
StatStrip® Ketone Strips Test Monitored: Blood Ketone, Haematocrit Corrected Ketone Test Reported: 10 seconds Test Strip Volume: 0.8 µL Test Methodology: Electrochemistry Sample Types & Operating Modes: Whole Blood, Arterial, Venous, Capillary Ketone Measurement Range: StatStrip Hospital Meter 0.0-7.0 mmol/L StatStrip Ketone Meter 0.0-8.0 mmol/L Interferences Eliminated: Haematocrit, Ascorbic Acid, Uric Acid, (Acetaminophen) Paracetamol, Bilirubin, Maltose, Galactose, Xylose, Oxygen Test Strip Stability: 24 months from date of manufacture 3 months open-stability

StatStrip® Xpress Meter Test Monitored: Blood Ketone, Haematocrit Corrected Ketone Test Reported: 10 seconds Test Strip Volume: 0.8 µL Test Methodology: Electrochemistry Sample Types & Operating Modes: Whole Blood, Arterial, Venous, Capillary Ketone Measurement Range: StatStrip Hospital Meter 0.0-7.0 mmol/L StatStrip Ketone Meter 0.0-8.0 mmol/L Interferences Eliminated: Haematocrit, Ascorbic Acid, Uric Acid, Paracetamol, N-acetylcysteine, Maltose, Galactose, Paracetamol, Bilirubin, Xylose, Oxygen Test Strip Stability: 24 months from date of manufacture 3 months open-stability

StatStrip® Handheld Meter Weight: 220 g (0.49 lbs) Size: 147 mm x 79 mm x 30 mm (5.8 in x 3.1 in x 1.18 in) Meter Data Storage: 1,000 tests QC Tests: 200 tests Users: 4,000 users Connectivity: RJ-45 Ethernet Port Protocol: TCP/IP Ethernet 100 Mbit Standard: POCT-C A Compliant Test Strip Operating Ranges: Temperature Glucose: 3°C-40°C (37°F-104°F) Temperature Ketone: 3°C-40°C (37°F-104°F) Altitude: Up to 4,572 meters (15,000 feet) Humidity: 10% to 90% relative humidity Battery Information: Type: 3.7V Li Polymer Rechargeable Battery

StatStrip® Handheld Meter Weight: 75 g (0.2 lbs) Size: 91 mm x 58 mm x 23 mm (3.6 in x 2.3 in x 0.9 in) Data Storage: Patient & QC Tests: 400 tests total (FIFO) Patient Tests: 1,000 tests QC Tests: 400 tests QC Tests: 400 tests Total: 4,000 users

Nova Biomedical

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Test Methodology:


Certifications and Compliance: Nova Biomedical is certified to the Quality System Regulations and JIS 13485:2001.

Test Methodology: Electrochemistry

Patient & QC Tests: 400 tests total (FIFO)

Battery Information: Type: 3.7V Li Polymer Rechargeable Battery

Certifications and Compliance: Nova Biomedical is certified to the Quality System Regulations and JIS 13485:2001.

Data Storage: Patient Tests: 1,000 tests QC Tests: 200 tests

Battery Information: Type: 3V Li Button Battery

Eliminates Interferences Due to Haematocrit, Maltose, Galactose, Paracetamol, N-acetylcysteine, Ascorbic Acid and Uric Acid

Eliminates Calibration Codes

Over 70 Publications

A New Class of Analytical Performance

Most Accurate Glucose Strip — Proven in Over 70 Publications

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Eliminates Calibration Codes

1.2 Microliter Sample, Glucose Results in 6 Seconds

Wireless Connectivity Available

Measures Beta-hydroxybutyrate, the Preferred Ketone for Monitoring Ketoadosis

StatStrip® Glucose Strips

StatStrip® Ketone Strips

StatStrip® Xpress Meter

StatStrip® Hospital Meter
Most Accurate Glucose Strip Performance
Nova Biomedical has developed advanced biosensor strip technology to meet the demand for greater accuracy in glucose meters used on hospitalized patients.

StatStrip is the world’s first glucose meter to measure and eliminate interferences that cause erroneous glucose readings on other glucose meters and strips. StatStrip eliminates haematocrit interferences; electrochemical interferences such as paracetamol, uric acid, and ascorbic acid; and interferences from maltose and galactose (immunoglobulin preparations), icodextrin (dialysis solutions), and oxygen. Since StatStrip requires no calibration codes, it not only saves an operator step but also prevents the use of an incorrect code and the resulting glucose error.

