In vitro blood gas analyzers

Part 1 of 12

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	Abbott Diagnostics **Eric Perreault** eric.perreault@abbott.com **4A Crosby Dr.** **Bedford, MA 01730** **781-276-4797** www.abbott.com	**Abbott Diagnostics** **Eric Perreault** eric.perreault@abbott.com **4A Crosby Dr.** **Bedford, MA 01730** **781-276-4797** www.abbott.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	**500/250/$8,500**	**11,000 worldwide/$5,000**
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, Hb, Na, K, Cl, iCa, lactate, glucose, creatinine, BUN**	**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/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	**point-of-care testing**	**point-of-care 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 1 disposable reagent/electrode system	**1**	**1**
List price per disposable reagent system	**$3–$7**	**$3–$9**
Reagent unit storage requirements	**refrigerate, 2 weeks of shelf life at room temperature**	**refrigerate, 2 weeks 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. 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**
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/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 identifier, reagent lot number, hospital specific information**	**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 ID, result, 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 ID, result, QC identifier**	**device unique identifier, operator & patient ID, result, 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 numbers, 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	**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

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Name of device/first year sold	Rapidpoint 400/2001	Synthesis 10 & 15/1997
No. of devices sold in U.S./outside U.S./list price	n/a/n/a/$38,000	>100 worldwide/Synthesis 10: $29,925, Synthesis 15: $42,000
Dimensions (H x W x D)/weight	21.5 x 11.5 x 16 in/34 lbs	20 x 16 x 20 in/77 lbs
Analytes measured on device	pH, pCO_2, pO_2, Hct, Na, K, Cl, iCa, glucose	pH, pO_2, pCO_2; Synthesis 15: THb, O_2Hb, COHb, MetHb, RHb
Parameters calculated on device	O_2SAT, BE, TCO_2, HCO_3-	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
Barometric pressure	recorded	tracking
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	pH: potentiometry; pCO_2: Severinghaus electrode-voltage; pO_2: Clark electrode-current; Hb: nonhemolytic Hb absorption (Synthesis 15)
Device is part of a series of related models	yes	yes (Synthesis family offering different analyte options)
User list/group available	yes	yes (through local sales representative)
Device warranty	1 yr	1 yr
Loaner devices provided	yes	yes
Average expected life of device	5–7 yrs	7–10 yrs
Open or closed system/external gas tanks required	—/no	closed/yes
For POC testing or laboratory	point-of-care testing	laboratory
POC:		
Uses disposable prepackaged reagent/electrode system for analysis	reagent/electrode (multiuse cartridge)	—
No. of disposable reagent system units in basic shipment package	1 measurement cartridge/3 waste/wash cartridges	—
No. of samples analyzed per 1 disposable reagent/electrode system	750 samples	—
List price per disposable reagent system	$3,500	—
Reagent unit storage requirements	refrigeration	—
Shelf life of disposable units	reagent/electrode: 4 mos	—
Laboratory:		
No. of different disposable reagents required to maintain device	—	3
Max. No. specific analyte reagents that can reside in device at once	—	—
Shelf life	—	reagent: 24 mos, electrode: 4 mos–1 yr
Cost per test/reagent cost per test	—	$.71/$.73 @ 50 tests per day at list price/$.24 @ 50 tests per day at list
Calibrations required	1 & 2 point (automatic)	1 & 2 point (automatic & manual)
Calibration frequency	1 point: 30 min; 2 point: 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 QC every 8 hrs testing, aqueous based	1 level per 8 hrs, IL controls recommended
QC features	L-J plots, comparable plot, statistical calculations, monthly cumulative reports (onboard & available with external system)	L-J plots, QC tracking
Remote control of device from laboratory	yes	yes
System can use LOINC to transmit results to LIS	yes	no
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial, venous	w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas
Acceptable anticoagulants	heparin	heparin
Sampling technique	aspiration	aspiration, injection, capillary
Suitable for samples from well/sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	100 µL	60 µL/100 µL
Sample size differs with No. of analytes selected	no	yes
Recommended collection device	syringe or capillary tube	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	140/—	50/150–400
Optimal throughput when calibrated and awaiting specimens	35 samples per hr	30 samples per hr
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	if calibration is interrupted repeatedly, it will force a mandatory calibration to be completed before sampling	none
Known interferences	benzalkonium	none
Restrictions based on Hct	no	no
Sampler has self-wiping probe	yes	yes
Time required for maintenance by lab personnel	maintenance free	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	yes (1 day on-site)
Method of analyst ID in system	password (customizable)	manual entry of ID & password (customizable)
Response for hardware & software failure/user ID & QC failure/calibration & power failure	flag-prompt/user ID: customizable; QC: customizable-flag/calibration: flag–recalibration	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 ID, accession No., results, temperature, other information	operator & patient ID, QC values
User can search for and review previous patient results on screen	yes	yes
Built-in printer/data port	yes/RS 232, ethernet	yes/4-RS 232, 1 parallel, standalone CO-ox port, alphanumeric keyboard port, bar-code reader port
Information on hard copy report	operator & patient ID, accession No., results, temperature, other information	patient demographics, hospital name, results
Analyzer connects to	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options)	interfaced direct with HIS/LIS or Impact for Critical Care, which can be interfaced to HIS/LIS
Interface standards supported	LIS 3	interfaced with LIS or Impact for Critical Care, ASTM protocol
To upload patient & QC results, how analyzer connects to external system	direct serial, hospital network	direct serial, modem dial-in, hospital network
Information included in transmission from analyzer to external system	device unique identifier, operator & patient ID, result, QC identifier	device identifier, operator & patient ID, result, QC ID
Hardware/software for data management system	HP platform/Windows NT, SQL server	Impact for Critical Care
No. of different management reports system produces	customizable	customizable
Contents downloaded from DMS to analyzer	valid control values, valid operator IDs	patient ID, demographics
System connected (live installations) to which LISs/HISs		
• using screen animation/screen scraping	—	none
• using standard HL7 interface	yes	none
• using proprietary protocol interface	yes	none
Use a third-party interfacing tool/engine for LIS/HIS interfaces	yes	no
Distinguishing features	no maintenance, multiuse cartridge; fast time to patient results; onboard audio-video training videos; auto QC	continuous calibration corrects every 3 seconds for drift seen in Clark & Severinghaus electrodes–ensures accurate results before patient sampling; maintenance-free disposable electrodes for convenience & system uptime; integrated co-oximeter uses no extra reagent & minimizes maintenance

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In vitro blood gas analyzers

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	Instrumentation Laboratory **Tim Lynch** tlynch@ilww.com **101 Hartwell Ave.** **Lexington, MA 02421** **781-861-0710** www.ilww.com	**Instrumentation Laboratory** **Tim Lynch** tlynch@ilww.com **101 Hartwell Ave.** **Lexington, MA 02421** **781-861-0710** www.ilww.com
Name of device/first year sold	**Synthesis 20 & 25/1997**	**Synthesis 30 & 35/1997**
No. of devices sold in U.S./outside U.S./list price	**>100 worldwide/Synthesis 20: $38,325; Synthesis 25: $48,300**	**>100 worldwide/Synthesis 30: $42,000; Synthesis 35: $52,500**
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-; Synthesis 25: THb, O_2Hb, COHb, MetHb, RHb**	**pH, pO_2, pCO_2, Na, K+, Ca++, Cl-, glucose; Synthesis 35: 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, 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**	**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**
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/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 1 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. specific analyte reagents that can reside in device at once	**12**	**12**
Shelf life	**—**	**—**
Cost per test/reagent cost per test	**$.84/$.86 @ 50 tests per day at list price/$.24 @ 50 tests per day at list**	**$1.67/$1.69 @ 50 tests per day at list price/$.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**
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/sick neonates	**yes/yes**	**yes/yes**
Sample size for complete panel of analyte results	**80 µL/150 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	**50/350–600**	**40/280–480**
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 ID, result, QC ID**	**device identifier, operator & patient ID, result, 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	**continuous calibration corrects every 3 seconds for drift seen in Clark & Severinghaus electrodes–ensures accurate results before patient sampling; maintenance-free disposable electrodes for convenience & system uptime; integrated co-oximeter uses no extra reagent & minimizes maintenance**	**continuous calibration corrects every 3 seconds for drift seen in Clark & Severinghaus electrodes–ensures accurate results before patient sampling; maintenance-free disposable electrodes for convenience & system uptime; integrated co-oximeter uses no extra reagent & minimizes maintenance**

