



Critical Care Blood Gas Analyser

A technology evolution in critical care testing



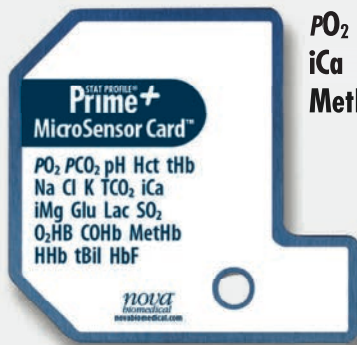
New Technologies Simplify Use and Offer Additional Tests

Stat Profile Prime Plus is a comprehensive, whole blood critical care analyser that combines blood gases, electrolytes, metabolites, co-oximetry, and 32 calculated results in a simple, compact analyser. Prime Plus combines maintenance-free, replaceable cartridge technology for sensors and reagents with patented, new, maintenance-free, and non-lysing whole blood co-oximetry technology.

Prime Plus results are produced very rapidly, a complete test menu panel in about one minute, and are combined with bidirectional connectivity and a powerful onboard data management system.

Nova MicroSensor Card™ Technology

Most comprehensive critical care menu



**PO₂ PCO₂ pH Hct tHb Na Cl K TCO₂
iCa iMg Glu Lac SO₂ O₂HB COHb
MetHb HHb tBil HbF**

- All Prime Plus biosensors use proven Nova technology in a miniaturised, maintenance-free sensor card format.
- Nova MicroSensor cards combine all 22 whole blood assays including co-oximetry.



Important New Assays

Urea (BUN), Creatinine and eGFR

Over 50% of patients admitted to the ICU will develop some stage of acute kidney injury (AKI).¹ Prime Plus is the only blood gas analyser to provide optional whole

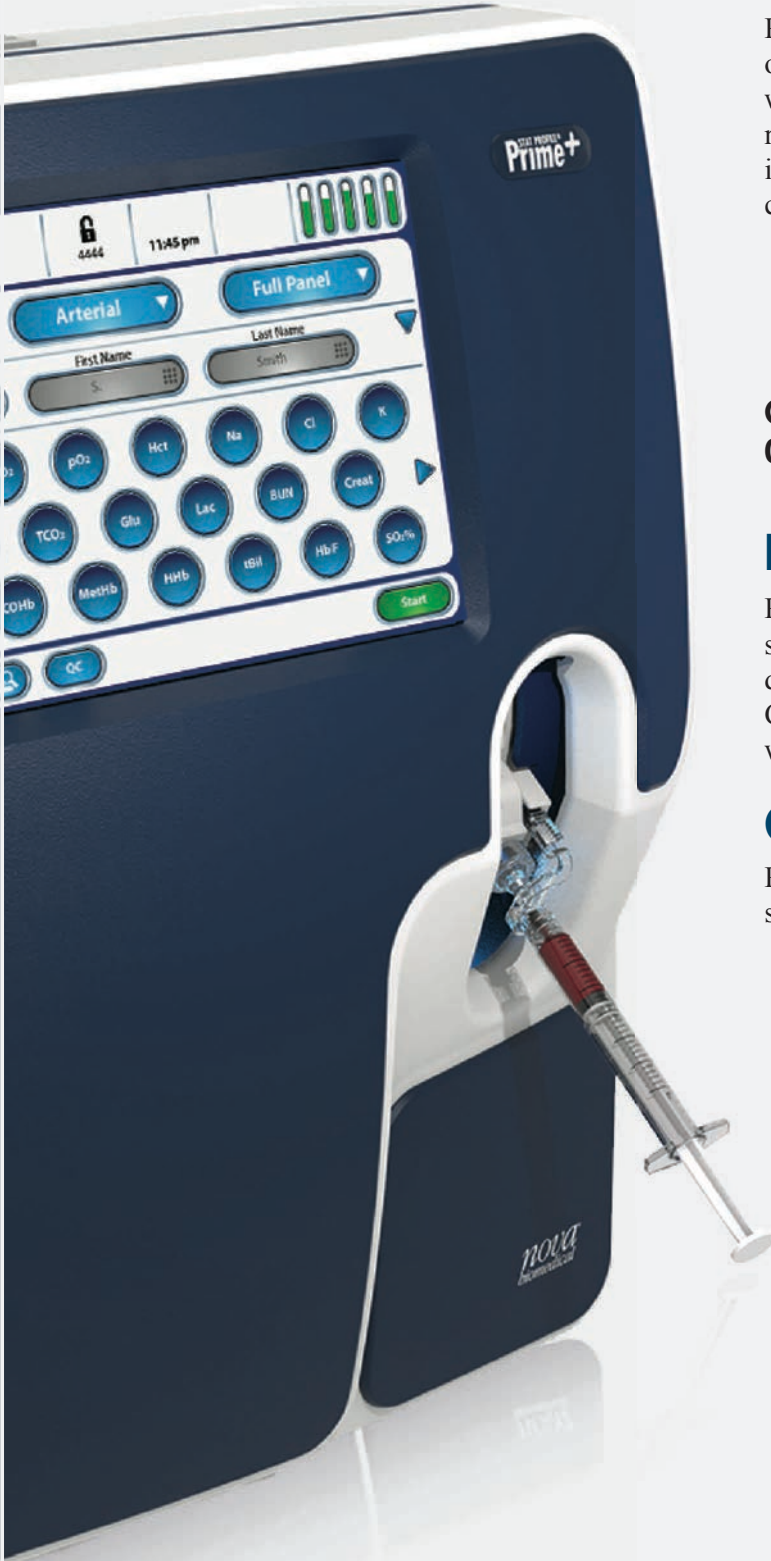
blood urea (BUN) and creatinine (plus eGFR) tests for rapid assessment of kidney function.