Open Connectivity
NovaConnects enables connectivity to a large library of POC devices. With NovaConnects, hospitals have the flexibility to make POC device decisions based on device needs and benefits.

Management of POC Operators
NovaConnects provides a summary of due or overdue operator certifications as well as online documentation of individual operator certification histories. Batch certification of multiple operators and devices, and automatic recertification according to pre-determined requirements, can be easily performed. Operator performance reports can be generated to show total results and samples history from all operators, or operators from selected locations.

Unlimited Data Capture and Reporting
NovaConnects is a repository for unlimited patient and QC data capture and mining. Data can be mined from current and historical POCT results, including a complete record of system and operator initiated actions. Features include:
- Unlimited data filters and reports based on customer-defined, reusable, or ad hoc queries.
- Electronic notes, pre-defined or free text, with date, time, and operator ID can be added to a single result or a group of results.
- Utilization analysis with counts by operator, device, or result type can be viewed.
- Graphic display of data simplifies analysis.

Glucose Results by Unit

<table>
<thead>
<tr>
<th>Glucose Level</th>
<th>% of Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;3.8 mmol/L</td>
<td>20%</td>
</tr>
<tr>
<td>3.8-5.8 mmol/L</td>
<td>20%</td>
</tr>
<tr>
<td>5.9-8.3 mmol/L</td>
<td>20%</td>
</tr>
<tr>
<td>8.4-10 mmol/L</td>
<td>20%</td>
</tr>
<tr>
<td>&gt;10 mmol/L</td>
<td>20%</td>
</tr>
</tbody>
</table>

Online StatStrip E-Learning
Nova Biomedical offers the StatStrip E-Learning training course, a self-paced operator training and certification program. E-Learning combines slides, video, periodic quizzes, and feedback to optimize effectiveness.

The StatStrip E-Learning program includes modules on system overview, QC, patient testing, and additional procedures.
Remote Customization and Control of StatStrip Meters

POC coordinators can upload setup and control functions for meters assigned to each location. Supervisory controls include:
- Operators and privilege levels
- Normal, abnormal, and critical ranges
- Mandatory data fields
- Quality control (QC) requirements (pass/fail or numeric option, QC frequency, QC lockout, or QC prompting)
- Download docking requirements

Unique StatStrip Connectivity Features

StatStrip can be custom configured for each meter location, department, and facility. StatStrip meters are network ready, eliminating the need for costly terminal servers. 1D or 2D barcode scanning is available. On-screen, operator messages can be broadcast to multiple users or a specific user for viewing at meter log-on.

Consolidate and Manage Connectivity

NovaConnects™ is an easy-to-use total system for point-of-care (POC) connectivity that represents the many connectivity options for Nova Biomedical’s products. NovaConnects provides a total solution for managing an entire POC testing program that encompasses Nova branded devices, multiple networking options, and partnerships with the leading middleware companies around the world. Features include:

- Connects to LIS/HIS via POCT 1-A2, ASTM or HL7
- Open connectivity to most POC devices
- Dashboard indicators for rapid identification of data flow exceptions
- A consolidated view of all results held for operator intervention prior to being sent to the LIS/EMR

Accuracy Proven in Over 70 Publications

Over 70 published hospital studies throughout the world prove that Nova’s StatStrip glucose sensor technology dramatically improves accuracy by eliminating hematocrit and other interferences. These studies have been conducted at some of the most prestigious hospitals and diabetes centers in the world including the Mayo Clinic; Johns Hopkins University School of Medicine; University of Toronto, Sunnybrook Health Sciences Centre; Addenbrooke’s Hospital, Cambridge University Hospitals, UK; WEQAS and University Hospital, Cardiff, Wales; and Isala Klinieken, Netherlands.

“StatStrip demonstrated greater accuracy compared to the other meters used and was the only meter satisfying the requirements of ISO 15197 performance criteria.”

Herkner et al.

“Results of this study indicated good method performance, with total error within allowable limits for laboratory glucose measurement, which is a fundamental prerequisite in setting adequate treatment decisions improving critically ill patient outcomes.”

Biljak et al.

