

StatStrip™

Nova Hospital Glucose Monitoring System

A New Class of Analytical Performance



StatStrip™ Xpress™ Meter



StatStrip™ Connectivity Meter

Eliminates Interferences Due to Hematocrit, Maltose, Galactose, Oxygen, Paracetamol, Ascorbic Acid, and Uric Acid

Eliminates Calibration Codes

Laboratory Quality Accuracy at Extended Hypo and Hyperglycemic Ranges

Fast, 6 Second Results

Small, 1.2 Microliter Sample

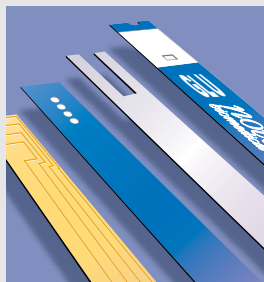
Simple, Color Touch Screen Operation

Flexible POC Control

nova[®]
biomedical

A New Class of Analytical Performance

StatStrip Multi-Well™ Technology Delivers Lab-Like Analytical Performance



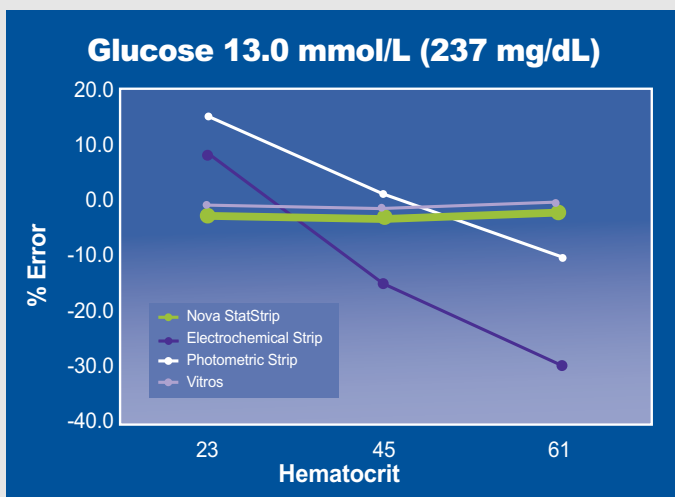
The Nova StatStrip Glucose Monitoring System features a patented Multi-Well™ measuring technology that meets the escalating demands of today's hospital glucose testing. StatStrip technology elevates bedside glucose monitoring to a level of accuracy, precision, and patient safety that approaches the quality of central laboratory testing.

Only Bedside Meter to Eliminate Errors Caused by Hematocrit, Maltose, Galactose, Oxygen, and Electrochemical Interferences

Interferences By Test Strip Technology

Interferences	Glucose Oxidase Optical	Glucose Oxidase Electrochemical	Glucose Dehydrogenase Electrochemical	Nova StatStrip
Hematocrit	YES	YES	YES	NO
Ascorbic Acid	YES	YES	YES	NO
Paracetamol (Acetaminophen)	YES	YES	YES	NO
Uric Acid	YES	YES	YES	NO
Maltose	NO	NO	YES	NO
Galactose	NO	NO	YES	NO
Oxygen	YES	YES	NO	NO

Measures and Eliminates Hematocrit Interferences



800 Bed Teaching Hospital, Rochester, MN

StatStrip is the only bedside glucose meter to measure and eliminate glucose errors due to varying hematocrit levels. One of StatStrip's four measuring wells measures hematocrit.

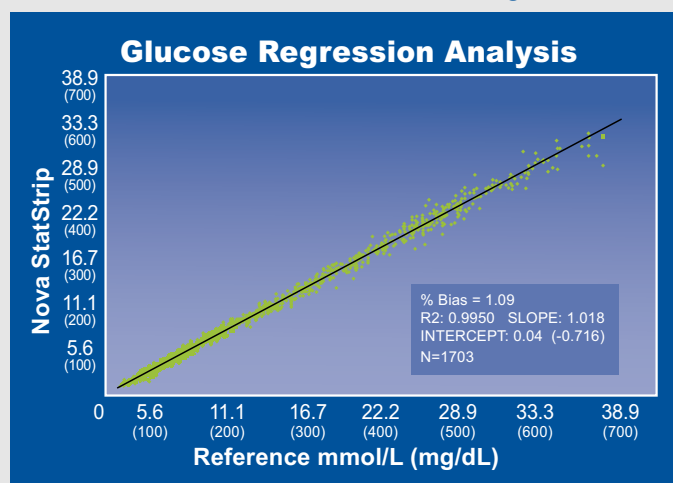
Hematocrit interferences can cause errors as large as 40%.

