

Stat Profile Prime Plus® Critical Care Analyzer



New Technologies Simplify Use and Offer Additional Tests

Stat Profile Prime Plus is a comprehensive, whole blood critical care analyzer that combines blood gases, electrolytes, metabolites, CO-Oximetry, and 32 calculated results in a simple, compact analyzer. Prime Plus combines maintenance-free, component 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, a complete test menu panel in about one minute, and are combined with bidirectional connectivity, a robust data management system, and comprehensive cybersecurity protection.

Nova MicroSensor Card™ Technology

Most comprehensive critical care menu

PO₂ PCO₂ pH Hct tHb Na Cl K iCa TCO₂ iMg Glu Lac Urea (BUN) Creat SO₂%
O₂Hb COHb MetHb HHb

- All Stat Profile Prime Plus biosensors use proven Nova technology in a miniaturized, maintenance-free sensor card format.
- Nova MicroSensor cards combine all 20 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 Stat Profile Prime Plus is the only blood gas analyzer to provide whole blood urea (BUN) and creatinine (plus eGFR) test options for rapid assessment of kidney function.

Ionized 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 analyzer to provide a comprehensive profile of electrolytes including iMg.

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.

- 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

Fast Stat Results

Prime Plus's exceptional throughput easily handles the high sample workload of a busy critical care setting. Prime Plus delivers a 20-test critical care profile in about one minute. Competitors' analyzers can require up to four minutes, even with fewer tests reported.

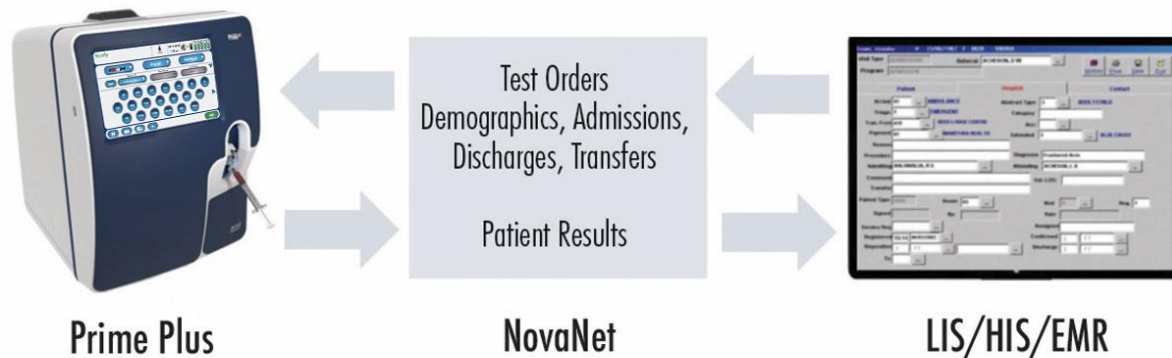
Clot Protection

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

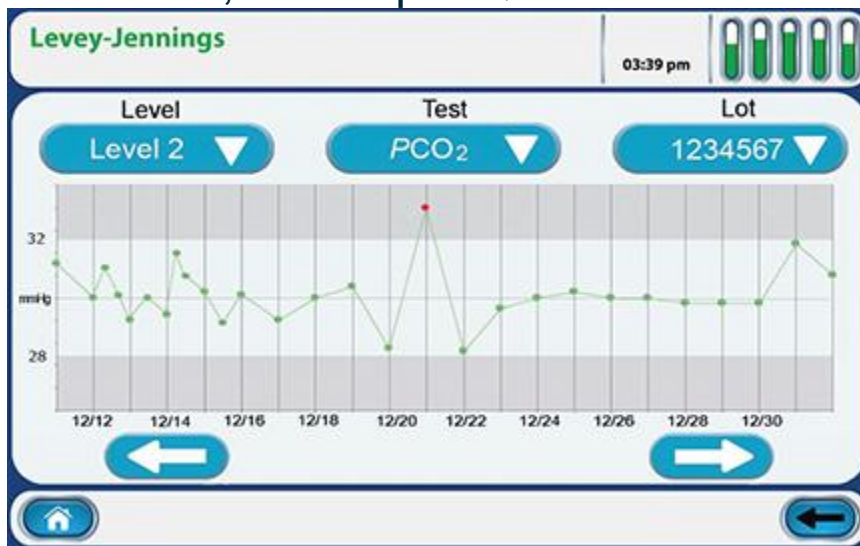
Bidirectional Connectivity Patient Management

