



FREESTYLE LIBRE 2 SYSTEM

Formulary Kit



Product images are for illustrative purposes only. Not actual patient data.

Medicare and other payor criteria may apply.

The FreeStyle Libre systems apps are only compatible with certain mobile devices and operating systems. Please check the Support section of our website for more information about device compatibility before using the apps. Use of the FreeStyle Libre systems apps may require registration with LibreView.

The FreeStyle Libre 2 app and the FreeStyle Libre 2 reader have similar but not identical features. Fingersticks are required for treatment decisions when you see the Check Blood Glucose symbol and when your glucose alarms and readings from the system do not match symptoms or expectations.

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November 2024

Dear Health Plan Administrator,

The FreeStyle Libre 2 system provides patients with real-time glucose readings every minute with a simple scan¹. The FreeStyle Libre 2 system is part of the FreeStyle Libre portfolio, which is the #1 CGM in the US*, provides accurate, up-to-the minute sensor readings², and features:

- **FreeStyle Libre 2 sensor:** An available iCGM platform that measures glucose accurately every minute¹
- **FreeStyle Libre 2 Plus sensor:** The ease^{†3} of the FreeStyle Libre 2 system, now with 15-day sensor wear
- An **iCGM sensor easy to apply**^{†3,4} with no in-person patient training required⁵

This FreeStyle Libre 2 system Formulary Kit contains the following:

- Product information
- Clinical guidelines
- Clinical highlights
- Digital health tools
- Pricing information
- Prescribing information
- Resources

Please reach out to your Abbott account manager for more information about the FreeStyle Libre 2 system.

Best regards,

Jody Boeddeker

General Manager, Market Access

* Based on retail and DME sales data for patient's last-filled prescription, by manufacturer. † Study was performed with the outside US version of the FreeStyle Libre 14 day system. Data is applicable to FreeStyle Libre 2 system, as feature sets are similar as FreeStyle Libre 14 day system, excluding alarms.

References: **1.** Alva, S. ADCES. Accessed September 12, 2024. https://www.adces.org/docs/default-source/dana-files/adc-23842v3-revised-august-3-2020cd070ee4-83cd-472c-a990-892684a26df3.pdf?sfvrsn=26ee6959_5. **2.** FreeStyle Libre 2 User's Manual. **3.** Haak T, et al. *Diabetes Ther* (2017): <https://doi.org/10.1007/s13300-016-0223-6>. **4.** Campbell, F. *Pediatr Diabetes* (2018): <https://doi.org/10.1111/peci.12735>. **5.** Data on file. Abbott Diabetes Care.

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System Components

The FreeStyle Libre 2 system has two main parts: a compatible smartphone* or handheld reader†, and a disposable sensor that patients wear on their bodies. They use their compatible smartphone or 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 includes an iCGM sensor easy to apply^{‡1,2} with no in-person patient training required³.



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.

FreeStyle Libre 2 Plus sensor

The FreeStyle Libre 2 Plus sensor brings the latest innovative technology to the FreeStyle Libre 2 system, adding the following new features to the FreeStyle Libre 2 sensor:

- Extends the sensor wear up to 15 days
- Has innovative partnerships that allow for a cohesive experience with insulin pumps
- Expands the age indication to 2 years and older
- Is compatible with the current FreeStyle Libre 2 app* and FreeStyle Libre 2 reader†



FreeStyle Libre 2 app*

The app* performs some similar functions as the reader†. Patients can use it to start a sensor, receive glucose alarms[§], get glucose readings from a scan of the sensor, and store glucose history and entered notes. The FreeStyle Libre 2 iOS app is available for download from the App Store. The FreeStyle Libre 2 Android app is available for download from the Google Play Store.



FreeStyle Libre 2 reader†

The reader gets glucose readings from a scan of the sensor and can issue glucose alarms[§]. It is handheld and lightweight, with a backlit color touchscreen. 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).

