

New Generation

STAT PROFILE®

pHOx® Ultra™

Best Value for Blood Gas Critical Care Testing

**One Analyzer, Up to
20 User Selected
Critical Care Tests**

**New Simplified
Operation with Easy
to Use High Resolution
Touch Screen**

**Proven pHOx Hardware Platform
Gives Exceptional Reliability**



nova[®]
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pHOx® Ultra™

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Low Cost Critical Care Testing

pHOx Ultra combines long life sensors plus low cost reagent cartridges to provide the most cost effective way for a hospital to offer blood gas/critical care testing. pHOx Ultra provides a 20-test critical care profile at a cost equivalent to testing performed in the central laboratory. Other point of care devices that use single-test or 30-day sensor cartridges can be 5 to 10-times more costly.¹

The pHOx Ultra comprehensive on-board Data Management System eliminates the high cost of purchasing a separate data manager. The Data Management System enables networking of multiple pHOx Ultra analyzers, reducing connectivity and record keeping costs.

One Analyzer, Up to 20 Tests

No other blood gas analyzer can match the clinical value of pHOx Ultra to deliver up to 20 critical care tests from one small, 210 microliter sample in only 2 minutes. Other partial test panels are available in less than one minute. Measured tests include:

- pH, PCO₂, PO₂, SO₂%
- Na, K, iCa, iMg, Cl
- Glucose, Urea /BUN, Creatinine, Lactate
- Hct, Hb
- O₂Hb, HHb, COHb, MetHb, tBil

Limited Maintenance

Sixteen of the twenty available tests require very little maintenance. They typically require replacement only 1 to 4 times per year. In addition, because replacement is fast and simple, little time is needed for maintenance.

Customized Menus

pHOx Ultra can be custom configured with as few as 5 tests to as many as 20 tests on-board to satisfy the exact test menu requirements of each department. However the complete test menu does not have to be run on each sample. Up to 30 specific user-defined subsets (panels) can be created for patient populations such as pulmonary, surgical, pediatric, or emergency care.

Simpler, Faster Touchscreen Operation

A new streamlined user interface is very fast and easy to use. The new interface uses graphic icons and clearly labeled buttons for instrument operation. Color shading and highlighting provide visual prompting through a simple, 3-step operation:

1. Select tests
2. Identify the sample
3. Aspirate the sample

New High Resolution Color Display

Stat Profile Ultra incorporates a large, high-resolution color display. The large format, bright colors and high resolution provide exceptional viewing, and easy to read graphics and data

Measured SO₂%, Hb, and HCT on Each Sample Without CO-Oximetry

A unique technology feature of Nova pHOx analyzers is their ability to measure hemoglobin, hematocrit and oxygen saturation on each sample. Advanced biosensors, optics and algorithms enable measurement of these parameters without the added cost, hardware and sample volume of a CO-Oximeter.

Optional On Board CO-Oximeter

When a complete profile of hemoglobin fractions is needed as part of the analyzer test menu, pHOx Ultra offers an on-board CO-Oximeter with advanced features:

- Complete CO-Oximetry test panel including O₂ Hb, HHb, COHb, MetHb, tBil
- Automatic calibration
- Automatic cleaning of the optical components

Ionized Magnesium

pHOx Ultra provides ionized magnesium as part of its electrolyte panel. Ionized magnesium is a very important electrolyte for cardiac health. This electrolyte works with potassium and calcium to maintain strong and rhythmic cardiac contraction. It is the most common electrolyte abnormality among post operative intensive care patients.²

1. DiLulio R. *The Right Stuff*. RT April 2010. 20-24.

2. Chernow B. *Hypomagnesemia in patients in postoperative intensive care*. *Chest* 95:391-97 (1989)..

Ca⁺⁺Mg⁺⁺

Glucose

Urea/BUN

Creatinine

eGFR

Hct

Hb



pHox Ultra Measured Tests

pH PCO₂ PO₂ SO₂% Na⁺ K⁺ iCa iMg Cl Gluc Urea/BUN Creat Lac Hct Hb O₂Hb HHb COHb MetHb tBil

Small Blood Microsample

pHox Ultra can dramatically reduce the volume of whole blood needed to perform critical care testing. Blood samples can be as small as 60 µl for blood gases, or 210 µl for a complete 20-test profile.

