In vitro blood gas analyzers

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Name of device/first year sold	i-Stat 1/2001	i-Stat System/1992
No. of devices sold in U.S./outside U.S./list price	1,500/1,000/$9,500	20,000 worldwide/$7,900
Dimensions (H x W x D)/weight	23.48 cm x 7.68 cm x 7.24 cm/22.4 oz	8.26 x 2.52 x 2.05 in/18.34 oz
Analytes measured on device	pH, pCO_2, pO_2, Hct, Na, K, Cl, iCa, glucose, creatinine, BUN, ACT_c, lactate	pH, pCO_2, pO_2, Hct, Na, K, Cl, iCa, glucose, creatinine, BUN, ACT_c, lactate
Parameters calculated on device	Hb, O_2SAT, BE, TCO_2, HCO_3-	Hb, O_2SAT, BE, TCO_2, HCO_3-
Barometric pressure	measured	measured
Analytical method(s)/technology(ies) employed	electrochemical for all analytes	electrochemical for all analytes
Device is part of a series of related models	no	no
User list/group available	yes (through local sales representative)	yes (through local sales representative)
Device warranty	1 yr replacement	1 yr replacement
Loaner devices provided	n/a	n/a
Average expected life of device	8 yrs	8 yrs
Open or closed system/external gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC testing	POC testing
POC:		
Uses disposable prepackaged reagent/electrode system for analysis	reagent/electrode (single use)	reagent/electrode (single use)
No. of disposable reagent system units in basic shipment package	25 per box	25 per box
No. of samples analyzed per 1 disposable reagent/electrode system	1	1
List price per disposable reagent system	$3–$9	$3–$9
Reagent unit storage requirements	refrigerate, 2 weeks of shelf life at room temperature	refrigerate, 2 weeks of shelf life at room temperature
Shelf life of disposable units	reag./electrode: 6–9 mos; 2 weeks at room temperature	reag./electrode: 6–9 mos refrig.; 2 weeks at room temperature
Laboratory:		
No. of different disposable reagents required to maintain device	—	—
Max. No. specific analyte reagents that can reside in device at once	—	—
Shelf life	—	—
Cost per test/reagent cost per test	—	—
Calibrations required	1 point (automatic)	1 point (automatic)
Calibration frequency	every test	every test
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	electronic QC, automated internal wet QC	electronic QC, automated internal wet QC
QC features	comparable plot, monthly cumulative reports (available with external system)	monthly cumulative reports (available with external system), QC can be fully automated, QC lockout
Remote control of device from laboratory	yes	yes
System can use LOINC to transmit results to LIS	yes	yes
How labs get LOINC codes for reagent kits	—	—
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial, venous	whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	heparin	heparin
Sampling technique	injection, capillary transfer and fill	injection, capillary transfer and fill
Suitable for samples from well/sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	blood gas 95 µL, electrolytes 65 µL	blood gas 95 µL, electrolytes 65 µL
Sample size differs with No. of analytes selected	no	yes
Recommended collection device	syringe or capillary tube	syringe or capillary tube
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	about 2 min	about 2 min
Max. No. of patient samples per hr/max. No. of measured parameters per hr	20/160	20/160
Optimal throughput when calibrated and awaiting specimens	—	—
Calibration can be interrupted to perform stat sample	n/a	n/a
Contraindications	—	—
Known interferences	—	—
Restrictions based on Hct	—	—
Sampler has self-wiping probe	—	—
Time required for maintenance by lab personnel	n/a	n/a
Onboard diagnostics for troubleshooting/limited to software	yes/no	no/no
Diagnostics performed through modem	yes	yes
Training & certification program for user	yes, based on number to be trained	yes
Method of analyst ID in system	keypad/bar-code entry	keypad entry (required)
Response for hardware & software failure/user ID & QC failure/ calibration & power failure	code No. error message/—/—	—/—/—
Supports bar-code scanning of:	operator & patient IDs, reagent lot No., hospital specific 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 IDs, results, QC identifier	patient data & results, date, time, analyzer serial No., sample type, ventilator settings
Analyzer connects to	data management system, which in turn connects to LIS/HIS	data management system, which connects to LIS/HIS
Interface standards supported	ASTM 1394 & 1238, HL7, other	ASTM 1394 & 1238, HL7, other
To upload patient & QC results, how analyzer connects to external system	direct serial/900 hospitals installed; modem dial-in/25 hospitals installed; hospital network/250 hospitals installed	direct serial/700 hospitals installed; modem dial-in/25 installed; hospital network/200 installed
Information included in transmission from analyzer to external system	device unique identifier, operator & patient IDs, results, QC identifier	device unique identifier, operator & patient IDs, results, QC identifier
Hardware/software for data management system	QC MGR 2.0/Precision Net/5x software/Central Data Station	QC MGR 2.0/Precision Net/Central Data Station
No. of different management reports system produces	35+	35+
Contents downloaded from DMS to analyzer	strip lot Nos., valid control values, valid operator IDs, certification, analyzer location, lockouts, customized info	—
System connected (live installations) to which LISs/HISs		
• using screen animation/screen scraping	all major LIS vendors	all major LIS vendors
• using standard HL7 interface	Cerner	Cerner
• using proprietary protocol interface	—	none
Use a third-party interfacing tool/engine for LIS/HIS interfaces	yes, Sybase	none
Distinguishing features	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^-, full co-oximetry	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 tracking
Barometric pressure	recorded	
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	POC 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	—	$0.71/$0.73 @ 50 tests per day at list price/$0.24 @ 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
How labs get LOINC codes for reagent kits	—	n/a
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 IDs, accession No., results, temperature, other information	operator & patient IDs, 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 IDs, 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 IDs, results, QC identifier	device identifier, operator & patient IDs, results, 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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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, lactate; 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	$0.84/$0.86 @ 50 tests per day at list price/$0.24 @ 50 tests per day at list price	$1.67/$1.69 @ 50 tests per day at list price/$0.24 @ 50 tests per day at list price
Calibrations required	1 & 2 point (automatic & manual)	1 & 2 point (automatic & manual)
Calibration frequency	1 point: after each sample, 2 point: every 2 hrs	1 point: after each sample, 2 point: every 2 hrs
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	1 level per 8 hrs, IL controls recommended	1 level per 8 hrs, IL controls recommended
QC features	L-J plots, QC tracking	L-J plots, QC tracking
Remote control of device from laboratory	yes	yes
System can use LOINC to transmit results to LIS	no	no
How labs get LOINC codes for reagent kits	n/a	n/a
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas	w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas
Acceptable anticoagulants	heparin	heparin
Sampling technique	aspiration, injection, capillary	aspiration, injection, capillary
Suitable for samples from well/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 IDs, results, QC ID	device identifier, operator & patient IDs, results, QC ID
Hardware/software for data management system	Impact for Critical Care	Impact for Critical Care
No. of different management reports system produces	customizable	customizable
Contents downloaded from DMS to analyzer	patient ID, demographics	patient ID, demographics
System connected (live installations) to which LISs/HISs		
• using screen animation/screen scraping	none	none
• using standard HL7 interface	none	none
• using proprietary protocol interface	none	none
Use a third-party interfacing tool/engine for LIS/HIS interfaces	no	no
Distinguishing features	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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In vitro blood gas analyzers

