<table>
<thead>
<tr>
<th>Name of device/First year sold/No. of analyzers sold in 2007</th>
<th>i-STAT System/1992/—</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of devices sold in U.S./Outside U.S./List price</td>
<td>30,000 worldwide/$6,761</td>
</tr>
<tr>
<td>Dimensions (H x W x D)/Weight</td>
<td>9.25 × 3.0 × 2.85 in./22.4 oz</td>
</tr>
<tr>
<td>Analytes measured on device</td>
<td>pH, pCO2, pO2, Hct, Na, K, Cl, lactate, glucose, creatinine, BUN, TC02</td>
</tr>
<tr>
<td>Parameters calculated on device</td>
<td>Hb, HCT, O2SAT, BE, TC02, HCO3-</td>
</tr>
<tr>
<td>Analytical method(s), technology(ies) employed</td>
<td>electrochemical for all analytes</td>
</tr>
<tr>
<td>Device is part of a series of related models</td>
<td>no</td>
</tr>
<tr>
<td>Device warranty</td>
<td>1-yr replacement</td>
</tr>
<tr>
<td>Leaner devices provided</td>
<td>yes</td>
</tr>
<tr>
<td>Average expected life of device</td>
<td>5 yrs</td>
</tr>
<tr>
<td>Open or closed system/External gas tanks required</td>
<td>closed/no</td>
</tr>
<tr>
<td>For POC testing or laboratory</td>
<td>POC testing</td>
</tr>
<tr>
<td>POC:</td>
<td>Uses disposable prepackaged reagent/Electrode system for analysis</td>
</tr>
<tr>
<td>No. of disposable reagent system units in basic shipment package</td>
<td>25 per box</td>
</tr>
<tr>
<td>No. of samples analyzed per disposable reagent system</td>
<td>1</td>
</tr>
<tr>
<td>Reagent unit storage requirements</td>
<td>refrigerate, 2-week shelf life at room temperature</td>
</tr>
<tr>
<td>Shelf life of disposable units</td>
<td>reag./electrode: 6–9 months</td>
</tr>
<tr>
<td>Laboratory:</td>
<td>No. of different disposable reagents required to maintain device</td>
</tr>
<tr>
<td>Max. No. of specific analytic reagents that can reside in device at once</td>
<td>none</td>
</tr>
<tr>
<td>Shelf life</td>
<td>—</td>
</tr>
<tr>
<td>Cost per test/Reagent cost per test</td>
<td>—</td>
</tr>
<tr>
<td>Calibrations required</td>
<td>1 point (automatic)</td>
</tr>
<tr>
<td>Calibration frequency</td>
<td>every test</td>
</tr>
<tr>
<td>Calibrants traceable to NIST standards</td>
<td>yes</td>
</tr>
<tr>
<td>Internal QC program recommended</td>
<td>electronic QC, automated internal wet QC</td>
</tr>
<tr>
<td>QC features</td>
<td>comparable plot, monthly cumulative reports (available with external system)</td>
</tr>
<tr>
<td>Remote control of device from laboratory</td>
<td>yes</td>
</tr>
<tr>
<td>System can use LOINC to transmit results to LIS</td>
<td>yes</td>
</tr>
<tr>
<td>How labs get LOINC codes for reagent kits</td>
<td>yes</td>
</tr>
<tr>
<td>Detects clots within analysis chamber</td>
<td>—</td>
</tr>
<tr>
<td>Specimen types suitable for device</td>
<td>whole blood, capillary, mixed venous, arterial, venous</td>
</tr>
<tr>
<td>Acceptable anticoagulants</td>
<td>heparin</td>
</tr>
<tr>
<td>Sampling technique</td>
<td>injection, capillary transfer and fill</td>
</tr>
<tr>
<td>Suitable for samples from well neonates/Sick neonates</td>
<td>yes/yes</td>
</tr>
<tr>
<td>Sample size for complete panel of analytic results</td>
<td>blood gas 95 µL, electrolytes 65 µL</td>
</tr>
<tr>
<td>Sample size differs with No. of analytes selected</td>
<td>no</td>
</tr>
<tr>
<td>Recommended collection device</td>
<td>syringe or capillary tube</td>
</tr>
<tr>
<td>Provides for patient temperature corrected results</td>
<td>yes</td>
</tr>
<tr>
<td>Time from sample introduction to result availability</td>
<td>about 2 min</td>
</tr>
<tr>
<td>Max. No. of patient samples per hr/Max. No. of measured parameters per hr</td>
<td>20 per unit/160</td>
</tr>
<tr>
<td>Optimal throughput when calibrated and awaiting specimens</td>
<td>—</td>
</tr>
<tr>
<td>Calibration can be interrupted to perform stat sample</td>
<td>—</td>
</tr>
<tr>
<td>Centrications</td>
<td>—</td>
</tr>
<tr>
<td>Known interferences</td>
<td>—</td>
</tr>
<tr>
<td>Restrictions based on Hct</td>
<td>—</td>
</tr>
<tr>
<td>Sampler has self-wiping probe</td>
<td>—</td>
</tr>
<tr>
<td>Time required for maintenance by lab personnel</td>
<td>—</td>
</tr>
<tr>
<td>Onboard diagnostics for troubleshooting/Limited to software</td>
<td>yes/no</td>
</tr>
<tr>
<td>Diagnostics performed through modem</td>
<td>yes</td>
</tr>
<tr>
<td>Training &amp; certification program for user</td>
<td>yes, No. of training days varies</td>
</tr>
<tr>
<td>Method of analyst ID in system</td>
<td>keypad entry/bar-code scanner (customizable)</td>
</tr>
<tr>
<td>Response for hardware &amp; software failure/User ID &amp; QC failure/Calibration &amp; power failure</td>
<td>code No. error message/code No. error message/code No. error message</td>
</tr>
<tr>
<td>Supports bar-code scanning of</td>
<td>operator &amp; patient IDs, reagent lot No.</td>
</tr>
<tr>
<td>User can search for and review previous patient results on screen</td>
<td>yes</td>
</tr>
<tr>
<td>Built-in printer/Data port</td>
<td>—</td>
</tr>
<tr>
<td>Information on hard copy report</td>
<td>—</td>
</tr>
<tr>
<td>Analyzer connects to</td>
<td>LIS/HIS, via data management system</td>
</tr>
<tr>
<td>Interface standards supported</td>
<td>ASTM 1384 &amp; 1238, HL7, others</td>
</tr>
<tr>
<td>To upload patient &amp; QC results, how analyzer connects to external system</td>
<td>direct serial; modem dial-in; hospital network</td>
</tr>
<tr>
<td>Information included in transmission from analyzer to external system</td>
<td>device unique identifier; operator &amp; patient IDs, results, QC results, QC identifier</td>
</tr>
<tr>
<td>Hardware/Software for data management system</td>
<td>GC Manager 3.0/Central Data Station</td>
</tr>
<tr>
<td>No. of different management systems used to analyze data</td>
<td>35+</td>
</tr>
<tr>
<td>Contents downloaded from OMS to analyzer</td>
<td>strip lot Nos., valid control values, valid operator IDs, customizations, analyzer locations</td>
</tr>
<tr>
<td>System connected (five installations) to which LISs, HISs</td>
<td>all major LIS vendors</td>
</tr>
<tr>
<td>• using screen animation, screen scraping</td>
<td>multiple vendors</td>
</tr>
<tr>
<td>• using standard HL7 interface</td>
<td>yes, Sybase</td>
</tr>
<tr>
<td>• using proprietary protocol interface</td>
<td>—</td>
</tr>
<tr>
<td>Use a third-party interfacing tool, engine for LIS, HIS interfaces</td>
<td>—</td>
</tr>
<tr>
<td>Distinguishing features (provided by vendor)</td>
<td>handheld portable, single-use test cartridge menu; broadest test menu available on a single POC platform; laboratory accurate results at the bedside</td>
</tr>
</tbody>
</table>
### Part 2 of 13