Studies Cover Many Patient Care Areas

- Inpatient Floors Evaluation of a Point-of-Care (POC) Glucose Meter Suitable for Use in Complex Tertiary Care Facilities. Chan et al.
- Comparison of Four Hospital Based Glucose Meter Technologies for Accuracy, Precision and Interferences Encountered in Hospitalized Patients. Bewley et al.
- ICU Improved Blood Glucose Levels Achieved in ICU Patients Using Hematocrit Corrected Glucose Meter and Blood Gas Analyzer Results. Roman et al.
- Validation of a glucose meter at an intensive care unit. Castano Lopez et al.
- NICU Performance of the Nova StatStrip Point-of-Care Glucose Meter in a Neonatal Intensive Care Unit. Tendl et al.
- Clinical performance of the new glucometer in the nursery and neonatal intensive care unit. Nuntanumit et al.
- Burn Unit Hematocrit Effects Lead to Inadequate Glycemic Control and Insulin Dosing in Adult Burn Patients. Godwin et al.
Only Bedside Glucose Meter to Measure and Correct Glucose Errors Caused by Abnormal Haematocrit Levels

Abnormal haematocrit levels are commonly found in hospitalized patients. Low haematocrit levels result in erroneously high glucose results, while high haematocrit levels result in erroneously low glucose results. Glucose meter errors of 40% or more have been reported, due to the effects of haematocrit. These errors can cause either under- or over-dosing of insulin, resulting in unsafe levels of hyperglycemia or hypoglycemia.

According to a published study at the Mayo Clinic, “only the Nova 4-channel StatStrip glucometer continued to provide accurate glucose results as patient haematocrits varied from 20 to 65%.”

StatStrip is the only bedside glucose meter to measure and correct glucose results for varying haematocrit levels. One of its four measuring wells measures and corrects for haematocrit.

“With the exception of the Nova StatStrip, all meters were affected by variable haematocrit.”

“StatStrip also showed little effect from varying levels of hematocrit that are encountered in our hospital patients – especially those...cardiac surgery patients on perfusion pumps.”

1.2 Microliter Capillary, Venous, Arterial, or Neonatal Samples

A 1.2 microliter sample size results in less pain for the patient, as sampling from central venous or arterial lines eliminates the fingerstick.

End-filled capillary action test strips are designed for fast, easy sample uptake.

Glucose Results in 6 Seconds, Ketone Results in 10 Seconds

The time spent by point-of-care (POC) personnel to perform frequent bedside testing is reduced by the fast analysis time and elimination of the calibration code step.

Prevents Sample Dosing Errors

StatStrip prevents glucose errors due to sensor over- or under-filling. StatStrip electrochemically monitors the movement of blood across each of the four measurement wells. Results are reported only if all four measurement wells are filled.

Manual Offline Test Entry

StatStrip supports touchscreen entry of an unlimited number of user-defined offline tests which can be transmitted to the LIS/EMR via Nova middleware. These results can be quantitative or qualitative, numeric input, or free text. Test and control ranges, as well as the lot number, can be input for each test.

• The new StatStrip meter design is 55% smaller and 39% lighter for easier handling. Actual size is shown above.
  - Length 147 mm (5.8 in.)
  - Width 79 mm (3.1 in.)
  - Depth 30 mm (1.18 in.)
• StatStrip has a large results display for easier reading and touchscreen use.
• Abnormal and critical results are prominently flagged with color highlighting and symbols.
Fast, Easy Glucose and Ketone Testing

Simple, Color Touchscreen Operation
An easy-to-read color display prompts the user through simple operating steps and is bright enough to read in a darkened patient's room.

User-defined normal, abnormal, and critical test results are prominently flagged by both color highlighting and symbols.

User comments can be attached to results via selection from a pre-determined list or by free text entry.

No Calibration Coding for Glucose or Ketones
An operator step and possible source of error are eliminated. Erroneous results (up to 43%) can be reported due to miscoding of other meters.

ID or 2D Scanning of Operator and Patient Identification
An integrated scanner can accommodate one-dimensional (1D) or two-dimensional (2D) barcode formats.

Entry of patient ID or operator ID can also be performed via StatStrip’s on-screen, alpha numeric touchpad.

Confirm Patient ID

194546646 is a valid Pt ID

Patient Name: Meltzer, Jessica
Gender: F
Bed: 1152W
DOB: 11/03/1974

Multiple Identifiers, Positive Patient ID
Positive patient ID is available. The display validates patient ID, name, date of birth, gender, room, and bed number—confirming two or more patient identifiers in compliance with regulatory patient safety goals.