Part 4 of 13 *See accompanying article on page 62*	**Instrumentation Laboratory** **Todd Sheldon** tsheldon@ilww.com **101 Hartwell Ave.** **Lexington, MA 02421** **781-861-0710** www.ilus.com	**Instrumentation Laboratory** **Patti Williams** pwilliams@ilww.com **101 Hartwell Ave.** **Lexington, MA 02421** **781-861-0710** www.ilus.com
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**	**A-aDo_2, Hb, pAO_2, paO_2/pAO_2, RI, O_2cap*, CtO_2*, CaO_2*, CvO_2*, CcO_2*, a-vDO_2*, Qsp/Qt*, P50***
Barometric pressure	**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	**—**	**yes (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-, & 600-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	**—**	**1**
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/$0.24 @ 50 tests per day at list price**	**varies with size & menu**
Calibrations required	**1 & 2 point (automatic & manual)**	**1 & 2 point (automatic)**
Calibration frequency	**1 point: after each sample, 2 point: every 2 hrs**	**1 point: each patient sample; 2 point: at least every 4 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**
How labs get LOINC codes for reagent kits	**n/a**	**n/a**
Detects clots within analysis chamber	**yes**	**yes**
Specimen types suitable for device	**w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas**	**whole blood, arterial, venous, or capillary**
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**	**syringe or capillary tube**
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**	**LIS/HIS via direct interface or via IL's Impact Data Management System; vendor-neutral data management systems**
Interface standards supported	**interfaced with LIS or Impact for Critical Care, ASTM protocol**	**ASTM protocol**
To upload patient & QC results, how analyzer connects to external system	**direct serial, modem dial-in, hospital network**	**direct serial, Ethernet, modem dial-in**
Information included in transmission from analyzer to external system	**device identifier, operator & patient IDs, results, QC ID**	**device identifier, operator & patient IDs, results, QC ID & results**
Hardware/software for data management system	**Impact for Critical Care**	**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**	**yes**
• using standard HL7 interface	**none**	**yes**
• using proprietary protocol interface	**none**	**yes**
Use a third-party interfacing tool/engine for LIS/HIS interfaces	**no**	**yes**
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 available in 13 menu/size options for use in any hospital location; 14-yr history of proven cartridge technology; remote management from any PC via GemWeb; consolidated workstation for blood gas, electrolytes, Hct, glucose, lactate, co-oximetry, and coagulation** **** when interfaced to IL CO-Oximeter***

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In vitro blood gas analyzers

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	Instrumentation Laboratory Patti Williams pwilliams@ilww.com 101 Hartwell Ave., Lexington, MA 02421 781-861-0710 www.ilus.com	Medica Corp. Leslie Boone lboone@medicacorp.com 14 DeAngelo Dr., Bedford, MA 01730 800-777-5983 or 781-275-4892 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	A-aDo_2, Hb, pAO_2, paO_2/pAO_2, RI, O_2cap*, CtO_2*, CaO_2*, CvO_2*, CcO_2*, a-vDO_2*, Qsp/Qt*, P50*	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-potentiometry; pCO_2: ISE-potentiometry; pO_2: ISE-amperometry
Device is part of a series of related models	yes	yes (basic model first gen., related to expanded model EasyStat)
User list/group available	yes (through local sales representative)	yes
Device warranty	5 yrs	1 yr
Loaner devices provided	yes	yes
Average expected life of device	7–10 yrs	>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	yes (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	cartridges available: 75-, 150-, 300-, 450-, & 600-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	1	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	reag. & elec.: 1 yr; QC material: 3 yrs
Cost per test/reagent cost per test	varies with menu & cartridge size	$0.57 at 20 samples per day/$0.26 at 20 samples per day
Calibrations required	1 & 2 point (automatic)	1 & 2 point (automatic)
Calibration frequency	1 point: each patient sample; 2 point: at least every 4 hrs	1 point: during each sample analysis; 2 point: can be set for 2-, 4-, or 8-hr increments
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	1 level per 8 hrs, 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
How labs get LOINC codes for reagent kits	n/a	n/a
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	whole blood, arterial, venous, or capillary	whole blood, capillary, mixed venous, arterial, venous
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 tube	heparinized capillary or syringe
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 (optional)
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	HW: oper. warning & error msg.; SW: error msg./user ID: sampling lockout; QC failure; flagged results/calib.: error msg. & 2nd attempt for 2-pt. calib. auto.; power: display not illuminated, data retained & auto reset
Supports bar-code scanning of:	operator & patient IDs, QC values	operator & patient IDs, reagent lot No., 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 & calculated parameters
Analyzer connects to	LIS/HIS via direct interface or via IL's Impact Data Management system; vendor-neutral data management systems	data management system, which in turn connects to LIS/HIS; data management system, which can further transmit data; directly to LIS/HIS
Interface standards supported	ASTM protocol	Medica protocol
To upload patient & QC results, how analyzer connects to external system	direct serial, modem dial-in, Ethernet	direct serial
Information included in transmission from analyzer to external system	device identifier, operator & patient IDs, results, QC ID	patient ID, results
Hardware/software for data management system	Impact for Critical Care	internal
No. of different management reports system produces	customizable	QC, L-J chart, patient & proficient reports
Contents downloaded from DMS to analyzer	patient ID, demographics	—
System connected (live installations) to which LISs/HISs		
• using screen animation/screen scraping	yes	—
• using standard HL7 interface	yes	—
• using proprietary protocol interface	yes	—
Use a third-party interfacing tool/engine for LIS/HIS interfaces	yes	TBD
Distinguishing features	maintenance-free, multiuse cartridge available in 13 menu/size options for use in any hospital location; 14-yr history of proven cartridge technology; remote management from any PC via GemWeb; consolidated workstation for blood gas, electrolytes, Hct, glucose, lactate, co-oximetry, and coagulation ** when interfaced to IL CO-Oximeter*	modular components; simple operation & maintenance; low purchase price & low operation cost; disposable maintenance-free sensor; no gas tanks

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In vitro blood gas analyzers

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	Medica Corp. Leslie Boone lboone@medicacorp.com 14 DeAngelo Dr., Bedford, MA 01730 800-777-5983 or 781-275-4892 www.medicacorp.com	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813
Name of device/first year sold	EasyStat/2002 (510k approved 7/02)	Stat Profile pHOx/1998
No. of devices sold in U.S./outside U.S./list price	—/—/—	—/—/$15,000
Dimensions (H x W x D)/weight	14.5 x 12.5 x 7.0 in/18 lbs	15 x 12 x 15 in/18 lbs
Analytes measured on device	pH, pCO_2, pO_2, Hct, Na, K, iCa	pH, pCO_2, pO_2, Hct, Hb, O_2SAT
Parameters calculated on device	Hb, O_2SAT, BE, TCO_2, HCO_3-	BE, TCO_2, HCO_3-
Barometric pressure	measured and recorded	tracked
Analytical method(s)/technology(ies) employed	pH and pCO_2: ISE-potentiometry; pO_2: ISE-amperometry; Hct: conductivity; Hb: calculated from Hct; iCa: ISE; K: 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 (expanded parameter menu, related to EasyBloodGas)	yes
User list/group available	yes	yes (upon request)
Device warranty	1 yr analyzer warranty	1 yr, travel & labor, repair or replacement
Loaner devices provided	yes (planned)	yes
Average expected life of device	>5 yrs	5–7 yrs
Open or closed system/external gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC & laboratory	POC & laboratory
POC:		
Uses disposable prepackaged reagent/electrode system for analysis	reagent & electrode	reagent
No. of disposable reagent system units in basic shipment package	1	200–500 analyses
No. of samples analyzed per 1 disposable reagent/electrode system	—	n/a
List price per disposable reagent system	TBD	$200–$265
Reagent unit storage requirements	room temperature	room temperature
Shelf life of disposable units	reagent module: 18 mos; electrodes: 12 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	reagent module: 18 mos; electrodes: 12 mos	reagents & electrodes: 18 mos; membrane kits: 12–24 mos
Cost per test/reagent cost per test	<$0.80 per sample at 20 samples per day/—	<$0.11 at 35 analyses per day/<$0.08 at 35 analyses per day
Calibrations required	1 & 2 point (automatic)	1 & 2 point (automatic)
Calibration frequency	1 point: with every sample analysis; 2 point: can be set for 2-, 4-, or 8-hr increments	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	1 level per 8 hrs, CLIA recommendations, Medica controls recom.	min. CLIA recommendations
QC features	L-J plots; monthly cum. report	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
How labs get LOINC codes for reagent kits	n/a	
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	plasma, serum, whole blood, capillary, mixed venous, arterial, venous	whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	heparin	heparin
Sampling technique	aspiration	aspiration & capillary
Suitable for samples from well/sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	125 µL syringe; 95 µL capillary	70 µL
Sample size differs with No. of analytes selected	no	yes, pHOx offers micropanel; standard 3-test micropanel req., 45 µL
Recommended collection device	heparinized capillary or syringe	syringe, capill., microcollect. containers, standard vacuum cont.
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	—	45 sec
Max. No. of patient samples per hr/max. No. of measured parameters per hr	30/210	50/300 tests
Optimal throughput when calibrated and awaiting specimens	30 samples	300 tests per hr
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	no	none
Known interferences	incorrect anticoagulant	none
Restrictions based on Hct	no	no
Sampler has self-wiping probe	yes	yes
Time required for maintenance by lab personnel	daily: 0.5 min; weekly: 3.5 min; monthly: 15 min	weekly: <5 min; monthly: <10 min
Onboard diagnostics for troubleshooting/limited to software	yes/no	yes/no
Diagnostics performed through modem	no	yes
Training & certification program for user	yes (through distributor)	yes (on-site)
Method of analyst ID in system	manual or bar-code entry (optional)	password with unique user ID No. (optional)
Response for hardware & software failure/user ID & QC failure/ calibration & power failure	HW: operator warning-error message; SW: error message/user ID: sampling lockout; QC: flagged results/calibration: error message & 2nd 2 pt calibration automatically run; power: display not illuminated, data retained-auto reset	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:	operator & patient IDs, reagent lot No., QC controls	patient identifier
User can search for and review previous patient results on screen	yes	yes
Built-in printer/data port	yes/RS 232	yes/multiple RS 232
Information on hard copy report	patient information, measured & calculated results, date, operator ID	patient ID w/ access. No., entered settings, meas. & calc. results
Analyzer connects to	data management system, which in turn connects to LIS/HIS; data management system, which can further transmit data; directly to LIS/HIS	data management system and/or directly to LIS/HIS
Interface standards supported	—	ASTM E1381-91 & ASTM 1394-91 (HL7 available with external device)
To upload patient & QC results, how analyzer connects to external system	direct serial	direct serial/>500 hospitals installed; hospital network/>100 installed
Information included in transmission from analyzer to external system	operator & patient IDs, results	device unique identifier, operator & patient IDs, results, QC identifier, accession No.
Hardware/software for data management system	internal	Pentium with Microsoft Windows 2000/Nova Patient Data Manager
No. of different management reports system produces	QC, L-J chart, patient & proficiency reports	>60
Contents downloaded from DMS to analyzer	—	yes, patient name, passwords
System connected (live installations) to which LISs/HISs		
• using screen animation/screen scraping	—	>20
• using standard HL7 interface	—	>100
• using proprietary protocol interface	—	>500
Use a third-party interfacing tool/engine for LIS/HIS interfaces	TBD	yes
Distinguishing features	modular components; simple operation & maintenance; low purchase price & low operation cost; disposable maintenance-free sensors; no gas tanks, easy inside & out	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