NovaNet bidirectional middleware for all Nova connected devices

NovaNet ensures timely, accurate capture of Nova analyzer test results for clinicians and managers to retrieve wherever and whenever needed. Also included is comprehensive cybersecurity protection and encryption that provides protection against attempts to access a hospital's network.



Automated, True Liquid QC



Liquid QC provides

the only reliable test of analyzer performance

United States federal government regulations and many international government regulations have eliminated electronic equivalent QC and are requiring true liquid QC.²

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

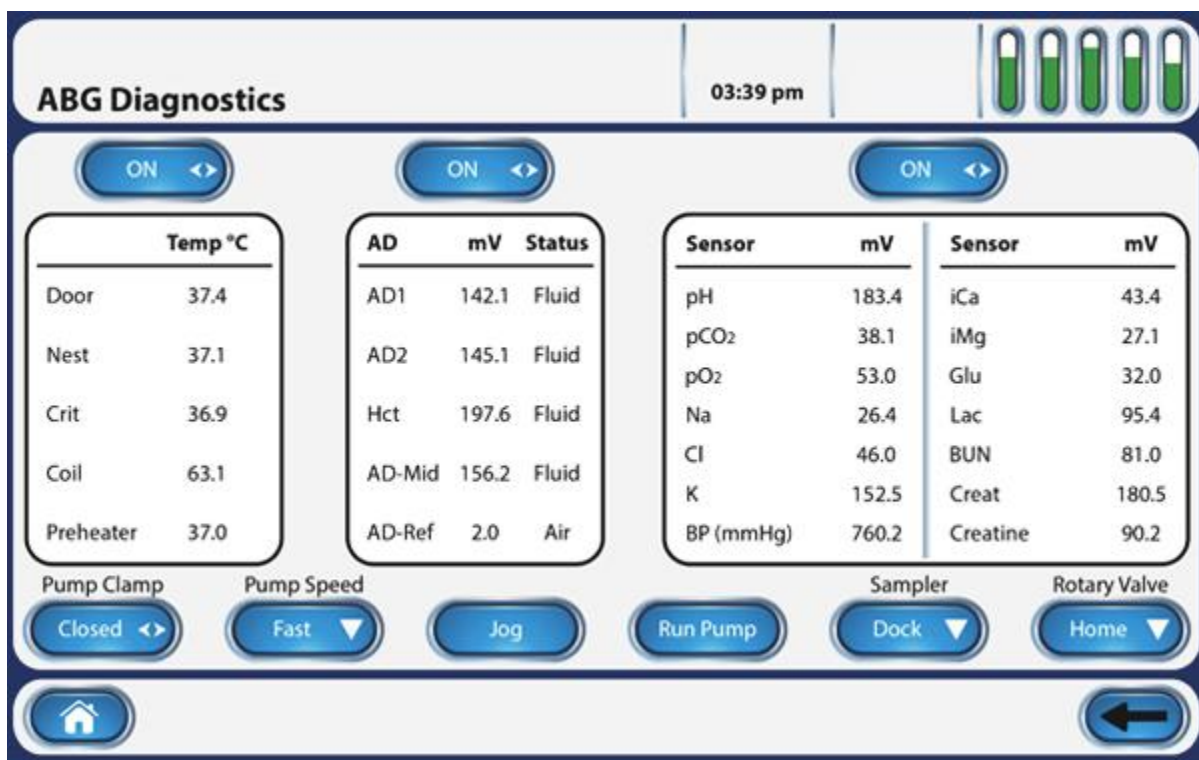
QC cartridges contain a 30-day supply of liquid QC material. Controls are run automatically at user-selected intervals. Prime Plus quality controls:

- 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.

