“New designs work wonders,” says Mary Catherine Coyle, of Roche Diagnostics. And judging by the number of companies in CAP TODAY’s in vitro blood gas analyzers guide that are offering new or upgraded products, others agree.

Appearing for the first time in the guide is Roche’s Cobas b 123 point-of-care system, which was launched last month at the American Association for Clinical Chemistry’s annual meeting. The analyzer’s fluid pack features fully integrated maintenance, says Coyle, director of point-of-care product marketing. The system also has four levels of clot protection. “The design of the sample port helps ensure clots do not enter the system,” Coyle says. “We use specific design elements at the sensor and CO-oximeter path to prevent clots from impacting the flow of the sample. When flow sensors detect a clot, they will reverse the flow of the fluid and, effectively, expel the clot to the waste through the sample port.”

New from Nova Biomedical is the Stat Profile pHOx Ultra blood gas/critical care analyzer, which was cleared by the FDA late last year. The analyzer provides test results in 45 seconds and includes snap-in reagent cartridges, autocalibration, automated quality control, and long-life sensors, says marketing specialist Rick Rollins. The Ultra performs 20 measured tests, including pH, pO₂, pCO₂, SO₂%, ionized magnesium, and blood urea nitrogen/creatinine. It comes with built-in networking that allows users to connect multiple pHOx Ultra analyzers into a single, common database, a feature that Rollins says allows operators to access all patient and QC results as well as reports from all analyzers.

While the i-Stat wireless system from Abbott Point of Care is not new, the product now includes five “advanced quality features” to help organizations improve compliance, oversight, and control of their point-of-care programs, says Joe B. Freels, marketing manager of acute care and clinical support. The features, introduced in May, are liquid quality control pass/fail determination, which allows users to download electronic value-assignment information; liquid quality control scheduling and lock-out, which ensures that QC is completed successfully and on schedule by halting further testing unless the QC check occurs on time; customizable reportable ranges, which allow the lab to set upper and lower measurement limits for better control of test reporting; operator competency notification, which informs operators when their recertification is due; and positive patient identification, which allows the system to display the patient’s name, date of birth, and gender.

The company last year released the i-Stat learning system, which, Freels says, combines online delivery of educational content with “the best features of classroom interaction and live instruction to personalize learning, allow thoughtful reflection, and differentiate instruction from student to student.” Also released in May was Siemens Healthcare Diagnostics’ lactate assay for the company’s RapidPoint 500 blood gas system. Among the planned enhancements for the RapidPoint 500 are wireless connectivity, support for ventilator settings, and 100-test measurement cartridges for customers with lower test volumes, says Peter Koerte, PhD, vice president of Siemens’ point-of-care business unit. Last October, the company added neonatal total bilirubin to its RapidPoint 405 blood gas system. And for its RapidLab 1200 blood gas system, Siemens has released software that allows for the simultaneous transmission of information from the serial and Ethernet port to multiple data/patient management systems. The software also includes a read/write application for the USB port and e-mail customization, Dr. Koerte says.

Siemens now has two free mobile blood gas resources for download: “RAPID Analysis—Blood Gases and More,” an e-book reference manual continued on page 76
Blood gas analyzers
continued from page 75

that covers such topics as blood gas testing, pre-exam considerations, and electrolytes; as well as ABG Guide, an interactive iPhone/iPad app to educate users about parameters commonly measured in critical care testing, including those for acid base balance, electrolytes, and metabolites. “It identifies normal and abnormal result ranges, corresponding clinical significance, and possible underlying causes for the specified result values of 18 different analytes,” Dr. Koerte says.

Another company implementing mobile applications is Radiometer America, which, last month, released a preanalytical error prevention app for iPhone users. The app will be available for Android and Windows phones in September, says representative Jan Weaver. Also last month, the company released a 200-test sensor cassette, with an on-analyzer life of two months, for the ABL80 Flex (OSM version). In June, Radiometer released a 100-test sensor cassette for its ABL90 Flex point-of-care blood gas analyzer for sites that run fewer than 100 tests per month. The company released pleural fluid pH on the ABL800 Flex analyzer late last year.

