STAT PROFILE Prime+®

The Most Clinically Advanced Test Menu
The Simplest to Operate

ICU
LAB
RESPIRATORY
EMERGENCY DEPARTMENT
CARDIAC SURGERY
NICU

nova biomedical®

Stat Profile Prime Plus is a comprehensive, whole blood point-of-care analyser that combines blood gases, electrolytes, metabolites, CO-Oximetry, plus four important new assays not available on other critical care analysers. 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 rapidly–in about 90 seconds– and are combined with bidirectional connectivity and a powerful onboard data management system.

Important New Tests for Clinicians

Urea (BUN), Creatinine and eGFR

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

Estimated Plasma Volume

Plasma volume status is one of the top priorities in evaluating and treating many different conditions including, shock, sepsis, congestive heart failure, acute or chronic kidney disease, chronic pulmonary disease, as well as general postoperative care. ePV calculated with the Strauss equation requires both measured haemoglobin and measured haematocrit. Prime Plus is the only blood gas analyser to provide this critical value.

Mean Corpuscular Haemoglobin Concentration (MCHC)

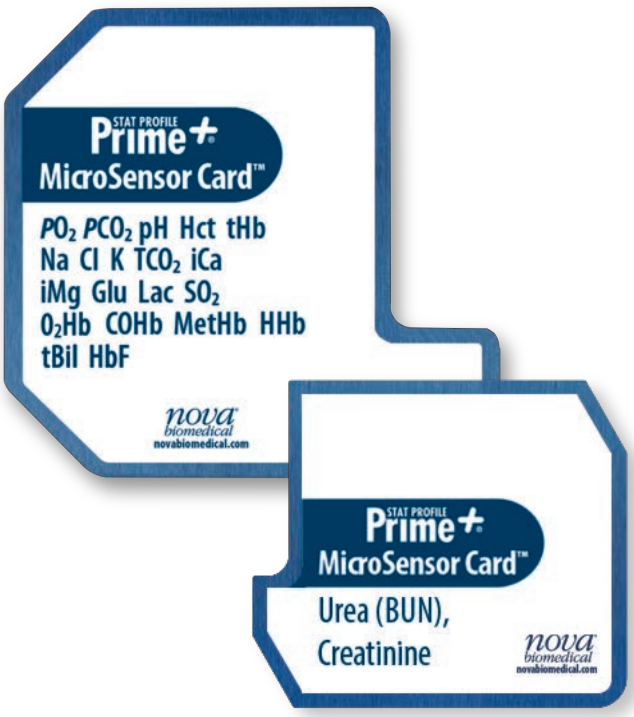
Mean corpuscular haemoglobin concentration provides insight into certain causes of anaemia, such as iron deficiency or inability of the body to absorb iron, chronic low grade blood loss over time, and autoimmune haemolysis.

1. Mandelbaum T et al. Outcome of critically ill patients with acute kidney injury using the AKIN criteria. *Crit Care Med* 2011;39(12):2659-2664.

MicroSensor Card™ Comprehensive Test Menu

PO_2 PCO_2 pH Hct tHb Na Cl K TCO_2 iCa iMg Glu Lac Urea Creat/eGFR SO_2% COHb O_2Hb MetHb HHb tBil HbF ePV

- All Prime Plus biosensors use proven Nova technology in a miniaturised, maintenance-free sensor card format.
- Two MicroSensor cards capture all whole blood assays including CO-Oximetry.



Disposable CO-Oximeter Technology

CO-Oximetry test menu

O_2Hb COHb MetHb HHb tBil HbF tHb

Stat Profile Prime Plus incorporates a new, patented*, multi-wavelength optical system that scans a continuous spectrum of wavelengths to produce a comprehensive CO-Oximetry panel. The optical components in contact with blood are contained in the disposable sensor card.

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

Fast Stat Results

Prime Plus's exceptional throughput easily handles the high sample workload of a busy critical care setting. Prime Plus delivers test results in about 90 seconds. Other 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.

** Patent numbers: 95350531, 9933411B2*

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.

New Nova technology cards have fastest replacement time

MicroSensor cards can be replaced and automatically hydrated, calibrated, and quality controlled in about one hour. Other combined cartridge systems usually take one hour to begin the calibration process and remain unstable with drift, requiring frequent calibrations for up to 24 hours.

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 combined technology reagent/sensor 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, Stat Profile Prime Plus eliminates waste and reduces overall consumable costs by maximising the full life of each card and cartridge.

Bidirectional Connectivity and Point-of-Care Management

NovaNet bidirectional middleware for all Nova devices, Prime Plus and StatStrip Glucose

NovaNet is a single, 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.

