



The Only Glucose Meter Cleared by the U.S. FDA for Use with Critically Ill Patients

In the last several years an unacceptably high number of adverse patient events and more than 16 deaths¹ have been traced to the use of glucose meters in hospitals in the U.S. The FDA has just announced that it now requires hospital meters to be designed for and tested on critically ill patients in order to be cleared for use in these patient populations. To date, only one meter, the Nova StatStrip Glucose Hospital Meter System has been found to be accurate enough to obtain this new FDA clearance.

StatStrip Glucose has been designed specifically to be free of clinical interferences that can be present in critically ill patients. The proof data submitted to the FDA included:

- 1,698 individual critical care patients from five university medical centers had StatStrip Glucose results paired with an IDMS traceable laboratory glucose reference method.
- Data from multiple intensive care settings representing 19 medical condition categories and 257 subcategories as designated by the World Health Organization were included.
- Over 8,000 medications representing 33 parent drug classes and 134 drug subclasses as designated by the United States Pharmacopeia were studied for possible clinical interferences; no clinical interferences were observed.

All other glucose meters currently in use with critically ill patients are now classified as “off-label” by the FDA and become subject to “high complexity testing” requirements under CMS². These requirements are so stringent that off label use of glucose meters on critically ill patients is not a practical alternative. Testing would have to be performed only by MDs or individuals degreed in laboratory medical technology.



StatStrip® Glucose
Hospital Meter System

1. DIABETES CARE, VOLUME 33, Number 4, April 2010.
2. Centers for Medicare & Medicaid Services.



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FDA clears glucose monitoring system for use in hospital critical care units

Today the U.S. Food and Drug Administration cleared a new indication for the Nova StatStrip Glucose Hospital Meter System, extending its use to critically ill patients who have been hospitalized. This is the first blood glucose monitoring system (BGMS) cleared by FDA for use in these patients.

Blood glucose monitoring systems, also called blood glucose meters, are handheld devices that measure the amount of sugar (glucose) in blood by analyzing a small drop of blood that is placed on a test strip. After inserting the test strip into the device, the system displays a glucose level reading. Blood glucose measurements are used in the management of many patients in the hospital, including patients requiring insulin to manage blood sugar, and in the assessment of blood glucose levels in newborn babies.

The Nova StatStrip Glucose Hospital Meter System is the first FDA clearance of a device specifically indicated for use in all types of hospital patients, including critically ill patients.

Users of BGMS with manufacturer instructions that do not provide for use with critically ill hospital patients would be subject to the high complexity testing requirements under the Clinical Laboratory Improvement Amendments (CLIA) if such systems were to be used in the critically ill hospital population. Those requirements include the validation of how well the BGMS worked in that patient population.

The FDA determined that the Nova StatStrip Glucose Hospital Meter System is simple to use and has a low risk for false results, and granted with the clearance “waived” test system status under CLIA. This waived status will allow a broad variety of health care professionals, such as nurses and technicians, to perform the test at the point-of-care, such as at a patient’s bedside, instead of requiring that the test be performed in a hospital lab (or other lab) that meets the CLIA requirements for high complexity testing. The CLIA waiver will also allow hospital labs to safely provide blood glucose monitoring to their critically ill patients without having to meet the significant CLIA requirements for high complexity testing.

“This device provides an important public health resource for critically ill hospitalized patients, who often have conditions or are taking medications that can cause incorrect blood glucose reading,” said Alberto Gutierrez, director of the Office of In Vitro Diagnostics and Radiological Devices at the FDA’s Center for Devices and Radiological Health. “It is important for manufacturers of glucose meters used in hospitals to design and test their devices for use in all hospitalized patients.”

The FDA originally cleared the Nova StatStrip Glucose Hospital Meter System in April of 2006 for use in hospitals as an aid in monitoring the effectiveness of a diabetes control program, but not for use with critically ill patients. The device manufacturer submitted a new premarket submission to the FDA seeking clearance of the device with this new indication.
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Today’s clearance is for indications that include using arterial or venous whole blood from patients in all areas of a hospital with various conditions, including: trauma, cancer, sepsis and infection; cardiac, kidney, neurological, obstetric, gynecological, gastroenterological, endocrine, and lung issues; and people recovering from general or cardiothoracic surgery.

Data supporting this clearance included a study of more than 1,650 patients with a range of medical conditions, taking various medications, and being treated in a variety of hospital departments, such as cardiac, emergency intensive care, and surgical. Results showed agreement in blood glucose results compared to a comparator laboratory glucose analyzer in all patients types tested.

The Nova StatStrip Glucose Hospital Meter System is manufactured by Nova Biomedical in Waltham, Massachusetts.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.



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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

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.



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