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**FOR IMMEDIATE RELEASE**

**OptiScan Biomedical Receives CE Mark for OptiScanner Automatic Bedside Glucose Monitoring System**

*Certification Enables European Sale and Marketing of World's First Automated Device  
Designed to Continuously Monitor Glucose Levels in Critically Ill Patients*

**Hayward, CA, September 19, 2011** – OptiScan Biomedical Corporation, a developer of innovative continuous glucose monitoring systems for use in intensive care units (ICU), today announced that the company's OptiScanner™ Automatic Bedside Glucose Monitoring System has received CE Mark certification for use in the European Union. This CE Mark certifies that the OptiScanner has met all relevant European Union consumer safety, health and environmental requirements, allowing it to be sold and marketed in the 30 countries that make up the European Economic Area (EEA). The company plans to initiate marketing of the OptiScanner during the first quarter of 2012, and is presently engaging in dialogue with appropriate distributors in the various countries. Additionally, OptiScan is currently in active discussions with the United States Food and Drug Administration regarding the approval of the OptiScanner in the U.S.

The OptiScanner is a first-of-its-kind automated, bedside glucose monitoring system that overcomes the limitations of today's current handheld, manually operated glucose meters and provides physicians with the tools and information they need to best manage patient glucose levels in the ICU. The device represents a significant advancement in the delivery of care to ICU patients by helping to combat both hyperglycemia and hypoglycemia through automated monitoring of patients' glucose in plasma, as opposed to whole blood. It is estimated that approximately 20 percent of ICU patients have pre-existing diabetes and an additional 40 to 70 percent of ICU patients suffer from "stress hyperglycemia" or a temporary elevation of glucose levels, with all of these patients requiring accurate glucose monitoring to maintain tight glycemic control.

"There is a very real crisis related to patient blood glucose levels that is being played out daily in ICUs around the world. With hyperglycemia, hypoglycemia and glucose variability all prevalent in ICU patients and associated with death, there is a significant need for technology that can enable tighter glycemic control through automated, accurate and near continuous glucose monitoring," stated James S. Krinsley, MD, FCCM, FCCP, Director of Critical Care at Stamford Hospital in Stamford, CT., and Clinical Professor of Medicine, Columbia University College of Physicians and Surgeons. "Unfortunately, both the quality and manual nature of the current

glucose monitoring technologies prevent ICU physicians from reaching therapeutic goals for their patients. The result is often that physicians set ICU patient glucose targets higher than they would like in order to avoid the more dangerous potential of hypoglycemia. A breakthrough glucose monitoring system would help correct this problem and increase ICU patient safety.”

The OptiScanner offers several key advantages as compared to current handheld devices including:

- Measuring glucose in plasma as opposed to current devices which measure in whole blood. Research has proven that plasma provides more accurate glucose readings than whole blood by eliminating various elements that interfere with accurate measurements, while also more accurately representing the brain’s use of glucose in the body.

The issue of accuracy is critical as whole blood monitors are impacted by a variety of error sources that can place ICU patients at risk for being over and/or under-dosed with insulin. It is important to note that the OptiScanner’s level of accuracy and sensitivity allows for the measurement of glucose levels up to 1000 mg/dl as compared to handheld meter devices that typically have a limit of 300 mg/dl.

- Automatically providing serial blood glucose measurements every 15 minutes and offering trending information related to changes in patients’ glucose levels. Handheld devices are not automated, do not offer important trending information, and typical staffing levels in the ICU do not allow routine blood glucose monitoring at frequencies of even every one to two hours.
- Attaching directly to patients’ existing intravenous (IV) lines and enabling the use of already existing catheters. This allows blood samples to be drawn automatically as opposed to handheld devices which require manual blood draws for each measurement.
- Automating the heparinization of the patients’ blood sample without returning heparin back to the patient. This is a critical advancement as it eliminates the risk of heparin induced thrombocytopenia (HIT), a potentially deadly complication.
- Incorporating a range of ease-of-use features including: touch screen; graphic user interface that virtually eliminates the need for in-service to assist in set up or operation; and reagent-free measurement which removes the need for daily calibration.

Extensive evaluation of the OptiScanner in a number of studies completed in animals and diabetic patients has resulted in the publication of multiple peer-reviewed papers demonstrating the safety and efficacy of the OptiScanner. Furthermore the system’s measurement technology has been studied in a variety of ICU settings involving a broad range of critically ill patients, with results from this research being presented at five major medical conferences. OptiScanner is broadly protected by OptiScan’s portfolio of 20 issued U.S. patents which cover key technologies such as fluid separation, automatic sample anti-coagulation without return to patient and network connectivity, among others.

“This CE Mark certification is a key milestone for OptiScan in our efforts to improve the overall standard of care delivered in ICUs around the world. There is a broad consensus in the medical community regarding the need for automated, continuous and highly accurate glucose monitoring in the ICU and we believe the OptiScanner is positioned as the product-of-choice to address this need,” said Peter Rule, chairman and chief executive officer of OptiScan Biomedical. “We look forward to continuing our development and regulatory efforts to secure approval and introduce the OptiScanner in Europe, the U.S. and other key countries. At the same time, we’re focused on next-generation products that can bring even greater capabilities and benefits to physicians and patients in the ICU.”

### **About OptiScan Biomedical**

OptiScan Biomedical is a leading developer of innovative continuous glucose monitoring systems for use in intensive care units (ICU). The company’s lead product is the OptiScanner™, a first-of-its-kind automated, bedside glucose monitoring system that provides highly accurate, continuous monitoring of patients’ glucose levels measured in plasma, as opposed to whole blood. The system prominently displays glucose level trend data updated every 15 minutes to help manage patients’ glucose levels within an optimum target range. OptiScan has received CE Mark certification for the OptiScanner in the European Union and is in active discussions with the United States Food and Drug Administration regarding approval of the product in the U.S.

The company is currently working to expand the capability of the OptiScanner platform technology by detecting additional analytes within the same blood sample, thereby providing additional information about the condition of a critically ill patient.

For more information visit: [www.optiscancorp.com](http://www.optiscancorp.com)

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