

## For blood gas analyzers, larger menus and new features

Brendan Dabkowski

As testing for blood gas and other critical care analytes continues to migrate from the laboratory to the point of care, caregivers are demanding test systems that are easy to use yet equipped with extensive test menus, says Sheila Gavan of Siemens Healthcare Diagnostics. In the blood gas testing market, customers are asking questions such as: "Can I use a continuous blood gas system in the ER, in the OR, in the ICU?" says Roche Diagnostics' Larry Healy.

The makers of in vitro blood gas analyzers, the focus of this month's product guide on pages 22-38, are developing new instruments and adding tests and features to existing instruments to meet the abovementioned demands and address questions such as the one posed by Healy, Roche's marketing manager for professional diagnostics-hospital.

Roche, for instance, is developing a point-of-care version of its Cobas b 221 blood gas system, and it anticipates filing for FDA 510(k) clearance in December. Using the system, Healy says, caregivers will be able to monitor patients at the bedside quickly and efficiently and "treat them, move them through the hospital continuum, and get them home." The company recently introduced version 7.05 operator software for its benchtop Cobas b 221 blood gas analyzer and plans to launch a new IT connectivity solution in December.

At least two companies have in the past year introduced bilirubin tests on their blood gas systems. Instrumentation Laboratory received FDA 510(k) clearance last month for a total bilirubin assay to run on its GEM Premier 4000 critical care analyzer, while Siemens recently added a neonatal bilirubin parameter to its RapidLab 1200 blood gas analyzer. On the RapidLab 1200, the bilirubin parameter can be used separately or as part of a panel that includes blood gases as well as pH, electrolytes, glucose, lactate, total hemoglobin, and

CO-oximetry, says Gavan, Siemens' global marketing manager, blood gas. It requires only 100 uL of blood, and users can obtain results in one minute. Siemens is developing the same parameter as a software upgrade for its RapidPoint 405 point-of-care blood gas analyzer.

In addition to its new total bilirubin assay, IL will soon introduce a basic metabolic panel with BUN, creatinine, and measured TCO<sub>2</sub> on its GEM Premier 4000 critical care analyzer, says IL

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### Specimen storage containers 2 oz to 165 oz



• 2 oz, 3 oz, 4 oz, 5 oz containers are made of polypropylene with leak-resistant screw caps.

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## Blood gas analyzers

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group manager Bill Manchester, who adds that the panel will be “extremely valuable to the emergency department.” IL recently began offering automated and customizable operator certification, with exams and advanced regulatory compliance management, for its GEMweb Plus Custom Connectivity information management software. GEMweb Plus now receives admission discharge and transfer transmissions and allows staff to create POC orders, Manchester says.

New from Radiometer America—pending FDA clearance—is the ABL90 Flex compact blood gas system, which, says vice president of marketing Shane Hawes, is similar to the company’s ABL80 Flex CO-OX point-of-care blood gas analyzer. The ABL90 Flex improves on the ABL80 Flex system, introduced in 2008, by offering a broader parameter profile, faster measurement speed, higher throughput capacity, and onboard sample mixing, Hawes says.

Nova Biomedical continues to market its Stat Profile pHox line of blood gas/critical care analyzers, which can provide test results in 45 seconds. Used in the OR, ED, ICU, and stat labs, the analyzers feature color touchscreens, advanced user interfaces, snap-in reagent cartridges, autocalibration, and fully automated quality control, says Rick Rollins, Nova marketing specialist. The analyzers’ menus feature 20 measured tests, including a frequently ordered basic metabolic panel and a blood gas panel.

Abbott Point of Care has extended room-temperature expiration on its blood gas cartridges from two weeks to two months, and the company now manufactures individual testing cartridges with bar codes on the pouches, says Kevin Ball, global marketing manager for acute care. And still available from Abbott is the i-Stat 1 handheld analyzer, which runs tests not only for blood gas but also coagulation, cardiac, and chemistries.

The capability to run different types of test panels on one system is important, the companies say, and the increasing demand to standardize point-of-care testing on one platform is helping drive the development of new blood gas analyzers. Says Roche’s Healy: “Some of the applications are radically changing, and that’s why they’re [customers] demanding larger menus. Typically,” he adds, customers want “not only the blood gas values and the electrolytes, but they do want metabolites now; they want glucose and lactate, in particular.” Manufacturers will also need to address requests that their products integrate informatics and data-management solutions at the point of care, says Siemens’ Gavan. Healy predicts: “Many new instruments will incorporate sensor technology. Will it be indwelling sensors? Will it be clips that you put on people’s fingers?” he asks. Only time will tell.

CAP TODAY’s guide to in vitro blood gas analyzers includes instruments from the aforementioned manufacturers and from ITC and Opti Medical Systems. Companies supplied the information listed. Readers interested in a particular analyzer should confirm it has the stated features and capabilities. □

Brendan Dabkowski is CAP TODAY associate editor.

## In vitro blood gas analyzers

Part 1 of 11	Abbott Point of Care Dan Molloy daniel.molloy@apoc.abbott.com 400 College Road East Princeton, NJ 08540 800-827-7828 www.abbottpointofcare.com
Name of device/First year sold/No. of analyzers sold in 2009 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight	i-STAT System/1992/— 30,000+/20,000+/\$8,761 9.25 x 3.0 x 2.85 in./22.4 oz
Analytes measured on device	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Na, K, Cl, iCa, lactate, glucose, creatinine, BUN, TC02
Parameters calculated on device	Hb, HcT, O2SAT, BE, TC02, HC03
Barometric pressure	measured
Analytical method(s), technology(ies) employed	electrochemical for all analytes
Device is part of a series of related models	no
User list or group available	yes (through local sales representative)
Device warranty	1-year replacement
Loaner devices provided	yes
Average expected life of device	8 years
Open or closed system/External gas tanks required	closed/no
For POC testing or laboratory	POC testing
POC: Uses 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 unit storage requirements Shelf life of disposable units	reagent/electrode (single use) 25 per box 1 varies refrigerate, two-week shelf life at room temperature reag./electrode: 6 to 9 months
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	— — — —
Calibrations required Calibration frequency Calibrants traceable to NIST standards Internal QC program recommended QC features	1 point (automatic) every test yes electronic QC, automated internal wet QC comparable plot, monthly cumulative reports (available with external system)
Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	yes no —
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/Sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/Max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe	— whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer, and fill yes/yes blood gas 96 µL, electrolytes 65 µL no syringe or capillary tube yes about 2 minutes 20 per unit/160 — — — — — — —
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user	— yes/no yes yes, no. of training days varies
Method of analyst ID in system Response for hardware & software failure/User ID & QC failure/ Calibration & power failure	keypad entry/bar-code scanner (customizable) code no. error message/code no. error message/code no. error message
Supports bar-code scanning of User can search for and review previous patient results on screen Built-in printer/Data port Information on hard copy report	operator & patient IDs, reagent lot no. yes no/— device unique identifier, operator & patient IDs, results, QC results, QC identifier
Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer to external system Hardware/Software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs, HISs • using screen animation, screen scraping • using standard HL7 interface • using proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	LIS/HIS, via data management system ASTM 1394 & 1238, HL7 hospital network device unique identifier, operator & patient IDs, results, QC identifier, others PrecisionWeb/Central Data Station 35+ valid operator IDs, device behavior customizations all major LIS vendors all major LIS vendors — yes, Sybase Interface Manager
Distinguishing features (provided by vendor)	handheld, portable, single-use test cartridge menu; broad test menu on a single POC platform; laboratory-accurate results at the bedside

## In vitro blood gas analyzers

Part 2 of 11	Instrumentation Laboratory Mike Wright mwright@ilww.com 180 Hartwell Road Bedford, MA 01730 781-861-4165 www.ilus.com	Instrumentation Laboratory Mike Wright mwright@ilww.com 180 Hartwell Road Bedford, MA 01730 781-861-4165 www.ilus.com
Name of device/First year sold/No. of analyzers sold in 2009 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight	GEM Premier 3000/2000/1,450 >2,000/>8,000/\$39,995 17 x 12 x 12 in./29.5 lbs	GEM 3500/2009/430 290/140/\$45,000 17.5 x 13 x 11.8 in./31.2 lbs
Analytes measured on device	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Hct, Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , glucose, lactate	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Hct, Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , glucose, lactate
Parameters calculated on device	A-aDO <sub>2</sub> , Hb, pAO <sub>2</sub> , paO <sub>2</sub> /pAO <sub>2</sub> , RI, O <sub>2</sub> cap*, O <sub>2</sub> Ct*, CtO <sub>2</sub> *, CaO <sub>2</sub> *, CvO <sub>2</sub> *, CcO <sub>2</sub> *, a-vDO <sub>2</sub> *, Qsp/Qt, P50, HCO <sub>3</sub> <sup>-</sup> , BEb, BEecf, S02c	A-aDO <sub>2</sub> , Hb, pAO <sub>2</sub> , paO <sub>2</sub> /pAO <sub>2</sub> , RI, O <sub>2</sub> cap*, O <sub>2</sub> Ct*, CtO <sub>2</sub> *, CaO <sub>2</sub> *, CvO <sub>2</sub> *, CcO <sub>2</sub> *, a-Qsp/Qt, P50, HCO <sub>3</sub> <sup>-</sup> , tCO <sub>2</sub> <sup>-</sup> , BEb, BEecf, S02c
Barometric pressure	—	—
Analytical method(s), technology(ies) employed	pH, pCO <sub>2</sub> : potentiometry; pO <sub>2</sub> , glucose, lactate: Na, iCa, K: amperometry; Hct: conductivity; potentiometric ion selective electrode	pH, pCO <sub>2</sub> : potentiometry; pO <sub>2</sub> , glucose, lactate, Na, iCa, K: amperometry; Hct: conductivity; potentiometric ion selective electrode
Device is part of a series of related models	yes	yes
User list or group available	yes (through local sales representative)	yes (through local sales representative)
Device warranty	5 years	5 years
Loaner devices provided	yes	yes
Average expected life of device	7 to 10 years	7 to 10 years
Open or closed system/External gas tanks required	closed/no	closed/no
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 one disposable reagent, electrode system	yes (multi-use cartridge) 1 per pack 35-, 75-, 150-, 300-, 450-, & 600-test cartridge	yes (multi-use cartridge) 1 per pack 75-, 150-, 300-, 450-, & 600-test cartridge
List price per disposable reagent system	varies with size & menu	varies with size & menu
Reagent unit storage requirements	room temperature	room temperature
Shelf life of disposable units	6 months	6 months
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	1 1 multiuse cartridge 6 months varies with size & menu	1 1 multiuse cartridge 6 months varies with size & menu
Calibrations required Calibration frequency Calibrants traceable to NIST standards Internal QC program recommended QC features	automated continuous with IQM automated continuous with IQM yes internal, automated, continuous quality management included Onboard Intelligent Quality Management; monthly report includes no. of measurements, mean, max, and min delta values	automated continuous with IQM automated continuous with IQM yes internal, automated, continuous quality management included Onboard Intelligent Quality Management; monthly report includes no. of measurements, mean, max, and min delta values
Remote control of device from laboratory	yes	yes
System can use LOINC to transmit results to LIS	no	no
How labs get LOINC codes for reagent kits	—	—
Detects clots within analysis chamber	yes; automatically attempts to clear	yes; automatically attempts to clear
Specimen types suitable for device	whole blood, arterial, venous, or capillary	whole blood, arterial, venous, or capillary
Acceptable anticoagulants	heparin	heparin
Sampling technique	aspiration	aspiration
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	135 to 150 µL	135 to 150 µL
Sample size differs with No. of analytes selected	no	no
Recommended collection device	syringe or capillary tube	syringe or capillary tube
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	85 seconds	85 seconds
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	20/180	20/180
Optimal throughput when calibrated and awaiting specimens	20 samples per hour	20 samples per hour
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	—	—
Known interferences	—	—
Restrictions based on Hct	no	no
Sampler has self-wiping probe	yes	yes
Time required for maintenance by lab personnel	no maintenance required (disposable cartridge)	no maintenance required (disposable cartridge)
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	no (but can through VPN)	no (but can through VPN)
Training & certification program for user	yes	yes
Method of analyst ID in system	manual or bar-code entry of ID & password (customizable)	manual or bar-code entry of 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	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	operator & patient IDs, QC values	operator & patient IDs, QC values
User can search for and review previous patient results on screen	yes	yes
Built-in printer/Data port	yes/3 RS-232, 1 parallel, bar-code reader port, Ethernet port	yes/4 USB, 3 RS-232, 1 parallel, bar-code reader port, Ethernet
Information on hard copy report	patient demographics, hospital name and address, results	patient demographics, hospital name and address, results
Analyzer connects to	GEMweb, GEMweb Plus, Impact for Critical Care	GEMweb, GEMweb Plus, Impact for Critical Care
Interface standards supported	ASTM protocol	ASTM and HL7 protocols
To upload patient & QC results, how analyzer connects to external system	direct serial, Ethernet, modem dial-in	direct serial, Ethernet, modem dial-in
Information included in transmission from analyzer to external system	device identifier, operator & patient IDs, results, QC ID & results	device identifier, operator & patient IDs, results, QC ID & results
Hardware/Software for data management system	Impact for Critical Care	GEMweb, GEMweb Plus, Impact for Critical Care
No. of different management reports system produces	customizable	customizable
Contents downloaded from DMS to analyzer	patient ID, demographics	patient ID, demographics
System connected (live installations) to which LISs, HISs	—	—
• using screen animation, screen scraping	yes	yes
• using standard HL7 interface	all major HIS/LIS vendors	all major HIS/LIS vendors
• using proprietary protocol interface	yes	yes
Use a third-party interfacing tool, engine for LIS, HIS interfaces	MAS/RALS, Telcor	MAS/RALS, Telcor
Distinguishing features (provided by vendor)	iQM detects, corrects, and documents instrument errors, reducing error detection time to minutes; maintenance-free, multi-use cartridge available in customized configurations for use in any hospital location; wireless communication to LIS or HIS; 20-year history of cartridge technology; remote management from any PC via GEMweb; consolidated workstation for blood gas, electrolytes, Hct, glucose, lactate	iQM detects, corrects, and documents instrument errors, reducing error detection time to minutes; maintenance-free, multi-use cartridge available in customizable configurations for use in any hospital location; wireless communication to LIS or HIS; LED lighted sampling area; 20-year history of cartridge technology; remote management from any PC via GEMweb; consolidated workstation for blood gas, electrolytes, Hct, glucose, lactate

