FreeStyle Libre 2

FLASH GLUCOSE MONITORING SYSTEM

Formulary Kit

FreeStyle Libre 2 System

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Abbott

FreeStyle Libre 2
FLASH GLUCOSE MONITORING SYSTEM

June 2020

Dear Health Plan Administrator,

Abbott is pleased to announce that the FreeStyle Libre 2 Flash Glucose Monitoring System has been cleared by the FDA.

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.

This FreeStyle Libre 2 System Formulary Kit contains more information about the following:

- Product
- Clinical highlights
- Pricing
- Prescribing
- Clinical guidelines
- Resources

The FreeStyle Libre 2 system has unsurpassed 14 day accuracy[1] for adults and children (age 4 and older), and offers optional, real-time glucose alarms† with readings every minute. The FreeStyle Libre Family of Personal CGMs is the #1 CGM in the US‡ and Worldwide.§

Best regards,
Glenn Johnson
General Manager, Market Access

* Please refer to www.freestylelibre.us for the Indications and Important Safety Information.

† Notifications will only be received when alarms are turned on and the sensor is within 20 feet of the reading device.

‡ Data based on the number of patients assigned to each manufacturer based on last filled prescription in US Retail Pharmacy and DME.

§ Data based on the number of users worldwide for FreeStyle Libre personal CGM compared to the number of users for other leading personal CGM brands.

Reference: 1. FreeStyle Libre 2 User's Manual.

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Indications and Important Safety Information

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.*

WARNINGS/LIMITATIONS*:
The System must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems. Remove the sensor before MRI, CT scan, X-ray, or diathermy treatment. Do not take high doses of vitamin C (more than 500 mg per day), as this may falsely raise your Sensor readings. Failure to use the System according to the instructions for use may result in missing a severe low blood glucose or high blood glucose event and/or making a treatment decision that may result in injury. If glucose alarms and readings from the System do not match symptoms or expectations, use a fingerstick blood glucose value to make diabetes treatment decisions. Seek medical attention when appropriate and contact Abbott Toll Free (855-632-8658) or visit * www.FreeStyleLibre.us for detailed indications for use and safety information.

* Please refer to www.freestylelibre.us for the indications and important safety information.

FreeStyle Libre 2
FLASH GLUCOSE MONITORING SYSTEM

Table of Contents

FreeStyle Libre 2
FLASH GLUCOSE MONITORING SYSTEM

Product Information

System Components

The FreeStyle Libre 2 system (“system”) has two main parts: a handheld reader and a disposable sensor that patients wear on their bodies. They use the reader to wirelessly scan the sensor and display their glucose readings. The reader only works with FreeStyle Libre 2 sensors and cannot be used with other sensors.

The FreeStyle Libre 2 system is the easiest iCGM to apply[1,*] with no in-person patient training required.

The **FreeStyle Libre 2 reader**

The reader gets glucose readings from a scan of the sensor and can issue glucose alarms. The reader can store approximately 90 days of glucose history and notes entered about activities, such as taking insulin, eating food, or exercising. This information can help patients understand how these activities affect their glucose. The reader also includes a built-in meter for blood glucose testing. To use the built-in meter, patients need the FreeStyle Precision Neo blood glucose test strips, control solution, a lancing device, and lancets. These items are not included in the reader kit and must be obtained separately from their FreeStyle Libre 2 system provider (pharmacy or mail order supplier).

The **FreeStyle Libre 2 sensor**

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, patients prepare and apply the sensor on the back of the 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.

* Based on a comparison to Dexcom G6.

Reference: 1. Data on File. Abbott Diabetes Care.

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Product Information

Alarms

The FreeStyle Libre 2 system provides optional, real-time glucose alarms* with readings every minute. When in range of the reader, the sensor automatically communicates with the reader to give low and high glucose alarms. These alarms are on by default.

