



FreeStyle
Libre 2

Formulary Kit

FreeStyle Libre 2 system



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The FreeStyle Libre 2 app is only compatible with certain mobile devices and operating systems. Please check our website for more information about device compatibility before using the app. Use of the FreeStyle Libre 2 app requires 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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FreeStyle Libre 2

September 2023

The FreeStyle Libre 2 system is a continuous glucose monitoring (CGM) device with real-time alarms* indicated for use in people living with diabetes ages 4 and older. The FreeStyle Libre 2 system is part of the FreeStyle Libre portfolio, which is the #1 CGM in the US† and worldwide‡1, and features:

- Unsurpassed 14-day accuracy² for adults and children with diabetes (ages 4 and older)
- Real-time alarms* every single minute²
- An easy iCGM to apply^{§3,4} with no in-person patient training required¹

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

* 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.

† 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 family of personal CGMs compared to the number of users for other leading personal CGM brands and based on CGM sales dollars compared to other leading personal CGM brands.

§ Data from this study was collected with the outside US version of FreeStyle Libre 14 day system. FreeStyle Libre 2 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.

References: **1.** Data on file. Abbott Diabetes Care. **2.** FreeStyle Libre 2 User's Manual. **3.** Haak, T. *Diabetes Ther* (2017); <https://doi.org/10.1007/s13300-016-0223-6>
4. Campbell, F. *Pediatr Diabetes* (2018); <https://doi.org/10.1111/ pedi.12735>



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FreeStyle Libre 2

Product Information

System Components

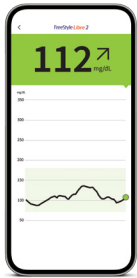
The FreeStyle Libre 2 system has two main parts: a compatible smartphone* or handheld reader†, and a disposable sensor that patients wear on their bodies. They use their compatible smartphone or reader to wirelessly scan the sensor and display their glucose readings. The reader only works with FreeStyle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

The FreeStyle Libre 2 system is an easy, integrated CGM to apply‡1,2 with no in-person patient training required§.



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 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.

OR



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 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.

‡ Data from this study was collected with the outside US version of FreeStyle Libre 14 day system. FreeStyle Libre 2 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.

§ 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/peidi.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.

		
<p>Optional, low glucose alarm: Notifies when glucose is BELOW a set level (60-100 mg/dL)</p>	<p>Optional, high glucose alarm: Notifies when glucose is ABOVE a set level (120-400 mg/dL)</p>	<p>Optional, signal loss alarm: Notifies when sensor is not communicating with reader and that low or high glucose alarms will not be received</p>

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.

Accuracy

The FreeStyle Libre 2 system has unsurpassed 14-day accuracy¹ for adults and children (ages 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.

	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 (%)
Overall Accuracy to YSI	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) [‡]	341	8	85.9	87.9	90.9	11.8

* 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.

† The FreeStyle Libre 2 app is only compatible with certain mobile devices and operating systems. Please check our website for more information about device compatibility before using the app. Use of the FreeStyle Libre 2 app requires registration with LibreView.

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

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

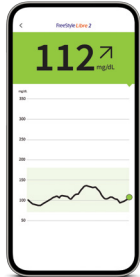
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FreeStyle Libre 2

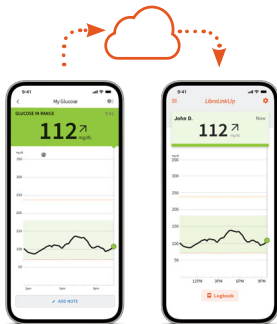
Digital Health Tools



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^{††}. Uploaded 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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† 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.

‡ 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.

§ 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.

‡‡ 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 days system with optional real-time glucose alarms. Therefore, the study data is applicable to both products.

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

Several clinical organizations, including the ADA and AACE, have published guidelines for the use of CGM in the management of diabetes¹⁻³.

American Diabetes Association (ADA) American Diabetes Association.

The ADA published diabetes treatment guidelines as part of the 2023 Standards of Care in Diabetes, making the following clinical and access recommendations for CGM¹:

- CGM is recommended for all insulin-using patients, choice of the device should be made on the individual's circumstances, preferences, and needs
- CGM can be a useful tool 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.

The AACE published recommendations in 2022² and 2023³ regarding the use of CGM systems in the management of people with diabetes. The following recommendations were highlighted with respect to continuous glucose monitoring^{2,3}:

- Lifestyle intervention and ongoing glucose monitoring with CGM preferred²
- CGM is recommended for all insulin-using patients and those at risk for hypoglycemia²
- CGM is highly recommended for all patients to reach glycemic goals safely³
- CGM metrics can be used as a surrogate to HbA1c³
- isCGM could be helpful to newly diagnosed T2D patients and those at low risk for hypoglycemia³

CGM Metrics: Recommendations from ADA and AACE American Diabetes Association. AACE.

