No Known Interferences—Evaluated in more than 110 Studies

Studies conducted at some of the most prestigious hospitals and diabetes centers in the world prove that Nova Biomedical’s StatStrip glucose sensor technology dramatically improves accuracy by eliminating hematocrit and other interferences. Study sites include Mayo Clinic, The Johns Hopkins University School of Medicine, University of Toronto Sunnybrook Health Sciences Centre, Addenbrook’s Hospital, Cambridge University Hospitals (United Kingdom), WeQAS and University Hospital (Wales), Isala Klinieken (Netherlands), and Saitama Medical University (Japan). The studies have been performed in several hospitalized patient populations, including neonatal.

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Background
Point-of-care glucose testing can be a challenge in the hospital setting. Interfering substances such as anemia, medications, and elevation of endogenous metabolites—very common in hospitalized patients — have all been shown to interfere with the measurement of glucose testing in handheld glucose meters. Nova’s StatStrip glucose monitoring system was designed to measure and eliminate the effects of abnormal hematocrit, electrochemical interferences, and endogenous metabolites. The following list comprises peer-reviewed publications and presentations delivered at national and international meetings that evaluate the performance of StatStrip in a variety of settings.

Adult Clinical Populations


9. Creed, G. M. (2009, June). Nova StatStrip®: Could this device be used to effectively implement tight glycaemic control and triage blood glucose and insulin management in critical illness (device evaluation compared to Roche Cobas b221 reference methodology)? Poster session presented at the meeting of the European Congress of Clinical Chemistry and Laboratory Medicine, Innsbruck, Austria.


**Diabetic Patient Populations**


**Dialysis Patient Populations**


**Laboratory Evaluations**


**Neonatal Patient Populations**


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**StatStrip Product Labeling**

The listed scientific and medical journal publications and presentations herein describe information and uses of the Nova StatStrip family of meters and StatStrip Glucose Test Strips. The U. S. Food and Drug Administration has not cleared any glucose monitoring system for use with critically ill patients.

**Indications for Use**

The Nova StatStrip Glucose Hospital Meter is intended for *in vitro diagnostic use* by health care professionals and for Point-Of-Care usage for the quantitative measurement of glucose in capillary, venous and arterial whole blood. It is indicated for use in a clinical setting by healthcare professionals as an aid to monitor the effectiveness of diabetes control.

Nova StatStrip Glucose Test Strips are intended for use only with the StatStrip Glucose Hospital Meter for quantitative tests. The glucose meter is intended to quantitatively measure glucose (sugar) in whole blood. The Glucose Meter is calibrated to provide plasma equivalent results to laboratory methods. Nova StatStrip Glucose Test Strips are for testing outside the body (in vitro diagnostic use only).

Nova StatStrip Control Solutions is intended for use with the Nova StatStrip Glucose Hospital Meter and Nova StatStrip Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results. There are three levels of controls, (Level 1, Level 2, and Level 3). These solutions will be offered for sale separately from the meter.

Nova StatStrip Glucose Linearity Kit solutions are used to check the linearity of the Nova StatStrip Glucose Hospital Meter System. (U. S. Food and Drug Administration, Office of In Vitro Diagnostic Device Evaluation and Safety, 2006)

**Precautions**

- Prior to use, read the StatStrip Glucose Meter Instructions for Use Manual.
- Capillary blood glucose testing may not be appropriate for persons with decreased peripheral blood flow, as it may not reflect the true physiological state. Examples include, but are not limited to, severe hypotension, shock, hyperosmolar-hyperglycemia (with or without ketosis) and severe dehydration.
- DO NOT reuse test strips. Strips are designed to be disposed after a single use.
- Discard used test strips according to local regulations.
- Use only the Nova StatStrip Glucose Test Strips for testing with the Nova StatStrip Glucose Meter.
- If test result is higher or lower than expected, run a control solution test.
• Remove the test strip from the vial only when ready to test.
• Do not use the test strip if the expiration date has passed, for this may cause inaccurate results.
• Do not tamper with the test strip. (Nova Biomedical, 2012)

**Glucose Interferences:**
The StatStrip Glucose Meter exhibits no interference from the following substances at known therapeutic levels: Acetaminophen, Ascorbic Acid, Dopamine, Ephedra, D(+) Galactose, Ibuprofen, L-Dopa, Methyl-Dopa, Salicylate, Tetracycline, Tolazamide, and Tobutamide.
The StatStrip Glucose Meter exhibits no interference from the following substances at or above the upper clinical normal range concentrations: Bilirubin, Cholesterol, Creatinine, Triglycerides, and Uric Acid.
The StatStrip Glucose Meter exhibits no interference from the following substances at the normal therapeutic levels found in renal dialysis: D(+) Maltose monohydrate, D(+) Maltotetraose, and D(+) Maltotriose.
The StatStrip Glucose Meter exhibits no interference in blood specimens with hematocrits from 20% to 65% or with varying oxygen content. (Nova Biomedical, 2012)
