Medtronic News

Medtronic Receives FDA Approval for Next Generation Professional Continuous Glucose Monitoring

iPro®2 Simplifies Professional CGM for Improved Diabetes Therapy Management

MINNEAPOLIS--(BUSINESS WIRE)--Nov. 22, 2011-- Medtronic, Inc. (NYSE:MDT) today announced the Food and Drug Administration (FDA) approval of iPro®2, a next generation Professional continuous glucose monitoring (CGM) system and the latest in a series of recent diabetes technology approvals and innovations from the company. iPro2 simplifies Professional CGM and enables healthcare providers to obtain a more complete picture of glucose control for the patients they treat. Professional CGM is used by healthcare providers to reveal low (hypoglycemia) and high (hyperglycemia) glucose excursions that can lead to the dangerous health complications of diabetes. These excursions often go unnoticed with traditional A1C tests and standard glucose meter measurements.

“My vision is to make an iPro2 evaluation part of routine visits for many of my patients with diabetes. I find it particularly helpful in identifying repeated glucose lows at night and glucose highs after meals, issues that a near-normal A1C does not reveal,” said Dr. David Huffman of University Diabetes and Endocrine Consultants, a center that participated in a pre-market study for iPro2. “I am one doctor in a busy office, but the advances with iPro2 will make Professional CGM accessible to more patients who need it. I see that as better medicine.”

iPro2 provides healthcare providers insight into how diet, medication, and daily activities affect their patients’ glucose levels. The system can be used to identify nocturnal hypoglycemia or hyperglycemia following meals, providing an opportunity to make therapy adjustments that can result in better glucose control. Good glucose control can greatly reduce the risk of diabetes complications including blindness, kidney failure, amputation, impotence and heart disease.

AACE Supports Use of Professional CGM for Broad Range of Patients with Diabetes

The American Association of Clinical Endocrinologists (AACE) and the Endocrine Society, professional communities of physicians specializing in endocrinology, both recently published recommendations for use of Professional CGM on a broad range of patients with diabetes. The AACE Consensus statement indicates that Professional CGM is ideal for type 1 or type 2 diabetes patients who are not achieving target A1C levels, and for patients who have recurrent hypoglycemia or hypoglycemia unawareness. The statement also recommended Professional CGM for all pregnant women with type 1 diabetes and intermittent use in youth with type 1 diabetes. The Endocrine Society’s Clinical Guidelines suggested intermittent use in patients in whom clinicians worry about the dawn phenomenon, high glucose levels after meals, and in patients undergoing significant changes in their diabetes regimen.

“We are dedicated to bringing new innovations in continuous glucose monitoring to healthcare professionals and patients with the introduction of our fourth-generation Professional CGM, as well as ongoing sensor enhancements,” said Greg Meehan, Vice President and General Manager of the Continuous Glucose Monitoring business at Medtronic. “CGM adoption is on the rise. We believe the combination of improved reimbursement for both clinicians and patients, increased clinical evidence as seen in the Medtronic STAR 3 and JDRF trials, as well as ongoing product advancements, are moving CGM devices toward the standard of care for diabetes management.”

How iPro2 Professional CGM Works

iPro2 is a three day evaluation and is designed to make CGM easy for healthcare professionals and patients to use. The setup procedure is now a simple three-step process enabled by a new all-in-one “Smart” Dock, which reduces the number of required components and eliminates the need for a computer. Setup can be completed in a few minutes and includes inserting a glucose sensor into the patient’s skin, educating the patient, and connecting the iPro2 to the sensor. The patient then conducts normal daily activities while the iPro2 records and stores as many as 288 glucose readings over each 24-hour period.

iPro2 is adaptable to almost any patient’s lifestyle because of its small, light and water-tight profile, and the patient is not required to interact with the device. After three days of wear, the patient returns iPro2 for upload to new web-based CareLink™ iPro software, which provides a summary of glucose data in easy-to-read reports. Patient data and CareLink software can be accessed by any computer with an internet connection. The new reports are also designed to be user-friendly and can be used as a teaching tool to motivate patients to implement changes in their diabetes management by seeing the effects that food, exercise, stress, medications, or other activities have on glucose levels.

More information on iPro2 is available for healthcare providers at (www.medtronicdiabetes.com/iPro2) and for patients at (www.medtronicdiabetes.com/iProEvaluation).

About CGM Systems

A Professional CGM system, such as iPro2, is a clinician-owned device that collects glucose data without patient interaction for retrospective review. A Personal CGM system is a patient-owned device that displays real-time glucose data; it is available in a standalone CGM device – the Guardian® REAL-Time System – or as part of the Medtronic integrated insulin system, the MiniMed Paradigm® REAL-Time Revel™ System, which combines CGM with insulin pump therapy.

About the Diabetes Business at Medtronic

The Diabetes business at Medtronic (www.medtronicdiabetes.com) is the world leader in advanced diabetes management solutions, including integrated diabetes management systems, insulin pump therapy, continuous glucose monitoring systems and therapy management software, as well as world-class, 24/7 expert consumer and professional service and support.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology – alleviating pain, restoring health and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic’s periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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