Stat Profile® pHOx® Series

Advanced Technology for Blood Gas and Critical Care Analyses

Stat Profile pHOx Basic  Blood Gas Profile
pH  PCO₂  PO₂

Stat Profile pHOx Oximetry  Blood Gas/Oximetry Profile
pH  PCO₂  PO₂  SO₂%  Hct  Hb

Stat Profile pHOx Respiratory  Blood Gas/Respiratory Profile
pH  PCO₂  PO₂  SO₂%  Hct  Hb  Lac

Stat Profile pHOx Plus  Critical Care Profile
pH  PCO₂  PO₂  SO₂%  Hct  Hb  Na⁺  K⁺  Ca²⁺ or Cl⁻  Glu

Stat Profile pHOx Plus C  Critical Care Profile
pH  PCO₂  PO₂  SO₂%  Hct  Hb  Na⁺  K⁺  Ca²⁺  Cl⁻  Glu

Stat Profile pHOx Plus L  Critical Care Profile
pH  PCO₂  PO₂  SO₂%  Hct  Hb  Na⁺  K⁺  Ca²⁺ or Cl⁻  Glu  Lac

NOVA biomedical
Six Models with Blood Gas and Critical Care Menus

Using a unique combination of advanced optical and electrode technology, Stat Profile pHox® analyzers offer blood gas or point-of-care (POC) test menus.

The Stat Profile pHox Basic test menu consists of pH, PCO₂, and PO₂. The other five pHox menus include pH, PCO₂, PO₂, and add choices of measured hemoglobin, hematocrit, SO₂%, glucose, lactate, sodium, potassium, calcium and chloride assays in the combinations shown in the table below.

A unique technology feature of Nova Stat Profile analyzers is that they can measure hemoglobin, hematocrit and SO₂% on each sample without the added cost and added sample volume of a CO-Oximeter. For many users, these basic oxygenation tests greatly reduce the number of separate CO-Oximetry analyses that need to be done. However, when a full CO-Oximeter profile, including the hemoglobin fractions, is needed, a Stat Profile pHox CO-Oximeter is available.

### pHox Models/Menu

- **Stat Profile pHox Basic:** pH; PCO₂; PO₂
- **Stat Profile pHox Oximetry:** pH; PCO₂; PO₂; SO₂% Hct Hb
- **Stat Profile pHox Respiratory:** pH; PCO₂; PO₂; SO₂% Hct Hb Lac
- **Stat Profile pHox Plus:** pH; PCO₂; PO₂; SO₂% Hct Hb Na⁺ K⁺ Glu Ca⁺⁺ or Cl⁻
- **Stat Profile pHox Plus C:** pH; PCO₂; PO₂; SO₂% Hct Hb Na⁺ K⁺ Glu Ca⁺⁺ and Cl⁻
- **Stat Profile pHox Plus L:** pH; PCO₂; PO₂; SO₂% Hct Hb Na⁺ K⁺ Glu Lac Ca⁺⁺ or Cl⁻

**Advanced Analytics**

### Microsensors

New, smaller electrode designs create several improvements. A 45 microliter blood sample is offered for pediatric patients. New disposable sensor elements eliminate electrode maintenance. When a disposable element needs to be replaced, it can be done in seconds.

### Optics

Oxygen saturation and hemoglobin are measured based upon advanced multi-wavelength optical reflectance technology.

### Measured vs. Calculated SO₂% without CO-Oximeter

Measured rather than calculated oxygen saturation (SO₂%) is officially recognized by the National Committee for Clinical Laboratory Standards (NCCLS) as necessary for accurate assessment of oxygen saturation. The 1997 NCCLS Standard C-25A recommends that calculated SO₂% values of blood gas analyzers **not** be used to assess a patient’s oxygenation status because of the potential errors that can result. All models except the Stat Profile pHox Basic provide measured SO₂% without the need for a separate CO-Oximeter.