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In vitro blood gas analyzers

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	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813
Name of device/first year sold	Stat Profile pHOx Plus/2000; Stat Profile pHOx Plus L/2001	Stat Profile Critical Care Xpress/2002
No. of devices sold in U.S./outside U.S./list price	pHO Plus: —/—/$29,000; pHOx Plus L: —/—/$32,000	n/a/n/a/—
Dimensions (H x W x D)/weight	15 x 12 x 15 in/18 lbs	17.2 x 22.4 x 17.3 in/53 lbs
Analytes measured on device	pH, pCO_2, pO_2, Hct, Hb, O_2SAT, Na, K, Cl or iCa, glucose; pHOx Plus L measures preceding analytes plus lactate	pH, pCO_2, pO_2, Hct, Hb, Na, K, Cl, iCa, iMg, lactate, glucose, creatinine, BUN, SO_2%
Parameters calculated on device	BE, TCO_2, HCO_3-; pHOx Plus L: Hb, HCT, BE, TCO_2, HCO_3-	BE, TCO_2, HCO_3-
Barometric pressure	tracked	tracked
Analytical method(s)/technology(ies) employed	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	pH: direct ISE; pCO2: Severinghaus; pO2: amperometric; Hct: conductivity; Hb & SO2%: optical, relectance; Na, K, Cl, & iCa: direct ISE; iMg: direct ISE; lactate, glucose, & creatinine: enzyme/amperometric; BUN: enzyme/ISE
Device is part of a series of related models	yes	yes
User list/group available	yes (upon request)	yes (upon request)
Device warranty	1 yr, travel and labor, repair or replacement	1 yr warranty
Loaner devices provided	yes	loaners not typically available
Average expected life of device	5–7 yrs	5–7 yrs
Open or closed system/external gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC & laboratory	POC (clearance pending fall 2002) & 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	$210–$275	$269–$349
Reagent unit storage requirements	room temperature	no special requirements
Shelf life of disposable units	reagents: 18 mos room temperature, electrodes: up to 18 mos	reagents: 18 mos (room temp); electrodes: up to 18 mos
Laboratory:		
No. of different disposable reagents required to maintain device	1	1 reagent for up to 15 tests
Max. No. specific analyte reagents that can reside in device at once	1	15
Shelf life	reagents & electrodes: 18 mos; membrane kits: 12–24 mos	reagents & electrodes: 18 mos; membrane kits: 12–24 mos
Cost per test/reagent cost per test	<$0.11 at 35 analyses per day/<$0.08 at 35 analyses per day	<$0.08 at 40 analyses per day/$0.04 at 40 analyses per day
Calibrations required	1 & 2 point (automatic)	1 & 2 point (automatic)
Calibration frequency	1 point: 30 or 45 min or with every sample (user selectable), 2 point: 2, 4, or 6 hr (user defined)	1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 3, 4, 5, or 6 hr (user defined)
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	min. CLIA recommendations	minimum CLIA recommendations
QC features	L-J plots, statistical calcs., monthly cum. report (onboard, more extensive reporting avail. with Nova Patient Data Manager)	L-J plots, comparable plot, statistical calculations (mean, CV & SD), monthly cum. report, onboard, avail. w/external system
Remote control of device from laboratory	no	yes
System can use LOINC to transmit results to LIS	no	yes
How labs get LOINC codes for reagent kits	—	package insert
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial, venous; pHOx Plus L can accommodate preceding specimens as well as serum plasma	whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	heparin	heparin
Sampling technique	aspiration & capillary	aspiration from syringes, capillaries, ampules & open tubes
Suitable for samples from well/sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	pHOx Plus: 115 µL; pHOx Plus L: 125 µL	150 µL
Sample size differs with No. of analytes selected	yes, pHOx offers micropanel; standard 3-test micropanel req., 50 µL	yes, variety of micropanel options offered
Recommended collection device	syringe, capill., microcollect. containers, standard vacuum cont.	syringe, capillary, micro collection, vacuum collection containers
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	pHOx Plus: 50 sec; pHOx Plus L: 52 sec	140 sec
Max. No. of patient samples per hr/max. No. of measured parameters per hr	50/500 tests	26/450
Optimal throughput when calibrated and awaiting specimens	300 tests per hr	390 tests per hr
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	none	no
Known interferences	none	none
Restrictions based on Hct	no	no
Sampler has self-wiping probe	yes	yes
Time required for maintenance by lab personnel	weekly: <5 min, monthly: <10 min	daily: none; weekly: <5 min; monthly: <10 min
Onboard diagnostics for troubleshooting/limited to software	yes/no	yes/no
Diagnostics performed through modem	yes	yes
Training & certification program for user	yes (on-site)	yes (3 days on-site)
Method of analyst ID in system	password with unique user ID No. (optional)	multilevel password with unique user ID No.
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.	HW & SW: self-diagnostic SW informs and classifies operator of HW failure; hotline and field support avail./user ID: optional setup feature; lock out without proper ID; QC: options include flagging QC failure to not reporting last test that fails QC/calibration: results not reported w/failures, instrument notifies operator of failure reason; power: momentary power interruption requires no recover; automatic calibration
Supports bar-code scanning of:	patient ID	operator & patient IDs, automated reagent lot No.
User can search for and review previous patient results on screen	yes	yes
Built-in printer/data port	yes/multiple RS 232	yes/yes (Ethernet, USB)
Information on hard copy report	patient ID w/ access. No., entered settings, meas. & calc. results	patient ID, entered settings, measured & calculated results
Analyzer connects to	data management system and/or directly to LIS/HIS	directly to LIS/HIS, DMS that in turn connects to LIS/HIS
Interface standards supported	ASTM E1381-91 & ASTM 1394-91 (HL7 available with external device)	ASTM E1394-91, ASTM 1381-91, HL7
To upload patient & QC results, how analyzer connects to external system	direct serial/>500 hospitals inst.; hospital network/>100 inst.	modem dial-in, hospital network
Information included in transmission from analyzer to external system	device unique identifier, operator & patient IDs, results, QC identifier, accession No.	device unique identifier, operator & patient IDs, results, QC identifier
Hardware/software for data management system	Pentium with Microsoft Windows 2000/Nova Patient Data Manager	full-featured onboard DMS capability, external DMS avail.
No. of different management reports system produces	>60	>30
Contents downloaded from DMS to analyzer	yes, patient name, passwords	valid control Nos, valid operator IDs, patient demographics
System connected (live installations) to which LISs/HISs		
• using screen animation/screen scraping	>20	n/a
• using standard HL7 interface	>100	n/a
• using proprietary protocol interface	>500	n/a
Use a third-party interfacing tool/engine for LIS/HIS interfaces	yes	most analyzers interfaced to LIS using LIS vendor's drivers
Distinguishing features	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	largest whole blood, critical care menu; creatinine and iMg are only available from Nova Biomedical; total 15 tests, onboard co-oximeter in development; user interface can be customized to meet specific testing needs; automated 30-day QC cartridge