Ionised magnesium (iMg)

Disruptions in the balance of iMg, Na, K, and iCa can cause cardiac arrhythmias, reduced cardiac contraction, and cardiac arrest. Prime Plus is the only blood gas analyser to provide a comprehensive profile of electrolytes including iMg.



1. Mandelbaum T et al. Outcome of critically ill patients with acute kidney injury using the Akin criteria. *Crit Care Med* 2011;39:2259-2264.



New Disposable Co-oximetry Technology Eliminates Maintenance

Prime Plus incorporates a new, patented multi-wavelength optical system that scans a continuous spectrum of optical wavelengths to enable a comprehensive co-oximetry panel result without lysing the sample. The optical components in contact with blood are contained in the disposable sensor card, which is replaced every 16 days.

- Cleaning and deproteinising are completely eliminated.
- Lysing and all its required mechanical components are eliminated, as are lysing and deproteinising reagents. This improves reliability and reduces maintenance and costs.

Co-oximetry test menu

O₂Hb COHb MetHb HHb THb HbF Tbil

Fast Stat Results

Prime Plus's exceptional throughput easily handles the high sample workload of a busy critical care setting. Prime Plus delivers a 22-test critical care profile in about one minute. Competitors' analysers can require up to four minutes, even with fewer tests reported.

Clot Protection

Prime Plus's unique Clot Block™ sample flow path protects sensor cards from blood clot blockages.

Individual Sensors and Calibrators Maximise Uptime

Individual sensor cards and calibrator cartridges offer a significant benefit in analyser uptime compared to combined sensor/calibrator cartridge systems.



MicroSensor cards have fastest replacement time

MicroSensor cards can be replaced and calibrated in 45 minutes. Other combined systems usually take one hour to calibrate and remain unstable with drift and frequent re-calibrations for two hours or longer.

Calibrator cartridges replaced in seconds

Calibrator and quality control (QC) cartridges are immediately ready to use and easily replaced in seconds. Replacing only a calibrator cartridge significantly reduces analyser downtime because it has no warm-up time, compared to the over two-hour wait for competitors' combined systems.

Individual Sensors and Calibrators Lower Costs

Individual sensor cards and calibrator cartridges are a low cost alternative to the inflexibility and waste of combined sensor/calibrator cartridge systems. For example, an analyser in a high patient workload setting requires fewer sensor cards than calibrators, and a low volume workload setting requires the reverse. In both cases, Prime Plus eliminates waste and reduces overall consumable costs by using the full life of each card and cartridge.

Onboard Bidirectional Connectivity and Point-of-Care Management

NovaNet bidirectional middleware for all Nova connected devices

NovaNet is a single source, economical solution for bidirectional interface of all Nova point-of-care (POC) devices to the LIS/HIS/EMR. NovaNet ensures timely, accurate capture of Nova analyser POC test results for clinicians and managers to retrieve wherever and whenever needed.



