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# In vitro blood gas analyzers

D-14-640		
Part For 13	Abbott Diagnostics	Abbott Diagnostics
	Eric Perreault eric.perreault@abbott.com	Eric Perreault eric.perreault@abbott.com 44 Crosby Dr.
	Bedford, MA 01730	Bedford, MA 01730
See accompanying article on page 62	781-276-4797	781-276-4797
מו נוסוס טוו אושר טב	www.abbdtt.com	www.abbolt.com
Name of device/first year sold	i-Stat 1/2001	i-Stat System/1992 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
Analytee measured on device	nu nco no llat Na K Cl iCa alugada arastinina PUN ACT	nH nCO nO Hat No K CI iCo glucoso orostinino PIIN ACT
Analytes measured on device	lactate	lactate
Parameters calculated on device	Hb, O <sub>2</sub> SAT, BE, TCO <sub>2</sub> , HCO <sub>3</sub> -	Hb, 0 <sub>2</sub> SAT, BE, TCO <sub>2</sub> , HCO <sub>3</sub> -
Barometric pressure	measured	measured
Analytical method(s)/technology(les) employed	electrochemical for all analytes	electrochemical for all analytes
Device is work of a series of valated models		
User list/group available	yes (through local sales representative)	yes (through local sales representative)
Device warranty	1 yr replacement	1 yr replacement
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 unsposable prepackaged reagent/electrode system for analysis No, of disposable reagent system units in basic shinment backage	reagent/electrode (singlé use) 25 per box	reagent/electrode (singlé usé) 25 per box
No. of samples analyzed per 1 disposable reagent/electrode system	1	1
List price per disposable reagent system Reagent unit storage requirements	\$3-\$9 refrigerate 2 weeks of shelf life at room temperature	\$3-\$9 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
aboratory		
No. of different disposable reagents required to maintain device	-	_
Max. No. specific analyte reagents that can reside in device at once	-	-
Cost per test/reagent cost per test	_	_
Calibrations required	1 point (automatic)	1 point (automatic)
Calibration frequency	every test	every test
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	monthly cumulative reports (available with external system), QC
Remote control of device from laboratory	yes	yes
System can use LOINC to transmit results to LIS	yes	yes
How labs get LUINC codes for reagent kits	-	_
Detects clots within analysis chamber	yes	yes
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoaquilants	yes whole blood, capillary, mixed venous, arterial, venous henarin	yes whole blood, capillary, mixed venous, arterial, venous heparin
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sample ince the sample of the	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes/yes blood are 95 ut electrolytes 65 ut	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes/yes blood are 05 ut alectrolote 55 ut
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes/yes blood gas 95 µL, electrolytes 65 µL no	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes/yes blood gas 95 µL, electrolytes 65 µL yes
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Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analyte selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr Optimal throughput when calibrated and avaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through moder Training & certification program for user Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration & power failure Supports bar-code scanning of: User can search for and review previous patient results on screen Built-in printer/data port Information on hard copy report Analyzer connects to Interface standards supported Interface standards supported Information included in transmission from analyzer to external system Hardware/software for data management system	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes/yes blood gas 95 µL, electrolytes 65 µL no syringe or capillary tube yes about 2 min 20/160 	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes blood gas 95 µL, electrolytes 65 µL yes about 2 min 20/160 — — — — — — — — — — — — — — — — — — —
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Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size differs with N. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per tri/max. No. of measured parameters per tri Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through modem Training & certification program for user Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration & power failure Supports bar-code scanning of: User can search for and review previous patient results on screen Built-in printer/data port Inferface standards supported To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer to external system No. of different management reports system produces Contents downloaded from DMS to analyzer to	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes/yes blood gas 95 µL, electrolytes 65 µL no syringe or capillary tube yes about 2 min 20/160 	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes/yes blood gas 95 µL, electrolytes 65 µL yes about 2 min 20/160 
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size differs with N. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per In/max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics and performed through modem Training & certification program for user Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration & power failure Supports bar-code scanning of: User can search for and review previous patient results on screen Built-in printer/data port Information on hard copy report Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Hardware/software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs/HISs • using screen animation/screen scraping	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes/yes blood gas 95 µL, electrolytes 65 µL no syringe or capillary tube yes about 2 min 20/160 	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes/yes blood gas 95 µL, electrolytes 65 µL yes about 2 min 20/160 
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size for complete panel of analyte results Sample size for complete panel of analyte results Sample size for complete panel of analyte results Time from sample introduction to result availability Max. No. of patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per h/max. No. of measured parameters per hr Optimal throughput when calibrated and avaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through modem Training & certification program for user Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration & power failure Supports bar-code scanning of: User can search for and review previous patient results on screen Built-in printer/data port Information on hard copy report Analyzer connects to Interface standards supported Information included in transmission from analyzer to external system Information included in transmission from analyzer to external system Hardware/software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs/HISs • using screament in furcherace • using screament in tempere.	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes/yes blood gas 85 µL, electrolytes 65 µL no syringe or capillary tube yes about 2 min 20/160 	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes/yes blood gas 95 µL, electrolytes 65 µL yes about 2 min 20/160 
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient tsamples per h/max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through modem Training & certification program for user Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration & power failure Supports bar-code scanning of: User can search for and review previous patient results on screen Buili-In printer/data port Information on hard copy report Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer to external system Information included in transmission from analyzer to external system Mardware/software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs/HISs • using screen animation/screen scraping • using screen animation/screen scraping • using stront-pri interfacion gov/enpi interface • using proprietary protocol interface • using proprietary protocol interface	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes/yes blood gas 85 µL, electrolytes 65 µL no syringe or capillary tube yes about 2 min 20/160 	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes/yes blood gas 95 µL, electrolytes 65 µL yes about 2 min 20/160 
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr Optimal throughput when calibrated and avaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through moder Training & certification program for user Method of analyst ID in system Response for hardware & Sattware failure/user ID & QC failure/ calibration & power failure Supports bar-code scanning of: User can search for and review previous patient results on screen Buili-in printer/data port Information on hard copy report Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Hardware/software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs/HISs • using screen animation/screen scraping • using standard H.Z interface • using proprietary protocol interface • using proprietary protocol interface • using proprietary protocol interface • using proprietary protocol interface	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes/yes blood gas 55 µL, electrolytes 65 µL no syringe or capillary tube yes about 2 min 20/160 	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes yes syringe or capillary tube yes about 2 min 20/160 
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient temperature corrected results Time trous patient temperature corrected results Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through moden Training & certification program for user Method of analyst ID in system Response for hardware & Software failure/user ID & QC failure/ calibration can be and review previous patient results on screen Built-in printer/data port Information on hard copy report Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Hardware/software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LLS/HISS • using screen animation/screen scraping • using standard H.Z interface • using proprietary protocol interface Use a third-party interfacing to/lengine for LLS/HIS interfaces • using spreen animation/screen scraping • using standard H.Z interface	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes/yes blood gas 95 µL, electrolytes 65 µL no syringe or capillary tube yes about 2 min 20/160 	yes whole blood, capillary, mixed venous, arterial, venous heparin injection, capillary transfer and fill yes/yes blood gas 95 µL, electrolytes 65 µL yes about 2 min 20/160 