Prime Plus LIS/HIS

- 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 acknowledgments. NovaNet flags and reports any results that fail to transmit.
- NovaNet's industry standard HL7, ASTM, or POCT1-A2 formats are easily implemented with LIS/HIS/EMR 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 remote review and remote control capabilities for connected Nova analysers.

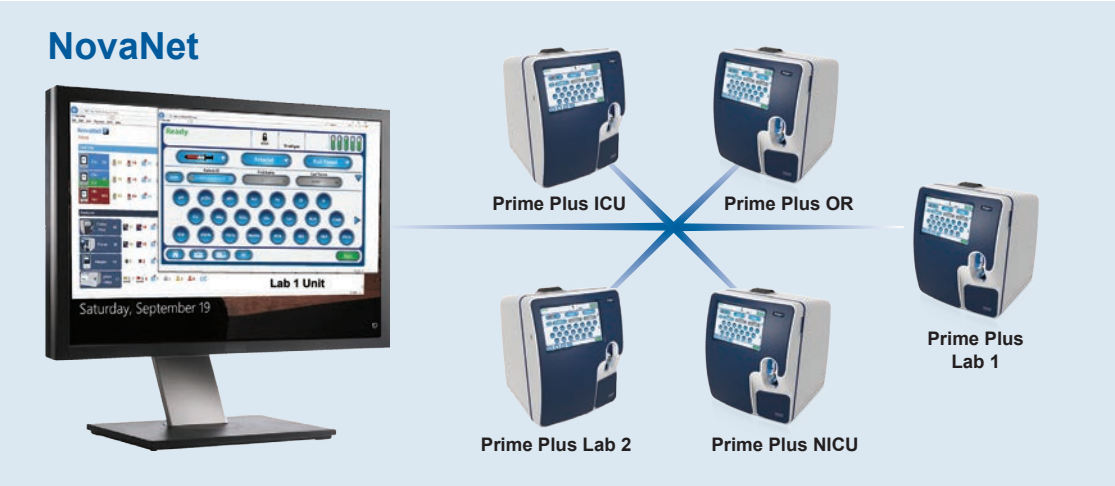
Management reports for patient and QC data, devices, and operators

NovaNet is specifically designed to meet POC program 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 dashboard provides information on analyser connectivity, calibration, QC, reagent, and sensor status. The dashboard allows POC coordinators to review the status of remote analysers.



Dashboard review

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

Dashboard indicators

- Analysers connected and ready for analysis
- Analysers connected but need attention
- Not connected or communicating
- Analyser lock mode
- Operator certifications
- Daily results / history graph
- Device location

High Level Data Encryption and Network Security

CYBERSECURITY

As part of Nova's cybersecurity and protected health information (PHI) risk protection, Stat Profile Prime Plus analysers and NovaNet middleware comply with U.S. Homeland Security and U.S. Food and Drug Administration cybersecurity risk mitigation measures, and U.S. HIPAA PHI security measures.[1] Prime Plus analysers provide technical measures to support data protection and are EU-GDPR, UK-GDPR compliant. 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
- 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

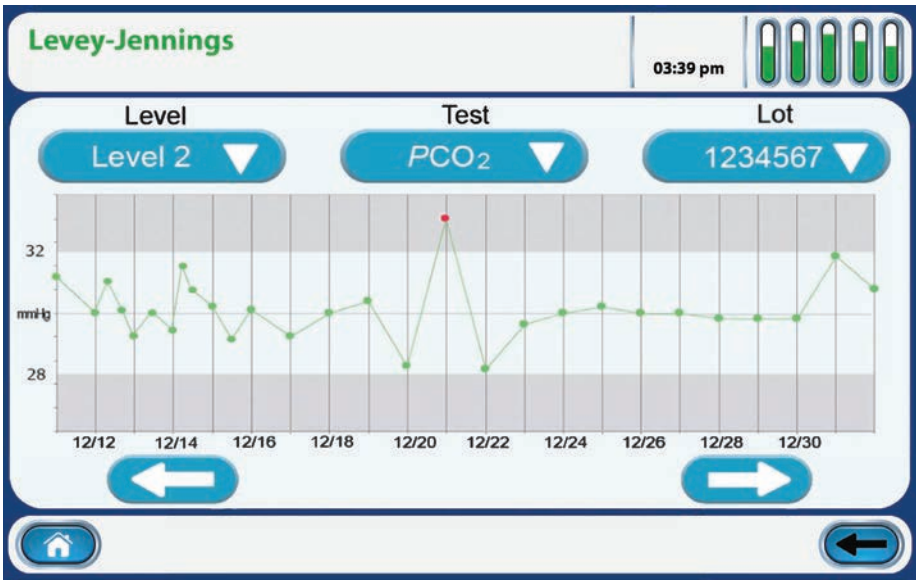
Liquid QC provides the only reliable test of an analyser

U.S. federal government 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 independent, different reagents from calibrators.
- Comprise 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.