- Can cause undetected hypoglycemia
- Can cause insulin overdose

Severe hematocrit abnormalities are very common in ICUs.

- Up to 77% of ICU patients have low hematocrit levels.^{1,2}
- Nearly half of ICU patients require red cell transfusions due to low hematocrit. Average hematocrit of these patients pre-transfusion is 22-25%.^{2,3}

Laboratory Quality Accuracy from 0.5-33.3 mmol/L (10 to 600 mg/dL)



¹ von Ahnen N, et al. Crit Care Med. 1999 27:2630-2639.

² Vincent, JL et al. Anemia and Blood Transfusion in Critically Ill Patients. JAMA. 2002 Sept;288(12):1499-507.

³ Corwin HL et al. The CRIT Study: Anemia and blood transfusion in the critically ill – Current clinical practice in the United States. Crit Care Med. 2004 32:39-49.

StatStrip™

Eliminates Calibration Codes

StatStrip's patented Multi-Well technology provides such strict consistency that calibration codes are not necessary.

- Errors due to coding are eliminated
- Testing steps are reduced
- Strip lots can be used interchangeably

Rapidfill™ Prevents Dosing Errors

The StatStrip design incorporates a feature to prevent glucose errors due to over-filling or under-filling of the sensor. Rapidfill electrochemically monitors the blood volume in each of the four measurement wells. Results are reported only if all four measurement wells are filled with blood.

StatStrip™ Xpress™



The StatStrip Xpress meter is an option for hospitals or clinics which do not need data interface/connectivity capability.

- Uses same Multi-Well test strip
- Provides same laboratory quality analytical performance
- Xpress meter is simple, fast and easy to use

Fast, 6 Second Analysis Time

Small, 1.2 Microliter Sample Size

Simple, Color Touch Screen Operation



StatStrip Connectivity Meter

StatStrip™



StatStrip™ Glucose Strips

Tests Measured: Blood Glucose,
Hematocrit 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:

0.5-33.3 mmol/L (10-600 mg/dL)

Interferences Eliminated:

Hematocrit, Ascorbic Acid, Uric Acid,
Paracetamol (Acetaminophen), Bilirubin,
Maltose, Galactose, Xylose, Oxygen

Operating Ranges:

Temperature: 15°C- 40°C (59°F-104°F)
Altitude: Up to 4,570 meters (15,000 feet)
Humidity: 10% to 90% relative humidity
Hematocrit 20%-65%

Reagents and Strips:

Strips: Cases of 36 Boxes
50 strips/box
QC: Three levels (Low, Normal, High);
sold separately
Linearity: Five levels available

Test Strip & QC Stability:

24 months from date of manufacture
3 months open-vial stability

Certifications & Compliance:

Compliance with FDA Quality System
Regulation (QSR), ISO 13485:2003, CSA,
TUV, CE Self-Declared Complies to IVDD,
IEC 61010-2-101:2002, EN 55011:1998,
EN 61000-6-1 and EN 61326 Annex A

FDA Labeling:

For in-vitro diagnostic use



StatStrip™ Connectivity Meter

Weight: 360 g (0.8 lbs)
Size: 153 mm x 82.5 mm x 46 mm
(6.0 in x 3.25 in x 1.8 in)

Data Storage:

Patient Tests: 1,000 tests
QC Tests: 200 tests
Users: 4,000 users

Connectivity:

Meter Data Output: RJ-45 Ethernet Port
Protocol: TCP/IP Ethernet 10 Mbit
Standard: POCT1-A Compliant
Setup Program: NovaNet™ Web-Based
Instrument Manager Software

Battery Information:

Type: 3.7V Li Polymer Rechargeable Battery
Features: Rechargeable/Replaceable
Life: 8 hours in use (approximately 40 tests
w/barcode scans) / 12-24 hours standby

Docking Station:

Optional accessory; desk or wall-mount charging
station with RJ-45 Ethernet jack. 3 LED indicator
lights showing connection status, transmit/receive
data, and charging status. Extra battery slot included
for recharging and storage of spare battery.