StatStrip Glucose Has the Best Correlation to Lab Methods
StatStrip glucose strips with Multi-Well™ technology provide exceptional accuracy, even at critical levels of hypoglycemia and hyperglycemia. In one of the largest studies of any glucose meter (35 participating hospitals, 1,703 data points), StatStrip provided excellent correlation versus plasma hexokinase reference methods throughout a range of 0.5 to 33.3 mmol/L (10 to 600 mg/dL).

StatStrip Glucose Has the Best Correlation to Lab Methods

<table>
<thead>
<tr>
<th>Reference mmol/L (mg/dL)</th>
<th>StatStrip mmol/L (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (100)</td>
<td>5.56 (100)</td>
</tr>
<tr>
<td>5.56 (200)</td>
<td>11.11 (200)</td>
</tr>
<tr>
<td>11.11 (300)</td>
<td>22.22 (400)</td>
</tr>
<tr>
<td>22.22 (400)</td>
<td>44.44 (500)</td>
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<tr>
<td>44.44 (600)</td>
<td>66.66 (700)</td>
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<tr>
<td>66.66 (700)</td>
<td>88.88 (800)</td>
</tr>
<tr>
<td>88.88 (800)</td>
<td>111.11 (900)</td>
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</table>

Competitor A Correlation Study

<table>
<thead>
<tr>
<th>Reference mmol/L (mg/dL)</th>
<th>GDH Meter A mmol/L (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (100)</td>
<td>5.56 (100)</td>
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</tr>
<tr>
<td>88.88 (800)</td>
<td>111.11 (900)</td>
</tr>
</tbody>
</table>

Competitor B Correlation Study

<table>
<thead>
<tr>
<th>Reference mmol/L (mg/dL)</th>
<th>GDH Meter B mmol/L (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (100)</td>
<td>5.56 (100)</td>
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Nova StatStrip demonstrated superior performance based on assessment of slope, intercept, correlation coefficient ($R^2$), mean bias, and standard deviation (SD) of bias.

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Slope</th>
<th>Intercept</th>
<th>$R^2$</th>
<th>Mean Bias</th>
<th>SD of Bias</th>
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<tbody>
<tr>
<td>Nova StatStrip</td>
<td>1703</td>
<td>1.018</td>
<td>0.040</td>
<td>0.995</td>
<td>0.38</td>
<td>9.795</td>
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<tr>
<td>GDH Meter A</td>
<td>559</td>
<td>0.89</td>
<td>0.005</td>
<td>0.950</td>
<td>1.078</td>
<td>33.194</td>
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<tr>
<td>GDH Meter B</td>
<td>251</td>
<td>0.82</td>
<td>1.000</td>
<td>0.974</td>
<td>0.822</td>
<td>33.130</td>
</tr>
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</table>

“Nova StatStrip showed good clinical accuracy and performance for measuring and monitoring glucose levels...in NICU patients and is a suitable alternative to a blood gas analyzer for measuring glucose...in a challenging preterm neonatal population.”

Stahl et al.

“In this study, we found that four-channel glucometers (Nova StatStrip) that use proprietary software to correct hematocrit error before reporting a result, perform at least as well as our correction formula.”

Pocock et al.
Maltose, galactose, and n-acetylcysteine.

Electrochemical interferences eliminated are paracetamol (acetaminophen), ascorbic acid (vitamin C), uric acid, and non-glucose sugars including maltose, galactose, and n-acetylcysteine.

StatStrip’s Multi-Well technology employs a patented, electrochemical methodology that can have glucose errors as large as 100 mg/dL in the presence of non-glucose sugars including maltose and galactose. StatStrip does not have these interferences because it does not employ the glucose dehydrogenase PQQ methodology.

Eliminates Glucose Errors Due to Maltose and Galactose Interferences

Different manufacturing lots of conventional glucose test strips vary widely in their sensitivity to blood glucose. This results in the need for a different calibration code to be entered in the meter for each lot of strips. An incorrectly entered calibration code can change the reported glucose value by as much as 43% (Baum et al). StatStrip test strips are code-free and consistent from lot to lot. They are also extremely stable, with a 2-year shelf life and 6-month open vial stability.