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Name of device/first year sold	Synthesis 40 & 45/1999	Gem Premier 3000/2000
No. of devices sold in U.S./outside U.S./list price	n/a/Synthesis 40: $48,300; Synthesis 45: $60,375	—/—/$39,995
Dimensions (H x W x D)/weight	20 x 16 x 20 in/77 lbs	17 x 12 x 12 in/29.5 lbs
Analytes measured on device	pH, pO_2, pCO_2, Na+, K+, Ca++, Cl-, glucose, lactate; Synthesis 45: THb, O_2Hb, COHb, MetHb, RHb	pH, pO_2, pCO_2, Hct, Na+, K+, Ca++, glucose, lactate
Parameters calculated on device	pH(T), pO_2(T), pCO_2(T), HCO_3-, SBC, TCO_2, Beb, BEecf, %sO_2c, pAO_2, paO_2/pAO_2, RI, A-aDO_2, anion gap, osmolality, O_2cap, O_2ct, p50	O_2SAT, BE, TCO_2, HCO_3-, Ca++ (7.4)
Barometric pressure	tracking	n/a
Analytical method(s)/technology(ies) employed	pH: potentiometry; pCO_2: Severinghaus electrode-voltage; pO_2: Clark electrode-current; Hct: conductivity; Hb: nonhemolytic Hb absorption; Na, Cl, iCa, K: ISE; glucose, lactate: enzymatic	pH, pCO_2: potentiometry; pO_2, glucose, lactate: amperometry; Hct: conductivity; Na, iCa, K: ISE
Device is part of a series of related models	yes (Synthesis family offering different analyte options)	yes
User list/group available	yes (through local sales representative)	yes (through local sales representative)
Device warranty	1 yr	5 yrs
Loaner devices provided	yes	yes
Average expected life of device	7–10 yrs	7–10 yrs
Open or closed system/external gas tanks required	closed/yes	closed/no
For POC testing or laboratory	laboratory	POC & laboratory
POC:		
Uses disposable prepackaged reagent/electrode system for analysis	—	reagent/electrode (multiuse cartridge)
No. of disposable reagent system units in basic shipment package	—	2 per pack
No. of samples analyzed per 1 disposable reagent/electrode system	—	75-, 150-, 300-, & 450-test cartridge
List price per disposable reagent system	—	varies with size & menu
Reagent unit storage requirements	—	room temperature
Shelf life of disposable units	—	6 mos
Laboratory:		
No. of different disposable reagents required to maintain device	—	0
Max. No. specific analyte reagents that can reside in device at once	13	1 multiuse cartridge
Shelf life	—	6 mos
Cost per test/reagent cost per test	TBD/$.24 @ 50 tests per day at list price	varies with size & menu
Calibrations required	1 & 2 point (automatic & manual)	1 & 2 point (automatic & manual)
Calibration frequency	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	bar-code identification of QC material, QC statistics, QC scheduling, QC lockout
Remote control of device from laboratory	yes	yes
System can use LOINC to transmit results to LIS	no	no
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas	whole blood, capill., arterial, venous with lithium heparin
Acceptable anticoagulants	heparin	heparin
Sampling technique	aspiration, injection, capillary	aspiration
Suitable for samples from well/sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	95 µL/165 µL	135–150 µL
Sample size differs with No. of analytes selected	yes	no
Recommended collection device	universal sampler accepts all devices	—
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	60 sec	<100 sec
Max. No. of patient samples per hr/max. No. of measured parameters per hr	40/320–520	15/135
Optimal throughput when calibrated and awaiting specimens	30 samples per hr	15 samples
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	disposable cartridge/no maintenance required
Onboard diagnostics for troubleshooting/limited to software	Yes/no	yes/no
Diagnostics performed through modem	Yes	no
Training & certification program for user	Yes (1 day on-site)	yes
Method of analyst ID in system	manual 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/4-RS 232, 1 parallel, standalone co-ox port, alphanumeric keyboard port, bar-code reader port	yes/3-RS 232, 1 parallel, bar-code reader port, ethernet port
Information on hard copy report	patient demographics, hospital name, results	patient demographics, hospital name and address, results
Analyzer connects to	interfaced direct with HIS/LIS or Impact for Critical Care, which can be interfaced to HIS/LIS	interfaced direct with LIS/HIS 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, result, QC ID	device identifier, operator & patient IDs, result, QC ID & result
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	continuous calibration corrects every 3 seconds for drift seen in Clark & Severinghaus electrodes–ensures accurate results before patient sampling; maintenance-free disposable electrodes for convenience & system uptime; integrated co-oximeter uses no extra reagent & minimizes maintenance	maintenance-free multiuse cartridge used through institution for critical care testing; proven dependable technology for >12 yrs; only system that provides consolidated workstation for blood gases, electrolytes, Hct, glucose, lactate, coagulation, and co-oximetry

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

In vitro blood gas analyzers

Part 5 of 12

See accompanying article on page 58

	Instrumentation Laboratory	Medica Corp.
	Patti Eames peames@ilww.com	Leslie Boone lboone@medicacorp.com
	101 Hartwell Ave.	14 DeAngelo Dr.
	Lexington, MA 02421	Bedford, MA 01730
	781-861-0710	800-777-5983
	www.ilww.com	www.medicacorp.com
Name of device/first year sold	Gem 3100/2000	EasyBloodGas/2000
No. of devices sold in U.S./outside U.S./list price	—/—/—	<500/>500/$10,500
Dimensions (H x W x D)/weight	22 x 12 x 12 in/31.5 lbs	14.5 x 12.5 x 7 in/16 lbs
Analytes measured on device	pH, pO_2, pCO_2, Hct, Na+, K+, Ca++, glucose, lactate: PT, APTT, ACT, ACT-LR	pH, pO_2, pCO_2
Parameters calculated on device	O_2SAT, BE, TCO_2, HCO_3-, Ca++ (7.4)	O_2SAT, BE, TCO_2, HCO_3-
Barometric pressure	n/a	measured
Analytical method(s)/technology(ies) employed	pH, pCO_2: potentiometry; pO_2, glucose, lactate: amperometry; Hct: conductivity; Na, iCa, K: ISE; PT, APTT, ACT, ACT-LR: mechanical clot detection	pH: ISE; pO_2: ISE; pCO_2: ISE
Device is part of a series of related models	yes	yes (EasyElectrolytes)
User list/group available	yes (through local sales representative)	yes (through individual dealers)
Device warranty	5 yrs	1 yr
Loaner devices provided	yes	yes
Average expected life of device	7–10 yrs	>5 yrs
Open or closed system/external gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC & laboratory	laboratory
POC:		
Uses disposable prepackaged reagent/electrode system for analysis	reagent/electrode (multiuse cartridge); single-use coag. cartridge	—/—
No. of disposable reagent system units in basic shipment package	2 per pack	—
No. of samples analyzed per 1 disposable reagent/electrode system	cartridges available: 75-, 150-, 300-, & 450-test cartridge, 1 sample per cartridge for coagulation tests	—
List price per disposable reagent system	coagulation tests per cart.: PT: $6, APTT: $8, ACT: $4, ACT-LR: $4.50	—
Reagent unit storage requirements	room temperature	—
Shelf life of disposable units	6 mos	—
Laboratory:		
No. of different disposable reagents required to maintain device	0	1
Max. No. specific analyte reagents that can reside in device at once	2:1 for blood gas/electrolytes, 1 for coagulation	1
Shelf life	6 mos	reagent & electrode: 1 yr; membrane kit: n/a, disposable electrodes; cartridge: n/a
Cost per test/reagent cost per test	varies with menu & cartridge size	$0.57 at 20 tests per day/$0.26 at 20 tests per day
Calibrations required	1 & 2 point (automatic & manual)	1 & 2 point (automatic)
Calibration frequency	—	1 point: during each sample analysis; 2 point: can be set for 2, 4, 8 hr increments
Calibrants traceable to NIST standards	yes	—
Internal QC program recommended	1 level per 8 hrs, IL controls recommended	1 level per 8 hrs, Medica controls recommended
QC features	bar-code identification of QC material, electronic & liquid QC available for coagulation tests	L-J plots; monthly cumulative reports
Remote control of device from laboratory	yes	no
System can use LOINC to transmit results to LIS	no	no
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	whole blood, capill., arterial, venous with lithium heparin	whole blood, capillary, mixed venous, arterial
Acceptable anticoagulants	heparin, fresh whole blood for coagulation tests	heparin
Sampling technique	aspiration	aspiration
Suitable for samples from well/sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	135–150 µL, 50 µL for coagulation	75 µL capillary, 100 µL syringe
Sample size differs with No. of analytes selected	no	no
Recommended collection device	—	syringe or capillary, heparinized
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	<100 sec; under 5 min for coagulation	125 sec, includes 1-point calibration
Max. No. of patient samples per hr/max. No. of measured parameters per hr	15/135	25/75
Optimal throughput when calibrated and awaiting specimens	15 samples (with stat option)	25
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	—	no
Known interferences	—	incorrect anticoagulant
Restrictions based on Hct	no	no
Sampler has self-wiping probe	yes	yes
Time required for maintenance by lab personnel	no operator involvement	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	yes (through distributors)
Method of analyst ID in system	manual or bar-code wand entry of ID & password (customizable)	manual or bar-code wand for ID entry
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	SW displays error/prevents use until corrected/watch dog reset/ SW lockout, displays error, prevents use until corrected/calibration: SW lockout, displays error, prevents use until corrected; power: no data lost, auto reset, will need to be recalibrated
Supports bar-code scanning of:	operator & patient ID, QC values	operator & patient ID, reagent lot number, QC control, reagent pack automatically read when reagent module installed
User can search for and review previous patient results on screen	yes	yes
Built-in printer/data port	yes/2-RS 232, 1 parallel, bar-code reader port, ethernet port	yes/RS 232
Information on hard copy report	patient demographics, hospital name, results	patient information; measured parameters: pH, pCO_2, pO_2; 11 calculated parameters
Analyzer connects to	interfaced direct with HIS/LIS or IMPACT for Critical Care, which can be interfaced to HIS/LIS	data management system, which in turn connects to LIS/HIS
Interface standards supported	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
Information included in transmission from analyzer to external system	device identifier, operator & patient ID, result, QC ID	patient ID, result
Hardware/software for data management system	Impact for Critical Care	internal
No. of different management reports system produces	customizable	QC, L-J, patient reports
Contents downloaded from DMS to analyzer	patient ID, demographics	valid control values, valid operator IDs, ranges, patient IDs
System connected (live installations) to which LISs/HISs		
• using screen animation/screen scraping	none	—
• using standard HL7 interface	none	—
• using proprietary protocol interface	none	—
Use a third-party interfacing tool/engine for LIS/HIS interfaces	no	TBD
Distinguishing features	maintenance-free multiuse cartridges used in >100,000 open-heart surgery cases annually; dependability of being the pioneer in cartridge-based blood gas systems for >10 yrs; only system that provides consolidated workstation for blood gases, electrolytes, glucose, lactate, Hct, coagulation	all components are modular; the analyzer can be repaired and maintained by anyone; due to its modularity, replacement parts are easy to install; no need for a service contract

