Stat Strip® GLU/KET

Nova Hospital Glucose and Ketone Monitoring System

Only glucose meter technology FDA-cleared for use with all patients including critically ill

StatStrip Xpress® 2 Meter

StatStrip® Hospital Connectivity Meter

Accuracy proven in study of 1,698 critically ill patients with 257 different and specific medical conditions

No known clinical interferences

8,000 medications investigated - no clinical interferences found

Wireless connectivity to LIS/HIS

nova® biomedical

Nova StatStrip® Glucose Monitoring System

The only glucose meter technology cleared by the U.S. FDA for use with all patients including critically ill

In the last several years an unacceptably high number of adverse patient events and more than 14 deaths have been traced to the use of glucose meters in hospitals in the U.S.[1-3] The FDA now requires hospital meters to be designed for and tested with critically ill patients in order to be cleared for use with this patient population. 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.[4]

StatStrip Glucose has been designed specifically to measure and correct for 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 complex 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.

StatStrip® Glucose Hospital Meter System

"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. It is important for manufacturers of glucose meters used in hospitals to design and test their devices for use in all hospitalized patients."[4]

Alberto Gutierrez, Director of the Office of In Vitro Diagnostics and Radiological Devices
Center for Devices and Radiological Health, FDA

Only glucose meter technology FDA-cleared for use with ALL patients, ALL departments

Nursing and point-of-care (POC) operators can perform StatStrip Glucose testing with all patients including critically ill.

Accuracy proven in over 138 publications

Over 138 published studies throughout the world have proven that Nova's StatStrip Glucose test strip sensor technology dramatically improves accuracy by measuring and correcting for haematocrit 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 College of Medicine, Rochester, Minnesota; The Johns Hopkins University School of Medicine, Baltimore, Maryland; University of Toronto Sunnybrook Health Sciences Centre, Toronto, Canada; Addenbrook's Hospital, Cambridge University Hospitals, United Kingdom; University Hospital of Wales, Cardiff, Wales; Isala Klinieken, Zwolle, Netherlands; Saint-Pierre Hospital, Brussels, Belgium; and Saitama Medical University, Saitama, Japan.

Studies cover many patient care areas

Inpatient

Evaluation of a Point-of-Care Glucose Meter for General Use in Complex Tertiary Care Facilities[5]

Comparison of Four Hospital Based Glucose Meter Technologies for Accuracy, Precision and Interferences Encountered in Hospitalise Patients[6]

ICU

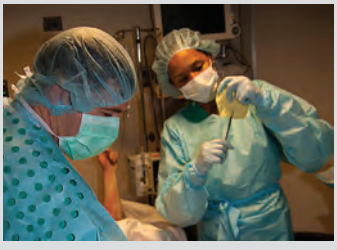
Improved Blood Glucose Levels Achieved in ICU Patients Using Haematocrit Corrected Glucose Meter and Blood Gas Analyser Results[7]

Validation of a Glucose Meter at an Intensive Care Unit[8]

NICU

Performance of the Nova StatStrip Point-of-Care Glucose Meter in a Neonatal Intensive Care Unit[9]

Clinical Performance of the New Glucometer in the Nursery and Neonatal Intensive Care Unit[10]



Burn Unit

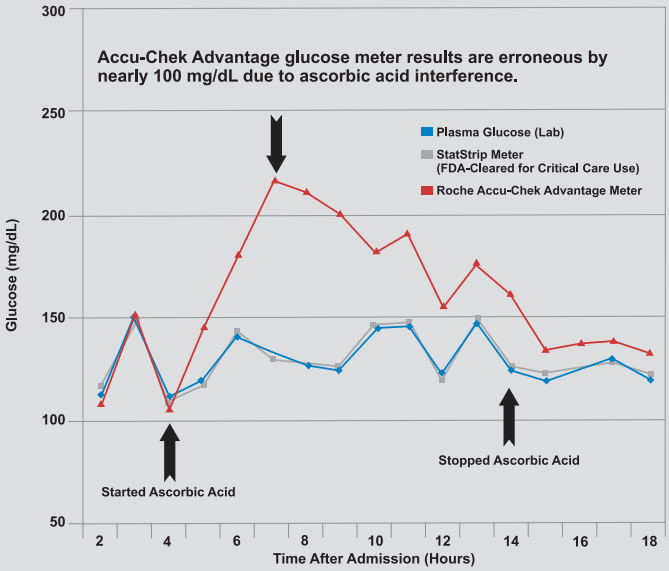
Haematocrit Effects Lead to Inadequate Glycemic Control and Insulin Dosing in Adult Burn Patients[11]

No Known Clinical Interferences

Measures and corrects for errors caused by interferences

StatStrip Glucose Multi-Well technology employs a patented, additional inference test well to measure and correct for electrochemical interferences, including paracetamol, ascorbic acid (vitamin C), uric acid, maltose, galactose, dopamine, and n-acetylcysteine.

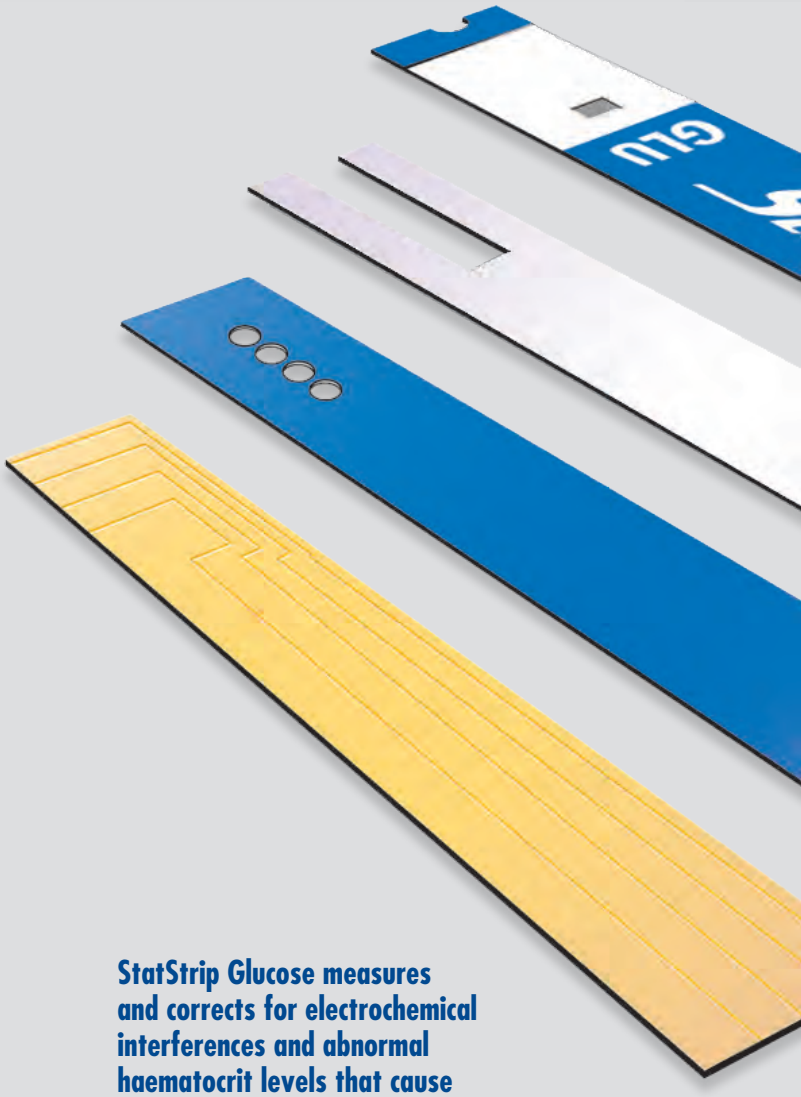
Glucose Error from Ascorbic Acid Interference[12]



StatStrip Glucose results provide excellent equivalence to the central laboratory reference method for critically ill patients on ascorbic acid therapy. The Roche Accu-Chek Advantage meter results were incorrect by nearly 100 mg/dL due to ascorbic acid interference. Treatment based on Accu-Chek results would have caused insulin dosing errors and possible hypoglycaemia.[12]

Glucose errors due to interferences result in insulin dosing errors

Boyd et al. studied the effect of glucose measurement errors on insulin dosing error rates. Glucose errors of 15% resulted in very significant insulin dosing error rates, with two-step or greater errors of insulin dosing occurring more than 5% of the time.[13]



StatStrip Glucose measures and corrects for electrochemical interferences and abnormal haematocrit levels that cause glucose meter error.

