In vitro blood gas analyzers

Part 1 of 8	Abbott Point of Care Kevin Ball kevin.ball@apoc.abbott.com 400 College Road East Princeton, NJ 08540 800-827-7828 www.abbottpointofcare.com	Alere, Inc. Mark Steinberg mark.steinberg@alere.com 30 South Keller Rd., Suite 100 Orlando, FL 32810 888-893-6225 www.alere.com	Instrumentation Laboratory Mike Wright mwright@ilww.com 180 Hartwell Road Bedford, MA 01730 781-861-4165 www.ilus.com
Name of device/First year sold/Number of analyzers sold in 2010	i-STAT System/1992/—	epoc Blood Analysis System/2008/—	GEM Premier 3000/2000/1,450
Number of devices sold in U.S./outside U.S./List price	30,000+/20,000+/$8,761	—/—/$7,500	>2,000/>8,000/$39,995
Dimensions (H x W x D)/Weight	9.25 × 3.0 × 2.85 inches/22.4 ounces	3 × 3.4 × 8.5 inches/~1.5 pounds	17 × 12 × 12 inches/29.5 pounds
Analytes measured on device	pH, pCO2, pO2, Hct, Na, K, Cl, iCa, lactate, glucose, creatinine, BUN, TCO2, cTnI, CK-MB, BNP, ACT, PT/INR	pH, pCO2, pO2, Hct, Na, K, iCa, lactate, glucose	pH, pO2, pCO2, Hct, Na+, K+, Ca++, glucose, lactate
Parameters calculated on device	Hb, HcT, O2SAT, BE, TCO2, HCO3	Hb, 02SAT, BE, TCO2, HCO3	A-aDo2, Hb, pAO2, paO2/pAO2, RI, O2cap*, O2Ct*, CtO2*, CaO2*, CvO2*, CcO2*, a-vDO2*, Qsp/Qt, P50, HCO3-, BEb, BEcecf, S02c
Barometric pressure	measured	recorded	—
Analytical method(s) or technologies employed	electrochemical for all analytes	pH, iCa, pC02, Na, K: potentiometry; p02, lactate, glucose: amperometry; Hct: conductometric; Hb: calculated	pH, pCO2: potentiometry; pO2, glucose, lactate: Na, iCa, K: amperometry; Hct: conductivity; potentiometric ion selective electrode
Device is part of a series of related models	no	no	yes
Device warranty/Loaner devices provided	1-year replacement/yes	initial 1-year warranty; extended warranty available	5 years/yes
Average life expectancy of device	8 years	—	7–10 years
Open or closed system/External gas tanks required	closed/no	closed/no	closed/no
Categorized for point-of-care testing or laboratory	point-of-care testing	point-of-care testing	point-of-care testing and laboratory
Point of care:			
Disposable prepackaged system used for analysis	reagent/electrode (single use)	reagent/electrode (single use)	multi-use cartridge
No. of disposable reagent system units in standard package	25 per box	50	1 per pack
No. of samples analyzed per one disposable reagent, electrode system	1	1	35-, 75-, 150-, 300-, 450-, and 600-test cartridge
Reagent unit storage requirements	refrigerate, two-month shelf life for blood gas cartridges, two- week shelf life for all others	room temperature	room temperature
Shelf life of disposable units	6–9 months	up to 6 months	6 months
Laboratory:			
No. of different disposable reagents required to maintain device	—	—	1
Max. No. of analyte reagents that can reside in device at once	—	—	1 multi-use cartridge
Shelf life of components	—	—	6 months
Cost per test/Reagent cost per test	—	—	varies with size and menu
Calibrations required	1 point (automatic)	1 point (automatic)	automated continuous with iQM
Calibration frequency	every test	every test	automated continuous with iQM
Internal QC program recommended	electronic QC, automated internal wet QC	—	internal, automated, continuous quality mgmt. included
QC features/Capabilities of QC features	comparable plot/monthly cumulative reports (available with external system)	—	onboard Intelligent Quality Management/monthly report includes number of measurements, mean, maximum, and minimum delta values
Remote control of device from laboratory	yes	yes	yes
System can use LOINC to transmit results to LIS	no	yes	no
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial, venous	whole blood, capillary, mixed venous, arterial, venous	whole blood, arterial, venous, or capillary
Acceptable anticoagulants/Sampling technique	heparin/injection, capillary transfer, and fill	heparin/injection, capillary transfer and fill	heparin/aspiration
Sample size for complete panel of analyte results	blood gas 96 µL, electrolytes 65 µL	~92 mL	135 to 150 µL
Sample size differs with number of analytes selected	no	no	no
Time from sample introduction to result availability	about 2 minutes	~35 seconds	85 seconds
Maximum No. of patient samples per hour/Maximum No. measured results per hour	20 per unit/160	—	20/180
Optimal throughput when analyzer calibrated, awaiting specimens	—	—	20 samples per hour
Calibration can be interrupted to perform stat sample	—	no	yes
Known interferences	—	—	—
Sampler has self-wiping probe	—	no	yes
Time required for maintenance by lab personnel	—	—	none (disposable cartridge)
Service center performs diagnostics through modem	yes	no	no (but can through VPN)
Method of analyst ID in system	keypad entry/bar-code scanner (customizable)	—	manual or bar-code entry of ID and password (customizable)
Instrument response for:			
• hardware failure/software failure	code number error message	error code, rejection of card	operator warning, sampling lockout
• QC failure	code number error message	failure noted on final report	channel flagged
• calibration failure	code number error message	card rejected	no results for channel
For what bar-code scanning is provided	operator and patient IDs, reagent lot number	operator and patient IDs, reagent lot number, all open fields	operator and patient IDs, QC values
Built-in printer/Data port	no/—	no/—	yes/3 RS-232, 1 parallel, bar-code reader port, Ethernet port
Information listed on hard copy report	device-unique identifier, operator and patient IDs, results, QC results, QC identifier	all	patient demographics, hospital name and address, results
Analyzer connections	LIS/HIS, via data management system	LIS/HIS, via data management system	GEMweb, GEMweb Plus, Impact for Critical Care
Interface standards supported	ASTM 1394 and 1238, HL7	HL7	ASTM protocol
How analyzer connects to external system to upload patient and QC results	hospital network	real-time wireless (RF)	direct serial, Ethernet, modem dial-in
Information included in transmission from analyzer to external system	device-unique identifier, operator and patient IDs, results, QC identifier, others	device-unique identifier, operator and patient IDs, results, QC identifier, others	device identifier, operator and patient IDs, results, QC ID and results
Hardware and software for data management system	PrecisionWeb, Central Data Station	software only	Impact for Critical Care
No. of different management reports system produces	35+	customizable	customizable
Contents downloaded from data management system to analyzer	valid operator IDs, device behavior customizations	valid operator IDs, others	patient ID, demographics
System connected (live installations) to which LISs, HISs	major LIS vendors	most	major HIS/LIS vendors
Use a third-party interfacing tool, engine for LIS, HIS interfaces	yes, Sybase Interface Manager	yes, Mirth	MAS/RALS, Telcor
Distinguishing features (provided by company)	handheld, portable, single-use test cartridge menu; broad test menu on a single point-of-care platform; laboratory-accurate results at the bedside	room-temperature card storage (up to 6 months); bar-coded test cards for quality and inventory management; fully wireless data transfer to data manager, real time (no need to dock for download)	iQM detects, corrects, and documents instrument errors, reducing error detection time to minutes; maintenance-free, multi-use cartridge available in customized configurations for use in any hospital location; wireless communication to LIS or HIS

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

In vitro blood gas analyzers

Part 2 of 8	Instrumentation Laboratory Mike Wright mwright@ilww.com 180 Hartwell Road, Bedford, MA 01730 781-861-4165 www.ilus.com	Instrumentation Laboratory Bill Manchester billm@ilww.com 180 Hartwell Road, Bedford, MA 01730 781-861-4360 www.ilus.com	ITC Nexus Dx 8 Olsen Ave. Edison, NJ 08820 800-631-5945 www.itcmed.com
Name of device/First year sold/Number of analyzers sold in 2010	GEM Premier 3500/2009/—	GEM Premier 4000/2006/—	IRMA TRUpoint Blood Analysis System/1994/—
Number of devices sold in U.S./outside U.S./List price	778 worldwide/$45,000	>4,100 worldwide/$50,000	6,000 worldwide/—
Dimensions (H x W x D)/Weight	17.5 × 13 × 11.8 inches/31.2 pounds	18 × 12 × 15 inches/44 pounds	11.5 × 9.5 × 5 inches/5 pounds, 4 ounces
Analytes measured on device	pH, pO2, pCO2, Hct, Na+, K+, Ca++, glucose, lactate	pH, pCO2, pO2, Hct, Na, K, Cl, iCa, lactate, glucose, tHb, O2Hb, COHb, MetHb, HHb, tBili	pH, pCO2, pO2, Hct, Na, K, Cl, iCa, glucose, BUN, creatinine, lactate
Parameters calculated on device	A-aDo2, Hb, pAO2, paO2/pAO2, RI, O2cap*, O2Ct*, CtO2*, CaO2*, CvO2*, CcO2*, a-Qsp/Qt, P50, HCO3-, tCO2-, BEB, BEcecf, SO2c	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), others	Hb, O2SAT, BEb, BEecf, TCO2, HCO3-, iCa(n), creatinine MDRD-GFR
Barometric pressure	—	—	measured
Analytical method(s) or technologies employed	pH, pCO2: potentiometry; pO2, glucose, lactate, Na, iCa, K: amperometry; Hct: conductivity; potentiometric ion-selective electrode	pH, pCO2: potentiometry; pO2, glucose, lactate: amperometry; Hct: conductivity; Hb, tBili: 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
Device is part of a series of related models	yes	yes	yes
Device warranty/Loaner devices provided	5 years/yes	5 years/yes	1 year/yes
Average life expectancy of device	7–10 years	7–10 years	7 years
Open or closed system/External gas tanks required	closed/no	closed/no	closed/no
Categorized for point-of-care testing or laboratory	point-of-care testing and laboratory	point-of-care testing and laboratory	point-of-care testing
Point of care:			
Disposable prepackaged system used for analysis	multi-use cartridge	multi-use cartridge	reagent/electrode (single use)
No. of disposable reagent system units in standard package	1 per pack	1 per pack	25 per box
No. of samples analyzed per one disposable reagent, electrode system	75-, 150-, 300-, 450-, and 600-test cartridge	cartidges available: 75, 150, 300, 450, 600	1
Reagent unit storage requirements	room temperature	room temperature	room temperature; creatinine 2°–8°C
Shelf life of disposable units	6 months	6 months	up to 6 months
Laboratory:			
No. of different disposable reagents required to maintain device	1	1	—
Max. No. of analyte reagents that can reside in device at once	1 multi-use cartridge	1 multi-use cartridge	—
Shelf life of components	6 months	6 months (cartridge)	—
Cost per test/Reagent cost per test	varies with size and menu	varies with cartridge size and menu/—	—
Calibrations required	automated continuous with iQM	automated continuous with iQM	2 point (automatic)
Calibration frequency	automated continuous with iQM	automated continuous with iQM	automatic with each sample
Internal QC program recommended	internal, automated, continuous quality management included	internal, automated, continuous quality management included	automatic electronic QC per 8 hours
QC features/Capabilities of QC features	onboard Intelligent Quality Management/monthly report includes number of measurements, mean, maximum, and minimum delta values	onboard Intelligent Quality Management/monthly report includes number of measurements, mean, maximum, and minimum delta values	L-J plots/statistical calculations, monthly cumulative reports (IDMS)
Remote control of device from laboratory	yes	yes	yes
System can use LOINC to transmit results to LIS	no	no	no
Specimen types suitable for device	whole blood, arterial, venous, or capillary	whole blood, capillary, mixed venous, arterial, venous	whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants/Sampling technique	heparin/aspiration	heparin/aspiration	heparin, EDTA (glucose strip only)/injection
Sample size for complete panel of analyte results	135–150 µL	150 µL, 95 µL (electrochemical only), 65 µL micro mode (electrochemical only)	125 µL capillary, 200 µL syringe
Sample size differs with number of analytes selected	no	yes	no
Time from sample introduction to result availability	85 seconds	70 seconds for electrochemical; 25 additional seconds for CO-ox	60–90 seconds on average
Maximum No. of patient samples per hour/Maximum No. measured results per hour	20/180	20/300	25/175
Optimal throughput when analyzer calibrated, awaiting specimens	20 samples per hour	20 samples per hour	20 samples per hour
Calibration can be interrupted to perform stat sample	yes	yes	—
Known interferences	—	interfering substance detected, operator notified	—
Sampler has self-wiping probe	yes	yes	no, not needed
Time required for maintenance by lab personnel	none (disposable cartridge)	none	none
Service center performs diagnostics through modem	no (but can through VPN)	no (but can through VPN)	no
Method of analyst ID in system	manual or bar-code entry of ID and password (customizable)	wireless bar-code gun or manual virtual keyboard entry	LCD touchscreen, numeric (customizable)
Instrument response for:			
• hardware failure/software failure	operator warning, sampling lockout	operator warning, sampling lockout	EQC failure or screen prompt; software: screen prompt
• QC failure	channel flagged	iQM disables analyte channel; no result reported	if QC required, no access to patient testing mode
• calibration failure	no results for channel	system automatically performs checks before samples can be analyzed	test ends–no injection of sample allowed
For what bar-code scanning is provided	operator and patient IDs, QC values	operator and patient IDs, cartridge lot number and expiration date	operator and patient IDs, cartridge information, lot number, quality control ranges
Built-in printer/Data port	yes/4 USB, 3 RS-232, 1 parallel, bar-code reader port, Ethernet	yes/4 RS-232, 1 parallel port, 1 Ethernet port, 4 USB ports	yes/RS-232, modem, Ethernet, LAN
Information listed on hard copy report	patient demographics, hospital name and address, results	patient demographics, hospital info, results, result flags and legend, reference and critical ranges (optional), comments, notification info	analyzer serial number, date, calibration successful, calibration code, lot number, patient ID and temperature, results, barometric pressure, SW version optional: user ID, reference ranges, O2 therapy, sample information
Analyzer connections	GEMweb, GEMweb Plus, Impact for Critical Care	LIS/HIS via direct interface or GEMweb Plus Custom Connectivity; vendor-neutral or Web-based systems	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options)
Interface standards supported	ASTM and HL7 protocols	ASTM 1394, HL7	IRMA (ASTM protocol), IDMS (script, HL7, or EDI)
How analyzer connects to external system to upload patient and QC results	direct serial, Ethernet, modem dial-in	direct serial, hospital network, real-time wireless	hospital network, direct serial, LAN
Information included in transmission from analyzer to external system	device identifier, operator and patient IDs, results, QC ID and results	device identifier, operator and patient IDs, results, QC ID	device unique identifier, operator and patient IDs, results, QC identifier, patient O2 therapy information
Hardware and software for data management system	GEMweb, GEMweb Plus, Impact for Critical Care	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	customizable	4	24
Contents downloaded from data management system to analyzer	patient ID, demographics	most configuration information, including valid operator IDs, QC lots, and ranges	all analyzer settings, software upgrades
System connected (live installations) to which LISs, HISs	major HIS/LIS vendors	major HIS/LIS vendors	major HIS/LIS vendors
Use a third-party interfacing tool, engine for LIS, HIS interfaces	MAS/RALS, Telcor	MAS/RALS, Telcor	yes
Distinguishing features (provided by company)	iQM detects, corrects, and documents instrument errors, reducing error detection time to minutes; maintenance-free, multi-use cartridge available in customizable configurations for use in any hospital location; wireless communication to LIS or HIS	iQM detects, corrects, documents instrument errors, reducing error detection time to minutes; single component, multi-use GEM Premier 4000 cartridge includes all testing components, is changed every 30 days, requires no refrigeration or maintenance; GEMweb Plus Custom Connectivity software allows access and control from any networked PC or GEM Premier 4000 analyzer	self-contained and easy to use; contains onboard printer, interactive touchscreen, bar-code scanning, automatic electronic QC, and site-specific custom correlation reference ranges; complete data management from patient information to lot traceability; self-calibrating cartridges with Luer lockport, which forms a closed system and reduces biohazards

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

In vitro blood gas analyzers

Part 3 of 8	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	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813
Name of device/First year sold/Number of analyzers sold in 2010	Stat Profile pHOx Basic/2002/—	Stat Profile pHOx/1998/—	Stat Profile pHOx Respiratory/2006/—
Number of devices sold in U.S./outside U.S./List price	—	—	—
Dimensions (H x W x D)/Weight	15 × 12 × 15 inches/18 pounds	15 × 12 × 15 inches/18 pounds	15 × 12 × 15 inches/18 pounds
Analytes measured on device	pH, pCO2, pO2	pH, PCO2, PO2, Hct, Hb, SO2%	pH, PCO2, PO2, Hct, Hb, SO2%, lactate
Parameters calculated on device	BE, TCO2, HCO3-	BE, TCO2, HCO3-	BE, TCO2, HCO3-
Barometric pressure	tracked	tracked	tracked
Analytical method(s) or technologies employed	pH: direct ISE; PCO2: Severinghaus; PO2: amperometry	pH: direct ISE; PCO2: Severinghaus; PO2: amperometry; Hct: conductivity; Hb and SO2%: optical–reflectance	pH: direct ISE; PCO2: Severinghaus; PO2: amperometry; Hct: conductivity; Hb and SO2%: optical–reflectance; lactate: enzyme/amperometric
Device is part of a series of related models	yes	yes	yes
Device warranty/Loaner devices provided	1 year, repair or replace any part, including labor/yes	1 year, travel and labor, repair, or replacement/yes	1 year, travel and labor, repair, or replacement/yes
Average life expectancy of device	5–7 years	5–7 years	5–7 years
Open or closed system/External gas tanks required	closed/no	closed/no	closed/no
Categorized for point-of-care testing or laboratory	point-of-care testing and laboratory	point-of-care testing and laboratory	point-of-care testing and laboratory
Point of care:			
Disposable prepackaged system used for analysis	reagent	reagent	reagent
No. of disposable reagent system units in standard package	200 to 500 analyses	200 to 500 analyses	200 to 500 analyses
No. of samples analyzed per one disposable reagent, electrode system	—	—	—
Reagent unit storage requirements	room temperature	room temperature	room temperature
Shelf life of disposable units	reagents: 18 months at room temperature; electrodes: up to 18 months	reagents: 18 months at room temperature; electrodes: up to 18 months	reagents: 18 months at room temperature; electrodes: up to 18 months
Laboratory:			
No. of different disposable reagents required to maintain device	1	1	1
Max. No. of analyte reagents that can reside in device at once	1	1	1
Shelf life of components	reagents and electrodes: 18 months; membrane kits: 12 to 24 months	reagents and electrodes: 18 months; membrane kits: 12 to 24 months	reagents and electrodes: 18 months; membrane kits: 12 to 24 months
Cost per test/Reagent cost per test	<$0.11 at 35 analyses per day/<$0.08 at 35 analyses per day	<$0.11 at 35 analyses per day/<$0.08 at 35 analyses per day	<$0.11 at 35 analyses per day/<$0.08 at 35 analyses per day
Calibrations required	1 and 2 point (automatic)	1 and 2 point (automatic)	1 and 2 point (automatic)
Calibration frequency	1 point: 30 or 45 minutes or with every sample (user selectable); 2 point: 2, 4, or 6 hours (user defined)	1 point: 30 or 45 minutes or with every sample (user selectable); 2 point: 2, 4, or 6 hours (user defined)	1 point: 30 or 45 minutes or with every sample (user selectable); 2 point: 2, 4, or 6 hours (user defined)
Internal QC program recommended	minimum CLIA recommendations	minimum CLIA recommendations	minimum CLIA recommendations
QC features/Capabilities of QC features	L-J plots/statistical calculations, monthly cumulative report (onboard, more extensive reporting available with Nova Point-of-Care Manager)	L-J plots/statistical calculations, monthly cumulative report (onboard, more extensive reporting available with Nova Point-of-Care Manager)	L-J plots/statistical calculations, monthly cumulative report (onboard, more extensive reporting available with Nova Point-of-Care Manager)
Remote control of device from laboratory	no	no	no
System can use LOINC to transmit results to LIS	no	no	no
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial	whole blood, capillary, mixed venous, arterial	whole blood, capillary, mixed venous, arterial
Acceptable anticoagulants/Sampling technique	heparin/aspiration and capillary	heparin/aspiration and capillary	heparin/aspiration and capillary
Sample size for complete panel of analyte results	70 µL	70 µL	125 µL
Sample size differs with number of analytes selected	yes, standard three-test blood gas micro-panel sample required is 45 µL	yes, standard 3-test blood gas micro-panel sample required is 45 µL	yes, standard 3-test micro-panel required is 60 µL
Time from sample introduction to result availability	45 seconds	45 seconds	52 seconds
Max. No. of patient samples per hour/Max. No. measured results per hour	300/300 tests	300/300 tests	50/500 tests
Optimal throughput when analyzer calibrated, awaiting specimens	300 tests per hour	300 tests per hour	300 tests per hour
Calibration can be interrupted to perform stat sample	yes	yes	yes
Known interferences	—	—	—
Sampler has self-wiping probe	yes	yes	yes
Time required for maintenance by lab personnel	weekly: <5 minutes; monthly: <10 minutes	weekly: <5 minutes; monthly: <10 minutes	weekly: <5 minutes; monthly: <10 minutes
Service center performs diagnostics through modem	yes	yes	yes
Method of analyst ID in system	password with unique user ID number (optional)	password with unique user ID number (optional)	password with unique user ID number (optional)
Instrument response for:			
• hardware failure/software failure	self-diagnosis software informs and notifies operator of HW and SW failure; hotline and field support	self-diagnosis software informs and notifies operator of HW and SW failure; hotline and field support	self-diagnosis software informs and notifies operator of HW and SW failure; hotline and field support
• QC failure	options range from flagging to not reporting test to lock-out for QC failure or exceeding scheduled QC interval	options range from flagging to not reporting test to lock-out for QC failure or exceeding scheduled QC interval	options range from flagging to not reporting test to lock-out for QC failure or exceeding scheduled QC interval
• calibration failure	any test that does not calibrate will not report results and instrument notifies operator of reason for failure	any test that does not calibrate will not report results and instrument notifies operator of reason for failure	any test that does not calibrate will not report results and instrument notifies operator of reason for failure
For what bar-code scanning is provided	patient ID	patient ID	patient ID
Built-in printer/Data port	yes/multiple RS-232	yes/multiple RS-232	yes/multiple RS-232
Information listed on hard copy report	patient ID with accession number, entered settings, measures and calculates results	patient ID with accession number, entered settings, measures and calculates results	patient ID with accession number, entered settings, measures and calculates results
Analyzer connections	data-management system that connects to LIS/HIS	data-management system or directly to LIS/HIS, or both	data-management system or directly to LIS/HIS, or both
Interface standards supported	ASTM E1381-91 and ASTM 1394-91 (HL7 available with external device)	ASTM E1381-91 and ASTM 1394-91 (HL7 available with external device)	ASTM E1381-91 and ASTM 1394-91 (HL7 available with external device)
How analyzer connects to external system to upload patient and QC results	direct serial/>500 hospitals institutions; hospital network/>100 institutions	direct serial/>500 hospitals institutions; hospital network/>100 institutions	direct serial/>500 hospitals institutions; hospital network/>100 institutions
Information included in transmission from analyzer to external system	device-unique identifier, operator and patient IDs, results, QC identifier, accession number	device-unique identifier, operator and patient IDs, results, QC identifier, accession number	device-unique identifier, operator and patient IDs, results, QC identifier, accession number
Hardware and 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	Pentium with Microsoft Windows 2000/Nova Point-of-Care Manager
No. of different management reports system produces	>60	>60	>60
Contents downloaded from data management system to analyzer	—	yes, patient name, passwords	yes, patient name, passwords
System connected (live installations) to which LISs, HISs	—	—	—
Use a third-party interfacing tool, engine for LIS, HIS interfaces	yes	yes	yes
Distinguishing features (provided by company)	onboard auto-cartridge QC; all-liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration and waste collection	onboard auto-cartridge QC; all-liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration and waste collection	onboard auto-cartridge QC; all-liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration and waste collection

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

In vitro blood gas analyzers

Part 4 of 8	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	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813
Name of device/First year sold/Number of analyzers sold in 2010	Stat Profile pHOx Plus/2000/—	Stat Profile pHOx Plus L/2001/—	Stat Profile pHOx Plus C/2003/—
Number of devices sold in U.S./outside U.S./List price	—	—	—
Dimensions (H x W x D)/Weight	15 × 12 × 15 inches/18 pounds	15 × 12 × 15 inches/18 pounds	15 × 12 × 15 inches/18 pounds
Analytes measured on device	pH, PCO2, PO2, Hct, Hb, SO2%, Na, K, Cl or iCa, glucose	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-	BE, TCO2, HCO3-
Barometric pressure	tracked	tracked	tracked
Analytical method(s) or technologies employed	pH: direct ISE; PCO2: Severinghaus; PO2: amperometry; Hct: conductivity; Hb and SO2%: optical–reflectance; Na, K, Cl, iCa: direct ISE; glucose: enzyme/amperometric	pH: direct ISE; PCO2: Severinghaus; PO2: amperometry; Hct: conductivity; Hb and SO2%: optical–reflectance; Na, K, Cl, iCa: direct ISE; glucose, lactate: enzyme/amperometric	pH: direct ISE; PCO2: Severinghaus; PO2: amperometry; Hct: conductivity; Hb and SO2%: optical–reflectance; Na, K, Cl, iCa: direct ISE; glucose: enzyme/amperometric
Device is part of a series of related models	yes	yes	yes
Device warranty/Loaner devices provided	1 year, travel and labor, repair or replacement/yes	1 year, travel and labor, repair or replacement	1 year, travel and labor, repair or replacement
Average life expectancy of device	5–7 years	5–7 years	5–7 years
Open or closed system/External gas tanks required	closed/no	closed/no	closed/no
Categorized for point-of-care testing or laboratory	point-of-care testing and laboratory	point-of-care testing and laboratory	point-of-care testing and laboratory
Point of care:			
Disposable prepackaged system used for analysis	reagent	reagent	reagent
No. of disposable reagent system units in standard package	200 to 500 analyses	200 to 500 analyses	200 to 500 analyses
No. of samples analyzed per one disposable reagent, electrode system	—	—	—
Reagent unit storage requirements	room temperature	room temperature	room temperature
Shelf life of disposable units	reagents: 18 months at room temperature; electrodes: up to 18 months	reagents: 18 months at room temperature; electrodes: up to 18 months	reagents: 18 months at room temperature; electrodes: up to 18 months
Laboratory:			
No. of different disposable reagents required to maintain device	1	1	1
Max. No. of analyte reagents that can reside in device at once	1	1	1
Shelf life of components	reagents and electrodes: 18 months; membrane kits: 12 to 24 months	reagents and electrodes: 18 months; membrane kits: 12 to 24 months	reagents and electrodes: 18 months; membrane kits: 12 to 24 months
Cost per test/Reagent cost per test	<$0.11 at 35 analyses per day/<$0.08 at 35 analyses per day	<$0.11 at 35 analyses per day/<$0.08 at 35 analyses per day	<$0.11 at 35 analyses per day/<$0.08 at 35 analyses per day
Calibrations required	1 and 2 point (automatic)	1 and 2 point (automatic)	1 and 2 point (automatic)
Calibration frequency	1 point: 30 or 45 minutes or with every sample (user selectable); 2 point: 2, 4, or 6 hours (user defined)	1 point: 30 or 45 minutes or with every sample (user selectable); 2 point: 2, 4, or 6 hours (user defined)	1 point: 30 or 45 minutes or with every sample (user selectable); 2 point: 2, 4, or 6 hours (user defined)
Internal QC program recommended	minimum CLIA recommendations	minimum CLIA recommendations	minimum CLIA recommendations
QC features/Capabilities of QC features	L-J plots/statistical calculations, monthly cumulative report (onboard, more extensive reporting available with Nova Point-of-Care Manager)	L-J plots/statistical calculations, monthly cumulative report (onboard, more extensive reporting available with Nova Point-of-Care Manager)	L-J plots/statistical calculations, monthly cumulative report (onboard, more extensive reporting available with Nova Point-of-Care Manager)
Remote control of device from laboratory	no	no	no
System can use LOINC to transmit results to LIS	no	no	no
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial	whole blood, capillary, mixed venous, arterial, serum plasma	whole blood, capillary, mixed venous, arterial, serum plasma
Acceptable anticoagulants/Sampling technique	heparin/aspiration and capillary	heparin/aspiration and capillary	heparin/aspiration and capillary
Sample size for complete panel of analyte results	115 µL	125 µL	125 µL
Sample size differs with number of analytes selected	yes, micro-panel; standard 3-test micro-panel required is 55 µL	yes, standard 3-test micro-panel required is 60 µL	yes, standard 3-test micro-panel required is 60 µL
Time from sample introduction to result availability	50 seconds	52 seconds	52 seconds
Maximum No. of patient samples per hour/Maximum No. measured results per hour	50/500 tests	50/500 tests	50/500 tests
Optimal throughput when analyzer calibrated, awaiting specimens	300 tests per hour	300 tests per hour	300 tests per hour
Calibration can be interrupted to perform stat sample	yes	yes	yes
Known interferences	—	none	none
Sampler has self-wiping probe	yes	yes	yes
Time required for maintenance by lab personnel	weekly: <5 minutes; monthly: <10 minutes	weekly: <5 minutes; monthly: <10 minutes	weekly: <5 minutes; monthly: <10 minutes
Service center performs diagnostics through modem	yes	yes	yes
Method of analyst ID in system	password with unique user ID number (optional)	password with unique user ID number (optional)	password with unique user ID number (optional)
Instrument response for:			
• hardware failure/software failure	self-diagnosis software informs and notifies operator of HW and SW failure; hotline and field support	self-diagnosis software informs and notifies operator of HW and SW failure; hotline and field support	self-diagnosis software informs and notifies operator of HW and SW failure; hotline and field support
• QC failure	options range from flagging to not reporting test to lock-out for QC failure or exceeding scheduled QC interval	options range from flagging to not reporting test to lock-out for QC failure or exceeding scheduled QC interval	options range from flagging to not reporting test to lock-out for QC failure or exceeding scheduled QC interval
• calibration failure	any test that does not calibrate will not report results and instrument notifies operator of reason for failure	any test that does not calibrate will not report results and instrument notifies operator of reason for failure	any test that does not calibrate will not report results and instrument notifies operator of reason for failure
For what bar-code scanning is provided	patient ID	patient ID	patient ID
Built-in printer/Data port	yes/multiple RS-232	yes/multiple RS-232	yes/multiple RS-232
Information listed on hard copy report	patient ID with accession number entered settings, measures and calculates results	patient ID with accession number entered settings, measures and calculates results	patient ID with accession number entered settings, measures and calculates results
Analyzer connections	data-management system or directly to LIS/HIS, or both	data-management system or directly to LIS/HIS, or both	data-management system or directly to LIS/HIS, or both
Interface standards supported	ASTM E1381-91 and ASTM 1394-91 (HL7 available with external device)	ASTM E1381-91 and ASTM 1394-91 (HL7 available with external device)	ASTM E1381-91 and ASTM 1394-91 (HL7 available with external device)
How analyzer connects to external system to upload patient and QC results	direct serial/>500 hospitals institutions; hospital network/>100 institutions	direct serial/>500 hospitals institutions; hospital network/>100 institutions	direct serial/>500 hospitals institutions; hospital network/>100 institutions
Information included in transmission from analyzer to external system	device unique identifier, operator and patient IDs, results, QC identifier, accession number	device unique identifier, operator and patient IDs, results, QC identifier, accession number	device unique identifier, operator and patient IDs, results, QC identifier, accession number
Hardware and 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	Pentium with Microsoft Windows 2000/Nova Point-of-Care Manager
No. of different management reports system produces	>60	>60	>60
Contents downloaded from data management system to analyzer	yes, patient name, passwords	yes, patient name, passwords	yes, patient name, passwords
System connected (live installations) to which LISs, HISs	—	—	—
Use a third-party interfacing tool, engine for LIS, HIS interfaces	yes	yes	yes
Distinguishing features (provided by company)	onboard auto-cartridge QC; all-liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration and waste collection	onboard auto-cartridge QC; all-liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration and waste collection	onboard auto-cartridge QC; all-liquid calibration cartridge eliminates gas tanks; single reagent cartridge has all supplies for calibration and waste collection

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

In vitro blood gas analyzers

Part 5 of 8	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	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/Number of analyzers sold in 2010	Stat Profile Critical Care Xpress/2003/—	Stat Profile Critical Care Xpress 3 Plus/2003/—	OPTI R/2006/—
Number of devices sold in U.S./outside U.S./List price	—	—	—
Dimensions (H x W x D)/Weight	17.2 × 22.4 × 17.3 inches/53 pounds	17.2 × 22.4 × 17.3 inches/53 pounds	4.7 × 14.2 × 14 inches/4.5 kg (10 pounds) without fluid pack
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	pH, pCO2, pO2, tHb, Na, K, iCa, SO2
Parameters calculated on device	BE, TCO2, HCO3-	BE, TCO2, HCO3-	Hct, HCO3, BE, BEecf, BEact, BB, tCO2, st. HCO3, st. pH, O2ct, cH+, AaDO2, AG, p50, nCa++
Barometric pressure	tracked	tracked	measured
Analytical method(s) or technologies employed	pH: direct ISE; pCO2: Severinghaus; pO2: amperometric; Hct: conductivity; Hb and SO2%: optical-reflectance; Na, K, Cl, iMg, and iCa: direct ISE; lactate, glucose, and creatinine: enzyme/amperometric; BUN: enzyme/ISE; bilirubin, CO-ox: optical, reflectance	pH: direct ISE; pCO2: Severinghaus; pO2: amperometric; CO-ox: optical-reflectance	optical fluorescence and reflectance
Device is part of a series of related models	yes	yes	yes, Opti series
Device warranty/Loaner devices provided	1 year	1 year/yes	1 year (service contract available for subsequent years)/yes
Average life expectancy of device	5–7 years	5–7 years	7 years
Open or closed system/External gas tanks required	closed/no	closed/no	closed/no
Categorized for point-of-care testing or laboratory	point-of-care testing and laboratory	point-of-care testing and laboratory	point-of-care testing and laboratory
Point of care:			
Disposable prepackaged system used for analysis	reagent	reagent	reagent/multi-use cartridge
No. of disposable reagent system units in standard package	200–500 analyses	200–500 analyses	4
No. of samples analyzed per one disposable reagent, electrode system	—	—	50
Reagent unit storage requirements	no special requirements	no special requirements	room temperature
Shelf life of disposable units	reagents: 18 months (at room temperature); electrodes: up to 18 months	reagents: 18 months (at room temperature); electrodes: up to 18 months	cassette: 7 months; fluid pack: 12 months
Laboratory:			
No. of different disposable reagents required to maintain device	1	1	2
Max. No. of analyte reagents that can reside in device at once	20	7	8
Shelf life of components	reagents and electrodes: 18 months; membrane kits: 12–24 months	reagents and electrodes: 18 months; membrane kits: 12–24 months	cassette: 7 months; fluid pack: 12 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	depends on volume
Calibrations required	1 and 2 point (automatic)	1 and 2 point (automatic)	2 point (automatic)
Calibration frequency	1 point: 30 or 45 minutes or with every sample (user selectable); 2 point: 2, 3, 4, 5, or 6 hours (user defined)	1 point: 30 or 45 minutes or with every sample (user selectable); 2 point: 2, 3, 4, 5, or 6 hours (user defined)	1 point: after every sample or 30 minutes; 2 point: every 3 hours
Internal QC program recommended	minimum CLIA recommendations	minimum CLIA recommendations	minimum CLIA recommendations; auto QC can be programmed to meet requirements
QC features/Capabilities of QC features	L-J plots/statistical calculations, monthly cumulative report (onboard, more extensive reporting available with Nova Point-of-Care Manager)	L-J plots/comparable plot, statistical calculations, monthly cumulative report, onboard, available with external system	—/auto QC, statistics reports
Remote control of device from laboratory	no	no	no
System can use LOINC to transmit results to LIS	yes	yes	yes
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial, venous	whole blood, capillary, mixed venous, arterial, venous	plasma, serum, whole blood
Acceptable anticoagulants/Sampling technique	heparin/aspiration and capillary	heparin/aspiration and capillary	heparin/aspiration and capillary
Sample size for complete panel of analyte results	210 µL	210 µL	125 µL
Sample size differs with number of analytes selected	yes, variety of micro-panel options offered and can be customized	yes, variety of micro-panel options offered and can be customized	no
Time from sample introduction to result availability	134 seconds	61 seconds	~1 minute
Maximum No. of patient samples per hour/Maximum No. measured results per hour	22/440	32/224	24/192
Optimal throughput when analyzer calibrated, awaiting specimens	437 tests per hour	190 tests per hour	24 per hour
Calibration can be interrupted to perform stat sample	yes	yes	no
Known interferences	none	none	—
Sampler has self-wiping probe	yes	yes	no
Time required for maintenance by lab personnel	weekly: <5 minutes; monthly: <10 minutes	weekly: <5 minutes; monthly: <10 minutes	weekly: 1 minute; quarterly: 5 minutes
Service center performs diagnostics through modem	yes	yes	no
Method of analyst ID in system	multilevel password with unique user ID number	multilevel password with unique user ID number	bar code or secure PIN for 300 operators
Instrument response for:			
• hardware failure/software failure	self-diagnosis software informs and notifies operator of HW and SW failure; hotline and field support	self-diagnosis software informs and notifies operator of HW and SW failure; hotline and field support	error message
• QC failure	options range from flagging to not reporting test to lockout for QC failure or exceeding scheduled QC interval	options range from flagging to not reporting test to lockout for QC failure or exceeding scheduled QC interval	QC lockout
• calibration failure	any test that does not calibrate will not report results and instrument notifies operator of reason for failure	any test that does not calibrate will not report results and instrument notifies operator of reason for failure	error message with automatic retry
For what bar-code scanning is provided	operator and patient IDs	operator and patient IDs	operator and patient IDs, reagent, QC
Built-in printer/Data port	yes/Ethernet, USB	yes/Ethernet, USB	yes/RS-232, Ethernet
Information listed on hard copy report	patient ID and accession numbers, entered settings, measured and calculated results	patient ID and accession numbers, entered settings, measured and calculated results	patient ID, results, patient demographics (customized), critical ranges
Analyzer connections	directly to LIS/HIS, DMS that in turn connects to LIS/HIS	directly to LIS/HIS, DMS that in turn connects to LIS/HIS	directly to LIS/HIS, DMS that in turn connects to LIS/HIS, Prism POC data manager
Interface standards supported	ASTM E1394-91, ASTM 1381-91, HL7	ASTM E1394-91, ASTM 1381-91, HL7	ASTM, ASCII
How analyzer connects to external system to upload patient and QC results	modem dial-in, hospital network	modem dial-in, hospital network	direct serial, Ethernet hospital network
Information included in transmission from analyzer to external system	device unique identifier, operator and patient IDs, results, QC identifier	device unique identifier, operator and patient IDs, results, QC identifier	device unique identifier, operator and patient IDs, results, QC identifier, all information pertinent to patient and QC data
Hardware and software for data management system	full-featured onboard DMS capability, external DMS also available	full-featured onboard DMS capability, external DMS also available	Prism POC data manager
No. of different management reports system produces	>30	>30	40
Contents downloaded from data management system 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	—		Meditech, McKesson, Cerner, Siemens, others
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 company)	large whole blood critical care menu (20 tests), BUN, iMg available exclusively from Nova; onboard CO-oximeter	onboard QC cartridge provides sufficient QC materials for 30-day autmatic QC analysis; allows user to program frequency and select report protocol with full QC SMD	three independent levels of automatic QC, stable optical fluorescence technology, multiple-use cassette, low maintenance, and color touchscreen

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

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In vitro blood gas analyzers

Part 6 of 8	Opti Medical Systems Inc. Sales Department 235 Hembree Park Drive, Roswell, GA 30076 800-490-6784 www.optimedical.com	Radiometer America Inc. Telesales Department info@radiometeramerica.com 810 Sharon Drive, Westlake, OH 44145 800-736-0600 www.radiometeramerica.com	Radiometer America Inc. Telesales Department info@radiometeramerica.com 810 Sharon Drive, Westlake, OH 44145 800-736-0600 www.radiometeramerica.com
Name of device/First year sold/Number of analyzers sold in 2010	OPTI CCA-TS Blood Gas Analyzer/2003/—	ABL90 FLEX/2010 in U.S./—	ABL 800 Series/2004/—
Number of devices sold in U.S./outside U.S./List price	—	—/—/$40,000	—/—/depends on configuration
Dimensions (H x W x D)/Weight	4.7 × 14.2 × 9 inches/12 pounds (10 lbs w/o battery)	17.7 × 9.8 × 11.4 inches/24 pounds	22 × 28 × 21 inches/70 pounds
Analytes measured on device	pH, pCO2, pO2, Na, K, Cl, iCa, tHb, SO2, glucose, BUN, lactate	pH, pCo2, p02, Hb, Na, K,Cl, iCa, lactate, glucose, sO2, tHb, FO2Hb, FCOHb, FMetHb, FHHb, FHbF	pH, pCO2, p02, Hb, Na, K, Cl, iCa, lactate, glucose, bilirubin, fetal Hb, O2Hb, MetHb, RHb, COHb, O2SAT, creatinine
Parameters calculated on device	Hct, HCO3, BE, BEecf, BEact, BB, tCO2, st. HCO3, st. pH, O2ct, cH+, AaDO2, AG, p50, nCa++	Hct, BE, TCO2, HCO3, and 44 additional parameters	Hct, BE, TCO2, HCO3-, plus 40 additional parameters
Barometric pressure	measured	recorded, measured	measured
Analytical method(s) or technologies employed	optical fluorescence and reflectance	pH, iCa, pCO2, lactate, glucose, Na, Cl, K: thick film, potentiometric analysis; pO2: optical phosphorescence; Hct: calculation; Hb: multi-wavelength CO-ox spectrophotometric analysis	pH: pH-sensitive glass (ISE); pCO2, pO2, Na, Cl, iCa, K, ISE; Hct: calculated from measuring Hb, bilirubin; Hb: optical, multiwavelength analysis, intra-cuvette ultrasonic hemolysis, and more
Device is part of a series of related models	yes, Opti series	no	yes, ABL 800 series
Device warranty/Loaner devices provided	1 year (service contract available for subsequent years)/yes	1 year (parts, labor, and travel) with service plans available after year one/yes	2 years, parts, labor, and travel/yes
Average life expectancy of device	>7 years	10+ years	20 years, with full support
Open or closed system/External gas tanks required	closed/no	closed/no	closed/yes (low-pressure, premixed)
Categorized for point-of-care testing or laboratory	point-of-care testing and laboratory	point-of-care testing and laboratory	point-of-care testing and laboratory
Point of care:			
Disposable prepackaged system used for analysis	single-use cassettes	reagent, electrode (multiuse cartridge)	—
No. of disposable reagent system units in standard package	25 individual packaged cassettes	1	—
No. of samples analyzed per one disposable reagent, electrode system	1	100, 300, 600, 900	—
Reagent unit storage requirements	room temperature	small SC only needs refrigeration	—
Shelf life of disposable units	cassette: 6–12 months, depends on type	reagent/electrode system: four months	—
Laboratory:			
No. of different disposable reagents required to maintain device	1	2	4
Max. No. of analyte reagents that can reside in device at once	8	all	4
Shelf life of components	cassette: 6–8 months, depends on type	reagent and sensor cartridge: four months	reagent, electrode, membrane kit, cartridge: 2+ years
Cost per test/Reagent cost per test	depends on volume	depends on configuration/depends on configuration	depends on sample volume and any extra included items/same
Calibrations required	1 point (automatic)	1 and 2 point (manual and automatic)	1 and 2 point (automatic)
Calibration frequency	with each cassette	1 point with each sample analysis; 2 point every 8 hours (user configurable)	1 point: 1/2 hour BG/pH, 4 hours—manufacturer; 2 point: every 8 hours
Internal QC program recommended	minimum CLIA recommendations; electronic QC can be used for daily QC requirements	standard QC according to CAP, CLIA, JCAHO guidelines; user configurable for increased QC frequency	depends on hospital management and inspection agency
QC features/Capabilities of QC features	—/electronic QC, statistics reports	L-J plots, comparable plot via DMS/auto QC (statistical calculations, monthly cumulative reports, on board and through DMS)	L-J plots/comparable plot (via DMS), statistical calcs., automatic QC, monthly cumulative reports (onboard and available with external system)
Remote control of device from laboratory	no	—	yes
System can use LOINC to transmit results to LIS	yes	yes	yes
Specimen types suitable for device	plasma, serum, whole blood	whole blood, capillary, mixed venous, arterial, venous	whole blood, capillary, mixed venous, arterial, venous, expired air
Acceptable anticoagulants/Sampling technique	heparin/aspiration and capillary	heparin, electrolyte-balanced heparin/aspiration, auto aspiration, capillary, test tube, micro-sample	heparin, electrolyte-balanced heparin/autoaspiration, syringe and/or capillary tube and/or test tube
Sample size for complete panel of analyte results	125 µL	65 µL	95 µL for 17 measured parameters
Sample size differs with number of analytes selected	—	no	yes, with fewer measured parameters, smaller micro-modes available from 35 µL
Time from sample introduction to result availability	~1 minute from sample aspiration	35 seconds	~1 minute (depends on tests ordered)
Maximum No. of patient samples per hour/Maximum No. measured results per hour	24/192	50/800	25/425
Optimal throughput when analyzer calibrated, awaiting specimens	24 per hour	800 tests (equals 50 patient samples)	25 per hour
Calibration can be interrupted to perform stat sample	no	yes	yes
Known interferences	—	—	halothane, thiocyanic and glycolic acids
Sampler has self-wiping probe	no, single use	yes	yes
Time required for maintenance by lab personnel	weekly: 1 minute; quarterly: 5 minutes	monthly: as needed	monthly: as needed; annually: dependent on version
Service center performs diagnostics through modem	no	—	yes
Method of analyst ID in system	bar code or secure PIN for 300 operators	customizable user log-ons, bar code, on-board keyboard; built-in bar code scanner	customizable onboard keyboard, bar code
Instrument response for:			
• hardware failure/software failure	error message	system message; traffic light; audible, visual signals, parameter bar traffic light; self-correcting when possible	system message with customized ("traffic light") visual and audible signals, parameter status bar
• QC failure	QC lockout	same as hardware/software failure	—
• calibration failure	error message	same as hardware/software failure	—
For what bar-code scanning is provided	operator and patient IDs, reagent, QC	operator and patient IDs; uses smart-chips for reagents, no scanning needed	operator and patient IDs, reagent and QC lot numbers, expiration, software keys
Built-in printer/Data port	yes/RS-232, Ethernet	yes/RS-232, parallel, Ethernet, others	yes/RS-232, Ethernet/USB
Information listed on hard copy report	patient ID, results, patient demographics (customized), critical ranges	patient information and demographics, patient therapy settings, measured and calculated results, system messages, reference and critical values, analyzer set-up and configuration, and more	patient information/demographics, patient therapy settings, measures and calculates results, system messages, reference and critical ranges
Analyzer connections	directly to LIS/HIS, DMS that in turn connects to LIS/HIS, Prism POC data manager	directly to LIS/HIS; LIS/HIS, via data management system	RADIANCE stat information management system that connects to LIS/HIS or directly to LIS/HIS
Interface standards supported	ASTM, ASCII	ASTM 1394, HL7, serial, POCT1-A, network, TCP/IP	ASTM, HL7, serial, POCT1A, network TCP/IP
How analyzer connects to external system to upload patient and QC results	direct serial, Ethernet hospital network	direct serial, hospital network	direct serial/thousands of hospitals 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 and patient IDs, results, QC identifier, all information pertinent to patient and QC data	device-unique identifier, operator and patient IDs, results, QC identifier, calibration and analyzer status	device-unique identifier, operator and patient IDs, results, QC identifier, per ASTM/HL7 standards plus calibration and analyzer status information
Hardware and software for data management system	Prism POC data manager	internal system and external: RADIANCE and all other DMS systems	internal system plus optional external system, RADIANCE
No. of different management reports system produces	40	standard and user definable reports	user-definable searches/reports
Contents downloaded from data management system to analyzer	—	valid operator IDs	—
System connected (live installations) to which LISs, HISs	Meditech, McKesson, Cerner, Siemens, others	Cerner, McKesson, Meditech, Sunquest, many others	Cerner, Meditech, Misys, others
Use a third-party interfacing tool, engine for LIS, HIS interfaces	—	no (an interfacing tool/engine could be used)	—
Distinguishing features (provided by company)	stable optical fluorescence technology, easy-to-use touchscreen, measured tHb and SO2, no standby costs (single-use system), low maintenance	fast results (35 seconds on 65 uL sample with 44–55 per hour throughput); easy to use: walk-up ready; one-handed operation with integrated user guides and no user maintenance; automatic quality management supports regulatory compliance requirements, performs continuous checks and corrective actions are performed automatically	IDMS-traceable creatinine; FLEXQ automated inlet part of automatic system; bilirubin and fetal Hb measured on whole blood with no extra sample volume, low maintenance and cost of operation

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

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In vitro blood gas analyzers

Part 7 of 8	Radiometer America Inc. Telesales Department info@radiometeramerica.com 810 Sharon Dr., Westlake, OH 44145 800-736-0600 www.radiometeramerica.com	Roche Diagnostics Tonya Sullivan tonya.sullivan@roche.com 9115 Hague Rd., Indianapolis, IN 46256 800-428-5076 www.mylabonline.com	Siemens Healthcare Diagnostics Inc. 1717 Deerfield Road Deerfield, IL 60015-0778 800-255-3232 www.siemens.com/diagnostics
Name of device/First year sold/Number of analyzers sold in 2010	ABL80/2006/—	Roche cobas b 221 system/2004/—	RAPIDPoint 500 system (in development, not for sale in the U.S.)/2011/—
Number of devices sold in U.S./outside U.S./List price	—/—/depends on configuration	—	—
Dimensions (H x W x D)/Weight	16 × 9 × 11 inches/19 pounds	23 × 20 × 23.6 inches/99 pounds (without solutions and AutoQC)	21.5 × 11.5 × 16 inches/36.5 pounds
Analytes measured on device	pH, pCO2, pO2, Hct, Na, K, iCa, Cl-, Glu, Hb, O2SAT, O2Hb, COHb, MetHb, HHb	pH, pCO2, pO2, Hct, Hb, Na, K, Cl, iCa, lactate, glucose, BUN, bilirubin, pH pleural fluid	pH, pCO2, pO2, Hb, Na, K, Cl, iCa, glucose, neonatal total bilirubin (pending clearance), CO-oximeter fractions (fO2Hb, fCOHb, fMetHb, fHHb)
Parameters calculated on device	Hb, O2SAT, TCO2, HCO3-, ctO2 (a-v), ctO2, anion gap (K+), cCa2+ (7.40), cBase (B), ABE, SBE, others	Hb, Hct, O2SAT, BE, TCO2, HCO3-	O2SAT, BE, TCO2, HCO3
Barometric pressure	—	recorded or measured	recorded
Analytical method(s) or technologies employed	pH, pCO2, pO2, Na, K, iCa, Cl, Glu: thick film; amperometric/potentiometric technology; HCT: conductivity	pH: electrode ion-selective galvanometric; pCO2, pO2: electrode ion selective membrane; Hct: conductivity; Hb: CO-ox spectrophotometry; Na, Cl, iCa, K: ion selective potentiometry; lactate, glucose, BUN: MSS sensor enzyme	pH, iCa, Na, Cl, K: potentiometry using ISE; pCO2: potentiometry based on severinghaus; pO2: amperometric; glucose: amperometric, glucose oxidase; Hb: spectrophotometric
Device is part of a series of related models	yes	yes, three models in series	no
Device warranty/Loaner devices provided	1 year, parts, labor, and travel, with service plans available after year 1/yes	1 year (parts and services warranty)/no	1 year/yes
Average life expectancy of device	analyzer: 10+ years	7 years	7–10 years
Open or closed system/External gas tanks required	closed/no	closed/no	closed/no
Categorized for point-of-care testing or laboratory	point-of-care testing and laboratory	point-of-care testing and laboratory	point-of-care testing and laboratory
Point of care:			
Disposable prepackaged system used for analysis	electrode (multi-use cartridge)	reagent and electrode	multi-use cartridge
No. of disposable reagent system units in standard package	1	depends on model, contact Roche	1 measurement and 1 wash-waste cartridge; 1 AQC cartridge
No. of samples analyzed per one disposable reagent, electrode system	50/100/200/300	dependent on use	250, 400, 750 samples
Reagent unit storage requirements	room temperature	room-temperature storage	measurement and AQC cartridge: refrigeration; wash/waste cartridge: room temperature
Shelf life of disposable units	90–100 days	12 months (reagents)/18 months (electrodes)	9 months
Laboratory:			
No. of different disposable reagents required to maintain device	2	depends on model, contact Roche	1 measurement and 1 wash-waste cartridge; 1 AQC cartridge
Max. No. of analyte reagents that can reside in device at once	2	3	1 measurement and 1 wash-waste cartridge; 1 AQC cartridge
Shelf life of components	reagent: 100 days, cartridge: 90 days	reagent: 1 year; electrode: 18 months onboard	cartridge: 9 months
Cost per test/Reagent cost per test	depends on configuration/same	volume-dependent/volume-dependent	—
Calibrations required	1 and 2 point (manual and automatic)	1 and 2 point (automatic)	1 and 2 point (manual and automatic)
Calibration frequency	1 point: with each test; 2 point: 8 hours (user definable)	1 point: 30 minutes; two point: 8 hours	one point: 30 minutes; two point: 2 hours
Internal QC program recommended	QC material according to CLIA, CAP, JCAHO	CAP and JCAHO guidelines	1 AQC cartridge; fully user programmable
QC features/Capabilities of QC features	L-J plots/statistical calculations, monthly cumulative (onboard–current mean, STD, CV%) reports (onboard and available with external system, PC download to Excel)	L-J plots/comparable plot, lot-to-lot comparisons, statistical calculations, monthly cumulative reports, onboard, eQAP	L-J plots/external RAPIDComm Data Management, statistical calculations, monthly cumulative reports
Remote control of device from laboratory	yes	yes	yes
System can use LOINC to transmit results to LIS	yes	yes	no
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial, venous	plasma, serum, whole blood, capillary, arterial, venous	whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants/Sampling technique	heparinized, electrolyte balanced heparin/aspiration	EDTA, heparin, citrate/aspiration, injection, capillary transfer and fill, microsamples	heparin/aspiration
Sample size for complete panel of analyte results	70 µL	200 µL for full panel	100 µL minimum
Sample size differs with number of analytes selected	no	yes, BG: 40 µL; ISE: 40 µL; CO-ox 44 µL, glucose, lactate, BUN: 75 µL	no
Time from sample introduction to result availability	90 seconds	~1 minute (test dependent)	~60 seconds
Maximum No. of patient samples per hour/Maximum No. measured results per hour	30/270	30/360	25/up to 325
Optimal throughput when analyzer calibrated, awaiting specimens	30 tests per hour	30 patients per hour (full panel)	25 samples per hour
Calibration can be interrupted to perform stat sample	yes	yes	yes
Known interferences	—	—	benzalkonium
Sampler has self-wiping probe	no	yes	yes
Time required for maintenance by lab personnel	—	daily: 2 minutes, monthly: 5 minutes, quarterly: 5 minutes	monthly: 1-minute cartridge replacement
Service center performs diagnostics through modem	no	yes	no
Method of analyst ID in system	customizable onboard keyboard, bar code	32-level password system (customizable)	password (customizable)
Instrument response for:			
• hardware failure/software failure	system message with customized (“traffic light”) visual and audible signals, parameter status bar	HW: identified onscreen and with diagnostic routine; SW: onscreen with messages	diagnostic codes/diagnostic codes
• QC failure	—	onscreen report with high/low flagging, lockout capabilities	fully customizable flags
• calibration failure	—	onscreen reporting with lockout capabilities	diagnostic codes
For what bar-code scanning is provided	operator and patient IDs, reagent and QC lot numbers, expiration, software keys	operator and patient IDs, reagent lot number, RF with transponders, expiration	operator and patient IDs
Built-in printer/Data port	yes/RS-232, Ethernet/USB	yes/RS-232, parallel, Ethernet	yes/RS-232, Ethernet
Information listed on hard copy report	patient information/demographics, patient therapy settings, measures and calculates results, system messages, reference and critical ranges	options can be customized; direct and measured parameters	operator and patient IDs, accession number, patient measured and calculated results, temperature, more
Analyzer connections	Radiance stat analyzer management system that connects to LIS/HIS or directly to LIS/HIS	cobas bge link, data management systems, LIS or HIS	directly to LIS/HIS, data management system, which connects to LIS/HIS
Interface standards supported	ASTM, HL7, serial, network, TCP/IP	ASTM, HL7, USB port	LIS3
How analyzer connects to external system to upload patient and QC results	serial, Ethernet	Ethernet	direct serial, Ethernet
Information included in transmission from analyzer to external system	device-unique identifier, operator and patient IDs, results, QC identifier	device-unique identifier, operator and patient IDs, results, QC identifier	device-unique identifier, operator and patient IDs, results, QC identifier
Hardware and software for data management system	Radiance	cobas bge link	RAPIDComm Data Management system
No. of different management reports system produces	user definable	13 base reports, unlimited customized reports	fully customizable
Contents downloaded from data management system to analyzer	—	valid operator IDs	valid control values and operator IDs
System connected (live installations) to which LISs, HISs	Cerner, Meditech, Misys, others	Cerner, Meditech, others	—
Use a third-party interfacing tool, engine for LIS, HIS interfaces	no (use interface templates)	Data Innovations	—
Distinguishing features (provided by company)	portable, true battery operation; fast startup/warmup and analysis time; simple and easy-to-use system	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 cobas bge link and Axeda software	no maintenance, multi-use cartridge; fast time to patient results and sample to sample throughput; 28-day, onboard, automatic quality control cartridge

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In vitro blood gas analyzers

Part 8 of 8	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	Siemens Healthcare Diagnostics Inc. 1717 Deerfield Road Deerfield, IL 60015-0778 800-255-3232 www.siemens.com/diagnostics
Name of device/First year sold/Number of analyzers sold in 2010	RAPIDPoint 300 Series/2009/—	RAPIDPoint 400 Series/2001/—	RAPIDLab 1200 Series/2005/—
Number of devices sold in U.S./outside U.S./List price	—	—	—
Dimensions (H x W x D)/Weight	12.5 × 14.5 × 7 inches/16–17 pounds	21.5 × 11.5 × 16 inches/34 pounds	22.75 × 20.5 × 21 inches/65–68 pounds
Analytes measured on device	pH, pCO2, pO2, Hct, Na+, K+, Cl-, iCa++	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	Hb, 02SAT, BE, TCO2, HCO3	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 recorded	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 measured, tracked
Barometric pressure	recorded, measured		
Analytical method(s) or technologies employed	pH: ISE-potentiometry; iCa: ISE; PCO2: ISE-potentiometry; pO2: ISE-amperometry; Hct: conductivity; Hb: calculated from hematocrit; Na: ISE; Cl: ISE; K: ISE	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, two models: RAPIDPoint 340 offers blood gas; RAPIDPoint 350 offers blood gas, electrolytes, and hematocrit	yes	yes, series offers different analyte options
Device warranty/Loaner devices provided	1-year warranty (country specific)/yes	1 year/yes	1 year/no
Average life expectancy of device	7–10 years	7–10 years	7–10 years
Open or closed system/External gas tanks required	closed/no	closed/no	closed/no
Categorized for point-of-care testing or laboratory	laboratory	point-of-care testing and laboratory	point-of-care testing and laboratory
Point of care:			
Disposable prepackaged system used for analysis	multi-use cartridge	multi-use cartridge	multi-use cartridges, electrode measurement chamber
No. of disposable reagent system units in standard package	1	1 measurement and 1 wash-waste cartridge	1 reagent cartridge, 1 wash cartridge
No. of samples analyzed per one disposable reagent, electrode system	based on daily testing volumes	250, 400, 750 samples	Reagent cartridge is not sample dependent
Reagent unit storage requirements	room temperature	refrigeration	Reagent cartridge/AQC cartridge–refrigeration; wash cartridge–room temperature
Shelf life of disposable units	reagents: 7 to 9 months; electrodes: 12 months	9 months	reagent/wash cartridge: 8 months; AQC cartridge: 9 months; electrodes: varies based on type
Laboratory:			
No. of different disposable reagents required to maintain device	1	1 measurement cartridge, 1 wash-waste cartridge	1 reagent cartridge, 1 wash cartridge
Max. No. of analyte reagents that can reside in device at once	1	1 measurement cartridge, 1 wash-waste cartridge	1 reagent cartridge, 1 wash cartridge, all electrodes
Shelf life of components	reagents: 7–9 months; electrodes: 12 months	9 months	electrodes: vary based on type; reagent cartridge: 8 months; wash cartridge: 8 months; AQC cartridge: 9 months
Cost per test/Reagent cost per test	varies based on configuration and test volume/—	varies based on configuration	varies based on configuration
Calibrations required	1 and 2 point (manual and automatic)	1 and 2 point (automatic)	1 and 2 point (manual and automatic)
Calibration frequency	1 point (with each sample); 2 point (can be set to 2-, 4-, or 8-hour increments)	1 point: 30 minutes; 2 point: 2 hours	1 point: every 30 minutes; 2 point: every 8 hours
Internal QC program recommended	one-level QC every 8 hours of testing (CLIA recommendation): Siemens QC material recommended	AQC cartridge, fully user programmable	AQC cartridge, fully user programmable
QC features/Capabilities of QC features	L-J plots/statistical calculations, monthly cumulative reports, onboard	AQC cartridge, L-J plots/comparable plots, statistical calculations, monthly cumulative reports (available with external system)	L-J plots/comparable plots, statistical calculations, monthly cumulative reports (available with external system)
Remote control of device from laboratory	no	yes	yes
System can use LOINC to transmit results to LIS	no	no	no
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial, venous	whole blood, capillary, mixed venous, arterial, venous	whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants/Sampling technique	heparin/aspiration	heparin/aspiration	heparin/aspiration
Sample size for complete panel of analyte results	75 µL/95 µL capillary (RP340/RP350) 100 µL/120 µL syringe (RP340/RP350)	100 µL	95–175 µL
Sample size differs with number of analytes selected	no	no	yes (microsample mode available)
Time from sample introduction to result availability	125 seconds (RP340), <120 seconds (RP350)	60 seconds	60 seconds
Maximum No. of patient samples per hour/Maximum No. measured results per hour	25 samples (RP340), 30 samples (RP350)/75 (RP340), 210 (RP350)	25/—	24/up to 336 tests
Optimal throughput when analyzer calibrated, awaiting specimens	25 samples per hour (RP340), 30 samples per hour (RP350)	25 samples per hour	24 samples per hour
Calibration can be interrupted to perform stat sample	yes	yes	yes
Known interferences	certain anticoagulants	benzalkonium	—
Sampler has self-wiping probe	yes	yes	yes
Time required for maintenance by lab personnel	daily: <1 minute	none	weekly: 5 minutes; monthly: 5 minutes
Service center performs diagnostics through modem	no	no	no
Method of analyst ID in system	manual or bar-code entry (optional)	password (customizable)	password (customizable)
Instrument response for:			
• hardware failure/software failure	operator warning, error messages	flag-prompt	diagnostic codes prompt the operator
• QC failure	sampling lock-out, flagged high or low QC results	customizable-flag	diagnostic codes
• calibration failure	automatic calibration repeat, error messages, blank screen display	flag–recalibration	recalibrates, generates diagnostic code if unsuccessful
For what bar-code scanning is provided	operator identifier, patient identifier, and reagent lot number	operator and patient IDs, accession number results, temperature, other information	patient ID
Built-in printer/Data port	yes/RS-232	yes/RS-232, Ethernet	yes/RS-232, Ethernet
Information listed on hard copy report	patient information, operator ID, measured and calculated results, date	operator and patient IDs, accession number results, temperature, other information	operator and patient IDs, accession number, results, temperature, patient demographics, others
Analyzer connections	directly to LIS/HIS	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	ASTM 1394 and E1381	LIS 3	LIS 4
How analyzer connects to external system to upload patient and QC results	direct serial	direct serial, hospital network	direct serial, hospital network
Information included in transmission from analyzer to external system	operator ID, patient ID, results	device-unique identifier, operator and patient IDs, results, QC identifier	device-unique identifier, operator and patient IDs, results, QC identifier
Hardware and software for data management system	internal data management	RapidComm Data Management System	RapidComm Data Management System
No. of different management reports system produces	patient reports, QC statistics, L-J charts	customizable	customizable
Contents downloaded from data management system to analyzer	—	valid control values, valid operator IDs	valid control values, valid operator IDs
System connected (live installations) to which LISs, HISs			
Use a third-party interfacing tool, engine for LIS, HIS interfaces	no	yes	yes
Distinguishing features (provided by company)	multi-use cartridge-based system eliminates gas tanks; no maintenance, easy-to-replace electrodes; small, portable, and economical; dialysate fluid testing application in select countries	no maintenance, multi-use cartridge; fast time to patient results; onboard audio-video training videos; auto QC	cartridge-based high-throughput analyzer with minimal maintenance; fast time to patient results; onboard troubleshooting tutorials

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