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

OF INSTRUMENTS

In vitro blood gas analyzers

Part 6 of 12

See accompanying article on page 58

	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 M/1998**	**Stat Profile pHOx/1998**
No. of devices sold in U.S./outside U.S./list price	**—/—/$52,000**	**—/—/$15,000**
Dimensions (H x W x D)/weight	**18.5 x 22.25 x 19 in/70 lbs**	**15 x 12 x 15 in/18 lbs**
Analytes measured on device	**pH, pCO_2, pO_2, Hct, Hb, Na, K, Cl, iCa, iMg, lactate, glucose, BUN, O_2SAT**	**pH, pCO_2, pO_2, Hct, Hb, O_2SAT**
Parameters calculated on device	**BE, TCO_2, HCO_3-**	**BE, TCO_2, HCO_3-**
Barometric pressure	**tracked**	**tracked**
Analytical method(s)/technology(ies) employed	**Na, Cl, iCa, iMg, pH, K: direct ISE; pCO_2: potentiometry; pO_2: amperometry, Hct: conductivity; Hb: optical–reflectance; lactate, glucose: enzyme/amperometric; BUN: enzyme/ISE**	**pH: direct ISE; pCO_2: potentiometry; pO_2: amperometry; Hct: conductivity; Hb & SO_2%: optical–reflectance**
Device is part of a series of related models	**yes, user configurable; max. tests: 14**	**yes**
User list/group available	**yes (upon request)**	**yes (upon request)**
Device warranty	**1 yr, travel & labor, repair or replacement**	**1 yr, travel & labor, repair or replacement**
Loaner devices provided	**yes**	**yes**
Average expected life of device	**5–7 yrs**	**5–7 yrs**
Open or closed system/external gas tanks required	**closed/yes**	**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 1 disposable reagent/electrode system	**n/a**	**n/a**
List price per disposable reagent system	**$148–$221**	**$200–$265**
Reagent unit storage requirements	**room temperature**	**room temperature**
Shelf life of disposable units	**reagents: 18 mos room temperature; electrodes: up to 18 mos**	**reagents: 18 mos room temperature, electrodes: up to 18 mos**
Laboratory:		
No. of different disposable reagents required to maintain device	**1**	**1**
Max. No. specific analyte reagents that can reside in device at once	**1**	**1**
Shelf life	**reagents & electrodes: 18 mos; membrane kits: 12–24 mos**	**reagents & electrodes: 18 mos; membrane kits: 12–24 mos**
Cost per test/reagent cost per test	**<$.07 at 35 analyses per day/<$.03 at 35 analyses per day**	**<$.11 at 35 analyses per day/<$.08 at 35 analyses per day**
Calibrations required	**1 & 2 point (automatic)**	**1 & 2 point (automatic)**
Calibration frequency	**1 point: 30 or 45 min (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	**min. CLIA recommendations**	**min. 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	**no**	**yes**
System can use LOINC to transmit results to LIS	**no**	**no**
Detects clots within analysis chamber	**yes**	**yes**
Specimen types suitable for device	**plasma, serum, whole blood, capill., 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/sick neonates	**yes/yes**	**yes/yes**
Sample size for complete panel of analyte results	**195 µL**	**70 µL**
Sample size differs with No. of analytes selected	**yes, Profile M offers micropanel; standard 12-test micropanel req., 85 µL**	**yes, pHOx offers micropanel; standard 3-test micropanel req., 40 µL**
Recommended collection device	**syringe, capill., microcollect. containers, standard vacuum cont.**	**syringe, capill., microcollect. containers, standard vacuum cont.**
Provides for patient temperature corrected results	**yes**	**yes**
Time from sample introduction to result availability	**1.2 min–2.5 min**	**45 sec**
Max. No. of patient samples per hr/max. No. of measured parameters per hr	**35/490 tests**	**50/300 tests**
Optimal throughput when calibrated and awaiting specimens	**490–552 tests per hr**	**300 tests per hr**
Calibration can be interrupted to perform stat sample	**yes**	**yes**
Contraindications	**none**	**none**
Known interferences	**not reported**	**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: <15 min**	**weekly: <5 min, monthly: <10 min**
Onboard diagnostics for troubleshooting/limited to software	**yes/no**	**yes/no**
Diagnostics performed through modem	**yes**	**yes**
Training & certification program for user	**yes (on-site)**	**yes (on-site)**
Method of analyst ID in system	**password with unique user ID No. (optional)**	**password with unique user ID No. (optional)**
Response for hardware & software failure/user ID & QC failure/ calibration & power failure	**self-diag. SW informs & notifies oper. of HW failure; hotline & field support depending on problem/optional lockout w/o user ID; options for QC failure range from flagging to not reporting test that fails QC to lockout for QC failure or exceeding scheduled QC interval/ any test that does not calibrate will not report results & instrument notifies oper. of reason for failure; momentary power interrupts require no recover–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 recover–extended power failure results in automatic calib.**
Supports bar-code scanning of:	**patient identifier**	**patient identifier**
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 with access. No., entered settings, meas. & calc. results**	**patient ID w/ access. No., entered settings, meas. & calc. results**
Analyzer connects to	**data management system &/or directly to LIS/HIS**	**data management system &/or directly to LIS/HIS**
Interface standards supported	**ASTM E1381-91 (HL7 available with external device)**	**ASTM E1381-91 (HL7 available with external device)**
To upload patient & QC results, how analyzer connects to external system	**direct serial/>500 hospitals installed; hospital network/>100 installed**	**direct serial/>500 hospitals installed; hospital network/>100 installed**
Information included in transmission from analyzer to external system	**device unique identifier, operator & patient IDs, result, QC identifier, accession No.**	**device unique identifier, operator & patient IDs, result, QC identifier, accession No.**
Hardware/software for data management system	**Pentium with Microsoft Windows 2000/Nova Patient Data Manager**	**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	**broad critical care test menu—user can select up to 14 meas. tests on one system; only critical care analyzer offering these diagnostic tests. iMg–unique test offered; "remote review" of patient results prior to results reporting; unique automated test ordering, accessioning, & reporting feature that requires oper. to enter patient ID & POCT site; these features require Nova Patient Data Manager**	**onboard QC cartridge provides sufficient QC materials for 30-day auto QC analysis; no external gas tanks (supplies for calibrations incorporated into single reagent cartridge–waste collect. also incorporated); includes key oximetry values without need for co-ox**

