SURVEY OF INSTRUMENTS

In vitro blood gas analyzers

Part 1 of 12 *See accompanying article on page 24*	**Abbott Diagnostics** **Joey Baugh** joey.baugh@abbott.com **4A Crosby Dr.** **Bedford, MA 01730** **781-276-7774** www.abbottdiagnostics.com	**Abbott Diagnostics** **Joey Baugh** joey.baugh@abbott.com **4A Crosby Dr.** **Bedford, MA 01730** **781-276-7774** www.abbottdiagnostics.com
Name of device/First year sold	i-Stat 1/2001	i-Stat System/1992
No. of devices sold in U.S./Outside U.S./List price	1,500/1,000/$9,500	20,000 worldwide/$7,900
Dimensions (H x W x D)/Weight	23.48 cm x 7.68 cm x 7.24 cm/22.4 oz	8.26 x 2.52 x 2.05 in/18.34 oz
Analytes measured on device	pH, pCO_2, pO_2, Hct, Na, K, Cl, iCa, glucose, creatinine, BUN, ACT_c, lactate	pH, pCO_2, pO_2, Hct, Na, K, Cl, iCa, glucose, creatinine, BUN, ACT_c, lactate
Parameters calculated on device	Hb, O_2SAT, BE, TCO_2, HCO_3-	Hb, O_2SAT, BE, TCO_2, HCO_3-
Barometric pressure	measured	measured
Analytical method(s), technology(ies) employed	electrochemical for all analytes	electrochemical for all analytes
Device is part of a series of related models	no	no
User list or group available	yes (through local sales representative)	yes (through local sales representative)
Device warranty	1 yr replacement	1 yr replacement
Loaner devices provided	n/a	n/a
Average expected life of device	8 yrs	8 yrs
Open or closed system/External gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC testing	POC testing
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	reagent/electrode (single use)	reagent/electrode (single use)
No. of disposable reagent system units in basic shipment package	25 per box	25 per box
No. of samples analyzed per one disposable reagent, electrode system	1	1
List price per disposable reagent system	$3–$9	$3–$9
Reagent unit storage requirements	refrigerate, 2 weeks of shelf life at room temperature	refrigerate, 2 weeks of shelf life at room temperature
Shelf life of disposable units	reag./electrode: 6–9 mos; 2 weeks at room temperature	reag./electrode: 6–9 mos refrig.; 2 weeks at room temperature
Laboratory:		
No. of different disposable reagents required to maintain device	—	—
Max. No. of specific analyte reagents that can reside in device at once	—	—
Shelf life	—	—
Cost per test/Reagent cost per test	—	—
Calibrations required	1 point (automatic)	1 point (automatic)
Calibration frequency	every test	every test
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	electronic QC, automated internal wet QC	electronic QC, automated internal wet QC
QC features	comparable plot, monthly cumulative reports (available with external system)	monthly cumulative reports (available with external system), QC can be fully automated, QC lockout
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, capillary, mixed venous, arterial, venous	whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	heparin	heparin
Sampling technique	injection, capillary transfer and fill	injection, capillary transfer and fill
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	blood gas 95 µL, electrolytes 65 µL	blood gas 95 µL, electrolytes 65 µL
Sample size differs with No. of analytes selected	no	yes
Recommended collection device	syringe or capillary tube	syringe or capillary tube
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	about 2 min	about 2 min
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	20/160	20/160
Optimal throughput when calibrated and awaiting specimens	—	—
Calibration can be interrupted to perform stat sample	n/a	n/a
Contraindications	—	—
Known interferences	—	—
Restrictions based on Hct	—	—
Sampler has self-wiping probe	—	—
Time required for maintenance by lab personnel	n/a	n/a
Onboard diagnostics for troubleshooting/Limited to software	yes/no	no/no
Diagnostics performed through modem	yes	yes
Training & certification program for user	yes, based on number to be trained	yes
Method of analyst ID in system	keypad/bar-code entry	keypad entry (required)
Response for hardware & software failure/User ID & QC failure/ Calibration & power failure	code No. error message/—/—	—/—/—
Supports bar-code scanning of	operator & patient IDs, reagent lot No., hospital specific info	no bar-code scanner
User can search for and review previous patient results on screen	yes	yes
Built-in printer/Data port	no/other	no/other
Information on hard copy report	device unique identifier, operator & patient IDs, results, QC identifier	patient data & results, date, time, analyzer serial No., sample type, ventilator settings
Analyzer connects to	data management system, which in turn connects to LIS/HIS	data management system, which connects to LIS/HIS
Interface standards supported	ASTM 1394 & 1238, HL7, other	ASTM 1394 & 1238, HL7, other
To upload patient & QC results, how analyzer connects to external system	direct serial/900 hospitals installed; modem dial-in/25 hospitals installed; hospital network/250 hospitals installed	direct serial/700 hospitals installed; modem dial-in/25 installed; hospital network/200 installed
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	QC MGR 2.0/Precision Net/5x software/Central Data Station	QC MGR 2.0/Precision Net/Central Data Station
No. of different management reports system produces	35+	35+
Contents downloaded from DMS to analyzer	strip lot Nos., valid control values, valid operator IDs, certification, analyzer location, lockouts, customized info	—
System connected (live installations) to which LISs, HISs		
• using screen animation, screen scraping	all major LIS vendors	all major LIS vendors
• using standard HL7 interface	Cerner	Cerner
• using proprietary protocol interface	—	none
Use a third-party interfacing tool, engine for LIS, HIS interfaces	yes, Sybase	none
Distinguishing features (provided by vendor)	handheld portable, single-use test cartridge, complete data management integration via Precision Net system; bar-code scanner built-in; full lockout menu for program testing protection	handheld portable, single-use test cartridge, complete data integration via Precision Net data management system

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Survey editor: Raymond D. Aller, MD

In vitro blood gas analyzers

Part 2 of 12

See accompanying article on page 24

	Bayer Corp., Diagnostics Division 511 Benedict Ave. Tarrytown, NY 10591 800-255-3232 www.bayerdiag.com	Diametrics Medical Inc. 2658 Patton Rd. St. Paul, MN 55113 800-949-4762
Name of device/First year sold	Rapidpoint 400 Series/2001	IRMA Blood Analysis System/1994
No. of devices sold in U.S./Outside U.S./List price	n/a/n/a/$38,000	—/—/varies based on quantity
Dimensions (H x W x D)/Weight	21.5 x 11.5 x 16 in/34 lbs	11.5 x 9.5 x 5 in/5 lbs, 4 oz
Analytes measured on device	pH, pCO_2, pO_2, Hct, Na, K, Cl, iCa, glucose	pH, pCO_2, pO_2, Hct, Na, K, Cl, iCa, glucose, BUN
Parameters calculated on device	O_2SAT, BE, TCO_2, HCO_3-, full co-oximetry	Hb, O_2SAT, BEb, BEecf, TCO_2, HCO_3-
Barometric pressure	recorded	measured
Analytical method(s), technology(ies) employed	pH, Na, Cl, iCa, K: potentiometry using ISE; pCO_2: potentiometry based on Severinghaus; pO_2: amperometric meas. (Clark); glucose: amperometric-glucose oxidase; Hct: conductivity; co-oximetry: spectrophotometric	pH, pCO_2, Na, Cl, iCa, K, BUN (enzymatic): potentiometric; pO_2, glucose (enzymatic): amperometric; Hct: conductometric; glucose strip (enzymatic): colormetric
Device is part of a series of related models	yes	yes, 2nd-generation analyzer
User list or group available	yes	list of customers available
Device warranty	1 yr	1 yr
Loaner devices provided	yes	yes
Average expected life of device	5–7 yrs	7 yrs
Open or closed system/External gas tanks required	—/no	closed/no
For POC testing or laboratory	POC testing	POC testing
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	reagent/electrode (multiuse cartridge)	reagent/electrode (single use and multiuse cartridge available)
No. of disposable reagent system units in basic shipment package	1 measurement cartridge/3 waste/wash cartridges	25
No. of samples analyzed per one disposable reagent, electrode system	400, 750 samples	1
List price per disposable reagent system	$2,300–$3,500	varies based on quantity
Reagent unit storage requirements	refrigeration	room temperature
Shelf life of disposable units	reagent/electrode: 9 mos	reagent/electrode: 6 mos
Laboratory:		
No. of different disposable reagents required to maintain device	—	—
Max. No. of specific analyte reagents that can reside in device at once	—	—
Shelf life	—	—
Cost per test/Reagent cost per test	—	—
Calibrations required	1 & 2 point (automatic)	2 point (automatic)
Calibration frequency	1 point: 30 min; 2 point: 2 hrs	each sample
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	1 level QC every 8 hrs testing, aqueous based	electronic QC per 8 hrs patient testing, 2 liquid QC per cartridge shipment
QC features	L-J plots, comparable plot, statistical calculations, monthly cumulative reports (onboard & available with external system)	L-J plots, statistical calculations, monthly cumulative reports (available with external system)
Remote control of device from laboratory	yes	yes
System can use LOINC to transmit results to LIS	yes	no
How labs get LOINC codes for reagent kits	—	—
Detects clots within analysis chamber	yes	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	100 µL	125 µL capillary, 200 µL syringe
Sample size differs with No. of analytes selected	no	no
Recommended collection device	syringe or capillary tube	standard blood gas syringe
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	60 sec	<2 min
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	140/—	20/120
Optimal throughput when calibrated and awaiting specimens	35 samples per hr	20
Calibration can be interrupted to perform stat sample	yes	—
Contraindications	if calibration is interrupted repeatedly, it will force a mandatory calibration to be completed before sampling	none
Known interferences	benzalkonium	—
Restrictions based on Hct	no	no
Sampler has self-wiping probe	yes	no, not needed
Time required for maintenance by lab personnel	maintenance free	no maintenance
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	yes	no
Training & certification program for user	yes	yes
Method of analyst ID in system	password (customizable)	LCD touchscreen, numeric (customizable)
Response for hardware & software failure/User ID & QC failure/ Calibration & power failure	flag-prompt/user ID: customizable; QC: customizable-flag/calibration: flag–recalibration	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, accession No., results, temperature, other information	operator & patient IDs, cartridge information
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, modem
Information on hard copy report	operator & patient IDs, accession No., results, temperature, other information	analyzer serial No., date, calib. successful, calib. code, lot No., patient ID & temp., results, barometric press., SW version optional: user ID, ref. ranges, O_2 therapy, sample info.
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	script or HL7
To upload patient & QC results, how analyzer connects to external system	direct serial, hospital network	hospital network, direct serial, modem dial-in
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, patient O_2 therapy information
Hardware/Software for data management system	HP platform/Windows NT, SQL server	IDMS v. 7.0
No. of different management reports system produces	customizable	24
Contents downloaded from DMS to analyzer	valid control values, valid operator IDs	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	yes	all major HIS/LIS vendors
• using proprietary protocol interface	yes	customizable EDI interface to HIS/LIS vendors
Use a third-party interfacing tool, engine for LIS, HIS interfaces	yes	none
Distinguishing features (provided by vendor)	no maintenance, multiuse cartridge; fast time to patient results; onboard audio-video training videos; auto QC	cartridges do not require refrig. (room temp.); true QC lockout—lab manager controls QC test requirements, user access, patient info requirements, e.g. patient ID requirements; cartridge design with luer lock port provides barrier between user and sample—no overfilling risk; complete data integration with IDMS interface

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SURVEY OF INSTRUMENTS

In vitro blood gas analyzers

Part 3 of 12

See accompanying article on page 24

	Instrumentation Laboratory	Instrumentation Laboratory
	Sandy Anderson sanderson@ilww.com	Sandy Anderson sanderson@ilww.com
	101 Hartwell Ave.	101 Hartwell Ave.
	Lexington, MA 02421	Lexington, MA 02421
	781-861-4244	781-861-4244
	www.ilus.com	www.ilus.com
Name of device/First year sold	Synthesis 10 & 15/1997	Synthesis 20 & 25/1997
No. of devices sold in U.S./Outside U.S./List price	>100 worldwide/Synthesis 10: $29,925, Synthesis 15: $42,000	>100 worldwide/Synthesis 20: $38,325; Synthesis 25: $48,300
Dimensions (H x W x D)/Weight	20 x 16 x 20 in/77 lbs	20 x 16 x 20 in/77 lbs
Analytes measured on device	pH, pO_2, pCO_2; Synthesis 15: THb, O_2Hb, COHb, MetHb, RHb	pH, pO_2, pCO_2, Na+, K+, Ca++, Cl-; Synthesis 25: THb, O_2Hb, COHb, MetHb, RHb
Parameters calculated on device	pH(T), pO_2(T), pCO_2(T), HCO_3-, SBC, TCO_2, Beb, BEecf, $\%sO_2c$, pAO_2, paO_2/pAO_2, RI, A-aDO_2, O_2cap, O_2ct, p50	pH(T), pO_2(T), pCO_2(T), HCO_3-, SBC, TCO_2, Beb, BEecf, $\%sO_2c$, pAO_2, paO_2/pAO_2, RI, A-aDO_2, anion gap, O_2cap, O_2ct, p50
Barometric pressure	tracking	tracking
Analytical method(s), technology(ies) employed	pH: potentiometry; pCO_2: Severinghaus electrode-voltage; pO_2: Clark electrode-current; Hb: nonhemolytic Hb absorption (Synthesis 15)	pH: potentiometry; pCO_2: Severinghaus electrode-voltage; pO_2: Clark electrode-current; Hct: conductivity; Hb: nonhemolytic Hb absorption; Na, Cl, iCa, K: ISE
Device is part of a series of related models	yes (Synthesis family offering different analyte options)	yes (Synthesis family offering different analyte options)
User list or group available	yes (through local sales representative)	yes (through local sales representative)
Device warranty	1 yr	1 yr
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/yes	closed/yes
For POC testing or laboratory	laboratory	laboratory
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	—	—
No. of disposable reagent system units in basic shipment package	—	—
No. of samples analyzed per one disposable reagent, electrode system	—	—
List price per disposable reagent system	—	—
Reagent unit storage requirements	—	—
Shelf life of disposable units	—	—
Laboratory:		
No. of different disposable reagents required to maintain device	3	—
Max. No. of specific analyte reagents that can reside in device at once	—	12
Shelf life	reagent: 24 mos, electrode: 4 mos–1 yr	—
Cost per test/Reagent cost per test	$0.71-$0.73 @ 50 tests per day at list price/$0.24 @ 50 tests per day at list	$0.84-$0.86 @ 50 tests per day at list price/$0.24 @ 50 tests per day at list price
Calibrations required	1 & 2 point (automatic & manual)	1 & 2 point (automatic & manual)
Calibration frequency	1 point: after each sample, 2 point: every 2 hrs	1 point: after each sample, 2 point: every 2 hrs
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	1 level per 8 hrs, IL controls recommended	1 level per 8 hrs, IL controls recommended
QC features	L-J plots, QC tracking	L-J plots, QC tracking
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	n/a	n/a
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas	w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas
Acceptable anticoagulants	heparin	heparin
Sampling technique	aspiration, injection, capillary	aspiration, injection, capillary
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	60 µL/100 µL	80 µL/150 µL
Sample size differs with No. of analytes selected	yes	yes
Recommended collection device	universal sampler accepts all devices	universal sampler accepts all devices
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	60 sec	60 sec
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	50/150–400	50/350–600
Optimal throughput when calibrated and awaiting specimens	30 samples per hr	30 samples per hr
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	none	—
Known interferences	none	—
Restrictions based on Hct	no	no
Sampler has self-wiping probe	yes	yes
Time required for maintenance by lab personnel	monthly: 5 min	monthly: 5 min
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	yes	yes
Training & certification program for user	yes (1 day on site)	yes (1 day on site)
Method of analyst ID in system	manual entry of ID & password (customizable)	manual 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/4 RS-232, 1 parallel, standalone co-ox port, alphanumeric keyboard port, bar-code reader port	yes/4 RS-232, 1 parallel, standalone co-ox port, alphanumeric keyboard port, bar-code reader port
Information on hard copy report	patient demographics, hospital name, results	patient demographics, hospital name, results
Analyzer connects to	interfaced direct with HIS/LIS or Impact for Critical Care, which can be interfaced to HIS/LIS	interfaced direct with HIS/LIS or Impact for Critical Care, which can be interfaced to HIS/LIS
Interface standards supported	interfaced with LIS or Impact for Critical Care, ASTM protocol	interfaced with LIS or Impact for Critical Care, ASTM protocol
To upload patient & QC results, how analyzer connects to external system	direct serial, modem dial-in, hospital network	direct serial, modem dial-in, hospital network
Information included in transmission from analyzer to external system	device identifier, operator & patient IDs, results, QC ID	device identifier, operator & patient IDs, results, QC ID
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	none	none
• using standard HL7 interface	none	none
• using proprietary protocol interface	none	none
Use a third-party interfacing tool, engine for LIS, HIS interfaces	no	no
Distinguishing features (provided by vendor)	continuous calibration corrects every three seconds for drift seen in Clark and Severinghaus electrodes–ensures accurate results before patient sampling; maintenance-free disposable electrodes for convenience and system uptime; integrated co-oximeter uses no extra reagent and minimizes maintenance	continuous calibration corrects every three seconds for drift seen in Clark and Severinghaus electrodes–ensures accurate results before patient sampling; maintenance-free disposable electrodes for convenience and system uptime; integrated co-oximeter uses no extra reagent and minimizes maintenance

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In vitro blood gas analyzers

Part 4 of 12

See accompanying article on page 24

	Instrumentation Laboratory Sandy Anderson sanderson@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4244 www.ilus.com	Instrumentation Laboratory Sandy Anderson sanderson@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4244 www.ilus.com
Name of device/First year sold	Synthesis 30 & 35/1997	Synthesis 40 & 45/1999
No. of devices sold in U.S./Outside U.S./List price	>100 worldwide/Synthesis 30: $42,000; Synthesis 35: $52,500	n/a/n/a/Synthesis 40: $48,300; Synthesis 45: $60,375
Dimensions (H x W x D)/Weight	20 x 16 x 20 in/77 lbs	20 x 16 x 20 in/77 lbs
Analytes measured on device	pH, pO_2, pCO_2, Na, K+, Ca++, Cl-, glucose, lactate; Synthesis 35: THb, O_2Hb, COHb, MetHb, RHb	pH, pO_2, pCO_2, Na+, K+, Ca++, Cl-, glucose, lactate; Synthesis 45: THb, O_2Hb, COHb, MetHb, RHb
Parameters calculated on device	pH(T), pO_2(T), pCO_2(T), HCO_3-, SBC, TCO_2, Beb, BEecf, %sO_2c, pAO_2, paO_2/pAO_2, RI, A-aDO_2, anion gap, osmolality, O_2cap, O_2ct, p50	pH(T), pO_2(T), pCO_2(T), HCO_3-, SBC, TCO_2, Beb, BEecf, %sO_2c, pAO_2, paO_2/pAO_2, RI, A-aDO_2, anion gap, osmolality, O_2cap, O_2ct, p50
Barometric pressure	tracking	tracking
Analytical method(s), technology(ies) employed	pH: potentiometry; pCO_2: Severinghaus electrode-voltage; pO_2: Clark electrode-current; Hct: conductivity; Hb: nonhemolytic Hb absorption; Na, Cl, iCa, K: ISE; glucose: enzymatic	pH: potentiometry; pCO_2: Severinghaus electrode-voltage; pO_2: Clark electrode-current; Hct: conductivity; Hb: nonhemolytic Hb absorption; Na, Cl, iCa, K: ISE; glucose, lactate: enzymatic
Device is part of a series of related models	yes (Synthesis family offering different analyte options)	yes (Synthesis family offering different analyte options)
User list or group available	yes (through local sales representative)	yes (through local sales representative)
Device warranty	1 yr	1 yr
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/yes	closed/yes
For POC testing or laboratory	laboratory	laboratory
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	—	—
No. of disposable reagent system units in basic shipment package	—	—
No. of samples analyzed per one disposable reagent, electrode system	—	—
List price per disposable reagent system	—	—
Reagent unit storage requirements	—	—
Shelf life of disposable units	—	—
Laboratory:		
No. of different disposable reagents required to maintain device	—	—
Max. No. of specific analyte reagents that can reside in device at once	12	13
Shelf life	—	—
Cost per test/Reagent cost per test	$1.67-$1.69 @ 50 tests per day at list price/$0.24 @ 50 tests per day at list price	TBD/$0.24 @ 50 tests per day at list price
Calibrations required	1 & 2 point (automatic & manual)	1 & 2 point (automatic & manual)
Calibration frequency	1 point: after each sample, 2 point: every 2 hrs	1 point: after each sample, 2 point: every 2 hrs
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	1 level per 8 hrs, IL controls recommended	1 level per 8 hrs, IL controls recommended
QC features	L-J plots, QC tracking	L-J plots, QC tracking
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	n/a	n/a
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas	w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas
Acceptable anticoagulants	heparin	heparin
Sampling technique	aspiration, injection, capillary	aspiration, injection, capillary
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	80 µL/150 µL	95 µL/165 µL
Sample size differs with No. of analytes selected	yes	yes
Recommended collection device	universal sampler accepts all devices	universal sampler accepts all devices
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	60 sec	60 sec
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	40/280–480	40/320–520
Optimal throughput when calibrated and awaiting specimens	30 samples per hr	30 samples per hr
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	monthly: 5 min	monthly: 5 min
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	yes	yes
Training & certification program for user	yes (1 day on site)	yes (1 day on site)
Method of analyst ID in system	manual entry of ID & password (customizable)	manual 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/4 RS-232, 1 parallel, standalone co-ox port, alphanumeric keyboard port, bar-code reader port	yes/4 RS-232, 1 parallel, standalone co-ox port, alphanumeric keyboard port, bar-code reader port
Information on hard copy report	patient demographics, hospital name, results	patient demographics, hospital name, results
Analyzer connects to	interfaced direct with HIS/LIS or Impact for Critical Care, which can be interfaced to HIS/LIS	interfaced direct with HIS/LIS or Impact for Critical Care, which can be interfaced to HIS/LIS
Interface standards supported	interfaced with LIS or Impact for Critical Care, ASTM protocol	interfaced with LIS or Impact for Critical Care, ASTM protocol
To upload patient & QC results, how analyzer connects to external system	direct serial, modem dial-in, hospital network	direct serial, modem dial-in, hospital network
Information included in transmission from analyzer to external system	device identifier, operator & patient IDs, results, QC ID	device identifier, operator & patient IDs, results, QC ID
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	none	none
• using standard HL7 interface	none	none
• using proprietary protocol interface	none	none
Use a third-party interfacing tool, engine for LIS, HIS interfaces	no	no
Distinguishing features (provided by vendor)	continuous calibration corrects every three seconds for drift seen in Clark and Severinghaus electrodes–ensures accurate results before patient sampling; maintenance-free disposable electrodes for convenience and system uptime; integrated co-oximeter uses no extra reagent and minimizes maintenance	continuous calibration corrects every three seconds for drift seen in Clark and Severinghaus electrodes–ensures accurate results before patient sampling; maintenance-free disposable electrodes for convenience and system uptime; integrated co-oximeter uses no extra reagent and minimizes maintenance

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In vitro blood gas analyzers

Part 5 of 12

See accompanying article on page 24

	Instrumentation Laboratory Tim Lynch tlynch@ilww.com 101 Hartwell Ave., Lexington, MA 02421 781-861-4259 www.ilus.com	Instrumentation Laboratory Tim Lynch tlynch@ilww.com 101 Hartwell Ave., Lexington, MA 02421 781-861-4259 www.ilus.com
Name of device/First year sold	Gem Premier 3000/2000	Gem 3100/2000
No. of devices sold in U.S./Outside U.S./List price	—/—/$39,995	—/—/—
Dimensions (H x W x D)/Weight	17 x 12 x 12 in/29.5 lbs	22 x 12 x 12 in/31.5 lbs
Analytes measured on device	pH, pO_2, pCO_2, Hct, Na+, K+, Ca++, glucose, lactate	pH, pO_2, pCO_2, Hct, Na+, K+, Ca++, glucose, lactate: PT, APTT, ACT, ACT-LR, citrate PT
Parameters calculated on device	A-aDo_2, Hb, pAO_2, paO_2/pAO_2, RI, O_2cap*, CtO_2*, CaO_2*, CvO_2*, CcO_2*, a-vDO_2*, Qsp/Qt*, P50*	A-aDo_2, Hb, pAO_2, paO_2/pAO_2, RI, O_2cap*, CtO_2*, CaO_2*, CvO_2*, CcO_2*, a-vDO_2*, Qsp/Qt*, P50*
Barometric pressure	n/a	n/a
Analytical method(s), technology(ies) employed	pH, pCO_2: potentiometry; pO_2, glucose, lactate: amperometry; Hct: conductivity; Na, iCa, K: ISE	pH, pCO_2: potentiometry; pO_2, 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	2 per pack	2 per pack
No. of samples analyzed per one disposable reagent, electrode system	75-, 150-, 300-, 450-, & 600-test cartridge	cartridges available: 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 mos	6 mos
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 mos	6 mos
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 quality management	internal, automated quality management
QC features	Intelligent Quality Management (IQM): internal, automated program that performs continuous quality management	Intelligent Quality Management (IQM): internal, automated program that performs continuous quality management
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	n/a	n/a
Detects clots within analysis chamber	yes	yes
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	<100 sec	<100 sec; under 5 min for coagulation
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	15/135	15/135
Optimal throughput when calibrated and awaiting specimens	15 samples	15 samples (with stat option)
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 wand entry of ID & password (customizable)	manual or bar-code wand 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	LIS/HIS via direct interface or via IL's Impact Data Management System; vendor-neutral data management systems	LIS/HIS via direct interface or via IL's Impact Data Management system; vendor-neutral data management systems
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 (IQM); maintenance-free, multiuse cartridge available in 28 menu/size options for use in any hospital location; 15-year history of proven 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 (IQM) maintenance-free, multiuse cartridge available in 28 menu/size options for use in any hospital location; 15-year history of proven cartridge technology; remote management from any PC via Gemweb; consolidated workstation for blood gas, electrolytes, Hct, glucose, lactate, co-oximetry, and coagulation ** when interfaced to IL CO-Oximeter*

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SURVEY OF INSTRUMENTS

In vitro blood gas analyzers

Part 6 of 12 *See accompanying article on page 24*	**Medica Corp.** **Kevin McCollum** kmccollum@medicacorp.com **14 DeAngelo Dr., Bedford, MA 01730** **800-777-5983 or 781-275-4892** www.medicacorp.com	**Medica Corp.** **Kevin McCollum** kmccollum@medicacorp.com **14 DeAngelo Dr., Bedford, MA 01730** **800-777-5983 or 781-275-4892** www.medicacorp.com
Name of device/First year sold	EasyBloodGas/2000	EasyStat/2002
No. of devices sold in U.S./Outside U.S./List price	<500/>500/$10,500	—/—/—
Dimensions (H x W x D)/Weight	14.5 x 12.5 x 7 in/16 lbs	14.5 x 12.5 x 7.0 in/18 lbs
Analytes measured on device	pH, pO_2, pCO_2	pH, pCO_2, pO_2, Hct, Na, K, iCa
Parameters calculated on device	O_2SAT, BE, TCO_2, HCO_3-	Hb, O_2SAT, BE, TCO_2, HCO_3-
Barometric pressure	measured	measured and recorded
Analytical method(s), technology(ies) employed	pH: ISE-potentiometry; pCO_2: ISE-potentiometry; pO_2: ISE-amperometry	pH and pCO_2: ISE-potentiometry; pO_2: 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	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	room temperature
Shelf life of disposable units	reagent module, 10 mos; electrodes, 12 mos	reagent module: 10 mos; electrodes: 12 mos
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	reag. & elec.: 1 yr; QC material: 3 yrs	reagent module: 10 mos; electrodes: 12 mos
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, 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	n/a	n/a
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	75 µL capillary, 100 µL syringe	125 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 sec, includes 1-point calibration	<120 sec, 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	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 distributor)
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, reagent lot No., QC controls
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 in turn connects to LIS/HIS; 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	—
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 purchase price and low operation cost; disposable maintenance-free sensor; no gas tanks	modular components; simple operation and maintenance; low purchase price and low operation cost; disposable maintenance-free sensors; no gas tanks, easy inside and out

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In vitro blood gas analyzers

Part 7 of 12

See accompanying article on page 24

	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	Stat Profile pHOx/1998; pHOx Basic/2002	Stat Profile pHOx Plus/2000; Stat Profile pHOx Plus L/2001
No. of devices sold in U.S./Outside U.S./List price	pHOx: —/—/$15,000; pHOx Basic: —/—/$12,000	pHO Plus: —/—/$29,000; pHOx Plus L: —/—/$32,000
Dimensions (H x W x D)/Weight	15 x 12 x 15 in/18 lbs	15 x 12 x 15 in/18 lbs
Analytes measured on device	pHOx: pH, pCO_2, pO_2, Hct, Hb, SO_2%; pHOx Basic: pH, pCO_2, pO_2	pH, pCO_2, pO_2, Hct, Hb, O_2SAT, Na, K, Cl or iCa, glucose; pHOx Plus L measures preceding analytes plus lactate
Parameters calculated on device	BE, TCO_2, HCO_3-	BE, TCO_2, HCO_3-; pHOx Plus L: Hb, HCT, BE, TCO_2, HCO_3-
Barometric pressure	tracked	tracked
Analytical method(s), technology(ies) employed	pH: direct ISE; pCO_2: Sevinghaus; pO_2: amperometry; Hct: conductivity; Hb & SO_2%: optical–reflectance	pH: direct ISE; pCO_2: potentiometry; pO_2: amperometry; Hct: conductivity; Hb & SO_2%: 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, 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	n/a	n/a
List price per disposable reagent system	$200–$265	$210–$275
Reagent unit storage requirements	room temperature	room temperature
Shelf life of disposable units	reagents: 18 mos room temperature; electrodes: up to 18 mos	reagents: 18 mos room temperature, electrodes: up to 18 mos
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 mos; membrane kits: 12–24 mos	reagents & electrodes: 18 mos; membrane kits: 12–24 mos
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 Patient Data Manager)	L-J plots, statistical calcs., monthly cum. report (onboard, more extensive reporting avail. with Nova Patient Data 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, venous; pHOx Plus L can accommodate preceding specimens as well as 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	70 µL	pHOx Plus: 115 µL; pHOx Plus L: 125 µL
Sample size differs with No. of analytes selected	yes, pHOx, pHOx Basic offers micro-panel; standard 3-test blood gas micro-panel sample req. is 40 µL	yes, pHOx offers micro-panel; standard 3-test micro-panel req., 50 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 sec	pHOx Plus: 50 sec; pHOx Plus L: 52 sec
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	300/300 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 & 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 available with external device)	ASTM E1381-91 & ASTM 1394-91 (HL7 available 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 Patient Data Management SW	Pentium with Microsoft Windows 2000/Nova Patient Data Manager
No. of different management reports system produces	>60	>60
Contents downloaded from DMS to analyzer	n/a	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 QC cartridge provides sufficient QC materials for 30-day auto QC analysis; allows user to program frequency & select report protocol with full QC DMS; no external gas tank (more shared features listed under pHOx Plus, pHOx Plus L)	single reagent cartridge has all supplies needed for calibration and waste collection; has same features as pHOx/pHOx Basic plus pHOx Plus/pHOx Plus L and also has key oximetry values without need for co-ox

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In vitro blood gas analyzers

Part 8 of 12

See accompanying article on page 24

	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	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	n/a/n/a/—	n/a/n/a/—
Dimensions (H x W x D)/Weight	17.2 x 22.4 x 17.3 in/53 lbs	17.2 x 22.4 x 17.3 in/53 lbs
Analytes measured on device	pH, pCO_2, pO_2, Hct, Hb, Na, K, Cl, iCa, iMg, lactate, glucose, creatinine, BUN, SO_2%, co-oximetry	pH, pCO_2, pO_2, co-oximetry
Parameters calculated on device	BE, TCO_2, HCO_3-	BE, TCO_2, HCO_3-
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; co-ox: optical, reflectance	pH: direct ISE; pCO_2: Severinghaus; pO_2: 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	n/a	n/a
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 mos (room temp.); electrodes: up to 18 mos	reagents: 18 mos (room temp.); electrodes: up to 18 mos
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	19	7
Shelf life	reagents & electrodes: 18 mos; membrane kits: 12–24 mos	reagents & electrodes: 18 mos; membrane kits: 12–24 mos
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	150 µL	150 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	140 sec	140 sec
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	26/494	26/182
Optimal throughput when calibrated and awaiting specimens	445 tests per hr	163 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/yes (Ethernet, USB)	yes/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	n/a	n/a
• using standard HL7 interface	n/a	n/a
• using proprietary protocol interface	n/a	n/a
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 (19 tests), BUN, iMg available exclusively from Nova; onboard co-oximeter; open architecture SW allows design of dedicated user interface (more shared features listed under Critical Care Xpress 3 Plus)	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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SURVEY OF INSTRUMENTS

In vitro blood gas analyzers

Part 9 of 12

See accompanying article on page 24

	Osmetech Inc. Sales Department 235 Hembree Park Drive Roswell, GA 30076 800-470-OPTI www.osmetech.com	Philips Medical Systems Deborah Matthews deborah.matthews@philips.com 3000 Minuteman Rd. Andover, MA 01810 800-934-7372 www.medical.philips.com
Name of device/First year sold	Osmetech Opti CCA Blood Gas Analyzer/1998	Blood Analysis Portal System/2002
No. of devices sold in U.S./Outside U.S./List price	—/—/$8,500	—/—/—
Dimensions (H x W x D)/Weight	4.7 x 14.2 x 9 in/9 lbs without battery, 11 lbs with	3 x 3.9 x 9 in/22 oz
Analytes measured on device	pH, pCO_2, pO_2, Na, K, Cl, iCa, tHb, SO_2, glucose	pH, pCO_2, pO_2, Hct, Na, K, Cl, iCa, BUN
Parameters calculated on device	Hct, BE, TCO_2, HCO_3- (12 additional parameters; call Osmetech for list)	Hb, O_2SAT, BE, TCO_2, HCO_3-
Barometric pressure	measured	recorded & measured
Analytical method(s), technology(ies) employed	pH, pCO_2, pO_2, Na, Cl, iCa, K, glucose: optical fluorescence; tHb, SO_2: optical reflectance	pH, pCO_2, Na, Cl, iCa, BUN, & K: potentiometric; pO_2: amperometric; Hct: conductimetric
Device is part of a series of related models	yes, Osmetech Opti Series	no
User list or group available	yes (through Osmetech sales dept.)	no
Device warranty	1 yr (service contract available for subsequent years)	1 yr
Loaner devices provided	yes	yes
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	POC testing
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	reagent/optode	uses Diametrics Medical cartridges (single use)
No. of disposable reagent system units in basic shipment package	25 individual packaged cassettes	25
No. of samples analyzed per one disposable reagent, electrode system	1	1
List price per disposable reagent system	depends on cassette configuration–contact Osmetech	varies based on volume
Reagent unit storage requirements	room temperature	room temperature
Shelf life of disposable units	reagent/electrode: 6 mos	reagent/electrode system: 26 wks
Laboratory:		
No. of different disposable reagents required to maintain device	1	—
Max. No. of specific analyte reagents that can reside in device at once	1	—
Shelf life	cassette: 6 mos	—
Cost per test/Reagent cost per test	depends on volume—contact Osmetech/same	—
Calibrations required	1 point (automatic)	2 point (automatic)
Calibration frequency	with each cassette	every test
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	3 levels liquid with change of cassette lot No., 2-mo intervals	electronic QC per 8 hrs, 2 liquid QC per cartridge lot or shipment
QC features	electronic QC–1 level per 8 hrs of operation; elec. & liquid statistical calcs., L-J with external system (DataCare); stores 1 mo—3 levels onboard of each (elec. & liq.)	available with external system
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	no—sample path visible
Specimen types suitable for device	plasma, serum, w. blood, capill., mixed ven., arterial, venous	whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	heparin, lithium	heparin
Sampling technique	aspiration	injection
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	125 µL	125 µL capillary, 200 µL syringe
Sample size differs with No. of analytes selected	no	no
Recommended collection device	heparinized syringe, capillary	standard blood gas syringe
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	~1 min from sample aspiration	<2 min
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	24/192	20/140
Optimal throughput when calibrated and awaiting specimens	—	20 per min
Calibration can be interrupted to perform stat sample	no	no
Contraindications	none	no
Known interferences	none	—
Restrictions based on Hct	no (Hct calculated based on meas. Hb)	no
Sampler has self-wiping probe	no	no (not needed)
Time required for maintenance by lab personnel	weekly: 1 min; quarterly: 5 min	none
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 as needed)	yes (4 days on site)
Method of analyst ID in system	oper. ID and/or secure 4-digit PIN No. for 150 oper. (customizable)	6 digit (in patient monitor; customizable)
Response for hardware & software failure/User ID & QC failure/ Calibration & power failure	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	splash screen for hardware/user ID & QC faulure: notice message/calibration: splash screen
Supports bar-code scanning of	oper. & patient IDs, reag. lot No., QC ranges, cassette lot No., expiration, factory calibration info. & cassette type	cartridge type, cartridge lot No.
User can search for and review previous patient results on screen	no (printed review available for all patients)	yes
Built-in printer/Data port	yes/RS 232, IR	yes (inpatient monitor)/—
Information on hard copy report	customizable, can incl. input values, meas. values, calc. values	test results, patient name & ID, operator ID, blood type, cartridge type, software revision, temperature, barometric pressure
Analyzer connects to	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options)	Philips patient monitor connects to data management system, which in turn connects to LIS/HIS
Interface standards supported	ASTM 1394, ASTM 1238, HL7	ASTM 1394 & 1238 (through patient monitor system)
To upload patient & QC results, how analyzer connects to external system	direct serial or IR	hospital network
Information included in transmission from analyzer to external system	device unique identifier, oper. & patient IDs, results, QC identifier, all info. pertinent to patient & QC data	device unique identifier, operator ID, patient ID, results
Hardware/Software for data management system	Osmetech Opti has onboard data management capabilities, additionally Roche DataCare software is available as a client/server	Diametrics Medical IDMS 6.0.1 or earlier, standard PC with Windows NT or 2000
No. of different management reports system produces	40	18
Contents downloaded from DMS to analyzer	none	—
System connected (live installations) to which LISs, HISs		
• using screen animation, screen scraping	none	all major LIS vendors
• using standard HL7 interface	Meditech, McKesson, Cerner, Siemens, others (call Osmetech for updated list)	McKesson
• using proprietary protocol interface	Kaiser Permanente, others	none
Use a third-party interfacing tool, engine for LIS, HIS interfaces	Dawning, Cloverleaf, Data Innovations (not required but can use)	no
Distinguishing features (provided by vendor)	meas. tHb/SO_2; 6-mo shelf life of cass. stored at room temp. simplifies logistics; auto. sample asp. from syringe and capill.; extensive list of input params.; onboard printer	offers POC testing integrated with Philips patient monitors; offers common user interface providing physiological and biochemical measurements at the bedside

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In vitro blood gas analyzers

Part 10 of 12

See accompanying article on page 24

	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	ABL 5/1994	ABL 700 Series/1998
No. of devices sold in U.S./Outside U.S./List price	—/—/$15,493	—/—/$31,668–$82,127 (depends on configuration options)
Dimensions (H x W x D)/Weight	13 x 13 x 8 in/18 lbs	17 x 28 x 20 in/66 lbs
Analytes measured on device	pH, pCO_2, pO_2	pH, pCO_2, pO_2, Hb, Na, K, Cl, iCa, lactate, glucose, bilirubin, fetal Hb, O_2Hb, MetHb, RHb, COHb, O_2SAT
Parameters calculated on device	Hct, O_2SAT, BE, TCO_2, HCO_3-, ctO_2, $AaDpO_2$, SBE, ABE, SBC, $pCO_2(T)$, $ctCO_2(P)$, pH(T), $cH^+(T)$, $pO_2(T)$	Hct, BE, TCO_2, HCO_3-, plus 40 additional parameters
Barometric pressure	measured	measured
Analytical method(s), technology(ies) employed	pH: pH-sensitive glass (ISE); pCO_2, pO_2: ISE	pH: pH-sensitive glass (ISE); pCO_2, pO_2, Na, Cl, iCa, K: 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 700 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 (NIST traceable gases)	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 external 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	plasma, serum, whole blood, capill., mixed venous, arterial, venous	plasma, serum, whole blood, capill., mixed venous, arterial, venous
Acceptable anticoagulants	heparin, balanced heparin	EDTA, heparin, electrolyte-balanced heparin
Sampling technique	aspiration	aspiration, 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	n/a	no (always use well-mixed samples)
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 as needed)	yes (on site as needed)
Method of analyst ID in system	operator ID entry (optional)	password system (customizable)
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, parallel, Ethernet
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, which connects to LIS/HIS or directly to LIS/HIS	Radiance Stat information management system, which connects to LIS/HIS or directly to LIS/HIS
Interface standards supported	ASTM 1394 & 1238, serial	ASTM 1394 & 1238, HL7, serial, network TCP/IP
To upload patient & QC results, how analyzer connects to external system	direct serial/thousands; modem dial-in/hundreds; real-time wireless future option	direct serial/thousands of hosp. installed; modem dial-in/hundreds; hospital network/hundreds; real time wireless future option
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 w/ Windows NT
No. of different management reports system produces	user definable	user-definable searches/reports
Contents downloaded from DMS to analyzer	—	valid control values, valid operator IDs
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)	no (use interface templates)
Distinguishing features (provided by vendor)	provides basic blood gases (pH, pCO_2, pO_2) test profile; easy to use with minimal maintenance; low cost of operation via standby usage; fast restart, in 2 min, out of standby mode	market first—bilirubin and fetal Hb meas. on whole blood with no extra sample volume, low maintenance and cost of operation; interference-free accuracy; smallest automated microsample mode options with no loss in performance specs. (conserves blood); flexible/modular platform running on Windows (enhanced), Pentium processors, automatic QC, remote support

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SURVEY OF INSTRUMENTS

In vitro blood gas analyzers

Part 11 of 12

See accompanying article on page 24

	Radiometer America Inc. Telesales Department info@radiometeramerica.com 810 Sharon Dr. Westlake, OH 44145 800-736-0600 ext. 333 www.radiometeramerica.com	Roche Diagnostics Corp. Sales Department 9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 us.labsystems.roche.com
Name of device/First year sold	ABL 77/2000	Roche Omni C Analyzer/2001
No. of devices sold in U.S./Outside U.S./List price	—/—/$14,462–$17,129 (depends on configuration)	—/—/$18,000
Dimensions (H x W x D)/Weight	13 x 8 x 9 in/16 lbs	18 x 14 x 16 in/51 lbs
Analytes measured on device	pH, pCO_2, pO_2, Hct, Na, K, iCa, Cl-	pH, pCO_2, pO_2, Hct, Hb, Na, K, Cl, iCa, SO_2
Parameters calculated on device	Hb, O_2SAT, TCO_2, HCO_3-, ctO_2 (a-v), ctO_2, anion gap (K+), cCa^{2+} (7.40), cBase (B), ABE, SBE, others	Hct, O_2SAT, BE, TCO_2, HCO_3-
Barometric pressure	n/a	recorded, tracking barometer
Analytical method(s), technology(ies) employed	pH, pCO_2, pO_2, Na, K, iCa, Cl: thick film; amperometric/potentiometric technology; HCT: conductivity	pH: ion selective galvonometric; pCO_2, pO_2: ion selective membrane; Hct: conductivity; Hb: spectrophotometry; Na, Cl, iCa, K: ion selective potentiometry
Device is part of a series of related models	yes	yes (Roche provides added menu & functionality w/Omni Modular series)
User list or group available	yes (through local sales representative)	yes (contact sales department)
Device warranty	1 yr parts, labor, & travel, with service plans available after yr 1	1 yr
Loaner devices provided	yes	no
Average expected life of device	analyzer: 10+ yrs	7 yrs
Open or closed system/External gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC testing, laboratory, cRT department	laboratory
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	electrode (multiuse cartridge)	—
No. of disposable reagent system units in basic shipment package	1	—
No. of samples analyzed per one disposable reagent, electrode system	50/100/150/300	—
List price per disposable reagent system	depends on configuration & GPO affiliation	—
Reagent unit storage requirements	room temperature	—
Shelf life of disposable units	3 mos	—
Laboratory:		
No. of different disposable reagents required to maintain device	1	3
Max. No. of specific analyte reagents that can reside in device at once	2	n/a
Shelf life	reagent: 3 mos, cartridge: 3 mos	reagent: 2 yrs; electrode: install data recommendation for warranty
Cost per test/Reagent cost per test	depends on configuration & GPO affiliation	—
Calibrations required	1 & 2 point (manual & automatic)	1 & 2 point (automatic)
Calibration frequency	1 point: with each test; 2 point: 1–4 hrs (user definable)	1 point: 30–60 min; 2 point: 4, 8, 12, 24 hrs
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	QC material according to CLIA, CAP, JCAHO	1 per 8 hrs—3 levels in 24 hrs—assayed for system
QC features	L-J plots, statistical calcs., monthly cum. (onboard–current mean, STD, CV%) reports (onboard & available with external system, PC download to Excel)	L-J plots; stat calcs. (mean, SD, %CV), monthly cumulative reports, onboard, available with external system
Remote control of device from laboratory	yes	yes
System can use LOINC to transmit results to LIS	yes	no
How labs get LOINC codes for reagent kits	—	e-mail query
Detects clots within analysis chamber	yes	fluid movement error recognition
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial, venous	plasma, serum, whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	heparinized whole blood	heparin
Sampling technique	aspiration	aspiration, capillary transfer and fill
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	70 µL	65 µL
Sample size differs with No. of analytes selected	no	no
Recommended collection device	heparinized syringe or capillary tube	heparinized syringes, capillary Microsampler
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	70 sec	45 sec
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	40/320	average 30 samples per hr, all measured analytes
Optimal throughput when calibrated and awaiting specimens	40 tests per hr	—
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	no	no
Known interferences	—	—
Restrictions based on Hct	no	—
Sampler has self-wiping probe	no	yes
Time required for maintenance by lab personnel	n/a	—
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	no	no
Training & certification program for user	yes	yes (2 days on site)
Method of analyst ID in system	bar-code or onboard keyboard (customizable)	bar-code, screen, or keyboard (customizable)
Response for hardware & software failure/User ID & QC failure/Calibration & power failure	error msg./error msg./calib.: error msg., power: blank screen & color indicator for battery level	HW: stop; SW: stop/user ID: lockout (optional); QC: lockout (optional)/calibration: lockout by analyte failure; power: short—return to operation; long—stop
Supports bar-code scanning of	operator & patient IDs, reag. & sensor lot Nos., QC*	operator & patient IDs, reagent lot No., input QC ranges, lot No.
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	all meas. & calc. values, exp., test remaining info., dispos. lot No., basic statistics, time & date, user & patient info., temp. corrected at 37°C	results, errors, patient & sample input (customizable)
Analyzer connects to	Radiance Stat information management system, which connects to LIS/HIS or directly to LIS/HIS	data management system, which in turn connects to LIS/HIS, directly to LIS/HIS
Interface standards supported	ASTM, HL7	HL7
To upload patient & QC results, how analyzer connects to external system	serial, Ethernet	direct serial, 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	Radiance with Windows NT	onboard data management capabilities
No. of different management reports system produces	user definable	—
Contents downloaded from DMS to analyzer	—	valid control values, valid operator IDs, patient demographics
System connected (live installations) to which LISs, HISs		
• using screen animation, screen scraping	Cerner, Meditech, Misys, others	—
• 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)	—
Distinguishing features (provided by vendor)	portable, optional battery operation; quickest startup/warmup and analysis time; simple and easy-to-use system	automatic sample aspiration; clot and air detection; QC and user lockout; Roche Auto QC loads 120 ampules for automatic and precise measurement and configurable for a variety of QC regimens

** all open tests*

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In vitro blood gas analyzers

Part 12 of 12

See accompanying article on page 24

	Roche Diagnostics Corp. Sales Department 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 us.labsystems.roche.com
Name of device/First year sold	Roche Omni Modular System/1996
No. of devices sold in U.S./Outside U.S./List price	—/—/$29,900–$56,200
Dimensions in inches (H x W x D)/Weight	16.5 x 21 x 18.5 in/88 lbs
Analytes measured on device	pH, pCO_2, pO_2, Hct, Hb, Na, K, Cl, iCa, lactate, glucose, BUN, co-ox values: O_2Hb, COHb, SulfHb, HHb, metHb
Parameters calculated on device	40+ parameters, including BE, BB, HCO_3^-, TCO_2, SO_2, $NiCa^{++}$, ctO_2, p50, shunt, AG, OSM (call Roche for list)
Barometric pressure	measured
Analytical method(s), technology(ies) employed	pH: ion selective galvanometric; pCO_2, pO_2: ion selective membrane; Hct: conductivity; Hb: spectrophotometry; Na, Cl, iCa, K: ion selective potentiometry; lactate: lact. oxidase enzyme; glucose: glucose oxidase enzyme; BUN: urease enzyme
Device is part of a series of related models	yes, models 1–9
User list or group available	yes (through Roche sales dept.)
Device warranty	1 yr (service contract available for subsequent years)
Loaner devices provided	yes
Average expected life of device	>7 yrs
Open or closed system/External gas tanks required	closed/no
For POC testing or laboratory	POC & laboratory (transportable on cart system)
POC:	
Uses disposable prepackaged reagent/Electrode system for analysis	n/a
No. of disposable reagent system units in basic shipment package	n/a
No. of samples analyzed per one disposable reagent, electrode system	n/a
List price per disposable reagent system	n/a
Reagent unit storage requirements	n/a
Shelf life of disposable units	n/a
Laboratory:	
No. of different disposable reagents required to maintain device	depends on model, contact Roche
Max. No. of specific analyte reagents that can reside in device at once	n/a
Shelf life	reagents: 1 yr
Cost per test/Reagent cost per test	depends on sample volume/same
Calibrations required	1 & 2 point (automatic)
Calibration frequency	1 point: 30 min and with each sample, 2 point: selectable 4–12 hrs
Calibrants traceable to NIST standards	yes
Internal QC program recommended	1 liquid QC sample per 8 hrs of operation
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
Remote control of device from laboratory	yes
System can use LOINC to transmit results to LIS	no
How labs get LOINC codes for reagent kits	—
Detects clots within analysis chamber	yes
Specimen types suitable for device	plasma, serum, w. blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	heparin, lithium
Sampling technique	aspiration, injection
Suitable for samples from well neonates/Sick neonates	yes/yes
Sample size for complete panel of analyte results	160 µL for full panel, 40 µL per module
Sample size differs with No. of analytes selected	yes, 40 µL per module; i.e.: pH/BG, electrolytes, co-ox, metabolites
Recommended collection device	heparinized syringe, capillary, Microsampler
Provides for patient temperature corrected results	yes
Time from sample introduction to result availability	~1 min (depends on tests analyzed)
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	40/490 tests per hr
Optimal throughput when calibrated and awaiting specimens	40 samples per hr
Calibration can be interrupted to perform stat sample	yes
Contraindications	none
Known interferences	none
Restrictions based on Hct	no (automatically checks Hct: tHb ratio)
Sampler has self-wiping probe	no
Time required for maintenance by lab personnel	weekly: 5 min, quarterly: 5 min
Onboard diagnostics for troubleshooting/Limited to software	yes/no
Diagnostics performed through modem	yes, with Omni-Link via network can remotely control, realtime continuously monitor, activate calib., QC sampling (with AutoQC module), and activate troubleshooting routines remotely
Training & certification program for user	yes (on site)
Method of analyst ID in system	4-level password system for 200 operators
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
Supports bar-code scanning of	oper. & patient identifiers, reag. & electrode lot Nos., QC ranges, expir.
User can search for and review previous patient results on screen	yes (up to 50,000 online onboard analyzer)
Built-in printer/Data port	yes/RS 232, parallel, Ethernet
Information on hard copy report	customizable, can incl. input values, meas. values, calc. values
Analyzer connects to	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options)
Interface standards supported	ASTM 1394, ASTM 1238, HL7 (DataCare available)
To upload patient & QC results, how analyzer connects to external system	direct serial, hospital network, realtime wireless (RF)
Information included in transmission from analyzer to external system	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
No. of different management reports system produces	40
Contents downloaded from DMS to analyzer	valid control values, valid operator IDs, patient demographics
System connected (live installations) to which LISs, HISs	
• using screen animation, screen scraping	none
• using standard HL7 interface	Meditech, HBOC, 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)
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

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

Be on alert for blood gas traps

Anne Ford

Sure, blood gas laboratories vary, but in the realm of inspection deficiencies, they have quite a bit in common. A survey of about 700 labs last year found five Laboratory Accreditation Program checklist questions on which blood gas labs most often slipped up, with three to five percent of surveyed labs deficient for each question. C. Robert Baisden, MD, Gulf regional commissioner for the CAP Commission on Laboratory Accreditation, reviewed these common deficiencies during an accreditation program audioconference May 14.

Just over five percent of the laboratories surveyed, Dr. Baisden noted, came up short on checklist item BGL.22100: *Is there documentation of at least annual review of all policies and procedures in the blood gas laboratory section by the current laboratory director or designee?* If not, the lab has some paperwork to catch up on. The remedy lies in reviewing about half of all procedures each month, dating and signing each procedure as reviewed, or implementing a sign-off sheet. The sign-off sheet should list the name and effective date of each procedure. The reviewer's signature and the date of review must be at the level of each procedure. A single signature on a title page or index of all procedures is not sufficient. If the lab director delegates the review, there should be documentation of the authorized worker. Laboratories can indicate in writing the title, rather than the name, of the appointed reviewer, so they don't have to make a revision every time personnel change.

"There's no need to sign the front page of each procedure," Dr. Baisden said, "although it's acceptable to do so." He warned, however, that it's not uncommon to miss signing and dating a procedure or two using this strategy.

Written modus operandi are the solution as well for labs deficient on question BGL.27485: *Does the laboratory have an action protocol when data from imprecision statistics change significantly from previous data?* For 4.4 percent of the laboratories surveyed, the answer was no. Developing a written troubleshooting protocol for data that don't measure up entails consulting the instrument manual or incorporating several steps into the lab's testing or QC procedure: cleaning and recalibrating the instrument, checking the calibration fluid/gas integrity, tracking possible operator error, and, if

continued on page 40

Blood gas traps

continued from page 38

necessary, retraining in sampling technique.

A similar number of labs were deficient on question BGL.27250: *Is verification of the analytic measurement range (AMR) performed with matrix-appropriate materials of known analyte value appropriate to the AMR of the method system, and is the process documented?* Most deficiencies in this area, Dr. Baisden said, arise because laboratories don't perform AMR verification every six months. When verifying AMR, labs should use matrix-appropriate materials with target values that, at the minimum, are near the low, midpoint, and high values of the AMR. Laboratories should ask the manufacturer to supply material of extreme high and low values. Dr. Baisden added that labs must report values lower or higher than the verified AMR as "greater than" or "less than."

If the laboratory has more than one method system for performing tests for a given analyte, are they checked against each other at least twice a year for correlation of patient results? Just over four percent of surveyed labs didn't measure up on this question, BGL.27316. Dr. Baisden says laboratories can perform this correlation by using a combination of patient specimens and QC and linearity materials.

The final checklist item labs commonly missed, BGL.29760, asked: *Are at least two levels of quality control specimens analyzed at least every eight hours of operation for all parameters when patient specimens are tested?* Dr. Baisden hopes that this deficiency will become less prevalent now that the latest checklist, issued March 31, has adopted the less stringent CLIA standard. This standard requires labs to analyze only one level of QC specimens for pH, pCO_2, and pO_2 at least every eight hours of operation when patient specimens are tested. Now that the checklist has been modified, Dr. Baisden says, "this should then no longer be a frequent deficiency."

Anne Ford is CAP TODAY *senior editor.*