Instrumentation Laboratory in June added Plus Technology to its Gem Premier 4000 system. The technology includes integrated wireless and remote service and faster touchscreen response, says director of marketing William Manchester. An expanded test menu is being developed for the Gem Premier 4000; it will include blood urea nitrogen, creatinine, and measured TCO2. IL continues to offer its Gem Premier family of critical care analyzers—including the Gem Premier 3000, 3500, and 4000—all of which continues to offer its Gem Premier family of critical care analyzers—including the Gem Premier 3000, 3500, and 4000—all of which includes products from the aforementioned companies and from Alere, ITC, and Opti Medical. Readers interested in a particular system should confirm it has the stated features and capabilities.

Brendan Dubkowski is CAP TODAY associate editor.

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Part 1 of 8
Abbott Point of Care
Joe Freels
Joe.freels@apc.abbott.com
400 College Road East
Princeton, NJ 08540
800-827-7828 www.abbottpointcare.com

Alere Inc.
Martin Berner
martin.berner@alere.com
30 South Keller Road, Suite 100
Orlando, FL 32810
888-935-6225 www.alere.com

Name of device/First year sold/Number of analyzers sold in 2011
Number of devices sold in U.S./Outside U.S./List price
Dimensions (H × W × D)/Weight

Analyzers measured on device
pH, pCO2, pO2, Hct, Na, K, Cl, Ica, lactate, glucose, creatinine, BUN, TCO2, tHct, CK-MB, BNP, ACT, PT/INR

Parameters calculated on device

Barometric pressure
measured electrochemically for all analytes

Parameter(s) or technologies employed

Device is part of a series of related models
no

Device warranty/Loader devices provided
1-year replacement/yes

Open or closed system/External gas tanks required
no

Categorized for point-of-care testing or laboratory
point-of-care testing

Point of care:

Analyser
Reagent, electrode (single use)
20
1

No. of samples analysed per one disposable reagent, electrode system
reagent, two-month shelf life for blood gas cartridges, two-week shelf life for all others
up to 6 months

Shell life of disposable units
up to 6 months

Lab system:

Analyser
Reagent, electrode (single use)
50
1

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

Calibration required
1 point (automatic) every test
20
1

Internal QC program recommended
electronic QC, automated internal wet QC

Calibration frequency
every test
—

Calibrations required
1 point (automatic) every test

Average life expectancy of device
8 years

Initial 1-year warranty/extended warranty available

Reagent unit storage requirements
closed/no

Categorization of instrument

Temperature
refrigerate, two-month shelf life for blood gas cartridges, two-week shelf life for all others
room temperature

Water content

Cost per test/Reagent cost per test

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

Acceptable anticoagulants/Sampling technique
heparin/injection, capillary transfer, and fill blood gas, 96 µL; electrolytes, 65 µL

Sample size for complete panel of analyte results
—

Time from sample introduction to result availability
—

Maximum No. of patient samples per hour/Maximum No. of results per hour
20 per unit/160

Optimal throughput when analyzer calibrated, awaiting specimens
—

Calibration can be interrupted to perform stat sample
—

Known interferences
—

Sampler has self-wiping probe
—

Time required for maintenance by lab personnel
—

Service center performs diagnostics through modem
—

Method of analyte ID in system
keypad entry/bar-code scanner (customizable)

Instrument response for:
—

Built-in printer/Data port
—

Information listed on hard copy report
device-unique identifier, operator and patient IDs, results, QC results, QC identifier

Analyzer connections
LIS/HIS, via data-management system

Software supported

LIS/HIS, via data-management system

Hardware and software for data-management system
LIS/HIS, via data-management system

