

Next Generation Hospital Glucose/Ketone System

New meter features

- Linux® OS with advanced cybersecurity
- Rugged external meter casing
- Wireless charging
- Sealed battery casing
- RFID (NFC) option
- Haematocrit range extended to 5-75%

Also measures β-hydroxybutyrate (ketones)

Only glucose meter FDA-cleared for use with all critically ill patient samples

- No known clinical interferences
8,000 medications investigated
- Proven in a study of 1,698
critically ill patients with 257
specific medical conditions
- Glucose accuracy proven in over
200 publications



StatStrip Hospital Connectivity Meter



StatStrip Xpress®2
Limited Connectivity Meter

New features

Nova's new Linux-based StatStrip Hospital Glucose/Ketone Meter System has important new features:

- Linux OS advanced cybersecurity
- Rugged external meter casing
- Larger color touchscreen
- Wireless charging
- Improved battery charging capacity
- RFID data entry option

These features add to StatStrip's exceptionally accurate glucose measuring technology that has been validated in over 200 peer reviewed publications and extensively proven in hospital critical care settings for over 15 years.

Linux advanced cybersecurity

StatStrip's Linux based operating system is very secure against computer viruses and other types of malware that affect Microsoft® Windows based operating systems. Linux is the platform of choice for most governments and over 95% of the world's top one million domains due to its inherent defense against attacks and system compromise.¹

CYBERSECURITY

Rugged, external meter casing

To meet the challenges of occasional rough meter use and repeated exposure to harsh disinfecting chemicals, StatStrip's new meter casing uses a unique soft-touch over-molding material.

- Improves grip and significantly reduces the potential for damage due to dropping
- Provides excellent resistance to chemicals and stress cracking from repeated use of the more aggressive disinfectants used in today's healthcare settings
- Meter casing, touchscreen, and sealed battery compartment have been designed and tested to withstand more than 10,950 cleaning and disinfection cycles



Ketone blood test

Ketone testing with a separate test strip facilitates the management of diabetic ketoacidosis (DKA), a potentially life-threatening complication of both type 1 and type 2 diabetes. The American Diabetes Association, European Association for the Study of Diabetes, American Association of Clinical Endocrinology, Diabetes Technology Society and Joint British Diabetes Societies for Inpatient Care recommend blood testing for elevated ketones whenever glucose >11.1 mmol/L to rapidly differentiate lifethreatening diabetic ketoacidosis (DKA) and to direct therapy.

- Measures blood beta-hydroxybutyrate (BHB), the preferred ketone for detecting DKA^{2,3,4}
- Blood BHB is more accurate than urine testing for diagnosing DKA^{3,4}
- Blood BHB monitoring reduces costs and ICU length of stay versus urine testing for DKA patients^{5,6}

Simply insert the ketone test strip and the meter automatically converts to ketone testing mode. No further steps are necessary.

Enhanced data entry options

• RFID Data Entry

StatStrip's new RFID (NFC) tap-and-go feature provides a fast and simple alternative to line-of-sight barcode scanning or touchscreen entry of operator ID and patient ID.



• Improved, illuminated barcode scanner

A new barcode scanner reads both 1D and 2D barcodes, delivers excellent barcode scanning speed and acuity, and accommodates a broad range of barcode types. The lighted barcode scanner brightly illuminates the barcode label for easier scanning.



• Touchscreen Entry

StatStrip's 4-inch color touchscreen screen provides a large onscreen keyboard for gloved-hand entry of alphanumeric operator and patient ID.



Larger color touchscreen

The larger touchscreen provides a brighter and easier to read display.

Improved battery charging capacity

A new battery with 75% more capacity extends meter use-time between charges.

Wireless charging

Wireless meter charging provides faster, easier and safer meter charging in a smaller package. The battery is charged in the meter's sealed compartment and the charger automatically shuts off when the meter is fully charged, reducing energy use and preventing battery overheating.

Expanded wireless connectivity network

A single NovaNet server can support wireless connectivity for all meters throughout multiple facilities.



Measures and corrects errors from clinical interferences

A 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.⁷⁻¹⁸ The Food and Drug Administration (FDA) now requires hospital glucose meters to be accurate even in the presence of the many interferences found in critically ill patients. In order to be cleared for use with this patient population, the FDA requires more stringent clinical proof of accuracy. To date, only the Nova StatStrip Glucose Hospital Meter System has been found to be accurate enough to obtain this FDA critical care clearance for all patients and all sample types.¹⁹

StatStrip is designed specifically to measure and correct clinical interferences that can be present in critically ill patients. The proof data submitted to the FDA included:

StatStrip results from 1,698 critically ill patients from five university medical centers that were 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.

