Abbott's FreeStyle Libre® 3 Receives U.S. FDA Clearance - Features World's Smallest, Thinnest And Most Accurate 14-Day Glucose Sensor

- The FreeStyle Libre 3 system is the most accurate 14-day continuous glucose monitor[1], with readings sent directly to a smartphone every minute.[2]
- Designed for access and affordability, the FreeStyle Libre 3 system will be available at the same price as previous versions, which is one-third the cost of other competing continuous glucose monitoring systems available today.[3,4]

ABBOTT PARK, Ill., May 31, 2022 /PRNewswire/ -- Abbott (NYSE: ABT) today announced the U.S. Food and Drug Administration (FDA) cleared its next-generation FreeStyle Libre 3 system for use by people four years and older[6] living with diabetes.

"The FreeStyle Libre 3 system is a direct result of listening to our customers – and giving them the innovation and sensing technology they've been looking for," said Jared Watkin, senior vice president of Abbott's diabetes care business. "It's a game changer for the millions of people living with diabetes. They'll be able to manage their health minute-by-minute with the world's smallest and thinnest sensor and most accurate 14-day continuous glucose monitoring system."

FreeStyle Libre 3 System Features:

- **Greatest accuracy** – with a 7.9% overall mean absolute relative difference (MARD), the FreeStyle Libre 3 system is the most accurate 14-day continuous glucose monitor (CGM) with readings sent directly to a smartphone every minute.[6] It's the first CGM to demonstrate a sub-8% MARD[1,6] – which is the standard way to measure continuous glucose accuracy – the lower percentage, the better.
- **Smallest and thinnest** – at the size of two stacked U.S. pennies (worn inconspicuously on the back of one's upper arm), it's the smallest and thinnest[4,7] CGM sensor in the world.
- **Even easier to use** – with a one-piece applicator the sensor is uncomplicated to apply.[4]
- **Strongest Bluetooth® integration** with a range of up to 33 feet – 50% further range than other CGMs.[4,8]

Priced for Access and Affordability

Abbott will price the FreeStyle Libre 3 system the same as previous versions[9] with the goal of enabling the greatest number of people living with diabetes to benefit from the next-generation technology.

"We continue to disrupt the notion that CGMs have to sacrifice quality or accuracy for affordability," said Watkin. "Access to breakthrough diabetes technologies should not be out of reach for the people who can benefit most from them. Innovation for access and affordability is a core pillar in Abbott's business and sustainability strategy."

There is a vast and growing need for new innovations in diabetes care. There are now more than 133 million Americans living with diabetes or prediabetes (nearly half of the U.S. population), according to the American Diabetes Association.[10] The organization also notes that diabetes is the most common underlying chronic condition in the U.S. and 1.4 million Americans aged 18 years or older are newly diagnosed with diabetes each year, which equates to one every 23 seconds.[10]

"I have seen real-world evidence that diabetes technologies like CGMs have helped my patients safely achieve improved glycemic control," said Dr. Eugene E. Wright, Jr., consulting associate at Duke University's department of medicine. "I applaud Abbott for making their CGM system the most affordable and addressing disparities in care so patients living with diabetes can avoid complications and optimize their quality of life."

Digital Health Tools

The FreeStyle Libre 3 system was cleared for use with the FreeStyle Libre 3 iOS and Android mobile apps, which enable users to view their glucose levels in real time, track their glucose history and trends, and set up optional alarms plus notifications to help them be alerted of serious medical events like hypoglycemia.[11]

The mobile app integrates with the FreeStyle Libre digital ecosystem, including LibreView and LibreLinkUp,[12,13,14] enabling caregivers and healthcare professionals to remotely monitor loved ones and patients as needed.

Availability

The FreeStyle Libre 3 sensor will be available at participating pharmacies later this year.[15]

Recognized Health Tech Innovator

Over the last year, the FreeStyle Libre 3 system has been recognized multiple times[16] as a top health tech innovation by:

- Consumer Technology Association's 2022 Consumer Electronics Show (CES) Best Health & Wellness Innovation
- The Edison 2022 Gold Award for Science & Medical, Technology & Tools
- Business Intelligence Group's 2022 Healthcare Innovation Award
- Medical Device and Diagnostic Industry's 2022 Medical Design Excellence Bronze Award for Digital Health Products and Mobile Medical Apps; and
- Lucintel's 2021 Product Innovation Award in the Biosensors Market

The FreeStyle Libre portfolio is the most widely used continuous glucose monitoring system in the U.S. and worldwide and has changed the lives of approximately four million people across more than 60 countries.[17] Abbott has secured partial or full reimbursement for the FreeStyle Libre system in over 40 countries, including Canada, France, Germany, Japan, the United Kingdom, and the U.S.[5] For more information visit FreeStyleLibre.com.

Indications and Important Safety Information
Failure to use FreeStyle Libre 3 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 FreeStyleLibre.us safety info.

About Abbott Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 113,000 colleagues serve people in more than 160 countries.

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1. Data on File, Abbott Diabetes Care. Comparison based on publicly available information.
2. 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.
3. 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.
4. Data on file, Abbott Diabetes Care.
5. Based on a comparison of list prices of FreeStyle Libre 3 system versus competitors' CGM systems. The actual cost to patients may or may not be lower than other CGM systems, depending on the amount covered by insurance, if any. Does not include Medicare, Medicaid, and uninsured patients. At this time, FreeStyle Libre 3 is not currently eligible for Medicare reimbursement, and Medicaid eligibility may vary by state. 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 payers.
6. FreeStyle Libre 3 User's Manual.
7. Among patient-applied sensors.
8. Based on the signal range in Dexcom G6 CGM User Guide and Medtronic Guardian Connect System User Guide.
9. Based on a comparison of list prices of the FreeStyle Libre 3 system versus previous generations of FreeStyle Libre Personal CGM systems.
10. American Diabetes Association, Fast Facts: Data and Statistics about Diabetes, from the National Diabetes Statistics Report, 2022.
11. 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.
12. The user's device must have internet connectivity for glucose data to automatically upload to LibreView and to transfer to connected LibreLinkUp app users.
13. LibreView is ISO27001/27018/27701 certified and HITRUST CSF Certified.
14. 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.
15. At this time, FreeStyle Libre 3 is not currently eligible for Medicare reimbursement, and Medicaid eligibility may vary by state.
16. CES Innovation Award; Edison Awards; BIG Innovation Awards; Medical Design Excellence Awards; and Lucintel Award of Excellence.
17. Data on file, Abbott Diabetes Care. Data based on the number of users worldwide for the FreeStyle Libre portfolio compared to the number of users for other leading personal use, sensor-based glucose monitoring systems.

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