## In vitro blood gas analyzers

Part 3 of 11	<b>Instrumentation Laboratory</b> Bill Manchester billm@ilww.com 180 Hartwell Road Bedford, MA 01730 781-861-4360 www.ilus.com	ITC 8 Olsen Ave. Edison, NJ 08820 800-631-5945 www.itcmed.com
Name of device/First year sold/No. of analyzers sold in 2009 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight	GEM Premier 4000/2006/— 1,000 worldwide/\$50,000 18 x 12 x 15 in./44 lbs	IRMA TRUpoint Blood Analysis System/1994/— 6,000 worldwide/— 11.5 x 9.5 x 5 in./5 lbs, 4 oz
Analytes measured on device Parameters calculated on device	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Na, K, Cl, iCa, lactate, glucose, tHb, O <sub>2</sub> Hb, COHb, Methb, HHb, tBili Hct, TC0 <sub>2</sub> , BEecf (in vivo), BE(B) (in vivo), tHb(c), Ca <sup>++</sup> (7.4), anion gap, P/F ratio, pA0 <sub>2</sub> , Ca0 <sub>2</sub> , Cv0 <sub>2</sub> , P50, O <sub>2</sub> cap, sO <sub>2</sub> , sO <sub>2</sub> (c), HCO <sub>3</sub> -std, HCO <sub>3</sub> -(c), A-aD0 <sub>2</sub> , paO <sub>2</sub> /pA0 <sub>2</sub> , RI, Cc0 <sub>2</sub> , a-vD0 <sub>2</sub> , Qsp/Qt(est), Qsp/Qt	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Na, K, Cl, iCa, glucose, BUN, creatinine, lactate Hb, O <sub>2</sub> SAT, BEb, BEecf, TC0 <sub>2</sub> , HCO <sub>3</sub> -, iCa(n), creatinine MDRD-GFR
Barometric pressure Analytical method(s), technology(ies) employed	— pH, pCO <sub>2</sub> : potentiometry; pO <sub>2</sub> , glucose, lactate: amperometry; Hct: conductivity; Hb, tBili: spectrophotometric; Na, Cl, iCa, K: potentiometric ion selective electrode	measured pH, pCO <sub>2</sub> , Na, Cl, iCa, K, BUN, creatinine, lactate (enzymatic): potentiometric; pO <sub>2</sub> , glucose (enzymatic): amperometric; Hct: conductometric; glucose strip (enzymatic): colorimetric
Device is part of a series of related models User list or group available Device warranty Loaner devices provided Average expected life of device Open or closed system/External gas tanks required For POC testing or laboratory	yes yes (through local sales representative) 5 years yes 7 to 10 years closed/no POC & laboratory	yes yes 1 year yes 7 years closed/no POC testing
POC: Uses 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 unit storage requirements Shelf life of disposable units	yes (multi-use cartridge) 1 per pack cartridges available: 75, 150, 300, 450, 600 varies with size and menu room temperature 6 months	reagent/electrode (single use) 25 per box 1 \$6 to \$7 room temperature; creatinine 2° to 8°C reagent/electrode: 6 months
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	1 1 multi-use cartridge 6 months (cartridge) varies with cartridge size and menu	— — — —
Calibrations required Calibration frequency Calibrants traceable to NIST standards Internal QC program recommended QC features	automated continuous with IQM automated continuous with IQM yes internal, automated, continuous quality management included Onboard Intelligent Quality Management; monthly report includes no. of measurements, mean, max, and min delta values	2 point (automatic) automatic with each sample yes automatic electronic QC per 8 hrs L-J plots, statistical calculations, monthly cumulative reports (IDMS)
Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	yes no —	yes no —
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/Sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/Max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe	yes; automatically attempts to clear whole blood, capillary, mixed venous, arterial, venous heparin aspiration yes/yes 150 µL, 95 µL (electrochemical only), 65 µL micro mode (electrochemical only) yes heparinized syringe or capillary tube yes 70 seconds for electrochemical and 25 additional seconds for CO-ox 20/300  20 samples per hour yes no interfering substance would be detected and operator notified no yes	no—sample path visible whole blood, capillary, mixed venous, arterial, venous heparin, EDTA (glucose strip only) injection yes/yes 125 µL capillary, 200 µL syringe no standard blood gas syringe or capillary collection device yes 60 to 90 seconds on average 25/175  20 per hour — none — no no, not needed
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user	none yes/no no (but can through VPN) yes	maintenance free yes/no no yes
Method of analyst ID in system Response for hardware & software failure/User ID & QC failure/ Calibration & power failure	wireless bar-code gun or manual virtual keyboard entry operator warning, sampling lockout/user ID: no system access/QC: IQM disables analyte channel; no result reported/IQM disables analyte channel; no result reported/power: system automatically performs checks before samples can be analyzed	LCD touchscreen, numeric (customizable) EQC failure or screen prompt, software: screen prompt/if user ID required, no access to menu, if QC required, no access to patient testing mode/calib.: test ends—no injection of sample allowed, power: blank screen—resume testing with power operator & patient IDs, cartridge information, lot No., quality control ranges yes yes/RS-232, modem, Ethernet, LAN analyzer serial no., date, calib. successful, calib. code, lot no., patient ID & temp., results, barometric press., SW version optional: user ID, ref. ranges, O <sub>2</sub> therapy, sample information
Supports bar-code scanning of User can search for and review previous patient results on screen Built-in printer/Data port Information on hard copy report	operator & patient IDs, cartridge lot number & expiration date yes yes/4 RS-232, 1 parallel port, 1 Ethernet port, 4 USB ports patient demographics, hospital info, results, result flags and legend, reference and critical ranges (optional), comments, notification info	operator & patient IDs, cartridge information, lot No., quality control ranges yes yes/RS-232, modem, Ethernet, LAN analyzer serial no., date, calib. successful, calib. code, lot no., patient ID & temp., results, barometric press., SW version optional: user ID, ref. ranges, O <sub>2</sub> therapy, sample information
Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to ext. system Information included in transmission from analyzer to external system	LIS/HIS via direct interface or via IL's GEMweb Plus Custom Connectivity; vendor-neutral or Web-based systems ASTM 1394, HL7 direct serial, hospital network, real-time wireless device identifier, operator & patient IDs, results, QC ID	data mgmt. system, which connects to LIS/HIS; directly to LIS/HIS (both options)  IRMA (ASTM protocol), IDMS (script, HL7, or EDI) hospital network, direct serial, LAN device unique identifier, operator & patient IDs, results, QC identifier, patient O <sub>2</sub> therapy information
Hardware/Software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs, HISs • using screen animation, screen scraping • using standard HL7 interface • using proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	GEMweb Plus  4 most configuration information, including valid operator IDs, QC lots and ranges  — all major HIS/LIS vendors — MAS/RALS, Telcor	integrated data management system, also integrates ITC co-oximetry and coagulation devices, connects to MAS, Telcor, and Aegis POC data managers 24 all analyzer settings, software upgrades  all major HIS/LIS vendors all major HIS/LIS vendors customizable EDI interface to HIS/LIS vendors yes
Distinguishing features (provided by vendor)	iQM detects, corrects, and documents instrument errors, reducing error detection time to minutes; single component, multi-use GEM Premier 4000 cartridge includes all testing components, is changed every 30 days, requires no refrigeration or maintenance; GEMweb Plus Custom Connectivity software allows access and control from any networked PC or GEM Premier 4000 analyzer	self-contained and easy to use; contains onboard printer, interactive touchscreen, bar-code scanning, automatic electronic QC, and site-specific custom correlation reference ranges; complete data management from patient information to lot traceability; self-calibrating cartridges with Luer lockport, which forms a closed system and reduces biohazards, room-temperature cartridge storage

## In vitro blood gas analyzers

Part 4 of 11	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813
Name of device/First year sold/No. of analyzers sold in 2009 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight	Stat Profile pH0x Basic/2002/— —/—/— 15 x 12 x 15 in./18 lbs	Stat Profile pH0x/1998/— —/—/— 15 x 12 x 15 in./18 lbs
Analytes measured on device Parameters calculated on device Barometric pressure Analytical method(s), technology(ies) employed  Device is part of a series of related models User list or group available Device warranty Loaner devices provided Average expected life of device Open or closed system/External gas tanks required For POC testing or laboratory	pH, pCO <sub>2</sub> , pO <sub>2</sub> BE, TC0 <sub>2</sub> , HC0 <sub>3</sub> - tracked pH: direct ISE; PCO <sub>2</sub> : Severinghaus; PO <sub>2</sub> : amperometry  yes yes (upon request) 1 year, repair or replacement of any part, including labor yes 5 to 7 years closed/no POC & laboratory	pH, PCO <sub>2</sub> , PO <sub>2</sub> , Hct, Hb, SO <sub>2</sub> % BE, TC0 <sub>2</sub> , HC0 <sub>3</sub> - tracked pH: direct ISE; PCO <sub>2</sub> : Severinghaus; PO <sub>2</sub> : amperometry; Hct: conductivity; Hb & SO <sub>2</sub> %; optical-reflectance  yes yes (upon request) 1 year, travel and labor, repair or replacement yes 5 to 7 years closed/no 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 one disposable reagent, electrode system List price per disposable reagent system Reagent unit storage requirements Shelf life of disposable units	reagent 200 to 500 analyses — — room temperature reagents: 18 months at room temperature; electrodes: up to 18 months	reagent 200 to 500 analyses — — room temperature reagents: 18 months at room temperature, electrodes: up to 18 months
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	1 1 reagents & electrodes: 18 months; membrane kits: 12 to 24 months <\$0.11 at 35 analyses per day/<\$0.08 at 35 analyses per day	1 1 reagents & electrodes: 18 months; membrane kits: 12 to 24 months <\$0.11 at 35 analyses per day/<\$0.08 at 35 analyses per day
Calibrations required Calibration frequency  Calibrants 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 How labs get LOINC codes for reagent kits	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)  yes minimum CLIA recommendations L-J plots, statistical calcs., monthly cum. report (onboard, more extensive reporting avail. with Nova Point-of-Care Manager)  no no —	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)  yes minimum CLIA recommendations L-J plots, statistical calcs., monthly cum. report (onboard, more extensive reporting avail. with Nova Point-of-Care Manager)  no no —
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/Sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/Max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe	yes whole blood, capillary, mixed venous, arterial heparin aspiration & capillary yes/yes 70 µL yes, standard 3-test blood gas micro-panel sample req. is 45 µL syringe, capill., micro-collect. containers, standard vacuum cont. yes 45 seconds 300/300 tests  300 tests per hour yes none none no yes	yes whole blood, capillary, mixed venous, arterial heparin aspiration & capillary yes/yes 70 µL yes, standard 3-test blood gas micro-panel sample req. is 45 µL syringe, capill., micro-collect. containers, standard vacuum cont. yes 45 seconds 300/300 tests  300 tests per hour yes none none no yes
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user	weekly: <5 min; monthly: <10 min yes/no yes yes	weekly: <5 min; monthly: <10 min yes/no yes yes
Method of analyst ID in system Response for hardware & software failure/User ID & QC failure/ Calibration & power failure   Supports bar-code scanning of User can search for and review previous patient results on screen Built-in printer/Data port  Information on hard copy report	password with unique user ID No. (optional) self-diag. SW informs & notifies oper. of HW & SW failure; hotline & field support depending on problem/optional lockout w/o proper user ID; options for QC failure range 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 interrupts require no recovery—extended power failure results in automatic calib. patient ID yes yes/multiple RS-232  patient ID w/ access. No., entered settings, meas. & calc. results	password with unique user ID No. (optional) 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 range 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 interrupts require no recovery—extended power failure results in automatic calib. patient ID yes yes/multiple RS-232  patient ID w/ access. no., entered settings, meas. & calc. results
Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer to external system  Hardware/Software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs, HISs • using screen animation, screen scraping • using standard HL7 interface • using proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	data management system that connects to LIS/HIS ASTM E1381-91 & ASTM 1394-91 (HL7 avail. with external device) direct serial/>500 hospitals inst.; hospital network/>100 inst.  device unique identifier, operator & patient IDs, results, QC identifier, accession No. Pentium with Microsoft NT 4.0/Nova Point-of-Care Manager SW >60 —  >20 >100 >500 yes	data management system or directly to LIS/HIS, or both ASTM E1381-91 & ASTM 1394-91 (HL7 avail. with external device) direct serial/>500 hospitals inst.; hospital network/>100 inst.  device unique identifier, operator & patient IDs, results, QC identifier, accession no. Pentium with Microsoft Windows 2000/Nova Point-of-Care Manager >60 yes, patient name, passwords  >20 >100 >500 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	onboard auto-cartridge QC; all-liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration & waste collection