Over 8,000 medications representing 33 parent drug classes and 134 subclasses as designated by the United States Pharmacopeia that were studied for clinical interference; no clinical interferences were observed.



StatStrip Glucose/Ketone
Hospital Connectivity Meter

"This device provides an important public health resource for critically ill hospitalised 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 hospitalised patients."¹⁹

"Users of BGMS [blood glucose monitoring systems] 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."¹⁹

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

FDA-cleared for use with ALL patients, ALL sample types, ALL departments

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



ALL Patients ALL Departments ALL Sample Types

Accuracy proven in over 200 publications

Over 200 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 Facilities²⁰

Comparison of Four Hospital Based Glucose Meter Technologies for Accuracy, Precision and Interferences Encountered in Hospitalised Patients²¹



NICU

Performance of the Nova StatStrip Point-of-Care Glucose Meter in a Neonatal Intensive Care Unit²⁴

Clinical Performance of the New Glucometer in the Nursery and Neonatal Intensive Care Unit²⁵



ICU

Improved Blood Glucose Levels Achieved in ICU Patients Using Haematocrit Corrected Glucose Meter and Blood Gas Analyser Results²²

Validation of a Glucose Meter at an Intensive Care Unit²³



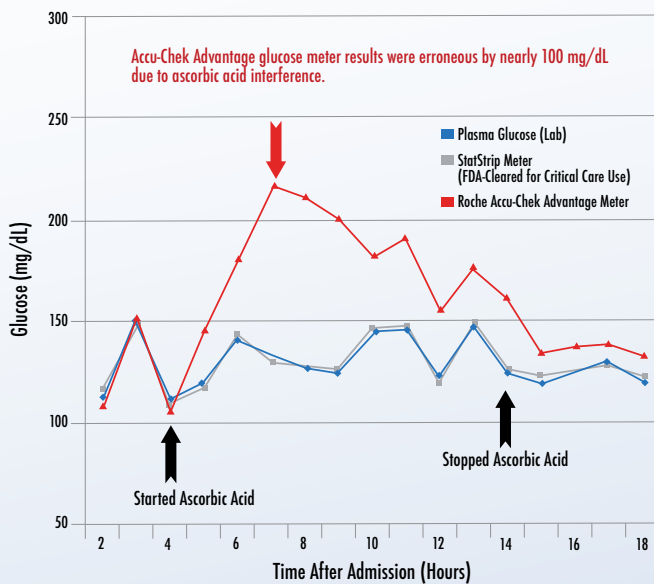
Burn Unit

Haematocrit Effects Lead to Inadequate Glycaemic Control and Insulin Dosing in Adult Burn Patients²⁶

StatStrip technology measures and corrects errors caused by interferences

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

In a university medical center study²⁷, StatStrip provided excellent equivalence to the central laboratory reference method for critically ill burn 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's results would have caused insulin dosing errors and possible hypoglycaemia.



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 in insulin dosing occurring more than 5% of the time.²⁸



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

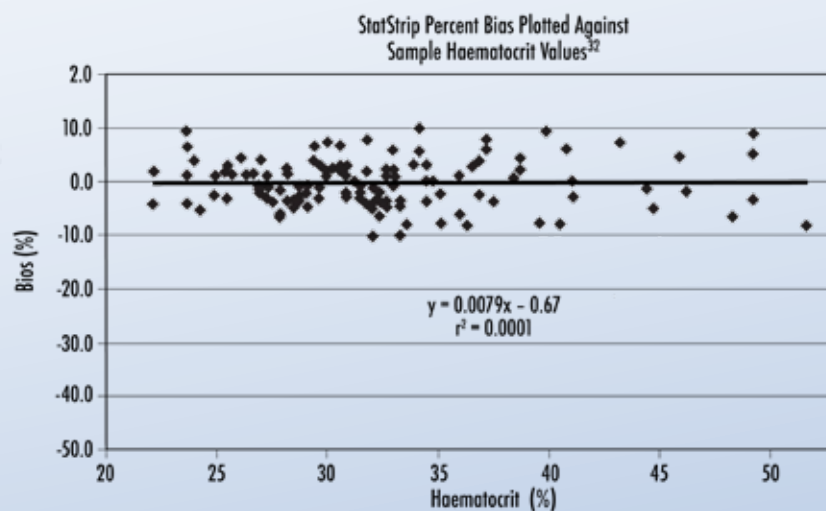
Separate test strip wells measure and correct electrochemical interferences and haematocrit levels, ensuring the most accurate results.

