

Children In Europe Now Have Access To First-Of-Its-Kind Diabetes Sensing Technology - Eliminates Routine Finger Pricks(I)

- Abbott obtains European CE Mark for FreeStyle® Libre flash glucose monitoring system for children aged 4-17 years old
- System measures glucose levels through small sensor on the back of the upper arm for up to 14 days, requiring no finger prick calibration

ABBOTT PARK, Ill., Feb. 4, 2016 /PRNewswire/ -- Today, Abbott (NYSE: ABT) announced that it has obtained CE Mark (Conformité Européenne) for the FreeStyle Libre flash glucose monitoring system indicated for children and teens with diabetes aged 4-17 years old.ⁱⁱ This means that children and young people with diabetes living in Europe are able to experience the liberation from the pain and hassle of routine finger pricks.ⁱ

A person with diabetes typically self-monitors their glucose by pricking their fingers routinely to check their glucose level, enabling appropriate adjustments to insulin, diet, and activity based on their health care professionals' recommendations to help achieve good glycemic control. However, according to researchⁱⁱⁱ, there is often reluctance from people with diabetes, especially children and adolescents, to perform this task, based in part on the discomfort and pain of finger pricking.

"I still wake up in the night to check my daughter's blood glucose level with a [finger prick]. I'm very much looking forward to the day that I can use a FreeStyle Libre instead, so that I don't have to wake her up to check her levels," said Joanne Blackham, mother to a Type 1 person with diabetes Madeleine, aged 13.

Abbott's FreeStyle Libre flash glucose monitoring system, which is available in several European countries, is designed to change how people with diabetes measure their glucose levels and ultimately help them achieve better health outcomes. The system reads glucose levels through a sensor that is worn on the back of the upper arm for up to 14 days, eliminating the need for routine finger pricks.ⁱⁱ In addition, no finger prick calibration is needed—a key differentiator from current continuous glucose monitoring systems.

"Children and teens with diabetes and their families have to navigate many challenges in their daily lives as they care for this complex condition," said Jared Watkin, senior vice president, diabetes care, Abbott. "The scientists and engineers at Abbott have made it their life's work to provide the most innovative technology to help people with diabetes improve their diabetes management and ultimately, live happier and healthier lives."

In a recent accuracy study, Abbott's FreeStyle Libre flash glucose monitoring system was clinically proven to be accurate, stable and consistent for up to 14 days without the need for finger prick calibration, for children and teens aged 4-17 years old. In addition, more than 97 percent of these children and teens said that the FreeStyle Libre system is easier to use than finger prick testing.^{iv}

According to the International Diabetes Federation (IDF), the Europe region has the highest number of children—ages 0-14—with type 1 diabetes compared with the other IDF regions* — approximately 140,000. Within that region, the United Kingdom, the Russia Federation, and Germany have the highest population of children with type 1 diabetes.^v

"The availability of FreeStyle Libre for children is a critical milestone for children living with diabetes," said Dr Emanuele Bosi, associate professor, Department of Endocrinology and Diabetology, Università Vita-Salute, San Raffaele Hospital in Milan, Italy. "The technology in Abbott's FreeStyle Libre is transformative because it changes how self-monitoring has been done for decades—and is proven to be accurate and stable. I look forward to seeing my young patients achieve better diabetes management, while giving their parents and caretakers more peace of mind."

Caregivers of children with diabetes also can be challenged as they worry about such things as night-time hypoglycemia (a low glucose level), which is the number one concern of parents of children with diabetes, and a potentially life-threatening condition. Authors of a 2013 study published in the journal Quality of Life Research noted that people with diabetes — type 1 or type 2 — experience hypoglycemia while sleeping more frequently than many doctors realize.^{vi} A parent or caregiver often has to wake their child up during the night to test glucose—now with FreeStyle Libre flash glucose monitoring system that can be done quickly, painlessly and without disturbing sleep.

Abbott's FreeStyle Libre system is currently available in Austria, Belgium, France, Germany, Italy, Netherlands, Norway, Spain, Sweden and the United Kingdom.

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ⁱ 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.

ii A caregiver at least 18 years old is responsible for supervising, managing, and assisting the child or young person ages 4-17 years old in using the FreeStyle Libre system and interpreting its readings.

iii <http://adc.bmj.com/content/89/6/516.full.pdf>

iv Data on file, Abbott Diabetes Care, Inc., Evaluation of the Accuracy of the Abbott Sensor Based Glucose Monitoring System- Paediatric Label Extension Study (CE) (2015)

v 7th Edition of the IDF Diabetes Atlas, chapter 4, <http://www.diabetesatlas.org/>

* IDF regions include Africa, Europe, Middle East and North Africa, North American and Caribbean, South and Central America, South East Asia, and Western Pacific

vi [Quality of Life Research](#), June 2013, Volume 22, [Issue 5](#), pp 997-1004, <http://link.springer.com/article/10.1007/s11136-012-0234-3>

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