**Name of device/First year sold/No. of analyzers sold in 2007**

- **GEM Premier 3000/2000/1,580**
- **GEM 3100/2000/1,580**

<table>
<thead>
<tr>
<th>Name of device/Part</th>
<th>First year sold</th>
<th>No. of analyzers sold in 2007</th>
<th>GEM Premier 3000/2000/1,580</th>
<th>GEM 3100/2000/1,580</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>2,760&gt;7,860&gt;3,999,995</td>
<td>22 × 12 × 12 in.29.5 lbs</td>
<td>(pH, pO2, pCO2, Hct, Na+, K+, Ca++, glucose, lactate)</td>
<td>(pH, pO2, pCO2, Hct, Na+, K+, Ca++, glucose, lactate)</td>
</tr>
</tbody>
</table>

#### Analytics measured on device


#### Parameters calculated on device

- **A-aDo2**, **Hb**, **pH**

#### Barometric pressure

- **Na**, **pH**, **pO2**, **pCO2**, **Hct**, **No. of measuring devices**

#### Device is part of a series of related models

- **Yes**

#### User list or group available

- **Yes** (through local sales representative)

#### Device warranty

- **5 years**

#### Loaner devices provided

- **Yes**

#### Average expected life of device

- **7–10 years**

#### Open or closed system/External gas tanks required

- **Closed /no**

#### For POC testing or laboratory

- **POC & laboratory**

#### POC:

- **Uses disposable prepackaged reagent/Electrode system for analysis**
  - **Yes** (multiuse cartridge)**
  - **No**

- **No. of disposable reagent system units in basic shipment package**
  - **1**

- **No. of samples analyzed per one disposable reagent, electrode system**
  - **20 samples per hour**

- **List price per disposable reagent system**
  - **$21 per 100 cartridges**

- **Shelf life of disposable units**
  - **6 months**

### Laboratory:

- **No. of different disposables required to maintain device**
  - **1**

- **Max. No. of specific analytic reagents that can reside in device at once**
  - **1**

- **Shelf life**
  - **6 months**

### Calibrations required

- **1 & 2 point (automatic)**

- **Calibration frequency**
  - **1 point each patient sample; 2 point: at least every 4 hrs**

- **Calibrants traceable to NIST standards**

- **Internal QC program recommended**

- **QC features**

- **Remote control of device from laboratory**
  - **No**

- **System can use LOINC to transmit results to LIS**

- **How labs get LOINC codes for reagent kits**
  - **No**

### Calibrations required

- **1 & 2 point (automatic)**

- **Calibration frequency**
  - **1 point each patient sample; 2 point: at least every 4 hrs**

- **Calibrants traceable to NIST standards**

- **Internal QC program recommended**

- **QC features**

- **Remote control of device from laboratory**
  - **Yes**

- **System can use LOINC to transmit results to LIS**

### Detects clots within analyser chamber

- **Yes; automatically attempts to clear**

### Specimen types suitable for device

- **Whole blood, arterial, venous, or capillary**

### Acceptable anticoagulants

- **Heparin**

### Sampling technique

- **Aspiration**

### Suitable for samples from well neonates/Seck neonates

- **Yes/yes**

### Sample size for complete panel of analytic results

- **120–150 μL**

### Sample size differs with No. of analytes selected

- **No**

### Recommended collection device

- **Syringe or capillary tube**

### Provides for patient temperature corrected results

- **Yes**

### Time from sample introduction to result availability

- **85 seconds**

### Max. No. of patient samples per hr/Max. No. of measured parameters per hr

- **20/80**

### Optimal throughput when calibrated and awaiting specimens

- **20 samples per hour**

### Calibration can be interrupted to perform stat sample

- **Yes**

### Contraindications

- **No**

### Known interferences

- **No**

### Restrictions based on Hct

- **No**

### Sampler has self-wiping probe

- **Yes**

### Time required for maintenance by lab personnel

- **No operator intervention**

### Onboard diagnostics for troubleshooting/Limited to software diagnostics performed through modem

- **No**

### Training & certification program for user

- **Yes**

### Method of analyte ID in system

- **Manual or bar-code entry ID & password (customizable)**

### Response for hardware & software failure/User ID & QC failure/Calibration & power failure

- **Operator warning, sampling lockout/user ID: no system access, QC: channel flagged/calibration: no results for channel, power: automatic recalibration**

### Supports bar-code scanning of

- **User can search for and review previous patient results on screen**

### Built-in printer/Data port

- **Yes/3 RS-232, 1 parallel, bar-code reader port, Ethernet port**

### Information on hard copy report

- **Patient demographics, hospital name and address, results**

### Analyzer connects to

- **GEMweb, GEMweb Plus, Impact for Critical Care**

### Interface standards supported

- **ASTM protocol**

### To upload patient & QC results, how analyzer connects to external system

- **Yes**

### Information included in transmission from analyzer to external system Hardware/Software for data management system

- **Device identifies; operator & patient IDs, results, QC ID & results**

### No. of different management reports system produces

- **Impact for Critical Care**

### Contents downloaded from DMS to analyzer System connected (live installations) to which LISs, HISs

- **Yes**

### • using screen animation, screen scraping

- **Yes**

### • using standard HTML interface

- **Yes**

### • using proprietary protocol interface

- **Yes**

### Use a third-party interfacing tool, engine for LIS, HIS interfaces

- **Yes**

### Distinguishing features (provided by vendor)

- **Intelligent Quality Management; maintenance-free, multiuse cartridge available in 30 menu/size options for use in any hospital location; 20-year history of cartridge technology; remote management from any PC via GEMweb; consolidated workstation for blood gas, electrolytes, Hct, glucose, lactate, co-oximetry, and coagulation**

### Calibration & power failure

- **Response for hardware & software failure/User ID & QC failure/Calibration & power failure**

- **Manual or bar-code entry ID & password (customizable)**

### Support for bar-code scanning of

- **User can search for and review previous patient results on screen**

### Built-in printer/Data port

- **Yes/3 RS-232, 1 parallel, bar-code reader port, Ethernet port**

### Information on hard copy report

- **Patient demographics, hospital name and address, results**

### Analyzer connects to

- **GEMweb, GEMweb Plus, Impact for Critical Care**

### Interface standards supported

- **ASTM protocol**

### To upload patient & QC results, how analyzer connects to external system

- **Yes**

### Information included in transmission from analyzer to external system Hardware/Software for data management system

- **Device identifies; operator & patient IDs, results, QC ID & results**

### No. of different management reports system produces

- **Impact for Critical Care**

### Contents downloaded from DMS to analyzer System connected (live installations) to which LISs, HISs

- **Yes**

### • using screen animation, screen scraping

- **Yes**

### • using standard HTML interface

- **Yes**

### • using proprietary protocol interface

- **Yes**

### Use a third-party interfacing tool, engine for LIS, HIS interfaces

- **Yes**

### Distinguishing features (provided by vendor)

- **Intelligent Quality Management; maintenance-free, multiuse cartridge available in 30 menu/size options for use in any hospital location; 20-year history of cartridge technology; remote management from any PC via GEMweb; consolidated workstation**

### Calibration & power failure

- **Response for hardware & software failure/User ID & QC failure/Calibration & power failure**

- **Manual or bar-code entry ID & password (customizable)**

### Support for bar-code scanning of

- **User can search for and review previous patient results on screen**

### Built-in printer/Data port

- **Yes/3 RS-232, 1 parallel, bar-code reader port, Ethernet port**

### Information on hard copy report

- **Patient demographics, hospital name and address, results**

### Analyzer connects to

- **GEMweb, GEMweb Plus, Impact for Critical Care**

### Interface standards supported

- **ASTM protocol**

### To upload patient & QC results, how analyzer connects to external system

- **Yes**

### Information included in transmission from analyzer to external system Hardware/Software for data management system

- **Device identifies; operator & patient IDs, results, QC ID & results**

### No. of different management reports system produces

- **Impact for Critical Care**

### Contents downloaded from DMS to analyzer System connected (live installations) to which LISs, HISs

- **Yes**

### • using screen animation, screen scraping

- **Yes**

### • using standard HTML interface

- **Yes**

### • using proprietary protocol interface

- **Yes**

### Use a third-party interfacing tool, engine for LIS, HIS interfaces

- **Yes**

### Distinguishing features (provided by vendor)

- **Intelligent Quality Management; maintenance-free, multiuse cartridge available in 30 menu/size options for use in any hospital location; 20-year history of cartridge technology; remote management from any PC via GEMweb; consolidated workstation**