"We present a case of glucose meter interference caused by extremely high therapeutic doses of vitamin C. While the Nova StatStrip glucose meter effectively detected the presence of ascorbic acid interferant and suppressed glucose results, the Roche Inform II and Abbott Precision Xceed Pro demonstrated falsely increased results that could have impacted patient care or possibly led to inappropriate patient treatment."⁹

"In one of our patients' samples with intravenously administered ascorbic acid we saw a positive bias in all glucose meters except StatStrip."²⁹

Measures and corrects errors caused by abnormal haematocrit

Low haematocrit is one of the leading causes 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.^{30,31} Low haematocrit levels result in erroneously high glucose results, while high haematocrit levels result in erroneously low glucose results. StatStrip measures and corrects for the effects of haematocrit throughout the haematocrit range encountered in hospitalised patients.



"With the exception of the StatStrip, all meters were affected by variable haematocrit."³²

"Nova StatStrip Glucose meter showed good clinical accuracy and performance for measuring and monitoring glucose levels...[and] was unaffected by varying levels of haematocrit and pH, and is a suitable alternative to a blood gas analyser for measuring glucose."³³

"The study reports that the implementation of an auto-correcting POC GMS [glucose measuring system] robust to confounding factors enables proper IIT [intensive insulin therapy] and improves glycaemic control."²⁷

"Improved accuracy was associated with fewer endocrinology consults and a decrease in relative mortality; there was no change in LOS [length of stay]."³⁴

Improves sensitivity for neonatal hypoglycaemia

Raizman et al. compared StatStrip and a competitive meter to the laboratory reference method in a large population of critically ill neonatal patients. The study reported that StatStrip improved detection of hypoglycaemia and critically low glucose results:³⁵

	Period 1 Competitor Meter	Period 2 StatStrip	Outcome
Hypoglycaemia sensitivity	63.6%	71.4%	12.3% improvement in detecting Hypoglycaemia with StatStrip
Critical low Glu results sensitivity	68.9%	80.9%	17.4% improvement in detecting critical low Glu results with StatStrip

StatStrip's accuracy improved test utilisation and efficiency, leading to less frequent testing and contributing to reduced overall costs of care (especially important in high volume testing patient populations).

Improves glycaemic variability and time in target range for cardiac surgical patients

A Karon et al. study of critically ill cardiovascular surgical patients found that StatStrip resulted in improved glycaemic variability and time in target range:³⁶

	Period 1 Competitor Meter	Period 2 StatStrip	Outcome
Glycaemic variability (standard deviation)	21.6 mg/dL	13.7 mg/dL	36.5% reduction in glycaemic variability with StatStrip
% GLU values in target range (110-150 mg/dL)	66.7%	74.5%	11.7% increase in time in target range with StatStrip

Improves insulin dosing for critically ill patients

Another Karon et al. study compared StatStrip and a competitive meter to the laboratory reference method using critically ill patients from six different ICUs. The study found that StatStrip:

- Meets the more stringent CLSI POCT12-A3 glucose accuracy guidelines
- Improves insulin dosing, with 99% of StatStrip's data points within the same or one-category dosing as the lab, leading to the same clinical treatment³⁷

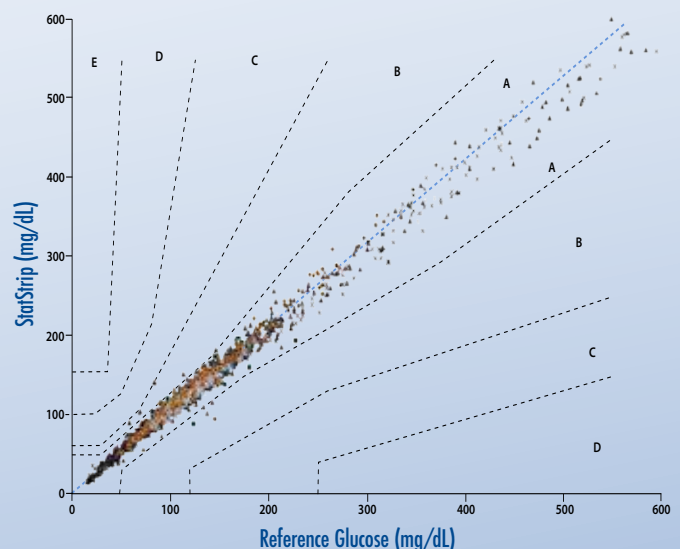
Reduces hypoglycaemia for severely burned patients receiving intensive insulin therapy (IIT)

A study by Tran et al. randomized severely burned patients ($\geq 20\%$ total body surface area) to receive IIT, targeting a glucose level of 111-151 mg/dL and guided by StatStrip or the hospital's current meter. The trial reported lower glycaemic variability, mean insulin rate, and frequency of hypoglycaemia with StatStrip than with the hospital's current meter.²⁷

	Group 1 Competitor Meter	Group 2 StatStrip	Outcome
Glycaemic variability (CONGA)	34.3 mg/dL	21.3 mg/dL	38% reduction in glycaemic variability with StatStrip
Mean insulin rate (Units/hour)	4.02	2.66	34% reduction in insulin rate with StatStrip
Hypoglycaemic events	14 events	2 events	86% reduction in hypoglycaemic events with StatStrip

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

An unprecedented, international, multi-site study of StatStrip's accuracy in critically ill patients demonstrated excellent equivalence to the IDMS aligned hexokinase laboratory reference method, and met or exceeded the FDA's final guidance for glucose meters used in hospitalised patients, including critically ill.^{38,39,40}



Parkes error grid analysis: StatStrip's patient data (n=1,698) versus reference glucose method.

Measures Ketones Using the Same Meter

Blood ketone testing should be performed whenever glucose exceeds 11 mmol/L (200 mg/dL)

The American Diabetes Association, European Association for the Study of Diabetes, American Association of Clinical Endocrinology, Diabetes Technology Society and Joint British Diabetes Societies for Inpatient Care recommend blood testing for elevated ketones whenever glucose >11.1 mmol/L to rapidly differentiate life threatening diabetic ketoacidosis (DKA) and to direct therapy.

StatStrip Glucose/Ketone measures blood beta-hydroxybutyrate, the preferred ketone for diagnosing ketoacidosis^{2,3,4}

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.

Easy to use

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

Ketone testing results obtained from blood samples

Blood samples are not only preferred over urine samples to detect DKA, they are also easier to obtain and allow for immediate POC reflex testing of ketones whenever glucose is greater than 11 mmol/L.

Blood ketone is more accurate than urine ketone testing

Blood ketones indicate 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, or when the urine test strip has been exposed to air for prolonged periods of time. Drugs such as the ACE inhibitor captopril, or high doses of vitamin C can also cause produce erroneous urine ketone results.

Blood ketone monitoring reduces 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.⁵

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 for 28 hours. The mean lag between the blood ketone and urine ketone groups was 11 hours, ranging from 1 to 36 hours.⁶

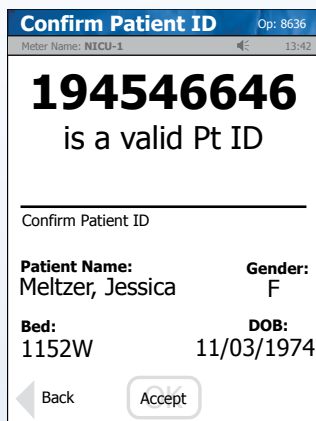


Simple, color touchscreen operation

- A bright, color display prompts the user through simple operating steps and 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.

RFID, barcode or touchscreen entry of operator and patient identification

StatStrip's RFID (NFC) sensor wirelessly reads patient and operator RFID tags. An integrated scanner accommodates one-dimensional (1D) and two-dimensional (2D) barcodes. Patient and operator IDs can also be entered via the touchpad.



Multiple identifiers for positive patient ID

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 Multi-Well® test strips prevent glucose errors due to sensor over- or under-filling by electrochemically monitoring the movement of blood across each of the four measurement wells. Results are reported only if all four wells are filled.

1.2 microliter capillary, venous, arterial, or neonatal sample

The small sample size means less pain for the patient and easy sampling with end-filled, capillary-action test strips.

Glucose results in 6 seconds, ketone results in 10 seconds

Fast analysis reduces the time POC personnel spend performing frequent bedside testing.

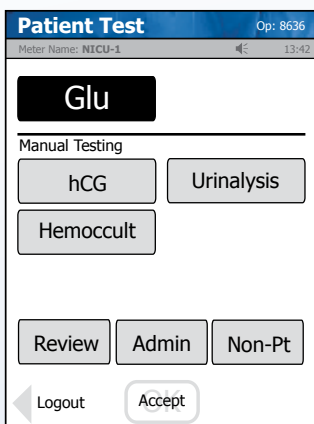


Test strip ejector

StatStrip's ejector button eliminates handling of used test strips, a potential biohazard.

