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FDA Approves Dexcom G5® Mobile Continuous Glucose Monitoring System

August 24, 2015

[First and Only Fully Mobile CGM System Allows Adults and Children as young as 2 years old to Conveniently and Discreetly Monitor and Share Glucose Levels.](#)

Dexcom announced today that the U.S. Food and Drug Administration (FDA) has approved the [Dexcom G5® Mobile Continuous Glucose Monitoring \(CGM\) System](#). With wireless Bluetooth® technology built into the device transmitter, the G5 Mobile CGM System is the first and only fully mobile CGM system approved by the FDA for both adults and children as young as 2 years of age that sends glucose data directly to a smartphone, freeing users from the need to carry a separate receiver. The new transmitter securely sends vital glucose information directly to an app on iOS-enabled devices for real-time diabetes management. [Android applications](#) will follow early next year. Like its predecessor, the G4 PLATINUM CGM with Share, users can also select up to five designated recipients, or "followers". These followers can remotely monitor a patient's glucose information and receive alert notifications from almost anywhere.

"Dexcom is rapidly advancing technology for continuous glucose monitoring devices to improve diabetes management. Since January, the company has introduced the G4 PLATINUM CGM with *Share*, apps to enable the first CGM on the Apple Watch™ and now the Dexcom G5® Mobile CGM. These advances are making diabetes management more convenient and flexible than ever before," stated Kevin Sayer, President and Chief Executive Officer of Dexcom. "We are excited for the promise this new technology holds for patients and caregivers."

About the Dexcom U.S. G5 Mobile Launch

- The G5 Mobile system is anticipated to begin shipping in late September 2015.
- All purchasers of a G4 Platinum with Share system from August 1, 2015, until the G5 Mobile system is shipped, will be eligible to receive a no-cost upgrade to the G5 Mobile system.



- There will be a [low cost cash upgrade to the G5 Mobile system](#) for those patients who are still under warranty with their existing system.

“Obviously there are a lot of moving parts to our commercial launch plans given this sooner-than-expected approval, and the financial ramifications, such as inventory adjustments and revenue recognition policies are being evaluated and will be discussed in detail on the Q3-2015 earnings call in early November,” remarked Sayer.

Enhanced Mobility and Flexibility

Available by prescription, the Dexcom G5 Mobile CGM System features the most accurate glucose sensor on the market while providing enhanced mobility and flexibility to view and share personal glucose data and trends. The only CGM with single digit MARD (Mean Absolute Relative Difference), the Dexcom G5 Mobile comes with the longest-wear sensor on the market and features customizable alerts and a built-in low glucose alarm (55 mg/dL alarm) to warn patients of highs and lows and how quickly they may be happening through a simplified mobile interface. Data from the Dexcom G5 Mobile can be integrated with Dexcom CLARITY™, a Cloud-based reporting software, for personalized, easy-to-understand analysis of trends that may improve diabetes management. Continuous glucose monitoring is considered the most significant breakthrough in diabetes management in the past 40 years¹. The traditional standard-of-care for glucose (blood sugar) monitoring has been a finger stick meter. CGM augments the use of glucose meters for the management of diabetes. Meters are still required to calibrate CGMs and for guidance in making therapy and meal decisions. CGM is important because, in addition to providing the glucose level, it provides the direction and rate of glucose change with the push of a button and alerts users when glucose is too low or too high.

Diabetes affects 29.1 million Americans and is the 7th leading cause of death in the United States.² With diabetes, the body cannot produce or use the hormone insulin effectively, causing a buildup of glucose, or sugar, in the blood. It is estimated that approximately 86 million Americans over the age of 20 years old are at risk for developing diabetes (primarily Type 2), largely due to obesity, physical inactivity and poor diet.² People with diabetes who take insulin must monitor their blood glucose levels frequently. Uncontrolled glucose can cause health complications and even death.^{3,4}

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2. 2014 National Diabetes Statistics Report. Centers for Disease Control and Prevention. <http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf> Accessed March 31, 2015.
3. Hyperglycemia (High blood glucose). American Diabetes Association Web site. <http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/hyperglycemia.html>. Updated August 5, 2013. Accessed December 3, 2013.
4. Hypoglycemia (Low blood glucose). American Diabetes Association Web site. <http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/hypoglycemia-low-blood.html>. Updated July 16, 2013. Accessed December 3, 2013.

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