

Abbott Receives U.S. FDA Clearance For Two New Over-The-Counter Continuous Glucose Monitoring Systems

- Abbott's consumer biowearable, Lingo™, is designed for general consumers who are looking to improve their overall health and wellness
- Libre Rio™ is designed for adults with Type 2 diabetes who do not use insulin and typically manage their diabetes through lifestyle modifications
- Both products are based on FreeStyle Libre® sensing technology, the world's most widely used¹ continuous glucose monitoring (CGM) systems, pioneered by Abbott and used by about 6 million people globally²

ABBOTT PARK, Ill., June 10, 2024 /PRNewswire/ -- Abbott (NYSE: ABT) today announced U.S. Food and Drug Administration (FDA) clearance for two new over-the-counter continuous glucose monitoring (CGM) systems – Lingo™ and Libre Rio™, which are based on Abbott's world-leading FreeStyle Libre® continuous glucose monitoring technology¹, now used by about 6 million people globally². The newly cleared systems have been intentionally designed to meet different needs – Lingo for consumers who want to better understand and improve their health and wellness, and Libre Rio for adults with Type 2 diabetes who do not use insulin and typically manage their diabetes through lifestyle modifications.

"There is no one-size-fits all approach for glucose monitoring, which is why we've designed different products for different people – all based on the same world-leading biowearable technology¹," said Lisa Earnhardt, executive vice president and group president of Abbott's medical devices business. "People living with diabetes need certain features like tracking medications or sharing data with a healthcare provider. People without diabetes need different features to manage their metabolic health, including personalized coaching to promote actionable lifestyle changes."

Lingo

Abbott's consumer biowearable, Lingo, is designed for consumers 18 years and older who are looking to improve their overall health and wellness. Lingo will track glucose and provide personalized insights and customized coaching to help people create healthy habits, retrain their metabolism and improve their overall well-being.

According to a University of North Carolina study, only 12 percent of Americans are metabolically healthy³ based on five key indicators of metabolic health, including glucose levels, indicating that most of the U.S. population has room to improve their metabolism. In addition, in a recent online consumer survey conducted by The Harris Poll on behalf of Abbott, 82 percent of Americans say they would change their habits if a biowearable provided actionable, personalized coaching to help them manage their health.⁴

The Lingo system combines a biosensor that is worn on the upper arm for 14 days⁵ and continuously streams glucose data to a coaching application on a smart phone – translating the body's language and giving insights on the person's reaction to food, exercise and life's daily stressors.

"Continuous glucose monitors are a tool I recommend to my patients to raise their overall awareness of factors that affect their glucose and are an invaluable holistic wellness solution," said Fred St. Goar, M.D., cardiologist and medical director of El Camino Health Heart and Vascular Institute. "Research has shown that overall lower glucose exposure in the general population is associated with reduced long-term risk to developing cardiovascular disease, diabetes, Alzheimer's and certain cancers. Making continuous glucose monitors widely available will undoubtedly have a dramatic effect on the overall health and well-being of the broader population."

Visit www.hellolingo.com and sign up to be notified as soon as Lingo is available in the U.S. Lingo is also available in the UK.

Libre Rio

Libre Rio will be Abbott's first over-the-counter CGM system for people with diabetes in the U.S. It is designed for people ages 18 and older with Type 2 diabetes who do not use insulin and typically manage their diabetes through lifestyle modifications. Libre Rio is the first over-the-counter CGM system with a measurement range of 40-400 mg/dL, allowing for measurement of extremely low or high glucose events.

Diabetes is among the top public health challenges in the U.S., with approximately 38.4 million people living with the condition⁶. FreeStyle Libre systems have been available over-the-counter in more than 50 countries over the last decade; however, in the U.S., they have only been available through prescription.

Libre Rio will join Abbott's overall Libre portfolio of CGM systems, now used by about 6 million people across more than 60 countries². The Libre portfolio in the U.S. consists of the [FreeStyle Libre 2](#) and [FreeStyle Libre 3](#) systems for people with all types of diabetes – Type 1, Type 2 and gestational. FreeStyle Libre systems require a prescription and have wide reimbursement by most major insurers in the U.S.² Libre Rio may make it easier for Americans with diabetes to try a CGM and begin to see progress toward their health goals, empowering them with information to discuss with their healthcare provider at their next visit.

Clinical and real-world data from the millions of people that use FreeStyle Libre systems show that the technology helps people improve their glucose control, lower their HbA1c, decrease diabetes-related hospital admissions, and improve their quality of

life^{7,8}. Libre systems consist of a biosensor placed on the back of the arm for up to 15 days, and a reader or a compatible smartphone app⁹, which displays glucose measurements.

Abbott continues to invest in its world-leading innovation for people with diabetes, including expanding manufacturing capacity and developing a first-of-its-kind sensor that is designed to measure both glucose and ketone in the same sensor.

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, nutritional and branded generic medicines. Our 114,000 colleagues serve people in more than 160 countries. Connect with us at www.abbott.com and on [LinkedIn](#), [Facebook](#), [Instagram](#), [X](#) and [YouTube](#).

About Lingo:

The Lingo Glucose System is intended for users 18 years and older not on insulin. It is not intended for diagnosis of diseases, including diabetes.

The Lingo program does not guarantee that everyone will achieve the same results as individual responses may vary. Consult your healthcare professional before making changes to your diet or exercise regimen or if you have an eating disorder or a history of eating disorders.

About Libre Rio:

Libre Rio is an over-the-counter integrated continuous glucose monitoring (iCGM) device indicated for non-insulin using persons ages 18 and older. Failure to use Libre Rio as instructed in labeling may result in missing a severe low or high glucose event. If readings do not match symptoms or expectations, use a fingerstick value from a blood glucose meter for treatment decisions.

Important Safety Information about FreeStyle Libre systems:

For Important Safety Information, please visit <https://www.freestyle.abbott/us-en/safety-information.html>.

1. Data on file. Abbott Diabetes Care. Data based on the number of patients assigned to each manufacturer.
2. Data on file. Abbott Diabetes Care.
3. Prevalence of Optimal Metabolic Health in American Adults: National Health and Nutrition Examination Survey 2009-2016.
4. This survey was conducted online within the United States by The Harris Poll on behalf of Abbott from March 7 - 11, 2024 among 2,060 adults ages 18 and older. The sampling precision of Harris online polls is measured by using a Bayesian credible interval. For this study, the sample data is accurate to within +/- 2.5 percentage points using a 95% confidence level.
5. A study was conducted to assess the biosensor life where 77.1% of biosensors lasted the full 14 days. In other words, when using the product per the package labeling, approximately 22.9% of biosensors may not last for the full 14 days. 14.7% of biosensors may last less than 11 days.
6. American Diabetes Association, [Statistics About Diabetes](#), accessed March 20, 2024.
7. The American Journal of Managed Care, [Flash CGM Associated With Event Reduction in Nonintensive Diabetes Therapy](#) 2021.
8. American Diabetes Association, [Continuous Glucose Monitors](#), accessed March 20, 2024.
9. The FreeStyle Libre systems are only compatible with certain mobile devices and operating systems. Please check our [compatibility guide](#) for more information about device compatibility before using the app.

SOURCE Abbott

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Additional assets available online:

