



FOR IMMEDIATE RELEASE  
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## **Nova StatStrip Glucose Hospital Meter System Receives FDA Clearance for Intensive Care Use**

***Only glucose monitoring system FDA-cleared for use throughout all hospital settings, all professional healthcare settings, and all patient populations including critical care***

**Waltham, MA** – Nova Biomedical’s StatStrip Glucose Hospital Meter System is the first blood glucose monitoring system to receive clearance from the U.S. Food and Drug Administration (FDA) for use throughout all hospital and all professional healthcare settings, including intensive care settings. StatStrip Glucose is now the **ONLY** glucose monitoring system that is FDA-cleared for the detection and management of dysglycemia throughout all professional healthcare settings including critical care. It is also CLIA\*-waived in all settings. The announcement comes after an extensive, four-year project with the FDA and five prestigious university medical centers. It represents a landmark clinical breakthrough in improved patient care and safety.

Because of the unacceptably high rate of adverse patient events, including deaths, linked to the point-of-care (POC) use of glucose meters within hospitals, the FDA recognized the need for more accuracy and better performance standards for POC glucose testing in hospitals, particularly in intensive care settings. Nova recognized this need in 2010 and met with the FDA to define the rigorous studies necessary to clear StatStrip Glucose for use throughout all patient populations and all hospital settings. Studies included extensive evaluations in intensive and critical care settings with patients receiving intensive medical intervention/therapy.

The StatStrip Glucose performance comparative evaluation submitted to the FDA included 1,698 patients receiving intensive medical intervention and 1,815 data points. It included data from five university medical centers in multiple clinical intensive care settings. All of these whole blood glucose measurements were compared to plasma central laboratory IDMS traceable methods. The patient data included 19 medical condition categories as designated by the World Health Organization, representing 257 different medical condition sub-categories, in which approximately 8,000 medications were administered to patients. These complex drug regimens represent 33 parent drug classes as designated by the United States Pharmacopeia and 144 subclasses of medications. For each major medical condition and drug class category, StatStrip Glucose was evaluated against several rigorous performance criteria, statistical analyses tools, and insulin dosing error risk assessment models used by medical professionals, standards organizations, and regulators.

All of the performance assessment tools, including the insulin dosing risk models, demonstrated that StatStrip Glucose has acceptable clinical performance within intensive care settings when testing is performed by healthcare professionals or point-of-care waived operators. More



importantly, StatStrip Glucose demonstrated substantial equivalence to central laboratory IDMS traceable reference methods, when used with patients receiving intensive medical intervention/therapy.

In addition to the extensive FDA evaluation, over additional 136 independent studies—including 53 intensive care settings—have found no clinical interferences for StatStrip Glucose. It is the world's most extensively studied and best understood glucose test. After seven years of extensive studies and significant field use, StatStrip Glucose is now cleared by the FDA to be safe and effective for use with all patients in all professional healthcare settings including intensive care and critical care settings.

To learn more about how StatStrip Glucose can bring lab-equivalent accuracy to the bedside, call Nova Customer Service at 800-458-5813.

\*Clinical Laboratory Improvement Act

\*\*Clinical and Laboratory Standards Institute

\*\*\*International Organization for Standardization

### **About Nova Biomedical**

Incorporated in 1976 and based in Waltham, MA, Nova Biomedical is a world leader in the development and manufacturing of state-of-the-art, whole blood, point-of-care and critical care analyzers, and is one of the fastest growing in vitro diagnostic companies in the world. Nova's whole blood biosensor technology is incorporated in products ranging from handheld meters for glucose self- and point-of-care testing to critical care whole blood analyzers designed for rapid measurement of over 20 analytes. Nova employs over 1,000 people worldwide and has wholly owned subsidiaries located in Canada, France, Germany, Great Britain, Japan, and Taiwan. Certified by the International Organization for Standardization, Nova has manufacturing operations located in the U.S., Taiwan, and Brazil.