- NovaNet provides bidirectional connectivity to transfer patient test orders, demographics, admissions, discharges, and data to Prime Plus analysers.
- POC data is captured seamlessly for medical record review, retention, and billing.
- POC patient and QC results transmissions are confirmed with acknowledgements. NovaNet flags and reports any results that fail to transmit.
- NovaNet's industry standard HL7, ASTM, or POCT01-A2 formats are easily implemented with LIS/HIS systems.

No third party middleware connectivity costs

NovaNet eliminates the cost of third party middleware to connect Nova analysers to the LIS/HIS/EMR. For hospitals that already have third party middleware connectivity, NovaNet provides supplemental remote review and remote control capabilities for connected Nova analysers.

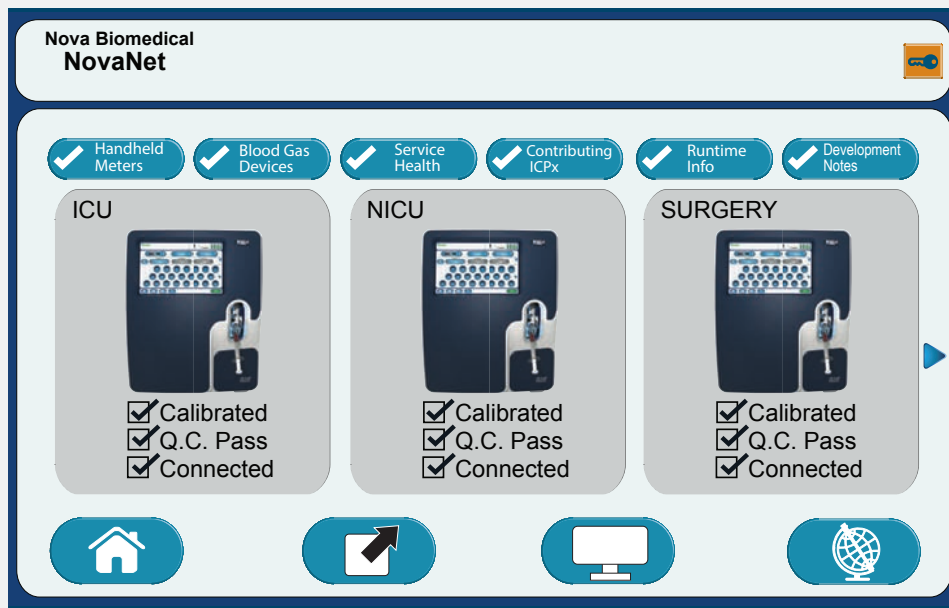
Management reports for patient and QC data, devices, and operators

NovaNet is specifically designed to meet POC programme management and regulatory requirements by capturing patient testing, QC compliance, and operator records. A large library of reports is available including:

- Patient abnormal/critical results
- Patient report exceptions
- Daily QC
- QC cumulative statistics
- Sample comments
- Operator certifications
- Corrective actions
- Calibrator and sensor replacements

Remote Review and Remote Control

NovaNet provides information on analyser connectivity, calibration, QC, reagent, and sensor status. The dashboard allows POC coordinators to review the status of remote analysers and correct for calibration or QC needs.