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* The FreeStyle Libre systems apps are only compatible with certain mobile devices and operating systems. Please check the Support section of our website for more information about device compatibility before using the apps. Use of the FreeStyle Libre systems apps may require registration with LibreView. † The FreeStyle Libre 2 app and the FreeStyle Libre 2 reader have similar but not identical features. Fingersticks are required for treatment decisions when you see the Check Blood Glucose symbol and when your glucose alarms and readings from the system do not match symptoms or expectations. ‡ Study was performed with the outside US version of the FreeStyle Libre 14 day system. Data is applicable to FreeStyle Libre 2 system, as feature sets are similar as FreeStyle Libre 14 day system, excluding alarms. § Notifications will only be received when alarms are turned on and the sensor is within 20 feet unobstructed of the reading device. You must enable the appropriate settings on your smartphone to receive alarms and alerts, see the FreeStyle Libre 2 User's Manual for more information.

References: 1. Haak, T. *Diabetes Ther* (2017): <https://doi.org/10.1007/s13300-016-0223-6> 2. Campbell, F. *Pediatr Diabetes* (2018): <https://doi.org/10.1111/pedi.12735> 3. Data on file. Abbott Diabetes Care.

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Alarms

The FreeStyle Libre 2 system provides real-time glucose alarms* with readings every minute¹. When in range, the sensor automatically communicates to give real-time high and low glucose alarms*. These alarms* are on by default.



Optional low glucose alarm:

Notifies when glucose is BELOW a set level (60-100 mg/dL)



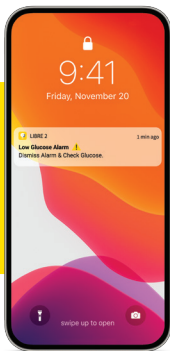
Optional high glucose alarm:

Notifies when glucose is ABOVE a set level (120-400 mg/dL)



Optional signal loss alarm:

Notifies when sensor is NOT communicating with smartphone[†] or reader[‡] and that low or high glucose alarms will not be received



The FreeStyle Libre 2 app[†] also has a mandatory **Urgent Low Glucose Alarm** that lets users know when their glucose value is below 55 mg/dL.

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

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Overall Accuracy to YSI

FreeStyle Libre 2 sensor¹

Subject Group	Number of CGM Reference Pairs	Number of Subjects	Percent within $\pm 20\% / \pm 20$ mg/dL	Percent within $\pm 20\% / \pm 20$ mg/dL on Day 1	Percent within $\pm 20\% / \pm 20$ 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) ^{*1}	341	8	85.9	87.9	90.9	11.8

FreeStyle Libre 2 Plus sensor¹

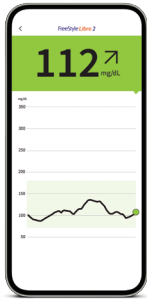
Subject Group	Number of CGM Reference Pairs	Number of Subjects	Percent within $\pm 20\% / \pm 20$ mg/dL	Percent within $\pm 20\% / \pm 20$ mg/dL on Day 1	Percent within $\pm 20\% / \pm 20$ mg/dL in first 12 hours	MARD (%)
Adults	20497	149	93.7	82.9	79.2	8.2
Children (age 6-17)	7025	124	93.5	89.8	90.5	8.2
Children (age 2-5) [†]	135	10	86.7	78.9	88.9	9.7

* No YSI measurements were obtained for children ages 4-5; results displayed are from CGM-SMBG matched paired measurements. † No YSI measurements were obtained for children ages 2-5; results displayed are from CGM-SMBG matched paired measurements obtained during clinic visits from 10 of the 12 subjects; 2 of the 12 subjects did not have CGM-SMBG matched paired measurements obtained from clinic visits.

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

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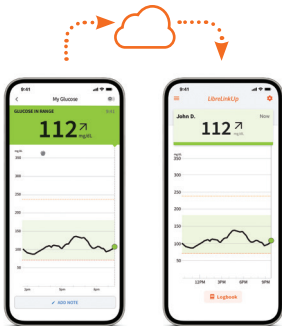
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FreeStyle Libre 2 app* — *for the patient*

The FreeStyle Libre 2 app* is designed to be used by people living with diabetes. The app* enables the user to carry out routine glucose monitoring† using a smartphone* and FreeStyle Libre 2 sensor. The FreeStyle Libre 2 app* is only compatible with certain mobile devices and operating systems*. The user can access glucose data and receive optional, real-time high and low glucose alarms‡ on the FreeStyle Libre 2 app*.