Eliminates Calibration Codes

Eliminates Glucose Errors as a Function of Ascorbic Acid

Glucose Error mmol/L (mg/dL)

Ascorbic Acid (mg/dL)

0 5 10 15

StatStrip, Competitor A, Competitor B, Reference

Glucose Error as a Function of Ascorbic Acid

Blood Ketone Is More Accurate than Urine Ketone Testing

Blood ketone testing indicates the patient’s status at the time of the test, whereas urine may have been in the bladder for several hours. Urine testing can also produce false-positive or negative results due to highly colored urine, highly acidic urine, exposure of the urine test strips to air for prolonged periods, drugs such as the ACE inhibitor captopril, or high doses of vitamin C.

Easy to Use

No meter preparation or calibration coding steps are required. Insert a ketone strip and StatStrip automatically recognizes the strip and converts the meter to ketone measuring mode.

Blood Ketone Monitoring Reduces Costs and ICU Length of Stay for DKA Patients

An ICU study evaluated the effectiveness of blood ketone testing versus urine ketone testing for DKA patients. The blood ketone testing group of patients left the ICU 6.5 hours earlier than the urine ketone testing group. This led to savings of 22 hours of nursing time and 375 laboratory investigations, for a total saving of €2,940.

A second study of DKA patients compared a DKA therapy endpoint of pH > 7.3 and blood ketones < 1.0 mmol/L, versus an endpoint of pH > 7.3 and negative urine ketones. The pH/blood ketone endpoint was reached after 17 hours, whereas the pH/urine ketone endpoint was not reached until 28 hours after starting treatment. The mean lag between the blood ketone and urine ketone groups was 11 hours, ranging from 1 to 36 hours.

Blood Ketone Testing Should Be Performed Whenever Glucose Exceeds 14 mmol/L (250 mg/dL)

According to the European Society for Paediatric Endocrinology, the American Diabetes Association (ADA) recommend that blood ketone testing be performed whenever glucose exceeds 14 to 17 mmol/L, for rapid detection or prevention of diabetic ketoacidosis (DKA).

StatStrip Measures Blood Beta-hydroxybutyrate, the Preferred Ketone for Diagnosing Ketoacidosis

According to the European Society for Paediatric Endocrinology, Diabetes UK, ADA and others, blood ketone testing methods that quantify beta-hydroxybutyrate, the predominant ketone body in DKA, are recommended over urine ketone testing for diagnosing and monitoring ketoacidosis.

Blood Ketone Testing Results Obtained From Capillary Samples

Capillary blood samples are not only preferred over urine samples to detect and monitor DKA, they are also easier to obtain and allow for immediate reflex testing of ketones whenever glucose is greater than 14 mmol/L.

Glucose and Ketone Testing Results Obtained From Capillary Samples

Capillary blood samples are not only preferred over urine samples to detect and monitor DKA, they are also easier to obtain and allow for immediate reflex testing of ketones whenever glucose is greater than 14 mmol/L.

“Blood Ketone Testing Should Be Performed Whenever Glucose Exceeds 14 mmol/L (250 mg/dL)”

“Blood Ketone Monitoring Reduces Costs and ICU Length of Stay for DKA Patients”

“The design of StatStrip incorporates separate reaction zones that measure and correct for hematocrit levels and other interfering substances. As a result and as confirmed in this study, StatStrip achieves greater accuracy compared to commonly used glucose meters when applied to samples with known interferences or to a challenging patient population such as peritoneal dialysis patient population.”

“The resolution of DKA depends upon the suppression of ketonemia, therefore measurement of blood ketones now represents best practice in monitoring the response to treatment.”

“The NovaStatStrip glucose meter showed good clinical accuracy and performance for measuring and monitoring glucose levels...was unaffected by varying levels of hematocrit and pH, and is a suitable alternative to a blood gas analyser for measuring glucose.”

“Capillary blood samples are not only preferred over urine samples to detect and monitor DKA, they are also easier to obtain and allow for immediate reflex testing of ketones whenever glucose is greater than 14 mmol/L.”

“Blood beta-hydroxybutyrate testing indicates the patient’s status at the time of the test, whereas urine may have been in the bladder for several hours. Urine testing can also produce false-positive or negative results due to highly colored urine, highly acidic urine, exposure of the urine test strips to air for prolonged periods, drugs such as the ACE inhibitor captopril, or high doses of vitamin C.”

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