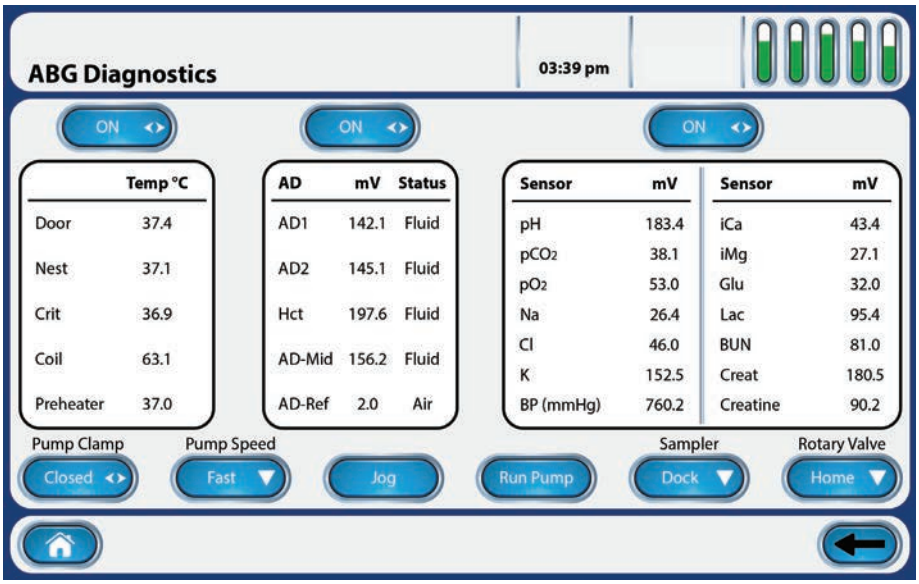
QC statistics and reports are automatically maintained and easily accessed.

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 individualised QC plans (IQCPs) and manually running controls.

Supplemental Quality Monitoring (SQM)

Stat Profile 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.

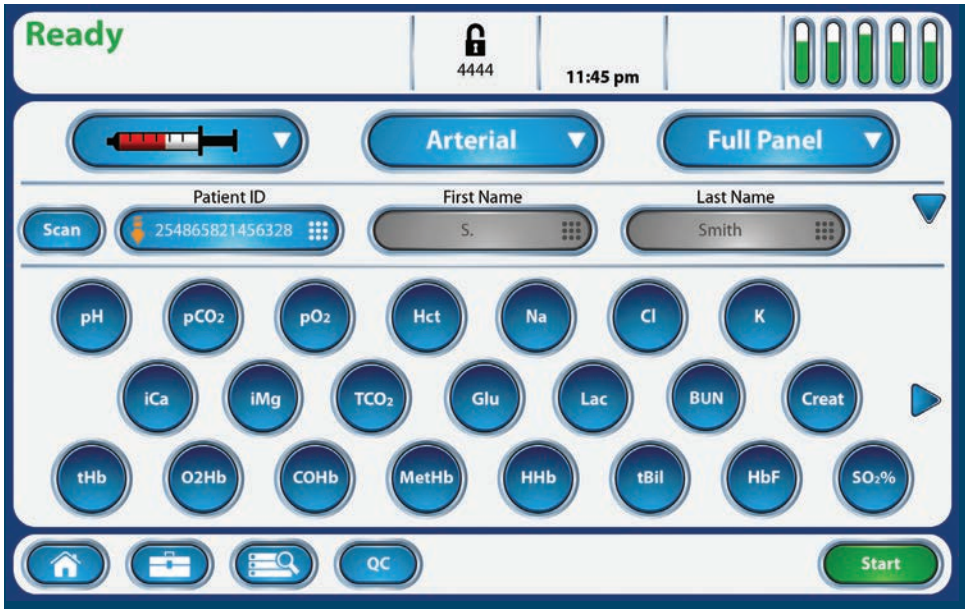


1. Centers for Medicare and Medicaid Services, Center for Clinical Standards and Quality/Survey and Certification Group. Policy clarification or acceptable control materials used when quality control (QC) is performed in laboratories. Baltimore, MD: CMS, April 8, 2016.

Simple, Fast Operation

10-inch wide, high definition, colour touchscreen operation

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



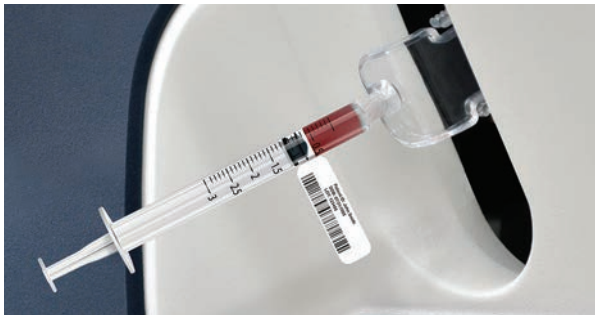
Three simple steps to initiate a full 22-test profile

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

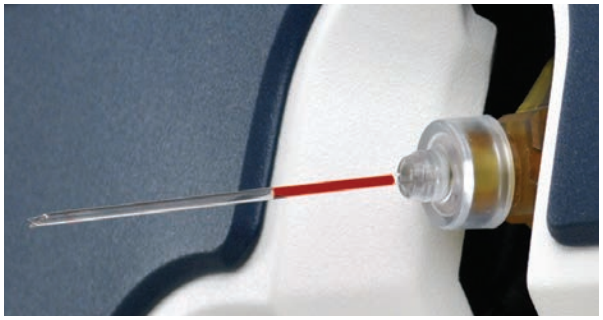
Integrated barcode scanner

The 1D/2D barcode scanner, conveniently located within the sample port, allows for fast, error-free entry of operator and patient IDs. The optional, wireless, external barcode scanner also allows for positive patient ID, further eliminating pre-analytical error.

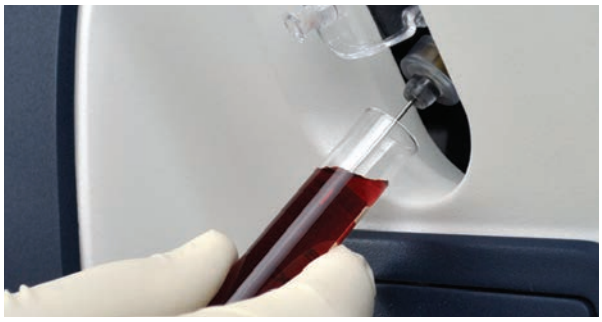
Safety Sample Port



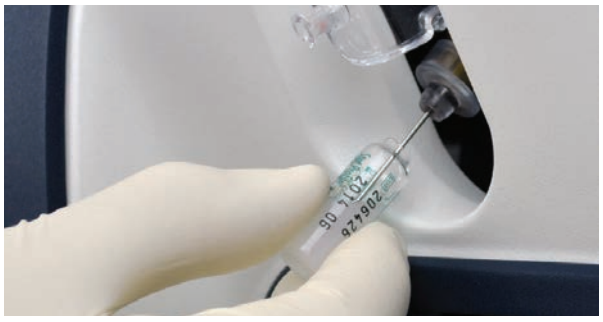
Syringes can be docked and sampled with hands-free operation.



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 ampules can be sampled without adapters.

STAT PROFILE Prime+®

ICU

Only Critical Care Analyser with ePV, iMg, Urea, and Creatinine

Clinical Importance of ePV

- Fluid overload is increasingly recognised as an important and treatable risk factor for adverse outcomes in the critically ill.[1]
- Plasma Volume Status (PVS) is a useful risk marker in ARDS and could be further assessed as a treatment target.[1]
- Elevated PVS is associated with greater risk of mortality and fewer ICU- and ventilator- free days, even after adjustment for age, sex, and degree of critical illness.[1]

iMg and iCa balance is key to cardiac function

- Ionised calcium (iCa) is an important factor for cardiac contractility.
- Ionised magnesium (iMg) is a natural calcium channel blocker, regulating cardiac contraction.
- Maintaining a balanced ion ratio is crucial to sustaining normal cardiac rhythm.

Why measure iMg and not total Mg?

- iMg is the physiologically active and clinically important form of magnesium.[2,3]
- iMg and total magnesium do not correlate in critically ill patients:
  - Up to 85% of hypomagnesaemic critically ill patients measured with total magnesium have normal iMg levels.[3-5]
- iMg monitoring allows for targeted treatment and avoids unnecessary repeat testing.[2,5]
- Patients with preoperative ionised hypomagnesaemia are nearly twice as likely to experience AKI-dialysis and in-hospital mortality than normomagnesaemic patients.[6]

Urea and Creatinine

- Over 50% of patients admitted to the ICU will develop acute kidney injury.[7]
- The Prime Plus provides Urea and creatinine (plus eGFR) tests for rapid assessment of kidney function.

References

1. Niedermeyer, SE et al. Calculated Plasma Volume Status Is Associated With Mortality in Acute Respiratory Distress Syndrome. *Critical Care Explorations Journal* 2021; Vol3(9) 1-9.
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4. Yeh DD et al. Total and ionized magnesium testing in the surgical intensive care unit—Opportunities for improved laboratory and pharmacy utilization. *J Crit Care* 2017;42:147-151.
5. Huijgen HJ et al. Magnesium levels in critically ill patients. What should we measure? *Am J Clin Pathol* 2000;114:688-695.
6. Koh, HB et al. Preoperative Ionized Magnesium Levels and Risk of Acute Kidney Injury After Cardiac Surgery. *Am J Kidney Dis* 10.1053/j.ajkd.2022.03.004
7. Mandelbaum T et al. Outcome of critically ill patients with acute kidney injury using the AKIN criteria. *Crit Care Med* 2011;39(12):2659-2664.

STAT PROFILE Prime+®

Most Comprehensive Critical Care Analyser for the ICU

24 tests including new tests for iMg, Urea, Creatinine and ePV

Blood gases

pH PCO_2 PO_2 SO_2%

Electrolytes

Na K iCa iMg Cl TCO_2

Metabolites

Glu Lac Urea Creat/eGFR

Haematology

Hb Hct ePV MCHC

CO-Oximetry

O_2Hb COHb MetHb HHb tBil HbF

Broadest electrolyte panel for full assessment of electrolyte status

Results in about 90 seconds

Maintenance-free measurement sensors

Automated liquid QC

Bidirectional connectivity with comprehensive cybersecurity protection

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STAT PROFILE Prime+®

LAB

Comprehensive Critical Care Analyser with Broadest Test Menu

Stat Profile Prime Plus provides a comprehensive whole blood test menu including blood gases, electrolytes, metabolites, haematology, and non-lysing CO-Oximetry for critical care testing in any hospital department. Prime Plus is always ready at the point of care for stat analysis of up to 24 critical care analytes in about 90 seconds.

pH pCO_2 pO_2 Na K iCa iMg Cl TCO_2 Glu Lac Hct Hb ePV SO_2% MCHC O_2Hb COHb HHb MetHb tBil HbF Creat/eGFR Urea

Clinical Importance of ePV

- Fluid overload is increasingly recognised as an important and treatable risk factor for adverse outcomes in the critically ill.[1]
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- Elevated PVS is associated with greater risk of mortality and fewer ICU- and ventilator- free days, even after adjustment for age, sex, and degree of critical illness.[1]

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STAT PROFILE Prime+®

Flexible Point-of-Care Analyser Serves ALL Departments

Standardise on One Platform

Stat Profile Prime Plus can provide various whole blood tests for critically ill patients in any hospital department including the ICU and ED, as well as outpatient centers, clinics, and urgent care centers.

Prime Plus's MicroSensor Card™ technology and calibrator and QC cartridges offer the **flexibility to meet the specific test menu and throughput needs of any care setting or patient population**. Tests include:

pH pCO_2 pO_2 Na K iCa iMg Cl TCO_2 Glu Lac Hct Hb ePV SO_2% MCHC O_2Hb COHb HHb MetHb tBil HbF Creat/eGFR Urea

Choose:

- Blood gases, electrolytes, and metabolites **with non-lysing CO-Oximetry**.
- Blood gases, electrolytes, and metabolites **without CO-Oximetry**. Prime Plus provides measured Hb, Hct, and SO_2% without the need for CO-Ox, reducing costs for departments that don't use it.
- Creat/eGFR and Urea tests on a separate MicroSensor Card.
- MicroSensor Card, calibrator, and QC cartridge sizes for high and low sample throughput, which eliminates the waste of unused cartridge life and reducing costs.

Total Quality Management

Prime Plus features **dual quality systems** to provide continuous, real-time verification of analyser performance:

- **Automated, liquid QC**—provides the only true test of analyser performance. It is EP23A compliant and saves hours of labour each week compared to manual QC or developing an individualised QC plan.
- **Supplemental Quality Monitoring** provides continuous, real-time, and automated performance verification of all analytical components between QC intervals.

Maintenance-Free Testing

Prime Plus' maintenance-free cartridges for sensors and reagents are easy to replace, allowing staff to focus on patient care.

Clot Protection

Clot Block technology "blocks" or traps a clot in the sample probe where it can be easily flushed out. Clots are blocked from entering the MicroSensor Card preventing prolonged downtime or loss of card life.

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STAT PROFILE Prime+®

RESPIRATORY

Fast and Flexible Blood Gas/Critical Care Analyser for Respiratory Care

Fast Testing

The Stat Profile Prime Plus whole blood critical care analyser features automated quality control (QC) calibration so it's **always ready at the point-of-care** for stat analysis of up to 24 critical care analytes in about 90 seconds.