Additional Features:

Color, touch screen • Built-in barcode scanner
• Traditional QC with target values assigned to
QC materials • Numeric or pass/fail QC • QC
prompting or QC lock out • Abnormal and
critical ranges flagged by color highlighting
• Canned or free text user comments • Rejecting
of results at meter (optional) for repeat testing
• Flagging of Tight Glycemic Control results
• Accepting patient ID or accession number
• Use of operator password (lock out) • Entry of
ICD-9 Diagnosis codes • Ordering physicians ID
• Slope and intercept adjustment • Web-based
meter configuration by location • Custom
meter configuration by medical unit • Connect
to hospital ADT • Connect to all LIS/EMR
• POCT1-A data output • Optional carrying case
• Units of measure mmol/L or mg/dL



StatStrip™ Xpress™ 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)

Connectivity:

Data Transfer: Strip Port Connection to USB
Data Program: Nova Microsoft®-Excel® based
data transfer software

Battery Information:

Type: 3V Li Button Battery
Features: Replaceable
Life: Minimum 600 tests

Additional Features:

LCD black/white display • Large numeric display
(30 mm) • Traditional QC with target values
assigned to QC materials • Units of measure
based on meter ordered (mg/dL or mmol/L
models) • Auto-shut off of meter when not in use
• Automatic sample detection and analysis start
• Automatic sample counter with date/time
stamp for data tracking • Optional carrying case

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

*Nova Biomedical® is a registered trademark of
Nova Biomedical Corporation.*

*Microsoft® and Microsoft®-Excel® are registered trademarks of
Microsoft Corporation in the United States and/or other countries.*

Specifications subject to change without notice.

nova
biomedical

NOVA BIOMEDICAL HEADQUARTERS: 200 Prospect St., Waltham, MA 02454-9141 U.S.A. TEL: 781-894-0800 800-458-5813 FAX: 781-894-5915 INTL FAX: 781-899-0417

NOVA BIOMEDICAL AUSTRIA: Laxenburger Strasse 33/6, A-1100 Vienna, Austria TEL: (43) 1-603 09 700 FAX: (43) 1-603 09 702 EMAIL: office@novabio.at

NOVA BIOMEDICAL CANADA, LTD: 6810 Kitimat Rd., Unit 5, Mississauga, Ontario L5N 5M2 Canada TEL: 905-567-7700 800-263-5999 FAX: 905-567-5496

NOVA BIOMEDICAL FRANCE: Z.I. de Courtaboeuf, 15 Avenue du Quebec, B.P. 632, 91965 Les Ulis Cedex, France TEL: (33) 1-69188140 FAX: (33) 1-69070160

NOVA BIOMEDICAL GmbH: Adam-Opel-Str. 19 A, 63322 Rödermark, F.R. Germany TEL: (49) 6074-8448-0 FAX: (49) 6074-844833 EMAIL: info@novabiomedical.de

NOVA BIOMEDICAL INDIA: 117C, Sector-2, Pocket-2, Dwarka, New Delhi 110045 India TEL: +91 11 2508 2664 FAX: +91 11 2508 9018 EMAIL: novabio@nde.vsnl.net.in

NOVA BIOMEDICAL K.K.: B-3F Omori Bellport, 26-Minami Oi 6-chome, Shinagawa-ku, Tokyo 140-0013, Japan TEL: (03) 5471-5461 FAX: (03) 5471-5474 EMAIL: m.amano@novabiomedical.co.jp

NOVA BIOMEDICAL U.K.: C3-5, Evans Business Centre, Deeside Industrial Park, Deeside, Flintshire CH5 2JZ United Kingdom TEL: (44) 1244 287087 FAX: (44) 1244 287080 EMAIL: office@novabiomedical.co.uk

IN THE U.S.A.: call toll-free 800-458-5813 **IN CANADA,** call toll-free 800-263-5999
Internet Address: www.novabiomedical.com **Email:** info@novabiomedical.com

No. INT 159 Rev. 02-11-08