Valid operator IDs, device behavior customizations

Device can be controlled from laboratory
yes

System connected (live installations) to which LISs, HISs and/or other systems
—

Contents downloaded from data-management system to analyzer
—

Distinguishing features (supplied by company)
handheld, portable, single-use test cartridge menu; broad test menu; laboratory-accurate results at the bedside; integrated 802.11b or g bidirectional data transmission to data manager

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Tabulation does not represent an endorsement by the College of American Pathologists.
### Part 2 of 8: Instrumentation Laboratory

<table>
<thead>
<tr>
<th>Date</th>
<th>Customer Service</th>
<th>Website</th>
<th>Tel.</th>
<th>Fax</th>
<th>Location</th>
<th>Tel.</th>
<th>Fax</th>
<th>Location</th>
</tr>
</thead>
</table>

#### Table: In vitro blood gas analyzers

<table>
<thead>
<tr>
<th>Model</th>
<th>Serial Number</th>
<th>Country of Manufacture</th>
<th>Year Manufactured</th>
<th>Warranty Period</th>
<th>Number of Devices Sold</th>
<th>Number of Reagent Kits Sold</th>
</tr>
</thead>
<tbody>
<tr>
<td>iQM</td>
<td>1100</td>
<td>United States</td>
<td>2011</td>
<td>5 years</td>
<td>3000</td>
<td>1000</td>
</tr>
</tbody>
</table>

**Data downloaded from data-management system to analyzer:**  
- Patient ID, demographics, hospital name and address, results
- Operative data, patient ID, demographics

**System connectivity:**  
- USB, Ethernet, modem, wireless

**Service center performs diagnostics through modem:**  
- Operator warning, sampling lockout, channel flagged
- No results for channel

**Remote control of device from laboratory:**  
- No (but can through VPN)

**Time required for maintenance by lab personnel:**  
- 805 Hartwell Road, Bedford, MA 01730
- 800-955-9525

**Customer Service:**  
- customerservice@ilww.com
- 180 Hartwell Road, Bedford, MA 01730
- 800-955-9525

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**Note:** A dash in lieu of an answer means the company did not answer the question or question is not applicable.

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**Distinguishing features (supplied by company):**  
- iQM detects, corrects, and documents instrument errors, reducing error detection time to minutes; maintenance-free, multi-cartridge available in customized configurations for use in any hospital location; wireless communication to LIS or HIS

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**Analyzer connections:**  
- GEMWeb, GEMWeb Plus, impact for Critical Care

---

**Service center performs diagnostics through modem:**  
- Manual or bar-code entry of ID and password (customizable)

---

**Time required for maintenance by lab personnel:**  
- No (but can through VPN)

---

**Data downloaded from data-management system to analyzer:**  
- Operator warning, sampling lockout, channel flagged
- No results for channel

---

**System connectivity:**  
- USB, Ethernet, modem, wireless

---

**Service center performs diagnostics through modem:**  
- Operator warning, sampling lockout, channel flagged
- No results for channel

---

**Remote control of device from laboratory:**  
- No (but can through VPN)
### Tabulation:

**In vitro blood gas analyzers**

#### Part 3 of 8

**See captodayonline.com/productguides for an interactive version of guide.**

<table>
<thead>
<tr>
<th>Name of device/First year sold/Number of analyzers sold in 2011</th>
<th>Number of devices sold in U.S./Outside U.S./List price &gt;6,000 worldwide</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRMA TriPoint Blood Analysis System/1994/—</td>
<td>&gt;10,000 worldwide/11.5 × 9.5–14.5 inches/4 pounds, 4 ounces</td>
</tr>
</tbody>
</table>