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.



[For more general product information, click here or contact Nova Biomedical at: Nova Biomedical / 200 Prospect Street / Waltham, MA 02454 / 781-894-0800](#)

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.
2. 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.

Stat Profile Prime Plus® Specifications

Critical Care Test Menu	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
iCa	Direct ISE
iMg	Direct ISE
Glucose	Enzyme/Amperometric
Lactate	Enzyme/Amperometric
Urea (BUN)	Enzyme/Amperometric
Creat	Enzyme/Amperometric

Calculated Tests

eGFR	A-aDO ₂	iCa/iMg Ratio
HCO ₃ ⁻	a/A	Normalized iCa
TCO ₂	PO ₂ /FIO ₂	Normalized iMg
BE _{ecf}	Anion Gap	Osmolality
BE _b	SBC	Hemoglobin
A	Base Excess	O ₂ Saturation

pH/PCO₂/PO₂ Corrected to Patient Temperature
Respiratory Index (If % FIO₂ value entered)
Actual Bicarbonate
Standard Bicarbonate

CO-Oximetry Tests

HHb, deoxyhemoglobin

O₂Hb, oxyhemoglobin

MetHb, methemoglobin

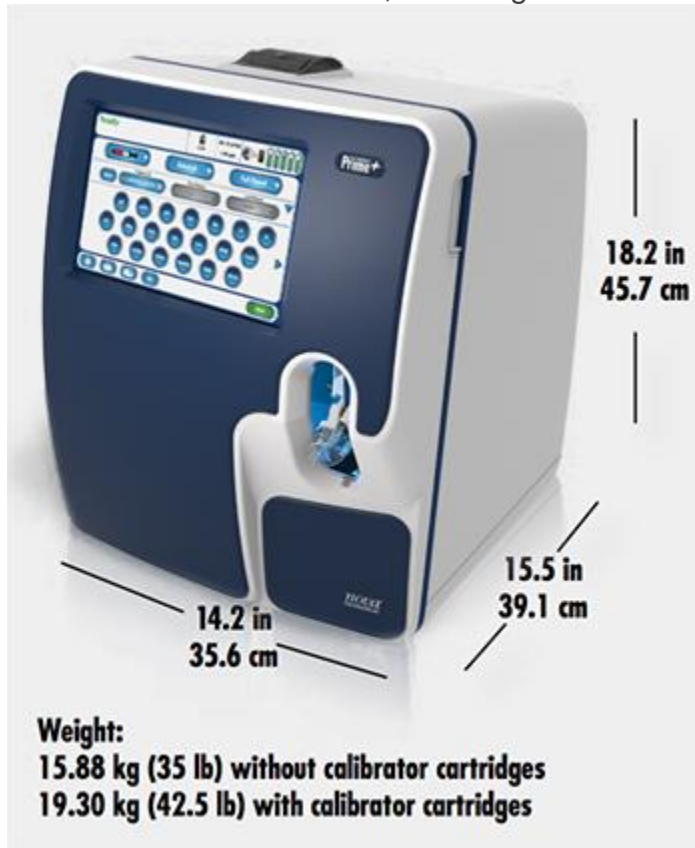
COHb, carboxyhemoglobin

tHb, total hemoglobin

SO₂%, oxygen saturation

Compact Size

Dimensions for Prime Plus, including CO-Oximetry and bidirectional connectivity:



Other Features

Full color, 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

MicroSensor Card

60 µL Sample Volume

Electrical Power Requirement

< 90 Watts

Acceptable Samples

Whole blood (heparinized), arterial, venous, mixed venous
135 µL Sample draw requirement

Communication Protocols

ASTM, HL7, or POCT01-A2 connectivity formats
<

Certifications and Compliance: Nova Biomedical is certified to FDA Quality System Regulations and EN ISO 13485:2016 Complies to IVDD Tested according to: EN 61010-1:2010, EN 61010-2-101:2015, EN 60825-1/A1:2014.
Specifications current as of revision date.