The FreeStyle Libre 2 app is not compatible with FreeStyle Libre 14 day sensors.



LibreLinkUp app§ — *for the caregivers*

LibreLinkUp is designed to be used by family, friends, and other caregivers of patients using the FreeStyle Libre 2 app. This app allows users to follow up to 20 different connections. LibreLinkUp users receive glucose readings on their smartphone whenever their connection scans their FreeStyle Libre 2 sensor and alarms¶||¶.



LibreView desktop application# — *for the healthcare professional and the patient*

LibreView is a secure**, cloud-based data management system. It is HIPAA compliant and allows data to be accessed at any time††. Streamed glucose data are compiled into easy-to-read‡‡ reports, glucose patterns, and trends. LibreView is intended for use by both patients and healthcare professionals to assist people with diabetes.

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§ The LibreLinkUp app is only compatible with certain mobile devices and operating systems. Please check www.librelinkup.com for more information about device compatibility before using the app. Use of the LibreLinkUp app requires registration with LibreView. LibreLinkUp is not intended to be used for dosing decisions. The user should follow instructions on the continuous glucose monitoring system. LibreLinkUp is not intended to replace self-monitoring practices as advised by a physician. || Glucose alarms will transfer to the LibreLinkUp app users when users are connected and alarms are enabled on the FreeStyle Libre 2 app. ¶ The user's device must have internet connectivity for glucose data to automatically upload to LibreView and to transfer to connected LibreLinkUp app users. # 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. ** LibreView is ISO27001/27018/27701 certified and HITRUST CSF Certified. †† The user's device must have internet connectivity for glucose data to automatically upload to LibreView. ‡‡ Study was performed with the outside US version of the FreeStyle Libre 14 day system. Data is applicable to FreeStyle Libre 2 system, as feature sets are similar as FreeStyle Libre 14 day system, excluding alarms.

Reference: 1. Unger, J. *Postgrad Med* (2020): <https://doi.org/10.1080/00325481.2020.1744393>.

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Clinical Guidelines for the Use of CGM: Highlights

Respected clinical organizations, including the ADA and AACE, have published guidelines for the use of continuous glucose monitoring (CGM) in the management of diabetes^{1,2}.

American Diabetes Association (ADA) American Diabetes Association.

2024 ADA Standards of Care Recommendations on CGM Use¹:

The ADA published diabetes treatment guidelines as part of the 2024 Standards of Care in Diabetes, making the following clinical and access recommendations for CGM:

- For all insulin-using patients as well as individuals at high risk for hypoglycemia
- To assess glycemic status by either A1c and/or appropriate CGM metrics at least 2 times a year
- For guiding medical nutrition therapy, physical activity, preventing hypoglycemia, and adjusting medications
- CGM users should have uninterrupted access through third-party payers

American Association of Clinical Endocrinology (AACE) AACE.

2023 AACE Clinical Practice Guidelines Recommendations on CGM Use²:

The AACE published recommendations in 2023 regarding the use of CGM systems in the management of people with diabetes. The following recommendations were highlighted with respect to continuous glucose monitoring:

- For all patients to reach glycemia goals safely
- For newly diagnosed T2DM patients and those at low risk for hypoglycemia
- For the use of CGM metrics, which can be used as a surrogate to HbA1c
- For the education of persons with T2DM (eg, effects on behaviors including diet and exercise)
- For alarms or alerts in persons with hypoglycemia who would benefit from these warnings
- For aiding clinicians in investigating avenues to improve glycemic control with medical therapies

References: 1. ADA. *Diabetes Care* (2024) <https://doi.org/10.2337/dc24-S007> 2. Samson SL, et al. *Endocr Pract* (2023). <https://doi.org/10.1016/j.eprac.2023.02.001>