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

In vitro blood gas analyzers

Part 7 of 12

See accompanying article on page 58

	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 M7/1999**	**Stat Profile pHOx Plus/2000; Stat Profile pHOx Plus L/2001**
No. of devices sold in U.S./outside U.S./list price	**—/—/$52,000**	**pHO Plus: —/—/$29,000; pHOx Plus L: —/—/$32,000**
Dimensions (H x W x D)/weight	**18.5 x 22.25 x 19 in/70 lbs**	**15 x 12 x 15 in/18 lbs**
Analytes measured on device	**pH, pCO_2, pO_2, Hct, Hb, Na, K, Cl, iCa, creatinine, lactate, glucose, BUN, O_2SAT**	**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	**Na, Cl, iCa, pH, K: direct ISE; pCO_2: potentiometry; pO_2: amperometry, Hct: conductivity; Hb: optical–reflectance; lactate, glucose, creatinine: enzyme/amperometric; BUN: enzyme/ISE**	**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, user configurable; max. tests: 14**	**yes**
User list/group available	**yes (upon request)**	**yes (upon request)**
Device warranty	**1 yr, travel & labor, repair or replacement**	**1 yr, travel & labor, repair or replacement**
Loaner devices provided	**yes**	**yes**
Average expected life of device	**5–7 yrs**	**5–7 yrs**
Open or closed system/external gas tanks required	**closed/yes**	**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 1 disposable reagent/electrode system	**n/a**	**n/a**
List price per disposable reagent system	**$185**	**$210–$275**
Reagent unit storage requirements	**room temperature**	**room temperature**
Shelf life of disposable units	**reagents: 18 mos room temperature, electrodes: up to 18 mos**	**reagents: 18 mos room temperature, electrodes: up to 18 mos**
Laboratory:		
No. of different disposable reagents required to maintain device	**1**	**1**
Max. No. specific analyte reagents that can reside in device at once	**1**	**1**
Shelf life	**reagents & electrodes: 18 mos; membrane kits: 12–24 mos**	**reagents & electrodes: 18 mos; membrane kits: 12–24 mos**
Cost per test/reagent cost per test	**<$.07 at 35 analyses per day/<$.03 at 35 analyses per day**	**<$.11 at 35 analyses per day/<$.08 at 35 analyses per day**
Calibrations required	**1 & 2 point (automatic)**	**1 & 2 point (automatic)**
Calibration frequency	**1 point: 30 or 45 min (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	**min. CLIA recommendations**	**min. 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	**no**	**no**
System can use LOINC to transmit results to LIS	**no**	**no**
Detects clots within analysis chamber	**yes**	**yes**
Specimen types suitable for device	**plasma, serum, whole blood, capill., mixed venous, arterial, venous**	**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/sick neonates	**yes/yes**	**yes/yes**
Sample size for complete panel of analyte results	**195 µL**	**110 µL**
Sample size differs with No. of analytes selected	**yes, M7 offers micropanel; standard 14-test micropanel req., 150 µL**	**yes, pHOx offers micropanel; standard 3-test micropanel req., 50 µL**
Recommended collection device	**syringe, capill., microcollect. containers, standard vacuum cont.**	**syringe, capill., microcollect. containers, standard vacuum cont.**
Provides for patient temperature corrected results	**yes**	**yes**
Time from sample introduction to result availability	**1.2 min–2.5 min**	**45 sec**
Max. No. of patient samples per hr/max. No. of measured parameters per hr	**35/490 tests**	**50/500 tests**
Optimal throughput when calibrated and awaiting specimens	**490–552 tests per hr**	**300 tests per hr**
Calibration can be interrupted to perform stat sample	**yes**	**yes**
Contraindications	**none**	**none**
Known interferences	**not reported**	**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: <15 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. softw. informs & notifies oper. of hardw. 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 recover–extended power failure results in automatic calib.**	**self-diag. softw. informs & notifies oper. of hardw. 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 recover–extended power failure results in automatic calib.**
Supports bar-code scanning of:	**patient identifier**	**patient identifier**
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 with access. No., entered settings, meas. & calc. results**	**patient ID w/ access. No., entered settings, meas. & calc. results**
Analyzer connects to	**data management system &/or directly to LIS/HIS**	**data management system &/or directly to LIS/HIS**
Interface standards supported	**ASTM E1381-91 (HL7 available with external device)**	**ASTM E1381-91 (HL7 available with external device)**
To upload patient & QC results, how analyzer connects to external system	**direct serial/>500 hospitals installed; hospital network/>100 inst.**	**direct serial/>500 hospitals inst.; hospital network/>100 ins.**
Information included in transmission from analyzer to external system	**device unique identifier, operator & patient IDs, result, QC identifier, accession No.**	**device unique identifier, operator & patient IDs, result, QC identifier, accession No.**
Hardware/software for data management system	**Pentium with Microsoft NT 4.0/Nova Patient Data Manager**	**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	**broad critical care test menu—user can select up to 14 meas. tests on one system; only critical care analyzer offering these diagnostic tests; creatinine–unique test offered; "remote review" of patient results prior to results reporting; unique automated test ordering, accessioning, & reporting feature that requires oper. to enter patient ID & POCT site; these features require Nova Patient Data Manager**	**onboard QC cartridge provides sufficient QC materials for 30-day auto QC analysis; no external gas tanks (supplies for calibrations incorporated into single reagent cartridge–waste collect. also incorporated); includes key oximetry values without need for co-ox**