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In vitro blood gas analyzers

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	Philips Medical Systems **Sales Department** **3000 Minuteman Rd.** **Andover, MA 01810** **978-659-7396** www.medical.philips.com	**Philips Medical Systems** **Deborah Matthews deborah.matthews@philips.com** **3000 Minuteman Rd.** **Andover, MA 01810** **978-659-7396** www.medical.philips.com
Name of device/first year sold	**IRMA Blood Analysis System/1994**	**Blood Analysis Portal System/2002**
No. of devices sold in U.S./outside U.S./list price	**—/—/varies based on quantity**	**—/—/—**
Dimensions (H x W x D)/weight	**11.5 x 9.5 x 5 in/5 lbs, 4 oz**	**3 x 3.9 x 9 in/22 oz**
Analytes measured on device	**pH, pCO_2, pO_2, Hct, Na, K, Cl, iCa, glucose, BUN**	**pH, pCO_2, pO_2, Hct, Na, K, Cl, iCa, BUN**
Parameters calculated on device	**Hb, O_2SAT, BEb, BEecf, TCO_2, HCO_3^-**	**Hb, O_2SAT, BE, TCO_2, HCO_3^-**
Barometric pressure	**measured**	**recorded & measured**
Analytical method(s)/technology(ies) employed	**pH, pCO_2, Na, Cl, iCa, K, BUN (enzymatic): potentiometric; pO_2, glucose (enzymatic): amperometric; Hct: conductometric; glucose strip (enzymatic): colormetric**	**pH, pCO_2, Na, Cl, iCa, BUN, & K: potentiometric; pO_2: amperometric; Hct: conductimetric**
Device is part of a series of related models	**yes, 2nd-generation analyzer**	**no**
User list/group available	**list of customers available**	**no**
Device warranty	**1 yr**	**1 yr**
Loaner devices provided	**yes**	**yes**
Average expected life of device	**7 yrs**	**7 yrs**
Open or closed system/external gas tanks required	**closed/no**	**closed/no**
For POC testing or laboratory	**POC testing**	**POC testing**
POC:		
Uses disposable prepackaged reagent/electrode system for analysis	**reagent/electrode (single use and multiuse cartridge available)**	**reagent/electrode (single use)**
No. of disposable reagent system units in basic shipment package	**25**	**25**
No. of samples analyzed per 1 disposable reagent/electrode system	**1**	**1**
List price per disposable reagent system	**varies based on quantity**	**varies based on volume**
Reagent unit storage requirements	**room temperature**	**room temperature**
Shelf life of disposable units	**reagent/electrode: 6 mos**	**reagent/electrode system: 26 wks**
Laboratory:		
No. of different disposable reagents required to maintain device	**—**	**—**
Max. No. specific analyte reagents that can reside in device at once	**—**	**—**
Shelf life	**—**	**—**
Cost per test/reagent cost per test	**—**	**—**
Calibrations required	**2 point (automatic)**	**2 point (automatic)**
Calibration frequency	**each sample**	**every test**
Calibrants traceable to NIST standards	**yes**	**yes**
Internal QC program recommended	**electronic QC per 8 hrs patient testing, 2 liquid QC per cartridge shipment**	**electronic QC per 8 hrs, 2 liquid QC per cartridge lot or shipment**
QC features	**L-J plots, statistical calculations, monthly cumulative reports (available with external system)**	**available with external system**
Remote control of device from laboratory	**yes**	**no**
System can use LOINC to transmit results to LIS	**no**	**no**
How labs get LOINC codes for reagent kits	**—**	**—**
Detects clots within analysis chamber	**no—sample path visible**	**no—sample path visible**
Specimen types suitable for device	**whole blood, capillary, mixed venous, arterial, venous**	**whole blood, capillary, mixed venous, arterial, venous**
Acceptable anticoagulants	**heparin, EDTA (glucose strip only)**	**heparin**
Sampling technique	**injection**	**injection**
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**	**125 µL capillary, 200 µL syringe**
Sample size differs with No. of analytes selected	**no**	**no**
Recommended collection device	**standard blood gas syringe**	**standard blood gas syringe**
Provides for patient temperature corrected results	**yes**	**yes**
Time from sample introduction to result availability	**<2 min**	**<2 min**
Max. No. of patient samples per hr/max. No. of measured parameters per hr	**20/120**	**20/140**
Optimal throughput when calibrated and awaiting specimens	**20**	**20 per min**
Calibration can be interrupted to perform stat sample	**—**	**no**
Contraindications	**none**	**no**
Known interferences	**—**	**—**
Restrictions based on Hct	**no**	**no**
Sampler has self-wiping probe	**no, not needed**	**no (not needed)**
Time required for maintenance by lab personnel	**no maintenance**	**none**
Onboard diagnostics for troubleshooting/limited to software	**yes/no**	**yes/no**
Diagnostics performed through modem	**no**	**no**
Training & certification program for user	**yes**	**yes (4 days on-site)**
Method of analyst ID in system	**LCD touchscreen, numeric (customizable)**	**6 digit (in patient monitor; customizable)**
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**	**splash screen for hardware/user ID & QC faulure: notice message/calibration: splash screen**
Supports bar-code scanning of:	**operator ID, patient ID, cartridge information**	**cartridge type, cartridge lot No.**
User can search for and review previous patient results on screen	**yes**	**yes**
Built-in printer/data port	**yes/RS 232, modem**	**yes (in patient monitor)/—**
Information on hard copy report	**analyzer serial No., date, calib. successful, calib. code, lot No., patient ID & temp., results, barometric press., SW version optional: user ID, ref. ranges, O_2 therapy, sample info.**	**test results, patient name & ID, operator ID, blood type, cartridge type, software revision, temperature, barometric pressure**
Analyzer connects to	**data management system, which connects to LIS/HIS; directly to LIS/HIS (both options)**	**data management system, which in turn connects to LIS/HIS**
Interface standards supported	**script or HL7**	**ASTM 1394 & 1238 (through patient monitor system)**
To upload patient & QC results, how analyzer connects to external system	**hospital network, direct serial, modem dial-in**	**hospital network**
Information included in transmission from analyzer to external system	**device unique identifier, operator & patient IDs, results, QC identifier, patient O_2 therapy information**	**device unique identifier, operator ID, patient ID, results**
Hardware/software for data management system	**IDMS 5.0.2**	**IDMS, standard PC with Windows NT or 2000**
No. of different management reports system produces	**24**	**18**
Contents downloaded from DMS to analyzer	**all analyzer settings, software upgrades**	**—**
System connected (live installations) to which LISs/HISs		
• using screen animation/screen scraping	**all major HIS/LIS vendors**	**all major LIS vendors**
• using standard HL7 interface	**all major HIS/LIS vendors**	**HBOC**
• using proprietary protocol interface	**customizable EDI interface to HIS/LIS vendors**	**none**
Use a third-party interfacing tool/engine for LIS/HIS interfaces	**none**	**no**
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**	**offers POC testing integrated with Philips patient monitors; offers common user interface providing physiological and biochemical measurements at the bedside**

