In vitro blood gas analyzers

Part 1 of 13	**Abbott Point of Care** **Glen Tinevez** glen.tinevez@abbott.com **104 Windsor Center Drive** **East Windsor, NJ 08520** **800-827-7828** www.abbottpointofcare.com
Name of device/First year sold/No. of analyzers sold in 2007	i-STAT System/1992/—
No. of devices sold in U.S./Outside U.S./List price	~30,000 worldwide/$8,761
Dimensions (H x W x D)/Weight	9.25 × 3.0 × 2.85 in./22.4 oz
Analytes measured on device	pH, pCO2, pO2, Hct, Na, K, Cl, iCa, lactate, glucose, creatinine, BUN, TCO2
Parameters calculated on device	Hb, HCT, O2SAT, BE, TCO2, HCO3-
Barometric pressure	measured
Analytical method(s), technology(ies) employed	electrochemical for all analytes
Device is part of a series of related models	no
User list or group available	yes (through local sales representative)
Device warranty	1-yr replacement
Loaner devices provided	yes
Average expected life of device	8 yrs
Open or closed system/External gas tanks required	closed/no
For POC testing or laboratory	POC testing
POC:	
Uses disposable prepackaged reagent/Electrode system for analysis	reagent/electrode (single use)
No. of disposable reagent system units in basic shipment package	25 per box
No. of samples analyzed per one disposable reagent, electrode system	1
List price per disposable reagent system	—
Reagent unit storage requirements	refrigerate, 2-week shelf life at room temperature
Shelf life of disposable units	reag./electrode: 6–9 months
Laboratory:	
No. of different disposable reagents required to maintain device	none
Max. No. of specific analyte reagents that can reside in device at once	—
Shelf life	—
Cost per test/Reagent cost per test	—
Calibrations required	1 point (automatic)
Calibration frequency	every test
Calibrants traceable to NIST standards	yes
Internal QC program recommended	electronic QC, automated internal wet QC
QC features	comparable plot, monthly cumulative reports (available with external system)
Remote control of device from laboratory	yes
System can use LOINC to transmit results to LIS	yes
How labs get LOINC codes for reagent kits	—
Detects clots within analysis chamber	—
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	heparin
Sampling technique	injection, capillary transfer and fill
Suitable for samples from well neonates/Sick neonates	yes/yes
Sample size for complete panel of analyte results	blood gas 95 µL, electrolytes 65 µL
Sample size differs with No. of analytes selected	no
Recommended collection device	syringe or capillary tube
Provides for patient temperature corrected results	yes
Time from sample introduction to result availability	about 2 min
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	20 per unit/160
Optimal throughput when calibrated and awaiting specimens	—
Calibration can be interrupted to perform stat sample	—
Contraindications	—
Known interferences	—
Restrictions based on Hct	—
Sampler has self-wiping probe	—
Time required for maintenance by lab personnel	—
Onboard diagnostics for troubleshooting/Limited to software	yes/no
Diagnostics performed through modem	yes
Training & certification program for user	yes, No. of training days varies
Method of analyst ID in system	keypad entry/bar-code scanner (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
Supports bar-code scanning of	operator & patient IDs, reagent lot No.
User can search for and review previous patient results on screen	yes
Built-in printer/Data port	no/—
Information on hard copy report	device unique identifier, operator & patient IDs, results, QC results, QC identifier
Analyzer connects to	LIS/HIS, via data management system
Interface standards supported	ASTM 1394 & 1238, HL7, others
To upload patient & QC results, how analyzer connects to external system	direct serial; modem dial-in; hospital network
Information included in transmission from analyzer to external system	device unique identifier, operator & patient IDs, results, QC identifier
Hardware/Software for data management system	QC Manager 3.0/Central Data Station
No. of different management reports system produces	35+
Contents downloaded from DMS to analyzer	strip lot Nos., valid control values, valid operator IDs, customizations, analyzer locations
System connected (live installations) to which LISs, HISs	
• using screen animation, screen scraping	all major LIS vendors
• using standard HL7 interface	multiple vendors
• using proprietary protocol interface	—
Use a third-party interfacing tool, engine for LIS, HIS interfaces	yes, Sybase
Distinguishing features (provided by vendor)	handheld portable, single-use test cartridge menu; broadest test menu available on a single POC platform; laboratory accurate results at the bedside

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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 101 Hartwell Ave. Lexington, MA 02421 781-861-4244 www.ilus.com	Instrumentation Laboratory Xavier Nogue-Vila xvila@ilww.com 101 Hartwell Ave., Lexington, MA 02421 781-861-4244 www.ilus.com
Name of device/First year sold/No. of analyzers sold in 2007	GEM Premier 3000/2000/1,580	GEM 3100/2000/1,580
No. of devices sold in U.S./Outside U.S./List price	>2,760/>7,580/$39,995	>2,760/>7,580/$39,995
Dimensions (H x W x D)/Weight	17 × 12 × 12 in./29.5 lbs	22 × 12 × 12 in./31.5 lbs
Analytes measured on device	pH, pO2, pCO2, Hct, Na+, K+, Ca++, glucose, lactate	pH, pO2, pCO2, Hct, Na+, K+, Ca++, glucose, lactate: PT, APTT, ACT, ACT-LR, citrate PT
Parameters calculated on device	A-aDo2, Hb, pAO2, paO2/pAO2, RI, O2cap*, CtO2*, CaO2*, CvO2*, CcO2*, a-vDO2*, Qsp/Qt*, P50*	A-aDo2, Hb, pAO2, paO2/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	pH, pCO2: potentiometry; pO2, glucose, lactate: amperometry; Hct: conductivity; Na, iCa, K: ISE; PT, APTT, ACT, ACT-LR, citrate PT, mechanical clot detection
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 yrs	5 yrs
Loaner devices provided	yes	yes
Average expected life of device	7–10 yrs	7–10 yrs
Open or closed system/External gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC & laboratory	POC & laboratory
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	yes (multiuse cartridge)	yes (multiuse 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	35-, 75-, 150-, 300-, 450-, & 600-test cartridge	cartridges available: 35-, 75-, 150-, 300-, 450-, & 600-test cartridge, 1 sample per cartridge for coagulation tests
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	1 multiuse cartridge	2:1 for blood gas/electrolytes, 1 for coagulation
Shelf life	6 months	6 months
Cost per test/Reagent cost per test	varies with size & menu	varies with menu & cartridge size
Calibrations required	1 & 2 point (automatic)	1 & 2 point (automatic)
Calibration frequency	1 point: each patient sample; 2 point: at least every 4 hrs	1 point: each patient sample; 2 point: at least every 4 hrs
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	heparin, fresh whole blood for coagulation tests
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	135–150 µL, 50 µL for coagulation
Sample size differs with No. of analytes selected	no	no
Recommended collection device	syringe or capillary tube	syringe or capillary tube
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	85 seconds	85 seconds; under 5 min for coagulation
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	disposable cartridge/no maintenance required	no operator involvement
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	manual or bar-code entry of ID & password (customizable)	manual or bar-code entry of ID & password (customizable)
Response for hardware & software failure/User ID & QC failure/ Calibration & power failure	operator warning, sampling lockout/user ID: no system access, QC: channel flagged/calibration: no results for channel, power: automatic recalibration	operator warning, sampling lockout/user ID: no system access, QC: channel flagged/calibration: no results for channel, power: automatic recalibration
Supports bar-code scanning of	operator & patient IDs, QC values	operator & patient IDs, QC values
User can search for and review previous patient results on screen	yes	yes
Built-in printer/Data port	yes/3 RS-232, 1 parallel, bar-code reader port, Ethernet port	yes/2 RS-232, 1 parallel, bar-code reader port, Ethernet port
Information on hard copy report	patient demographics, hospital name and address, results	patient demographics, hospital name, results
Analyzer connects to	GEMweb, GEMweb Plus, Impact for Critical Care	GEMweb, GEMweb Plus, Impact for Critical Care
Interface standards supported	ASTM protocol	ASTM protocol
To upload patient & QC results, how analyzer connects to external system	direct serial, Ethernet, modem dial-in	direct serial, modem dial-in, Ethernet
Information included in transmission from analyzer to external system	device identifier, operator & patient IDs, results, QC ID & results	device identifier, operator & patient IDs, results, QC ID
Hardware/Software for data management system	Impact for Critical Care	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	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)	Intelligent Quality Management; maintenance-free, multiuse cartridge available in 30 menu/size options for use in any hospital location; 20-year history of cartridge technology; remote management from any PC via GEMweb; consolidated workstation for blood gas, electrolytes, Hct, glucose, lactate, co-oximetry, and coagulation ** when interfaced to IL CO-Oximeter*	Intelligent Quality Management; maintenance-free, multiuse cartridge available in 30 menu/size options for use in any hospital location; 20-year history of cartridge technology; remote management from any PC via GEMweb; consolidated workstation ** when interfaced to IL CO-Oximeter*

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In vitro blood gas analyzers

Part 3 of 13	Instrumentation Laboratory Xavier Nogue-Vila xvila@ilww.com 101 Hartwell Ave., Lexington, MA 02421 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 2007	GEM Premier 4000/2006/100	IRMA TRUpoint Blood Analysis System/1994/—
No. of devices sold in U.S./Outside U.S./List price	1,000 worldwide/$50,000	5,800 worldwide/$8,900
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 yrs	1 yr
Loaner devices provided	yes	yes
Average expected life of device	7–10 yrs	7 yrs
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 (multiuse 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 cartidge size and menu	—
Calibrations required	1 & 2 point (automatic)	2 point (automatic)
Calibration frequency	1 point: each patient sample; 2 point: at least every 4 hrs	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
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 management 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 external system	direct serial, hospital network, real-time wireless	hospital network, direct serial, modem dial-in
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	SCC, Misys, Cerner, Meditech	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 Plus, Telecor Quick-Linc	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	Medica Corp. Charlene M. Soley csoley@medicacorp.com 5 Oak Park Drive, Bedford, MA 01730 800-777-5983 or 781-275-4892 www.medicacorp.com	Medica Corp. Charlene M. Soley csoley@medicacorp.com 5 Oak Park Drive, Bedford, MA 01730 800-777-5983 or 781-275-4892 www.medicacorp.com
Name of device/First year sold/No. of analyzers sold in 2007	EasyBloodGas/2000/255	EasyStat/2002/166
No. of devices sold in U.S./Outside U.S./List price	—/255/$10,750	—/166/$12,500
Dimensions (H x W x D)/Weight	12.5 × 14.5 × 7 in./16 lbs	12.5 × 14.5 × 7.0 in./17 lbs
Analytes measured on device	pH, pO2, pCO2	pH, pCO2, pO2, Hct, Na, K, iCa or Cl
Parameters calculated on device	O2SAT, BE, TCO2, HCO3-	Hb, O2SAT, BE, TCO2, HCO3-
Barometric pressure	measured	measured and recorded
Analytical method(s), technology(ies) employed	pH: ISE-potentiometry; pCO2: ISE-potentiometry; pO2: ISE-amperometry	pH and pCO2: ISE-potentiometry; pO2: ISE-amperometry; Hct: conductivity; Hb: calculated from Hct; iCa: ISE; K: ISE
Device is part of a series of related models	yes (basic model first gen., related to expanded model EasyStat)	yes (expanded parameter menu, related to EasyBloodGas)
User list or group available	yes	yes
Device warranty	1-yr analyzer warranty	1 yr analyzer warranty
Loaner devices provided	yes	yes (planned)
Average expected life of device	>5 yrs	>5 yrs
Open or closed system/External gas tanks required	closed/no	closed/no
For POC testing or laboratory	laboratory	laboratory
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	reagent & electrode	reagent & electrode
No. of disposable reagent system units in basic shipment package	1	1
No. of samples analyzed per one disposable reagent, electrode system	based on testing volume per day	based on testing volume per day
List price per disposable reagent system	—	—
Reagent unit storage requirements	room temperature: 5° to 25°C	room temperature: 5° to 25°C
Shelf life of disposable units	reagent module, 10 months; electrodes, 12 months	reagent module: 10 months; electrodes: 12 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	reagent module: 10 months; electrode: 12 months	reagent module: 10 months; electrode: 12 months
Cost per test/Reagent cost per test	$0.57 at 20 samples per day/$0.26 at 20 samples per day	<$0.80 per sample at 20 samples per day/$0.33 at 20 samples per day
Calibrations required	1 & 2 point (automatic)	1 & 2 point (automatic)
Calibration frequency	1 point: during each sample analysis; 2 point: can be set for 2-, 4-, or 8-hr increments	1 point: with every sample analysis; 2 point: can be set for 2-, 4-, or 8-hr increments
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	1 level per 8 hrs, CLIA recommendations, Medica controls recommended	1 level per 8 hrs, CLIA recommendations, Medica controls recommended
QC features	L-J plots; monthly cumulative reports	L-J plots; monthly cum. report
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, venous	plasma, serum, 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 syringe; 75 µL capillary	120 µL syringe; 95 µL capillary
Sample size differs with No. of analytes selected	no	no
Recommended collection device	heparinized capillary or syringe	heparinized capillary or syringe
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	125 seconds, includes 1 point calibration	<120 seconds, includes 1 point calibration
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	25/75	30/210
Optimal throughput when calibrated and awaiting specimens	25 samples	30 samples
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	no	no
Known interferences	incorrect anticoagulant	incorrect anticoagulant
Restrictions based on Hct	no	no
Sampler has self-wiping probe	yes	yes
Time required for maintenance by lab personnel	daily: 0.5 min; weekly: 3.5 min; monthly: 15 min	daily: 0.5 min; weekly: 3.5 min; monthly: 15 min
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	no	no
Training & certification program for user	yes (through distributors)	yes (through distributors)
Method of analyst ID in system	manual or bar-code wand for ID entry (optional)	manual or bar-code entry (optional)
Response for hardware & software failure/User ID & QC failure/ Calibration & power failure	HW: oper. warning & error msg.; SW: error msg./user ID: sampling lockout; QC failure; flagged results/calib.: error msg. & 2nd attempt for 2-pt. calib. auto.; power: display not illuminated, data retained & auto reset	HW: operator warning-error message; SW: error message/user ID: sampling lockout; QC: flagged results/calibration: error message & 2nd 2 pt calibration automatically run; power: display not illuminated, data retained-auto reset
Supports bar-code scanning of	operator & patient IDs, reagent lot No., QC control, reagent pack automatically read when reagent module installed	operator & patient IDs, QC controls, reagent pack automatically read when reagent module installed
User can search for and review previous patient results on screen	yes	yes
Built-in printer/Data port	yes/RS-232	yes/RS-232
Information on hard copy report	patient information; measured & calculated parameters	patient information, measured & calculated results, date, operator ID
Analyzer connects to	data management system, which can further transmit data; directly to LIS/HIS	data management system, which connects to LIS/HIS; data management system, which can further transmit data; directly to LIS/HIS
Interface standards supported	Medica protocol	Medica protocol
To upload patient & QC results, how analyzer connects to external system	direct serial	direct serial
Information included in transmission from analyzer to external system	patient ID, results	operator & patient IDs, results
Hardware/Software for data management system	internal	internal
No. of different management reports system produces	QC, L-J chart, patient reports	QC, L-J chart, patient & proficiency reports
Contents downloaded from DMS to analyzer	—	—
System connected (live installations) to which LISs, HISs		
• using screen animation, screen scraping	—	—
• using standard HL7 interface	—	—
• using proprietary protocol interface	—	—
Use a third-party interfacing tool, engine for LIS, HIS interfaces	TBD	TBD
Distinguishing features (provided by vendor)	modular components; simple operation and maintenance; low operation cost; disposable, maintenance-free sensors; no gas tanks; easy inside and out	modular components; simple operation and maintenance; low operation cost; disposable, maintenance-free sensors; no gas tanks, easy inside and out

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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	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 2007	Stat Profile pHOx Basic/2002/—	Stat Profile pHOx/1998/—
No. of devices sold in U.S./Outside U.S./List price	—/—/$12,000	—/—/$15,000
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 yr, repair or replacement of any part, including labor	1 yr, travel and labor, repair or replacement
Loaner devices provided	no	yes
Average expected life of device	5–7 yrs	5–7 yrs
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	$200–$265	$200–$265
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 (on site)	yes (on site)
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

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In vitro blood gas analyzers

Part Part 6 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 2007	Stat Profile pHOx Respiratory/2006/—	Stat Profile pHOx Plus/2000/—
No. of devices sold in U.S./Outside U.S./List price	—/—/$27,500	—/—/$29,000
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%, lactate	pH, PCO2, PO2, Hct, Hb, SO2%, Na, K, Cl or 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; 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 yr, travel and labor, repair or replacement	1 yr, travel and labor, repair or replacement
Loaner devices provided	yes	yes
Average expected life of device	5–7 yrs	5–7 yrs
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	$210–$275	$210–$275
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	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	125 µL	115 µL
Sample size differs with No. of analytes selected	yes, standard 3-test micro-panel req. is 60 µL	yes, micro-panel; standard 3-test micro-panel req. is 55 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	50 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 (on site)	yes (on site)
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 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 2007	Stat Profile pHOx Plus L/2001/—	Stat Profile pHOx Plus C/2003/—
No. of devices sold in U.S./Outside U.S./List price	—/—/$32,000	—/—/$32,000
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 yr, travel and labor, repair or replacement	1 yr, travel and labor, repair or replacement
Loaner devices provided	yes	yes
Average expected life of device	5–7 yrs	5–7 yrs
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	$210–$275	$210–$275
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 (on site)	yes (on site)
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 2007	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 yr	1 yr
Loaner devices provided	no	no
Average expected life of device	5–7 yrs	5–7 yrs
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	$294–$349	$269
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 sec
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 (3 days on site)	yes (3 days on site)
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)	largest 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; meets NCCLS POCT 1-A standards (more shared features listed under Critical Care Xpress)

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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 2007	OPTI R/2006/—	OPTI CCA Blood Gas Analyzer/1998/—
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
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	pH, pCO2, pO2, Hb, Na, Cl, iCa, K: optical fluorescence	pH, pCO2, pO2, Na, Cl, iCa, K, glucose: optical fluorescence; tHb, SO2: optical reflectance
Device is part of a series of related models	yes (OPTI CCA)	yes, OPTI Series
User list or group available	yes (upon request)	yes (through Opti Medical sales dept.)
Device warranty	one-year warranty on new analyzers from date analyzer is placed into service	1 yr (service contract available for subsequent years)
Loaner devices provided	yes	yes
Average expected life of device	5–7 yrs	>7 yrs
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	—	depends on cassette configuration–contact Opti Medical
Reagent unit storage requirements	room temperature	room temperature
Shelf life of disposable units	reagents: 7 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	1
Shelf life	7 months	cassette: 6–8 months, depends on type
Cost per test/Reagent cost per test	—	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	3 levels liquid with change of cassette lot No., 2-month intervals electronic QC–1 level per 8 hrs of operation; elec. & liquid statistical calcs., L-J with external system
QC features	auto QC, statistics reports	stores 1 month—3 levels onboard of each (elec. & liq.)
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, w. blood, capill., mixed ven., arterial, venous	plasma, serum, w. blood, capill., mixed ven., 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	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 min	~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	no	none
Known interferences	—	none
Restrictions based on Hct	no	no (Hct calculated based on meas. Hb)
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	1D code entry	oper. ID and/or secure 4-digit PIN No. for 300 oper. (customizable)
Response for hardware & software failure/User ID & QC failure/Calibration & power failure	HW & SW: error message/user ID: —; QC: failure message/calibration: error message with retry; power: memory recovery	identified on display & w/ diagnostic routine/user ID: identified on display (missing or not valid), QC: on display (report flagging param. high or low)/calib: on display prior to sample aspir., power: low batt. identified on display–warning; automatic customized QC lockout
Supports bar-code scanning of	oper. & patient IDs, reag. lot No., QC ranges, cassette lot No., expiration, factory calibration info. & cassette type	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
Information on hard copy report	patient ID, number, results, patient demographics (customized)	customizable, can incl. input values, meas. values, calc. values
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 1394, ASTM 1238, ASC II	mobile ASTM, ASTM, ASCII
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, 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	LDS Aegis	LDS Aegis
No. of different management reports system produces	—	40
Contents downloaded from DMS to analyzer	—	none
System connected (live installations) to which LISs, HISs		
• using screen animation, screen scraping	—	none
• using standard HL7 interface	—	Meditech, McKesson, Cerner, Siemens, others (call Opti Medical for updated list)
• using proprietary protocol interface	—	none
Use a third-party interfacing tool, engine for LIS, HIS interfaces	LDS Aegis	LDS Aegis
Distinguishing features (provided by vendor)	three independent levels of auto QC, stable optical fluorescence technology, multiple use cassette, low maintenance, and color touch screen	ColorTouch screen display; meas. tHb/SO2; 8-month shelf life of cass. stored at room temp. simplifies logistics; auto. sample asp. from syringe and capill.; extensive list of input params.; onboard printer

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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 2007	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, creatinine: ISE; Hct: calc. from meas. Hb, bilirubin; Hb: optical, multiwavelength anal., intra-cuvette ultrasonic hemolysis; lactate, gluc.: 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 yr, parts, labor, & travel	2 yrs, parts, labor, & travel
Loaner devices provided	yes	yes
Average expected life of device	20 yrs with full support	20 yrs 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–CLIA GAS, 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
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 basic blood gases (pH, pCO2, pO2) test profile; easy to use with minimal maintenance; low cost of operation via standby usage; fast restart, in 2 min, out of standby mode	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	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 2007	ABL 80/2006/—	NPT7/2001/—
No. of devices sold in U.S./Outside U.S./List price	—/—/depends on configuration	—/—/depends on configuration
Dimensions (H x W x D)/Weight	16 × 9 × 11 in./19 lbs	10 × 13 × 16 in./25 lbs
Analytes measured on device	pH, pCO2, pO2, Hct, Na, K, iCa, Cl-, Glu [Hb, O2SAT, O2Hb, COHb, MetHb, HHb]*	pH, pCO2, pO2, Hb, O2SAT, O2Hb, COHb, MetHb, HHb
Parameters calculated on device	Hb, O2SAT, TCO2, HCO3-, ctO2 (a-v), ctO2, anion gap (K+), cCa2+ (7.40), cBase (B), ABE, SBE, others	Hct, ABE, SBE, TCO2, HCO3-, SBC, TO2, p50
Barometric pressure	—	yes
Analytical method(s), technology(ies) employed	pH, pCO2, pO2, Na, K, iCa, Cl, Glu: thick film; amperometric/potentiometric technology; HCT: conductivity	pH, pCO2, pO2, oximetry: patented dry optical technology
Device is part of a series of related models	yes	no
User list or group available	yes (through local sales representative)	yes (through local sales representative)
Device warranty	1 yr parts, labor, & travel, with service plans available after yr 1	1 yr, parts, labor, & travel or depot loaner service
Loaner devices provided	yes	yes
Average expected life of device	analyzer: 10+ yrs	10+ yrs
Open or closed system/External gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC testing, laboratory	POC testing, laboratory
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	electrode (multiuse cartridge)	dry optical system
No. of disposable reagent system units in basic shipment package	1	multiuse cartridge contains 30 single-use cuvettes
No. of samples analyzed per one disposable reagent, electrode system	50/100/200/300	30
List price per disposable reagent system	depends on configuration & GPO affiliation	depends on configuration
Reagent unit storage requirements	room temperature	room temperature
Shelf life of disposable units	90–100 days	24 months
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	2	1
Shelf life	reagent: 100 days, cartridge: 90 days	24 months
Cost per test/Reagent cost per test	depends on configuration/same	depends on volume
Calibrations required	1 & 2 point (manual & automatic)	2-level check is performed as part of QualityGuard system (manual & automatic)
Calibration frequency	1 point: with each test; 2 point: 8 hrs (user definable)	—
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	QC material according to CLIA, CAP, JCAHO	QualityGuard incl. a 2-level check, system check & incl. meas. check
QC features	L-J plots, statistical calcs., monthly cum. (onboard–current mean, STD, CV%) reports (onboard & available with external system, PC download to Excel)	QualityGuard information onboard or available with external system, L-J plot and QC statistics, also available on external DMS
Remote control of device from laboratory	yes	no
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, capillary, mixed venous, arterial, venous	whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	heparinized, electrolyte balanced heparin	heparinized whole blood
Sampling technique	aspiration	aspiration
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	70 µL	90 µL
Sample size differs with No. of analytes selected	no	no
Recommended collection device	syringe or capillary tube	heparinized syringe or capillary tube
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	90 sec	60 sec
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	30/270	30/270
Optimal throughput when calibrated and awaiting specimens	30 tests per hr	30 tests per hr
Calibration can be interrupted to perform stat sample	yes	—
Contraindications	none	no
Known interferences	—	intralipid (concentrations over 4 vol%), fluoroscein
Restrictions based on Hct	no	no
Sampler has self-wiping probe	no	no, probe disposed of after measurement
Time required for maintenance by lab personnel	—	—
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	no	no
Training & certification program for user	yes (on site)	yes
Method of analyst ID in system	customizable onboard keyboard, bar code	optional/bar code or manual
Response for hardware & software failure/User ID & QC failure/ Calibration & power failure	system message with customized (“traffic light”) visual & audible signals, parameter status bar	system messages with visual signals
Supports bar-code scanning of	operator & patient IDs, reag. & QC lot Nos., exp., soft. keys	operator & patient IDs, QC lot No.
User can search for and review previous patient results on screen	yes	yes
Built-in printer/Data port	yes/RS-232, Ethernet/USB	yes/RS-232, Ethernet
Information on hard copy report	patient info./demographics, patient therapy settings, meas. and calc. results, system messages, reference and critical ranges	patient info, patient therapy settings; measured and calculated parameter results; system messages; reference ranges; cartridge lot & cartridge expiration date
Analyzer connects to	RADIANCE STAT analyzer management system that connects to LIS/HIS or directly to LIS/HIS	RADIANCE STAT analyzer management system that connects to LIS/HIS or directly to LIS/HIS
Interface standards supported	ASTM, HL7, serial, network, TCP/IP	ASTM
To upload patient & QC results, how analyzer connects to external system	serial, Ethernet	serial, Ethernet
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	PCM/CIA—internal DM or external DM
No. of different management reports system produces	user definable	user definable
Contents downloaded from DMS to analyzer	—	—
System connected (live installations) to which LISs, HISs		LIS vendors completing interface requirements
• using screen animation, screen scraping	Cerner, Meditech, Misys, others	—
• using standard HL7 interface	available from analyzer—LIS/HIS vendors can use	—
• using proprietary protocol interface	none	—
Use a third-party interfacing tool, engine for LIS, HIS interfaces	no (use interface templates)	no (use interface templates)
Distinguishing features (provided by vendor)	portable, true battery operation; fast startup/warmup and analysis time; simple and easy-to-use system ** pending FDA clearance*	dry optical technology, unique in the measurement of blood gases and full co-oximetry; maintenance-free; no cartridge preparation; QualityGuard; patient results in one minute

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In vitro blood gas analyzers

Part 12 of 13	Roche Laurence J. Healy laurence.healy@roche.com 9115 Hague Rd. Indianapolis, IN 46250 800-428-5076 us.labsystems.roche.com	Roche 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 2007	Roche OMNI Modular System/1996/—	Roche cobas b 221 system/2004/—
No. of devices sold in U.S./Outside U.S./List price	—/—/$29,900–$56,200	—/—/$44,400–$63,700
Dimensions (H x W x D)/Weight	16.5 × 21 × 18.5 in./88 lbs	23 × 20 × 23.6 in./99 lbs (w/o solutions and AutoQC)
Analytes measured on device	pH, pCO2, pO2, Hct, Hb, Na, K, Cl, iCa, lactate, glucose, BUN, co-ox values: O2Hb, COHb, SulfHb, HHb, metHb	pH, pCO2, pO2, Hct, Hb, Na, K, Cl, iCa, lactate, glucose, BUN, bilirubin, pH pleural flud
Parameters calculated on device	40+ parameters, including BE, BB, HCO3-, TCO2, SO2, NiCa++, ctO2, pSO, shunt, AG, OSM (call Roche for list)	Hb, Hct, O2SAT, BE, TCO2, HCO3-
Barometric pressure	measured	recorded or measured
Analytical method(s), technology(ies) employed	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	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
Device is part of a series of related models	yes, models 1–9	yes, 6 models in series
User list or group available	yes (through Roche sales dept.)	yes (via local sales representative)
Device warranty	1 yr (service contract available for subsequent years)	1 yr (parts and services warranty)
Loaner devices provided	yes	no
Average expected life of device	>7 yrs	7 yrs
Open or closed system/External gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC & laboratory (transportable on cart system)	POC & laboratory
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	—	reagent and electrode
No. of disposable reagent system units in basic shipment package	—	depends on model, contact Roche
No. of samples analyzed per one disposable reagent, electrode system	—	dependent on use
List price per disposable reagent system	—	—
Reagent unit storage requirements	—	room-temperature storage
Shelf life of disposable units	—	12 months (reagents)/18 months (electrodes)
Laboratory:		
No. of different disposable reagents required to maintain device	depends on model, contact Roche	depends on model, contact Roche
Max. No. of specific analyte reagents that can reside in device at once	—	3
Shelf life	reagents: 1 yr	reagent: 1 year; electrode: 18 months onboard; membrane kit: na, cartridge kit: na
Cost per test/Reagent cost per test	depends on sample volume/same	volume dependent/volume dependent
Calibrations required	1 & 2 point (automatic)	1 & 2 point (automatic)
Calibration frequency	1 point: 30 min and with each sample; 2 point: selectable 4–12 hrs	1 point: 30 min; 2 point: 8 hrs
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	1 liquid QC sample per 8 hrs of operation	CAP and JCAHO guidelines
QC features	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	L-J plots, comparable plot, lot-to-lot comparisons, statistical calcs., monthly cum. reports, onboard, eQAP
Remote control of device from laboratory	yes	yes
System can use LOINC to transmit results to LIS	no	yes
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, w. blood, capillary, mixed venous, arterial, venous	plasma, serum, whole blood, capillary, arterial, venous
Acceptable anticoagulants	heparin, lithium	EDTA, heparin, citrate
Sampling technique	aspiration, injection	aspiration, injection, capillary transfer & fill, microsamples
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	160 µL for full panel, 40 µL per module	200 µL for full panel
Sample size differs with No. of analytes selected	yes, 40 µL per module, ie: pH/BG, electrolytes, co-ox, metabolites	yes, BG: 40 µL; ISE: 40 µL; co-ox 44 µL, glucose, lactate, BUN: 75 µL
Recommended collection device	syringe, capillary, microsampler	—
Provides for patient temperature corrected results	yes	—
Time from sample introduction to result availability	~1 min (depends on tests analyzed)	~1 min (test dependent)
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	40/490 tests per hr	30 patients per hr (full panel)/360 tests per hr
Optimal throughput when calibrated and awaiting specimens	40 samples per hr	30 patients per hr (full panel)
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	none	no
Known interferences	none	none
Restrictions based on Hct	no (automatically checks Hct: tHb ratio)	no
Sampler has self-wiping probe	no	yes
Time required for maintenance by lab personnel	weekly: 5 min; quarterly: 5 min	daily: 2 min, monthly: 5 min, quarterly: 5 min
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	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	yes
Training & certification program for user	yes (on site)	yes (2.5 days on site)
Method of analyst ID in system	4-level password system for 200 operators	32-level password system (customizable)
Response for hardware & software failure/User ID & QC failure/ Calibration & power failure	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	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
Supports bar-code scanning of	oper. & patient identifiers, reag. & electrode lot Nos., QC ranges, expir.	operator & patient IDs, reagent lot No., RF w/transponders, expir.
User can search for and review previous patient results on screen	yes (up to 50,000 online, onboard analyzer)	yes
Built-in printer/Data port	yes/RS-232, parallel, Ethernet	yes/RS-232, parallel, Ethernet
Information on hard copy report	customizable, can incl. input values, meas. values, calc. values	options can be customized; direct & measured parameters
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; data management, which cannot further transmit data; directly to LIS/HIS
Interface standards supported	ASTM 1394, ASTM 1238, HL7 (DataCare available)	ASTM 1394, HL7, USB port
To upload patient & QC results, how analyzer connects to external system	direct serial, hospital network, real-time wireless (RF)	direct serial, hospital network
Information included in transmission from analyzer to external system	device unique identifier, oper. & patient IDs, results, QC identifier	device unique identifier, oper. & patient IDs, results, QC identifier
Hardware/Software for data management system	Roche OMNI has onboard DM capabilities; DataCare POC software is available as a client/server to connect OMNI analyzers	MAS RALS-Plus, DataCare POC
No. of different management reports system produces	40	50 (RALS-Plus), 40 (DataCare POC)
Contents downloaded from DMS to analyzer	valid control values, valid operator IDs, patient demographics	valid control values, valid operator IDs, critical patient results
System connected (live installations) to which LISs, HISs		
• using screen animation, screen scraping	none	—
• using standard HL7 interface	Meditech, McKesson, Cerner, SMS (call Roche for updated list)	—
• using proprietary protocol interface	Kaiser Permanente	—
Use a third-party interfacing tool, engine for LIS, HIS interfaces	Dawning, Cloverleaf, Data Innovations (not required but can use)	Data Innovations
Distinguishing features (provided by vendor)	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	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

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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 2007	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 yr	1 yr
Loaner devices provided	yes	no
Average expected life of device	7–10 yrs	7–10 yrs
Open or closed system/External gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC testing and laboratory	laboratory
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	yes, multiuse cartridge	—
No. of disposable reagent system units in basic shipment package	1 measurement and 1 wash/waste cartridge	—
No. of samples analyzed per one disposable reagent, electrode system	250, 400, 750 samples	—
List price per disposable reagent system	varies based on configuration	—
Reagent unit storage requirements	refrigeration	—
Shelf life of disposable units	9 months	—
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	electrode: varies 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, multiuse cartridge; fast time to patient results; onboard audio-video training videos; auto QC	cartridge-based, high-throughput analyzer with minimal maintenance; fast time to patient results; onboard troubleshooting tutorials

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