#### Analytes measured on device

<table>
<thead>
<tr>
<th>Parameters calculated on device</th>
<th>Barometric pressure</th>
<th>Analytical method(s) or technologies employed</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH, pCO2, pO2, Hct, Na, K, Cl, Ica, glucose, BUN, creatinine, lactate</td>
<td>760 mmHg (optimal), 860 mmHg (max)</td>
<td>pH: potentiometric; pO2, pCO2: amperometric (enzymatic); glucose: enzymatic-enzymometric; creatinine: enzymatic-enzymometric</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Device warranty/Loaner devices provided</th>
<th>Reagent unit storage requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>yes</td>
<td>room temperature: 24°C ± 4°C up to 6 months</td>
</tr>
</tbody>
</table>

#### QC features/Capabilities of QC features

<table>
<thead>
<tr>
<th>Calibrations required</th>
<th>QC features/Capabilities of QC features</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 point (automatic)</td>
<td>1 point: automatic</td>
</tr>
</tbody>
</table>

#### Specimen types suitable for device

<table>
<thead>
<tr>
<th>Acceptable anticoagulants/Sampling technique</th>
<th>Sample size for complete panel of analyte results</th>
<th>Time from sample introduction to result availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>whole blood, capillary, mixed venous, arterial, venous</td>
<td>whole blood, capillary, mixed venous, arterial, venous</td>
<td>90–120 seconds, average</td>
</tr>
</tbody>
</table>

#### Calibrations required

<table>
<thead>
<tr>
<th>Calibration frequency</th>
<th>Calibration options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 point: 30 or 45 minutes or with every sample (user selectable); 2 point: 2, 3, 4, 5, or 6 hours (user defined)</td>
<td>1 point: 30 or 45 minutes or with every sample (user selectable); 2 point: 2, 3, 4, 5, or 6 hours (user defined)</td>
</tr>
</tbody>
</table>

### Limitations

- Tabulation does not represent an endorsement by the College of American Pathologists.

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### In vitro blood gas analyzers

#### Tabulation does not represent an endorsement by the College of American Pathologists.

**August 2012 CAP TODAY**

### Name of device/First year sold/Number of analyzers sold in 2011
- **Stat Profile pHx Respiratory/2006/1**
  - Number of devices sold in U.S.: Outside U.S/Last price
  - Dimensions (H x W x D)/Weight

<table>
<thead>
<tr>
<th>Device</th>
<th>Name</th>
<th>Number of analyzers sold in U.S.</th>
<th>Outside U.S.</th>
<th>Last price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stat Profile pHx Plus/2008/1</td>
<td>15 x 12 x 15 inches/18 pounds</td>
<td>15 x 12 x 15 inches/18 pounds</td>
<td>15 x 12 x 15 inches/18 pounds</td>
<td></td>
</tr>
<tr>
<td>Stat Profile pHx Plus L/2007/1</td>
<td>15 x 12 x 15 inches/18 pounds</td>
<td>15 x 12 x 15 inches/18 pounds</td>
<td>15 x 12 x 15 inches/18 pounds</td>
<td></td>
</tr>
</tbody>
</table>

#### Parameterized on device

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH, PO2, PCO2, Hct, Hb, SO2%, lactate</td>
<td>BE, TC22, NGC-tracked</td>
</tr>
</tbody>
</table>

#### Calibrations required

<table>
<thead>
<tr>
<th>Calibration</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH, PO2, PCO2, Hct, Hb, SO2%, lactate</td>
<td>pH, PO2, PCO2, Hct, Hb, SO2%, Na, K, Cl or Ica, glucose, lactate, BE, TC22, NGC-tracked</td>
</tr>
</tbody>
</table>

#### Point of care:

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disposable packaged system used for analysis</td>
<td>Yes</td>
</tr>
<tr>
<td>Automated reagent unit storage requirements</td>
<td>Yes</td>
</tr>
<tr>
<td>Shelf life of disposable units</td>
<td>Yes</td>
</tr>
</tbody>
</table>