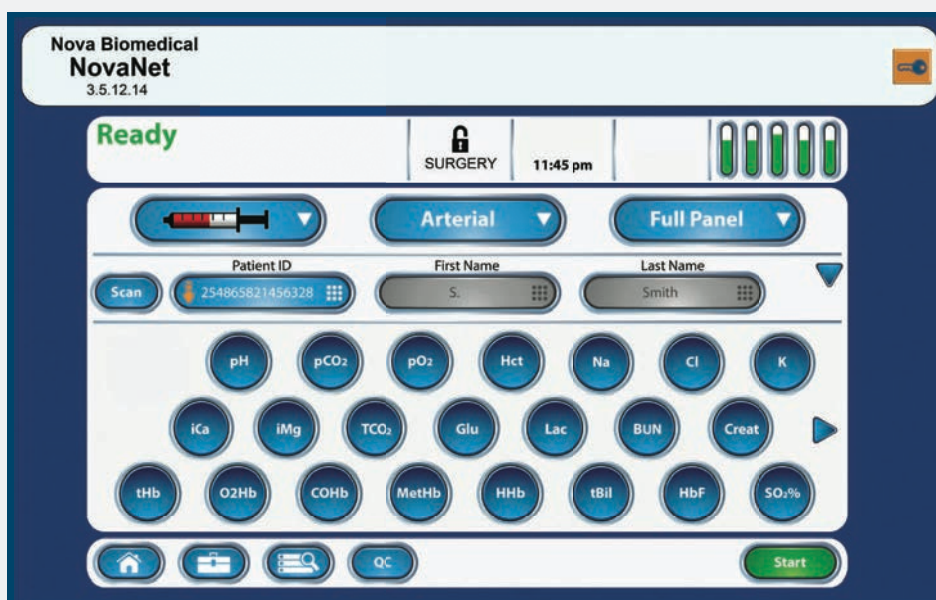
Dashboard review

Individuals with password privileges can view a dashboard of all connected devices from anywhere on the network.

Remote control

Key operators can remotely perform essential analyser functions such as:

- Initiate calibration and QC cycles
- Upload or edit set-up parameters
- Assign, certify, or remove operators and privilege levels



High Level Data Encryption and Network Security

As part of Nova's cybersecurity and protected health information (PHI) risk protection, Prime Plus analysers and NovaNet middleware comply with U.S. Homeland Security and FDA cybersecurity risk mitigation measures, and U.S. HIPAA PHI security measures.¹ Utilising high level proprietary and SSL encryption, the following capabilities can be enabled for Prime Plus analysers and NovaNet middleware:

- Encryption of the entire hard drive and all PHI data held in Prime Plus and NovaNet databases
- Encryption of all PHI traveling between Prime Plus, NovaNet, and the LIS or middleware
- Full lockdown on access to Windows, protecting the Prime Plus and NovaNet operating systems and the hospital network from malware intrusion

These features provide the highest level of analyser, PHI, and network security of any blood gas analyser.



1. Health Insurance Portability and Accountability Act

Automated, True Liquid QC

Liquid QC provides the only reliable test of an analyser

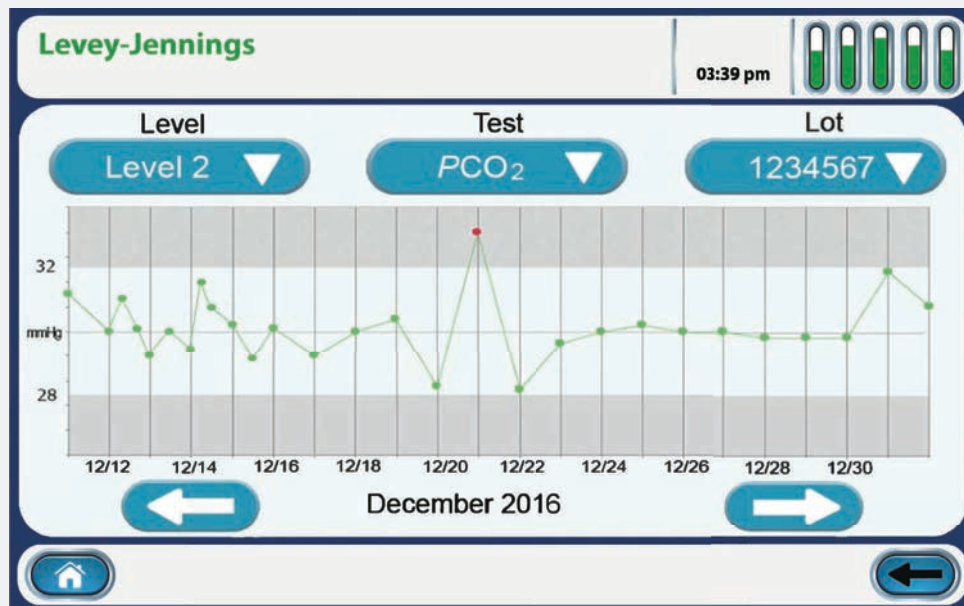
United States federal government regulations and many international government regulations have eliminated electronic equivalent QC and are requiring true liquid QC.¹

Automated QC complies with U.S. CLIA, German RiLiBAK, and other international QC requirements

QC cartridges contain a 30-day supply of liquid QC material.

Controls run automatically at user-selected intervals. Prime Plus quality controls:

- Are comprised of a matrix similar to patient samples.
- Are analysed as patient samples.
- Follow the same sample pathway as patient samples, from sample probe to waste container.
- Challenge all analytical phases of testing.
- Challenge multiple levels of each analyte.



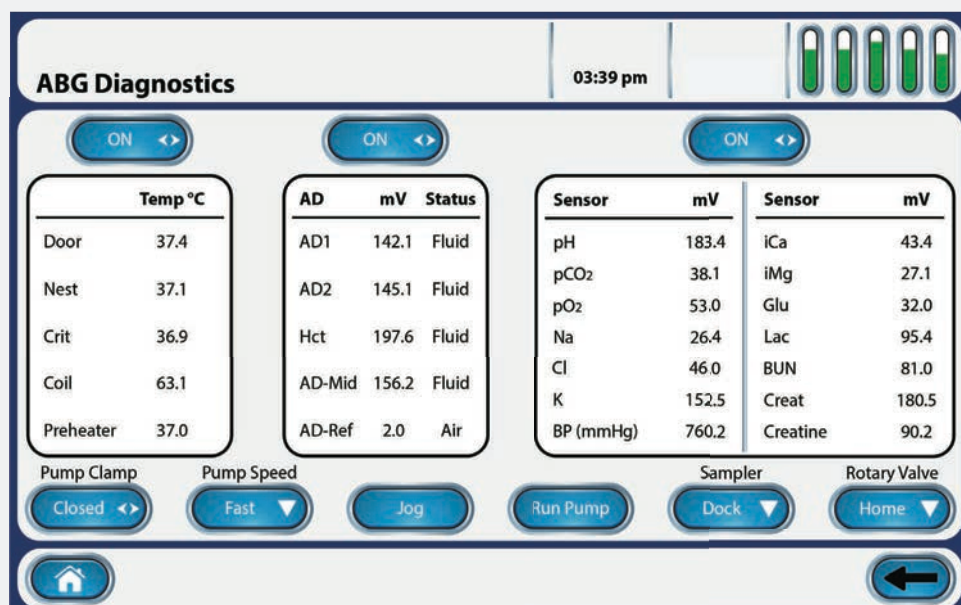
QC statistics and reports are automatically maintained and easily accessed.

Saves time and labour

Maintaining QC is one of the most time consuming aspects of critical care testing. Prime Plus's fully automated, onboard liquid QC saves hours of time each week compared to individualized QC plans (IQCPs) and manually running controls.

Supplemental Quality Monitoring (SQM)

Prime Plus provides an automated electronic quality monitoring supplement to liquid QC. SQM continuously monitors the status and performance of all analytical components (including sensors, reagents, calibrators, sample integrity, software, and electronics), providing real-time, sample-to-sample assurance of correct performance.

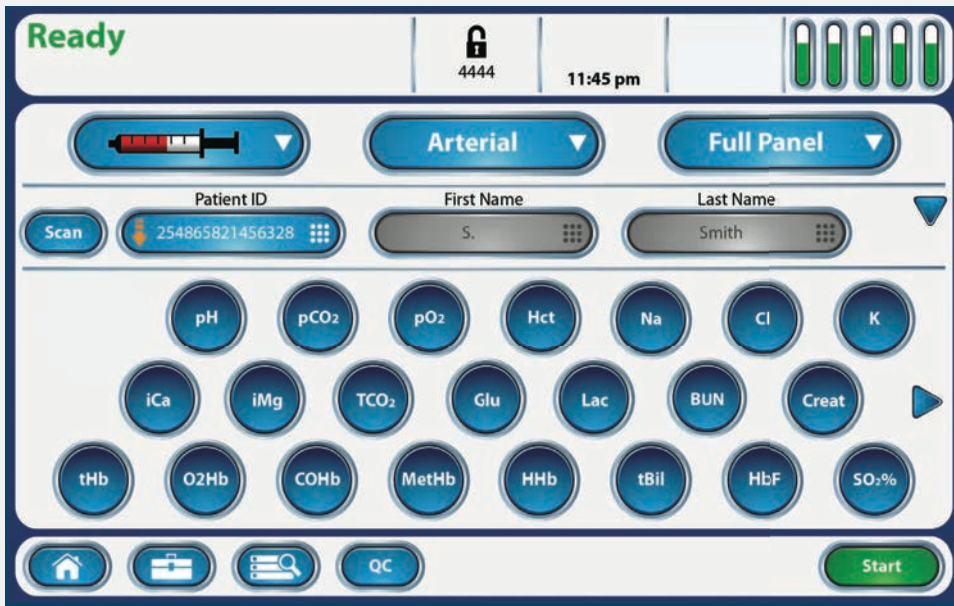


1. Centers for Medicare and Medicaid Services, Center for Clinical Standards and Quality/Survey and Certification Group. Policy clarification on acceptable control materials used when quality control (QC) is performed in laboratories. Baltimore, MD: CMS, April 8, 2016.