### *when interfaced to & CO-Oximeter*
Supports bar-code scanning of operator & patient IDs, cartridge lot number & expiration date operator & patient IDs, cartridge information, lot No., quality control ranges

- Using a third-party interfacing tool, engine for LIS, HIS interfaces MAS-Rals Plus, Telecor Quick-Linc
  - Yes, using proprietary protocol interface
  - Yes, using standard HL7 interface
  - Yes, using screen animation, screen scraping

System connected (live installations) to which LISs, HISs

Contents downloaded from DMS to analyzer most configuration information, including valid operator IDs, QC lots and ranges all analyzer settings, software upgrades

Calibration can be interrupted to perform stat sample

Acceptable anticoagulants heparin, EDTA (glucose strip only)

Specimen types suitable for device whole blood, capillary, mixed venous, arterial, venous

Sampling technique aspiration

Suitable for samples with non-well neonates/Sick neonates yes/no yes

Sample size for complete panel of analyte results 150 µL, 95 µL (electrochemical only), 65 µL micro mode (electrochemical only) 125 µL capillary, 200 µL syringe

Provides for patient temperature corrected results yes yes

Sample size for complete panel of analyte results 150 µL, 95 µL (electrochemical only), 65 µL micro mode (electrochemical only) 125 µL capillary, 200 µL syringe

Provides for patient temperature corrected results yes yes

Max. No. of specific analyte reagents that can reside in device at once 1 multi-use cartridge —

No. of different disposable reagents required to maintain device 1 —

Name of device/First year sold/No. of analyzers sold in 2007 GEM Premier 4000/2006/100 IRMA TRUpoint Blood Analysis System/1994/—

Shelf life of disposable units 6 months

Shelf life of disposable units 6 months

Hardware/Software for data management system GEMweb Plus

Distinguishing features (provided by vendor)

Analyzer connects to LIS/HS via direct interface or via LIS’s GEMWeb Plus data management system; vendor-neutral or Web-based systems

Analyzer connects to LIS/HS via direct interface or via LIS’s GEMWeb Plus data management system; vendor-neutral or Web-based systems

Analyzer connects to LIS/HS via direct interface or via LIS’s GEMWeb Plus data management system; vendor-neutral or Web-based systems

Analyzer connects to LIS/HS via direct interface or via LIS’s GEMWeb Plus data management system; vendor-neutral or Web-based systems
**Part 4 of 13**

**Name of device/First year sold/No. of analyzers sold in 2007**

EasyBloodGas/2000/255

**No. of disposable reagent units**

—/255/$1,760

**Dimensions (H x W x D)/Weight**

12.5 x 14.5 x 7 in./16 lbs

**List price**

$12,500

**Calibrations required**

1 & 2 point (automatic)

**Calibration frequency**

1 point: during each sample analysis; 2 point: can be set for 2-, 4-, or 8-hr increments

**Calibrants traceable to NIST standards**

Yes

**Internal QC program recommended**

1 level per 8 hrs, CLIA recommendations, Medica controls recommended

**OC features**

L-J plots; monthly cumulative reports

**Remote control of device from laboratory**

No

**System can use LOINC to transmit results to LIS**

No

**How labs get LOINC codes for reagent kits**

—

**Calibration & power failure**


**Method of analyst ID in system**

Manual or bar-code wand for ID entry (optional)

**Training & certification program for user**

Yes (through distributors)

**Time required for maintenance by lab personnel**

Daily: 0.5 min; weekly: 3.5 min; monthly: 15 min

**Onboard diagnostics for troubleshooting/Limited to software diagnostics**

Yes/no

**Diagnostics performed through modem**

Yes/no

**Training & certification program for user**

Yes (through distributors)

**Analyzer connects to**

Data management system, which can further transmit data; directly to LIS/HIS

**Analyzer standards supported**

Medica protocol

**External system information included in transmission from analyzer to external system**

Patient ID, results measured & calculated parameters

**Use a third-party interfacing tool, engine for LIS, HIS interfaces**

TBD

**Distinguishing features (provided by vendor)**

Modular components, simple operation and maintenance; low operation cost; disposable, maintenance-free sensors; no gas tanks; easy inside and out

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**Tabulation does not represent an endorsement by the College of American Pathologists.**
The provided text appears to be a detailed specification or description of a medical device, specifically an in vitro blood gas analyzer. Here is a structured representation of the content:

### In vitro blood gas analyzers

**Part 5 of 13**

**Name of device:** Stat Profile pH/Ox Basic

**List price:**>$500

**No. of different disposable reagents required to maintain device:** >60

**Calibrations required:**
- 1 & 2 point (automatic)
- 1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 4, or 6 hr (user defined)

**Time required for maintenance by lab personnel:** weekly: <5 min; monthly: <10 min

**List price per disposable reagent system:** $200–$265

**Details on device:**
- Single reagent cartridge has all supplies for calibration & waste collection
- Built-in printer/Data port yes/multiple RS-232
- Supports bar-code scanning of patient ID
- Calibrations required 1 & 2 point (automatic)
- Calibration frequency 1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 4, or 6 hr (user defined)
- Shelf life of disposable units reagents: 18 months; electrodes: up to 18 months

**Features:**
- Parameters calculated on device: BE, TCO2, HCO3
- Analytes measured on device: pH, pCO2, pO2
- Sample size for complete panel of analyte results: 70 µL
- Sample size differs with No. of analytes selected: yes, standard 3-test blood gas micro-panel sample req. is 45 µL
- Sample size for complete panel of analyte results: 70 µL
- pH, pCO2, pO2, Hct, Hb, SO2%

**Applications:**
- Suitable for samples from well neonates: yes
- Suitable for closed system/External gas tanks required: closed/no
- Suitable for samples from well neonates: yes
- Suitable for closed system/External gas tanks required: closed/no

**Technical specifications:**
- Dimensions (H x W x D): 15 in./18 lbs
- Weight: 15
- No. of devices sold in U.S./Outside U.S./List price: —/—/$12,000
- shelf: yes
- Built-in printer/Data port yes/multiple RS-232
- Supports bar-code scanning of patient ID

**Contact information:**
- Nova Biomedical
  - Sales info@novabiomedical.com
  - 200 Prospect St.
  - Waltham, MA 02454-9141
  - 800-458-5813

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This document provides detailed specifications for an in vitro blood gas analyzer, including its capabilities, features, and technical details. It is important to note that this information is subject to change and should be verified with the manufacturer for the latest data.
### In vitro blood gas analyzers

<table>
<thead>
<tr>
<th>Analytes measured on device</th>
<th>pH, PCO₂, PO₂, Hct, Hb, SO₂%, lactate</th>
<th>pH, PCO₂, PO₂, Hct, Hb, SO₂%, Na, K, Cl or iCa, glucose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parameters calculated on device</td>
<td>BE, TCO₂, HCO₃-</td>
<td>BE, TCO₂, HCO₃-</td>
</tr>
<tr>
<td>Barometric and temperature compensation</td>
<td>tracked</td>
<td>tracked</td>
</tr>
<tr>
<td>Analytical method(s), technology(ies) employed</td>
<td>pH: direct ISE; PCO₂: Severinghaus; PO₂: amperometry; Hct: conductivity; Hb &amp; SO₂%: optical–reflectance; lactate: enzyme/amperometric</td>
<td>pH: direct ISE; PCO₂: Severinghaus; PO₂: amperometry; Hct: conductivity; Hb &amp; SO₂%: optical–reflectance; Na, K, Cl, iCa: direct ISE; glucose: enzyme/amperometric</td>
</tr>
</tbody>
</table>

