

# ABBOTT RECEIVES CE MARK FOR FREESTYLE® LIBRE, A REVOLUTIONARY GLUCOSE MONITORING SYSTEM FOR PEOPLE WITH DIABETES

- FreeStyle Libre System eliminates routine finger pricks for glucose measurements<sup>1</sup> and requires no finger pricks for calibration
- Available for people living with diabetes in several European markets beginning in the coming weeks
- Advanced Ambulatory Glucose Profile software presents data in a user-friendly, visual chart, enabling productive treatment discussions

ABBOTT PARK, Ill., Sept. 3, 2014 /[PRNewswire](#)/ -- Abbott (NYSE: ABT) today announced that it has received CE Mark (Conformite Europeenne) for its FreeStyle® Libre Flash Glucose Monitoring System, a revolutionary new glucose sensing technology for people with diabetes. The system eliminates the need for routine finger pricks<sup>1</sup>, reading glucose levels through a sensor that can be worn on the back of the upper arm for up to 14 days. In addition, no finger prick calibration is needed—a key differentiator from current continuous glucose monitoring systems. The system will be available in seven countries across Europe in the coming weeks.

Abbott's FreeStyle Libre System consists of a small, round sensor—approximately the size of a two Euro coin—worn on the back of the upper arm, which measures glucose every minute in interstitial fluid through a small (5mm long, 0.4mm wide) filament that is inserted just under the skin and held in place with a small adhesive pad. A reader is scanned over the sensor to get a glucose result painlessly in less than one second. Scanning can take place while the sensor is under clothing<sup>2</sup>, making testing more discreet and convenient. Each scan displays a real-time glucose result, a historical trend and the direction the glucose is heading. The reader holds up to 90 days of data, providing a historical snapshot of glucose levels over time. The FreeStyle Libre System software enables the data to be presented in a user-friendly, visual chart for both healthcare professionals and patients, driving a more productive discussion around treatment and any necessary modification.

"The FreeStyle Libre System fulfills a major need for people living with diabetes," said Robert Ford, senior vice president, Diabetes Care, Abbott. "Our customers told us that the pain, inconvenience and indiscretion of finger pricking were the key reasons they weren't managing their diabetes as well as they should. Addressing these concerns has guided the development of FreeStyle Libre – a transformational product designed to not only remove the pain of finger pricking but also seamlessly integrate into their daily lives."

According to the International Diabetes Federation, there are 382 million people around the globe living with diabetes, more than 56 million of whom live in Europe, and that number is projected to increase by more than 20 percent by the year 2035<sup>3</sup>. FreeStyle Libre System eliminates the challenges of routine glucose monitoring for people with diabetes, enabling them to maintain a better understanding of their glucose levels.

Key features of Abbott's FreeStyle Libre System include:

- The system requires no finger prick calibration
- Disposable, water-resistant sensor can be worn on the back of the upper arm for up to 14 days
- Glucose readings can be taken as many times per day as needed or desired, with a painless one second scan
- Each scan provides a current glucose reading, 8-hour history and the direction glucose is heading
- The data generated by the system is designed to provide actionable trends and patterns that may help people determine how to modify food and other behaviors to better manage their diabetes in consultation with their healthcare professionals

"For decades, people with diabetes have had to prick their fingers routinely to check their glucose levels," said Cliff Bailey, professor of Clinical Science and Director of Biomedical Sciences Research at Aston University in Birmingham, England. "The pain and inconvenience of finger pricks has contributed to less frequent testing and suboptimal diabetes management. By eliminating the need for routine finger pricks, the FreeStyle Libre System will significantly advance the field of glucose monitoring. It offers a convenient and painless way to get more frequent glucose readings, which should help to improve diabetes management."

## Ambulatory Glucose Profile—Visual Depiction of Glucose Trends

The majority of people with diabetes are not at their target glucose levels<sup>4 5 6</sup> often because the data generated by their glucose meters don't provide a clear picture of where their glucose has been in the past or how their actions impact their glucose levels. The FreeStyle Libre System provides users and their physicians with the Ambulatory Glucose Profile (AGP), a report providing a visual snapshot of a person's typical day by utilizing dense glucose data revealing hypoglycemic and hyperglycemic trends to facilitate better patient therapy and education. The data are presented in a single, user-friendly, visual chart providing health care professionals the vantage point to link glucose trends to clinical decision-making, enabling a more productive discussion between

health care provider and patient. For more information, go to [www.AbbottNextFrontier.com](http://www.AbbottNextFrontier.com).

A recent study conducted by Abbott<sup>7</sup> has shown that the FreeStyle Libre System is clinically proven to be accurate, stable and consistent over 14 days without the need for finger prick calibration. More details on this study will be made available during the Abbott Symposium at the European Association for the Study of Diabetes (EASD) medical conference September 15.

The FreeStyle Libre System will be available in France, Germany, Italy, Netherlands, Spain, Sweden and United Kingdom in the coming weeks and will be available for purchase online through a website in each market.

#### **About Abbott Diabetes Care**

Abbott Diabetes Care, based in Alameda, Calif., is a leader in developing, manufacturing and marketing glucose monitoring systems designed to help people better manage their diabetes. Additional information about Abbott Diabetes Care may be found at [www.AbbottDiabetesCare.com](http://www.AbbottDiabetesCare.com).

#### **About Abbott**

Abbott is a global healthcare company devoted to improving life through the development of products and technologies that span the breadth of healthcare. With a portfolio of leading, science-based offerings in diagnostics, medical devices, nutritionals and branded generic pharmaceuticals, Abbott serves people in more than 150 countries and employs approximately 69,000 people.

Visit Abbott at [www.Abbott.com](http://www.Abbott.com) and connect with us on Twitter at @AbbottNews.

<sup>1</sup>A finger prick test using a blood glucose meter is required during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels or if hypoglycaemia or impending hypoglycaemia is reported by the System or when symptoms do not match the System readings

<sup>2</sup>The reader can capture data from the sensor when it is within 1cm to 4cm of the sensor

<sup>3</sup>IDF Diabetes Atlas; sixth edition [www.idf.org/diabetesatlas](http://www.idf.org/diabetesatlas)

<sup>4</sup>Davies M. The reality of glycaemic control in insulin treated diabetes: defining the clinical challenges. Int J Obes Relat Metab Disord 2004;28 Suppl 2:S14-22. <http://www.ncbi.nlm.nih.gov/pubmed/15306833>

<sup>5</sup>Del Prato S, Felton AM, Munro N et al. Improving glucose management: 10 steps to get more patients with type 2 diabetes to glycaemic goal. Int J Clin Pract 2005;59:1345-55 <http://www.ncbi.nlm.nih.gov/pubmed/16236091>

<sup>6</sup>Alvarez Guisasola F, Mavros P, Nocea G et al. Glycaemic control among patients with type 2 diabetes mellitus in seven European countries: findings from the Real-Life Effectiveness and Care Patterns of Diabetes Management (RECAP-DM) study. Diabetes Obes Metab 2008;10 Suppl 1:8

<sup>7</sup>Data on File, Abbott Diabetes Care Inc, Clinical Report: Evaluation of the Accuracy of the Abbott Sensor-Based Interstitial Glucose Monitoring System 2014

#### **SOURCE Abbott**

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