Simple, Fast Operation

25-cm wide, high definition, colour touchscreen operation

The large colour touchscreen is easy to read and operate with intuitive prompts.



Three simple steps to initiate a full 22-test profile

1. Press 
2. Scan or enter patient ID
3. Press 

Integrated barcode scanner

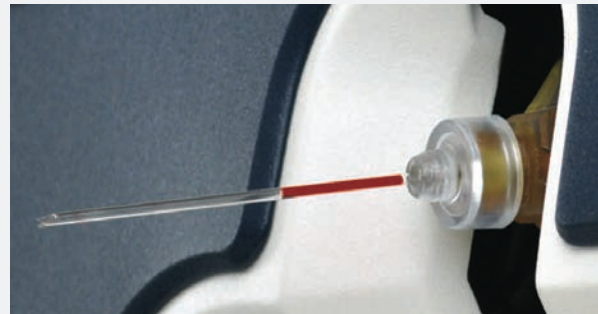
An optional integrated 1D/2D barcode scanner, conveniently located within the sample port, eliminates the need to use external handheld scanners and allows for fast, error-free entry of operator and patient IDs.

Safe Operation

The unique safety design of the sample port protects the user from accidental contact with the analyser probe.



Syringes can be docked and sampled with hands-free operation.



Hands-free capillary sampling can be performed without adapters.



Samples can be aspirated directly from tubes. Sample transfer to a syringe or capillary is eliminated.



QC proficiency ampoules can be sampled without adapters.

Stat Profile Prime Plus™ Specifications

Critical Care Tests

pH
PCO ₂
PO ₂
SO ₂ %
Haematocrit
Na ⁺
K ⁺
Cl ⁻
TCO ₂
Ca ⁺⁺
Mg ⁺⁺
Glucose
Lactate
Urea (BUN)
Creatinine

Methodology

Direct ISE
Severinghaus
Amperometric
Optical, reflectance
Conductivity/Na ⁺ correction
Direct ISE
Direct ISE
Direct ISE
Direct ISE
Direct ISE
Enzyme/Amperometric
Enzyme/Amperometric
Enzyme/Amperometric
Enzyme/Amperometric

Complete Management Reports

- Calibration Report
- Cartridge Log Report
- Daily Sample Log Report
- Edit Log Report
- Error Log Report
- Maintenance Log Report
- Operator Setup Report
- Patient Report
- Levey-Jennings QC Report
- QC Corrective Actions Report
- QC Data Report
- QC Statistics Report
- QC Setup Report
- Sample Audit Log Report

Other Features

Full colour, 10.1-inch touchscreen, multilingual, QC statistics, onboard data management, automatic sampler, integrated capillary adapter, optional barcode scanner, QC data storage, optional mobile cart with UPS

Sample Volume

135 microlitres whole blood

Operating Temperature Range

15°C–32°C

Physical Specifications

Height: 45.7 cm (18.2 in) Width: 35.6 cm (14.2 in) Depth: 39.1 cm (15.5 in) Weight: 15.88 kg (35 lb) without reagent packs

Electrical Power Requirement

< 90 Watts

Interfaces

ASTM Protocol, via serial RS232 TCP/IP, POCT01-A2, HL7

Printer

Onboard thermal printer

CE Marked, FDA Clearance Pending

Calibration

Fully automatic two-point calibration every 2 hours; user-selectable single-point calibration every 45 minutes or with each sample. Manual calibration initiated at any time.