#### Laboratory:

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of different management reports system produces</td>
<td>Yes</td>
</tr>
<tr>
<td>Cost per test/Reagent cost per test</td>
<td>$&lt;0.11 at 35 analyses per day/$&lt;0.08 at 35 analyses per day</td>
</tr>
</tbody>
</table>

#### Calibration frequency

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH, PO2, PCO2, Hct, Hb, SO2%, lactate</td>
<td>1 point: 30 or 45 minutes or with every sample (user selectable); 2 point: 2, 4, or 6 hours (user defined) minimum CLIA recommendations</td>
</tr>
</tbody>
</table>

#### Known interferences

<table>
<thead>
<tr>
<th>Interference</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH, PO2, PCO2, Hct, Hb, SO2%, lactate</td>
<td>None</td>
</tr>
</tbody>
</table>

#### Specimen types suitable for device

<table>
<thead>
<tr>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood, capillary, mixed venous, arterial</td>
<td>Whole blood, capillary, mixed venous, arterial</td>
</tr>
</tbody>
</table>

#### Analyzer connections

<table>
<thead>
<tr>
<th>Connection</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>data-management system or directly to LIS/HIS, or both</td>
<td>Data-management system or directly to LIS/HIS, or both</td>
</tr>
</tbody>
</table>

#### Hardware and software for data-management system

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data collection and analysis to which LIS, HISs connected</td>
<td>Yes</td>
</tr>
</tbody>
</table>

#### Distinguishing features (supplied by company)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onboard auto-cartridge QC; all-liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration and waste collection</td>
<td>Onboard auto-cartridge QC; all-liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration and waste collection</td>
</tr>
</tbody>
</table>

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**See captiononline.com/productguides for an interactive version of guide.**
### In vitro blood gas analyzers

**Part 5 of 8**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>pHOx Plus C</td>
<td>2003/—</td>
<td>—</td>
<td>15 x 12 x 15 inches/18 pounds</td>
<td>OPTI R/2006/—</td>
<td>4.7 x 14.2 x 14 inches/4.5 kg (10 pounds without fluid pack)</td>
</tr>
<tr>
<td>Opti Medical Systems Inc.</td>
<td>235 Hembre Park Drive</td>
<td>800-490-5874</td>
<td><a href="http://www.optimedical.com">www.optimedical.com</a></td>
<td>4.7 x 14.2 x 9 inches/12 pounds (10 pounds without battery)</td>
<td></td>
</tr>
</tbody>
</table>

### Analyzers measured on device

- pH, PCO2, PO2, Hct, Hb, SO2%, Na, K, Cl, iCa, glucose
- Parameters calculated on device: BE, TCO2, HCO3-
- Barometric pressure tracked
- Analytical method(s) or technologies employed: pH: direct ISE; PCO2: Severinghaus; PO2: amperometry; Hct: conductivity; Hb and SO2%: optical-reflection; Na, K, Cl: direct ISE; glucose: enzyme/amperometric

### Device

- Device is part of a series of related models: yes, Opti series
- Device warranty/Loaner devices provided: 1 year, travel and labor, repair or replacement
- Average life expectancy of device: 5–7 years
- Open or closed system/External gas tanks required: closed/no
- Point of care: point-of-care testing and laboratory

### System

- Shelf life of disposable units: 12 months at room temperature, membrane kits: 12 to 24 months
- Cost per test/Reagent cost per test: $0.11 at 35 analyses per day/$0.08 at 35 analyses per day

### Calibration

- Calibration frequency: 1 point: after every sample or 30 minutes; 2 point: every 3 hours
- Internal QC program recommended: minimum CLIA recommendations
- QC features/Capabilities of QC features: L-1 plots/statistical calculations, monthly cumulative report
- QC lockout: QC lockout

### Patient Information

- Patient ID: yes
- Sample size for complete panel of analyte results: 125 µL
- Time required for maintenance by lab personnel: weekly: <5 minutes; monthly: <10 minutes
- Service center performs diagnostics through modem: yes
- Method of analyst ID in system: password with unique user ID number (optional)