Manual, offline test entry

StatStrip supports touchpad entry of unlimited user-defined, offline tests, which can be transmitted to the LIS/EMR via NovaNet™. Results can be quantitative, qualitative, numeric input, or free text. Test and control range, as well as lot number, can be input for each test.



Eliminates the need for single lot use

StatStrip lots perform consistently without the need for lot-based calibration coding. Lots can be used interchangeably.

Eliminates the need for new lot validation studies and strip sequestering

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

No calibration codes

An operator step and possible error source are eliminated. Erroneous results (up to 60%) can be reported due to miscoding of other meters.⁴¹

Unique connectivity features

- StatStrip can be custom-configured for each meter location, department, and facility
- On-screen operator messages can be broadcast to multiple users or a specific user for viewing at meter log-on, and mandatory click-through acknowledgment can be enabled

Wireless meter connectivity

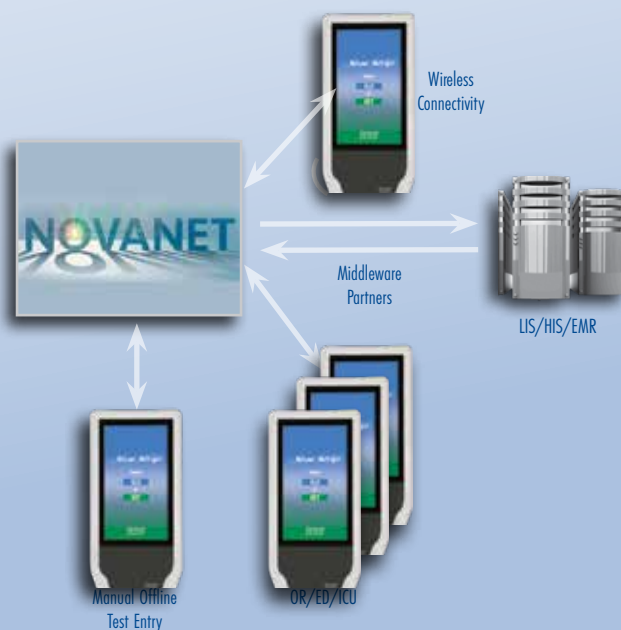
StatStrip Glucose/Ketone offers both hard wired and wireless bidirectional, dual-band meter connectivity for data integration with patient records. Complete security and encryption is provided in both formats. Results are captured in the medical record without the need for meter docking.

Bidirectional connectivity

NovaNet is a configuration and communication tool for StatStrip that runs on a hospital's server and is accessed using a web browser from secure network locations. NovaNet allows simple bidirectional communication between Nova's devices, middleware, and the LIS/HIS interface.

Features include:

- Connection to LIS/HIS via POCT1-A2, ASTM, or HL7
- Configuration of Nova's devices based on the unique requirements of each department or location
- Dashboard indicators for rapid identification of data flow exceptions





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)

Haematocrit Range:

5-75%

Interferences, Measured and Corrected:

Haematocrit, Ascorbic Acid, Uric Acid, Paracetamol, N-acetylcysteine, 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, Neonate

Ketone Measurement Range:

StatStrip Hospital Meter

0-7.0 mmol/L

StatStrip Xpress 2 Meter

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



StatStrip® Hospital Connectivity Meter

Weight:.....215 g (0.47 lb)
 Size:.....158 mm x 77 mm x 28 mm (6.23 in x 3.04 in x 1.11 in)

Meter Data Storage:

Patient Tests:.....1,500 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:.....1 °C - 40 °C (34 °F - 104 °F)
 Altitude:.....Up to 4,572 meters (15,000 feet)
 Humidity:.....10% to 90% relative humidity

Battery Information:

Type:.....3.6V Li Polymer Rechargeable Battery

Wireless Specifications:

Wireless Standard:.....IEEE 802.11a/b/g/n/ac
 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:.....78.5g (0.2lb)
 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:.....1 °C - 40 °C (34 °F - 104 °F)

Temperature Ketone:.....1 °C - 40 °C (34 °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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Certifications and Compliance:

Nova Biomedical complies with FDA Quality System Regulations and is certified to EN ISO 13485:2016. StatStrip meters are tested according to EN 61010-1:2010 EN 61010-2-101:2015.

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