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

In vitro blood gas analyzers

Part 9 of 13 *See accompanying article on page 62*	**Radiometer America Inc.** **Telesales Department** info@radiometeramerica.com **810 Sharon Dr., Westlake, OH 44145** **800-736-0600 ext. 333** www.radiometeramerica.com	**Radiometer America Inc.** **Telesales Department** info@radiometeramerica.com **810 Sharon Dr., Westlake, OH 44145** **800-736-0600 ext. 333** www.radiometeramerica.com
Name of device/first year sold	ABL 5/1994	ABL 700 Series/1998
No. of devices sold in U.S./outside U.S./list price	—/—/$14,755	—/—/$30,450–$72,300 (depends on configuration options)
Dimensions (H x W x D)/weight	13 x 13 x 8 in/18 lbs	17 x 28 x 20 in/66 lbs
Analytes measured on device	pH, pCO_2, pO_2	pH, pCO_2, pO_2, Hb, Na, K, Cl, iCa, lactate, glucose, bilirubin, fetal Hb, O_2Hb, MetHb, RHb, COHb, O_2SAT
Parameters calculated on device	Hct, O_2SAT, BE, TCO_2, HCO_3-, cH+, ctO_2, $AaDpO_2$, SBE, ABE, SBC, $pCO_2(T)$, $ctCO_2(P)$, pH(T), cH+(T), $pO_2(T)$	Hct, BE, TCO_2, HCO_3-, plus 40 additional parameters, upgradable for future options (call for list)
Barometric pressure	measured	measured
Analytical method(s)/technology(ies) employed	pH: pH-sensitive glass (ISE); pCO_2, pO_2: ISE	pH: pH-sensitive glass (ISE); pCO_2, pO_2, Na, Cl, iCa, K: ISE; Hct: calc. from meas. Hb, bilirubin; Hb: optical, multiwavelength anal., intra-cuvette ultrasonic hemolysis; lactate, gluc.: ISE w/enzyme
Device is part of a series of related models	no	yes, ABL 700 Series
User list/group available	yes (through local sales representative)	yes (through local sales representative)
Device warranty	1 yr, parts, labor, & travel	2 yrs, parts, labor, & travel
Loaner devices provided	yes	yes
Average expected life of device	20 yrs with full support	20 yrs with full support
Open or closed system/external gas tanks required	closed/yes (NIST traceable gases)	closed/yes (low-pressure, premixed)
For POC testing or laboratory	POC & laboratory	POC & laboratory (products on mobile carts for POCT/NPT)
POC:		
Uses disposable prepackaged reagent/electrode system for analysis	—	—
No. of disposable reagent system units in basic shipment package	—	—
No. of samples analyzed per 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	4
Max. No. specific analyte reagents that can reside in device at once	4	depends on future parameter upgrade options
Shelf life	reagent, electrode, membrane kit, cartridge: 2+ yrs	reagent, electrode, membrane kit, cartridge: 2+ yrs
Cost per test/reagent cost per test	depends on sample volume & any extra incl. items/same	depends on sample volume & any extra incl. items/same
Calibrations required	1 & 2 point (automatic)	1 & 2 point (automatic)
Calibration frequency	1 point: 1/2 hr—CLIA GAS, 4 hrs—mftr.; 2 point: 4 hrs	1 point: 1/2 hr–CLIA GAS, 4 hrs—mftr.; 2 point: every 8 hrs
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	depends on hospital management & inspection agency	depends on hospital management & inspection agency
QC features	statistical calculations (available with external system)	L-J plots, comparable plot (via DMS), statistical calcs., auto QC, monthly cum. reports (onboard & avail. w/external system, PC download to Excel)
Remote control of device from laboratory	yes	yes
System can use LOINC to transmit results to LIS	yes	yes
How labs get LOINC codes for reagent kits	—	—
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	plasma, serum, whole blood, capill., mixed venous, arterial, venous	plasma, serum, whole blood, capill., mixed venous, arterial, venous
Acceptable anticoagulants	heparin, balanced heparin	EDTA, heparin, electrolyte-balanced heparin
Sampling technique	aspiration	aspiration, syringe &/or capillary tube &/or test tube
Suitable for samples from well/sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	85 µL	95 µL for 17 measured parameters
Sample size differs with No. of analytes selected	yes, optional 35 µL for pH only	yes, with fewer meas. params., smaller micro-modes avail. from 35 µL
Recommended collection device	syringe or capillary	syringe or capillary
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	~1 min	~1 min (depends on tests ordered)
Max. No. of patient samples per hr/max. No. of measured parameters per hr	30/90	25/425
Optimal throughput when calibrated and awaiting specimens	30 per hr	25 per hr
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	none	none
Known interferences	halothane	halothane, thiocyanic & glycolic acids
Restrictions based on Hct	n/a	no (always use well-mixed samples)
Sampler has self-wiping probe	no	yes
Time required for maintenance by lab personnel	monthly: as needed; annually: 5 hrs	monthly: as needed, annually: ~2 hrs
Onboard diagnostics for troubleshooting/limited to software	yes/no	yes/no
Diagnostics performed through modem	no	yes
Training & certification program for user	yes (on-site as needed)	yes (on-site as needed)
Method of analyst ID in system	operator ID entry (optional)	password system (customizable)
Response for hardware & software failure/user ID & QC failure/ calibration & power failure	system messages	system message with customized ("traffic light") visual & audible signals
Supports bar-code scanning of:	no bar-code scanner	operator & patient identifiers, reag. & QC lot Nos., exp., soft. keys
User can search for and review previous patient results on screen	no	yes, multitask searches while analyzer performs other functions
Built-in printer/data port	yes/RS 232	yes/RS 232, parallel, Ethernet, USB
Information on hard copy report	patient info., meas. & calc. results, system messages	patient info./demographics, patient therapy settings, meas. & calc. results, system messages, reference & critical ranges
Analyzer connects to	Radiance Stat information management system, which connects to LIS/HIS or directly to LIS/HIS	Radiance Stat information management system, which connects to LIS/HIS or directly to LIS/HIS
Interface standards supported	ASTM 1394 & 1238, serial	ASTM 1394 & 1238, HL7, serial, network TCP/IP
To upload patient & QC results, how analyzer connects to external system	direct serial/thousands; modem dial-in/hundreds; realtime wireless future option	direct serial/thousands of hosp. 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, results, QC identifier, as per ASTM protocols	device unique identifier, operator & patient IDs, results, QC identifier, per ASTM/HL7 standards plus calib. & analyzer status info.
Hardware/software for data management system	external Radiance	internal system + optional external system, Radiance w/Windows NT
No. of different management reports system produces	user definable	user-definable searches/reports
Contents downloaded from DMS to analyzer	—	valid control values, valid operator IDs
System connected (live installations) to which LISs/HISs		
• using screen animation/screen scraping	Cerner, Meditech, Sunquest, others	Cerner, Meditech, Sunquest, others
• using standard HL7 interface	none	available from analyzer—LIS/HIS vendors can use
• using proprietary protocol interface	none	none
Use a third-party interfacing tool/engine for LIS/HIS interfaces	no (use interface templates)	no (use interface templates)
Distinguishing features	provides basic blood gases (pH, pCO_2, pO_2) test profile; easy to use with minimal maintenance; low cost of operation via standby usage; fast restart, in 2 min, out of standby mode	market first—bilirubin & 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

