FreeStyle Libre 3

# Formulary Kit

## FreeStyle Libre 3 system

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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.

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FreeStyle Libre 3

May 2022

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** accuracy[1] with a 7.9% overall MARD[1] (Adults and Pediatrics)
- **Easy to use**[§2], one-piece sensor application, **requiring no in-person training**[3]
- **The world's smallest, thinnest**[‡] **and most discreet**[3] 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 Therapy* (2017): https://doi.org/10.1007/s13300-016-0223-6 **3.** Data on file, Abbott Diabetes Care.

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FreeStyle Libre 3

# 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 apply[1], using a 1-piece applicator and easy to use*[2], requiring no in-person training[1].

### FreeStyle Libre 3 sensor

The FreeStyle Libre 3 sensor is the smallest CGM sensor on the market, designed to be discreet[1] 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).

Download on the App Store

GET IT ON Google Play

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* 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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FreeStyle Libre 3

# Product Information

## Alarms*

The FreeStyle Libre 3 system provides real-time glucose alarms* with readings streaming every minute[1]. 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 smart phone 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.**

## Accuracy[1]

**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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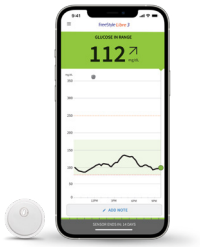
FreeStyle Libre 3

# Product Comparison

| | FreeStyle Libre 2 system[1] | FreeStyle Libre 3 system[2] |
|---|---|---|
| | |  |
| **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‡ Download on the App Store GET IT ON Google Play | Sensor with app§ Download on the App Store GET IT ON Google Play |
| **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.

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* 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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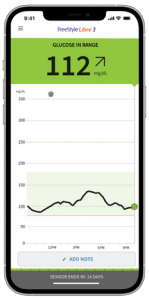
FreeStyle Libre 3

# Digital Health Tools

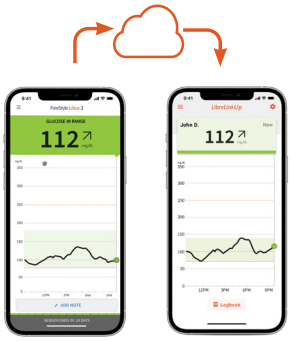


## FreeStyle Libre 3 app* — *for the patient*

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.

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* 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 device 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 diabetes[1-3].

## American Diabetes Association (ADA)

The ADA published diabetes treatment guidelines as part of the 2022 Standards of Medical Care in Diabetes, making the following clinical and access recommendations for CGM:

- [CGM] should be offered for diabetes management in adults and youth with type 1 (or type 2) diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using devices safely (either by themselves or with a caregiver)[1]
- [CGM] can be used for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely (either by themselves or with a caregiver)[1]
- The type(s) and selection of devices should be individualized based on a person's specific needs, desires, skill level, and availability of devices[1]
- People who have been using continuous glucose monitoring, continuous subcutaneous insulin infusion, and/or automated insulin delivery for diabetes management should have continued access across third-party payers[1]

## American Association of Clinical Endocrinology (AACE)

The AACE published recommendations in 2021[2] regarding the use of CGMs in the management of people with diabetes. The following recommendations were highlighted with respect to continuous glucose monitoring:

- CGMs are strongly recommended for all persons with diabetes treated with intensive insulin therapy, defined as 3 or more injections of insulin per day or the use of an insulin pump[2]
- CGMs are recommended for all individuals with problematic hypoglycemia (frequent/severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness[2])

## 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 targets[2]
- Time in range is associated with the risk of microvascular complications and can be used for assessment of glycemic control. Additionally, time below target and time above target are useful parameters for the evaluation of the treatment regimen[3]

**References: 1.** ADA. Standards of Medical Care in Diabetes – 2022. *Diabetes Care* (2022): https://doi.org/10.2337/dc22-S007 **2.** Grunberger G, et al. *Endocrine Practice* (2021): https://doi.org/10.1016/j.eprac.2021.04.008 **3.** ADA. Standards of Medical Care in Diabetes – 2022. *Diabetes Care* (2022): https://doi.org/10.2337/dc22-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*[1-6]

**↓ 0.42%-0.59%**
HbA1c reduction observed among patients with T1D/T2D in a meta-analysis*†[1]

**↓ 0.4%**
HbA1c reduction among children and teenagers (4-17 years) with T1D*[2]

**↓ 0.4%**
HbA1c reduction among patients with T1D*[3]

**↓ 0.52%-1.6%**
reduction in HbA1c among people with T2D*[4-6]

### Increased Time in Range (TIR)*[2,7,8]

**1hr/day**
increased TIR observed among patients with T1D*[2,7]

**2.36 hrs/day**
increased TIR observed among patients with T2D*[8]

### Reduced number of hypoglycemic events*[7,9]

**↓ 26%**
reduction in number of hypoglycemic events among patients with T1D*[7]

**↓ 28%**
reduction in number of hypoglycemic events among patients with T2D on intensive insulin regimens*[9]

### Reduced resource utilization*[10-12]

**↓ 85%**
reduction in diabetes-related hospital admission rates among patients with T1D*[10]

**↓ 61%**
reduction in acute diabetes events among patients with T2D on intensive insulin regimens*‡[11]

**↓ 32%**
reduction in all-cause hospitalization rates among patients with T2D on intensive insulin regimens*‡[11]

**↓ 37%**
reduction in acute diabetes event rates among patients with T2D on basal insulin*[12]

**↓ 25%**
reduction in acute diabetes event rates among patients with T2D on non-insulin therapies*[12]

* 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 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 Therapy* (2022): https://doi.org/10.1007/s13300-022-01253-9 **2.** Campbell, F. *Pediatr Diabetes* (2018): https://doi.org/10.1111/pedi.12735 **3.** Tyndall, V. *Diabetologia*, no. 62 (2019): https://doi.org/10.1007/s00125-019-4894-1 **4.** Kroger, J. *Diabetes Ther* (2020): https://doi.org/10.1007/s13300-019-00741-9 **5.** Wright, E. *Diabetes Spectr* (2021): https://doi.org/10.2337/ds20-0069 **6.** Eeg-Olofsson K, et al. *Diabetes* (2020): https://doi.org/10.2337/db20-74-LB **7.** Bolinder, J. *The Lancet* (2016): https://doi.org/10.1016/s0140-6736(16)31535-5 **8.** Wada E, et al. *BMJ Open Diabetes Res Care* (2020): https://doi.org/10.1136/bmjdrc-2019-00115 **9.** Haak, T. *Diabetes Ther* (2017): https://doi.org/10.1007/s13300-016-0223-6 **10.** Fokkert, M. *BMJ Open Diabetes Res Care* (2019): https://doi.org/10.1136/bmjdrc-2019-000809 **11.** Bergenstal, R. *J Endocr Soc* (2021): https://doi.org/10.1210/jendso/bvab013 **12**. 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 | $61.16 |
| 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 |

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FreeStyle Libre 3

# 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.**

Download on the App Store

GET IT ON Google Play

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FreeStyle Libre 3

# Resources

**Sign up to learn more:** Payer.FreeStyle.Abbott

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

**Website for providers:** FreeStyleProvider.com

- 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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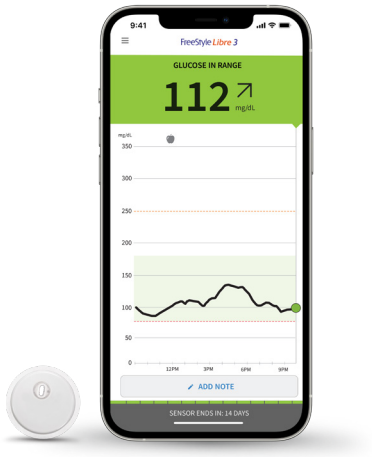
FreeStyle Libre 3

# 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.

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