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**Fast Stat Results**

Stat Profile pHox analyzers process samples rapidly. All test results are available and are displayed on-screen in 45 seconds (pHox Oximetry and pHox Basic), 50 seconds (pHox Plus), or 52 seconds (pHox Plus C, pHox Plus L, and pHox Respiratory). Throughput rates are 50 samples per hour for pHox Basic and pHox Oximetry, 44 samples per hour for the pHox Plus and pHox Plus C, and 40 samples per hour for the pHox Plus L and pHox Respiratory.

### All Liquid Calibration Cartridge Eliminates Gas Tanks

A new, liquid-only calibration cartridge eliminates bulky compressed gas tanks, gas regulators, gas tubing lines, and humidifiers. A single cartridge contains all calibrators. This integrated gas and reagent packaging system replaces up to five individual reagent bottles and two gas tanks with a simple, snap-in reagent cartridge. The single cartridge also eliminates the need to maintain logs and run both calibration and QC procedures each time one of the five individual reagent bottles or two gas tanks is replaced. When the calibration cartridge is used, all calibrator values, fluid volumes, and expiration dates are automatically downloaded to the computerized Reagent Management System (RMS). Fluid consumption is then automatically monitored and calibration reagent levels are displayed on-screen. In addition, the calibration cartridge includes a sealed waste container that stores the sample and reagent waste. The waste container is completely enclosed for safety and ease of disposal.
On-Board Cartridge QC Automates Quality Control

Nova’s Auto-Cartridge QC is a totally automated quality control system contained within a single on-board control cartridge. This unique system combines multiple levels of controls and dedicated software allowing any level of quality control to be run at any time, either on a pre-programmed schedule or on demand.

Time and Labor Savings
For most users, analyzing controls and entering quality control data require more time and labor than any other aspect of blood gas testing. The Auto-Cartridge QC system dramatically reduces costs by eliminating the time and labor required to manually perform quality control.

Each Nova Auto-Cartridge contains three levels of blood chemistry controls, two levels of SO₂%, hematocrit and hemoglobin controls, and software which automates running controls and storing quality control data.

When the cartridge is installed, all quality control target ranges, lot code, and expiration date are automatically downloaded to the analyzer.

Automatic QC Analysis
The user can program the analyzer to automatically analyze up to three quality control levels, three times per day.

Auto Repeat and Flagging
If any analyte value is outside the target range, it is automatically reanalyzed; if a control value remains outside of range, the user is notified.

Automatic Data Storage and Reporting
All quality control data is automatically stored. Daily and cumulative statistical reports and Levey-Jennings graphs can be printed at any time. This automation not only eliminates labor, it assures that quality control is always performed accurately and on schedule, and guarantees regulatory compliance.

Automated Activation from Standby
If the analyzer is put into standby mode for several hours or days, it can be programmed to automatically restart, calibrate itself, and perform QC at a pre-selected time and date.

QC Lockout
An optional QC lockout feature programs the analyzer to suppress test results for any analyte that is not within its control range.

Small Sample Volume
Blood conservation is an important initiative in every critical care department, especially the NICU. The average daily blood loss due to laboratory tests in critically ill patients is 25 to 125 mL/day per patient. Stat Profile pHOx analyzer sample volumes are important contributors to blood conservation with volumes as low as 45 µL for blood gas and only 125 µL for a full 11 test menu.

<table>
<thead>
<tr>
<th></th>
<th>Full Panel</th>
<th>Micro Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stat Profile</td>
<td>70 µL</td>
<td>45 µL</td>
</tr>
<tr>
<td>pHOx Basic</td>
<td>(3 tests)</td>
<td>(3 tests)</td>
</tr>
<tr>
<td>Stat Profile</td>
<td>70 µL</td>
<td>45 µL</td>
</tr>
<tr>
<td>pHOx Oximetry</td>
<td>(6 tests)</td>
<td>(3 tests)</td>
</tr>
<tr>
<td>Stat Profile</td>
<td>125 µL</td>
<td>60 µL</td>
</tr>
<tr>
<td>pHOx Respiratory</td>
<td>(7 tests)</td>
<td>(3 tests)</td>
</tr>
<tr>
<td>Stat Profile</td>
<td>115 µL</td>
<td>55 µL</td>
</tr>
<tr>
<td>pHOx Plus</td>
<td>(10 tests)</td>
<td>(3 tests)</td>
</tr>
<tr>
<td>Stat Profile</td>
<td>125 µL</td>
<td>60 µL</td>
</tr>
<tr>
<td>pHOx Plus C</td>
<td>(11 tests)</td>
<td>(3 tests)</td>
</tr>
<tr>
<td>Stat Profile</td>
<td>125 µL</td>
<td>60 µL</td>
</tr>
<tr>
<td>pHOx Plus L</td>
<td>(11 tests)</td>
<td>(3 tests)</td>
</tr>
</tbody>
</table>