Low Glucose Alarm: Notifies when glucose is below set level

High Glucose Alarm: Notifies when glucose is above set level

Signal Loss Alarm: Notifies when sensor is not communicating with reader and that low or high glucose alarms will not be received

Accuracy[1]

The FreeStyle Libre 2 system has unsurpassed 14 day accuracy[1] for adults and children (age 4 and older). Accuracy of the system was measured by comparing paired system glucose measurement (CGM) and Yellow Springs Instrument (YSI) analyzer blood glucose values. The percentage of total system readings that were within 20 mg/dL for YSI blood glucose values <70 mg/dL or 20% of YSI for blood glucose values ≥70 mg/dL is displayed in the table below. The mean absolute relative difference (MARD) gives an indication of the average percent disagreement between the CGM and the reference. For example, in the Adult study, 92.4% of the readings fell within ±20 mg/dL of YSI blood glucose values <70 mg/dL and within ±20% of YSI blood glucose values ≥70 mg/dL. The total number of data pairs considered in the analysis was 18,735. In the Adult study, the MARD was 9.2% for the comparison with YSI reference. In the Pediatric study, the MARD was 9.7% for the comparison with YSI reference.

Overall Accuracy to YSI

Subject group	Number of CGM reference pairs	Number of subjects	Percent within ±20% / ±20 mg/dL	Percent within ±20% / ±20 mg/dL on day 1	Percent within ±20% / ±20 mg/dL in first 12 hours	MARD (%)
Adults	18735	144	92.4	87.5	81.7	9.2
Children (age 6-17)	6546	129	91.6	84.1	80.3	9.7
Children (age 4-5)[a]	341	8	85.9	87.9	90.9	11.8

[a] No YSI measurements were obtained for children ages 4-5; results displayed are from CGM-SMBG matched paired measurements.

* Notifications will only be received when alarms are turned on and the sensor is within 20 feet of the reading device.

Reference: 1. Data on File. Abbott Diabetes Care.

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Clinical Outcomes: Highlights

Growing body of clinical evidence supports the use of the FreeStyle Libre family of personal CGM systems

Randomized Controlled Trials

↓ **38%** reduction in hypoglycemia for people with T1 diabetes[1]

↓ **43%** reduction in hypoglycemia for people with T2 diabetes[2]

↓ **0.85%** HbA1c reduction for people with T2 diabetes in the intervention group[3]

Real World Evidence

↓ **0.6%** average reduction in HbA1c for people with T1 diabetes[4]

Increased scanning frequency associated with increased time in range[5]

↑ **10%** increase in time in range for children with diabetes[6]

Meta-analysis

↓ **0.55%** average reduction in HbA1c for people with T1 or T2 diabetes[7]

↓ **0.9%** average reduction in HbA1c for people with T2 diabetes[8]

References: 1. Bolinder J, et al. *Lancet.* 2016;388(10057):2254-2263. Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 2 system has the same features as FreeStyle Libre 14 day system with optional real-time glucose alarms. Therefore the study data is applicable to both products. **2.** Haak T, et al. *Diabetes Ther.* 2017;8(1):55-73. Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 2 system has the same features as FreeStyle Libre 14 day system with optional real-time glucose alarms. Therefore the study data is applicable to both products. **3.** Yaron M, et al. [published online April 29, 2019]. *Diabetes Care.* 2019;42(7):1178-1184. Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 2 system has the same features as FreeStyle Libre 14 day system with optional real-time glucose alarms. Therefore the study data is applicable to both products. **4.** Tyndall V, et al. [published online June 9, 2019]. *Diabetologia.* 2019;62(8):1349-1356. Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 2 system has the same features as FreeStyle Libre 14 day system with optional real-time glucose alarms. Therefore the study data is applicable to both products. **5.** Dunn TC, et al. [published online December 24, 2017]. *Diabetes Res Clin Pract.* 2018;137:37-46. Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 2 system has the same features as FreeStyle Libre 14 day system with optional real-time glucose alarms. Therefore the study data is applicable to both products. **6.** Campbell FM, et al. [published online August 29, 2018]. *Pediatr Diabetes.* 2018;19(7):1294-1301. Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 2 system has the same features as FreeStyle Libre 14 day system with optional real-time glucose alarms. Therefore the study data is applicable to both products. **7.** Evans M, et al. [published online October 31, 2019]. *Diabetes Ther.* 2020;11:83-95. doi:10.1007/s13300-019-00720-0. Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 2 system has the same features as FreeStyle Libre 14 day system with optional real-time glucose alarms. Therefore the study data is applicable to both products. **8.** Kroeger J, et al. *Diabetes.* 2019;68(suppl 1):99-LB. doi:10.2337/db19-99-LB. Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 2 system has the same features as FreeStyle Libre 14 day system with optional real-time glucose alarms. Therefore the study data is applicable to both products.