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Use of the FreeStyle Libre family of personal CGMs is associated with:

Reduced HbA1c across multiple groups of patients* ¹⁻⁹	Increased Time in Range (TIR) ^{*2,3,10,11}	Reduced number of hypoglycemic events ^{**11-13}	Reduced resource utilization ^{**5,9,14}
<p>↓ 0.42%-0.59% HbA1c reduction observed among patients with T1D/T2D in a meta-analysis*¹</p> <p>↓ 0.4-0.5% HbA1c reduction among children and teenagers (4-17 years) with T1D*^{2,3}</p> <p>↓ 0.4% HbA1c reduction among patients with T1D*⁴</p> <p>↓ 0.9-1.6% reduction in HbA1c among people with T2D*⁵⁻⁸</p> <p>↓ 2.4% reduction in HbA1c when used in combination with a GLP-1 RA among patients with T2D*⁹</p>	<p>↑ 1-2.17 hrs/day increased TIR observed among patients with T1D*^{2,3,10}</p> <p>↑ 2.36 hrs/day increased TIR observed among patients with T2D*¹¹</p>	<p>↓ 26% reduction in number of hypoglycemic events among patients with T1D*¹¹</p> <p>↓ 28% reduction in number of hypoglycemic events among patients with T2D on intensive insulin regimens*¹²</p> <p>↓ 44% fewer severe hypoglycemia admissions among patients with T2D*¹³</p>	<p>↓ 83% reduction in number of diabetes-related hospital admissions among patients with T1D or T2D*¹⁴</p> <p>↓ 37% reduction in acute diabetes event rates among patients with T2D on basal insulin*⁵</p> <p>↓ 25% reduction in acute diabetes event rates among patients with T2D on non-insulin therapies*⁵</p> <p>↓ 75% DKA-related hospital admissions among patients with T2D*⁹</p>

* Study was performed with the outside US version of the FreeStyle Libre 14 day system. Data is applicable to FreeStyle Libre 2 system, as feature sets are similar as FreeStyle Libre 14 day system, excluding alarms. † A meta-analysis of 75 real-world observational studies on the impact of flash continuous glucose monitoring on glycemic control as measured by HbA1c. ‡ Acute diabetes events include hospitalizations or outpatient emergency room visits associated with hyper- or hypoglycemic events.

References: 1. Evans, M. *Diabetes Ther* (2022): <https://doi.org/10.1007/s13300-022-01253-9> 2. Campbell, F. *Pediatr Diabetes* (2018): <https://doi.org/10.1111/pedi.12735> 3. Leelarathna L, et al. *N Engl J Med* (2022): <https://doi.org/10.1056/nejmoa2205650> 4. Tyndall, V. *Diabetologia*, no. 62 (2019): <https://doi.org/10.1007/s00125-019-4894-1> 5. Miller M, et al. *Am J Manag Care*. (2021): <https://doi.org/10.37765/ajmc.2021.88780> 6. Wright E, et al. *Diabetes Spectr* (2021): <https://doi.org/10.2337/ds20-0069> 7. Miller R, et al. *Diabetes* (2020): <https://doi.org/10.2337/db20-84-LB> 8. Aronson R, et al. *Diabetes Obes Metab*. (2022): <https://doi.org/10.1111/dom.14949> 9. Wright E, et al. Initiating GLP-1 therapy in combination with FreeStyle Libre provides greater benefit compared to GLP-1 therapy alone. Abstract presented at: ATTD 2024, The International Conference on Advanced Technologies & Treatments for Diabetes, March 6-9, 2024; Florence, Italy, and online. 10. Bolinder, J. *Lancet* (2016): [https://doi.org/10.1016/s0140-6736\(16\)31535-5](https://doi.org/10.1016/s0140-6736(16)31535-5) 11. Wada E, et al. *BMJ Open Diabetes Res Care* (2020): <http://dx.doi.org/10.1136/bmjdr-2019-001115> 12. Haak, T. *Diabetes Ther* (2017): <https://doi.org/10.1007/s13300-016-0223-6> 13. Guerci B, et al. *Diabetes Technol Ther* (2022): <https://doi.org/10.1089/dia.2022.0271> 14. Fokkert, M. *BMJ Open Diabetes Res Care* (2019): <https://doi.org/10.1136/bmjdr-2019-000809>