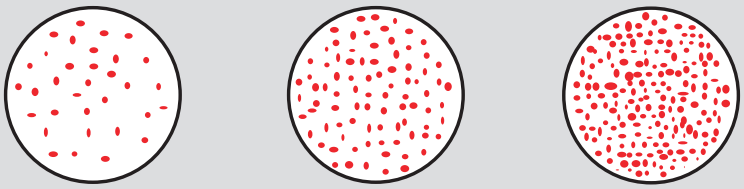
There is a separate test strip well that measures and corrects for electrochemical interferences and for haematocrit, respectively, ensuring the most accurate results.

"In one of our patients' samples with intravenously administered ascorbic acid we saw a positive bias in all glucose meters except StatStrip."[14]

"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 other commonly used glucose meters when applied to samples with known interferences or to a challenging patient population such as peritoneal dialysis patient population."[15]

Measures and corrects for glucose meter errors caused by abnormal haematocrit levels

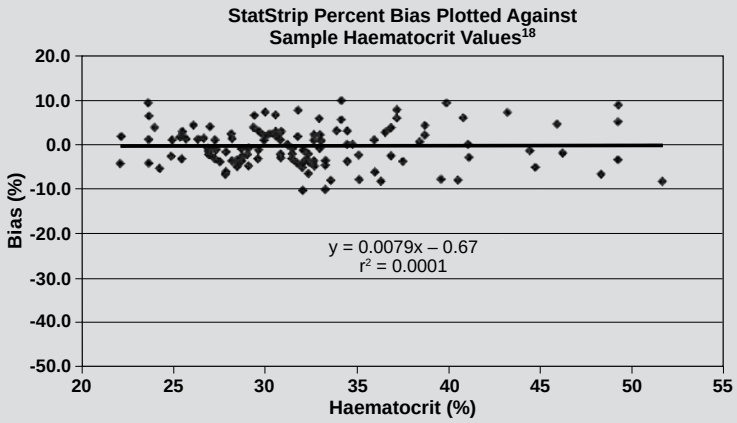
Low haematocrit (anemia) is the leading cause of glucose meter error. The average haematocrit among patients at intensive care unit (ICU) admission is 33% to 34% and continues to decline during ICU stay.[16,17] Low haematocrit levels result in erroneously high glucose results, while high haematocrit levels result in erroneously low glucose results. StatStrip Glucose measures and corrects for the effects of haematocrit throughout the haematocrit range encountered in hospitalised patients.



25% Hct
Glucose Results
Artificially High
Up to 25%

43% Hct
Glucose Results
Normal

65% Hct
Glucose Results
Artificially Low
Up to 30%



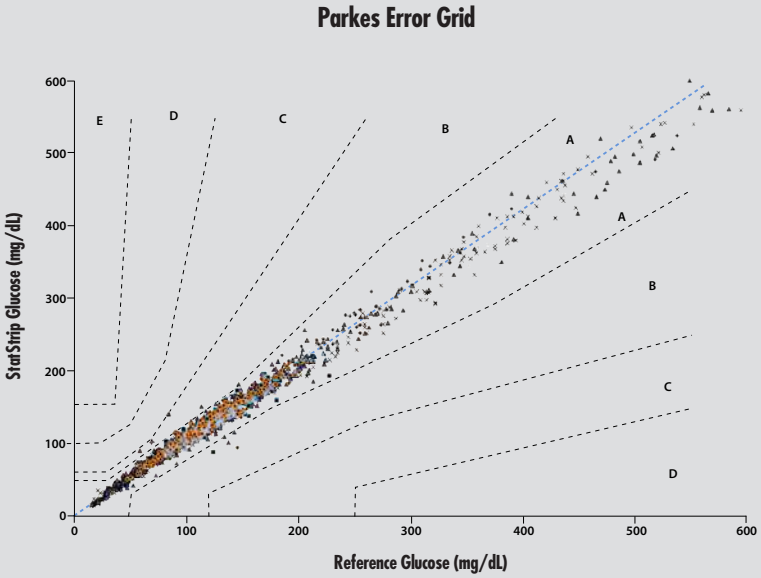
"With the exception of the StatStrip, all meters were affected by variable hematocrit."[19]

