Stat Strip®
GLU/KET

Point of Care Glucose and Ketones Monitoring System

The Only Point of Care Glucose/Ketones Meter Indicated for Critical Care Use in Australia

For more information or to arrange a demonstration to see the benefits for yourself, please contact us on **1300 845 762** or at **poc@amsl.com.au**

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amsl point of care

The Only Point of Care Glucose/ Ketones Meter Indicated for Critical Care Use in Australia

StatStrip® is designed specifically to measure and correct for clinical interferences that can be present in critically ill patients. To date, only one meter system, the StatStrip Glucose/Ketones Meter System, is indicated for critical care use in Australia.

Results to substantiate critical care use were obtained from 1,698 critically ill patients from five university medical centres that were paired with an isotope dilution mass spectrometry (IDMS) traceable laboratory glucose reference method.[1]

This data also represents multiple intensive care settings (19 complex medical condition categories and 257 subcategories) with over 8,000 medications (33 parent drug classes and 134 subclasses) studied for clinical interference. There were no clinical interferences observed with StatStrip.[1]

Accurate performance

- Over 170 published studies throughout the world have proven that Nova's StatStrip glucose biosensor technology improves accuracy by measuring and correcting for haematocrit and other interferences.[1]

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.[2]

StatStrip measures and corrects for errors caused by interferences and abnormal haematocrit levels

- StatStrip's Multi-Well™ technology employs a patented, additional interference test well to measure and correct for electrochemical interferences, including paracetamol, ascorbic acid (vitamin C), uric acid, maltose, galactose, dopamine, and n-acetylcysteine.
- Low haematocrit (anaemia) 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.[3-4] 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.

Use in all departments in the hospital

Healthcare professionals can use StatStrip for glucose/ketones testing with all patients including departments such as:

- Intensive Care Unit (ICU)
  - Cardiovascular
  - Surgical
  - Neonatal
- Emergency
- Labour and Delivery
- Trauma and Burn Unit
- Oncology
- Dialysis
- Recovery

Fast and Easy Glucose/Ketones 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 colour 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.[5]

Eliminates the need for single lot use

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

Eliminates the need for new lot validation studies

- StatStrip biosensor lots are factory verified for compliance with accuracy, linearity, precision and lot-to-lot bias. Biosensor lots can move directly from receiving docks to floors without new lot validation studies — saving time, labour and consumable costs.

Small and lightweight for easier use

- Length: 147 mm.
- Width: 79 mm.
- Weight: 220 g.

1.2 microlitre capillary, venous, arterial, or neonatal sample

- A small sample size and easy sampling with end-filled capillary action biosensors.

Glucose results in 6 seconds, ketone results in 10 seconds

- Fast analysis reduces the time Point of Care (POC) personnel spend performing frequent bedside testing.

Reduced dosing errors

- StatStrip prevents 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.
- StatStrip does not require the user to switch modes when using different blood samples, reducing the risk of a false result and likeliness of potential button press errors.

1D or 2D scanning for operator and patient identification

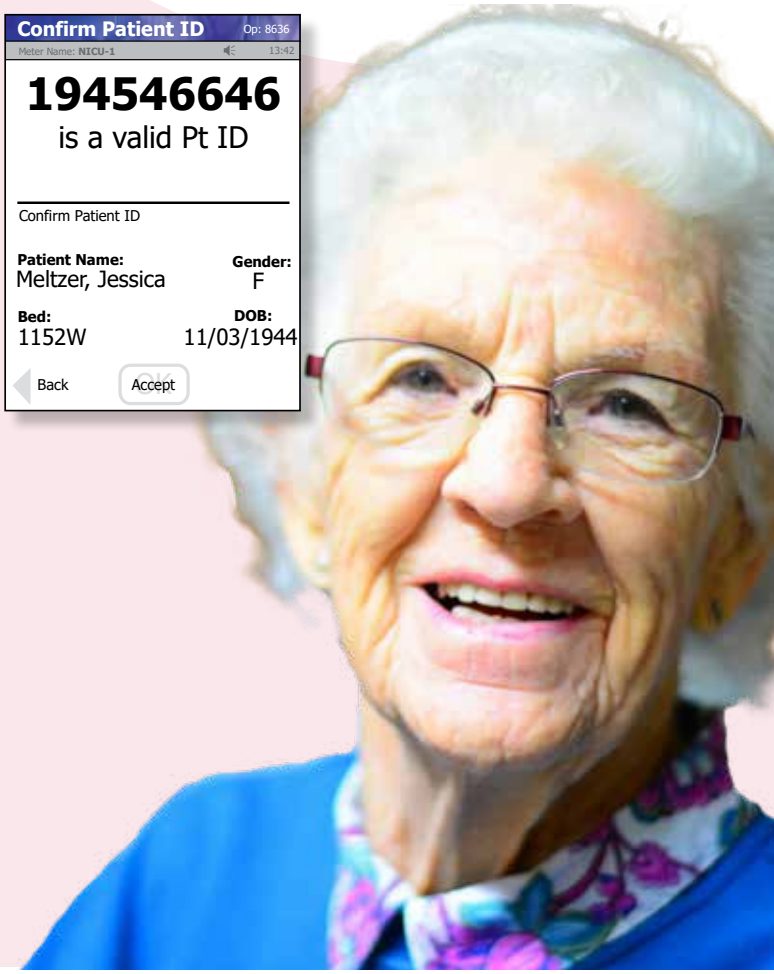
- An integrated scanner accommodates one-dimensional (1D) and two-dimensional (2D) barcodes. Patient and operator IDs can also be entered via the touchpad.