Comprehensive, Configurable, and Flexible

Prime Plus provides up to 24 user selectable tests, including new tests for ionised magnesium—a critical yet underutilised electrolyte test—and Urea and Creatinine/eGFR tests for kidney function. Prime Plus's MicroSensor Card™ technology and calibrator and QC cartridges offer the flexibility to meet the specific test menu and throughput needs of any care setting or patient population.

- Choose blood gases, electrolytes, and metabolites ***with or without non-lysing CO-Oximetry***. Prime Plus provides measured Hb, Hct, and SO_2% without the need for CO-Ox, reducing costs for departments that don't use it.
- MicroSensor Card, calibrator, and QC cartridge sizes accommodate high and low sample throughput, eliminating the waste of unused cartridge life and reducing costs.

Maximum Uptime

- Prime Plus maximises analyser uptime—and the time point-of-care staff can spend with patients—by using maintenance-free cartridge technology.
- Snap-in calibrator and QC cartridges can be replaced in seconds.
- Nova's MicroSensor cards can be replaced, calibrated, and QC verified in one hour.

Total Quality Management

Prime Plus features **dual quality systems** to provide continuous, real-time verification of analyser performance:

- **Automated, liquid control** analysis provides the only reliable test of analyser performance. It is EP23A compliant and saves hours of labour each week compared to manual QC or developing an individualised QC plan.
- **Supplemental Quality Monitoring** provides continuous, real-time, and automated performance verification of all analytical components between QC intervals.

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STAT PROFILE Prime+®

Ionised Magnesium (iMg) Monitoring Reduces Ventilator Days and Improves Patient Outcomes

Hypomagnesaemia is a highly prevalent and important, but under diagnosed, electrolyte abnormality in critically ill patients.

- Affects 24-59% of ICU patients and is associated with a 35-81% increase in mortality.[1-4]

Hypomagnesaemia increases the requirements for ventilatory support.

- Increases the need for ventilatory support by 26-44%.[1,2,4]
- Increased the duration of ventilatory support by 53-96%.[1,3,4]
- Leads to respiratory muscle weakness and respiratory failure, resulting in difficulty weaning the patient from the ventilator.[2,3]

Mg therapy guided by real-time, serial iMg measurement improves patient outcomes.[3,5]

- 21% reduction in the need for mechanical ventilation.[3]
- Up to 2.5 less days on a ventilator.[1,3,4]
- 77% reduction in ventricular tachycardia.[5]

Why measure iMg and not total Mg?

- iMg is the physiologically active and clinically important form of Mg.[5,6]
- iMg and total magnesium do not correlate in sick patients.
  - –Up to 85% of hypomagnesaemic critically ill patients measured with total magnesium have normal iMg levels.[6-8]
- POC iMg monitoring allows for accurate and real-time $MgSO_4$ titration compared to traditional bolus magnesium administration.[5]
- iMg monitoring avoids total magnesium toxicity and unnecessary repeat testing.[7]

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STAT PROFILE Prime+®

EMERGENCY DEPARTMENT

Emergency Department Point-of-Care Testing Reduces ED Length of Stay and Improves Patient Outcomes

Basic Metabolic Profile

Comprehensive point-of-care testing (POCT) including a metabolic panel has been shown to significantly reduce ED LOS.[1,2]

- POCT in the ED can provide results an average of 46 minutes earlier than the central lab.[3]
- POCT at ED triage may help identify critically ill patients and can help improve patient safety.[4]
- POCT has been shown to reduce delays to treatment[4] and ED care time by approximately one hour.[5]

POCT has been shown to increase early and timely patient discharge from the ED[2,3]—in some cases by 55 minutes[6]—compared to patients tested using the lab.

Estimated Plasma Volume: an Easy-to-Use Clinical Tool to Determine the Risk of Sepsis in ED Patients with Fever[7]

Fever is a common cause of Emergency Department admission. Fever may be the only symptom of rapidly evolving inflammatory diseases and a significant fraction of these patients may develop a septic state.[7,8] The ePVS value is a useful predictive tool to assess the severity of illness in ED patients with fever.[8] Prime Plus automatically calculates plasma volume as part of its 24 test menu.

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STAT PROFILE Prime+®

Fast, Simple, POC Analyser for the Emergency Department

Comprehensive Menu for Rapid Patient Triage

Blood gases

pH PCO_2 PO_2 SO_2%

Electrolytes

Na K iCa iMg Cl TCO_2

Metabolites

Glu Lac Urea Creat/eGFR

Haematology

Hb Hct ePV MCHC

CO-Oximetry

O_2Hb COHb MetHb HHb tBil HbF

Comprehensive tests for triage and treatment

- Basic metabolic profile.
- Renal Panel with eGFR critical for early AKI detection and mitigation.
- Lactate to identify and guide therapy for tissue hypoxia in sepsis.
- Measured Hb and Hct for evaluation of anaemia and O_2 transport capability.
- ePV for assessment of fluid balance and fever.
- Blood Gas and CO-Ox for acid-base disturbances and pulmonary function.

