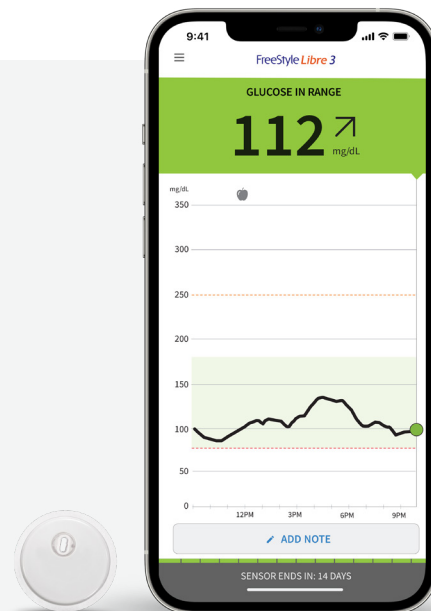




Formulary Kit

FreeStyle Libre 3 system



life. to the fullest.®

Abbott

The FreeStyle Libre 3 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 3 app requires registration with LibreView.

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

The circular shape of the sensor housing, FreeStyle, Libre, and related brand marks are marks of Abbott. Other trademarks are the property of their respective owners.

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February 2023

Dear Health Plan Administrator,

We are pleased to present Abbott's next-generation system, the FreeStyle Libre 3 system.

The FreeStyle Libre 3 system is a real-time continuous glucose monitoring (CGM) device with real-time alarms* indicated for use in people living with diabetes ages 4 and older.

The FreeStyle Libre 3 system provides the same real-time glucose alarms*, but also evolves the portfolio with new features, such as:

- **Real-time** glucose readings **every minute** to your members' smartphones[†]
- **Unsurpassed 14-day** accuracy¹ with a 7.9% overall MARD¹ (Adults and Pediatrics)
- **Easy to use**^{§2}, one-piece sensor application, **requiring no in-person training**³
- **The world's smallest, thinnest[‡] and most discreet³** sensor

This FreeStyle Libre 3 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 3 system.

Best regards,

Jody Boeddeker

General Manager, Market Access

The FreeStyle Libre 3 system is indicated for use in people with diabetes age 4 and older.

* Notifications will only be received when alarms are turned on and the sensor is within 33 feet unobstructed of the reading device. You must enable the appropriate settings on your smartphone to receive alarms and alerts, see the FreeStyle Libre 3 User's Manual for more information.

† The FreeStyle Libre 3 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 3 app requires registration with LibreView.

‡ Among patient-applied sensors.

§ Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 3 has the same features as FreeStyle Libre 14 day system with real-time glucose alarms. Therefore the study data is applicable to both products.

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

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Product Information

System Components

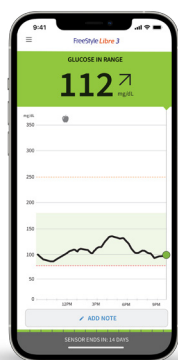
The FreeStyle Libre 3 system helps to build a complete glycemic picture that enables patients, caregivers, and healthcare providers to make informed disease management and treatment decisions.

The FreeStyle Libre 3 sensor is easy to apply¹, using a 1-piece applicator, and easy to use^{*2}, requiring no in-person training¹.



FreeStyle Libre 3 sensor

The FreeStyle Libre 3 sensor is the smallest CGM sensor on the market, designed to be discreet¹ and provide patients with greater flexibility. The sensor provides glucose readings streamed directly to your members' smartphone[†]. The sensor has 14-day wear and data storage, and simplified sensor application in the position of attachment. The sensor stores retrospective glucose data over the full 14-day wear period.



FreeStyle Libre 3 app[†]

The FreeStyle Libre 3 app is designed to be used by people living with diabetes. The app enables the user to carry out routine glucose monitoring using a compatible smartphone and the FreeStyle Libre 3 sensor. The FreeStyle Libre 3 app is designed to offer 3 optional alarms[‡] (low glucose, high glucose, and signal loss) and 1 mandatory urgent low alarm (set at 55 mg/dL).



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

* Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 3 has the same features as FreeStyle Libre 14 day system with real-time glucose alarms. Therefore the study data is applicable to both products.

† The FreeStyle Libre 3 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 3 app requires registration with LibreView.

‡ Notifications will only be received when alarms are turned on and the sensor is within 33 feet unobstructed of the reading device. You must enable the appropriate settings on your smartphone to receive alarms and alerts, see the FreeStyle Libre 3 User's Manual for more information.

References: 1. Data on file, Abbott Diabetes Care. 2. Haak, T. *Diabetes Ther* (2017); <https://doi.org/10.1007/s13300-016-0223-6>

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Product Information

Alarms*

The FreeStyle Libre 3 system provides real-time glucose alarms* with readings streaming every minute¹. The system is designed to offer 3 optional alarms (low glucose, high glucose, and signal loss) and 1 mandatory urgent low alarm (set at 55 mg/dL).

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 and that low or high glucose alarms will not be received

The FreeStyle Libre 3 app[†] has a mandatory Urgent Low Glucose Alarm that lets users know when their glucose value is below 55mg/dL.

Accuracy¹

FreeStyle Libre 3 system accuracy to YSI (n=95)

Patient population	Number of subjects	Total number of paired CGM-Reference	Percent within 20/20% Reference	MARD (%)
Overall	95	6836	93.2	7.9
≥ 18 years	56	4768	94.7	7.6
6-17 years	39	2068	89.7	8.7
4-5 years [‡]	5	72	88.9	10.1

* Notifications will only be received when alarms are turned on and the sensor is within 33 feet unobstructed of the reading device. You must enable the appropriate settings on your smartphone to receive alarms and alerts, see the FreeStyle Libre 3 User's Manual for more information.

[†] The FreeStyle Libre 3 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 3 app requires registration with LibreView.

[‡] Using BGM reference.

Reference: 1. FreeStyle Libre 3 User's Manual.

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Product Comparison

FreeStyle Libre 2 system¹



FreeStyle Libre 3 system²



Glucose data transfer to reader/smartphone

Real-time glucose readings and real-time alarms*

Real-time glucose readings and real-time alarms†

Glucose viewing

Scan

Stream (no scan)

Sensor wear

14-day

14-day

Configuration

Sensor with reader or app‡



Sensor with app§



Applicator

2-piece

1-piece

Age

4 and above

4 and above

Sensor size

1.18" x 0.2"



0.83" x 0.11"



At this time, FreeStyle Libre 3 is not currently eligible for Medicare reimbursement, and Medicaid eligibility may vary by state.

Medicare coverage is available for the FreeStyle Libre 2 system if the FreeStyle Libre 2 reader is used to review glucose data on some days every month. Medicare and other third party payor criteria apply.

Abbott provides this information as a courtesy, it is subject to change and interpretation. The customer is ultimately responsible for determining the appropriate codes, coverage, and payment policies for individual patients. Abbott does not guarantee third party coverage or payment for our products or reimburse customers for claims that are denied by third party payors.

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

* 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.

† Notifications will only be received when alarms are turned on and the sensor is within 33 feet unobstructed of the reading device. You must enable the appropriate settings on your smartphone to receive alarms and alerts, see the FreeStyle Libre 3 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.

§ The FreeStyle Libre 3 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 3 app requires registration with LibreView.

References: 1. FreeStyle Libre 2 User's Manual. 2. FreeStyle Libre 3 User's Manual.

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Digital Health Tools

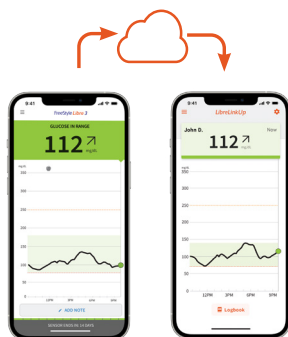


FreeStyle Libre 3 app* — for the patient

The FreeStyle Libre 3 app provides real-time glucose readings streamed every minute directly to your member's smartphone* so they can act faster and make timely diabetes treatment decisions.

With helpful reports, easy-to-read charts, and the ability to privately share user's glucose readings with up to 20 individuals from their care team, the FreeStyle Libre 3 app* helps users manage their diabetes daily.

The FreeStyle Libre 3 app is not compatible with the FreeStyle Libre 2 system.



LibreLinkUp app† — for the caregivers

The LibreLinkUp app is designed to be used by family, friends, and other caregivers of patients using the FreeStyle Libre 3 app. The LibreLinkUp app allows users to follow up to 20 different connections. LibreLinkUp users receive real-time glucose information (including a 12-hour graph) and can customize their own glucose 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 is compiled into easy-to-read^{#1} reports, glucose patterns, and trends. LibreView is intended for use by both patients and healthcare professionals to assist people living with diabetes.

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

* The FreeStyle Libre 3 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 3 app requires registration with LibreView.

† The LibreLinkUp app is only compatible with certain mobile devices and operating systems. Please check <http://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.

‡ 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.

Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 3 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.

Reference: 1. Unger, J. *Postgraduate Medicine* (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)

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] should be offered for diabetes management in **adults with diabetes on multiple daily injections or continuous subcutaneous insulin infusion** who are capable of using devices safely (either by themselves or with a caregiver)
- [CGM] should be offered for diabetes management in **youth with type 1 [or type 2] diabetes on multiple daily injections or continuous subcutaneous insulin infusion** who are capable of using the device safely (either by themselves or with a caregiver)
- [CGM] should be offered for diabetes management in **adults with diabetes on basal insulin** who are capable of using devices safely (either by themselves or with a caregiver)
- The type(s) and **selection of devices should be individualized** based on a person's specific needs, preferences, skill level
- People with diabetes should have **uninterrupted access** to their supplies to minimize gaps in continuous glucose monitoring

American Association of Clinical Endocrinology (AACE)

The AACE published recommendations in 2022² regarding the use of CGMs in the management of people with diabetes. The following recommendations were highlighted with respect to continuous glucose monitoring²:

- Real-time continuous glucose monitoring (rtCGM) or intermittently scanned continuous glucose monitoring (isCGM) is recommended for all persons with T1D, regardless of insulin delivery system, to improve A1C levels and to reduce the risk for hypoglycemia and DKA
- rtCGM or isCGM is recommended for persons with T2D who are treated with insulin therapy, or who have high risk for hypoglycemia and/or with hypoglycemia unawareness
- Persons with T2D and their health care professionals should use patient-centered shared decision-making to agree on therapy targets and treatments as well as a regimen for glucose monitoring (ie, BGM, structured BGM, or CGM)
- Glycemic targets for those using CGM should include achievement of CGM targets such as time in range (TIR), percentage in low and very low range, time above range, and glycemic variability

CGM Metrics: Recommendations from ADA and 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
- Time in Range is associated with the risk of microvascular complications and can be used for assessment of glycemic control. Additionally, time below range and time above range are useful parameters for the evaluation of the treatment regimen³

References: 1. ADA. Standards of Care in Diabetes—2023. *Diabetes Care* (2023) <https://doi.org/10.2337/dc23-S007> 2. AACE Clinical Practice Guidelines, Volume 28, Issue 10, P923-1049, (2022): <https://doi.org/10.1016/j.eprac.2022.08.002> 3. ADA. Standards of Care in Diabetes—2023. *Diabetes Care* (2023) <https://doi.org/10.2337/dc23-S006>

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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^{*†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>↓ 0.52%-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>

* Data from this study was collected with the outside US version of the 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.

† A meta-analysis of RCTs and single arm studies (in addition to 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. 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/endso/bvab013> 13. Miller E, et al. *AJMC* (2021): <https://doi.org/10.37765/ajmc.2021.88780>

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Pricing Information

FreeStyle Libre 3 system



FreeStyle Libre 3 Sensor Kit

SKU #	72081-01
Package Size	1 sensor
Unit Price	\$64.22
NDC	57599-0818-00
UPC	3-57599-81800-5
Unit Pkg. Weight	0.13 lb
Storage Temperature	36°F to 82°F (3°C to 28°C)
Storage Humidity	10% to 90%
Contains Battery	Yes



Prescribing Information

FreeStyle Libre 3 system



How to get the FreeStyle Libre 3 app*

Once your member receives their prescription for the FreeStyle Libre 3 system, they can download the app at no cost to their compatible smartphone.



* The FreeStyle Libre 3 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 3 app requires registration with LibreView.



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

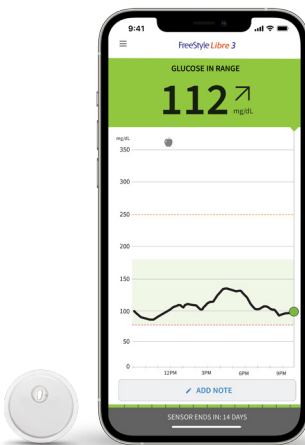


Important Safety Information

FreeStyle Libre 14 day system: Failure to use FreeStyle Libre 14 day 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 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.

FreeStyle Libre 2 and FreeStyle Libre 3 systems: Failure to use FreeStyle Libre 2 or FreeStyle Libre 3 systems as instructed in labeling may result in missing a severe low or high glucose event 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.

The circular shape of the sensor housing, FreeStyle, Libre, and related brand marks are marks of Abbott. Other trademarks are the property of their respective owners.




FreeStyle
Libre 3


life. to the fullest.®
Abbott

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