Compact POC Design
Stat Profile pHOx analyzers are the smallest instruments offering their respective test menus. The analyzer footprint is only 12” wide by 15” deep by 15” tall (31 cm x 38 cm x 38 cm), including on-board reagents and controls, and a sealed waste container to store used reagents and samples. These analyzers weigh less than 20 pounds (9 kg) and are easily transported on the optional pHOx Cart with an uninterruptible power manager.

Easy, Safe Capillary or Syringe Use
The Stat Profile pHOx sampler is designed for fast, easy use and operator safety. For samples in syringes, the sampler probe automatically positions itself at the optimal angle. For capillary samples, the sampler automatically presents a universal capillary sampling port in a horizontal position to prevent spillage or dripping. As sampling is performed directly from the capillary, no adapter or sample transfer is required. This assures that sample integrity and operator safety are optimized. Following sample aspiration from either syringes or capillaries, the sampler moves to an internal wash position and is automatically cleaned.
Benefits for the Physician, Laboratory, and Management

For the Physician: Improved Diagnosis
- Comprehensive diagnosis of patient acid/base oxygenation status plus key electrolyte, metabolite and hematology parameters.
- Small sample size for pediatric patients.
- 52 second stat analysis time for the full 11 test panel.

For the Laboratory: Time and Labor Savings
- On-board QC system eliminates running controls and entering data.
- Eliminating bulky gas tanks, regulators, humidifiers, and tubing lines avoids ongoing replacement and maintenance.
- Single calibration cartridge eliminates labor required to replace consumable items and perform separate recalibrations and QC procedures.
- Sealed on-board waste container with enclosed biocide can be disposed without operator contact to blood waste.
- Disposable sensor elements require no daily maintenance, have long operating lives, and can be replaced in seconds.

For Management: Real Cost Savings
- On-board QC ensures quality control, and eliminates 80% of the daily labor required to perform quality controls.
- Advanced microsensors, surface mount electronics, and reagent packaging significantly reduce analyzer cost and reagent consumption.
- Elimination of sensor maintenance, gas tank replacement, emptying and cleaning waste containers, cleaning gas lines, regulators, and humidifiers substantially reduces operating labor and inventory costs.
- Enhanced clinician satisfaction due to rapid turnaround of key diagnostic information.

A Complete POC Connectivity Solution

Any number of Nova analyzers can be interfaced with Nova’s powerful Point-of-Care Data Manager (PDM) software.

This connectivity software provides a flexible, integrated POC system performing these key functions:

Process Automation
PDM automates the order entry, accessioning, and reporting process. This process automation software reduces turnaround time, eliminates manual order entry and data reporting, prevents data errors, and improves efficiency of operation.

Remote Control
The lab can remotely view instrument status and initiate an automated analyzer calibration, maintenance cycle, or on-board QC testing for a POC analyzer. It also can restrict analyzer use by password access, and permit the lab to enable or disable any test channel on the analyzer.

Remote Review
PDM enables the central laboratory to have a constant overview of POC analyzers located at the point-of-care. Laboratory staff can review, verify, edit, store, and print POC test results, quality control, and instrument calibration without ever leaving the laboratory.

Data Capture
PDM captures data from multiple analyzers and connects with the LIS and HIS for seamless integration of data. PDM is the gateway to an open system allowing connectivity of instruments from other POC vendors. The HL7 data format used by the PDM allows for universal connectivity to any LIS system.