## In vitro blood gas analyzers

Part 5 of 11	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813
Name of device/First year sold/No. of analyzers sold in 2009 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight	Stat Profile pH0x Respiratory/2006/— —/—/— 15 x 12 x 15 in./18 lbs	Stat Profile pH0x Plus/2000/— —/—/— 15 x 12 x 15 in./18 lbs
Analytes measured on device Parameters calculated on device Barometric pressure Analytical method(s), technology(ies) employed	pH, PCO <sub>2</sub> , PO <sub>2</sub> , Hct, Hb, SO <sub>2</sub> %, lactate BE, TC0 <sub>2</sub> , HCO <sub>3</sub> - tracked pH: direct ISE; PCO <sub>2</sub> : Severinghaus; PO <sub>2</sub> : amperometry; Hct: conductivity; Hb & SO <sub>2</sub> %; optical-reflectance; lactate: enzyme/amperometric	pH, PCO <sub>2</sub> , PO <sub>2</sub> , Hct, Hb, SO <sub>2</sub> %, Na, K, Cl or iCa, glucose BE, TC0 <sub>2</sub> , HCO <sub>3</sub> - tracked pH: direct ISE; PCO <sub>2</sub> : Severinghaus; PO <sub>2</sub> : amperometry; Hct: conductivity; Hb & SO <sub>2</sub> %; optical-reflectance; Na, K, Cl, iCa: direct ISE; glucose: enzyme/amperometric
Device is part of a series of related models User list or group available Device warranty Loaner devices provided Average expected life of device Open or closed system/External gas tanks required For POC testing or laboratory	yes yes (upon request) 1 year, travel and labor, repair or replacement yes 5 to 7 years closed/no POC & laboratory	yes yes (upon request) 1 year, travel and labor, repair or replacement yes 5 to 7 years closed/no 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 one disposable reagent, electrode system List price per disposable reagent system Reagent unit storage requirements Shelf life of disposable units	reagent 200 to 500 analyses — — room temperature reagents: 18 months at room temperature, electrodes: up to 18 months	reagent 200 to 500 analyses — — room temperature reagents: 18 months at room temperature, electrodes: up to 18 months
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	1 1 reagents & electrodes: 18 months; membrane kits: 12 to 24 months <\$0.11 at 35 analyses per day/<\$0.08 at 35 analyses per day	1 1 reagents & electrodes: 18 months; membrane kits: 12 to 24 months <\$0.11 at 35 analyses per day/<\$0.08 at 35 analyses per day
Calibrations required Calibration frequency Calibrants 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 How labs get LOINC codes for reagent kits	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) yes minimum CLIA recommendations L-J plots, statistical calcs., monthly cum. report (onboard, more extensive reporting avail. with Nova Point-of-Care Manager) no no —	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) yes minimum CLIA recommendations L-J plots, statistical calcs., monthly cum. report (onboard, more extensive reporting avail. with Nova Point-of-Care Manager) no no —
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/Sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/Max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe	yes whole blood, capillary, mixed venous, arterial heparin aspiration & capillary yes/yes 125 µL yes, standard 3-test micro-panel req. is 60 µL syringe, capill., micro-collect. containers, standard vacuum cont. yes 52 seconds 50/500 tests 300 tests per hour yes none none no yes	yes whole blood, capillary, mixed venous, arterial heparin aspiration & capillary yes/yes 115 µL yes, micro-panel; standard 3-test micro-panel req. is 55 µL syringe, capill., micro-collect. containers, standard vacuum cont. yes 50 seconds 50/500 tests 300 tests per hour yes none none no yes
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user	weekly: <5 min; monthly: <10 min yes/no yes yes	weekly: <5 min; monthly: <10 min yes/no yes yes
Method of analyst ID in system Response for hardware & software failure/User ID & QC failure/ Calibration & power failure Supports bar-code scanning of User can search for and review previous patient results on screen Built-in printer/Data port Information on hard copy report	password with unique user ID No. (optional) 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 range 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 interrupts require no recovery—extended power failure results in automatic calib. patient ID yes yes/multiple RS-232 patient ID w/access. no., entered settings, meas. & calc. results	password with unique user ID No. (optional) 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 range 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 interrupts require no recovery—extended power failure results in automatic calib. patient ID yes yes/multiple RS-232 patient ID w/access. no., entered settings, meas. & calc. results
Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer to external system Hardware/Software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs, HISs • using screen animation, screen scraping • using standard HL7 interface • using proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	data management system or directly to LIS/HIS, or both ASTM E1381-91 & ASTM 1394-91 (HL7 avail. with external device) direct serial/>500 hospitals inst.; hospital network/>100 inst. device unique identifier, operator & patient IDs, results, QC identifier, accession no. Pentium with Microsoft Windows 2000/Nova Point-of-Care Manager >60 yes, patient name, passwords >20 >100 >500 yes	data management system or directly to LIS/HIS, or both ASTM E1381-91 & ASTM 1394-91 (HL7 avail. with external device) direct serial/>500 hospitals inst.; hospital network/>100 inst. device unique identifier, operator & patient IDs, results, QC identifier, accession No. Pentium with Microsoft Windows 2000/Nova Point-of-Care Manager >60 yes, patient name, passwords >20 >100 >500 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	onboard auto-cartridge QC; all-liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration & waste collection

## In vitro blood gas analyzers

Part 6 of 11	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813
Name of device/First year sold/No. of analyzers sold in 2009 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight	Stat Profile pH0x Plus L/2001/— —/—/— 15 x 12 x 15 in./18 lbs	Stat Profile pH0x Plus C/2003/— —/—/— 15 x 12 x 15 in./18 lbs
Analytes measured on device	pH, PCO <sub>2</sub> , PO <sub>2</sub> , Hct, Hb, SO <sub>2</sub> %, Na, K, Cl or iCa, glucose, lactate	pH, PCO <sub>2</sub> , PO <sub>2</sub> , Hct, Hb, SO <sub>2</sub> %, Na, K, Cl, iCa, glucose
Parameters calculated on device	BE, TC0 <sub>2</sub> , HC0 <sub>3</sub> -	BE, TC0 <sub>2</sub> , HC0 <sub>3</sub> -
Barometric pressure	tracked	tracked
Analytical method(s), technology(ies) employed	pH: direct ISE; PCO <sub>2</sub> : Severinghaus; PO <sub>2</sub> : amperometry; Hct: conductivity; Hb & SO <sub>2</sub> %; optical—reflectance; Na, K, Cl, iCa: direct ISE; glucose, lactate: enzyme/amperometric	pH: direct ISE; PCO <sub>2</sub> : Severinghaus; PO <sub>2</sub> : amperometry; Hct: conductivity; Hb & SO <sub>2</sub> %; optical—reflectance; Na, K, Cl, iCa: direct ISE; glucose: enzyme/amperometric
Device is part of a series of related models	yes	yes
User list or group available	yes (upon request)	yes (upon request)
Device warranty	1 year, travel and labor, repair or replacement	1 year, travel and labor, repair or replacement
Loaner devices provided	yes	yes
Average expected life of device	5 to 7 years	5 to 7 years
Open or closed system/External gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC & laboratory	POC & laboratory
POC: Uses disposable prepackaged reagent/Electrode system for analysis	reagent	reagent
No. of disposable reagent system units in basic shipment package	200 to 500 analyses	200 to 500 analyses
No. of samples analyzed per one disposable reagent, electrode system	—	—
List price per disposable reagent system	—	—
Reagent unit storage requirements	room temperature	room temperature
Shelf life of disposable units	reagents: 18 months at room temperature, electrodes: up to 18 months	reagents: 18 months at room temperature, electrodes: up to 18 months
Laboratory: No. of different disposable reagents required to maintain device	1	1
Max. No. of specific analyte reagents that can reside in device at once	1	1
Shelf life	reagents & electrodes: 18 months; membrane kits: 12 to 24 months	reagents & electrodes: 18 months; 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	<\$0.11 at 35 analyses per day/<\$0.08 at 35 analyses per day
Calibrations required	1 & 2 point (automatic)	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)	1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 4, or 6 hr (user defined)
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	minimum CLIA recommendations	minimum CLIA recommendations
QC features	L-J plots, statistical calcs., monthly cum. report (onboard, more extensive reporting avail. with Nova Point-of-Care Manager)	L-J plots, statistical calcs., monthly cum. report (onboard, more extensive reporting avail. with Nova Point-of-Care Manager)
Remote control of device from laboratory	no	no
System can use LOINC to transmit results to LIS	no	no
How 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, serum plasma	whole blood, capillary, mixed venous, arterial, serum plasma
Acceptable anticoagulants	heparin	heparin
Sampling technique	aspiration & capillary	aspiration & capillary
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	125 µL	125 µL
Sample size differs with No. of analytes selected	yes, standard 3-test micro-panel req. is 60 µL	yes, standard 3-test micro-panel req. is 60 µL
Recommended collection device	syringe, capill., micro-collect. containers, standard vacuum cont.	syringe, capill., micro-collect. containers, standard vacuum cont.
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	52 seconds	52 seconds
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	50/500 tests	50/500 tests
Optimal throughput when calibrated and awaiting specimens	300 tests per hour	300 tests per hour
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	none	none
Known interferences	none	none
Restrictions based on Hct	no	no
Sampler has self-wiping probe	yes	yes
Time required for maintenance by lab personnel	weekly: <5 min; monthly: <10 min	weekly: <5 min; monthly: <10 min
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	yes	yes
Training & certification program for user	yes	yes
Method of analyst ID in system	password with unique user ID No. (optional)	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 range 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 interrupts require no recovery—extended power failure results in automatic calib.	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 range 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 interrupts require no recovery—extended power failure results in automatic calib.
Supports bar-code scanning of	patient ID	patient ID
User can search for and review previous patient results on screen	yes	yes
Built-in printer/Data port	yes/multiple RS-232	yes/multiple RS-232
Information on hard copy report	patient ID w/access. no., entered settings, meas. & calc. results	patient ID w/access. No., entered settings, meas. & calc. results
Analyzer connects to	data management system or directly to LIS/HIS, or both	data management system or directly to LIS/HIS, or both
Interface standards supported	ASTM E1381-91 & ASTM 1394-91 (HL7 avail. with external device)	ASTM E1381-91 & ASTM 1394-91 (HL7 avail. with external device)
To upload patient & QC results, how analyzer connects to external system	direct serial/>500 hospitals inst.; hospital network/>100 inst.	direct serial/>500 hospitals inst.; hospital network/>100 inst.
Information included in transmission from analyzer to external system	device unique identifier, operator & patient IDs, results, QC identifier, accession No.	device unique identifier, operator & patient IDs, results, QC identifier, accession No.
Hardware/Software for data management system	Pentium with Microsoft Windows 2000/Nova Point-of-Care Manager	Pentium with Microsoft Windows 2000/Nova Point-of-Care Manager
No. of different management reports system produces	>60	>60
Contents downloaded from DMS to analyzer	yes, patient name, passwords	yes, patient name, passwords
System connected (live installations) to which LISs, HISs	>20	>20
• using screen animation, screen scraping	>100	>100
• using standard HL7 interface	>500	>500
• using proprietary protocol interface	yes	yes
Use a third-party interfacing tool, engine for LIS, HIS interfaces	yes	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	onboard auto-cartridge QC; all-liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration & waste collection

## In vitro blood gas analyzers

Part 7 of 11	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813
Name of device/First year sold/No. of analyzers sold in 2009 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight	Stat Profile Critical Care Xpress/2003/— —/—/— 17.2 x 22.4 x 17.3 in./53 lbs	Stat Profile Critical Care Xpress 3 Plus/2003/— —/—/— 17.2 x 22.4 x 17.3 in./53 lbs
Analytes measured on device Parameters calculated on device Barometric pressure Analytical method(s), technology(ies) employed Device is part of a series of related models User list or group available Device warranty Loaner devices provided Average expected life of device Open or closed system/External gas tanks required For POC testing or laboratory	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Hb, Na, K, Cl, iCa, iMg, lactate, glucose, creatinine, BUN, SO <sub>2</sub> %, bilirubin, co-oximetry BE, TC0 <sub>2</sub> , HC0 <sub>3</sub> - tracked pH: direct ISE; pCO <sub>2</sub> : Severinghaus; pO <sub>2</sub> : amperometric; Hct: conductivity; Hb & SO <sub>2</sub> %; optical-reflectance; Na, K, Cl, iMg, & iCa: direct ISE; lactate, glucose, & creatinine: enzyme/amperometric; BUN: enzyme/ISE; bilirubin, co-ox: optical, reflectance yes yes (upon request) 1 year yes 5 to 7 years closed/no POC & laboratory	pH, pCO <sub>2</sub> , pO <sub>2</sub> , co-oximetry BE, TC0 <sub>2</sub> , HC0 <sub>3</sub> - tracked pH: direct ISE; pCO <sub>2</sub> : Severinghaus; pO <sub>2</sub> : amperometric; co-ox: optical-reflectance yes yes (upon request) 1 year yes 5 to 7 years closed/no 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 one disposable reagent, electrode system List price per disposable reagent system Reagent unit storage requirements Shelf life of disposable units	reagent 200 to 500 analyses — — no special requirements reagents: 18 months (at room temp.); electrodes: up to 18 months	reagent 200 to 500 analyses — — no special requirements reagents: 18 months (at room temp.); electrodes: up to 18 months
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	1 20 reagents & electrodes: 18 months; membrane kits: 12 to 24 months <\$0.08 at 40 analyses per day/\$0.04 at 40 analyses per day	1 7 reagents & electrodes: 18 months; membrane kits: 12 to 24 months <\$0.08 at 40 analyses per day/\$0.04 at 40 analyses per day
Calibrations required Calibration frequency Calibrants 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 How labs get LOINC codes for reagent kits	1 & 2 point (automatic) 1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 3, 4, 5, or 6 hr (user defined) yes minimum CLIA recommendations L-J plots, comparable plot, statistical calculations, monthly cum. report, onboard, available with external system no yes package insert	1 & 2 point (automatic) 1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 3, 4, 5, or 6 hr (user defined) yes minimum CLIA recommendations L-J plots, comparable plot, statistical calculations, monthly cum. report, onboard, available with external system no yes package insert
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/Sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/Max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe	yes whole blood, capillary, mixed venous, arterial, venous heparin aspiration & capillary yes/yes 210 µL yes, variety of micro-panel options offered & can be customized syringe, capillary, micro-collection, or vacuum collection containers yes 134 seconds 22/440 437 tests per hour yes no none no yes	yes whole blood, capillary, mixed venous, arterial, venous heparin aspiration & capillary yes/yes 210 µL yes, variety of micro-panel options offered & can be customized syringe, capillary, micro-collection, or vacuum collection containers yes 61 seconds 32/224 190 tests per hour yes no none no yes
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user	daily: none; weekly: <5 min; monthly: <10 min yes/no yes yes	daily: none; weekly: <5 min; monthly: <10 min yes/no yes yes
Method of analyst ID in system Response for hardware & software failure/User ID & QC failure/ Calibration & power failure Supports bar-code scanning of User can search for and review previous patient results on screen Built-in printer/Data port Information on hard copy report	multilevel password with unique user ID No. HW & SW: self-diagnostic SW informs and classifies operator of HW & SW failure; hotline & field support avail./user ID: optional setup feature; lock out without proper ID; QC: optional setup & 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 & patient IDs yes yes/Ethernet, USB patient ID & accession nos., entered settings, measured & calculated results	multilevel password with unique user ID No. HW & SW: self-diagnostic SW informs and classifies operator of HW & SW failure; hotline & field support avail./user ID: optional setup feature; lock out without proper ID; QC: optional setup & 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 & patient IDs yes yes/Ethernet, USB patient ID & accession Nos., entered settings, measured & calculated results
Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer to external system Hardware/Software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs, HISs • using screen animation, screen scraping • using standard HL7 interface • using proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	directly to LIS/HIS, DMS that in turn connects to LIS/HIS ASTM E1394-91, ASTM 1381-91, HL7 modem dial-in, hospital network device unique identifier, operator & patient IDs, results, QC identifier full-featured onboard DMS capability, external DMS also avail. >30 valid control nos., valid operator IDs, patient demographics — — — most analyzers interfaced to LIS using LIS vendor's drivers	directly to LIS/HIS, DMS that in turn connects to LIS/HIS ASTM E1394-91, ASTM 1381-91, HL7 modem dial-in, hospital network device unique identifier, operator & patient IDs, results, QC identifier full-featured onboard DMS capability, external DMS also avail. >30 valid control nos., valid operator IDs, patient demographics — — — most analyzers interfaced to LIS using LIS vendor's drivers
Distinguishing features (provided by vendor)	large whole blood critical care menu (20 tests), BUN, iMg available exclusively from Nova; onboard co-oximeter	onboard QC cartridge provides sufficient QC materials for 30-day auto QC analysis; allows user to program frequency and select report protocol with full QC SMD