Results as Fast as 1 Minute

pHox Ultra test menu and turnaround time give clinicians the test results they need, when they need them. Depending on the tests selected, results are available as fast as 1 minute. A full 20-test panel is available in only 2 minutes.

Automated, True QC

An automated, true QC system eliminates all user steps involved in performing multi-level, true liquid quality control, dramatically reducing labor while maintaining the most stringent quality control.

Automated, Internal Quality Assurance (IQA)

An Internal Quality Assurance system extends quality assurance measures to every sample and calibration. IQA performs over 40 automatic checks during sample and calibration cycles to verify correct performance of sensors, reagents, fluidics, and electronics. The IQA system reports a test parameter only when all 40 performance checks are successful, providing a continual level of quality assurance.



pHox Ultra snap-in Calibrator and QC Cartridges are ready to use and are easily installed in minutes

Always Stat Ready

Stat Profile pHox Ultra maintains constant readiness through rapid, fully automatic single-point and two-point calibrations. An all-liquid Calibrator Cartridge onboard the pHox analyzer contains all reagents necessary for calibration and sample analysis for up to 30 days. A waste container within the Calibrator Cartridge eliminates maintenance and potential exposure to bio-hazardous waste.

The Calibrator Cartridge can be replaced and the analyzer calibrated in less than 10 minutes. Other cartridge-based analyzers can experience hours of service interruption due to failed calibrations, or lengthy cartridge stabilization periods.

Exceptional Reliability

Stat Profile pHox Ultra hardware and software designs are based on the extraordinary reliability of previous generation pHox analyzers that have been proven in thousands of installations during the last decade.



Multiple Department Applications

The customizable whole blood test menu, fast analysis time, and low operating cost make pHox Ultra ideal for multiple testing locations:

- OR, ICU: Provides the most comprehensive menu for managing high acuity ICU and OR patients
- Emergency Department: Reduces waiting times for essential laboratory tests, improving patient triage and satisfaction
- Stat Lab: Supports the stat testing workload of multiple departments
- Mobile Testing: pHox Ultra on a mobile cart with battery backup enables it to be moved to any hospital location for stat testing as needed.

Complete Data Management and Connectivity

Onboard Data Management System

A standard feature on all StatProfile pHox Ultra analyzers is a complete on-board Data Management System, allowing data capture and extensive reporting capabilities, including:

- Storage and retrieval of patient results, patient demographics, QC, and authorized users
- Data retrieval by name, ID, date, location, or operator
- Patient, QC, utilization and operator reports

Analyzer Networking At No Extra Cost

Multiple pHox Ultra analyzers can be networked together into a single, common database. A supervisor or authorized operator can access all patient results, QC results and reports from all analyzers. Competitors often offer this capability only as an expensive accessory, adding 30% - 40% to the cost of the analyzer.

Remote Set-up and Control

pHox Ultra offers comprehensive, time-saving remote set-up, control, and review of multiple pHox Ultra analyzers. From any point on the LAN, a manager can perform the following functions on a remote analyzer:

- Review reagent cartridge and QC cartridge status
- Review instrument calibration status
- Initiate a calibration cycle
- Review quality control status
- Initiate a quality control cycle
- Enable or disable an analyte
- Enable or disable operator access
- Edit normal ranges, critical ranges, QC ranges, QC frequency, operators, test menu, instrument defaults

Connectivity

pHox Ultra analyzers are compliant with industry standard POCT 1A and ASTM communication protocols for connectivity. These industry standards are used to easily interface pHox Ultra analyzers to a wide range of connectivity systems including LIS, HIS and middleware systems.



Lactate

O₂Hb

COHb

MetHb

HHb

SO₂%

tBil

Stat Profile pHox[®] Ultra[™] Specifications

Critical Care Test Menu: Methodology:

pH	Direct ISE
PCO ₂	Severinghaus
PO ₂	Amperometric
SO ₂ %	Optical, reflectance
Hematocrit	Conductivity/Na ⁺ correction
Hemoglobin	Multi-wavelength reflectance/ conductivity correction
Na ⁺	Direct ISE
K ⁺	Direct ISE
Cl ⁻	Direct ISE
Ca ⁺⁺	Direct ISE
Mg ⁺⁺	Direct ISE
Glucose	Enzyme/Amperometric
BUN/Urea	Enzyme/Direct ISE
Creatinine	Enzyme/Amperometric
Lactate	Enzyme/Amperometric