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STAT PROFILE Prime+®

CARDIAC SURGERY

Benefits of iMg and ePV Monitoring during Cardiac Surgery

Why monitor iMg in cardiothoracic surgical patients?

- 75% of cardiac bypass (CPB) patients have postoperative hypomagnesaemia.[1]
- Abnormal iMg levels can cause arrhythmias and cardiac arrest in these patients.[1]
- Maintaining normal iMg levels has cardio-protective benefits.[1]
- Intraoperative correction of magnesium guided by real-time serial measurement of iMg reduces risk of ventricular arrhythmia after CPB.[1]
  - **—77% reduction in ventricular tachycardia.[1]**
  - **—35% reduction in atrial fibrillation.[1]**
  - **—115% increase in number of patients maintaining. continuous sinus rhythm after surgery.[1]**

Why is iMg and iCa balance key to cardiac function?

- Ionised calcium (iCa) is an important factor for cardiac contractility.
- iMg is a natural calcium channel blocker, regulating cardiac contraction.
- Maintaining a balanced ion ratio is crucial to sustaining normal cardiac rhythm.

Why measure iMg and not total Mg?

- iMg is the physiologically active and clinically important form of magnesium.[1,2]
- iMg and total magnesium do not correlate in critically ill patients.
  - —Prior to CPB, 53% of patients have total hypomagnesaemia but only 11% have ionised hypomagnesaemia.[1]
  - —Up to 85% of critically ill patients with low total magnesium results have normal iMg levels.[2,3,4]
- Point-of-care iMg monitoring allows for accurate and real-time $MgSO_4$ titration compared to traditional bolus Mg administration.[1]
- iMg monitoring avoids Mg toxicity and unnecessary repeat testing.[3]

Why monitor estimated Plasma Volume in cardiothoracic surgical patients?[5,6,7,8]

- The ability to measure ePV rapidly to assess fluid balance can be of great benefit in managing complex patients, such as those with heart failure (HF).
- For inpatients being actively treated and diuresed for HF, a decreasing ePV is a sign of response to therapy.
- ePV gives clinicians additional data at minimal cost and may be able to prevent readmission by identifying subclinical congestion, allowing for outpatient treatment.

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The Most Clinically Advanced Test Menu for Cardiothoracic Surgery

24 tests including unique tests for **iMg, Urea, Creatinine/eGFR and Estimated Plasma Volume (ePV)**

Blood gases

pH PCO_2 PO_2 SO_2%

Electrolytes

Na K iCa iMg Cl TCO_2

Metabolites

Glu Lac Urea Creat/eGFR

Haematology

Hb Hct ePV MCHC

CO-Oximetry

O_2Hb COHb MetHb HHb tBil HbF

Results in about 90 seconds

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STAT PROFILE Prime+®

Ideal Point-of-Care Analyser for the NICU

NICU

Reduced blood volume enhances blood conservation capabilities of the Prime Plus

- Micro capillary sample mode assesses 11 measured parameters (pH, pCO_2, pO_2, Hct, Na, K, Cl, iCa, iMg, Gluc and Lac) from a small 90μL capillary sample.
- Small sample size helps conserve blood in neonates, avoiding complications from anaemia, cardiac arrest and transfusion.

Ionised Magnesium

Only POC blood gas analyser to directly measure ionised magnesium (iMg)—aids in preterm and neonatal patient care.

- Dysmagnesaemia is associated with increased mortality, morbidity, and length of stay.[1-7]
- iMg is the only marker that specifically identifies patients with dysmagnesaemia.[8,9]
- iMg monitoring of patients treated with Mg sulfate may improve neonatal outcomes and reduce length of stay when indicated.[9-11]

Causes of Hypermagnesaemia

- Maternal Mg sulfate treatment for preeclampsia and for preterm delivery risk can cause severe neonatal complications including hyporeflexia, hypotonia, and respiratory depression.[12-17]
- Newborn Mg therapy and Mg sulfate enema.[13,16]
- Decreased renal Mg excretion due to prematurity and asphyxia.[13,16]

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Fast, Simple, Blood Gas/Critical Care Analyser for the NICU