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

In vitro blood gas analyzers

Part 8 of 12

See accompanying article on page 58

	Philips Medical Systems (Manufactured by Diametrics Medical) Sales Department 3000 Minuteman Rd., Andover, MA 01810 978-659-7396 www.medical.philips.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	IRMA Blood Analysis System/1994	ABL 5/1994
No. of devices sold in U.S./outside U.S./list price	—/—/varies based on quantity	—/—/$14,325
Dimensions (H x W x D)/weight	11.5 x 9.5 x 5 in/5 lbs, 4 oz	13 x 13 x 8 in/18 lbs
Analytes measured on device	pH, pCO_2, pO_2, Hct, Na, K, Cl, iCa, glucose, BUN	pH, pCO_2, pO_2
Parameters calculated on device	Hb, O_2SAT, BE, TCO_2, HCO_3-	Hct, O_2SAT, BE, TCO_2, HCO_3-, cH+, ctO_2, $AaDpO_2$, SBE, ABE, SBC, $pCO_2(T)$, $ctCO_2(P)$, pH(T), cH+(T), $pO_2(T)$
Barometric pressure	measured	measured
Analytical method(s)/technology(ies) employed	pH, pCO_2, Na, Cl, iCa, K: potentiometry; pO_2: amperometry; Hct: conductivity; Hb: calculated; glucose: glucose oxidase-strip; BUN: enzymatic	pH: pH-sensitive glass (ISE); pCO_2, pO_2: ISE
Device is part of a series of related models	yes, 2nd-generation analyzer	yes, ABL 5
User list/group available	list of customers available	yes (through local sales representative)
Device warranty	1 yr	1 yr, parts, labor, & travel
Loaner devices provided	yes	yes
Average expected life of device	7 yrs	20 yrs with full support
Open or closed system/external gas tanks required	closed/no	closed/yes (NIST traceable gases)
For POC testing or laboratory	point-of-care testing	POC and laboratory
POC:		
Uses disposable prepackaged reagent/electrode system for analysis	reagent/electrode (single use and multiuse cartridge available)	—
No. of disposable reagent system units in basic shipment package	25	—
No. of samples analyzed per 1 disposable reagent/electrode system	1	—
List price per disposable reagent system	varies based on quantity	—
Reagent unit storage requirements	room temperature	—
Shelf life of disposable units	reagent/electrode: 6 mos	—
Laboratory:		
No. of different disposable reagents required to maintain device	—	4
Max. No. specific analyte reagents that can reside in device at once	—	4
Shelf life	—	reagent, electrode, membrane kit, cartridge: 2+ yrs
Cost per test/reagent cost per test	—	depends on sample volume & any extra incl. items/same
Calibrations required	2 point (automatic)	1 & 2 point (automatic)
Calibration frequency	each sample	1 point: 1/2 hr—CLIA setting, 4 hrs—mftr.; 2 point: 4 hrs
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	electronic QC per 8 hrs patient testing, 2 liquid QC per cartridge shipment	depends on hospital management & inspection agency
QC features	L-J plots, statistical calculations, monthly cumulative reports (available with external system)	statistical calculations (available with external system)
Remote control of device from laboratory	yes	yes
System can use LOINC to transmit results to LIS	no	yes
Detects clots within analysis chamber	no—sample path visible	yes
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial, venous	plasma, serum, whole blood, capill., mixed venous, arterial, venous
Acceptable anticoagulants	heparin, EDTA (glucose strip only)	heparin, balanced heparin
Sampling technique	injection	aspiration
Suitable for samples from well/sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	125 µL capillary, 200 µL syringe	85 µL
Sample size differs with No. of analytes selected	no	yes, optional 35 µL for pH only
Recommended collection device	standard blood gas syringe	syringe or capillary
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	<2 min	~1 min
Max. No. of patient samples per hr/max. No. of measured parameters per hr	20/120	30/90
Optimal throughput when calibrated and awaiting specimens	20	30 per hr
Calibration can be interrupted to perform stat sample	—	yes
Contraindications	none	none
Known interferences	—	halothane
Restrictions based on Hct	no	no (always use well-mixed samples)
Sampler has self-wiping probe	no, not needed	no
Time required for maintenance by lab personnel	no maintenance	monthly: as needed; annually: 5 hrs
Onboard diagnostics for troubleshooting/limited to software	yes/no	yes/no
Diagnostics performed through modem	no	no
Training & certification program for user	yes	yes (on-site as needed)
Method of analyst ID in system	LCD touchscreen, numeric (customizable)	operator ID entry (optional)
Response for hardware & software failure/user ID & QC failure/ calibration & power failure	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	system messages
Supports bar-code scanning of:	operator ID, patient ID, cartridge information	no bar-code scanner
User can search for and review previous patient results on screen	yes	no
Built-in printer/data port	yes/RS 232, modem	yes/RS 232
Information on hard copy report	analyzer serial No., date, calib. successful, calib. code, lot No., patient ID & temp., results, barometric press., softw. version optional: user ID, ref. ranges, O_2 therapy, sample info.	patient info., meas. & calc. results, system messages
Analyzer connects to	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options)	Radiance Stat information management system, which connects to LIS/HIS or directly to LIS/HIS
Interface standards supported	script or HL7	ASTM 1394 & 1238, serial
To upload patient & QC results, how analyzer connects to external system	hospital network, direct serial, modem dial-in	direct serial/thousands; modem dial-in/hundreds; realtime wireless future option
Information included in transmission from analyzer to external system	device unique identifier, operator & patient IDs, result, QC identifier, patient O_2 therapy information	device unique identifier, operator & patient IDs, result, QC identifier, as per ASTM protocols
Hardware/software for data management system	IDMS 5.0.2	external Radiance
No. of different management reports system produces	24	user-definable
Contents downloaded from DMS to analyzer	all analyzer settings	—
System connected (live installations) to which LISs/HISs		
• using screen animation/screen scraping	all major HIS/LIS vendors	Cerner, Meditech, Sunquest, others
• using standard HL7 interface	all major HIS/LIS vendors	none
• using proprietary protocol interface	customizable EDI interfact to HIS/LIS vendors	none
Use a third-party interfacing tool/engine for LIS/HIS interfaces	none	no (use interface templates)
Distinguishing features	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 w/ luer lock port provides barrier between user and sample—no overfilling risk; complete data integration w/IDMS interface	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

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

In vitro blood gas analyzers

Part 9 of 12

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	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 700 Series/1998**	**ABL 555/1998**
No. of devices sold in U.S./outside U.S./list price	**—/—/$29,560–$70,195 (depends on configuration options)**	**—/—/$31,615**
Dimensions (H x W x D)/weight	**17 x 28 x 20 in/66 lbs**	**depends on configuration options/82 lbs**
Analytes measured on device	**pH, pCO_2, pO_2, Hb, Na, K, Cl, iCa, lactate, glucose, bilirubin, fetal Hb, O_2Hb, MetHb, RHb, COHb, O_2SAT**	**pH, pCO_2, pO_2, Hct, Na, K, plus one of the following: Cl, iCa, lactate, glucose**
Parameters calculated on device	**Hct, BE, TCO_2, HCO_3-, plus 40 added parameters, upgradable for future options (call 800-736-0600 ext. 333 for list)**	**Hb, BE, TCO_2, HCO_3-, plus 40 added parameters (call 800-736-0600 ext. 333 for list)**
Barometric pressure	**measured**	**measured**
Analytical method(s)/technology(ies) employed	**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**	**pH: pH-sensitive glass (ISE); pCO_2, pO_2, Na, Cl, iCa, K: ISE; Hct: conductivity; lactate, glucose: ISE with enzyme**
Device is part of a series of related models	**yes, ABL 700 Series**	**no**
User list/group available	**yes (through local sales representative)**	**yes (through local sales representative)**
Device warranty	**2 yrs, parts, labor, & travel**	**1 yr, 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 (low-pressure, premixed)**	**closed/yes (one glass cylinder)**
For POC testing or laboratory	**POC & laboratory (products on mobile carts for POCT/NPT)**	**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 1 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**	**6**
Max. No. specific analyte reagents that can reside in device at once	**depends on future parameter upgrade options**	**user definable**
Shelf life	**reagent, electrode, membrane kit, cartridge: 2+ yrs**	**reagent, electrode, membrane kit, cartridge: 2+ years**
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–CLIA setting, 4 hrs—mftr.; 2 point: every 8 hrs**	**1 point: 1/2 hr–CLIA setting, 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	**L-J plots, comparable plot (via DMS), statistical calcs., auto QC, monthly cum. reports (onboard & avail. w/external system, PC download to Excel)**	**L-J plots, comparable plot (via DMS), statistical calcs., monthly cum. reports (on board & available with 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**
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 ven., arterial, venous**
Acceptable anticoagulants	**EDTA, heparin, electrolyte-balanced heparin**	**EDTA, heparin, electrolyte-balanced heparin**
Sampling technique	**aspiration, syringe &/or capillary tube &/or test tube**	**aspir., injec., syringe &/or capill. tube &/or aspir. from test tube**
Suitable for samples from well/sick neonates	**yes/yes**	**yes/yes**
Sample size for complete panel of analyte results	**95 µL for 17 measured parameters**	**125 µL for 17 measured parameters**
Sample size differs with No. of analytes selected	**yes, with fewer meas. params., smaller micro-modes avail. from 55 µL**	**yes, option to select smaller test profile with reduced sample volume 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 (depends on tests ordered)**	**~1 min, depends on tests ordered**
Max. No. of patient samples per hr/max. No. of measured parameters per hr	**25/425**	**20/27**
Optimal throughput when calibrated and awaiting specimens	**25 per hr**	**20 tests per hr**
Calibration can be interrupted to perform stat sample	**yes**	**yes**
Contraindications	**none**	**none**
Known interferences	**halothane, specif. anticoag., thiocyanic & glycolic acids, sod. fl.**	**halothane, specif. anticoag., thiocyanic & glycolic acids, sod. fl.**
Restrictions based on Hct	**no (always use well-mixed samples)**	**no (always use well-mixed samples)**
Sampler has self-wiping probe	**yes**	**yes**
Time required for maintenance by lab personnel	**monthly: as needed, annually: ~2 hrs**	**monthly: as needed, annually: 32 hrs**
Onboard diagnostics for troubleshooting/limited to software	**yes/no**	**yes/no**
Diagnostics performed through modem	**yes**	**no**
Training & certification program for user	**yes (on-site as needed)**	**yes (on-site as needed)**
Method of analyst ID in system	**password system (customizable)**	**password system (customizable)**
Response for hardware & software failure/user ID & QC failure/ calibration & power failure	**system message with customized ("traffic light") visual & audible signals**	**system messages with visual & audible signals**
Supports bar-code scanning of:	**operator & patient identifiers, reag. & QC lot Nos., exp., soft. keys**	**operator & patient identifiers, accession No.**
User can search for and review previous patient results on screen	**yes, multitask searches while analyzer performs other functions**	**yes**
Built-in printer/data port	**yes/RS 232, parallel, Ethernet, USB**	**yes/RS 232**
Information on hard copy report	**patient info./demographics, patient therapy settings, meas. & calc. results, system messages, reference & critical ranges**	**patient info./demographics, patient therapy settings, measured & calculated results, system messages**
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, HL7, serial, network TCP/IP**	**ASTM 1394 & 1238, HL7, serial**
To upload patient & QC results, how analyzer connects to external system	**direct serial/thousands of hosp. installed; modem dial-in/hundreds; hospital network/hundreds; realtime wireless future option**	**direct serial/thousands of hospitals installed; modem dial-in/hundreds; hospital network/hundreds; realtime wireless future option**
Information included in transmission from analyzer to external system	**device unique identifier, operator & patient IDs, result, QC identifier, per ASTM/HL7 standards plus calib. & analyzer status info.**	**device unique identifier, operator & patient IDs, result, QC identifier, as per ASTM/HL7 standards & calib. and system messages**
Hardware/software for data management system	**internal system + optional external system, Radiance w/Windows NT**	**internet and external system options**
No. of different management reports system produces	**user-definable searches/reports**	**user definable**
Contents downloaded from DMS to analyzer	**valid control values, valid operator IDs**	**valid control values, valid operator IDs**
System connected (live installations) to which LISs/HISs		
• using screen animation/screen scraping	**Cerner, Meditech, Sunquest, others**	**Cerner, Meditech, Sunquest, others**
• using standard HL7 interface	**available from analyzer—LIS/HIS vendors can use**	**none**
• using proprietary protocol interface	**none**	**none**
Use a third-party interfacing tool/engine for LIS/HIS interfaces	**no (use interface templates to fit into existing interfaces)**	**no (use interface templates to fit into existing interfaces)**
Distinguishing features	**market first—bilirubin & fetal Hb meas. on whole blood with no extra sample volume, low maintenance & 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 95 (enhanced), Pentium processors, automatic QC**	**interference-free accuracy; many options for microsample modes (conserves blood); easy to use and highly customizable; highest reliability on market**

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

In vitro blood gas analyzers

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	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 77/2000**	**NPT7/2001**
No. of devices sold in U.S./outside U.S./list price	**—/—/—**	**50/n/a/$18,550**
Dimensions (H x W x D)/weight	**13 x 8 x 9 in/16 lbs**	**10 x 13 x 16 in/25 lbs**
Analytes measured on device	**pH, pCO_2, pO_2, Hct, Na, K, iCa, Cl-**	**pH, pCO_2, pO_2, tHb, SO_2, O_2Hb, COHb, MetHb, HHb**
Parameters calculated on device	**Hb, O_2SAT, BE, TCO_2, HCO_3-, ctO_2 (a-v), ctO_2, anion gap (K+), cCa^{2+} (7.40), cBase (B)**	**Hct, ABE, SBE, TCO_2, HCO_3-, SBC, TO_2, p50**
Barometric pressure	**n/a**	**n/a**
Analytical method(s)/technology(ies) employed	**pH, pCO_2, pO_2, Na, iCa: thick film; Hct: conductivity; Hb: indirectly amperometric, potentiometric, & conductometric**	**pH, pCO_2, pO_2, oximetry: patented dry optical technology**
Device is part of a series of related models	**yes**	**no**
User list/group available	**yes (through local sales representative)**	**yes (through local sales representative)**
Device warranty	**1 yr, with service plans available after yr 1 depending on customer requirements**	**1 yr, parts, labor & travel or depot loaner service**
Loaner devices provided	**yes**	**yes**
Average expected life of device	**analyzer: 5+ yrs, disposables 14–30 d or 150 patient tests**	**10 yrs**
Open or closed system/external gas tanks required	**closed/no**	**closed/no**
For POC testing or laboratory	**POC & small laboratory**	**POC testing & small laboratory, RT department**
POC:		
Uses disposable prepackaged reagent/electrode system for analysis	**electrode (multiuse cartridge)**	**dry optical system**
No. of disposable reagent system units in basic shipment package	**1**	**multiuse cartridge contains 30 single-use cuvettes**
No. of samples analyzed per 1 disposable reagent/electrode system	**50/100/150**	**30**
List price per disposable reagent system	**depends on configuration & GPO affiliation**	**depends on configuration & GPO affiliation**
Reagent unit storage requirements	**none**	**none**
Shelf life of disposable units	**reagents: 3 mos, electrodes: 3 mos**	**18 months**
Laboratory:		
No. of different disposable reagents required to maintain device	**1**	**1**
Max. No. specific analyte reagents that can reside in device at once	**2**	**1**
Shelf life	**reagent: 3 mos, cartridge: 3 mos**	**2 yrs**
Cost per test/reagent cost per test	**depends on configuration & GPO affiliation**	**—**
Calibrations required	**1 & 2 point (manual & automatic)**	**two-level check is performed as part of QualityGuard system (manual & automatic)**
Calibration frequency	**1 point: after each test; 2 point: 30 min–4 hrs (user definable)**	**1 point: n/a; 2 point: n/a**
Calibrants traceable to NIST standards	**yes**	**yes**
Internal QC program recommended	**QC material according to CLIA**	**QualityGuard includes a two-level check, system check & measuring check**
QC features	**L-J plots, comparable plot (via DMS), statistical calcs., monthly cum. (onboard–current mean, STD, CV%) reports (onboard & available with external system, PC download to Excel)**	**QualityGuard information onboard or available with external system**
Remote control of device from laboratory	**yes**	**no**
System can use LOINC to transmit results to LIS	**yes**	**yes**
Detects clots within analysis chamber	**yes**	**yes**
Specimen types suitable for device	**whole blood, mixed venous, arterial, venous**	**whole blood, capillary, mixed venous, arterial, venous**
Acceptable anticoagulants	**heparin, heparinized whole blood**	**heparin**
Sampling technique	**aspiration**	**aspiration**
Suitable for samples from well/sick neonates	**yes/yes**	**yes/yes**
Sample size for complete panel of analyte results	**85 µL**	**90 µL**
Sample size differs with No. of analytes selected	**no**	**no**
Recommended collection device	**heparinized syringe**	**syringe or capillary tube**
Provides for patient temperature corrected results	**yes**	**yes**
Time from sample introduction to result availability	**79–90 sec**	**60 sec**
Max. No. of patient samples per hr/max. No. of measured parameters per hr	**40/320**	**30/270**
Optimal throughput when calibrated and awaiting specimens	**40 tests per hr**	**30 tests per hr**
Calibration can be interrupted to perform stat sample	**yes**	**n/a**
Contraindications	**must be heparinized whole blood**	**no**
Known interferences	**none**	**Intralipid (concentrations over 5 vol%), fluoroscein**
Restrictions based on Hct	**no (always use well-mixed samples)**	**no**
Sampler has self-wiping probe	**no**	**no, probe disposed of after measurement**
Time required for maintenance by lab personnel	**monthly: 1/2 hr**	**maintenance free**
Onboard diagnostics for troubleshooting/limited to software	**yes/no**	**yes/no**
Diagnostics performed through modem	**no**	**no**
Training & certification program for user	**yes**	**yes (on-site as needed)**
Method of analyst ID in system	**bar-code or onboard keyboard (customizable)**	**operator ID entry (optional)**
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**	**system messages with visual signals**
Supports bar-code scanning of:	**operator & patient identifiers, reag. & sensor lot Nos., QC**	**operator & patient ID, QC lot No.**
User can search for and review previous patient results on screen	**yes**	**yes**
Built-in printer/data port	**yes/RS 232, ethernet, RJ45**	**yes/RS 232, ethernet**
Information on hard copy report	**all meas. & calc. values, exp., test remaining info., QC & dispos. lot No., basic statistics, time & date, user & patient info., QC statistics, temp. corrected at 37°C, QC ranges w/ QC results on each run, hemoglobin value-measured or default**	**patient info, patient therapy settings; measured and calculated parameter results; system messages; reference ranges; cartidge lot & cartridge expiration date**
Analyzer connects to	**Radiance Stat information management system, which connects to LIS/HIS or directly to LIS/HIS**	**directly to LIS/HIS**
Interface standards supported	**ASTM, HL7, E1394-91 for serial communication**	**ASTM 1394 & 1238, serial, network**
To upload patient & QC results, how analyzer connects to external system	**direct serial, hospital network**	**direct serial, hospital network**
Information included in transmission from analyzer to external system	**device unique identifier, operator & patient ID, result, QC identifier**	**device unique identifier, operator & patient ID, result, QC identifier**
Hardware/software for data management system	**Radiance with Windows NT**	**PCM/CIA—internal DM or external DM**
No. of different management reports system produces	**user definable**	**user definable**
Contents downloaded from DMS to analyzer	**—**	**—**
System connected (live installations) to which LISs/HISs		**LIS vendors completing interface requirements**
• using screen animation/screen scraping	**Cerner, 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	**Radiance**	**Radiance**
Distinguishing features	**portable, battery-operated miniature benchtop analyzer that meets all federal & state regulations; quickest startup/warmup time; simplest and easiest-to-use system**	**patented dry optical technology, unique in the measurement of blood gases and full cooxymetry; maintenance-free; no cartridge preparation; QualityGuard; patient results in one minute**

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

In vitro blood gas analyzers

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	Roche Diagnostics Corp. Sales Department 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 www.roche.com	Roche Diagnostics Corp. Sales Department 9115 Hague Rd. Indianapolis, IN 46250 800-428-5074 www.roche.com
Name of device/first year sold	AVL Omni Modular System/1996	Opti Critical Care Analyzer/1998
No. of devices sold in U.S./outside U.S./list price	—/—/$29,900–$56,200	—/—/$8,500
Dimensions (H x W x D)/weight	16.5 x 21 x 18.5 in/88 lbs	4.7 x 14.2 x 9 in/9 lbs without battery, 11 lbs with
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	pH, pCO_2, pO_2, Na, K, Cl, iCa, tHb, sO_2, glucose, urea (BUN)
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)	Hct, DE, TCO_2, HCO_3- (12 additional parameters; call Roche for list)
Barometric pressure	measured	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	pH, pCO_2, pO_2, Na, Cl, iCa, K, glucose, urea (BUN): optical fluorescence; tHb, sO_2: optical reflectance
Device is part of a series of related models	yes, models 1–9	yes, Opti Series
User list/group available	yes (through Roche sales dept.)	yes (through Roche sales dept.)
Device warranty	1 yr (service contract available for subsequent years)	1 yr (service contract available for subsequent years)
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 (transportable on cart system)	POC & laboratory
POC:		
Uses disposable prepackaged reagent/electrode system for analysis	n/a	reagent/optode
No. of disposable reagent system units in basic shipment package	n/a	25 individual packaged cassettes
No. of samples analyzed per 1 disposable reagent/electrode system	n/a	1
List price per disposable reagent system	n/a	depends on cassette configuration–contact Roche
Reagent unit storage requirements	n/a	room temperature
Shelf life of disposable units	n/a	reagent/electrode: 6 mos
Laboratory:		
No. of different disposable reagents required to maintain device	depends on model, contact Roche	1
Max. No. specific analyte reagents that can reside in device at once	1	1
Shelf life	reagents: 1 yr	cassette: 6 mos
Cost per test/reagent cost per test	depends on sample volume/same	depends on volume—contact Roche/same
Calibrations required	1 & 2 point (automatic)	1 point (automatic)
Calibration frequency	1 point: 30 min and with each sample, 2 point: selectable 4–12 hrs	with each cassette
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	1 liquid QC sample per 8 hrs of operation	3 levels liquid with change of cassette lot No., 2 mo intervals;
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	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.)
Remote control of device from laboratory	yes	no
System can use LOINC to transmit results to LIS	no	no
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	plasma, serum, w. blood, capillary, mixed venous, arterial, venous	plasma, serum, w. blood, capill., mixed ven., arterial, venous
Acceptable anticoagulants	heparin, lithium	heparin, lithium
Sampling technique	aspiration, injection	aspiration
Suitable for samples from well/sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	160 µL for full panel, 40 µL per module	125 µL
Sample size differs with No. of analytes selected	yes, 40 µL per module; i.e.: pH/BG, electrolytes, CO-ox, metabolites	no
Recommended collection device	syringe, capillary, AVL microsampler	syringe, capillary, AVL microsampler
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	~ 1 min (depends on tests analyzed)	1 min from sample aspiration
Max. No. of patient samples per hr/max. No. of measured parameters per hr	40/490 tests per hr	24/192
Optimal throughput when calibrated and awaiting specimens	40 samples per hr	—
Calibration can be interrupted to perform stat sample	yes	no
Contraindications	none	none
Known interferences	none	none
Restrictions based on Hct	no (automatically checks Hct: tHb ratio)	no (Hct calculated based on meas. Hb)
Sampler has self-wiping probe	no	no
Time required for maintenance by lab personnel	weekly: 5 min, quarterly: 5 min	weekly: 1 min, quarterly: 5 min
Onboard diagnostics for troubleshooting/limited to software	yes/no	yes/no
Diagnostics performed through modem	yes, with Omni-Link via network can remotely control, realtime continuously monitor, activate calib., QC sampling (with AutoQC module), and activate troubleshooting routines remotely	no
Training & certification program for user	yes (on-site or at vendor office as needed)	yes (on-site as needed)
Method of analyst ID in system	4-level password system for 200 operators	oper. ID and/or secure 4-digit PIN No. for 150 oper. (customizable)
Response for hardware & software failure/user ID & QC failure/ calibration & power failure	identified on screen & w/ diagnostic routine/user ID: on screen w/ msg., QC: on screen–report w/ high-low flagging & multirule/calib.: identified on display w/ easy-to-read icons, auto. lockout of failed QC test, power: recorded in activities log, automatic customizable QC lockout of tests	identified on display & w/ diagnostic routine/user ID: identified on display (missing or not valid), QC: on display (report flagging param. high or low)/calib: on display prior to sample aspir., power: low batt. identified on display–warning; automatic customized QC lockout
Supports bar-code scanning of:	operator & patient identifiers, reagent lot No., electrode lot No., QC ranges, expiration	oper. & patient identifiers, reag. lot No., QC ranges, cassette lot no., expiration, factory calibration info. & cassette type
User can search for and review previous patient results on screen	yes (up to 50,000 online onboard analyzer)	no (printed review available for all patients)
Built-in printer/data port	yes/RS 232, parallel, Ethernet	yes/RS 232, IR
Information on hard copy report	customizable, can incl. input values, meas. values, calc. values	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)	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options)
Interface standards supported	ASTM 1394, ASTM 1238, HL7 (DataCare available)	ASTM 1394, ASTM 1238, HL7
To upload patient & QC results, how analyzer connects to external system	direct serial, hospital network, realtime wireless (RF)	direct serial or IR
Information included in transmission from analyzer to external system	device unique identifier, operator & patient ID, result, QC identifier	device unique identifier, oper. & patient ID, result, QC identifier, all info. pertinent to patient & QC data
Hardware/software for data management system	AVL Omni has onboard DM capabilities; DataCare POC software is available as a client/server to connect Omni analyzers	Opti has onboard data management capabilities, additionally Roche DataCare software is available as a client/server
No. of different management reports system produces	40	40
Contents downloaded from DMS to analyzer	valid control values, valid operator IDs, patient demographics	none
System connected (live installations) to which LISs/HISs		
• using screen animation/screen scraping	none	none
• using standard HL7 interface	Meditech, HBOC, Cerner, SMS (call Roche for updated list)	Meditech, HBOC, Cerner, SMS, others (call Roche for updated list)
• using proprietary protocol interface	Kaiser Permanente	Kaiser Permanente, others
Use a third-party interfacing tool/engine for LIS/HIS interfaces	Dawning, Cloverleaf, Data Innovations (not required but can use)	Dawning, Cloverleaf, Data Innovations (not required but can use)
Distinguishing features	AVL AutoQC for automatic & precise meas. of QC material following all regs.; reduces labor & eliminates preanalytical variables; liquid calib. eliminates hazardous gas tanks	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