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FreeStyle Libre 2 system


	FreeStyle Libre 2 Sensor Kit	FreeStyle Libre 2 Plus Sensor Kit	FreeStyle Libre 2 Reader Kit
SKU #	71992-01	78747-01	71953-01
Package Size	1 sensor	1 sensor	1
Unit Price	\$68.07	\$72.93	\$70.00
NRC	57599-0800-00	57599-0835-00	57599-0803-00
UPC	357599800000	357599835002	357599803001
Unit Pkg. Weight	0.214 lb	0.214 lb	0.865 lb
Storage Temperature	39°F to 77°F (4°C to 25°C)	39°F to 77°F (4°C to 25°C)	-4°F to 140°F (-20°C to 60°C)
Storage Humidity	10% to 90%	10% to 90%	10% to 90%
Contains Battery	Yes	Yes	Yes

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Pharmacy

Commercially insured / cash-pay patients

FreeStyle Libre 2 system Rx includes the FreeStyle Libre 2 app*:

- | | | |
|---|-----------|--|
| <ul style="list-style-type: none"> • FreeStyle Libre 2 sensor <ul style="list-style-type: none"> – Quantity: 2 sensors/month
NRC # 57599-0800-00 – Sensor refills: PRN or 12 refills annually | <p>OR</p> | <ul style="list-style-type: none"> • FreeStyle Libre 2 Plus sensor <ul style="list-style-type: none"> – Quantity: 2 sensors/month
NRC # 57599-0835-00 – Sensor refills: PRN or 12 refills annually |
|---|-----------|--|

Durable Medical Equipment (DME)

Medicare-eligible patients

1. **Determine if patient’s coverage is Medicare Fee-for-Service or Medicare Advantage**
 - Medicare Fee-for-Service: Refer to CMS Continuous Glucose Monitors coverage criteria and documentation requirements to confirm coverage^{†‡}
 - Medicare Advantage: Contact the patient’s insurer for eligibility criteria
2. FreeStyle Libre DME Supplier Grid provides options to select a DME[§]: <https://www.FreeStyleprovider.abbott/us-en/dme.html>
3. Medicare Detailed Written Order form to be completed with the patient’s information^{†||}
 - Medicare Detailed Written Order form can be found at: <http://www.FreeStylefoundations.abbott>
4. Patient to receive a call from the DME

How to get the FreeStyle Libre 2 app*

Once your member receives their prescription for the FreeStyle Libre 2 system, they can download the app to their compatible smartphone at no cost.



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* The FreeStyle Libre systems apps are only compatible with certain mobile devices and operating systems. Please check the Support section of our website for more information about device compatibility before using the apps. Use of the FreeStyle Libre systems apps may require registration with LibreView. † See Local Coverage Determination: Glucose Monitors (L33822), July 2021. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822>. ‡ Patients must meet Medicare eligibility coverage criteria. § DMEs are subject to change without notice. || See Local Coverage Article: Glucose Monitors (A52564). <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52464>

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- Support for Providers
- How to Prescribe
- Practice Resources

Website for members: FreeStyle.Abbott

- Support for Members
- Patient Stories
- Getting Started and MyFreeStyle Program



FREESTYLE LIBRE 2 SYSTEM
Important Safety
Information

Failure to use FreeStyle Libre 2 system as instructed in labeling may result in missing a severe low or high glucose event and/or making a treatment decision, resulting in injury. If glucose alarms and readings do not match symptoms or expectations, use a fingerstick value from a blood glucose meter for treatment decisions. Seek medical attention when appropriate or contact Abbott at 855-632-8658 or <https://www.FreeStyleprovider.abbott/us-en/safety-information.html> for safety info.

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FreeStyle Libre 2



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