### Device is part of a series of related models

| For POC testing or laboratory | yes | yes |

### List price per disposable reagent system

| - | $210–$275 | $210–$275 |

### List price per disposable reagent, electrode system

| - | — | — |

### For POC testing or laboratory

| - | POC & laboratory | POC & laboratory |

### POC:

- Uses disposable prepackaged reagent/Electrode system for analysis
- No. of disposable reagent system units in basic shipment package
- No. of samples analyzed per disposable reagent, electrode system
- List price per disposable reagent system
- Reagent unit storage requirements
- Shelf life of disposable units

### Laboratory:

- No. of different disposable reagents required to maintain device
- Max. No. of specific analytic reagents that can be reinserted in device at once
- Shelf life
- Cost per test/Reagent cost per test
- Calibrations required
- Calibration frequency
- Calibrants traceable to NSF standards
- Internal OC program recommended
- QC features
- Remote control of device from laboratory
- System can use LOINC to transmit results to LIS
- New labs get LOINC codes for reagent kits

### Detects drugs within analysis chamber

| - | whole blood, capillary, mixed venous, arterial |

### Acceptable anticoagulants

| - | heparin |

### Sampling technique

| - | aspiration & capillary |

### Suitable for samples from well neonates/Sick neonates

| - | whole blood, capillary, mixed venous, arterial |

### Sample size for complete panel of analytes

| - | 125 mL |

### Sample size differs with No. of analytes selected

| - | yes/yes |

### Recommended collection device

| - | yes, standard 3-test micro-panel req. is 60 mL |

### Provides for patient temperature corrected results

| - | yes |

### Time from sample introduction to result availability

| - | 52 seconds |

### Max. No. of patient samples per hr/Max. No. of measured parameters per hr

| - | 50/500 tests |

### Optimal throughput when calibrated and awaiting specimens

| - | 300 tests per hr |

### Calibration can be interrupted to perform stat sample

| - | yes |

### Contraindications

| - | none |

### Known interferences

| - | none |

### Restrictions based on Hct

| - | none |

### Sampler has self-wiping probe

| - | yes |

### Time required for maintenance by lab personnel

| - | weekly: <5 min; monthly: <10 min |

### Onboard diagnostics for troubleshooting/Limited to software

| - | yes/no |

### Diagnostics performed through modem

| - | yes |

### Training & certification program for user

| - | yes (on site) |

### Method of analyst ID in system

| - | password with unique user ID No. (optional) |

### Response for hardware & software failure/User ID & QC failure/Calibration & power failure

| - | self-diag. SW informs & notifies oper. of HW failure; hotline & field support depending on problem/optional lockout w/o user ID; options for QC failure ranging from flagging to not reporting test that fails QC to lockout for QC failure or exceeding scheduled QC interval/any test that does not calibrate will not report results & instrument notifies oper. of reason for failure; momentary power interruptions require no recovery–extended power failure results in automatic calib. |

### Supports bar-code scanning of

| - | yes/yes |

### User can search for and review previous patient results on screen

| - | yes/no |

### Built-in printer/User ID/Access

| - | yes |

### On hard copy data report

| - | patient ID |

### Method of analyzer ID in system

| - | password with unique user ID No. (optional) |

### Response for hardware & software failure/User ID & QC failure/Calibration & power failure

| - | self-diag. SW informs & notifies oper. of HW failure; hotline & field support depending on problem/optional lockout w/o user ID; options for QC failure ranging from flagging to not reporting test that fails QC to lockout for QC failure or exceeding scheduled QC interval/any test that does not calibrate will not report results & instrument notifies oper. of reason for failure; momentary power interruptions require no recovery–extended power failure results in automatic calib. |

### System connected (like installations to which LISs, HISs)

| - | yes |

### Use a third-party interfacing tool, engine for LIS, HIS interfaces

| - | yes |

### Distinguishing features (provided by vendor)

| - | onboard auto-cartridge QC; all liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration & waste collection |

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**Tabulation does not represent an endorsement by the College of American Pathologists.**
### In vitro blood gas analyzers

#### Nova Biomedical
- **Sales**: info@novabiomedical.com
- **Address**: 200 Prospect St.
  Waltham, MA 02454-9141
- **Phone**: 800-458-5813

#### Stat Profile pH/oX Plus C/2003
- **Dimensions**: 15 x 12 x 15 in/18 lbs
- **Price**: $32,000

### Table: Technical Specifications

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Calibrants</strong></td>
<td>Traceable to NIST standards</td>
</tr>
<tr>
<td><strong>Contraindications</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Optimal throughput when calibrated and awaiting specimens</strong></td>
<td>300 tests per hr</td>
</tr>
<tr>
<td><strong>Max. No. of specific analyte reagents that can reside in device at once</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>Max. No. of disposable reagents that required to maintain device</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>Room temperature</strong></td>
<td>18 months room temperature, electrodes: up to 18 months</td>
</tr>
<tr>
<td><strong>Calibrations required</strong></td>
<td>1 &amp; 2 point (automatic)</td>
</tr>
<tr>
<td><strong>Calibration frequency</strong></td>
<td>1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 4, or 6 hr (user defined)</td>
</tr>
<tr>
<td><strong>Calibrants traceable to NIST standards</strong></td>
<td>Minimum CLIA recommendations</td>
</tr>
<tr>
<td><strong>QC features</strong></td>
<td>L-J plots, statistical calcs., monthly cum. report (onboard, more extensive reporting avail. with Nova Point-of-Care Manager)</td>
</tr>
<tr>
<td><strong>Remote control of device from laboratory</strong></td>
<td>No</td>
</tr>
<tr>
<td><strong>Shelf life of disposable units</strong></td>
<td>18 months</td>
</tr>
<tr>
<td><strong>Cost per test/Reagent cost per test</strong></td>
<td>&lt;$0.11 at 35 analyses per day/$0.08 at 35 analyses per day</td>
</tr>
<tr>
<td><strong>Shelf life</strong></td>
<td>18 months</td>
</tr>
<tr>
<td><strong>Max. No. of patient samples per hr/Max. No. of measured tests per hr</strong></td>
<td>50/500 tests</td>
</tr>
<tr>
<td><strong>Calibration interrupt when calibrating and awaiting specimens</strong></td>
<td>300 tests per hr</td>
</tr>
<tr>
<td><strong>Contraindications</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Restrictions based on Hct</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Sample size for complete panel of analyte results</strong></td>
<td>125 µL</td>
</tr>
<tr>
<td><strong>Sample size differs with No. of analytes selected</strong></td>
<td>Standard 3-test micro-panel req. is 60 µL</td>
</tr>
<tr>
<td><strong>Sample size for well neonates/Sick neonates</strong></td>
<td>Capillary aspiration, capillary</td>
</tr>
<tr>
<td><strong>Sample size for complete panel of analyte results</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Specimen types suitable for device</strong></td>
<td>Whole blood, capillary, mixed venous, arterial, serum plasma</td>
</tr>
<tr>
<td><strong>Acceptable anticoagulants</strong></td>
<td>Heparin</td>
</tr>
<tr>
<td><strong>Sampling suitability</strong></td>
<td>aspiration &amp; capillary</td>
</tr>
<tr>
<td><strong>Turbidity</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Temperature correction</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Temperature range</strong></td>
<td>30/500 tests</td>
</tr>
<tr>
<td><strong>Time required for maintenance by lab personnel</strong></td>
<td>&lt;5 min; monthly: &lt;10 min</td>
</tr>
<tr>
<td><strong>Validity time</strong></td>
<td>Weekly: 12 months, monthly: 3 months</td>
</tr>
<tr>
<td><strong>User list or group available</strong></td>
<td>Yes (upon request)</td>
</tr>
<tr>
<td><strong>Loaner devices provided</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Device warranty</strong></td>
<td>1 yr, travel and labor, repair or replacement</td>
</tr>
<tr>
<td><strong>Emergency snapshot</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>System connected (live installations) to which LIS/HIS data management system is connected</strong></td>
<td>Direct serial&gt;500 hospitals inst.; hospital network&gt;100 inst.</td>
</tr>
<tr>
<td><strong>Hardware/Software for data management system</strong></td>
<td>Device unique identifier, operator &amp; patient IDs, results, QC identifier, access No.</td>
</tr>
<tr>
<td><strong>Contents downloaded from DMS to analyzer</strong></td>
<td>System connected (live installations) to which LIS, HIS interfaces</td>
</tr>
</tbody>
</table>