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

SURVEY OF INSTRUMENTS

In vitro blood gas analyzers

Part 12 of 12

See accompanying article on this page

Roche Diagnostics Corp.
Sales Department
9115 Hague Rd.
Indianapolis, IN 46250
800-428-5074
www.roche.com

Name of device/first year sold	**Opti R Critical Care Analyzer/2000**
No. of devices sold in U.S./outside U.S./list price	**—/—/$9,500**
Dimensions (H x W x D)/weight	**4.7 x 14.2 x 9 in/9 lbs without battery, 11 lbs with**
Analytes measured on device	**pH, pCO_2, pO_2, Na, K, iCa, tHb, sO_2**
Parameters calculated on device	**Hct, BE, TCO_2, HCO_3- (11 additional parameters; call Roche for list)**
Barometric pressure	**measured**
Analytical method(s)/technology(ies) employed	**pH, pCO_2, pO_2, Na, iCa, K: optical fluorescence; tHb, sO_2: optical reflectance**
Device is part of a series of related models	**yes, Opti Series**
User list/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**
POC:	
Uses disposable prepackaged reagent/electrode system for analysis	**reagent/optode**
No. of disposable reagent system units in basic shipment package	**4 individually packaged cassettes per pkg**
No. of samples analyzed per 1 disposable reagent/electrode system	**up to 25 patient samples per cassette + QC**
List price per disposable reagent system	**depends on volume—contact Roche**
Reagent unit storage requirements	**room temperature**
Shelf life of disposable units	**cassette: 6 mos, reagent pack—1 yr**
Laboratory:	
No. of different disposable reagents required to maintain device	**2**
Max. No. specific analyte reagents that can reside in device at once	**1**
Shelf life	**cassette: 6 mos, reagent pack—1 yr**
Cost per test/reagent cost per test	**depends on volume—contact Roche/same**
Calibrations required	**1 point (automatic)**
Calibration frequency	**with each sample or every 30 min**
Calibrants traceable to NIST standards	**yes**
Internal QC program recommended	**2 levels QC/8 hrs**
QC features	**statistical calcs., L-J with external system (DataCare); stores 1 mo—3 levels onboard**
Remote control of device from laboratory	**no**
System can use LOINC to transmit results to LIS	**no**
Detects clots within analysis chamber	**yes**
Specimen types suitable for device	**plasma, serum, w. blood, capill., mixed ven., arterial, venous**
Acceptable anticoagulants	**heparin, lithium**
Sampling technique	**aspiration**
Suitable for samples from well/sick neonates	**yes/yes**
Sample size for complete panel of analyte results	**125 µL**
Sample size differs with No. of analytes selected	**no**
Recommended collection device	**syringe, capillary, AVL microsampler**
Provides for patient temperature corrected results	**yes**
Time from sample introduction to result availability	**1 min from sample aspiration**
Max. No. of patient samples per hr/max. No. of measured parameters per hr	**20/160**
Optimal throughput when calibrated and awaiting specimens	**18 samples/hr**
Calibration can be interrupted to perform stat sample	**no**
Contraindications	**none**
Known interferences	**none**
Restrictions based on Hct	**no (Hct calculated based on meas. Hb)**
Sampler has self-wiping probe	**no**
Time required for maintenance by lab personnel	**weekly: 1 min, quarterly: 5 min**
Onboard diagnostics for troubleshooting/limited to software	**yes/no**
Diagnostics performed through modem	**no**
Training & certification program for user	**yes (on-site or at vendor office as needed)**
Method of analyst ID in system	**oper. ID and/or secure 4-digit PIN No. for 150 oper. (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**
Supports bar-code scanning of:	**operator & patient ID, accession No., QC ranges, cassette lot No./exp., reagent pack lot No./exp., factory cal. info. & cassette type**
User can search for and review previous patient results on screen	**no**
Built-in printer/data port	**yes/RS 232, IR**
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 (with DataCare)**
To upload patient & QC results, how analyzer connects to external system	**direct serial or IR**
Information included in transmission from analyzer to external system	**device unique identifier, operator & patient ID, result, QC identifier, all information pertinent to patient & QC data, accession No.**
Hardware/software for data management system	**Opti has onboard data management capabilities; additionally Roche DataCare software is available as a client/server**
No. of different management reports system produces	**40**
Contents downloaded from DMS to analyzer	**none**
System connected (live installations) to which LISs/HISs	
• using screen animation/screen scraping	**none**
• using standard HL7 interface	**Meditech, HBOC, Cerner, SMS, others (call Roche for updated list)**
• using proprietary protocol interface	**Kaiser Permanente, others**
Use a third-party interfacing tool/engine for LIS/HIS interfaces	**Dawning, Cloverleaf, Data Innovations (not required but can use)**
Distinguishing features	**meas. tHb/sO_2; 6 mo shelf life of cassettes stored at room temp. simplifies logistics; automatic sample aspir. from syringe and capillaries; cassettes provide up to 25 patient samples + QC; operates in cool temps. (10°–30°C/50°–86°F); extensive list of input parameters; onboard printer**

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Moderating menu to lighten load

Survey of Instruments

Raymond D. Aller, MD

Vendors of commercially available blood gas analyzers have made steady, albeit sometimes slow, progress in adding analytes to the menus of such devices.

In the early '80s, these instruments were restricted to pO_2, pCO_2, and pH. Hemoglobin soon was added. Technologies were introduced in the early '90s that allowed vendors to add a steady stream of additional analytes.

Many vendors in this arena view themselves as being in the critical care field—if the analyte is not done stat on ICU patients, they don't add it to the menu. The need for rapid results is just as great in the emergency department, but this area requires a slightly different menu.

In the ER, the blood gases that serve as the genesis of these critical analyte instruments can often be replaced by a pulse oximeter. More important are potassium, calcium, creatinine, alanine aminotransferase, and lipase.

Two years ago, while observing the slow demise of the traditional "med-surg" nursing unit and the shift toward routinely discharging all but the sickest patients to home care, I began to wonder why we still do 24-hour turnaround time procedures in hospital laboratories. What procedures really need to be available in the hospital instead of being provided, with eight-hour turnaround time, by a regional core lab?

This led me to propose, in the August 1999 issue of CAP TODAY (page 48), a minimum menu for a hospital lab. That menu, with a few additions, includes blood gases, glucose, potassium, sodium, total CO_2, creatinine, ionized calcium, ALT, alkaline phosphatase, lipase, bilirubin, hemoglobin, WBC, absolute neutrophil count, platelets, PT, PTT, fibrinogen, blood smear, Gram stain, and CSF cell count. Immunoassays include quantitative hCG, troponin, digoxin, phenytoin, RSV, rotavirus, D-dimer, ABO Rh, and red cell antibody screening. Clinical staff in some hospitals also might include lactate, oncotic pressure, ionized magnesium, and TSH. (If you take exception to any of these items or believe that a critical analyte was overlooked, please convey your opinion by sending an e-mail to raller@mdslabsus.com.)

This list presumes that specimens can be transported to a regional core laboratory within a two-hour radius for other analyses. The regional core lab would handle such vital analytes as HIV antibody, HBsAg, therapeutic drug monitoring and toxicity, most microbiology, and the 85 or more other chemistries commonly performed.

We urge vendors to move toward critical chemistry instruments that could be teamed with one or perhaps two other devices to encompass this range of analytes. With such an analyzer array, it would be feasible to close down the "big iron" laboratory instruments and provide essential services for a critical care hospital/ER. Until such analyzers are available, however, every hospital, no matter how small, must continue to maintain comprehensive and expensive "big iron" instrumentation.

Pages 36–58 profile 23 in vitro blood gas analyzers from eight vendors. Before purchasing an analyzer, talk to users of these instruments about vendors' performance claims, instrument reliability, and quality of customer support.

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