## In vitro blood gas analyzers

Part 8 of 11	Opti Medical Systems Inc. Sales Department 235 Hembree Park Drive Roswell, GA 30076 800-490-6784 www.optimedical.com	Opti Medical Systems Inc. Sales Department 235 Hembree Park Drive Roswell, GA 30076 800-490-6784 www.optimedical.com
Name of device/First year sold/No. of analyzers sold in 2009 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight	OPTI R/2006/— —/—/— 4.7 × 14.2 × 14 in./4.5 kg (10 lbs) without fluid pack	OPTI CCA-TS Blood Gas Analyzer/2003/— —/—/\$10,200 4.7 × 14.2 × 9 in./10 lbs without battery, 12 lbs with battery
Analytes measured on device Parameters calculated on device  Barometric pressure Analytical method(s), technology(ies) employed  Device is part of a series of related models User list or group available Device warranty Loaner devices provided Average expected life of device Open or closed system/External gas tanks required For POC testing or laboratory	pH, pCO <sub>2</sub> , pO <sub>2</sub> , tHb, Na, K, iCa, SO <sub>2</sub> Hct, HCO <sub>3</sub> , BE, BEecf, BEact, BB, tCO <sub>2</sub> , st. HCO <sub>3</sub> , st. pH, O <sub>2</sub> ct, cH+, AaDO <sub>2</sub> , AG, p50, nCa++ measured optical fluorescence and reflectance  yes, Opti series yes (upon request) 1 year (service contract available for subsequent years) yes 7 years closed/no POC & laboratory	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na, K, Cl, iCa, tHb, SO <sub>2</sub> , glucose, BUN, lactate (in development), Hct, HCO <sub>3</sub> , BE, BEecf, BEact, BB, tCO <sub>2</sub> , st. HCO <sub>3</sub> , st. pH, O <sub>2</sub> ct, cH+, AaDO <sub>2</sub> , AG, p50, nCa++ measured optical fluorescence and reflectance  yes, Opti series yes, upon request 1 year (service contract available for subsequent years) yes >7 years closed/no 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 one disposable reagent, electrode system List price per disposable reagent system Reagent unit storage requirements Shelf life of disposable units	reagent/multiuse cartridge 4 50 contact Opti Medical room temperature cassette: 7 months; fluid pack: 12 months	single-use cassettes/optode 25 individual packaged cassettes 1 depends on cassette configuration—contact Opti Medical room temperature cassette: 6 to 12 months, depends on type
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	2 8 cassette: 7 months; fluid pack: 12 months depends on volume—contact Opti Medical	1 8 cassette: 6 to 8 months, depends on type depends on volume—contact Opti Medical
Calibrations required Calibration frequency Calibrants 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 How labs get LOINC codes for reagent kits	2 point (automatic) one point: after every sample or 30 minutes; two point: every 3 hours yes 3 levels automatic QC run at least once per day  auto QC, statistics reports no no —	1 point (automatic) with each cassette yes liquid QC with change of cassette lot no. or 2-month intervals; electronic QC—1 level per 8 hours of operation  electronic QC, statistics reports no no —
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/Sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/Max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe	yes plasma, serum, whole blood heparin automatic aspiration yes/yes 125 µL no heparinized syringe, capillary, Comfort Sampler yes ~1 minute 24/192  24 tests per hour no none — no no	yes plasma, serum, whole blood heparin automatic aspiration yes/yes 125 µL, 60 µL blood gas only cassette (in development), no heparinized syringe, capillary, Comfort Sampler yes ~1 minute from sample aspiration 24/192  24 test per hour no none — no no, single use
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user	weekly: 1 min; quarterly: 5 min yes/no no yes (1 to 2 days on site)	weekly: 1 min; quarterly: 5 min yes/no no yes (on site as needed)
Method of analyst ID in system Response for hardware & software failure/User ID & QC failure/ Calibration & power failure  Supports bar-code scanning of  User can search for and review previous patient results on screen Built-in printer/Data port  Information on hard copy report	bar code or secure PIN for 300 operators error message/QC lockout/error message with automatic retry; power: memory recovery  oper. & patient IDs, reagent lot no., QC ranges, expiration  yes yes/RS-232, Ethernet  patient ID, results, patient demographics (customized), critical ranges	bar code or secure PIN for 300 operators error message/QC lockout/error message, memory recovery  oper. & patient IDs, reagent lot no., QC ranges, cassette lot no., expiration, factory calibration info. & cassette type  yes yes/RS-232, Ethernet  patient ID, results, patient demographics (customized), critical ranges
Analyzer connects to  Interface standards supported To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer to external system Hardware/Software for data management system  No. of different management reports system produces Contents downloaded from DMS to analyzer  System connected (live installations) to which LISs, HISs • using screen animation, screen scraping • using standard HL7 interface • using proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	directly to LIS/HIS, DMS that in turn connects to LIS/HIS, Prism POC data manager Meditech, Sunquest/Misys, Telcor, CPSI, Cerner, HMS, Datacare, AEGIS POC direct serial, hospital network device unique identifier, oper. & patient IDs, results, QC identifier, all info. pertinent to patient & QC data Prism POC data manager  40 none  none Meditech, McKesson, Cerner, Siemens, others (call Opti Medical for updated list) none none	directly to LIS/HIS, DMS that in turn connects to LIS/HIS, Prism POC data manager Meditech, Sunquest/Misys, Telcor, CPSI, Cerner, HMS, Datacare, Aegis POC direct serial, hospital network device unique identifier, oper. & patient IDs, results, QC identifier, all info. pertinent to patient & QC data Prism POC data manager  40 none  none Meditech, McKesson, Cerner, Siemens, others (call Opti Medical for updated list) none none
Distinguishing features (provided by vendor)	three independent levels of auto QC, stable optical fluorescence technology, multiple use cassette, low maintenance, and color touchscreen	stable optical fluorescence technology, easy-to-use touchscreen, measured tHb and SO <sub>2</sub> , no standby costs (single-use system), low maintenance