### Other Features
- **Distinguishing features (provided by vendor)**
  - Onboard auto-cartridge QC; all liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration & waste collection
  - Onboard auto-cartridge QC; all liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration & waste collection

### Technical Details
- **Barometric pressure**: Yes
- **Automated QC**: Onboard auto-cartridge QC; all liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration & waste collection
- **System connected (live installations) to which LIS/HIS data management system is connected**
  - Direct serial>500 hospitals inst.; hospital network>100 inst.
  - Device unique identifier, operator & patient IDs, results, QC identifier, access No.
  - System connected (live installations) to which LIS, HIS interfaces
  - Onboard auto-cartridge QC; all liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration & waste collection

### Contact Information
- **Nova Biomedical**
  - **Sales**: info@novabiomedical.com
  - **Address**: 200 Prospect St.
  - **Phone**: 800-458-5813
  - **Address**: Waltham, MA 02454-9141

### Additional Information
- **User Instructions**
  - For POC testing or laboratory
  - Open or closed system/External gas tanks required
  - Average expected life of device
  - Loaner devices provided
  - Device warranty
  - User list or group available
  - Device is part of a series of related models
  - Calibration & power failure
  - Time required for maintenance by lab personnel

### Notes
- **Hardware/Software for data management system**
  - Device unique identifier, operator & patient IDs, results, QC identifier, access No.
  - System connected (live installations) to which LIS, HIS interfaces
  - Onboard auto-cartridge QC; all liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration & waste collection

### Legal Note
- **Tabulation** does not represent an endorsement by the College of American Pathologists.
### In vitro blood gas analyzers

#### Nova Biomedical
Nova Biomedical
Sales: info@novabiomedical.com
200 Prospect St.
Waltham, MA 02454-9141
800-860-4581

#### Critical Care Xpress

<table>
<thead>
<tr>
<th>Name of device/First year sold/No. of analyzers sold in 2007</th>
<th>Stast Profile Critical Care Xpress/2003/—</th>
<th>Stast Profile Critical Care Xpress 3 Plus/2003/—</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of devices sold in U.S./Outside U.S./List price</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dimensions (h x W x D)/Weight</td>
<td>17.2 x 22.4 x 17.3 in./53 lbs</td>
<td>17.2 x 22.4 x 17.3 in./53 lbs</td>
</tr>
<tr>
<td><strong>Analytes measured on device</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parameters calculated on device</td>
<td>pH, pCO2, pO2, hct, hb, Na, K, Cl, iCa, iMg, lactate, glucose, creatinine, BUN, SO2%, bilirubin, co-oximetry</td>
<td>pH, pCO2, pO2, co-oximetry</td>
</tr>
<tr>
<td>Barometric pressure</td>
<td>BE; TC02, HC03-tracked</td>
<td>BE; TC02, HC03- tracked</td>
</tr>
<tr>
<td>Analytical method(s), technology(ies) employed</td>
<td>pH; direct ISE; pCO2: Severinghaus; pO2: amperometric; hct: conductivity; Hb &amp; SO2%, bilirubin, co-oximetry; enzyme/amperometric; BUN: enzyme/ISE; bilirubin, co-ox; optical, reflectance</td>
<td>pH; direct ISE; pCO2: Severinghaus; pO2: amperometric; co-ox: optical-reflectance</td>
</tr>
<tr>
<td><strong>Device is part of a series of related models</strong></td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>User list or group available</td>
<td>yes (upon request)</td>
<td>yes (upon request)</td>
</tr>
<tr>
<td>Device warranty</td>
<td>1 yr</td>
<td>1 yr</td>
</tr>
<tr>
<td>Loader devices provided</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Average expected life of device</td>
<td>5-7 yrs</td>
<td>5-7 yrs</td>
</tr>
<tr>
<td>Open or closed system/External gas tanks required</td>
<td>closed/no</td>
<td>closed/no</td>
</tr>
<tr>
<td>For POC testing or laboratory</td>
<td>POC, &amp; laboratory</td>
<td></td>
</tr>
<tr>
<td><strong>POC</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uses disposable prepackaged reagent/Electrode system for analysis</td>
<td>200-500 analyses</td>
<td>200-500 analyses</td>
</tr>
<tr>
<td>No. of disposable reagent system units in basic shipment package</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>No. of samples analyzed per one disposable reagent, electrode system</td>
<td>$294–$349</td>
<td>$299</td>
</tr>
<tr>
<td><strong>Reagent unit storage requirements</strong></td>
<td>no special requirements</td>
<td>no special requirements</td>
</tr>
<tr>
<td>Shelf life of disposable units</td>
<td>reagents: 18 months (room temp.); electrodes: up to 18 months</td>
<td>reagents: 18 months (room temp.); electrodes: up to 18 months</td>
</tr>
<tr>
<td><strong>Laboratory</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of different disposable reagents required to maintain device</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Max. No. of specific analytes required to maintain device</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td><strong>Calibrations required</strong></td>
<td>1 &amp; 2 point (automatic)</td>
<td>1 &amp; 2 point (automatic)</td>
</tr>
<tr>
<td>Calibration frequency</td>
<td>1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 3, 4, 5, or 6 hr (user defined)</td>
<td>1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 3, 4, 5, or 6 hr (user defined)</td>
</tr>
<tr>
<td>Calibrants traceable to NIST standards</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Internal QC program recommended</td>
<td>yes; minimum CLIA recommendations</td>
<td>yes; minimum CLIA recommendations</td>
</tr>
<tr>
<td>QC features</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Remote control of device from laboratory</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>System can use LOINC to transmit results to LIS</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>How labs get LOINC codes for reagent kits</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td><strong>Diagnostics performed through modern</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Specimen types suitable for device</strong></td>
<td>whole blood, capillary, mixed venous, arterial, venous</td>
<td>whole blood, capillary, mixed venous, arterial, venous</td>
</tr>
<tr>
<td>Acetabular aspirates</td>
<td>heparin</td>
<td>heparin</td>
</tr>
<tr>
<td>Sampling technique</td>
<td>aspiration &amp; capillary</td>
<td>aspiration &amp; capillary</td>
</tr>
<tr>
<td>Suitable for samples from well neonates/Sick neonate</td>
<td>yes/loading</td>
<td>yes/loading</td>
</tr>
<tr>
<td>Sample size in mg of sample analyte</td>
<td>yes/load; 30 µL</td>
<td>yes/load; 30 µL</td>
</tr>
<tr>
<td>Sample size differs with No. of analytes selected</td>
<td>yes; variety of micro-panel options offered &amp; can be customized</td>
<td>yes; variety of micro-panel options offered &amp; can be customized</td>
</tr>
<tr>
<td>Recommended collection device</td>
<td>syringes, capillary, micro-collection, or vacuum collection containers</td>
<td>syringes, capillary, micro-collection, or vacuum collection containers</td>
</tr>
<tr>
<td>Provides for patient temperature corrected results</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Time from sample introduction to result availability</td>
<td>14 sec</td>
<td>61 sec</td>
</tr>
<tr>
<td>Max. No. of patient samples per hr/Max. No. of measured parameters per hr</td>
<td>224/400</td>
<td>32/224</td>
</tr>
<tr>
<td><strong>Optimal throughput when calibrated and awaiting specimens</strong></td>
<td>437 tests per hr</td>
<td>190 tests per hr</td>
</tr>
<tr>
<td>Calibration can be interrupted to perform stat sample</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Contraindications</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Known interferences</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>Restrictions based on hct</td>
<td>none</td>
<td>none</td>
</tr>
<tr>
<td>Sampler has self-wiping probe</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td><strong>Time required for maintenance by lab personnel</strong></td>
<td>daily: none; weekly: &lt;5 min; monthly: &lt;10 min</td>
<td>daily: none; weekly: &lt;5 min; monthly: &lt;10 min</td>
</tr>
<tr>
<td>Onboard diagnostics for troubleshooting/Limited to software</td>
<td>no</td>
<td>yes/no</td>
</tr>
<tr>
<td><strong>Method of analysis ID in system</strong></td>
<td>yes (3 days on site)</td>
<td>yes (3 days on site)</td>
</tr>
<tr>
<td><strong>Response for hardware &amp; software failure/User ID &amp; QC failure</strong></td>
<td>multi-level password with unique user ID.No.</td>
<td>multi-level password with unique user ID. No.</td>
</tr>
<tr>
<td>Calibration &amp; power</td>
<td>HW &amp; SW: self-diagnostic SW informs and classifies operator of HW &amp; SW failure; field &amp; support avail., user ID: optional setup feature; lock out without proper ID; QC: optional setup or options range from flagging QC failure to not reporting last test that fails QC/calibration: results not reported w/ failures, instrument notifies operator of failure reason; power: momentary power interrupts require no recovery; instrument automatically calibrates operator &amp; patient IDs</td>
<td>HW &amp; SW: self-diagnostic SW informs and classifies operator of HW &amp; SW failure; field &amp; support avail., user ID: optional setup feature; lock out without proper ID; QC: optional setup or options range from flagging QC failure to not reporting last test that fails QC/calibration: results not reported w/ failures, instrument notifies operator of failure reason; power: momentary power interrupts require no recovery; instrument automatically calibrates operator &amp; patient IDs</td>
</tr>
<tr>
<td>Supports bar-code scanning of results</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>User can search for and review previous patient results on screen</td>
<td>yes/Ethernet, USB</td>
<td>yes/Ethernet, USB</td>
</tr>
<tr>
<td><strong>Information on hard copy report</strong></td>
<td>patient ID &amp; accession Nos., entered settings, measured &amp; calculated results</td>
<td>patient ID &amp; accession Nos., entered settings, measured &amp; calculated results</td>
</tr>
</tbody>
</table>

#### Tabulation does not represent an endorsement by the College of American Pathologists.
<table>
<thead>
<tr>
<th>Section</th>
<th>Information</th>
</tr>
</thead>
</table>
| **Part 9 of 13** | Opti Medical Systems Inc.  
Sales Department  
235 Hombre Park Drive  
Roswell, GA 30076  
800-600-6784  
www.optimedical.com |
| **Name of device/First year sold/No. of analyzers sold in 2007** | OPTI-8/2006/---  
OPTI CCA Blood Gas Analyzer/1998/--- |
| **No. of devices sold in U.S./Outside U.S./List price** | 4.7 × 1.2 × 14 in./4.5 kg (10 lbs) without fluid pack  
4.7 × 14.2 × 9 in./10 lbs without battery, 12 lbs with battery |
| **Analytics measured on device** | pH, pCO2, pO2, Hb, Na, K, SO2  
Hct, HCO3, BE, Biflu, BFec, BB, IDO2, st, HCO3, st, pH, O2ct, Ct+, AaDO2, AG, pCO2, pO2, nCa++ measured  
pH, pCO2, pO2, Na, K, Cl, Ica, Hb, SO2, glucose  
Hct, HCO3, BE, Biflu, BFec, BB, IDO2, st, HCO3, st, pH, O2ct, Ct+, AaDO2, AG, pCO2, pO2, nCa++ measured |
| **Parameters calculated on device** | yes (OPTI CCA)  
yes (upon request)  
yes (through Opti Medical sales dept.) |
| **Barometric pressure** | yes (OPTI CCA)  
yes (through Opti Medical sales dept.) |
| **Device warranty** | 1 year (service contract available for subsequent years) |
| **Loader devices provided** | yes  
>7 yrs  
closed/no |
| **Average expected life of device** | 5–7 yrs  
>7 yrs |
| **Open or closed system/External gas tanks required** | yes  
no |
| **For POC testing or laboratory** | POC & laboratory  
POC & laboratory |
| **POC:** | Uses disposable prepackaged reagent/Electrode system for analysis  
25 individual packaged cassettes  
24/192 |
| **System connected (live installations) to which LISs, HISs** | none  
none |
| **Contents downloaded from DMS to analyzer** | none  
none |
| **No. of different management reports system produces** | 40 |
| **Supports bar-code scanning of** | yes  
no |
| **User can search for and review previous patient results on screen** | yes  
no |
| **Supports bar-code scanning of** | yes  
no |
| **QC features** | auto QC, statistics reports  
no  
no  
--- |
| **Remote control of device from laboratory** | ---  
---  
--- |
| **Time required for maintenance by lab personnel** | weekly: 1 min; quarterly: 5 min  
weekly: 1 min; quarterly: 5 min  
--- |
| **Training & certification program for user** | yes/no  
yes/no  
--- |
| **Use a third-party interfacing tool, engine for LIS, HIS interfaces** | LDS Aegis  
LDS Aegis  
LDS Aegis |
| **System connected (live installations) to which LISs, HISs** | ---  
---  
--- |
| **Contents downloaded from DMS to analyzer** | none  
none  
none |
| **No. of different management reports system produces** | 40 |
| **Supports bar-code scanning of** | ---  
---  
--- |
| **User can search for and review previous patient results on screen** | yes  
no  
--- |
| **Supports bar-code scanning of** | yes  
no  
--- |
| **QC features** | ---  
---  
--- |
| **Remote control of device from laboratory** | ---  
---  
--- |
| **Time required for maintenance by lab personnel** | weekly: 1 min; quarterly: 5 min  
weekly: 1 min; quarterly: 5 min  
--- |
| **Training & certification program for user** | yes/no  
yes/no  
--- |
| **Use a third-party interfacing tool, engine for LIS, HIS interfaces** | LDS Aegis  
LDS Aegis  
LDS Aegis |
| **System connected (live installations) to which LISs, HISs** | ---  
---  
--- |
| **Contents downloaded from DMS to analyzer** | none  
none  
none |
| **No. of different management reports system produces** | 40 |
| **Supports bar-code scanning of** | ---  
---  
--- |
| **User can search for and review previous patient results on screen** | yes  
no  
--- |
| **Supports bar-code scanning of** | yes  
no  
--- |
| **QC features** | ---  
---  
--- |
| **Remote control of device from laboratory** | ---  
---  
--- |
| **Time required for maintenance by lab personnel** | weekly: 1 min; quarterly: 5 min  
weekly: 1 min; quarterly: 5 min  
--- |
| **Training & certification program for user** | yes/no  
yes/no  
--- |
| **Use a third-party interfacing tool, engine for LIS, HIS interfaces** | LDS Aegis  
LDS Aegis  
LDS Aegis |
| **System connected (live installations) to which LISs, HISs** | ---  
---  
--- |
| **Contents downloaded from DMS to analyzer** | none  
none  
none |
| **No. of different management reports system produces** | 40 |
| **Supports bar-code scanning of** | ---  
---  
--- |
| **User can search for and review previous patient results on screen** | yes  
no  
--- |
| **Supports bar-code scanning of** | yes  
no  
--- |
| **QC features** | ---  
---  
--- |
| **Remote control of device from laboratory** | ---  
---  
--- |
| **Time required for maintenance by lab personnel** | weekly: 1 min; quarterly: 5 min  
weekly: 1 min; quarterly: 5 min  
--- |
| **Training & certification program for user** | yes/no  
yes/no  
--- |
| **Use a third-party interfacing tool, engine for LIS, HIS interfaces** | LDS Aegis  
LDS Aegis  
LDS Aegis |
| **System connected (live installations) to which LISs, HISs** | ---  
---  
--- |
| **Contents downloaded from DMS to analyzer** | none  
none  
none |
| **No. of different management reports system produces** | 40 |
| **Supports bar-code scanning of** | ---  
---  
--- |
| **User can search for and review previous patient results on screen** | yes  
no  
--- |
| **Supports bar-code scanning of** | yes  
no  
--- |
| **QC features** | ---  
---  
--- |
| **Remote control of device from laboratory** | ---  
---  
--- |
Tabulation does not represent an endorsement by the College of American Pathologists.