CO-Oximetry Test Menu:

HHb, deoxyhemoglobin	O ₂ Hb, oxyhemoglobin
MetHb, methemoglobin	COHb, carboxyhemoglobin
tHb, total hemoglobin	SO ₂ %, oxygen saturation
O ₂ Ct, oxygen content	O ₂ Cap, oxygen capacity
tBil, Total Bilirubin	

Calculated Tests:

eGFR		
HCO ₃	a/A	Ca ⁺⁺ /Mg ⁺⁺ Ratio
TCO ₂	PO ₂ /FIO ₂	Normalized Ca ⁺⁺
BE-ecf	Anion Gap	Normalized Mg ⁺⁺
BE-b	SBC	Osmolality
O ₂ Ct	Base Excess	O ₂ Cap
A	O ₂ Saturation	Hemoglobin
A-aDO ₂	BUN/Creatinine Ratio	
pH/PCO ₂ /PO ₂	Corrected to Patient Temperature	
Respiratory Index	(If % FIO ₂ value entered)	

Special Calculated Tests (CO-Oximeter 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)

Complete Management Reports:

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

Monitored Interferences:

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

Measurement Range:

pH	6.50 - 8.000 (H ⁺ : 316.23 - 10.00 mmol/L)
PCO ₂	3.0 - 200 mmHg (0.4 - 26.6 kPa)
PO ₂	0 - 800 mmHg (0.0 - 106.4 kPa)
SO ₂ %	30 - 100 % (0.3 - 1.00)
Hct	12% - 70%
Hb	4.0 - 24.0 g/dL (2.5 - 14.9 mmol/L)
Na ⁺	80 - 200 mmol/L
K ⁺	1 - 20 mmol/L
Cl ⁻	50 - 200 mmol/L
Ca ⁺⁺	0.1 - 2.7 mmol/L
Mg ⁺⁺	0.1 - 1.5 mmol/L
Glucose	15 - 500 mg/dL (0.83 - 27.75 mmol/L)
BUN	3 - 100 mg/dL (2.1 - 17.4 mmol/L)
Urea	1.1 - 35.7 mmol/L (6.4 - 214.5 mg/dL)
Creatinine	0.2 - 20 mg/dL (18 - 1765.8 µmol/L)
Lactate	0.3 - 20 mmol/L (2.7 - 178.1 mg/dL)
HHb	0 to 100%
O ₂ Hb	0 to 100%
MetHb	0 to 100%
COHb	0 to 100%
SO ₂ %	0 to 100%
O ₂ Ct	0 to 34.75 vol. %
O ₂ Cap	0 to 34.75 vol. %
tBil	0.5-35.1 mg/dL
tHb	5 - 25 g/dL
sHb	Alert > 1.5%
BarP	400.0 - 800.0 mmHg (53.3 - 106.7 kPa)

Other Features:

Full color, 12.1 inch touch screen, multilingual, QC statistics, on-board data management, automatic sampler, integrated capillary adapter, optional bar code scanner, QC data storage, ASTM and HL7 communication protocols, optional mobile cart with UPS

Certifications:

ISO 13485: 2003, Quality System, Registration, CSA, TÜV, IVDD CE Self Declared, CSA, TÜV, Complies to EN 61010, EN 50081,82, Integrated RiLiBaK compliant QC module

Typical Sample Volume:

- 60 microliters whole blood micro sample for blood gases/pH
- 105 microliters whole blood for CO-Oximetry with total Bilirubin
- 120 microliters micro sample for full panel without CO-Oximetry
- 150 microliters whole blood sample for full panel without CO-Oximetry
- 210 microliters whole blood sample for full panel with CO-Oximetry

Physical Specifications:

Height: 17.22 in (43.7 cm) Width: 22.34 in (56.7 cm)
Depth: 18.7 in (43.8 cm) Weight: 61 lb (27.7kg)
without reagent pack

Electrical Power Requirements:

90-264 VAC, 50/60 Hz, 350 W

Interfaces:

ASTM Protocol, via serial RS232 TCP/IP, POCTIA

Temperature Thermostatting:

37°C ± 0.1°C

Printer:

Built in thermal

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

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