Manual, offline test entry

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

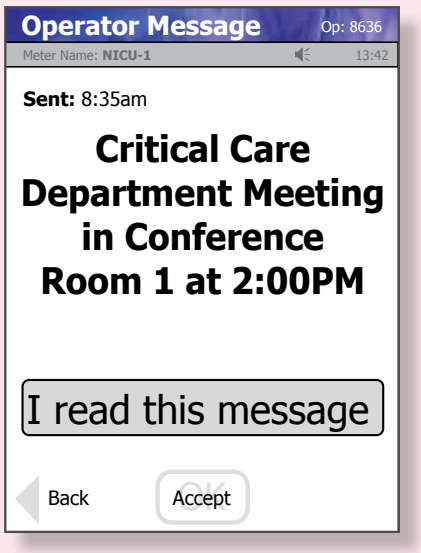
Admissions, Discharge, Transfer (ADT) for positive patient ID

- 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.



Comprehensive POC Connectivity

StatStrip customisation and control



- 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 connectivity features

- StatStrip can be custom-configured for each meter location, department and facility.
- StatStrip is 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.

Bi-directional connectivity

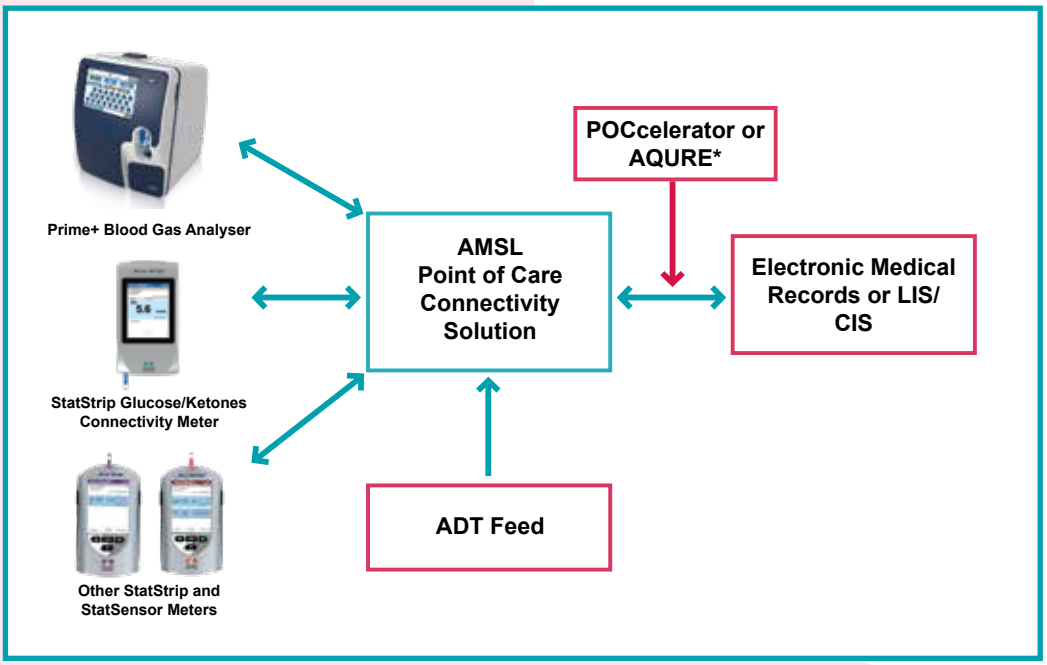
- NovaNet is a web-based configuration and communication tool for StatStrip that runs on a hospital's server and is accessed using a web browser from any secure network location. NovaNet allows for simple bi-directional communication between Nova's devices, middleware, and the LIS/HIS interface. Features 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
  - Consolidation and transfer of data from StatStrip to the LIS/HIS

Wireless meter connectivity

- StatStrip offers both hardwired and wireless bi-directional, 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.

AMSL POC connectivity features

- Single interface to LIS, HIS or EMR for all AMSL POC Devices.



Management of POC operators

- Summary of due or overdue operator certifications.
- Online documentation of operator certification history.
- 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.

Unlimited data capture and reporting

- NovaNet is a repository for unlimited patient and QC data. Data can be obtained 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

StatStrip® GLU/KET

StatStrip Connectivity Meter

Weight: ..... 220 g
Size: ..... 147 mm x 79 mm x 30 mm

Meter Data Storage:
Patient Tests: ..... 3,000 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: ..... 1˚C-40˚C
Altitude: ..... Up to 4,572 metres
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 g
Size: ..... 91 mm x 58 mm x 23 mm

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

Test Strip Operating Ranges:
Temperature: ..... 5˚C-40˚C
Altitude: ..... Up to 4,572 metres
Humidity: ..... 10% to 90% relative humidity

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

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

Specimen Types:
Fingerstick Capillary, Arterial, Venous, Neonatal Heel Stick, Neonatal Arterial

Glucose Measurement Range:
0.5-33.3 mmol/L

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

Specimen Types:
Whole blood - Arterial, Venous, Capillary

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

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References: **1.** Data on File. NovaBiomedical. **2.** Boyd J et al. Quality specification for glucose meters: Assessment by simulation modeling errors in insulin dose. Clin Chem 2001;47:209-214. **3.** Mann E et al. Error rates resulting from anemia can be corrected in multiple commonly used point-of-care glucometers. J Trauma 2008;64:15-20. **4.** Corwin H et al. The CRIT Study: Anemia and blood transfusion in the critically ill–current clinical practice in the United States. Crit Care Med 2004;32:39-52. **5.** Baum et al. Improving the quality of self-monitoring blood glucose measurement: A study in reducing calibration errors. Diabetes Technol Ther 2006;8:237-247. ARTG 197482, ARTG 200682. PR-100-176 October 2018