Critical Care Blood Gas Analyser
A technology evolution in critical care testing
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. The analyser combines maintenance-free, replaceable cartridge technology for sensors and reagents with a patented, new, maintenance-free, non-lysing whole blood co-oximetry technology.

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

**Nova MicroSensor Card Technology**

**Most comprehensive critical care menu**

- $\text{PO}_2$
- $\text{PCO}_2$
- pH
- Hct
- $\text{tHb}$
- Na
- Cl
- K
- $\text{TCO}_2$
- $\text{iCa}$
- $\text{iMg}$
- Glu
- Lac
- $\text{SO}_2$
- $\text{O}_2\text{HB}$
- $\text{COHb}$
- $\text{MetHb}$
- $\text{HHb}$
- $\text{tBil}$
- $\text{HBF}$

- All Stat Profile 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). Stat Profile Prime Plus is the only blood gas analyser to provide optional whole blood urea (BUN) and creatinine (plus eGFR) test options for rapid assessment of kidney function.

**Ionised magnesium (iMg)**

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

New Disposable Co-oximeter 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, fetal Hb, Tbil

Fast Stat Results

Prime Plus 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. Competitor 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 cartridges from blood clot blockages.
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 retrieval by clinicians and managers wherever and whenever needed.

- NovaNet provides bidirectional connectivity of patient test orders, demographics, admissions, discharges, and data transfer to Stat Profile 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 POCT1A-2 formats are easily implemented with LIS/HIS systems.

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 PHI (protected health information) risk protection, Prime Plus analysers and Nova Net middleware comply with U.S. Homeland Security and FDA cybersecurity risk mitigation measures, and U.S. HIPAA1 PHI security measures. 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 travelling 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.

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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 are run automatically at user-selected intervals. Prime Plus quality controls:
• Are comprised of a similar matrix to that of patient samples.
• Are treated in the same manner as patient samples.
• Follow the exact sample pathway as patient samples, from sample probe to waste container.
• Challenge all analytical phases of testing.
• Challenge testing at patient low, normal, and high value ranges.

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, calibrations, sample integrity, software, and electronics), providing real-time, sample-to-sample assurance of correct performance.

Supplemental Quality Monitoring (SQM)

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 manually running controls.

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

25 cm (10 in) 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 then automatically sampled with hands-free operation.

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.
### Critical Care Test Menu

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Methodology</th>
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</thead>
<tbody>
<tr>
<td>PO2</td>
<td>Direct ISE</td>
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<tr>
<td>PO2</td>
<td>Severinghaus</td>
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<tr>
<td>PO2</td>
<td>Amperometric</td>
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<tr>
<td>SO2</td>
<td>Optical, reflectance</td>
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<tr>
<td>Na</td>
<td>Direct ISE</td>
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<tr>
<td>K</td>
<td>Direct ISE</td>
</tr>
<tr>
<td>Cl</td>
<td>Direct ISE</td>
</tr>
<tr>
<td>Ca</td>
<td>Direct ISE</td>
</tr>
<tr>
<td>Mg</td>
<td>Direct ISE</td>
</tr>
<tr>
<td>Cap</td>
<td>Enzyme/Amperometric</td>
</tr>
<tr>
<td>Ct</td>
<td>Enzyme/Amperometric</td>
</tr>
<tr>
<td>Lactate</td>
<td>Enzyme/Amperometric</td>
</tr>
<tr>
<td>Urea (BUN)</td>
<td>Enzyme/Amperometric</td>
</tr>
<tr>
<td>Creat</td>
<td>Enzyme/Amperometric</td>
</tr>
</tbody>
</table>

### Calculated Tests

- eGFR A-aDO:
  - Ca / Mg Ratio
- HCO3 / pH:
  - Corrected to Patient Temperature
- A-aDO:
  - Cap 0.1 mL/dL (0.01 mL/L)
  - Ct 0.1 mL/dL (0.01 mL/L)
- Cap 0 to 34.75 vol. %
- Ct 0 to 34.75 vol. %

### Special Calculated Tests (CO-Oximeter Required) Tests

<table>
<thead>
<tr>
<th>Special Calculated Tests</th>
<th>Resolution</th>
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<tr>
<td>A-v DO2</td>
<td>0.1 mmHg (0.01 kPa)</td>
</tr>
<tr>
<td>CaO2</td>
<td>0.1 mL/dL (0.01 kPa)</td>
</tr>
<tr>
<td>CO2</td>
<td>0.1 mL/dL (0.01 kPa)</td>
</tr>
<tr>
<td>P50</td>
<td>0.1 mmHg (0.01 kPa)</td>
</tr>
<tr>
<td>CO-VO2</td>
<td>0.1 mmHg (0.01 kPa)</td>
</tr>
<tr>
<td>CVO2</td>
<td>0.1 mmHg (0.01 kPa)</td>
</tr>
<tr>
<td>Qsp/Qt</td>
<td>0.1 mmHg (0.01 kPa)</td>
</tr>
<tr>
<td>O2-Ct</td>
<td>0.1 mL/dL (0.01 mL/L)</td>
</tr>
<tr>
<td>O-Cap</td>
<td>0.1 mL/dL (0.01 mL/L)</td>
</tr>
</tbody>
</table>

### Point-of-Care 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 haemocrit, paracetamol, ascorbic acid, and uric acid that can cause erroneous results on other handheld whole blood meters.

**Other features:**
- 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

### Specifications

- **Critical Care Test Menu**
  - PO2
  - PO2
  - PO2
  - SO2
  - Na
  - K
  - Cl
  - Ca
  - Mg
  - Cap
  - Ct
  - Lactate
  - Urea (BUN)
  - Creat

- **Calculated Tests**
  - eGFR A-aDO:
    - Ca / Mg Ratio
  - HCO3 / pH:
    - Corrected to Patient Temperature
  - A-aDO:
    - Cap 0.1 mL/dL (0.01 mL/L)
    - Ct 0.1 mL/dL (0.01 mL/L)

**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**
- 145 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: 15.8 kg (33 lb) without reagent packs

**Electrical Power Requirement**
- ≤ 90 Watts

**Interfaces**
- ASTM Protocol, via serial RS232 TCP/IP, POCTIA

**FDA Labeling**
- For-in-vitro diagnostic use

**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 (heparinized), serum/plasma, arterial, mixed venous, capillary, CSF, dialysate

**Communication Protocols**
- ASTM, HL7 or POCTIA connectivity formats

**Compact Size for POC Use**
- Dimensions for Prime Plus, including the onboard co-oximetry and built-in bidirectional connectivity: