In vitro blood gas analyzers

Part 1 of 13	Abbott Point of Care Dan Molloy daniel.molloy@apoc.abbott.com 400 College Road East Princeton, NJ 08540 800-827-7828 www.abbottpointofcare.com	Instrumentation Laboratory Xavier Nogue-Vila xvila@ilww.com 180 Hartwell Road Bedford, MA 01730 781-861-4244 www.ilus.com
Name of device/First year sold/No. of analyzers sold in 2008	i-STAT System/1992/—	GEM Premier 3000/2000/—
No. of devices sold in U.S./Outside U.S./List price	30,000+/20,000+/$8,761	>2,760/>7,580/$39,995
Dimensions (H x W x D)/Weight	9.25 × 3.0 × 2.85 in./22.4 oz	17 × 12 × 12 in./29.5 lbs
Analytes measured on device	pH, pCO2, pO2, Hct, Na, K, Cl, iCa, lactate, glucose, creatinine, BUN, TCO2	pH, pO2, pCO2, Hct, Na+, K+, Ca++, glucose, lactate
Parameters calculated on device	Hb, HcT, O2SAT, BE, TCO2, HCO3	A-aDo2, Hb, pAO2, paO2/pAO2, RI, O2cap*, CtO2*, CaO2*, CvO2*, CcO2*, a-vDO2*, Qsp/Qt*, P50*
Barometric pressure	measured	—
Analytical method(s), technology(ies) employed	electrochemical for all analytes	pH, pCO2: potentiometry; pO2, glucose, lactate: amperometry; Hct: conductivity; Na, iCa, K: ISE
Device is part of a series of related models	no	yes
User list or group available	yes (through local sales representative)	yes (through local sales representative)
Device warranty	1-year replacement	5 years
Loaner devices provided	yes	yes
Average expected life of device	8 years	7–10 years
Open or closed system/External gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC testing	POC & laboratory
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	reagent/electrode (single use)	yes (multi-use cartridge)
No. of disposable reagent system units in basic shipment package	25 per box	1 per pack
No. of samples analyzed per one disposable reagent, electrode system	1	35-, 75-, 150-, 300-, 450-, & 600-test cartridge
List price per disposable reagent system	varies	varies with size & menu
Reagent unit storage requirements	refrigerate, 2-week shelf life at room temperature	room temperature
Shelf life of disposable units	reag./electrode: 6–9 months	6 months
Laboratory:		
No. of different disposable reagents required to maintain device	none	1
Max. No. of specific analyte reagents that can reside in device at once	—	1 multiuse cartridge
Shelf life	—	6 months
Cost per test/Reagent cost per test	—	varies with size & menu
Calibrations required	1 point (automatic)	automated continuous with iQM
Calibration frequency	every test	automated continuous with iQM
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	electronic QC, automated internal wet QC	internal, automated, continuous quality management included
QC features	comparable plot, monthly cumulative reports (available with external system)	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
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial, venous	whole blood, arterial, venous, or capillary
Acceptable anticoagulants	heparin	heparin
Sampling technique	injection, capillary transfer and fill	aspiration
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	blood gas 96 µL, electrolytes 65 µL	135–150 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	about 2 minutes	85 seconds
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	20 per unit/160	20/180
Optimal throughput when calibrated and awaiting specimens	—	20 samples per hour
Calibration can be interrupted to perform stat sample	—	yes
Contraindications	—	—
Known interferences	—	—
Restrictions based on Hct	—	no
Sampler has self-wiping probe	—	yes
Time required for maintenance by lab personnel	—	disposable cartridge/no maintenance required
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	yes	no (but can through VPN)
Training & certification program for user	yes, no. of training days varies	yes
Method of analyst ID in system	keypad entry/bar-code scanner (customizable)	manual or bar-code entry of ID & password (customizable)
Response for hardware & software failure/User ID & QC failure/ Calibration & power failure	code no. error message/code no. error message/code no. error message	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, reagent lot no.	operator & patient IDs, QC values
User can search for and review previous patient results on screen	yes	yes
Built-in printer/Data port	no/—	yes/3 RS-232, 1 parallel, bar-code reader port, Ethernet port
Information on hard copy report	device unique identifier, operator & patient IDs, results, QC results, QC identifier	patient demographics, hospital name and address, results
Analyzer connects to	LIS/HIS, via data management system	GEMweb, GEMweb Plus, Impact for Critical Care
Interface standards supported	ASTM 1394 & 1238, HL7	ASTM protocol
To upload patient & QC results, how analyzer connects to external system	hospital network	direct serial, Ethernet, modem dial-in
Information included in transmission from analyzer to external system	device unique identifier, operator & patient IDs, results, QC identifier, others	device identifier, operator & patient IDs, results, QC ID & results
Hardware/Software for data management system	PrecisionWeb/Central Data Station	Impact for Critical Care
No. of different management reports system produces	35+	customizable
Contents downloaded from DMS to analyzer	valid operator IDs, device behavior customizations	patient ID, demographics
System connected (live installations) to which LISs, HISs		
• using screen animation, screen scraping	all major LIS vendors	yes
• using standard HL7 interface	all major LIS vendors	all major HIS/LIS vendors
• using proprietary protocol interface	—	yes
Use a third-party interfacing tool, engine for LIS, HIS interfaces	yes, Sybase Interface Manager	MAS/RALS, Telcor
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	Intelligent Quality Management; maintenance-free, multi-use cartridge available in 30 menu/size options for use in any hospital location; 20-year history of cartridge technology; remote management from any PC via GEMweb; consolidated workstation for blood gas, electrolytes, Hct, glucose, lactate, co-oximetry, and coagulation

** when interfaced to IL CO-Oximeter*

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Survey Editor: Raymond Aller, MD

In vitro blood gas analyzers

Part 2 of 13	Instrumentation Laboratory Xavier Nogue-Vila xvila@ilww.com 180 Hartwell Road Bedford, MA 01730 781-861-4244 www.ilus.com	Instrumentation Laboratory Xavier Nogue-Vila xvila@ilww.com 180 Hartwell Road Bedford, MA 01730 781-861-4244 www.ilus.com
Name of device/First year sold/No. of analyzers sold in 2008	GEM 3100/2000/—	GEM 3500/2009/0
No. of devices sold in U.S./Outside U.S./List price	>2,760/>7,580/$39,995	>225>50/$45,000
Dimensions (H x W x D)/Weight	22 × 12 × 12 in./31.5 lbs	17.5 × 13 × 11.8 in./31.2 lbs
Analytes measured on device	pH, pO2, pCO2, Hct, Na+, K+, Ca++, glucose, lactate: PT, APTT, ACT, ACT-LR, citrate PT	pH, pO2, pCO2, Hct, Na+, K+, Ca++, glucose, lactate
Parameters calculated on device	A-aDo2, Hb, pAO2, pa02/pAO2, RI, O2cap*, CtO2*, CaO2*, CvO2*, CcO2*, a-vDO2*, Qsp/Qt*, P50*	A-aDo2, Hb, pAO2, pa02/pAO2, RI, O2cap*, CtO2*, CaO2*, CvO2*, CcO2*, a-vDO2*, Qsp/Qt*, P50*
Barometric pressure	—	—
Analytical method(s), technology(ies) employed	pH, pCO2: potentiometry; pO2, glucose, lactate: amperometry; Hct: conductivity; Na, iCa, K: ISE; PT, APTT, ACT, ACT-LR, citrate PT, mechanical clot detection	pH, pCO2: potentiometry; pO2, glucose, lactate: amperometry; Hct: conductivity; Na, iCa, K: ISE
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	7–10 years	7–10 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	yes (multi-use cartridge)	yes (multi-use cartridge)
No. of disposable reagent system units in basic shipment package	1 per pack	1 per pack
No. of samples analyzed per one disposable reagent, electrode system	cartridges available: 35-, 75-, 150-, 300-, 450-, & 600-test cartridge, 1 sample per cartridge for coagulation tests	35-, 75-, 150-, 300-, 450-, & 600-test cartridge
List price per disposable reagent system	—	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	1	1
Max. No. of specific analyte reagents that can reside in device at once	2:1 for blood gas/electrolytes, 1 for coagulation	1 multiuse cartridge
Shelf life	6 months	6 months
Cost per test/Reagent cost per test	varies with menu & cartridge size	varies with size & menu
Calibrations required	automated continuous with iQM	automated continuous with iQM
Calibration frequency	automated continuous with iQM	automated continuous with iQM
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	internal, automated, continuous quality management included	internal, automated, continuous quality management included
QC features	Onboard Intelligent Quality Management; monthly report includes no. of measurements, mean, max, and min delta values	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, fresh whole blood for coagulation tests	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	135–150 µL, 50 µL for coagulation	135–150 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; under 5 min for coagulation	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 operator involvement	disposable cartridge/no maintenance required
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/2 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, 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, modem dial-in, Ethernet	direct serial, Ethernet, modem dial-in
Information included in transmission from analyzer to external system	device identifier, operator & patient IDs, results, QC ID	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)	Intelligent Quality Management; maintenance-free, multi-use cartridge available in 30 menu/size options for use in any hospital location; 20-year history of cartridge technology; remote management from any PC via GEMweb; consolidated workstation * *when interfaced to IL CO-Oximeter*	Intelligent Quality Management; maintenance-free, multi-use cartridge available in 30 menu/size options for use in any hospital location; allows 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, co-oximetry, and coagulation * *when interfaced to IL CO-Oximeter*

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In vitro blood gas analyzers

Part 3 of 13	Instrumentation Laboratory Xavier Nogue-Vila xvila@ilww.com 180 Hartwell Road Bedford, MA 01730 781-861-4244 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 2008	GEM Premier 4000/2006/—	IRMA TRUpoint Blood Analysis System/1994/—
No. of devices sold in U.S./Outside U.S./List price	1,000 worldwide/$50,000	6,000 worldwide/—
Dimensions (H x W x D)/Weight	18 × 12 × 15 in./44 lbs	11.5 × 9.5 × 5 in./5 lbs, 4 oz
Analytes measured on device	pH, pCO2, pO2, Hct, Na, K, Cl, iCa, lactate, glucose, tHb, O2Hb, COHb, MetHb, HHb	pH, pCO2, pO2, Hct, Na, K, Cl, iCa, glucose, BUN, creatinine, lactate
Parameters calculated on device	Hct, TCO2, BEecf (in vivo), BE(B) (in vivo), tHb(c), Ca++ (7.4), anion gap, P/F ratio, pAO2,CaO2, CvO2, P50, O2cap, sO2, sO2(c), HCO3-std, HCO3-(c), A-aDO2, paO2/pAO2, RI, CcO2, a-vDO2, Qsp/Qt(est), Qsp/Qt	Hb, O2SAT, BEb, BEecf, TCO2, HCO3-, iCa(n), creatinine MDRD-GFR
Barometric pressure	—	measured
Analytical method(s), technology(ies) employed	pH, pCO2: potentiometry; pO2, glucose, lactate: amperometry; Hct: conductivity; Hb: spectrophotometric; Na, Cl, iCa, K: potentiometric ion selective electrode	pH, pCO2, Na, Cl, iCa, K, BUN, creatinine, lactate (enzymatic): potentiometric; pO2, glucose (enzymatic): amperometric; Hct: conductometric; glucose strip (enzymatic): colormetric
Device is part of a series of related models	yes	yes
User list or group available	yes (through local sales representative)	yes
Device warranty	5 years	1 year
Loaner devices provided	yes	yes
Average expected life of device	7–10 years	7 years
Open or closed system/External gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC & laboratory	POC testing
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	yes (multi-use cartridge)	reagent/electrode (single use)
No. of disposable reagent system units in basic shipment package	1 per pack	25 per box
No. of samples analyzed per one disposable reagent, electrode system	cartidges available: 75, 150, 300, 450, 600	1
List price per disposable reagent system	varies with size and menu	$6–$7
Reagent unit storage requirements	room termperature	room temperature; creatinine 2° to 8°C
Shelf life of disposable units	6 months	reagent/electrode: 6 months
Laboratory:		
No. of different disposable reagents required to maintain device	1	—
Max. No. of specific analyte reagents that can reside in device at once	1 multi-use cartridge	—
Shelf life	6 months (cartridge)	—
Cost per test/Reagent cost per test	varies with cartridge size and menu	—
Calibrations required	automated continuous with iQM	2 point (automatic)
Calibration frequency	automated continuous with iQM	automatic with each sample
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	internal, automated, continuous quality management included	automatic electronic QC per 8 hrs
QC features	Onboard Intelligent Quality Management; monthly report includes no. of measurements, mean, max, and min delta values	L-J plots, statistical calculations, monthly cumulative reports (IDMS)
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	no—sample path visible
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial, venous	whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	heparin	heparin, EDTA (glucose strip only)
Sampling technique	aspiration	injection
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	150 µL, 95 µL (electrochemical only), 65 µL micro mode (electrochemical only)	125 µL capillary, 200 µL syringe
Sample size differs with No. of analytes selected	yes	no
Recommended collection device	heparinized syringe or caillary tube	standard blood gas syringe or capillary collection device
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	70 seconds for electrochemical and 25 additional seconds for CO-Ox	60–90 seconds on average
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	20/300	25/175
Optimal throughput when calibrated and awaiting specimens	20 samples per hr	20 per hour
Calibration can be interrupted to perform stat sample	yes	—
Contraindications	no	none
Known interferences	interfering substance would be detected and operator notified	—
Restrictions based on Hct	no	no
Sampler has self-wiping probe	yes	no, not needed
Time required for maintenance by lab personnel	none	maintenance free
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	no (but can through VPN)	no
Training & certification program for user	yes	yes
Method of analyst ID in system	wireless bar-code gun or manual virtual keyboard entry	LCD touchscreen, numeric (customizable)
Response for hardware & software failure/User ID & QC failure/Calibration & power failure	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	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
Supports bar-code scanning of	operator & patient IDs, cartridge lot number & expiration date	operator & patient IDs, cartridge information, lot No., quality control ranges
User can search for and review previous patient results on screen	yes	yes
Built-in printer/Data port	yes/4 RS-232, 1 parallel port, 1 Ethernet port, 4 USB ports	yes/RS-232, modem, Ethernet, LAN
Information on hard copy report	patient demographics, hospital info, results, result flags and legend, reference and critical ranges (optional), comments, notification info	analyzer serial no., date, calib. successful, calib. code, lot no., patient ID & temp., results, barometric press., SW version optional: user ID, ref. ranges, O2 therapy, sample information
Analyzer connects to	LIS/HIS via direct interface or via IL's GEMweb Plus data management system; vendor-neutral or Web-based systems	data mgmt. system, which connects to LIS/HIS; directly to LIS/HIS (both options)
Interface standards supported	ASTM 1394, HL7	IRMA (ASTM protocol), idms (script, HL7, or EDI)
To upload patient & QC results, how analyzer connects to ext. system	direct serial, hospital network, real-time wireless	hospital network, direct serial, LAN
Information included in transmission from analyzer to external system	device identifier, operator & patient IDs, results, QC ID	device unique identifier, operator & patient IDs, results, QC identifier, patient O2 therapy information
Hardware/Software for data management system	GEMweb Plus	integrated data management system, also integrates ITC co-oximetry and coagulation devices, connects to MAS, Telcor, and Aegis POC data managers
No. of different management reports system produces	4	24
Contents downloaded from DMS to analyzer	most configuration information, including valid operator IDs, QC lots and ranges	all analyzer settings, software upgrades
System connected (live installations) to which LISs, HISs		
• using screen animation, screen scraping	—	all major HIS/LIS vendors
• using standard HL7 interface	all major HIS/LIS vendors	all major HIS/LIS vendors
• using proprietary protocol interface	—	customizable EDI interface to HIS/LIS vendors
Use a third-party interfacing tool, engine for LIS, HIS interfaces	MAS/RALS, Telcor	yes
Distinguishing features (provided by vendor)	IQM detects, corrects, and documents instrument errors, reducing time to error detection to minutes; single component, multi-use GEM Premier 4000 cartridge includes testing components, is changed every 30 days, requires no refrigeration or maintenance; GEMweb Plus is an information management system for the 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

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In vitro blood gas analyzers

Part 4 of 13	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 2008	Stat Profile pHOx Basic/2002/—	Stat Profile pHOx/1998/—
No. of devices sold in U.S./Outside U.S./List price	—/—/—	—/—/—
Dimensions (H x W x D)/Weight	15 × 12 × 15 in./18 lbs	15 × 12 × 15 in./18 lbs
Analytes measured on device	pH, pCO2, pO2	pH, PCO2, PO2, Hct, Hb, SO2%
Parameters calculated on device	BE, TCO2, HCO3-	BE, TCO2, HCO3-
Barometric pressure	tracked	tracked
Analytical method(s), technology(ies) employed	pH: direct ISE; PCO2: Severinghaus; PO2: amperometry	pH: direct ISE; PCO2: Severinghaus; PO2: amperometry; Hct: conductivity; Hb & SO2%: optical–reflectance
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, repair or replacement of any part, including labor	1 year, travel and labor, repair or replacement
Loaner devices provided	no	yes
Average expected life of device	5–7 years	5–7 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	200–500 analyses	200–500 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 room temperature; electrodes: up to 18 months	reagents: 18 months 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: 12–24 months	reagents & electrodes: 18 months; membrane kits: 12–24 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	yes	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	whole blood, capillary, mixed venous, arterial
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	70 µL	70 µL
Sample size differs with No. of analytes selected	yes, standard 3-test blood gas micro-panel sample req. is 45 µL	yes, standard 3-test blood gas micro-panel sample req. is 45 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	45 seconds	45 seconds
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	300/300 tests	300/300 tests
Optimal throughput when calibrated and awaiting specimens	300 tests per hr	300 tests per hr
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 & 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.	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 which connects to LIS/HIS	data management system and/or directly to LIS/HIS
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 NT 4.0/Nova Point-of-Care Manager SW	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
System connected (live installations) to which LISs, HISs		
• using screen animation, screen scraping	>20	>20
• using standard HL7 interface	>100	>100
• using proprietary protocol interface	>500	>500
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

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

In vitro blood gas analyzers

Part 5 of 13	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 2008	Stat Profile pHOx Respiratory/2006/—
No. of devices sold in U.S./Outside U.S./List price	—/—/—
Dimensions (H x W x D)/Weight	15 × 12 × 15 in./18 lbs
Analytes measured on device	pH, PCO2, PO2, Hct, Hb, SO2%, lactate
Parameters calculated on device	BE, TCO2, HCO3-
Barometric pressure	tracked
Analytical method(s), technology(ies) employed	pH: direct ISE; PCO2: Severinghaus; PO2: amperometry; Hct: conductivity; Hb & SO2%: optical–reflectance; lactate: enzyme/amperometric
Device is part of a series of related models	yes
User list or group available	yes (upon request)
Device warranty	1 year, travel and labor, repair or replacement
Loaner devices provided	yes
Average expected life of device	5–7 years
Open or closed system/External gas tanks required	closed/no
For POC testing or laboratory	POC & laboratory
POC:	
Uses disposable prepackaged reagent/Electrode system for analysis	reagent
No. of disposable reagent system units in basic shipment package	200–500 analyses
No. of samples analyzed per one disposable reagent, electrode system	—
List price per disposable reagent system	—
Reagent unit storage requirements	room temperature
Shelf life of disposable units	reagents: 18 months room temperature, electrodes: up to 18 months
Laboratory:	
No. of different disposable reagents required to maintain device	1
Max. No. of specific analyte reagents that can reside in device at once	1
Shelf life	reagents & electrodes: 18 months; membrane kits: 12–24 months
Cost per test/Reagent cost per test	<$0.11 at 35 analyses per day/<$0.08 at 35 analyses per day
Calibrations required	1 & 2 point (automatic)
Calibration frequency	1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 4, or 6 hr (user defined)
Calibrants traceable to NIST standards	yes
Internal QC program recommended	minimum CLIA recommendations
QC features	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
System can use LOINC to transmit results to LIS	no
How labs get LOINC codes for reagent kits	—
Detects clots within analysis chamber	yes
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial
Acceptable anticoagulants	heparin
Sampling technique	aspiration & capillary
Suitable for samples from well neonates/Sick neonates	yes/yes
Sample size for complete panel of analyte results	125 µL
Sample size differs with No. of analytes selected	yes, standard 3-test micro-panel req. is 60 µL
Recommended collection device	syringe, capill., micro-collect. containers, standard vacuum cont.
Provides for patient temperature corrected results	yes
Time from sample introduction to result availability	52 seconds
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	50/500 tests
Optimal throughput when calibrated and awaiting specimens	300 tests per hr
Calibration can be interrupted to perform stat sample	yes
Contraindications	none
Known interferences	none
Restrictions based on Hct	no
Sampler has self-wiping probe	yes
Time required for maintenance by lab personnel	weekly: <5 min; monthly: <10 min
Onboard diagnostics for troubleshooting/Limited to software	yes/no
Diagnostics performed through modem	yes
Training & certification program for user	yes
Method of analyst ID in system	password with unique user ID No. (optional)
Response for hardware & software failure/User ID & QC failure/ Calibration & power failure	self-diag. SW informs & notifies oper. of HW failure; hotline & field support depending on problem/optional lockout w/o user ID; options for QC failure 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
User can search for and review previous patient results on screen	yes
Built-in printer/Data port	yes/multiple RS-232
Information on hard copy report	patient ID w/ access. no., entered settings, meas. & calc. results
Analyzer connects to	data management system and/or directly to LIS/HIS
Interface standards supported	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.
Information included in transmission from analyzer to external system	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
No. of different management reports system produces	>60
Contents downloaded from DMS to analyzer	yes, patient name, passwords
System connected (live installations) to which LISs, HISs	
• using screen animation, screen scraping	>20
• using standard HL7 interface	>100
• using proprietary protocol interface	>500
Use a third-party interfacing tool, engine for LIS, HIS interfaces	yes
Distinguishing features (provided by vendor)	onboard auto-cartridge QC; all-liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration & waste collection

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

In vitro blood gas analyzers

Part 6 of 13	**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 2008	Stat Profile pHOx Plus/2000/—
No. of devices sold in U.S./Outside U.S./List price	—/—/—
Dimensions (H x W x D)/Weight	15 × 12 × 15 in./18 lbs
Analytes measured on device	pH, PCO2, PO2, Hct, Hb, SO2%, Na, K, Cl or iCa, glucose
Parameters calculated on device	BE, TCO2, HCO3-
Barometric pressure	tracked
Analytical method(s), technology(ies) employed	pH: direct ISE; PCO2: Severinghaus; PO2: amperometry; Hct: conductivity; Hb & SO2%: optical–reflectance; Na, K, Cl, iCa: direct ISE; glucose: enzyme/amperometric
Device is part of a series of related models	yes
User list or group available	yes (upon request)
Device warranty	1 year, travel and labor, repair or replacement
Loaner devices provided	yes
Average expected life of device	5–7 years
Open or closed system/External gas tanks required	closed/no
For POC testing or laboratory	POC & laboratory
POC:	
Uses disposable prepackaged reagent/Electrode system for analysis	reagent
No. of disposable reagent system units in basic shipment package	200–500 analyses
No. of samples analyzed per one disposable reagent, electrode system	—
List price per disposable reagent system	—
Reagent unit storage requirements	room temperature
Shelf life of disposable units	reagents: 18 months room temperature, electrodes: up to 18 months
Laboratory:	
No. of different disposable reagents required to maintain device	1
Max. No. of specific analyte reagents that can reside in device at once	1
Shelf life	reagents & electrodes: 18 months; membrane kits: 12–24 months
Cost per test/Reagent cost per test	<$0.11 at 35 analyses per day/<$0.08 at 35 analyses per day
Calibrations required	1 & 2 point (automatic)
Calibration frequency	1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 4, or 6 hr (user defined)
Calibrants traceable to NIST standards	yes
Internal QC program recommended	minimum CLIA recommendations
QC features	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
System can use LOINC to transmit results to LIS	no
How labs get LOINC codes for reagent kits	—
Detects clots within analysis chamber	yes
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial
Acceptable anticoagulants	heparin
Sampling technique	aspiration & capillary
Suitable for samples from well neonates/Sick neonates	yes/yes
Sample size for complete panel of analyte results	115 µL
Sample size differs with No. of analytes selected	yes, micro-panel; standard 3-test micro-panel req. is 55 µL
Recommended collection device	syringe, capill., micro-collect. containers, standard vacuum cont.
Provides for patient temperature corrected results	yes
Time from sample introduction to result availability	50 seconds
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	50/500 tests
Optimal throughput when calibrated and awaiting specimens	300 tests per hr
Calibration can be interrupted to perform stat sample	yes
Contraindications	none
Known interferences	none
Restrictions based on Hct	no
Sampler has self-wiping probe	yes
Time required for maintenance by lab personnel	weekly: <5 min; monthly: <10 min
Onboard diagnostics for troubleshooting/Limited to software	yes/no
Diagnostics performed through modem	yes
Training & certification program for user	yes
Method of analyst ID in system	password with unique user ID No. (optional)
Response for hardware & software failure/User ID & QC failure/ Calibration & power failure	self-diag. SW informs & notifies oper. of HW failure; hotline & field support depending on problem/optional lockout w/o user ID; options for QC failure 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
User can search for and review previous patient results on screen	yes
Built-in printer/Data port	yes/multiple RS-232
Information on hard copy report	patient ID w/ access. no., entered settings, meas. & calc. results
Analyzer connects to	data management system and/or directly to LIS/HIS
Interface standards supported	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.
Information included in transmission from analyzer to external system	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
No. of different management reports system produces	>60
Contents downloaded from DMS to analyzer	yes, patient name, passwords
System connected (live installations) to which LISs, HISs	
• using screen animation, screen scraping	>20
• using standard HL7 interface	>100
• using proprietary protocol interface	>500
Use a third-party interfacing tool, engine for LIS, HIS interfaces	yes
Distinguishing features (provided by vendor)	onboard auto-cartridge QC; all-liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration & waste collection

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In vitro blood gas analyzers

Part 7 of 13	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 2008	Stat Profile pHOx Plus L/2001/—	Stat Profile pHOx Plus C/2003/—
No. of devices sold in U.S./Outside U.S./List price	—/—/—	—/—/—
Dimensions (H x W x D)/Weight	15 × 12 × 15 in./18 lbs	15 × 12 × 15 in./18 lbs
Analytes measured on device	pH, PCO2, PO2, Hct, Hb, SO2%, Na, K, Cl or iCa, glucose, lactate	pH, PCO2, PO2, Hct, Hb, SO2%, Na, K, Cl, iCa, glucose
Parameters calculated on device	BE, TCO2, HCO3-	BE, TCO2, HCO3-
Barometric pressure	tracked	tracked
Analytical method(s), technology(ies) employed	pH: direct ISE; PCO2: Severinghaus; PO2: amperometry; Hct: conductivity; Hb & SO2%: optical–reflectance; Na, K, Cl, iCa: direct ISE; glucose, lactate: enzyme/amperometric	pH: direct ISE; PCO2: Severinghaus; PO2: amperometry; Hct: conductivity; Hb & SO2%: 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	5–7 years	5–7 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	200–500 analyses	200–500 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 room temperature, electrodes: up to 18 months	reagents: 18 months 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: 12–24 months	reagents & electrodes: 18 months; membrane kits: 12–24 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 hr	300 tests per hr
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 and/or directly to LIS/HIS	data management system and/or directly to LIS/HIS
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		
• using screen animation, screen scraping	>20	>20
• using standard HL7 interface	>100	>100
• using proprietary protocol interface	>500	>500
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

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In vitro blood gas analyzers

Part 8 of 13	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 2008	Stat Profile Critical Care Xpress/2003/—	Stat Profile Critical Care Xpress 3 Plus/2003/—
No. of devices sold in U.S./Outside U.S./List price	—/—/—	—/—/—
Dimensions (H x W x D)/Weight	17.2 × 22.4 × 17.3 in./53 lbs	17.2 × 22.4 × 17.3 in./53 lbs
Analytes measured on device	pH, pCO2, pO2, Hct, Hb, Na, K, Cl, iCa, iMg, lactate, glucose, creatinine, BUN, SO2%, bilirubin, co-oximetry	pH, pCO2, pO2, co-oximetry
Parameters calculated on device	BE, TCO2, HCO3-	BE, TCO2, HCO3-
Barometric pressure	tracked	tracked
Analytical method(s), technology(ies) employed	pH: direct ISE; pCO2: Severinghaus; pO2: amperometric; Hct: conductivity; Hb & SO2%: optical-reflectance; Na, K, Cl, iMg, & iCa: direct ISE; lactate, glucose, & creatinine: enzyme/amperometric; BUN: enzyme/ISE; bilirubin, co-ox: optical, reflectance	pH: direct ISE; pCO2: Severinghaus; pO2: amperometric; co-ox: optical-reflectance
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	1 year
Loaner devices provided	no	no
Average expected life of device	5–7 years	5–7 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	200–500 analyses	200–500 analyses
No. of samples analyzed per one disposable reagent, electrode system	—	—
List price per disposable reagent system	—	—
Reagent unit storage requirements	no special requirements	no special requirements
Shelf life of disposable units	reagents: 18 months (room temp.); electrodes: up to 18 months	reagents: 18 months (room temp.); 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	20	7
Shelf life	reagents & electrodes: 18 months; membrane kits: 12–24 months	reagents & electrodes: 18 months; membrane kits: 12–24 months
Cost per test/Reagent cost per test	<$0.08 at 40 analyses per day/$0.04 at 40 analyses per day	<$0.08 at 40 analyses per day/$0.04 at 40 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, 3, 4, 5, or 6 hr (user defined)	1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 3, 4, 5, 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, comparable plot, statistical calculations, monthly cum. report, onboard, available with external system	L-J plots, comparable plot, statistical calculations, monthly cum. report, onboard, available with external system
Remote control of device from laboratory	yes	yes
System can use LOINC to transmit results to LIS	yes	yes
How labs get LOINC codes for reagent kits	package insert	package insert
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial, venous	whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	heparin	heparin
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	210 µL	210 µL
Sample size differs with No. of analytes selected	yes, variety of micro-panel options offered & can be customized	yes, variety of micro-panel options offered & can be customized
Recommended collection device	syringe, capillary, micro-collection, or vacuum collection containers	syringe, capillary, micro-collection, or vacuum collection containers
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	134 sec	61 seconds
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	22/440	32/224
Optimal throughput when calibrated and awaiting specimens	437 tests per hr	190 tests per hr
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	no	no
Known interferences	none	none
Restrictions based on Hct	no	no
Sampler has self-wiping probe	yes	yes
Time required for maintenance by lab personnel	daily: none; weekly: <5 min; monthly: <10 min	daily: none; 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	multilevel password with unique user ID No.	multilevel password with unique user ID_No.
Response for hardware & software failure/User ID & QC failure/ Calibration & power failure	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	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
Supports bar-code scanning of	operator & patient IDs	operator & patient IDs
User can search for and review previous patient results on screen	yes	yes
Built-in printer/Data port	yes/ Ethernet, USB	yes/Ethernet, USB
Information on hard copy report	patient ID & accession nos., entered settings, measured & calculated results	patient ID & accession Nos., entered settings, measured & calculated results
Analyzer connects to	directly to LIS/HIS, DMS that in turn connects to LIS/HIS	directly to LIS/HIS, DMS that in turn connects to LIS/HIS
Interface standards supported	ASTM E1394-91, ASTM 1381-91, HL7	ASTM E1394-91, ASTM 1381-91, HL7
To upload patient & QC results, how analyzer connects to external system	modem dial-in, hospital network	modem dial-in, hospital network
Information included in transmission from analyzer to external system	device unique identifier, operator & patient IDs, results, QC identifier	device unique identifier, operator & patient IDs, results, QC identifier
Hardware/Software for data management system	full-featured onboard DMS capability, external DMS also avail.	full-featured onboard DMS capability, external DMS also avail.
No. of different management reports system produces	>30	>30
Contents downloaded from DMS to analyzer	valid control nos., valid operator IDs, patient demographics	valid control nos., valid operator IDs, patient demographics
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	most analyzers interfaced to LIS using LIS vendor's drivers	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

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

In vitro blood gas analyzers

Part 9 of 13	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 2008	OPTI R/2006/—	OPTI CCA-TS Blood Gas Analyzer/2003/—
No. of devices sold in U.S./Outside U.S./List price	—/—/—	—/—/$10,200
Dimensions (H x W x D)/Weight	4.7 × 14.2 × 14 in./4.5 kg (10 lbs) without fluid pack	4.7 × 14.2 × 9 in./10 lbs without battery, 12 lbs with battery
Analytes measured on device	pH, pCO2, pO2, tHb, Na, K, iCa, SO2	pH, pCO2, pO2, Na, K, Cl, iCa, tHb, SO2, glucose, BUN
Parameters calculated on device	Hct, HCO3, BE, BEecf, BEact, BB, tCO2, st. HCO3, st. pH, O2ct, cH+, AaDO2, AG, p50, nCa++	Hct, HCO3, BE, BEecf, BEact, BB, tCO2, st. HCO3, st. pH, O2ct, cH+, AaDO2, AG, p50, nCa++
Barometric pressure	measured	measured
Analytical method(s), technology(ies) employed	optical fluorescence and reflectance	optical fluorescence and reflectance
Device is part of a series of related models	yes, OPTI series	yes, OPTI Series
User list or group available	yes (upon request)	yes, upon request
Device warranty	1 year (service contract available for subsequent years)	1 year (service contract available for subsequent years)
Loaner devices provided	yes	yes
Average expected life of device	7 years	>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/multiuse cartridge	single-use cassettes/optode
No. of disposable reagent system units in basic shipment package	4	25 individual packaged cassettes
No. of samples analyzed per one disposable reagent, electrode system	50	1
List price per disposable reagent system	contact OPTI Medical	depends on cassette configuration–contact Opti Medical
Reagent unit storage requirements	room temperature	room temperature
Shelf life of disposable units	cassette: 7 months; fluid pack: 12 months	cassette: 6–12 months, depends on type
Laboratory:		
No. of different disposable reagents required to maintain device	2	1
Max. No. of specific analyte reagents that can reside in device at once	8	8
Shelf life	cassette: 7 months; fluid pack: 12 months	cassette: 6–8 months, depends on type
Cost per test/Reagent cost per test	depends on volume—contact OPTI Medical	depends on volume—contact Opti Medical
Calibrations required	2 point (automatic)	1 point (automatic)
Calibration frequency	one point: after every sample or 30 minutes; two point: every 3 hours	with each cassette
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	3 levels automatic QC run at least once per day	liquid QC with change of cassette lot no. or 2-month intervals; electronic QC–1 level per 8 hours of operation
QC features	auto QC, statistics reports	electronic QC, statistics reports
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	plasma, serum, whole blood	plasma, serum, whole blood
Acceptable anticoagulants	heparin	heparin
Sampling technique	automatic aspiration	automatic aspiration
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	no	no
Recommended collection device	heparinized syringe, capillary, Comfort Sampler	heparinized syringe, capillary, Comfort Sampler
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	~1 minute	~1 min from sample aspiration
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	24/192	24/192
Optimal throughput when calibrated and awaiting specimens	24 tests per hr	24
Calibration can be interrupted to perform stat sample	no	no
Contraindications	none	none
Known interferences	—	—
Restrictions based on Hct	no	no
Sampler has self-wiping probe	no	no, single use
Time required for maintenance by lab personnel	weekly: 1 min; quarterly: 5 min	weekly: 1 min; quarterly: 5 min
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	no	no
Training & certification program for user	yes (1 to 2 days on site)	yes (on site as needed)
Method of analyst ID in system	bar code or secure PIN for 300 operators	bar code or secure PIN for 300 operators
Response for hardware & software failure/User ID & QC failure/ Calibration & power failure	error message/QC lockout/error message with automatic retry; power: memory recovery	error message/QC lockout/error message, memory recovery
Supports bar-code scanning of	oper. & patient IDs, reag. lot no., QC ranges, expiration	oper. & patient IDs, reag. lot No., QC ranges, cassette lot no., expiration, factory calibration info. & cassette type
User can search for and review previous patient results on screen	yes	yes
Built-in printer/Data port	yes/RS-232, Ethernet	yes/RS-232, Ethernet
Information on hard copy report	patient ID, results, patient demographics (customized), critical ranges	patient ID, results, patient demographics (customized), critical ranges
Analyzer connects to	directly to LIS/HIS, DMS that in turn connects to LIS/HIS, Prism POC data manager	directly to LIS/HIS, DMS that in turn connects to LIS/HIS, Prism POC data manager
Interface standards supported	Meditech, Sunquest/Misys, Telcor, CPSI, Cerner, HMS, Datacare, AEGIS POC	Meditech, Sunquest/Misys, Telcor, CPSI, Cerner, HMS, Datacare, AEGIS POC
To upload patient & QC results, how analyzer connects to external system	direct serial, hospital network	direct serial, hospital network
Information included in transmission from analyzer to external system	device unique identifier, oper. & patient IDs, results, QC identifier, all info. pertinent to patient & QC data	device unique identifier, oper. & patient IDs, results, QC identifier, all info. pertinent to patient & QC data
Hardware/Software for data management system	Prism POC data manager	Prism POC data manager
No. of different management reports system produces	40	40
Contents downloaded from DMS to analyzer	none	none
System connected (live installations) to which LISs, HISs		
• using screen animation, screen scraping	none	none
• using standard HL7 interface	Meditech, McKesson, Cerner, Siemens, others (call Opti Medical for updated list)	Meditech, McKesson, Cerner, Siemens, others (call Opti Medical for updated list)
• using proprietary protocol interface	none	none
Use a third-party interfacing tool, engine for LIS, HIS interfaces	none	none
Distinguishing features (provided by vendor)	three independent levels of auto QC, stable optical fluorescence technology, multiple use cassette, low maintenance, and color touch screen	stable optical fluorescence technology, easy-to-use touchscreen, measured tHb and SO2, no standby costs (single-use system), low maintenance

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In vitro blood gas analyzers

Part 10 of 13	Radiometer America Inc. **Telesales Department** info@radiometeramerica.com 810 Sharon Dr., Westlake, OH 44145 800-736-0600 ext. 333 www.radiometeramerica.com	Radiometer America Inc. **Telesales Department** info@radiometeramerica.com 810 Sharon Dr., Westlake, OH 44145 800-736-0600 ext. 333 www.radiometeramerica.com
Name of device/First year sold/No. of analyzers sold in 2008	ABL 5/1994/—	ABL 800 Series/2004/—
No. of devices sold in U.S./Outside U.S./List price	—/—/—	—/—/depends on configuration
Dimensions (H x W x D)/Weight	13 × 13 × 8 in./18 lbs	22 × 28 × 21 in./70 lbs
Analytes measured on device	pH, pCO2, pO2	pH, pCO2, pO2, Hb, Na, K, Cl, iCa, lactate, glucose, bilirubin, fetal Hb, O2Hb, MetHb, RHb, COHb, O2SAT, creatinine
Parameters calculated on device	Hct, O2SAT, BE, TCO2, HCO3-, ctO2, AaDpO2, SBE, ABE, SBC, pCO2(T), ctCO2(P), pH(T), cH+(T), pO2(T)	Hct, BE, TCO2, HCO3-, plus 40 additional parameters
Barometric pressure	measured	measured
Analytical method(s), technology(ies) employed	pH: pH-sensitive glass (ISE); pCO2, pO2: ISE	pH: pH-sensitive glass (ISE); pCO2, pO2, 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
Device is part of a series of related models	no	yes, ABL 800 Series
User list or group available	yes (through local sales representative)	yes (through local sales representative)
Device warranty	1 year, parts, labor, & travel	2 years, parts, labor, & travel
Loaner devices provided	yes	yes
Average expected life of device	20 years with full support	20 years with full support
Open or closed system/External gas tanks required	closed/yes	closed/yes (low-pressure, premixed)
For POC testing or laboratory	POC & laboratory	POC & laboratory (products on mobile carts for POCT/NPT)
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	—	—
Laboratory:		
No. of different disposable reagents required to maintain device	4	4
Max. No. of specific analyte reagents that can reside in device at once	4	4
Shelf life	reagent, electrode, membrane kit, cartridge: 2+ yrs	reagent, electrode, membrane kit, cartridge: 2+ yrs
Cost per test/Reagent cost per test	depends on sample volume & any extra incl. items/same	depends on sample volume & any extra incl. items/same
Calibrations required	1 & 2 point (automatic)	1 & 2 point (automatic)
Calibration frequency	1 point: 1/2 hr; 2 point: 4 hrs	1 point: 1/2 hr BG/pH, 4 hrs—mftr.; 2 point: every 8 hrs
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	depends on hospital management & inspection agency	depends on hospital management & inspection agency
QC features	statistical calculations (available with RADIANCE data management system)	L-J plots, comparable plot (via DMS), statistical calcs., auto QC, monthly cum. reports (onboard & avail. w/ external system, PC download to Excel)
Remote control of device from laboratory	yes	yes
System can use LOINC to transmit results to LIS	yes	yes
How labs get LOINC codes for reagent kits	—	—
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	whole blood, capill., mixed venous, arterial, venous	whole blood, capill., mixed venous, arterial, venous, expired air
Acceptable anticoagulants	heparin, balanced heparin	heparin, electrolyte-balanced heparin
Sampling technique	aspiration	autoaspiration, syringe &/or capillary tube &/or test tube
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	85 µL	95 µL for 17 measured parameters
Sample size differs with No. of analytes selected	yes, optional 35 µL for pH only	yes, with fewer measured parameters, smaller micro-modes available from 35 µL
Recommended collection device	syringe or capillary	syringe or capillary
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	~1 min	~1 min (depends on tests ordered)
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	30/90	25/425
Optimal throughput when calibrated and awaiting specimens	30 per hr	25 per hr
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	none	none
Known interferences	halothane	halothane, thiocyanic & glycolic acids
Restrictions based on Hct	—	no
Sampler has self-wiping probe	no	yes
Time required for maintenance by lab personnel	monthly: as needed; annually: 5 hrs	monthly: as needed; annually: dependent on version
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	no	yes
Training & certification program for user	yes (on site)	yes (on site)
Method of analyst ID in system	operator ID entry (optional)	customizable onboard keyboard, bar code
Response for hardware & software failure/User ID & QC failure/Calibration & power failure	system messages	system message with customized (“traffic light”) visual & audible signals, parameter status bar
Supports bar-code scanning of	none	operator & patient IDs, reag. & QC lot Nos., exp., soft. keys
User can search for and review previous patient results on screen	no	yes, multitask searches while analyzer performs other functions
Built-in printer/Data port	yes/RS-232, optional	yes/RS-232, Ethernet/USB
Information on hard copy report	patient info., meas. & calc. results, system messages	patient info./demographics, patient therapy settings, meas. & calc. results, system messages, reference & critical ranges
Analyzer connects to	RADIANCE STAT information management system that connects to LIS/HIS or directly to LIS/HIS	RADIANCE STAT information management system that connects to LIS/HIS or directly to LIS/HIS
Interface standards supported	ASTM 1394 & 1238, serial	ASTM, HL7, serial, POCT1A, network TCP/IP
To upload patient & QC results, how analyzer connects to external system	direct serial/thousands; modem dial-in/hundreds; real-time	direct serial/thousands of hosp. installed; modem dial-in/hundreds; hospital network/hundreds; real time wireless-capable
Information included in transmission from analyzer to external system	device unique identifier, operator & patient IDs, results, QC identifier, as per ASTM protocols	device unique identifier, operator & patient IDs, results, QC identifier, per ASTM/HL7 standards plus calib. & analyzer status info.
Hardware/Software for data management system	external RADIANCE	internal system + optional external system, RADIANCE
No. of different management reports system produces	user definable	user-definable searches/reports
Contents downloaded from DMS to analyzer	—	—
System connected (live installations) to which LISs, HISs		
• using screen animation, screen scraping	Cerner, Meditech, Misys, others	Cerner, Meditech, Misys, others
• using standard HL7 interface	none	available from analyzer—LIS/HIS vendors can use
• using proprietary protocol interface	none	none
Use a third-party interfacing tool, engine for LIS, HIS interfaces	no (use interface templates)	—
Distinguishing features (provided by vendor)	provides blood gases (pH, pCO2, pO2); easy to use with minimal maintenance; low cost of operation; fast restart, in 2 min, from standby mode	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

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In vitro blood gas analyzers

Part 11 of 13	Radiometer America Inc. Telesales Department info@radiometeramerica.com 810 Sharon Dr. Westlake, OH 44145 800-736-0600 ext. 333 www.radiometeramerica.com	Roche Diagnostics Laurence J. Healy laurence.healy@roche.com 9115 Hague Rd. Indianapolis, IN 46250 800-428-5076 us.labsystems.roche.com
Name of device/First year sold/No. of analyzers sold in 2008	ABL 80/2006/—	Roche OMNI Modular System/1996/—
No. of devices sold in U.S./Outside U.S./List price	—/—/depends on configuration	—/—/$29,900–$56,200
Dimensions (H x W x D)/Weight	16 × 9 × 11 in./19 lbs	16.5 × 21 × 18.5 in./88 lbs
Analytes measured on device	pH, pCO2, pO2, Hct, Na, K, iCa, Cl-, Glu [Hb, O2SAT, O2Hb, COHb, MetHb, HHb]*	pH, pCO2, pO2, Hct, Hb, Na, K, Cl, iCa, lactate, glucose, BUN, co-ox values: O2Hb, COHb, SulfHb, HHb, metHb
Parameters calculated on device	Hb, O2SAT, TCO2, HCO3-, ctO2 (a-v), ctO2, anion gap (K+), cCa2+ (7.40), cBase (B), ABE, SBE, others	40+ parameters, including BE, BB, HCO3-, TCO2, SO2, NiCa++, ctO2, pSO, shunt, AG, OSM (call Roche for list)
Barometric pressure	—	measured
Analytical method(s), technology(ies) employed	pH, pCO2, pO2, Na, K, iCa, Cl, Glu: thick film; amperometric/potentiometric technology; HCT: conductivity	pH: ion selective galvanometric; pCO2, pO2: ion selective membrane; Hct: conductivity; Hb: spectrophotometry; Na, Cl, iCa, K: ion selective potentiometry; lactate: lact. oxidase enzyme; glucose: glucose oxidase enzyme; BUN: urease enzyme
Device is part of a series of related models	yes	yes, models 1–9
User list or group available	yes (through local sales representative)	yes (through Roche sales dept.)
Device warranty	1 year parts, labor, & travel, with service plans available after year 1	1 year (service contract available for subsequent years)
Loaner devices provided	yes	yes
Average expected life of device	analyzer: 10+ years	>7 years
Open or closed system/External gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC testing, laboratory	POC & laboratory (transportable on cart system)
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	electrode (multiuse cartridge)	—
No. of disposable reagent system units in basic shipment package	1	—
No. of samples analyzed per one disposable reagent, electrode system	50/100/200/300	—
List price per disposable reagent system	depends on configuration & GPO affiliation	—
Reagent unit storage requirements	room temperature	—
Shelf life of disposable units	90–100 days	—
Laboratory:		
No. of different disposable reagents required to maintain device	2	depends on model, contact Roche
Max. No. of specific analyte reagents that can reside in device at once	2	—
Shelf life	reagent: 100 days, cartridge: 90 days	reagents: 1 year
Cost per test/Reagent cost per test	depends on configuration/same	depends on sample volume/same
Calibrations required	1 & 2 point (manual & automatic)	1 & 2 point (automatic)
Calibration frequency	1 point: with each test; 2 point: 8 hrs (user definable)	1 point: 30 min and with each sample; 2 point: selectable 4–12 hrs
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	QC material according to CLIA, CAP, JCAHO	1 liquid QC sample per 8 hrs of operation
QC features	L-J plots, statistical calcs., monthly cum. (onboard–current mean, STD, CV%) reports (onboard & available with external system, PC download to Excel)	AutoQC sampling, L-J plots, statistical calcs., monthly cum. reports (onboard & external with DataCare POC software), multirules, auto. lock/unlock of individual tests based on QC criteria
Remote control of device from laboratory	yes	yes
System can use LOINC to transmit results to LIS	yes	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, venous	plasma, serum, w. blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	heparinized, electrolyte balanced heparin	heparin, lithium
Sampling technique	aspiration	aspiration, injection
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	70 µL	160 µL for full panel, 40 µL per module
Sample size differs with No. of analytes selected	no	yes, 40 µL per module, ie: pH/BG, electrolytes, co-ox, metabolites
Recommended collection device	syringe or capillary tube	syringe, capillary, microsampler
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	90 sec	~1 min (depends on tests analyzed)
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	30/270	40/490 tests per hr
Optimal throughput when calibrated and awaiting specimens	30 tests per hr	40 samples per hr
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	none	none
Known interferences	—	none
Restrictions based on Hct	no	no (automatically checks Hct: tHb ratio)
Sampler has self-wiping probe	no	no
Time required for maintenance by lab personnel	—	weekly: 5 min; quarterly: 5 min
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	no	yes, with OMNI-Link via network can remotely control, real-time continuously monitor, activate calib., QC sampling (with AutoQC module), and activate troubleshooting routines remotely
Training & certification program for user	yes (on site)	yes (on site)
Method of analyst ID in system	customizable onboard keyboard, bar code	4-level password system for 200 operators
Response for hardware & software failure/User ID & QC failure/Calibration & power failure	system message with customized ("traffic light") visual & audible signals, parameter status bar	identified on screen & w/ diagnostic routine/user ID: on screen w/ msg., QC: on screen–report w/ high-low flagging & multirule/calib.: identified on display w/ easy-to-read icons, auto. lockout of failed QC test, power: recorded in activities log, automatic customizable QC lockout of tests
Supports bar-code scanning of	operator & patient IDs, reag. & QC lot Nos., exp., soft. keys	oper. & patient identifiers, reag. & electrode lot Nos., QC ranges, expir.
User can search for and review previous patient results on screen	yes	yes (up to 50,000 online, onboard analyzer)
Built-in printer/Data port	yes/RS-232, Ethernet/USB	yes/RS-232, parallel, Ethernet
Information on hard copy report	patient info./demographics, patient therapy settings, meas. and calc. results, system messages, reference and critical ranges	customizable, can incl. input values, meas. values, calc. values
Analyzer connects to	RADIANCE STAT analyzer management system that connects to LIS/HIS or directly to LIS/HIS	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options)
Interface standards supported	ASTM, HL7, serial, network, TCP/IP	ASTM 1394, ASTM 1238, HL7 (DataCare available)
To upload patient & QC results, how analyzer connects to external system	serial, Ethernet	direct serial, hospital network, real-time wireless (RF)
Information included in transmission from analyzer to external system	device unique identifier, operator & patient IDs, results, QC identifier	device unique identifier, oper. & patient IDs, results, QC identifier
Hardware/Software for data management system	RADIANCE	Roche OMNI has onboard DM capabilities; DataCare POC software is available as a client/server to connect OMNI analyzers
No. of different management reports system produces	user definable	40
Contents downloaded from DMS to analyzer	—	valid control values, valid operator IDs, patient demographics
System connected (live installations) to which LISs, HISs		
• using screen animation, screen scraping	Cerner, Meditech, Misys, others	none
• using standard HL7 interface	available from analyzer—LIS/HIS vendors can use	Meditech, McKesson, Cerner, SMS (call Roche for updated list)
• using proprietary protocol interface	none	Kaiser Permanente
Use a third-party interfacing tool, engine for LIS, HIS interfaces	no (use interface templates)	Dawning, Cloverleaf, Data Innovations (not required but can use)
Distinguishing features (provided by vendor)	portable, true battery operation; fast startup/warmup and analysis time; simple and easy-to-use system ** pending FDA clearance*	Roche AutoQC for automatic and precise meas. of QC material following all regs.; reduces labor and eliminates preanalytical variables; liquid calib. eliminates hazardous gas tanks

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In vitro blood gas analyzers

Part 12 of 13	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 2008	Roche cobas b 221 system/2004/—	RAPIDPoint 300 Series/2009/—
No. of devices sold in U.S./Outside U.S./List price	—/—/$44,400–$63,700	—/—/—
Dimensions (H x W x D)/Weight	23 × 20 × 23.6 in./99 lbs (w/o solutions and AutoQC)	12.5 × 14.5 × 7 in./16–17 lbs
Analytes measured on device	pH, pCO2, pO2, Hct, Hb, Na, K, Cl, iCa, lactate, glucose, BUN, bilirubin, pH pleural flud	pH, pCO2, pO2, Hct, Na+, K+, Cl-, iCa++
Parameters calculated on device	Hb, Hct, O2SAT, BE, TCO2, HCO3-	Hb, 02SAT, BE, TCO2, HCO3
Barometric pressure	recorded or measured	recorded, measured
Analytical method(s), technology(ies) employed	pH: electrode ion selective galvanometric; pCO2, pO2: electrode ion selective membrane; Hct: conductivity; Hb: co-ox spectrophotometry; Na, Cl, iCa, K: ion selective potentiometry; lactate, glucose, BUN: MSS sensor enzyme	pH: ISE-potentiometry; iCa: ISE; PCO2: ISE-potentiometry; p02: ISE-amperometry; Hct: conductivity; Hb: calculated from hematocrit; Na: ISE; Cl: ISE; K: ISE
Device is part of a series of related models	yes, 6 models in series	yes, two models: RAPIDPoint 340 offers blood gas; RAPIDPoint 350 offers blood gas, electrolytes, and hematocrit
User list or group available	yes (via local sales representative)	yes, through local sales representative
Device warranty	1 year (parts and services warranty)	1-year warranty (country specific)
Loaner devices provided	no	yes
Average expected life of device	7 years	7–10 years
Open or closed system/External gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC & laboratory	laboratory
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	reagent and electrode	yes, multi-use cartridge
No. of disposable reagent system units in basic shipment package	depends on model, contact Roche	1
No. of samples analyzed per one disposable reagent, electrode system	dependent on use	based on daily testing volumes
List price per disposable reagent system	—	—
Reagent unit storage requirements	room-temperature storage	room temperature
Shelf life of disposable units	12 months (reagents)/18 months (electrodes)	reagents: 7–9 months; electrodes: 12 months
Laboratory:		
No. of different disposable reagents required to maintain device	depends on model, contact Roche	1
Max. No. of specific analyte reagents that can reside in device at once	3	1
Shelf life	reagent: 1 year; electrode: 18 months onboard	reagents: 7–9 months; electrodes: 12 months
Cost per test/Reagent cost per test	volume-dependent/volume-dependent	varies based on configuration and test volume/—
Calibrations required	1 & 2 point (automatic)	one and two point (manual and automatic)
Calibration frequency	1 point: 30 min; 2 point: 8 hrs	one point (with each sample); two point (can be set to 2, 4, or 8-hour increments)
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	CAP and JCAHO guidelines	one-level QC every 8 hours of testing (CLIA recommendation): Siemens QC material recommended
QC features	L-J plots, comparable plot, lot-to-lot comparisons, statistical calcs., monthly cum. reports, onboard, eQAP	L-J plots, statistical calculations, monthly cumulative reports, onboard
Remote control of device from laboratory	yes	no
System can use LOINC to transmit results to LIS	yes	no
How labs get LOINC codes for reagent kits	Web, package insert	—
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	plasma, serum, whole blood, capillary, arterial, venous	whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	EDTA, heparin, citrate	heparin
Sampling technique	aspiration, injection, capillary transfer & fill, microsamples	aspiration
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	200 µL for full panel	75 µL/95 µL capillary (RP340/RP350) 100 µL/120 µL syringe (RP340/RP350)
Sample size differs with No. of analytes selected	yes, BG: 40 µL; ISE: 40 µL; co-ox 44 µL, glucose, lactate, BUN: 75 µL	no
Recommended collection device	—	heparinized syringe or capillary
Provides for patient temperature corrected results	—	yes
Time from sample introduction to result availability	~1 min (test dependent)	125 seconds (RP340), <120 seconds (RP350)
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	30 patients per hr (full panel)/360 tests per hr	25 samples (RP340), 30 samples (RP350)/75 (RP340), 210 (RP350)
Optimal throughput when calibrated and awaiting specimens	30 patients per hr (full panel)	25 samples/hr (RP340), 30 samples/hr (RP350)
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	no	no
Known interferences	none	certain anticoagulants
Restrictions based on Hct	no	no
Sampler has self-wiping probe	yes	yes
Time required for maintenance by lab personnel	daily: 2 min, monthly: 5 min, quarterly: 5 min	daily: <1 minute
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	yes	no
Training & certification program for user	yes (2.5 days on site)	yes, less than 1 day (country specific)
Method of analyst ID in system	32-level password system (customizable)	manual or bar-code entry (optional)
Response for hardware & software failure/User ID & QC failure/ Calibration & power failure	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 warning, error messages; sampling lock-out, flagged high or low QC results; automatic calibration repeat, error messages, blank screen display
Supports bar-code scanning of	operator & patient IDs, reagent lot No., RF w/transponders, expir.	operator identifier, patient identifier, and reagent lot number
User can search for and review previous patient results on screen	yes	yes
Built-in printer/Data port	yes/RS-232, parallel, Ethernet	yes/RS-232
Information on hard copy report	options can be customized; direct & measured parameters	patient information, operator ID, measured and calculated results, date
Analyzer connects to	data management system, which connects to LIS/HIS; data management, which cannot further transmit data; directly to LIS/HIS	directly to LIS/HIS
Interface standards supported	ASTM 1394, HL7, USB port	ASTM 1394 & E1381
To upload patient & QC results, how analyzer connects to external system	direct serial, hospital network	direct serial
Information included in transmission from analyzer to external system	device unique identifier, oper. & patient IDs, results, QC identifier	operator ID, patient ID, results
Hardware/Software for data management system	MAS RALS-Plus, DataCare POC	internal data management
No. of different management reports system produces	50 (RALS-Plus), 40 (DataCare POC)	patient reports, QC statistics, L-J charts
Contents downloaded from DMS to analyzer	valid control values, valid operator IDs, critical patient results	—
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 Innovations	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

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In vitro blood gas analyzers

Part 13 of 13	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 2008	RAPIDPoint 400 Series/2001/—	RAPIDLab 1200 Series/2005/—
No. of devices sold in U.S./Outside U.S./List price	—/—/—	—/—/—
Dimensions (H x W x D)/Weight	21.5 × 11.5 × 16 in./34 lbs	22.75 × 20.5 × 21 in./65–68 lbs
Analytes measured on device	pH, pCO2, pO2, Hct, Na+, K+, Cl-, Ca++, tHB, FO2Hb, FCOHb, FMetHb, FHHb, glucose	pH, pCO2, pO2, tHb, Na+, K+, Cl-, iCa++, lactate, glucose, FO2Hb, FCOHb, FMetHb, FHHb, total neonatal bilirubin
Parameters calculated on device	HCO3-act, HCO3-std, BE(B), BE(ecf), ctCO2, Ca++(7.4), RI(T), O2SAT, PO2/FIO2, AnGAP, sO2, BO2, pO2(A-a)(T), pO2(a/A)(T), p50, Qsp/Qt(T), ctO2(Hb), ctO2(a), ctO2(v), ctO2(V), ctO2(a-v), DO2, VO2, others	HCO3-act, HCO3-std, BE(B), BE(ecf), ctCO2, Ca++(7.4), RI(T), O2SAT, PO2/FIO2, AnGAP, sO2, BO2, pO2(A-a)(T), pO2(a/A)(T), p50, Qsp/Qt(T), ctO2(Hb), ctO2(a), ctO2(v), ctO2(V), ctO2(a-v), DO2, VO2, others
Barometric pressure	recorded	measured, tracked
Analytical method(s), technology(ies) employed	pH, Na, Cl, iCa, K: potentiometry using ISE; pCO2: potentiometry based on Severinghaus; pO2: amperometric meas. (Clark); glucose: amperometric-glucose oxidase; Hct: conductivity; co-oximetry: spectrophotometric	pH: potentiometry; pCO2: Severinghaus electrochemical; pO2: amperometric; Hct: calculated; tHb: spectrophotometric; Na, Cl, iCa, K: ISE; lactate: lactate oxidase; glucose: glucose oxidase; total neonatal bilirubin: spectrophotometric
Device is part of a series of related models	yes	yes, series offers different analyte options
User list or group available	yes, through local sales rep	yes, thropugh local sales rep
Device warranty	1 year	1 year
Loaner devices provided	yes	no
Average expected life of device	7–10 years	7–10 years
Open or closed system/External gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC testing and laboratory	laboratory and POC testing
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	yes, multi-use cartridge	multi-use cartridges, electrode measurement chamber
No. of disposable reagent system units in basic shipment package	1 measurement and 1 wash/waste cartridge	1 reagent cartridge, 1 wash cartridge
No. of samples analyzed per one disposable reagent, electrode system	250, 400, 750 samples	Reagent cartridge is not sample dependent
List price per disposable reagent system	varies based on configuration	—
Reagent unit storage requirements	refrigeration	Reagent cartridge/AQC cartridge – refrigeration; wash cartridge – room temperature
Shelf life of disposable units	9 months	reagent/wash cartridge: 8 months; AQC cartridge: 9 months; electrodes: varies based on type
Laboratory:		
No. of different disposable reagents required to maintain device	1 measurement cartridge, 1 wash-waste cartridge	1 reagent cartridge, 1 wash cartridge
Max. No. of specific analyte reagents that can reside in device at once	1 measurement cartridge, 1 wash-waste cartridge	1 reagent cartridge, 1 wash cartridge, all electrodes
Shelf life	9 months	electrodes: vary based on type; reagent cartridge: 8 months; wash cartridge: 8 months; AQC cartridge: 9 months
Cost per test/Reagent cost per test	varies based on configuration	varies based on configuration
Calibrations required	1 & 2 point (automatic)	1 & 2 point (manual & automatic)
Calibration frequency	1 point: 30 min; 2 point: 2 hrs	1 point: every 30 min; 2 point: every 8 hrs
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	AQC cartridge, fully user programmable	AQC cartridge, fully user programmable
QC features	AQC cartridge, L-J plots, comparable plots, statistical calculations, monthly cum. reports (available with external system)	L-J plots, comparable plots, statistical calculations, monthly cum. reports (available with external system)
Remote control of device from laboratory	yes	yes
System can use LOINC to transmit results to LIS	yes	—
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, venous	whole blood, capillary, mixed venous, arterial, venous
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	100 µL	95 µL–175 µL
Sample size differs with No. of analytes selected	no	yes (microsample mode available)
Recommended collection device	syringe or capillary	syringe or capillary
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	60 seconds	60 seconds
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	25/—	24/up to 336 tests
Optimal throughput when calibrated and awaiting specimens	25 samples per hr	24 samples per hr
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	if calibration is interrupted repeatedly, it will force a mandatory calibration to be completed before sampling	none
Known interferences	benzalkonium	contact vendor
Restrictions based on Hct	no	no
Sampler has self-wiping probe	yes	yes
Time required for maintenance by lab personnel	maintenance free	weekly: 5 min; monthly: 5 min
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	no	no
Training & certification program for user	yes	yes
Method of analyst ID in system	password (customizable)	password (customizable)
Response for hardware & software failure/User ID & QC failure/ Calibration & power failure	flag-prompt/user ID: customizable; QC: customizable-flag/calibration: flag–recalibration	diagnostic codes prompt the operator/diagnostic codes/recalibrates, generates diagnostic code if unsuccessful
Supports bar-code scanning of	operator & patient IDs, accession No., results, temp., other infor.	patient ID
User can search for and review previous patient results on screen	yes	yes
Built-in printer/Data port	yes/RS-232, Ethernet	yes/RS-232, Ethernet
Information on hard copy report	operator & patient IDs, accession No., results, temperature, other information	operator & patient IDs, accession No., results, temperature, patient demographics, others
Analyzer connects to	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options)	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options)
Interface standards supported	LIS 3	LIS 4
To upload patient & QC results, how analyzer connects to external system	direct serial, hospital network	direct serial, hospital network
Information included in transmission from analyzer to external system	device unique identifier, operator & patient IDs, results, QC identifier	device unique identifier, operator & patient IDs, results, QC identifier
Hardware/Software for data management system	RapidComm Data Management System	RapidComm Data Management System
No. of different management reports system produces	customizable	customizable
Contents downloaded from DMS to analyzer	valid control values, valid operator IDs	valid control values, valid operator IDs
System connected (live installations) to which LISs, HISs		
• using screen animation, screen scraping	—	—
• using standard HL7 interface	yes	yes
• using proprietary protocol interface	yes	yes
Use a third-party interfacing tool, engine for LIS, HIS interfaces	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

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