In vitro blood gas analyzers

August 2008

Radiometer America Inc.
Telesales Department info@radiometeramerica.com
810 Sharon Dr., Westlake, OH 44145
800-736-0600 ext. 333
www.radiometeramerica.com

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Part 10 of 13

Name of device/First year sold/No. of analyzers sold in 2007

ABO Series 2000/2004—

No. of devices sold in U.S./Outside U.S./List price

22 + 28 = 21 /70 lbs

Dimensions (H x W x D)/Weight

20 yrs with full support

Shelf life of disposable units

—

Device is part of a series of related models

—

No. of different management reports system produces

—

Calibrations required

1 point: 1/2 hr—CLIA GAS, 4 hrs—not if: 2 point: every 8 hrs

Calibrator traceable to NIST standards yes yes

Cost per test/Reagent cost per test depends on sample volume & any extra incl. items/same

1 & 2 point (automatic)

Shelf life reagent, electrode, membrane kit, cartridge: 2+ yrs reagent, electrode, membrane kit, cartridge: 2+ yrs

Open or closed system/External gas tanks required closed/yes closed/yes (low-pressure, premixed)

Loaner devices provided yes yes

Device warranty 1 yr, parts, labor & travel 2 yrs, parts, labor & travel

List price per disposable reagent system — —

No. of different disposable reagents required to maintain device 4

Shelf life —

No. of analytes selected 35 µL

Max. No. of patient samples per hr Max. No. of measured parameters per hr

35 µL

Optimal throughput when calibrated and awaiting specimens 30 per hr

Contraindications none

Specimen types suitable for device whole blood, capil., mixed venous, arterial, venous

Known Interferences none


Sample collection/drawn times Hct, BE, TCO2, HCO3- plus 40 additional parameters

Unknown Interferences none

Temperature control —

System connected (live installations) to which LISs, HISs

Cerner, Meditech, Misys, others

Reagent system controls/calibration device —

Onboard diagnostics for troubleshooting/Limited to software yes/no yes/no

Diagnostics performed through modem none

Onboard diagnostics software system --

Hardware/Software for data management system RADIANCE STAT information management system that connects to LIS/HIS or directly to LIS/HIS

Analyzers measured on device pH, pCO2, pO2

Analytical methods, technology(ies) employed measured


Software and system configuration for analyzers FLEXMODE—small automated microfluidic system capable of interfacing with a wide variety of sample types and automated systems that may not be compatible with traditional blood gas analyzers

System messages, reference & critical ranges system message with customized (“traffic light”) visual & audible signals, parameter status bar

Response for hardware & software failure/User ID & QC failure/System connected (live installations) to which LISs, HISs

Method of analyst ID in system operator ID entry (optional)

Analyzer connects to

RADIANCE STAT information management system that connects to LIS/HIS or directly to LIS/HIS

Interface standards supported

To upload patient & QC results, how analyzer connects to external system

Onboard labeled identification kit, bar code

Responsive to lab information from LIS

Supports bar-code scanning of specimen barcodes

Distinguishing features (provided by vendor) provides basic blood gases (pH, pCO2, pO2) test profile; easy to use with minimal maintenance; low cost of operation via standby usage; fast restart, in 2 mins, out of standby mode

Flexibility automated inlet part of automatic system; bilirubin and fetal Hb measure on whole blood with no extra sample volume, low maintenance and cost of operation; interference-free accuracy; FLEXMODE—small automated microfluidic sample system with no loss in performance specs. (conserves blood); flexible/modular platform running on Windows XP (embedded), Penumbra processors, automatic QC, autoclave, remote support
<table>
<thead>
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### In vitro blood gas analyzers

**Radiometer ABL 800/800i**

- **Parameters calculated on device**: pH, pO2, pCO2, Hct, K, Cl, glucose (Hb, O2SAT, O2Hb, CO2Hb, MetHb, HHb)*
- **Barometric pressure**: Hb, O2SAT, TO2D, HCO3- , cO2D (a-v), cO2D (pH), cR, AB, SBE, others
- **Analytical method(s), technology(ies) employed**: pH, pCO2, pO2, Hb, K, Cl, Glu: thick film; amperometric/potentiometric technology; HCT: conductivity
- **Device is a part of a series of related models**: yes
- **User list or group available**: yes (through local sales representative)
- **Device warranty**: 1 yr, parts, labor, & travel, with service plans available after yr 1
- **Average expected life of device**: analyzer: 10+ yrs
- **Open or closed system/External gas tanks required**: closed/no
- **For POC testing or laboratory**: POC testing, laboratory

**PDC**

- **Uses disposable prepackaged reagent/Electrode system for analysis**: yes
- **No. of disposable reagent system units in basic shipment package**: 1
- **List price per disposable reagent system**: depends on configuration & GPO affiliation
- **Reagent unit storage requirements**: room temperature
- **Cost per test/Reagent cost per test**: depends on configuration/same
- **How labs get LOINC codes for reagent kits**: yes, yes

**Laboratory**

- **No. of different disposable reagents required to maintain device**:
  - Max. No. of specific analyte reagents that can reside in device at once: reagent: 100 days, cartridge: 90 days
- **Shell life of disposable units**: 90–100 days
- **Calibrations required**: 1 & 2 point (manual & automatic)
- **Calibration frequency**: 1 point: with each test; 2 point: 8 hrs (user definable)
- **Calibrators traceable to NIST standards**: yes
- **Internal QC program recommended**: yes
- **QC features**: L-J plots, statistical calcs., monthly cum. (onboard–current mean, STD, CV%)
- **Remote control of device from laboratory**: yes
- **System can use LOINC to transmit results to LIS**: yes
- **How labs get LOINC codes for reagent kits**: yes

**Detects clots within analysis chamber**

- **Specimen types suitable for device**: whole blood, capillary, mixed venous, arterial
- **Acceptable anticoagulants**: heparinized; electrolyte balanced heparin
- **Sampling technique**: aspiration
- **Suitable for samples from well neonates/Sick neonates**: yes/yes
- **Sample size**: 70 µL
- **Recommended collection device**: syringe or capillary tube
- **Provides for patient temperature corrected results**: yes
- **Time from sample introduction to result availability**: 90 sec
- **Max. No. of patient samples per hr/Max. No. of measured parameters per hr**: 90/270

**Optimal throughput when calibrated and awaiting specimens**

- **Calibration can be interrupted to perform stat sample**: yes
- **Contraindications**: none
- **Known interferences**: none
- **Restrictions based on Hct**: none
- **Sampler has self-wiping probe**: no

**Time required for maintenance by lab personnel**

- **Onboard diagnostics for troubleshooting/Limited to software diagnostics performed through modem**: yes/no
- **Training & certification program for user**: yes (on site)

**Method of analyst ID in system**

- **Response for hardware & software failure/User ID & QC failure**: onboard keyboard, bar code
- **Method of analyst ID in system customizable onboard keyboard, bar code optional/bar code or manual

**Supports bar-code scanning of**

- **Built-in printer/Data port**: yes/RS-232, Ethernet
- **Information on hard copy report**: patient info./demographics, patient therapy settings, meas. and calc. results, system messages, reference and critical ranges

**Analyzer connects to**

- **Interface standards supported**: RADIANCE STAT analyzer device
- **To upload patient & QC results, how analyzer connects to external system**: yes
- **Information included in transmission from analyzer to external system Hardware/Software for data management system**: device unique identifier, operator & patient IDs, results, QC identifier
- **Analyzer communicates with**: RADIANCE STAT analyzer device
- **Response to different data requirements**: user definable
- **Contents downloaded from DMS to analyzer System connected (like installations) to which LISs, HISs**
  - user definable
  - system connects
  - system connects
  - system connects
  - system connects
- **Use a third-party interfacing tool, engine for LIS, HIS interfaces**: no (use interface templates)

**Distinguishing features (provided by vendor)**

- **portable, true battery operation; fast startup/warmup and analysis time; simple and easy-to-use system**
  - pending FDA clearance
- **dry optical technology, unique in the measurement of blood gases and full co-oximetry; maintenance-free; no cartridge preparation; QualityGuard; patient results in one minute**
Tabulation does not represent an endorsement by the College of American Pathologists.