Acceptable Samples

Whole blood (heparinised), arterial, venous, mixed venous, capillary, dialysate

Communication Protocols

ASTM, HL7, or POCT01-A2 connectivity formats

Calculated Tests

eGFR	A-ADO ₂	Ca ⁺⁺ /Mg ⁺⁺ Ratio
HCO ₃ ⁻	a/A	Normalized Ca ⁺⁺
TCO ₂	PO ₂ /FIO ₂	Normalized Mg ⁺⁺
BE-ecf	Anion Gap	Osmolality
BE-b	SBC	Haemoglobin
A	Base Excess	O ₂ Saturation
pH/PCO ₂ /PO ₂	Corrected to Patient Temperature	
Respiratory Index	(If % FIO ₂ value entered)	
Actual Bicarbonate		
Standard Bicarbonate		

CO-Oximetry Tests

HHb, deoxyhaemoglobin	O ₂ Hb, oxyhaemoglobin
MetHb, methaemoglobin	COHb, carboxyhaemoglobin
tHb, total haemoglobin	SO ₂ %, oxygen saturation
tBil, total bilirubin	HbF, fetal haemoglobin

Special Calculated Tests (CO-Oximetry Required)

Tests	Resolution
A-v DO ₂	0.1 mmHg (0.01 kPa)
CaO ₂	0.1 mL/dL (0.01 kPa)
CcO ₂	0.1 mL/dL (0.01 kPa)
P50	0.1 mmHg (0.01 kPa)
C(a-v)O ₂	0.1 mmHg (0.001 kPa)
CvO ₂	0.1 mmHg (0.001 kPa)
Qsp/Qt	0.1 mmHg (0.001 kPa)
O ₂ Ct	0.1 mL/dL (0.01 mL/L)
O ₂ Cap	0.1 mL/dL (0.01 mL/L)

Monitored Interferences

sHb, sulphaemoglobin (Measured; user alerted if abnormal, > 1.5%)

Measurement Ranges

pH	6.5 - 8 (H ⁺ : 316.2 - 10 nmol/L)
PCO ₂	3 - 200 mmHg (0.4 - 26.7 kPa)
TCO ₂	5 - 70 mmol/L (90 - 1260 mg/dL)
PO ₂	5 - 765 mmHg (0.66 - 102 kPa)
Hct	12 - 70%
Na ⁺	80 - 200 mmol/L
K ⁺	1 - 20 mmol/L
Cl ⁻	50 - 200 mmol/L
Ca ⁺⁺	0.1 - 2.7 mmol/L (0.4 - 10.8 mg/dL)
Mg ⁺⁺	0.1 - 1.5 mmol/L (1.8 - 27 mg/dL)
Glucose	0.8 - 28 mmol/L (15 - 500 mg/dL)
Lactate	0.3 - 20 mmol/L (2.7 - 180.2 mg/dL)
Urea (BUN)	0.17 - 5.5 mmol/L (3 - 100 mg/dL)
Creatinine	10 - 660 µmol/L (0.2 - 12 mg/dL)
HHb	0 - 33% (0 - 0.33)
O ₂ Hb	0 - 100% (0 - 1)
MetHb	0 - 80% (0 - 0.8)
COHb	0 - 60% (0 - 0.6)
SO ₂ %	30 to 100%
O ₂ Ct	495.04 - 2952.56 µmol/L (5.6 - 33.4 mg/dL)
O ₂ Cap	495.04 - 2952.56 µmol/L (5.6 - 33.4 mg/dL)
tBil	44.2 - 3094 µmol/L (0.5 - 35 mg/dL)
HbF	0 - 92%
tHb	5 - 25 g/dL (50 - 250 g/L)
sHb	Alert > 1.5%
BarP	400 - 800 mmHg (53.3 - 106.7 kPa)

POC Monitoring Systems

Nova's whole blood meters and test strips provide accurate results by utilising Multi-Well™ biosensor technology, which measures and corrects for interferences such as haematocrit, paracetamol, ascorbic acid, and uric acid that can cause erroneous results on other handheld whole blood meters.

Other features include:

- Easy, handheld operation
- Samples as small as 0.6 microlitres
- Results as fast as 6 seconds
- No calibration coding
- Single connectivity solution
- Choice of hospital connectivity or Xpress meter



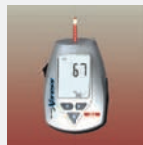
StatStrip® Glucose/
Ketone Meter



StatStrip® Xpress2
Glucose/Ketone
Meter



StatSensor®
Creatinine Meter



StatSensor® Xpress
Creatinine Meter



StatStrip®
Lactate Meter



StatStrip® Xpress
Lactate Meter

Compact Size for POC Use

Dimensions for Prime Plus, including onboard co-oximetry and built-in bidirectional connectivity:



Weight:
15.88 kg (35 lb) without calibrator cartridges
19.30 kg (42.5 lb) with calibrator cartridges

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