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Pricing Information

FreeStyle Libre 2 System

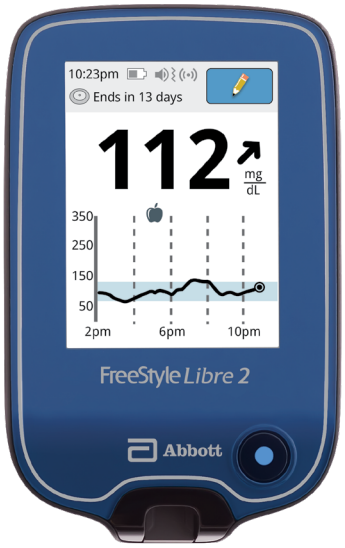
Reader Kit

Sensor Kit

	Reader Kit	Sensor Kit
Package Size	1	1
Unit Price	$70.00	$54.43
NDC	57599-0803-00	57599-0800-00
UPC	357599803001	357599800000

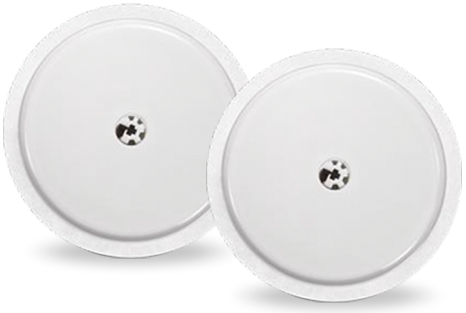
FreeStyle Libre 2
FLASH GLUCOSE MONITORING SYSTEM

Prescribing Information



1 Reader

Required for new prescriptions
(NDC# 57599-0803-00)



2 Sensors

28-day supply, filled monthly
(NDC# 57599-0800-00)

Refills: PRN or 12 fills annually

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FLASH GLUCOSE MONITORING SYSTEM

Clinical Guidelines for the Use of CGM: Highlights

Highlights of clinical guidelines for the use of CGM

Several clinical organizations including the ADA, AACE, and ACE have published guidelines for the use of CGM in the management of diabetes.[1,2]

American Diabetes Association (ADA)

The ADA published diabetes treatment guidelines as part of the 2020 Standards of Medical Care in Diabetes,[1] making the following clinical and access recommendations specific to CGM:

- Continuous glucose monitors, when used properly, together with insulin, are useful for lowering HbA1c and/or reducing hypoglycemia for people with type 1 diabetes and type 2 diabetes[1,*,†]
- CGM can be a tool to help improve glucose control among pediatric patients with type 1 diabetes[1]
- CGM users should have access through third-party payers[1]

American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE)

A 2019 consensus statement[2] by the AACE and ACE on a comprehensive type 2 diabetes mellitus management algorithm describes the role of CGM, making the following clinical recommendations:

- Patients' and clinicians' understanding of glucose trends has been enhanced for people with type 2 diabetes who use CGM[2]
- In helping patients better understand their glucose trends, CGM may also help with adherence[2]
- In providing real-time glucose data, CGM may support prevention of hypoglycemia[2]

Time in Range: Recommendations from 2019 International Consensus[3] and 2020 ADA Standards of Medical Care in Diabetes[1]

- Utility of HbA1c enhanced when complemented by CGM glycemic data[3]
- Time in Range, as a metric of glycemic control,[1] provides more actionable information than HbA1c alone[3]
- The primary goal for effective and safe glucose control is to increase the time in range (TIR) while reducing the time below range (TBR)[3]

* Applicable to people with T1D who are not meeting glucose targets, are hypoglycemic unaware, and/or experience hypoglycemic episodes.

† Applicable to people with T2D who are not meeting glucose targets.

References: 1. American Diabetes Association. *Standards of Medical Care in Diabetes—2020. Diabetes Care.* 2020;43(suppl 1). **2.** Garber AJ, et al. *Endocr Pract.* 2019;25(1):69-100. **3.** Battelino T, et al. [published online June 8, 2019]. *Diabetes Care.* 2019;42(8):1593-1603.

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FLASH GLUCOSE MONITORING SYSTEM

Resources

Sign up to learn more: Payer.FreeStyleLibre.us/FSL2

Website for providers: Provider.MyFreeStyle.com

Website for members: FreeStyleLibre.us

MORE PATIENTS CAN DO IT

WITHOUT FINGERSTICKS*

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* Fingersticks are required if your glucose alarms and readings do not match symptoms or when you see Check Blood Glucose symbol during the first 12 hours.