Password Protection
All pHOx analyzers accept up to 200 individual passwords with multiple privilege levels, thereby restricting access to authorized individuals only. Further, a test suppression function permits the lab to enable or disable any test channel on the analyzer.
Stat Profile pHOx Series Specifications

**Measured Tests:**
<table>
<thead>
<tr>
<th>Measured Tests</th>
<th>Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na⁺</td>
<td>Direct ISE</td>
</tr>
<tr>
<td>K⁺</td>
<td>Direct ISE</td>
</tr>
<tr>
<td>Ca²⁺</td>
<td>Direct ISE</td>
</tr>
<tr>
<td>Glucose</td>
<td>Enzyme/Amperometric</td>
</tr>
<tr>
<td>Lactate</td>
<td>Enzyme/Amperometric</td>
</tr>
<tr>
<td>Cl⁻</td>
<td>Direct ISE</td>
</tr>
<tr>
<td>pH</td>
<td>Direct ISE</td>
</tr>
<tr>
<td>PO₂</td>
<td>Seeringhaus</td>
</tr>
<tr>
<td>PO₂</td>
<td>Amperometric</td>
</tr>
<tr>
<td>SO₂%</td>
<td>Optical, reflectance</td>
</tr>
<tr>
<td>He/H₂O</td>
<td>Conductivity/Na⁺ correction</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>Multi-wavefront reflectance/ conductivity correction</td>
</tr>
</tbody>
</table>

**Special Calculated Tests (CO-Oximeter Required):**
<table>
<thead>
<tr>
<th>Tests</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>qSp/qQt</td>
<td>0.1</td>
</tr>
<tr>
<td>A-v O₂</td>
<td>0.1 mmHg (0.01 kPa)</td>
</tr>
<tr>
<td>ArCO₂</td>
<td>0.1 mmHg (0.01 kPa)</td>
</tr>
<tr>
<td>ArCO₂</td>
<td>0.1 mmHg (0.01 kPa)</td>
</tr>
<tr>
<td>PSCO₂</td>
<td>0.1 mmHg (0.01 kPa)</td>
</tr>
<tr>
<td>PSCO₂</td>
<td>0.1 mmHg (0.01 kPa)</td>
</tr>
</tbody>
</table>

**Measurement Range:**
- Na⁺: 80 - 200 mmol/L
- K⁺: 1 - 200 mmol/L
- Ca²⁺: 0.1 - 2.7 mmol/L
- Glu: 15 - 500 mg/dL
- Lac: 0.3 - 20 mmol/L
- Cl⁻: 0.1 - 200 mmol/L
- pH: 6.50 - 8.00 (H⁺: 516.23 - 10.00 mmol/L)
- PO₂: 3.0 - 2000 mmHg (0.4 - 26.7 kPa)
- PCO₂: 0.0 - 800 mmHg (0.00 - 106.7 kPa)
- SO₂%: 50 - 100 % (0.3 - 1.00)
- Hb: 4.0 - 24.0 g/dL (2.5 - 14.9 mmol/L)
- Hct: 12% - 70% (12 - 60% for micro in plus family and pHox Respiratory)

**BarP:** 400.0 - 800.0 mmHg (53.3 - 106.7 kPa)

** majors Features:**
1/4 VGA color display (color available 6/105); multilingual, visible flow path, automatic QC, QC statistics reports, Lee-Yennings plots, gasless calibration (no tanks or regulators), automatic sampler, integral capillary adapter, PCGMA type program changer, optional OCD bar code scanner, single snap-in reagent system, arterial venous physiological shunt mode, QC data storage, combined CO-Oximetry and blood gas results, ventilator settings, draw puncture site

**Certifications:**
- ISO 9001 Quality System Registration, CSA, TÜV, CE Self Declared Complies to EN 61010, EN 50801,82

**Physical Specifications:**
- Height: 15.0 in (38.1 cm)
- Width: 12.0 in (30.5 cm)
- Depth: 15.0 in (38.1 cm)
- Weight: 18 lb (8.19 kg) without reagent pack