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

## In vitro blood gas analyzers

Part 9 of 11	<b>Radiometer America Inc.</b> Telesales Department info@radiometeramerica.com 810 Sharon Dr. Westlake, OH 44145 800-736-0600 www.radiometeramerica.com	<b>Radiometer America Inc.</b> Telesales Department info@radiometeramerica.com 810 Sharon Dr. Westlake, OH 44145 800-736-0600 www.radiometeramerica.com
Name of device/First year sold/No. of analyzers sold in 2009 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight	ABL 800 Series/2004/— —/—/depends on configuration 22 x 28 x 21 in./70 lbs	ABL 80/2006/— —/—/depends on configuration 16 x 9 x 11 in./19 lbs
Analytes measured on device Parameters calculated on device Barometric pressure Analytical method(s), technology(ies) employed Device is part of a series of related models User list or group available Device warranty Loaner devices provided Average expected life of device Open or closed system/External gas tanks required For POC testing or laboratory	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hb, Na, K, Cl, iCa, lactate, glucose, bilirubin, fetal Hb, O <sub>2</sub> Hb, MetHb, RHb, COHb, O <sub>2</sub> SAT, creatinine Hct, BE, TC02, HCO <sub>3</sub> <sup>-</sup> , plus 40 additional parameters measured pH: pH-sensitive glass (ISE); pCO <sub>2</sub> , pO <sub>2</sub> , Na, Cl, iCa, K, ISE; Hct: calc. from meas. Hb, bilirubin; Hb: optical, multiwavelength anal., intra-cuvette ultrasonic hemolysis; lactate, gluc.: creatinine, ISE w/enzyme yes, ABL 800 series yes (through local sales representative) 2 years, parts, labor, & travel yes 20 years, with full support closed/yes (low-pressure, premixed) POC & laboratory (products on mobile carts for POCT/NPT)	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Na, K, iCa, Cl <sup>-</sup> , Glu, Hb, O <sub>2</sub> SAT, O <sub>2</sub> Hb, COHb, MetHb, HHb Hb, O <sub>2</sub> SAT, TC02, HCO <sub>3</sub> <sup>-</sup> , ctO <sub>2</sub> (a-v), ctO <sub>2</sub> , anion gap (K+), cCa <sup>2+</sup> (7.40), cBase (B), ABE, SBE, others — pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na, K, iCa, Cl, Glu: thick film; amperometric/potentiometric technology; HCT: conductivity yes yes (through local sales representative) 1 year, parts, labor, & travel, with service plans available after year 1 yes analyzer: 10+ years closed/no POC testing, 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 one disposable reagent, electrode system List price per disposable reagent system Reagent unit storage requirements Shelf life of disposable units	— — — — — —	electrode (multiuse cartridge) 1 50/100/200/300 depends on configuration & GPO affiliation room temperature 90 to 100 days
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	4 4 reagent, electrode, membrane kit, cartridge: 2+ years depends on sample volume & any extra incl. items/same	2 2 reagent: 100 days, cartridge: 90 days depends on configuration/same
Calibrations required Calibration frequency Calibrants 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 How labs get LOINC codes for reagent kits	1 & 2 point (automatic) 1 point: 1/2 hr BG/pH, 4 hrs—mftr.; 2 point: every 8 hrs yes depends on hospital management & inspection agency L-J plots, comparable plot (via DMS), statistical calcs., auto QC, monthly cum. reports (onboard & avail. w/ external system, PC download to Excel) yes yes —	1 & 2 point (manual & automatic) 1 point: with each test; 2 point: 8 hrs (user definable) yes QC material according to CLIA, CAP, JCAHO L-J plots, statistical calcs., monthly cum. (onboard—current mean, STD, CV%) reports (onboard & available with external system, PC download to Excel) yes yes —
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/Sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/Max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe	yes whole blood, capill., mixed venous, arterial, venous, expired air heparin, electrolyte-balanced heparin autoaspiration, syringe &/or capillary tube &/or test tube yes/yes 95 µL for 17 measured parameters yes, with fewer measured parameters, smaller micro-modes available from 35 µL syringe or capillary yes ~1 minute (depends on tests ordered) 25/425 25 per hour yes none halothane, thiocyanic & glycolic acids no yes	yes whole blood, capillary, mixed venous, arterial, venous heparinized, electrolyte balanced heparin aspiration yes/yes 70 µL no syringe or capillary tube yes 90 seconds 30/270 30 tests per hour yes none — no no
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user	monthly: as needed; annually: dependent on version yes/no yes yes (on site)	— yes/no no yes (on site)
Method of analyst ID in system Response for hardware & software failure/User ID & QC failure/Calibration & power failure Supports bar-code scanning of User can search for and review previous patient results on screen Built-in printer/Data port Information on hard copy report	customizable onboard keyboard, bar code system message with customized (“traffic light”) visual & audible signals, parameter status bar operator & patient IDs, reag. & QC lot Nos., exp., soft. keys yes, multitask searches while analyzer performs other functions yes/RS-232, Ethernet/USB patient info./demographics, patient therapy settings, meas. & calc. results, system messages, reference & critical ranges	customizable onboard keyboard, bar code system message with customized (“traffic light”) visual & audible signals, parameter status bar operator & patient IDs, reag. & QC lot Nos., exp., soft. keys yes yes/RS-232, Ethernet/USB patient info./demographics, patient therapy settings, meas. and calc. results, system messages, reference and critical ranges
Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer to external system Hardware/Software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs, HISs • using screen animation, screen scraping • using standard HL7 interface • using proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	Radiance stat information management system that connects to LIS/HIS or directly to LIS/HIS ASTM, HL7, serial, POCT1A, network TCP/IP direct serial/thousands of hosp. installed; modem dial-in/hundreds; hospital network/hundreds; real time wireless-capable device unique identifier, operator & patient IDs, results, QC identifier, per ASTM/HL7 standards plus calib. & analyzer status info. internal system + optional external system, Radiance user-definable searches/reports — Cerner, Meditech, Misys, others available from analyzer—LIS/HIS vendors can use none —	Radiance stat analyzer management system that connects to LIS/HIS or directly to LIS/HIS ASTM, HL7, serial, network, TCP/IP serial, Ethernet device unique identifier, operator & patient IDs, results, QC identifier Radiance user definable — Cerner, Meditech, Misys, others available from analyzer—LIS/HIS vendors can use none no (use interface templates)
Distinguishing features (provided by vendor)	IDMS traceable creatinine; FLEXQ automated inlet part of automatic system; bilirubin and fetal Hb meas. on whole blood with no extra sample volume, low maintenance and cost of operation; interference-free accuracy; FLEXMODE—small automated microsample mode options with no loss in performance specs. (conserves blood); flexible/modular platform running on Windows XP (embedded), Pentium processors, automatic QC, autocal, remote support	portable, true battery operation; fast startup/warmup and analysis time; simple and easy-to-use system

## In vitro blood gas analyzers

Part 10 of 11	Roche Diagnostics Laurence J. Healy laurence.healy@roche.com 9115 Hague Rd. Indianapolis, IN 46250 800-428-5076 us.labsystems.roche.com	Siemens Healthcare Diagnostics Inc. 1717 Deerfield Road Deerfield, IL 60015-0778 800-255-3232 www.siemens.com/diagnostics
Name of device/First year sold/No. of analyzers sold in 2009 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight	Roche cobas b 221 system/2004/— —/—/\$44,400–\$63,700 23 x 20 x 23.6 in./99 lbs (w/o solutions and AutoQC)	RAPIDPoint 300 Series/2009/— —/—/— 12.5 x 14.5 x 7 in./16–17 lbs
Analytes measured on device Parameters calculated on device	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Hb, Na, K, Cl, iCa, lactate, glucose, BUN, bilirubin, pH pleural fluid Hb, Hct, O <sub>2</sub> SAT, BE, TC0 <sub>2</sub> , HC0 <sub>3</sub> -	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Na+, K+, Cl-, iCa++ Hb, O <sub>2</sub> SAT, BE, TC0 <sub>2</sub> , HC0 <sub>3</sub>
Barometric pressure Analytical method(s), technology(ies) employed Device is part of a series of related models	recorded or measured pH: electrode ion selective galvanometric; pCO <sub>2</sub> , pO <sub>2</sub> : electrode ion selective membrane; Hct: conductivity; Hb: co-ox spectrophotometry; Na, Cl, iCa, K: ion selective potentiometry; lactate, glucose, BUN: MSS sensor enzyme yes, three models in series	recorded, measured pH: ISE-potentiometry; iCa: ISE; PCO <sub>2</sub> : ISE-potentiometry; pO <sub>2</sub> : ISE-amperometry; Hct: conductivity; Hb: calculated from hematocrit; Na: ISE; Cl: ISE; K: ISE yes, two models: RAPIDPoint 340 offers blood gas; RAPIDPoint 350 offers blood gas, electrolytes, and hematocrit
User list or group available Device warranty Loaner devices provided Average expected life of device Open or closed system/External gas tanks required For POC testing or laboratory	yes (via local sales representative) 1 year (parts and services warranty) no 7 years closed/no POC & laboratory	yes, through local sales representative 1-year warranty (country specific) yes 7 to 10 years closed/no 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 one disposable reagent, electrode system List price per disposable reagent system Reagent unit storage requirements Shelf life of disposable units	reagent and electrode depends on model, contact Roche dependent on use — room-temperature storage 12 months (reagents)/18 months (electrodes)	yes, multi-use cartridge 1 based on daily testing volumes — room temperature reagents: 7 to 9 months; electrodes: 12 months
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	depends on model, contact Roche 3 reagent: 1 year; electrode: 18 months onboard volume-dependent/volume-dependent	1 1 reagents: 7 to 9 months; electrodes: 12 months varies based on configuration and test volume/—
Calibrations required Calibration frequency Calibrants 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 How labs get LOINC codes for reagent kits	1 & 2 point (automatic) 1 point: 30 min; 2 point: 8 hrs yes CAP and JCAHO guidelines L-J plots, comparable plot, lot-to-lot comparisons, statistical calcs., monthly cum. reports, onboard, eQAP yes yes Web, package insert	one and two point (manual and automatic) one point (with each sample); two point (can be set to 2, 4, or 8-hour increments) yes one-level QC every 8 hours of testing (CLIA recommendation); Siemens QC material recommended L-J plots, statistical calculations, monthly cumulative reports, onboard no no —
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/Sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/Max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe	yes plasma, serum, whole blood, capillary, arterial, venous EDTA, heparin, citrate aspiration, injection, capillary transfer & fill, microsamples yes/yes 200 µL for full panel yes, BG: 40 µL; ISE: 40 µL; co-ox 44 µL, glucose, lactate, BUN: 75 µL — — ~1 min (test dependent) 30 patients per hour (full panel)/360 tests per hr 30 patients per hour (full panel) yes no none no yes	yes whole blood, capillary, mixed venous, arterial, venous heparin aspiration yes/yes 75 µL/95 µL capillary (RP340/RP350) 100 µL/120 µL syringe (RP340/RP350) no heparinized syringe or capillary yes 125 seconds (RP340), <120 seconds (RP350) 25 samples (RP340), 30 samples (RP350)/75 (RP340), 210 (RP350) 25 samples/hour (RP340), 30 samples/hour (RP350) yes no certain anticoagulants no yes
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user	daily: 2 min, monthly: 5 min, quarterly: 5 min yes/no yes yes (2.5 days on site)	daily: <1 minute yes/no no yes, less than 1 day (country specific)
Method of analyst ID in system Response for hardware & software failure/User ID & QC failure/ Calibration & power failure Supports bar-code scanning of User can search for and review previous patient results on screen Built-in printer/Data port Information on hard copy report	32-level password system (customizable) HW: identified onscreen & w/ diagnostic routine; SW: onscreen w/msg./user ID: identified onscreen; QC: onscreen report w/high/low flagging, lockout capabilities/calibration: onscreen reporting w/lockout capabilities; power: recorded in activities log operator & patient IDs, reagent lot No., RF w/transponders, expir. yes yes/RS-232, parallel, Ethernet options can be customized; direct & measured parameters	manual or bar-code entry (optional) operator warning, error messages; sampling lock-out, flagged high or low QC results; automatic calibration repeat, error messages, blank screen display operator identifier, patient identifier, and reagent lot number yes yes/RS-232 patient information, operator ID, measured and calculated results, date
Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer to external system Hardware/Software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs, HISs • using screen animation, screen scraping • using standard HL7 interface • using proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	data management system, which connects to LIS/HIS; data management, which cannot further transmit data; directly to LIS/HIS ASTM 1394, HL7, USB port direct serial, hospital network device unique identifier, oper. & patient IDs, results, QC identifier MAS RALS-Plus, DataCare POC 50 (RALS-Plus), 40 (DataCare POC) valid control values, valid operator IDs, critical patient results — — — Data Innovations	directly to LIS/HIS ASTM 1394 & E1381 direct serial operator ID, patient ID, results internal data management patient reports, QC statistics, L-J charts — — — no
Distinguishing features (provided by vendor)	FDA-510(k)-cleared pH pleural fluid results; 42-day onboard reagent packs; Roche AutoQC with up to 40 days of QC covered; screen sharing and remote protected access with OMNI-Link and Axeda instrument software	multi-use cartridge-based system eliminates gas tanks; no maintenance, easy-to-replace electrodes; small, portable, and economical