### Hardware and Software

- Built-in printer/Data port: yes/multiple RS-232; yes/RS-232, Ethernet
- Information listed on hard copy report: patient ID, results, QC identifier, all information pertinent to device-unique identifier, operator and patient IDs, operator and patient IDs, reagent, QC
- System connected (live installations) to which LISs, HISs: Meditech, McKesson, Cerner, Siemens, others

### Distinguishing features (supplied by company)

- on-board auto-cartridge QC; all-liquid calibration
- stable optical fluorescence technology, easy-to-use touchscreens, measured iCa and SO2, no standby costs (single-use system), low maintenance

---

**Note:** a dash in lieu of an answer means company did not answer question or question is not applicable.
### Point of Care

<table>
<thead>
<tr>
<th>Device Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of disposable reagent systems in standard package</td>
<td>pH, pO2, pCO2, Na, K, Cl, lactate, glucose, bilirubin, metabolic analysis, amperometric technology, Hb, Hct, calculated from measuring Hb, bilirubin; Hb, optical, multilaminate analysis, in-vitro ultrasonic hemolysis, and more.</td>
</tr>
<tr>
<td>Reagent and electrode system</td>
<td>electronic sensors (multisensor) cartridge, 2 months depending on configuration/depends on configuration/depends on configuration.</td>
</tr>
<tr>
<td>Shelf life of disposable units</td>
<td>—</td>
</tr>
</tbody>
</table>

### Laboratory

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibrations required for point-of-care testing or laboratory</td>
<td>1 point: with each test, 2 point: 8 hours — 1 point: 1/2 hour</td>
</tr>
</tbody>
</table>
### Tabulation

**Name of device/First year sold/Number of analyzers sold in 2011**
- cobas b 123 POC system/2004/25
- cobas b 221 system/2004/360
- RAPIDPoint 500 system/2011/336

**Dimensions (H x W x D)/Weight**
- 18.5 x 12.6 x 13 inches/84 pounds
- 21.5 x 11.5 x 16 inches/36 pounds

**Point of care:**
- Disposable prepackaged system used for analysis
  - Reagent and electrode on demand
  - Reagents: 12 months; electrodes: 18 months

**Laboratory:**
- No. of different disposable reagents required to maintain device
  - 1
- Max. No. of analyzer reagents that can reside in device at once
  - 1
- Shelf life of components
  - Reagent: 1 year; electrode: 7 years
- Cost per test/Reagent cost per test
  - 120 seconds ~1 minute (test dependent)

**Calibrations required**
- Calibration frequency
  - Internal QC program recommended: 1 and 2 point (manual and automatic)
  - L-J plots/external RapidComm data management; statistical calculations
- QC features/Capabilities of QC features
  - Lines; user configurable for increased QC frequency
  - QC failure plain language issue description; QC warning and regulatory
  - Calibration failure
  - Lockout/plain language issue description

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

**Analyzer connections**
- Interface standards supported
  - Direct serial, Ethernet
- Hardware and software for data-management system
  - Hardware: bge link software
  - Software: RapidComm data-management system
- No. of different management reports system produces
  - 13 base reports, unlimited customized reports
- Contents downloaded from data-management system to analyzer
  - Data Innovations
- System connected (fee installations) to which LISs, HISs
  - Data Innovations

**Distinguishing features (supplied by company)**
- FDA 510(k)-cleared pH/pleural fluid results; 42-day onboard reagent packs; Roche AutoQC with up to 40 days of QC coverage; screen sharing and remote protected access with cobas bge link and Aera software

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## Siemens Healthcare Diagnostics Inc.