"Nova StatStrip Glucose meter showed good clinical accuracy and performance for measuring and monitoring glucose levels...[and] was unaffected by varying levels of hematocrit and pH, and is a suitable alternative to a blood gas analyser for measuring glucose."[9]

Most Accurate Glucose Strip Performance

Exceptional accuracy proven in study of 1,698 critically ill patients

An international, five-hospital, multicentre study validated StatStrip Glucose accuracy against new Clinical and Laboratory Standards Institute (CLSI) POCT12-A3 accuracy guidelines. A total of 1,815 paired patient glucose results from acutely and critically ill patients were compared to an IDMS aligned plasma hexokinase laboratory reference method. StatStrip Glucose demonstrated excellent equivalence to the laboratory reference method and met new CLSI accuracy guidelines.[20]



System Accuracy Comparison: POCT12-A3

MPE	± 12 mg/dL	± 12.5 %	± 15 mg/dL or ± 20%
Glucose Concentration	<100 mg/dL	>100 mg/dL	75 mg/dL
Setpoint	>95%	>95%	<2%
Study Results	606/635 (95.4%)	1139/1180 (96.5%)	13/1815 (0.7%)

StatStrip Glucose accuracy improves outcomes for critically ill patients

Critically ill patients frequently exhibit confounding factors such as abnormal haematocrit levels and complex drug regimens that can cause glucose meter inaccuracy. Glucose meter inaccuracy exposes patients to greater risk for poor glycaemic control and hypoglycaemia. StatStrip Glucose patented technology automatically measures and corrects for these factors.

StatStrip Glucose accuracy has been shown to improve glycaemic control and outcomes in critically ill patients, including:

- Improved insulin dosing[22]
- 38% reduction in glycaemic variability (CONGA*)[12]
- 34% reduction in insulin rate (U/hr)[12]
- 86% reduction in hypoglycaemic events[12]
- Reduction in mortality (severe burns) from 9.2% to 6%[23]

*continuous overall net glycemic action

"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."[21]

Measures Ketones

Easy to use

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

Blood ketone testing should be performed whenever glucose exceeds 14 mmol/L (250 mg/dL)

Diabetes UK, the Canadian Diabetes Association, European Society for Paediatric Endocrinology, and 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 Glucose/Ketone 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.[27-30]

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.[29,30]

Blood ketone is more accurate than urine ketone testing

Blood beta-hydroxybutyrate testing indicates the patient's status in real time, whereas urine that may have been in the bladder for several hours does not. Urine testing can also produce false positive or negative results when the urine is very colored or highly acidic, and when the urine test strip has been exposed to air for prolonged periods, drugs such as the ACE inhibitor captopril, or high doses of vitamin C.

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 savings of €2,940.[25]

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.[26]

"The study reports that the implementation of an auto-correcting POC [point-of-care] GMS [glucose measuring system] robust to confounding factors enables proper IIT [intensive insulin therapy] and improves glycemic control."[12]

"Improved accuracy was associated with fewer endocrinology consults and a decrease in relative mortality; there was no change in LOS [length of stay]."[23]

"The accuracy of a new hospital glucose meter (StatStrip) was not affected by any of the interfering substances and therefore offers improved clinical accuracy and reliability for measuring glucose in hospitalised patients."[24]

Fast, Easy Glucose and Ketone Testing

Simple, colour touchscreen operation

A colour display prompts the user through simple operating steps. The bright screen is easy to read, even in a darkened patient 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 codes

An operator step and possible source of error are eliminated. Erroneous results (up to 60%) can be reported due to miscoding of other meters.[31]

Eliminates the need for single lot use

StatStrip Glucose/Ketone test strip lots perform consistently without the need for lot-based calibration coding. StatStrip Glucose/Ketone lots can be used interchangeably.

Eliminates the need for new lot validation studies

StatStrip Glucose/Ketone test strip lots are factory verified for compliance with accuracy, linearity, precision, and lot-to-lot bias. Test strip lots can move from receiving dock directly to floors without new lot validation studies —saving time, labor, and consumable costs.

Bidirectional wireless meter connectivity

StatStrip Glucose/Ketone now offers both hard wired and wireless bidirectional, dual-band meter connectivity for data integration with patient records. Complete security and encryption is provided in both formats. Results are captured in the medical record without the need for meter docking.