Name of device/First year sold/No. of analytes sold in 2007

No. of devices sold in U.S./Outside U.S./List price

Dimensions (W x D x H/Weight)

Cost per test/Reagent cost per test depends on sample volume/same volume dependent/volume dependent

Use a third-party interfacing tool, engine for LIS, HIS interfaces Dawning, Cloverleaf, Data Innovations (not required but can use) Data Innovations

- using proprietary protocol interface
- Kaiser Permanente —
  - using standard HL7 interface

System connected (live installations) to which LISs, HISs

No. of different management reports system produces

Hardware/Software for data management system Roche OMNI has onboard DM capabilities; DataCare POC software is available as

Information included in transmission from analyzer to external system device unique identifier, oper. & patient IDs, results, QC identifier device unique identifier, oper. & patient IDs, results, QC identifier

Interface standards supported

Acceptable anticoagulants

Specimen types suitable for device

Detects clots within analysis chamber

Use disposable prepackaged reagent/Electrode system for analysis

No. of disposable reagent system units in basic shipment package

No. of samples analyzed per one disposable reagent, electrode system

List price per disposable reagent system

Reagent shell life of disposable units

Calibrators traceable to NIST standards

Internal QC program recommended

QC features

Remote control of device from laboratory

System can use LOINC to transmit results to LIS

New labs get LOINC codes for reagent kits

Distinguishing features (provided by vendor)
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<td><strong>No. of devices sold in U.S./Outside U.S./List price</strong></td>
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<tr>
<td><strong>Dimensions (H x W x D)/Weight</strong></td>
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**Analyzers measured on device**
- pH, pCO2, pO2, Hct, Na+, K+, Cl−, Ca++, lactic acid, glucose, FOS28h, FCHb, FbicHb, total neonatal bilirubin
- pH, pCO2, pO2, Hb, Na+, K+, Cl−, lactic acid, glucose, FOS28h, FCHb, FbicHb, total neonatal bilirubin

**Parameters calculated on device**
- HCO3−, CO2-std, BE, BE(ser), cTcO2, Ca++(7.4), H+ (R), O2SAT, PO2/PO2
- HCO3−, CO2-std, BE(ser), cTcO2, Ca++(7.4), H+ (R), O2SAT, PO2/PO2

**Barometric pressure**
- recorded
- recorded

**Analytical method(s), technology(ies) employed**
- pH, Na, Cl, K; potassiumometry using ISE; cTcO2: potassiumometry based on Severinghaus; pO2: amperometric
- pH, Na, Cl, K; potassiumometry using ISE; cTcO2: potassiumometry based on Severinghaus; pO2: amperometric

**Device is part of a series of related models**
- yes
- yes

**User list or group available**
- yes
- yes

**Device warranty**
- 1 year
- 1 year

**Average expected life of device**
- 7–10 yrs
- 7–10 yrs

**Open or closed system/External gas tanks required**
- closed/no
- closed/no

**For POC testing or laboratory**
- POC testing and laboratory
- laboratory

**POC**
- Uses disposable prepackaged reagent/Electrode system for analysis
- yes, multiuse cartridge
- yes, multiuse cartridge

**Laboratory:**
- No. of disposable reagent systems units in basic shipment package
- 1 measurement and 1 wash/waste cartridge
- 1 measurement and 1 wash/waste cartridge

**Reagent unit storage requirements**
- refrigeration
- refrigeration

**Self life of disposable unit**
- 9 months
- 9 months

**Calibrations required**
- 1 point: 30 min; 2 point: 2 hrs
- 1 point: every 30 min; 2 point: every 8 hrs

**Calibrators traceable to NIST standards**
- yes
- yes

**Internal QC program recommended**
- AGC cartridge, fully user programmable
- AGC cartridge, L-J plots, comparable plots, statistical calculations, monthly cum. reports (available with external system)

**Remote control of device from laboratory**
- yes
- yes

**System can use LOINC to transmit results to LIS**
- yes
- yes

**New labs get LOINC codes for reagent kits**
- —
- —

**Detects clots within analysis chamber**
- yes
- yes

**Specimen types suitable for device**
- whole blood, capillary, mixed venous, arterial, venous
- whole blood, capillary, mixed venous, arterial, venous

**Acceptable anticoagulants**
- heparin
- heparin

**Samplers**
- whole blood, capillary, mixed venous, arterial, venous
- whole blood, capillary, mixed venous, arterial, venous

**Sampling technique**
- aspiration
- aspiration

**Sample size**
- 100 µL
- 100 µL

**Sample size differs with No. of analytes selected**
- no
- no

**Recommended preanalysis**
- yes
- yes

**Provides for patient temperature corrected results**
- yes
- yes

**Time from sample introduction to result availability**
- 60 seconds
- 60 seconds

**Calibration frequency**
- 1 point: 30 min; 2 point: 2 hrs
- 1 point: every 30 min; 2 point: every 8 hrs

**Calibrating using DCCP standards**
- yes
- yes

**AI in calibration process**
- yes
- yes

**Optimal throughput when calibrated and awaiting specimens**
- 25 samples per hr
- 24 samples per hr

**Known interferences**
- benzaldehyde
- contact vendor

**Restrictions based on Hct**
- yes
- yes

**Sampler has self-wiping probe**
- yes
- yes

**Time required for maintenance by lab personnel**
- maintenance free
- maintenance free

**Onboard diagnostics for troubleshooting/Limited to software**
- yes
- yes

**Training & certification program for user**
- yes
- yes

**Method of analyst ID in system**
- password (customizable)
- password (customizable)

**Response for hardware & software failure/User ID & QC failure/Method of analyst ID in system**
- flag–recalibration
- flag–recalibration

**Analyzer connects to**
- data management system, which connects to LIS/HIS; directly to LIS/HIS
- data management system, which connects to LIS/HIS; directly to LIS/HIS

**Interface standards supported**
- LIS 3
- LIS 4

**To upload patient & QC results, how analyzer connects to data management system, which connects to LIS/HIS; directly to LIS/HIS (both options)**
- direct serial, hospital network
- direct serial, hospital network

**Hardware/Software for data management system**
- device unique identifier, operator & patient IDs, results, QC identifier
- device unique identifier, operator & patient IDs, results, QC identifier

**No. of different management reports system produces**
- customizable
- customizable

**Contents downloaded from DMS to analyzer**
- valid control values, valid operator IDs
- valid control values, valid operator IDs

**System connected (like installations) to which LISs, HISs**
- operator & patient IDs, accession No., results, temperature, patient demographics, others
- operator & patient IDs, accession No., results, temperature, patient demographics, others

**Distinguishing features (provided by vendor)**
- no maintenance, multiuse cartridge; fast time to patient results; onboard audio-video training videos; auto QC
- cartridge-based, high-throughput analyzer with minimal maintenance; fast time to patient results; onboard troubleshooting tutorials

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**In vitro blood gas analyzers**

Siemens Healthcare Diagnostics Inc. 1717 Deerfield Road Deerfield, IL 60015-0778 800-255-3225 www.siemens.com/diagnostics

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