## In vitro blood gas analyzers

Part 11 of 11	Siemens Healthcare Diagnostics Inc. 1717 Deerfield Road Deerfield, IL 60015-0778 800-255-3232 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics Inc. 1717 Deerfield Road Deerfield, IL 60015-0778 800-255-3232 www.siemens.com/diagnostics
Name of device/First year sold/No. of analyzers sold in 2009 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight	RAPIDPoint 400 Series/2001/— —/—/— 21.5 × 11.5 × 16 in./34 lbs	RAPIDLab 1200 Series/2005/— —/—/— 22.75 × 20.5 × 21 in./65–68 lbs
Analytes measured on device Parameters calculated on device Barometric pressure Analytical method(s), technology(ies) employed Device is part of a series of related models User list or group available Device warranty Loaner devices provided Average expected life of device Open or closed system/External gas tanks required For POC testing or laboratory	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Na <sup>+</sup> , K <sup>+</sup> , Cl <sup>-</sup> , Ca <sup>++</sup> , tHb, F02Hb, FCOHb, FMethb, FHHb, glucose HCO <sub>3</sub> -act, HCO <sub>3</sub> -std, BE(B), BE(ecf), ctCO <sub>2</sub> , Ca <sup>++</sup> (7.4), RI(T), O <sub>2</sub> SAT, P02/FIO <sub>2</sub> , AnGAP, sO <sub>2</sub> , B02, pO <sub>2</sub> (A-a)(T), pO <sub>2</sub> (a/A)(T), p50, Qsp/Qt(T), ctO <sub>2</sub> (Hb), ctO <sub>2</sub> (a), ctO <sub>2</sub> (v), ctO <sub>2</sub> (a-v), DO <sub>2</sub> , VO <sub>2</sub> , others recorded pH, Na, Cl, iCa, K: potentiometry using ISE; pCO <sub>2</sub> : potentiometry based on Severinghaus; pO <sub>2</sub> : amperometric meas. (Clark); glucose: amperometric-glucose oxidase; Hct: conductivity; co-oximetry: spectrophotometric yes yes, through local sales rep 1 year yes 7 to 10 years closed/no POC testing and laboratory	pH, pCO <sub>2</sub> , pO <sub>2</sub> , tHb, Na <sup>+</sup> , K <sup>+</sup> , Cl <sup>-</sup> , iCa <sup>++</sup> , lactate, glucose, F02Hb, FCOHb, FMethb, FHHb, total neonatal bilirubin HCO <sub>3</sub> -act, HCO <sub>3</sub> -std, BE(B), BE(ecf), ctCO <sub>2</sub> , Ca <sup>++</sup> (7.4), RI(T), O <sub>2</sub> SAT, P02/FIO <sub>2</sub> , AnGAP, sO <sub>2</sub> , B02, pO <sub>2</sub> (A-a)(T), pO <sub>2</sub> (a/A)(T), p50, Qsp/Qt(T), ctO <sub>2</sub> (Hb), ctO <sub>2</sub> (a), ctO <sub>2</sub> (v), ctO <sub>2</sub> (a-v), DO <sub>2</sub> , VO <sub>2</sub> , others measured, tracked pH: potentiometry; pCO <sub>2</sub> : Severinghaus electrochemical; pO <sub>2</sub> : amperometric; Hct: calculated; tHb: spectrophotometric; Na, Cl, iCa, K: ISE; lactate: lactate oxidase; glucose: glucose oxidase; total neonatal bilirubin: spectrophotometric yes, series offers different analyte options yes, through local sales rep 1 year no 7 to 10 years closed/no laboratory and POC testing
POC: Uses 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 unit storage requirements Shelf life of disposable units	yes, multi-use cartridge 1 measurement and 1 wash/waste cartridge 250, 400, 750 samples varies based on configuration refrigeration 9 months	multi-use cartridges, electrode measurement chamber 1 reagent cartridge, 1 wash cartridge Reagent cartridge is not sample dependent — Reagent cartridge/AQC cartridge – refrigeration; wash cartridge – room temperature reagent/wash cartridge: 8 months; AQC cartridge: 9 months; electrodes: varies based on type
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	1 measurement cartridge, 1 wash-waste cartridge 1 measurement cartridge, 1 wash-waste cartridge 9 months varies based on configuration	1 reagent cartridge, 1 wash cartridge 1 reagent cartridge, 1 wash cartridge, all electrodes electrodes: vary based on type; reagent cartridge: 8 months; wash cartridge: 8 months; AQC cartridge: 9 months varies based on configuration
Calibrations required Calibration frequency Calibrants 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 How labs get LOINC codes for reagent kits	1 & 2 point (automatic) 1 point: 30 min; 2 point: 2 hrs yes AQC cartridge, fully user programmable AQC cartridge, L-J plots, comparable plots, statistical calculations, monthly cum. reports (available with external system) yes yes —	1 & 2 point (manual & automatic) 1 point: every 30 min; 2 point: every 8 hrs yes AQC cartridge, fully user programmable L-J plots, comparable plots, statistical calculations, monthly cum. reports (available with external system) yes — —
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/Sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/Max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe	yes whole blood, capillary, mixed venous, arterial, venous heparin aspiration yes/yes 100 µL no syringe or capillary yes 60 seconds 25/— 25 samples per hour yes if calibration is interrupted repeatedly, it will force a mandatory calibration to be completed before sampling benzalkonium no yes	yes whole blood, capillary, mixed venous, arterial, venous heparin aspiration yes/yes 95 to 175 µL yes (microsample mode available) syringe or capillary yes 60 seconds 24/up to 336 tests 24 samples per hour yes none contact vendor no yes
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user	maintenance free yes/no no yes	weekly: 5 min; monthly: 5 min yes/no no yes
Method of analyst ID in system Response for hardware & software failure/User ID & QC failure/ Calibration & power failure Supports bar-code scanning of User can search for and review previous patient results on screen Built-in printer/Data port Information on hard copy report	password (customizable) flag-prompt/user ID: customizable; QC: customizable-flag/calibration: flag-recalibration operator & patient IDs, accession No., results, temp., other infor. yes yes/RS-232, Ethernet operator & patient IDs, accession No., results, temperature, other information	password (customizable) diagnostic codes prompt the operator/diagnostic codes/recalibrates, generates diagnostic code if unsuccessful patient ID yes yes/RS-232, Ethernet operator & patient IDs, accession No., results, temperature, patient demographics, others
Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer to external system Hardware/Software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs, HISs • using screen animation, screen scraping • using standard HL7 interface • using proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options) LIS 3 direct serial, hospital network device unique identifier, operator & patient IDs, results, QC identifier RapidComm Data Management System customizable valid control values, valid operator IDs — yes yes yes	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options) LIS 4 direct serial, hospital network device unique identifier, operator & patient IDs, results, QC identifier RapidComm Data Management System customizable valid control values, valid operator IDs — yes yes yes
Distinguishing features (provided by vendor)	no maintenance, multi-use 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