Small and lightweight for easier use

Length:	148 mm	(5.8 in)
Width:	78 mm	(3.0 in)
Depth:	30 mm	(1.18 in)
Weight:	220 g	(0.49 lb)

1.2 microlitre capillary, venous, arterial, or neonatal sample

A small, 1.2 microlitre sample size results in less pain for the patient. End-filled capillary action test strips are designed for fast, easy sample uptake.

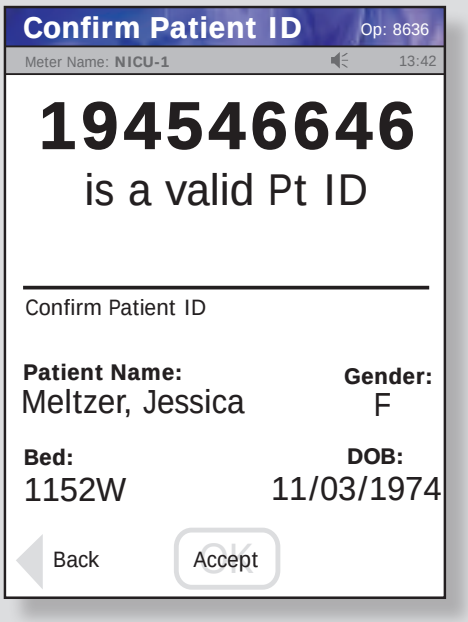
Glucose results in 6 seconds, ketone results in10 seconds

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

1D or 2D scanning for 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 Glucose's on-screen, alpha numeric touchpad.



Multiple identifiers for positive patient ID

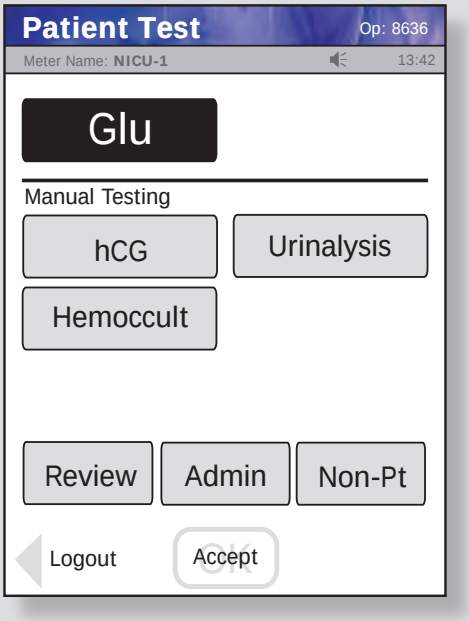
Positive patient ID is available. The display validates patient ID, name, date of birth, gender, and room and bed numbers—confirming two or more patient identifiers in compliance with regulatory patient safety goals.

No dosing errors

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

Manual, offline test entry

StatStrip Glucose/Ketone supports touchscreen entry of an unlimited number of user-defined, offline tests that 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 range, as well as lot number, can be input for each test.



Comprehensive Point-of-Care Connectivity

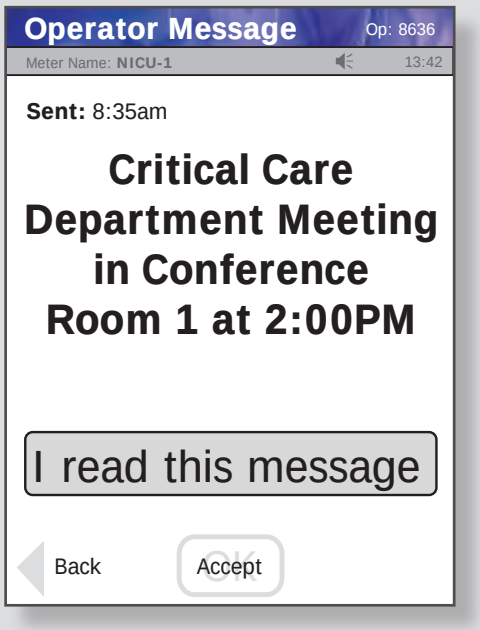
Remote customisation and control of StatStrip Glucose/Ketone meters

POC coordinators can upload set-up 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 Glucose/Ketone connectivity features

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



Consolidate and manage connectivity

NovaNet is a web-based configuration and communication tool for StatStrip meters that runs on a hospital's server and is accessed using a web browser from any secure network location. NovaNet allows simple bidirectional communications between Nova devices, middleware, and the LIS/HIS interface.
Features include:

- Connecting to LIS/HIS via POCT1-A2, ASTM, or HL7
- Configuration of Nova devices based on the unique requirements of each department or location
- Dashboard indicators for rapid identification of data flow exceptions
- Consolidation and transfer of data from Nova POC meters and Stat Profile analyzers into the LIS/HIS

Bidirectional wireless meter connectivity

StatStrip Glucose/Ketone now offers both hard wired and wireless bidirectional, dual-band meter connectivity for data integration with patient records. Complete security and encryption is provided in both formats. Results are captured in the medical record without the need for meter docking.

Management of POC operators

- Summary of due or overdue operator certifications
- Online documentation of individual operator certification histories
- Batch certification of multiple operators and devices, and automatic recertification according to pre-determined requirements
- Operator performance reports show total results and samples' history from all operators, or operators from selected locations

Operator Certification

File Edit View Exceptions Help

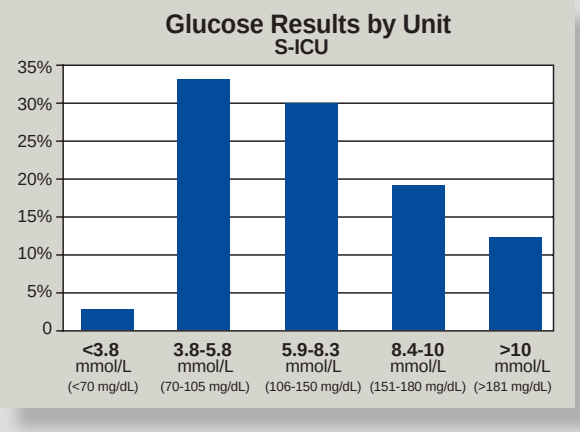
Certification

Location	Operator Code	Operator Name	Date Due
GH-N/ED	15283	Brown, Owen O	5/4/2012
GH-N/ED	1560	Clarke, Rebekah J	5/4/2012
GH-N/ED	90166	Dart, Rudy R	5/4/2012
GH-N/ED	26843	Hardy, Richard G	5/4/2012
GH-N/ED	49432	Lark, Aaron G	5/4/2012
GH-N/ED	304	Nova, Rebecca J	5/4/2012
GH-N/ED	84512	Ready, Herman N	5/4/2012
GH-N/ED	14987	Roster, Dawn X	5/4/2012
GH-N/ICU	19737	Yellow, Becky S	Expired
GH-N/ICU	10138	Zoo, Ann T	Expired
GH-N/Surg	37399	Jarvis, Wanda W	Expired
GH-N/Surg	72517	Penny, John M	Expired

Unlimited data capture and reporting

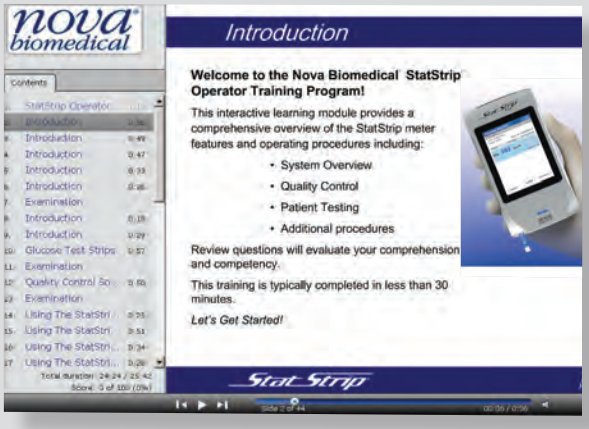
NovaNet is a repository for unlimited patient and QC data. Data can be mined from current and historical POC testing results, including a complete record of system and operator initiated actions. NovaNet's data capture and reporting capabilities can be expanded further through the use of middleware applications. Features include:

- Reporting and data filtering based on customer-defined, reusable, or ad hoc queries
- Electronic notes, pre-defined or free text, with date, time, and operator ID
- Utilisation analysis with counts by operator, device, or result type
- Graphic display of data through middleware to simplify analysis



Online StatStrip Glucose/Ketone E-Learning

Nova's StatStrip Glucose/Ketone E-Learning training course is a self-paced operator training and certification program. E-Learning combines slides, video, periodic quizzes, and feedback to optimise effectiveness.



