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Medtronic Sentrino® CGM System Gains CE Mark - System Designed to Improve Glucose Control in Critical Care Patients



Medtronic

Medtronic, Inc. announced on December 3, 2012, CE (Conformité Européenne) Mark approval of its innovative Sentrino® Continuous Glucose Management System, the first minimally invasive continuous glucose monitoring (CGM) system specifically designed for use in hospital critical care units (CCU). The Sentrino CGM System provides real-time trend data that serves as an early warning system, allowing clinicians to appropriately intervene to prevent glycemic excursions and maximize the patient's time in the target range. In addition, the system integrates simply into the clinical workflow in the hospital to improve the quality and efficiency of maintaining glucose control.

Improved glucose management in critical care patients may reduce morbidity, mortality and the length of stay.^{<1-3>} While glucose control is a standard practice for diabetic and non-diabetic patients in the CCU, it's difficult to achieve. The Sentrino CGM System and the trending data it provides help optimize glucose management practices. Sentrino is an investigational device only in the US and not approved for sale in the US.

"Introduction of the CGM technology in critically ill patients is a high priority that will help improve our insight in insulin resistance, will increase understanding of the effects of glycemic variability and will facilitate any blood glucose control strategy. Using the Sentrino CGM System for my intensive care patients will alert me to impending hypo or hyperglycemia, and will be invaluable in better maintaining glucose control," said Prof. M.J. Schultz, MD, PhD, in the Intensive Care Medicine Department at Academisch Medisch Centrum (AMC) in Amsterdam.

Sentrino continuously displays the patient's interstitial glucose value in real time on its monitor, and it provides predictive alarms and alerts if the patient's glucose values fall outside the target range selected by the physician so clinicians can react proactively. It enables clinicians to transition to an event-based protocol from a time-based measurement protocol, which is the current standard of care with blood glucose measurements taken every two-to-four hours.

The Sentrino CGM System was designed to address the unique needs of critical care patients with a highly innovative design and unique ability to integrate into clinical protocols including:

- Redundant sensing technology that optimizes signal reliability for more accurate visibility of glycemic variability.
- A minimally invasive, subcutaneous sensor customized for the critical care patient and inserts quickly

and easily with low complication rates.

- A novel drug interference rejection technology that ensures minimal interference with the wide array of pharmaceuticals used in the critical care unit.
- An easily configurable system that integrates simply into clinical workflow.

“Despite its many benefits, good glycemic control is difficult to achieve in the CCU, and that’s why we developed Sentrino. Medtronic has a decade of CGM expertise, and we coupled it with extensive clinical research to develop the Sentrino CGM System for critically ill patients,” said Greg Meehan, vice president and general manager of the Continuous Glucose Monitoring business at Medtronic. “Given the market need for CGM in CCU patients, we believe the market potential will exceed \$1 billion globally.”

About Hospital-based Continuous Glucose Monitoring (CGM)

Glucose control is a standard practice in critical care units whether or not patients have diabetes because it improves outcomes. Over the past 10 years, CGM has been evaluated in monitoring glucose trends in critically ill patients, yielding positive results^{<4-8>} with investigators achieving significantly lower rates of hypoglycemic events (BG < 2.2 mmol/L, 40 mg/dL).^{<8>} CGM provides a more complete picture because it reveals high and low glucose levels that periodic blood glucose testing might miss. This trending data allows clinicians to appropriately intervene to prevent glycemic excursions and maximize the patient’s time in the target range. The information provided by CGM is intended to supplement, not replace, readings obtained from approved blood glucose measuring devices and should be confirmed prior to making therapy adjustments.

References:

1. Krinsley JS, Schultz MJ, Spronk PE, et al. Mild hypoglycemia is independently associated with increased mortality in the critically ill. *Crit Care*. 2011;15(4):R173.
2. Krinsley JS, Schulz MJ, Spronk PE, et al. Mild hypoglycemia is strongly associated with increased intensive care unit length of stay. *Ann Intensive Care*. 2011;1:49.
3. Van den Berghe G, Wouters P, Weekers F, et al. Intensive insulin therapy in critically ill patients. *N Engl J Med*. 2001;345(19):1359-1367.
4. Brunner R, Kitzberger R, Miehsler W, et al., Accuracy and reliability of a subcutaneous continuous glucose-monitoring system in critically ill patients. *Crit Care Med*. 2011; 39:1-6.
5. Holzinger U, Warszawska J, Kitzberger R, et al., Impact of shock requiring norepinephrine on the accuracy and reliability of subcutaneous continuous glucose monitoring. *Intensive Care Med*. 2009; 35:1383-1389.
6. Monsod TP, Glanagan DE, Rife F, et al., Do sensor glucose levels accurately predict plasma glucose concentrations during hypoglycemia and hyperinsulinemia? *Diabetes Care*. 2002; 25:889-893.
7. Corstjens AM, Ligtenberg JJM, Van der Horst ICC, et al., Accuracy and feasibility of point-of-care and continuous blood glucose analyses in critically ill ICU patients. *Crit Care*. 2006;10(5):R135. Available at <http://ccforum.com/content/10/5/R135>.
8. Holzinger U, Warszawska J, Kitzberger R, et al., Real-time continuous glucose monitoring in critically ill patients. *Diabetes Care*. 2010; 33:467-472.

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