11 critical tests from 90 µL of capillary blood

pH PCO_2 PO_2 Na K Cl iCa iMg Glu Lac Hct

24-test test menu with 135 µL (syringe mode)

pH PCO_2 PO_2 Na K Cl iCa iMg TCO_2 Glu
Lac Urea Creat/eGFR tHb Hct MCHC ePV
O_2Hb COHb MetHb HHb tBil HbF SO_2%

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Stat Profile Prime Plus Specifications

Critical Care Tests

	Methodology
pH	Direct ISE
PCO_2	Severinghaus
PO_2	Amperometric
SO_2%	Optical, reflectance
Hematocrit	Conductivity/Na correction
Na	Direct ISE
K	Direct ISE
Cl	Direct ISE
TCO_2	Direct ISE
iCa	Direct ISE
iMg	Direct ISE
Glucose	Enzyme/Amperometric
Lactate	Enzyme/Amperometric
Urea (Urea)	Enzyme/Amperometric
Creatinine	Enzyme/Amperometric

Calculated Tests

A, a/A , A-aDO_2, Anion Gap, BE-b, BE-ecf, Urea/Creat, CaO_2, (C(a-v)O_2), CcO_2*, CvO_2, eGFR, ePV, ΔePV, FO_2Hb, Hb, HCO_3^-, MCHC, nCa/nMg, nCa, nCa/nMg, nMg, O_2Cap, O_2Ct, OI, OSM, PO_2, P_{50}, PO_2/FIO_2, Qsp/Qt, RI, SBC, SO_2%, TCO_2, Temperature Corrected pH/PCO_2, PO_2

CO-Oximetry Tests

HHb, deoxyhaemoglobin	O_2Hb, 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)
P_{50}	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_2Ct	0.1 mL/dL (0.01 mL/dL)
O_2 Cap	0.1 mL/dL (0.01 mL/dL)

Optional Accessories

Combined 1D/2D Barcode Scanner: An optional, factory-installed barcode scanner is available for all Stat Profile Prime models. The scanner reads both 1D and 2D barcodes for patient and operator IDs. QC package inserts can also be scanned for lot number and expiration date.

Mobile Cart: Compatible with all Stat Profile Prime models. Also available with uninterrupted power supply (UPS).

Complete Management Reports

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- 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

Measurement Ranges

pH	6.5 - 8.0 (H+: 316.2 - 10 nmol/L)
PCO_2	3 - 200 mmHg (0.4 - 26.7 kPa)
PO_2	5 - 765 mmHg (0.66 - 102 kPa)
TCO_2	90 - 1260 mg/dL (5 - 70 mmol/L)
Hct	12 - 70%
Na	80 - 200 mmol/L
K	1 - 20 mmol/L
Cl	50 - 200 mmol/L
iCa	0.4 - 10.8 mg/dL (0.1 - 2.7 mmol/L)
iMg	0.24 - 3.65 mg/dL (0.1 - 1.5 mmol/L)
Lactate	2.7 - 180.1 mg/dL (0.3 - 20 mmol/L)
Glucose	15 - 500 mg/dL (0.8 - 28 mmol/L)
Urea (Urea)	3 - 100 mg/dL (1.1 - 35.7 mmol/L)
Creatinine	0.2 - 12 mg/dL (18 - 1061 µmol/L)
O_2Hb	1.8 - 100% (0.018 - 1)
COHb	0.3 - 60% (0.03 - 0.6)
MetHb	0.3 - 60% (0.003 - 0.6)
HHb	0.4 - 40.0% (0.004 - 0.4)
HbF	0 - 95% (0 - 0.95)
tBil	0.5 - 35.0 mg/dl (8.6 - 598.5 µmol/L)
SO_2%	30 - 100%
O_2Ct	2 - 33.4 mL/dL (495.04 - 2952.56 µmol/L)
O_2Cap	2 - 33.4 mL/dL (495.04 - 2952.56 µmol/L)
tHb	5 - 25 g/dL (50 - 250 g/L)
sHb	Alert > 1.5%
BarP	400 - 800 mmHg (53.3 - 106.7 kPa)

Other Features

Full colour, 10.1-inch touchscreen, multilingual, QC statistics, onboard data management, automatic sampler, integrated capillary adapter, QC data storage.

Operating Temperature Range

59°F–89°F (15°C–32°C)

Physical Specifications

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

Electrical Power Requirement

< 90 Watts

Printer

Onboard thermal printer

Calibration

Fully automatic two-point calibration every two 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. Sample draw requirement is 135 µL.

Whole blood (heparinised) microcapillary, sample draw requirement is 90 uL.

Communication Protocols

ASTM, HL7, or POCT1-A2 connectivity formats.

Certifications

ISO 13485 Quality System Requirements,
Complies with EN IEC 61010, CE.

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