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SURVEY OF INSTRUMENTS

In vitro blood gas analyzers

Part 10 of 13 *See accompanying article on page 62*	**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 555/1998**	**ABL 77/2000**
No. of devices sold in U.S./outside U.S./list price	**—/—/$32,563**	**—/—/$16,470**
Dimensions (H x W x D)/weight	**depends on configuration options/82 lbs**	**13 x 8 x 9 in/16 lbs**
Analytes measured on device	**pH, pCO_2, pO_2, Hct, Na, K, plus one of the following: Cl, iCa, lactate, glucose**	**pH, pCO_2, pO_2, Hct, Na, K, iCa, Cl-**
Parameters calculated on device	**Hb, BE, TCO_2, HCO_3-, plus 40 additional parameters (call for list)**	**Hb, O_2SAT, TCO_2, HCO_3-, ctO_2 (a-v), ctO_2, anion gap (K+), cCa^{2+} (7.40), cBase (B), ABE, SBE**
Barometric pressure	**measured**	**n/a**
Analytical method(s)/technology(ies) employed	**pH: pH-sensitive glass (ISE); pCO_2, pO_2, Na, Cl, iCa, K: ISE; Hct: conductivity; lactate, glucose: ISE with enzyme**	**pH, pCO_2, pO_2, Na, iCa: thick film; Hct: conductivity; Hb: indirectly amperometric, potentiometric, & conductometric**
Device is part of a series of related models	**no**	**yes**
User list/group available	**yes (through local sales representative)**	**yes (through local sales representative)**
Device warranty	**1 yr, parts, labor, & travel**	**1 yr, with service plans available after yr 1 depending on customer requirements**
Loaner devices provided	**yes**	**yes**
Average expected life of device	**20 yrs with full support**	**analyzer: 10+ yrs**
Open or closed system/external gas tanks required	**closed/yes (one glass cylinder)**	**closed/no**
For POC testing or laboratory	**POC & laboratory (products on mobile carts for POCT/NPT)**	**POC testing, laboratory, cRT department**
POC:		
Uses disposable prepackaged reagent/electrode system for analysis	**—**	**electrode (multiuse cartridge)**
No. of disposable reagent system units in basic shipment package	**—**	**1**
No. of samples analyzed per 1 disposable reagent/electrode system	**—**	**50/100/150**
List price per disposable reagent system	**—**	**depends on configuration & GPO affiliation**
Reagent unit storage requirements	**—**	**room temperature**
Shelf life of disposable units	**—**	**3 mos**
Laboratory:		
No. of different disposable reagents required to maintain device	**6**	**1**
Max. No. specific analyte reagents that can reside in device at once	**user definable**	**2**
Shelf life	**reagent, electrode, membrane kit, cartridge: 2+ years**	**reagent: 3 mos, cartridge: 3 mos**
Cost per test/reagent cost per test	**depends on sample volume & any extra incl. items/same**	**depends on configuration & GPO affiliation**
Calibrations required	**1 & 2 point (automatic)**	**1 & 2 point (manual & automatic)**
Calibration frequency	**1 point: 1/2 hr–CLIA GAS, 4 hrs—mftr.; 2 point: every 8 hrs**	**1 point: with each test; 2 point: 1–4 hrs (user definable)**
Calibrants traceable to NIST standards	**yes**	**yes**
Internal QC program recommended	**depends on hospital management & inspection agency**	**QC material according to CLIA, CAP, JCAHO**
QC features	**L-J plots, comparable plot (via DMS), statistical calcs., monthly cum. reports (onboard & available with external system, PC download to Excel)**	**L-J plots, statistical calcs., monthly cum. (onboard–current mean, STD, CV%) reports (onboard & 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**
How labs get LOINC codes for reagent kits		**—**
Detects clots within analysis chamber	**yes**	**yes**
Specimen types suitable for device	**plasma, serum, whole blood, capill., mixed ven., arterial, venous**	**whole blood, capillary, mixed venous, arterial, venous**
Acceptable anticoagulants	**EDTA, heparin, electrolyte-balanced heparin**	**heparinized whole blood**
Sampling technique	**aspir., injec., syringe &/or capill. tube &/or aspir. from test tube**	**aspiration**
Suitable for samples from well/sick neonates	**yes/yes**	**yes/yes**
Sample size for complete panel of analyte results	**125 µL for 7 measured parameters**	**70 µL**
Sample size differs with No. of analytes selected	**yes, option to select smaller test profile with reduced sample volume from 35 µL**	**no**
Recommended collection device	**syringe or capillary**	**heparinized syringe or capillary tube**
Provides for patient temperature corrected results	**yes**	**yes**
Time from sample introduction to result availability	**~1 min, depends on tests ordered**	**70 sec**
Max. No. of patient samples per hr/max. No. of measured parameters per hr	**20/27**	**40/320**
Optimal throughput when calibrated and awaiting specimens	**20 tests per hr**	**40 tests per hr**
Calibration can be interrupted to perform stat sample	**yes**	**yes**
Contraindications	**none**	**no**
Known interferences	**halothane, specif. anticoag., thiocyanic & glycolic acids, sod. fl.**	**—**
Restrictions based on Hct	**no (always use well-mixed samples)**	**no**
Sampler has self-wiping probe	**n/a**	**no**
Time required for maintenance by lab personnel	**monthly: as needed, annually: 32 hrs**	**n/a**
Onboard diagnostics for troubleshooting/limited to software	**yes/no**	**yes/no**
Diagnostics performed through modem	**no**	**no**
Training & certification program for user	**yes (on-site as needed)**	**yes**
Method of analyst ID in system	**password system (customizable)**	**bar-code or onboard keyboard (customizable)**
Response for hardware & software failure/user ID & QC failure/ calibration & power failure	**system messages with visual & audible signals**	**error msg./error msg./calib.: error msg., power: blank screen & color indicator for battery level**
Supports bar-code scanning of:	**operator & patient identifiers, accession No.**	**operator & patient identifiers, reag. & sensor lot Nos., QC***
User can search for and review previous patient results on screen	**yes**	**yes**
Built-in printer/data port	**yes/RS 232**	**yes/RS 232, Ethernet**
Information on hard copy report	**patient info./demographics, patient therapy settings, measured & calculated results, system messages**	**all meas. & calc. values, exp., test remaining info., dispos. lot No., basic statistics, time & date, user & patient info., temp. corrected at 37°C**
Analyzer connects to	**Radiance Stat information management system, which connects to LIS/HIS or directly to LIS/HIS**	**LIS, HIS, Radiance**
Interface standards supported	**ASTM 1394 & 1238, HL7, serial**	**ASTM, HL7**
To upload patient & QC results, how analyzer connects to external system	**direct serial/thousands of hospitals installed; modem dial-in/hundreds; hospital network/hundreds; realtime wireless future option**	**serial, Ethernet**
Information included in transmission from analyzer to external system	**device unique identifier, operator & patient IDs, results, QC identifier, as per ASTM/HL7 standards & calib. and system messages**	**device unique identifier, operator & patient IDs, results, QC identifier**
Hardware/software for data management system	**internet and external system options**	**Radiance with Windows NT**
No. of different management reports system produces	**user definable**	**user definable**
Contents downloaded from DMS to analyzer	**valid control values, valid operator IDs**	**—**
System connected (live installations) to which LISs/HISs		**LIS vendors completing interface requirement**
• using screen animation/screen scraping	**Cerner, Meditech, Sunquest, others**	**—**
• using standard HL7 interface	**none**	**—**
• using proprietary protocol interface	**none**	**—**
Use a third-party interfacing tool/engine for LIS/HIS interfaces	**no (use interface templates)**	**no (use interface templates)**
Distinguishing features	**interference-free accuracy; many options for microsample modes (conserves blood); easy to use and highly customizable; highest reliability on market**	**portable, optional battery operation; quickest startup/warmup and analysis time; simplest and easiest-to-use system** ** all open tests*

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In vitro blood gas analyzers

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See accompanying article on page 62

	Radiometer America Inc. Telesales Department info@radiometeramerica.com 810 Sharon Dr., Westlake, OH 44145 800-736-0600 ext. 333 www.radiometeramerica.com	Roche Diagnostics Corp. Sales Department 9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 us.labsystems.roche.com
Name of device/first year sold	NPT7/2001	Roche Omni C Analyzer/2001
No. of devices sold in U.S./outside U.S./list price	—/—/$20,875	—/—/$18,000
Dimensions (H x W x D)/weight	10 x 13 x 16 in/25 lbs	18 x 14 x 16 in/51 lbs
Analytes measured on device	pH, pCO_2, pO_2, tHb, SO_2, O_2Hb, COHb, MetHb, HHb	pH, pCO_2, pO_2, Hct, Hb, Na, K, Cl, iCa, SO_2
Parameters calculated on device	Hct, ABE, SBE, TCO_2, HCO_3-, SBC, TO_2, p50	Hct, O_2SAT, BE, TCO_2, HCO_3-
Barometric pressure	yes	recorded, tracking barometer
Analytical method(s)/technology(ies) employed	pH, pCO_2, pO_2, oximetry: patented dry optical technology	pH: ion selective galvonometric; pCO_2, pO_2: ion selective membrane; Hct: conductivity; Hb: spectrophotometry; Na, Cl, iCa, K: ion selective potentiometry
Device is part of a series of related models	no	yes (Roche provides added menu & functionality w/Omni Modular series)
User list/group available	yes (through local sales representative)	yes (contact sales department)
Device warranty	1 yr, parts, labor & travel or depot loaner service	1 yr
Loaner devices provided	yes	no
Average expected life of device	10+ yrs	7 yrs
Open or closed system/external gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC testing & small laboratory, RT department	laboratory
POC:		
Uses disposable prepackaged reagent/electrode system for analysis	dry optical system	—
No. of disposable reagent system units in basic shipment package	multiuse cartridge contains 30 single-use cuvettes	—
No. of samples analyzed per 1 disposable reagent/electrode system	30	—
List price per disposable reagent system	depends on configuration & GPO affiliation	—
Reagent unit storage requirements	room temperature	—
Shelf life of disposable units	24 months	—
Laboratory:		
No. of different disposable reagents required to maintain device	1	3
Max. No. specific analyte reagents that can reside in device at once	1	n/a
Shelf life	2 yrs	reagent: 2 yrs; electrode: install data recommendation for warranty
Cost per test/reagent cost per test	depends on volume and GPO affiliation	—
Calibrations required	2-level check is performed as part of QualityGuard system (manual & automatic)	1 & 2 point (automatic)
Calibration frequency	1 point: n/a; 2 point: n/a	1 point: 30–60 min; 2 point: 4, 8, 12, 24 hrs
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	QualityGuard incl. a 2-level check, system check & meas. check	1 per 8 hrs—3 levels in 24 hrs—assayed for system
QC features	QualityGuard information onboard or available with external system, L-J plot and QC statistics, also available on external DMS	L-J plots; stat calcs. (mean, SD, %CV), monthly cumulative reports, onboard, available with external system
Remote control of device from laboratory	no	yes
System can use LOINC to transmit results to LIS	yes	no
How labs get LOINC codes for reagent kits	—	e-mail query
Detects clots within analysis chamber	yes	fluid movement error recognition
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial, venous	plasma, serum, whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	heparinized whole blood	heparin
Sampling technique	aspiration	aspiration, capillary transfer and fill
Suitable for samples from well/sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	90 µL	65 µL
Sample size differs with No. of analytes selected	no	no
Recommended collection device	heparinized syringe or capillary tube	heparinized syringes, capillary Microsampler
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	60 sec	45 sec
Max. No. of patient samples per hr/max. No. of measured parameters per hr	30/270	average 30 samples per hr, all measured analytes
Optimal throughput when calibrated and awaiting specimens	30 tests per hr	—
Calibration can be interrupted to perform stat sample	n/a	yes
Contraindications	no	no
Known interferences	intralipid (concentrations over 5 vol%), fluoroscein	—
Restrictions based on Hct	no	—
Sampler has self-wiping probe	no, probe disposed of after measurement	yes
Time required for maintenance by lab personnel	n/a	—
Onboard diagnostics for troubleshooting/limited to software	yes/no	yes/no
Diagnostics performed through modem	no	no
Training & certification program for user	yes	yes (2 days on-site)
Method of analyst ID in system	operator ID entry (optional)/bar code or manual	bar-code, screen, or keyboard (customizable)
Response for hardware & software failure/user ID & QC failure/ calibration & power failure	system messages with visual signals	HW: stop; SW: stop/user ID: lockout (optional); QC: lockout (optional)/calibration: lockout by analyte failure; power: short—return to operation; long—stop
Supports bar-code scanning of:	operator & patient IDs, QC lot No.	operator & patient IDs, reagent lot No., input QC ranges, lot No.
User can search for and review previous patient results on screen	yes	yes
Built-in printer/data port	yes/RS 232, Ethernet	yes/RS 232, Ethernet
Information on hard copy report	patient info, patient therapy settings; measured and calculated parameter results; system messages; reference ranges; cartridge lot & cartridge expiration date	results, errors, patient & sample input (customizable)
Analyzer connects to	LIS/HIS, Radiance	data management system, which in turn connects to LIS/HIS, directly to LIS/HIS
Interface standards supported	ASTM	HL7
To upload patient & QC results, how analyzer connects to external system	serial, Ethernet	direct serial, hospital network
Information included in transmission from analyzer to external system	device unique identifier, oper. & patient IDs, results, QC identifier	—
Hardware/software for data management system	PCM/CIA—internal DM or external DM	onboard data management capabilities
No. of different management reports system produces	user definable	—
Contents downloaded from DMS to analyzer	—	valid control values, valid operator IDs, patient demographics
System connected (live installations) to which LISs/HISs	LIS vendors completing interface requirements	
• using screen animation/screen scraping	—	—
• using standard HL7 interface	—	—
• using proprietary protocol interface	—	—
Use a third-party interfacing tool/engine for LIS/HIS interfaces	no (use interface templates)	—
Distinguishing features	patented dry optical technology, unique in the measurement of blood gases and full co-oxymetry; maintenance-free; no cartridge preparation; QualityGuard; patient results in one minute	automatic sample aspiration; clot & air detection; QC & user lockout; Roche Auto QC loads 120 ampules for automatic & precise measurement & configurable for a variety of QC regimens

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In vitro blood gas analyzers

Part 12 of 13

See accompanying article on page 62

	Roche Diagnostics Corp. Sales Department 9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 us.labsystems.roche.com	Roche Diagnostics Corp. Sales Department 9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 us.labsystems.roche.com
Name of device/first year sold	Roche Opti Critical Care Analyzer/1998	Roche Opti R Critical Care Analyzer/2000
No. of devices sold in U.S./outside U.S./list price	—/—/$8,500	—/—/$9,500
Dimensions (H x W x D)/weight	4.7 x 14.2 x 9 in/9 lbs without battery, 11 lbs with	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, Cl, iCa, tHb, SO_2, glucose	pH, pCO_2, pO_2, Na, K, iCa, tHb, SO_2
Parameters calculated on device	Hct, BE, TCO_2, HCO_3- (12 additional parameters; call Roche for list)	Hct, BE, TCO_2, HCO_3- (11 additional parameters; call Roche for list)
Barometric pressure	measured	measured
Analytical method(s)/technology(ies) employed	pH, pCO_2, pO_2, Na, Cl, iCa, K, glucose: optical fluorescence; tHb, SO_2: optical reflectance	pH, pCO_2, pO_2, Na, iCa, K: optical fluorescence; tHb, SO_2: optical reflectance
Device is part of a series of related models	yes, Opti Series	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	POC & laboratory
POC:		
Uses disposable prepackaged reagent/electrode system for analysis	reagent/optode	reagent/optode
No. of disposable reagent system units in basic shipment package	25 individual packaged cassettes	4 individually packaged cassettes per pkg
No. of samples analyzed per 1 disposable reagent/electrode system	1	up to 25 patient samples per cassette + QC
List price per disposable reagent system	depends on cassette configuration–contact Roche	depends on volume—contact Roche
Reagent unit storage requirements	room temperature	room temperature
Shelf life of disposable units	reagent/electrode: 6 mos	cassette: 6 mos; reagent pack: 1 yr
Laboratory:		
No. of different disposable reagents required to maintain device	1	2
Max. No. specific analyte reagents that can reside in device at once	1	1
Shelf life	cassette: 6 mos	cassette: 6 mos; reagent pack: 1 yr
Cost per test/reagent cost per test	depends on volume—contact Roche/same	depends on volume—contact Roche/same
Calibrations required	1 point (automatic)	1 point (automatic)
Calibration frequency	with each cassette	with each sample or every 30 min
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	3 levels liquid with change of cassette lot No., 2-mo intervals;	2 levels QC/8 hrs
QC features	electronic QC–1 level per 8 hrs of operation, elec. & liquid statistical calcs., L-J with external system (DataCare); stores 1 mo—3 levels onboard of each (elec. & liq.)	statistical calcs., L-J with external system (DataCare); stores 1 mo—3 levels onboard
Remote control of device from laboratory	no	no
System can use LOINC to transmit results to LIS	no	no
How labs get LOINC codes for reagent kits	—	—
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	plasma, serum, w. blood, capill., mixed ven., arterial, venous	plasma, serum, w. blood, capill., mixed ven., arterial, venous
Acceptable anticoagulants	heparin, lithium	heparin, lithium
Sampling technique	aspiration	aspiration
Suitable for samples from well/sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	125 µL	125 µL
Sample size differs with No. of analytes selected	no	no
Recommended collection device	heparinized syringe, capillary, Microsampler	heparinized syringe, capillary, Microsampler
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	~1 min from sample aspiration	~1 min from sample aspiration
Max. No. of patient samples per hr/max. No. of measured parameters per hr	24/192	20/160
Optimal throughput when calibrated and awaiting specimens	—	18 samples/hr
Calibration can be interrupted to perform stat sample	no	no
Contraindications	none	none
Known interferences	none	none
Restrictions based on Hct	no (Hct calculated based on meas. Hb)	no (Hct calculated based on meas. Hb)
Sampler has self-wiping probe	no	no
Time required for maintenance by lab personnel	weekly: 1 min; quarterly: 5 min	weekly: 1 min; quarterly: 5 min
Onboard diagnostics for troubleshooting/limited to software	yes/no	yes/no
Diagnostics performed through modem	no	no
Training & certification program for user	yes (on-site as needed)	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)	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	identified on display & w/ diagnostic routine/user ID: identified on display (missing or not valid), QC: on display (report flagging param. high or low)/calib: on display prior to sample aspir., power: low batt. identified on display–warning; automatic customized QC lockout
Supports bar-code scanning of:	oper. & patient IDs, reag. lot No., QC ranges, cassette lot No., expiration, factory calibration info. & cassette type	operator & patient IDs, 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 (printed review available for all patients)	no
Built-in printer/data port	yes/RS 232, IR	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	ASTM 1394, ASTM 1238, HL7 (with DataCare)
To upload patient & QC results, how analyzer connects to external system	direct serial or IR	direct serial or IR
Information included in transmission from analyzer to external system	device unique identifier, oper. & patient IDs, results, QC identifier, all info. pertinent to patient & QC data	device unique identifier, operator & patient IDs, results, 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	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	none	none
System connected (live installations) to which LISs/HISs		
• using screen animation/screen scraping	none	none
• using standard HL7 interface	Meditech, HBOC, Cerner, SMS, others (call Roche for updated list)	Meditech, HBOC, Cerner, SMS, others (call Roche for updated list)
• using proprietary protocol interface	Kaiser Permanente, others	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	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	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

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

SURVEY OF INSTRUMENTS

In vitro blood gas analyzers

Part 13 of 13	
	Roche Diagnostics Corp. Sales Department 9115 Hague Rd. Indianapolis, IN 46250
See accompanying article on page 62	800-428-5074 us.labsystems.roche.com
Name of device/first year sold	Roche Omni Modular System/1996
No. of devices sold in U.S./outside U.S./list price	—/—/$29,900–$56,200
Dimensions (H x W x D)/weight	16.5 x 21 x 18.5 in/88 lbs
Analytes measured on device	pH, pCO_2, pO_2, Hct, Hb, Na, K, Cl, iCa, lactate, glucose, BUN, co-ox values: O_2Hb, COHb, SulfHb, HHb, metHb
Parameters calculated on device	40+ parameters, including BE, BB, HCO_3^-, TCO_2, SO_2, NiCa++, ctO_2, p50, shunt, AG, OSM (call Roche for list)
Barometric pressure	measured
Analytical method(s)/technology(ies) employed	pH: ion selective galvanometric; pCO_2, pO_2: ion selective membrane; Hct: conductivity; Hb: spectrophotometry; Na, Cl, iCa, K: ion selective potentiometry; lactate: lact. oxidase enzyme; glucose: glucose oxidase enzyme; BUN: urease enzyme
Device is part of a series of related models	yes, models 1–9
User list/group available	yes (through Roche sales dept.)
Device warranty	1 yr (service contract available for subsequent years)
Loaner devices provided	yes
Average expected life of device	>7 yrs
Open or closed system/external gas tanks required	closed/no
For POC testing or laboratory	POC & laboratory (transportable on cart system)
POC:	
Uses disposable prepackaged reagent/electrode system for analysis	n/a
No. of disposable reagent system units in basic shipment package	n/a
No. of samples analyzed per 1 disposable reagent/electrode system	n/a
List price per disposable reagent system	n/a
Reagent unit storage requirements	n/a
Shelf life of disposable units	n/a
Laboratory:	
No. of different disposable reagents required to maintain device	depends on model, contact Roche
Max. No. specific analyte reagents that can reside in device at once	n/a
Shelf life	reagents: 1 yr
Cost per test/reagent cost per test	depends on sample volume/same
Calibrations required	1 & 2 point (automatic)
Calibration frequency	1 point: 30 min and with each sample, 2 point: selectable 4–12 hrs
Calibrants traceable to NIST standards	yes
Internal QC program recommended	1 liquid QC sample per 8 hrs of operation
QC features	AutoQC sampling, L-J plots, statistical calcs., monthly cum. reports (onboard & external with DataCare POC software), multirules, auto. lock/unlock of individual tests based on QC criteria
Remote control of device from laboratory	yes
System can use LOINC to transmit results to LIS	no
How labs get LOINC codes for reagent kits	—
Detects clots within analysis chamber	yes
Specimen types suitable for device	plasma, serum, w. blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	heparin, lithium
Sampling technique	aspiration, injection
Suitable for samples from well/sick neonates	yes/yes
Sample size for complete panel of analyte results	160 µL for full panel, 40 µL per module
Sample size differs with No. of analytes selected	yes, 40 µL per module; i.e.: pH/BG, electrolytes, co-ox, metabolites
Recommended collection device	heparinized syringe, capillary, Microsampler
Provides for patient temperature corrected results	yes
Time from sample introduction to result availability	~1 min (depends on tests analyzed)
Max. No. of patient samples per hr/max. No. of measured parameters per hr	40/490 tests per hr
Optimal throughput when calibrated and awaiting specimens	40 samples per hr
Calibration can be interrupted to perform stat sample	yes
Contraindications	none
Known interferences	none
Restrictions based on Hct	no (automatically checks Hct: tHb ratio)
Sampler has self-wiping probe	no
Time required for maintenance by lab personnel	weekly: 5 min, quarterly: 5 min
Onboard diagnostics for troubleshooting/limited to software	yes/no
Diagnostics performed through modem	yes, with Omni-Link via network can remotely control, realtime continuously monitor, activate calib., QC sampling (with AutoQC module), and activate troubleshooting routines remotely
Training & certification program for user	yes (on-site)
Method of analyst ID in system	4-level password system for 200 operators
Response for hardware & software failure/user ID & QC failure/calibration & power failure	identified on screen & w/ diagnostic routine/user ID: on screen w/ msg., QC: on screen–report w/ high-low flagging & multirule/calib.: identified on display w/ easy-to-read icons, auto. lockout of failed QC test, power: recorded in activities log, automatic customizable QC lockout of tests
Supports bar-code scanning of:	oper. & patient identifiers, reag. & electrode lot Nos., QC ranges, expir.
User can search for and review previous patient results on screen	yes (up to 50,000 online onboard analyzer)
Built-in printer/data port	yes/RS 232, parallel, Ethernet
Information on hard copy report	customizable, can incl. input values, meas. values, calc. values
Analyzer connects to	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options)
Interface standards supported	ASTM 1394, ASTM 1238, HL7 (DataCare available)
To upload patient & QC results, how analyzer connects to external system	direct serial, hospital network, realtime wireless (RF)
Information included in transmission from analyzer to external system	device unique identifier, oper. & patient IDs, results, QC identifier
Hardware/software for data management system	Roche Omni has onboard DM capabilities; DataCare POC software is available as a client/server to connect Omni analyzers
No. of different management reports system produces	40
Contents downloaded from DMS to analyzer	valid control values, valid operator IDs, patient demographics
System connected (live installations) to which LISs/HISs	
• using screen animation/screen scraping	none
• using standard HL7 interface	Meditech, HBOC, Cerner, SMS (call Roche for updated list)
• using proprietary protocol interface	Kaiser Permanente
Use a third-party interfacing tool/engine for LIS/HIS interfaces	Dawning, Cloverleaf, Data Innovations (not required but can use)
Distinguishing features	Roche AutoQC for automatic and precise meas. of QC material following all regs.; reduces labor and eliminates preanalytical variables; liquid calib. eliminates hazardous gas tanks

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