The E-Learning program modules cover system overview, QC, patient testing, and additional procedures.

Stat Strip® GLU/KET

StatStrip® Glucose Strips

Test Measured:..... Blood Glucose, Haematocrit Corrected
Test Reported: ..... Glucose
Test Time: ..... 6 Seconds
Test Strip Volume: ..... 1.2 µL
Test Methodology: ..... Electrochemistry

Sample Types & Operating Modes:
Whole Blood: ..... Arterial, Venous, Capillary, Neonatal

Glucose Measurement Range:
0.6-33.3 mmol/L (10-600 mg/dL)

Interferences, Measured and Corrected:
Haematocrit, Ascorbic Acid, Uric Acid, Paracetamol, Bilirubin, Maltose, Galactose, Oxygen

Test Strip Stability:
30 months from date of manufacture
6 months open-vial stability

StatStrip® Ketone Strips

Test Measured:..... Blood Ketone, Haematocrit Corrected
Test Reported: ..... Ketone
Test Time: ..... 10 Seconds
Test Strip Volume: ..... 0.8 µL
Test Methodology: ..... Electrochemistry

Sample Types & Operating Modes:
Whole Blood: ..... Venous, Capillary

Ketone Measurement Range:
StatStrip Hospital Meter
0.1-7.0 mmol/L

StatStrip Xpress 2 Meter
0.0-8.0 mmol/L

Interferences, Measured and Corrected:
Haematocrit, Ascorbic Acid, Uric Acid, Paracetamol, Bilirubin, Maltose, Galactose, Oxygen

Test Strip & QC Stability:
24 months from date of manufacture
3 months open-vial stability

Certifications and Compliance:
Nova Biomedical is certified to FDA Quality System Regulations and ISO 13485:2003.
Complies to IVDD
Tested According to: EN 61010-1:2001, EN 61010-2-101:2002,EN 60825-1/A1:2002

FDA Labelling: For In-vitro Diagnostic Use.

Nova Biomedical Patent Numbers:
US 6,258,229 US 6,287,451 US 6,837,976 US 6,942,770 EP 1 212 609
CA 2,375,089 CA 2,375,092

Specifications subject to change without notice.

StatStrip® Hospital Meter

Weight: ..... 220 g (0.49 lb)
Size: ..... 146 mm x 79 mm x 30 mm (5.8 in x 3.1 in x 1.18 in)

Meter Data Storage:
Patient Tests: ..... 1,000 Tests
QC Tests: ..... 200 Tests
Users: ..... 8,000 Users

Connectivity:
Data Output: ..... RJ-45 Ethernet Port
Protocol: ..... TCP/IP Ethernet 100 Mbit
Standard: ..... POCT1-A2 Compliant

Operating Ranges:
Temperature Glucose:..... 5˚C-40˚C (41˚F-104˚F)
Temperature Ketone: ..... 5˚C-40˚C (41˚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

Wireless Specifications:
Wireless Standard: ..... IEEE 802.11a/b/g, Ethernet: IEEE 802.3u
Data Rate: ..... Up to 54Mbps
Modulation: ..... 64QAM, 16QAM, BPSK, QPSK, DBPSK, DQPSK and CCK
Frequency Range:..... 2.4 and 5Ghz supported
Wireless Security:..... WEP, WPA, WPA2, RADIUS, 802.1x
Encryption Types:..... RC4, TKIP, AES, PSK, EAP-FAST, EAP-TLS, EAP-TTLS, PEAP-GTC, PEAP-MSCHAPv2, PEAP-TLS, LEAP

StatStrip® Xpress 2 Meter

Weight:..... 75 - 78.5 g (0.2 lb)
Size: ..... 98 mm x 61 mm x 23 mm (3.6 in x 2.4 in x 0.9 in)

Data Storage:
Patient & QC Tests: ..... 400 Tests Total (FIFO)

Operating Ranges:
Temperature Glucose:..... 5˚C-40˚C (41˚F-104˚F)
Temperature Ketone: ..... 5˚C-40˚C (41˚F-104˚F)
Altitude: ..... Up to 4,572 meters (15,000 feet)
Humidity:..... 10% to 90% relative humidity

Battery Information:
Type: ..... 2 AAA Batteries

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