**Part 8 of 8**

**Name of devices/First year sold/Number of analyzers sold in 2011**

<table>
<thead>
<tr>
<th>Device</th>
<th>Year Sold</th>
<th>Number of Analyzers Sold</th>
</tr>
</thead>
<tbody>
<tr>
<td>RapidPoint 400 Series</td>
<td>2001</td>
<td>—</td>
</tr>
<tr>
<td>RapidPoint 300 Series</td>
<td>2008</td>
<td>—</td>
</tr>
<tr>
<td>RapidLab 1200 Series</td>
<td>2005</td>
<td>—</td>
</tr>
</tbody>
</table>

**Number of devices sold in U.S./Outside U.S./List price**

<table>
<thead>
<tr>
<th>Dimensions (H x W x D)/Weight</th>
<th>U.S. Price</th>
<th>Outside U.S. Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>21.5 × 11.5 × 16 inches/34 pounds</td>
<td>255–3232</td>
<td>800–255–3232</td>
</tr>
<tr>
<td>19 × 17 × 20 inches/45 pounds</td>
<td>272.5–283.2</td>
<td>800–255–3232</td>
</tr>
</tbody>
</table>

**Analytes measured on device**

- pH, pCO2, pO2, Hct, Na+, K+, Cl-, Ca++, tHb, FO2Hb,
- Barometric pressure recorded,
- Analytical method(s) or technologies employed pH, Na, Cl, iCa, potassium ion using ISE; pCO2: potentiometry based on Severinghaus; pO2: amperometric measure; Clark; glucose: amperometric-enzymatic; lactate: amperometric, lactate oxidase; bicarbonate: amperometric; CO2: amperometric, lactate oxidase; pH: calculated from bicarbonate; Na, Cl, iCa, K; ISE; lactate: amperometric, lactate oxidase; glucose: amperometric-enzymatic; Ca2+: amperometric; Cl: amperometric-enzymatic; O2: amperometric; H2S: amperometric; HCO3: spectrophotometric.

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

- No

**Device warranty/Lauser devices provided**

1 year/yes

**Average life expectancy of device**

- 3 years

**Categorized for point-of-care testing or laboratory**

- Point-of-care testing

**Point of care:**

- Disposable packaged system used for analysis

**Shelf life of disposable units**

- 1 year

**Laboratory:**

- No

**Calibrations required**

1 point: every 30 minutes; 2 point: every 8 hours

**Internal QC program recommended**

- AQC cartridge, fully user programmable

**QC features/Capabilities of QC features**

- AQC cartridge, L-J plots/statistical calculations, monthly cumulative reports (available with external system)

**Remote control of device from laboratory**

- Yes

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

- Yes

**Analyzers used on device**

- pH, pCO2, pO2, Hct, Na+, K+, Cl-, iCa++, lactate, glucose, iCa++, FCO2, pHb, pHb, total bilirubin: spectrophotometric

**Barometric pressure recorded**

- Reagents: 9 months; electrodes: vary based on type; reagent cartridge: 8 months; AQC cartridge: 7–9 months; electrodes: 12 months

**Time required for maintenance by lab personnel**

- None daily: <1 minute; weekly: 5 minutes; monthly: 5 minutes

**Time for bar-code scanning is provided**

- Yes

**Built-in printer/Data port information listed on hard copy report**

- Yes

**Analyzer connections**

- Directly to LIS/HIS

**Interface standards supported**

- ASTM 1294 and E1381

**Information included in transmission from analyzer to external system**

- Operator identifier, patient identifier, results device-unique identifier, operator and patient IDs, results, date information

**Hardware and software for data-management system**

- RapidComm data-management system customizable

**Distinguishing features (supplied by company)**

- Multi-use cartridge-based system eliminates gas tanks; no maintenance, easy-to-replace electrodes; small, portable, and economical; dialyse fluid testing application in select countries

**Other**

- Cartridge-based high-throughput analyzer with minimal maintenance; fast time to patient results; onboard troubleshooting tutorials

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**Note:** a dash in lieu of an answer means company did not answer question or question is not applicable.

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**Tabulation does not represent an endorsement by the College of American Pathologists.**