- Two metrics, %TIR (Time in Range) and %TBR (Time Below Range), should be used as a starting point for the assessment of quality of glycemic control and as the basis for therapy adjustment, with emphasis on reducing %TBR when the percentages of CGM values falling below 54 mg/dL or 70 mg/dL are close to or exceed targets²
- Due to the limitations of HbA1c, clinicians should exercise judgement when using HbA1c as the sole basis for assessing glycemic control; recommend the inclusion of CGM metrics such as Glucose Variability (GV) and Time in Range (TIR)¹



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Clinical Outcomes: Highlights

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

Reduced HbA1c across multiple groups of patients ^{*1-7}	Increased Time in Range (TIR) ^{*2,3,8,9}	Reduced number of hypoglycemic events ^{*8,10}	Reduced resource utilization ^{*11-13}
<p>↓ 0.42%-0.59% HbA1c reduction observed among patients with T1D/T2D in a meta-analysis^{*11}</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>↓ 0.52%-1.6% reduction in HbA1c among people with T2D^{*5-7}</p>	<p>↑ 1-2.17 hrs/day increased TIR observed among patients with T1D^{*2,3,8}</p> <p>↑ 2.36 hrs/day increased TIR observed among patients with T2D^{*9}</p>	<p>↓ 26% reduction in number of hypoglycemic events among patients with T1D^{*8}</p> <p>↓ 28% reduction in number of hypoglycemic events among patients with T2D on intensive insulin regimens^{*10}</p>	<p>↓ 83% reduction in number of diabetes-related hospital admissions among patients with T1D or T2D^{*11}</p> <p>↓ 61% reduction in acute diabetes events among patients with T2D on intensive insulin regimens^{*12}</p> <p>↓ 32% reduction in all-cause hospitalization rates among patients with T2D on intensive insulin regimens^{*12}</p> <p>↓ 37% reduction in acute diabetes event rates among patients with T2D on basal insulin^{*13}</p> <p>↓ 25% reduction in acute diabetes event rates among patients with T2D on non-insulin therapies^{*13}</p>

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† 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/peidi.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. Kroger, J. *Diabetes Ther* (2020); <https://doi.org/10.1007/s13300-019-00741-9> 6. Wright, E. *Diabetes Spectr* (2021); <https://doi.org/10.2337/ds20-0069> 7. Eeg-Olofsson K. *Diabetes* (2020); <https://doi.org/10.2337/db20-74-LB> 8. Bolinder, J. *The Lancet* (2016); [https://doi.org/10.1016/s0140-6736\(16\)31535-5](https://doi.org/10.1016/s0140-6736(16)31535-5) 9. Wada E, et al. *BMJ Open Diabetes Res Care* (2020); <http://dx.doi.org/10.1136/bmjdc-2019-001115> 10. Haak, T. *Diabetes Ther* (2017); <https://doi.org/10.1007/s13300-016-0223-6> 11. Fokkert, M. *BMJ Open Diabetes Res Care* (2019); <https://doi.org/10.1136/bmjdc-2019-000809> 12. Bergenstal, R. *J Endocr Soc* (2021); <https://doi.org/10.1210/endo/bvab013> 13. Miller E, et al. *AJMC* (2021); <https://doi.org/10.37765/ajmc.2021.88780>

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FreeStyle Libre 2 system



	Reader kit	Sensor kit
SKU #	71953-01	71992-01
Package Size	1	1
Unit Price	\$70.00	\$64.22
NRC	57599-0803-00	57599-0800-00
UPC	357599803001	357599800000
Unit pkg. weight	0.865 lb	0.214 lb
Storage temperature	-4°F to 140°F (-20°C to 60°C)	39°F to 77°F (4°C to 25°C)
Storage humidity	10% to 90%	10% to 90%
Contains battery	Yes	Yes



1 Reader

Per year
(NRC# 57599-0803-00)

No refills



2 Sensors

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

Refills: PRN or 12 fills annually

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 at no cost to their compatible smartphone



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Resources

Sign up to learn more: Payer.FreeStyle.Abbott

- Support for Payers
- Latest Clinical Evidence
- Connect with an Account Manager

Website for providers: FreeStyleProvider.Abbott

- Support for Providers
- How to Prescribe
- Practice Resources

Website for members: FreeStyle.Abbott

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



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FreeStyle Libre 2 system: 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.FreeStyle.abbott/us-en/safety-information.html> for safety info.

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