 48	795	813	97.8
48 - 72	1170	1201	97.4
72 - 96	1053	1080	97.5
96 - 120	1187	1230	96.5
120 - 144	2630	2725	96.5
144 - 168	3262	3356	97.2
168 - 192	4478	4617	97.0
192 - 216	5101	5223	97.7
216 - 240	3413	3531	96.7
240 - 264	5611	5759	97.4
264 - 288	7021	7184	97.7
288 - 312	6300	6400	98.4
312 - 336	111067	114850	96.7
Overall	153169	158052	96.9

Precision

Precision of the System was evaluated by comparing the results from two separate sensors worn on the same subject at the same time. Data from two sensors worn at the same time for 72 subjects provided 49,806 pairs of GM measurements. The mean PARD during the study was 8.6% with a coefficient of variation of 6.1%.

Sensor Wear Duration

Sensors may be worn for up to 14 days (≥324 hours). To estimate how long a sensor will work over 14 days, 34 sensors were evaluated to determine how many days of readings each sensor provided. Results show that 85.3% of sensors lasted for the intended 14-day wear duration.

Adverse Events

No device-related serious adverse events occurred during the study. Mild skin irritation, such as erythema, edema, rash, bleeding, itching, bruising, scaling skin, and induration were reported around the insertion site and adhesive area by a moderate frequency of subjects (26 out of 72 or 36%). Pain was mostly reported as none with only one reported instance of mild pain.

Electromagnetic Compatibility

- The System 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 System.
- 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 System.
- The System should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the System should be observed to verify normal operation in the configuration in which it will be used.
- 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.
- Changes or modifications not approved by Abbott could void the user's authority to operate the equipment.

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations / flicker emissions	Not applicable

The System 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.

The System is suitable for use in all establishments, other than domestic 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 System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.

IMMUNITY test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 seconds	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the System requires continued operation during power mains interruptions, it is recommended that the System be powered from an uninterruptible power supply or a battery.

IMMUNITY test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

IMMUNITY test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	6 Vrms 150 kHz to 80 MHz	6 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$

IMMUNITY test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	**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 meters (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 (cellular/cordless) 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 System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System.

[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 System

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

Limited Warranty

We hope that you are happy with your FreeStyle Libre Pro system. Please refer to the Operator's Manual before using your Reader for the first time.

Abbott Diabetes Care ("Abbott") warrants that the FreeStyle Libre Pro reader ("Reader") shall be free from defects in material and workmanship and shall be of satisfactory quality for a period of one (1) year from the original date of purchase provided it is not modified, altered, damaged, misused or used other than in accordance with the applicable labeling, inserts and/or manuals. This Limited Warranty is valid if the Reader is defective in material or workmanship, and it has been used only in accordance with the Operator's Manual. Abbott's sole obligation is to replace the Reader, free of charge, with the same or an alternative reader as determined by Abbott in its sole discretion. Your replacement may be a different model or type. This Limited Warranty covers only the Reader, does not cover disposable accessories, extends only to the original purchaser, and is not assignable or transferable. This warranty does not affect or preclude any other rights which you may have by law.

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LIMITED WARRANTY SERVICES

If you do not agree to the terms and conditions of this Limited Warranty, you may return the FreeStyle Libre Pro reader for a full refund within 30 days of purchase. You must have proof of purchase, i.e., a copy of the dated itemized purchase receipt and the original packaging to obtain this refund. For questions or warranty service, contact Customer Service at 1-855-632-5297.

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