**Analytical Specifications for Imprecision:**
- (Normal Aspiration Mode)

<table>
<thead>
<tr>
<th>Analyte</th>
<th>CV%</th>
<th>SD</th>
<th>CV%</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na⁺</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>K⁺</td>
<td>1.5</td>
<td>0.15</td>
<td>3.0</td>
<td>0.15</td>
</tr>
<tr>
<td>Ca²⁺</td>
<td>2.0</td>
<td>0.05</td>
<td>4.0</td>
<td>0.05</td>
</tr>
<tr>
<td>Glucose</td>
<td>5.0</td>
<td>2.0</td>
<td>6.5</td>
<td>3.0</td>
</tr>
<tr>
<td>Lactate</td>
<td>3.0</td>
<td>0.3</td>
<td>6.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Cl⁻</td>
<td>1.5</td>
<td>2.0</td>
<td>2.5</td>
<td>2.0</td>
</tr>
<tr>
<td>SO₂%</td>
<td>N/A</td>
<td>1.0%</td>
<td>N/A</td>
<td>1.5%</td>
</tr>
<tr>
<td>PO₂</td>
<td>3.0</td>
<td>1.0 mmHg</td>
<td>5.0</td>
<td>2.0 mmHg</td>
</tr>
<tr>
<td>PO₂+</td>
<td>3.0</td>
<td>1.5 mmHg</td>
<td>5.0</td>
<td>3.0 mmHg</td>
</tr>
<tr>
<td>PO₂+</td>
<td>3.0</td>
<td>6.0 mmHg</td>
<td>5.0</td>
<td>6.0 mmHg</td>
</tr>
<tr>
<td>Hct</td>
<td>N/A</td>
<td>1.0%</td>
<td>N/A</td>
<td>1.0%</td>
</tr>
<tr>
<td>Hb</td>
<td>0.005</td>
<td>0.013</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.5</td>
<td>0.3 g/dL</td>
<td>2.5</td>
<td>0.3 g/dL</td>
<td></td>
</tr>
</tbody>
</table>

**Calculations:**
- Test Resolution
- Resolution

**Stat Profile pHOx Series Co-Oximeter Specifications**

**Test Menu:**
- COHb, carboxyhemoglobin; Hb, deoxyhemoglobin; O₂Hb, oxyhemoglobin; MetHb, methemoglobin; tHb, total hemoglobin; SO₂, oxygen saturation; O₂, oxygen content; O₂Cap, oxygen capacity

**Monitored Interferences:**
- Sulfbh, sulfhemoglobin

**Sample Volume:**
- 115 µL

**Cycle Time:**
- 80 seconds

**Samples/Hours:**
- 45

**Sample Type:**
- Hemiparenit hemonized blood

**Operating Ranges:**
- COHb: 0 to 100 %
- Hb: 0 to 100 %
- O₂Hb: 0 to 100 %
- O₂Cap: 0 to 40.3 vol% 50% to 30 g/dL
- tHb: Alert > 1.5 %

**Physical Specifications:**
- Height: 15.0 in (38.1 cm) Width: 12.0 in (30.5 cm) Depth: 15.0 in (38.1 cm) Weight: 18 lb (8.19 kg) without reagent pack

**Electrical Power Requirements:**
- 90-264 V AC, 50/60 Hz, 200W

**Data Ports:**
- 2 bidirectional serial I/O data ports, 1 printer port 1 port for optional external bar code reader

**Printer Options:**
- External, 6-1/2” x 11” dot matrix
- External thermal roll printer

**Display Languages (user selectable):**
- English, French, German, Italian, Japanese, and Spanish

**Optical System:**
- Spectrophotometer

**Wavelengths Measured:**
- 557, 577, 597, 605, 624, 655, 690 nm

**Light Source:**
- Halogen

**Expected Light Source Use Life:**
- 50,000 Hours (5+ Years)

**Cuvette Temperature Control:**
- 37°C ± 0.5°C

**Certifications:**
- ISO 9001 Quality System Registration, CSA, TÜV, CE Self Declared Complies to EN 61010, EN 50801,82

**References:**

Specifications are subject to change without notice. No. 95/s46