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September 2002

# In vitro blood gas analyzers

Part 2 of 13		
Part 2 of 13	Bayer Corp., Diagnostics Division	Instrumentation Laboratory
	Kathleen Fallon kathleen.fallon.b@bayer.com	Todd Sheldon tsheldon@ilww.com
	511 Benedict Ave.	101 Hartwell Ave.
See accompanying	800-255-3232	781-861-0710
article on page 62	www.bayerdiag.com	www.ilus.com
Name of douise/first year cold	Panidpoint 400/2001	Sunthagia 10 8 15/1007
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	nll nCO nO list No K Ol iCo stucces	all an anno Suathania 15: Tille O lile Collie Maille Dille
Parameters calculated on device	0-SAT. BE. TCO HCO full co-oximetry	pH(T), pO <sub>2</sub> , pCO <sub>2</sub> , Synthesis 15: Thb, O <sub>2</sub> Hb, COHb, Methb, Rhb pH(T), pO <sub>2</sub> (T), pCO <sub>2</sub> (T), HCO <sub>2</sub> -, SBC, TCO <sub>2</sub> , Beb, BEecf, %sO <sub>2</sub> C,
	-2,2,3, ,,	pAO <sub>2</sub> , paO <sub>2</sub> /pAO <sub>2</sub> , RI, A-aDO <sub>2</sub> , O <sub>2</sub> cap, O <sub>2</sub> ct, p50
Barometric pressure	recorded	tracking
Analytical method(s// technology(les/ employed	based on Severinghaus: p0 <sub>2</sub> : amperometric meas. (Clark):	pO <sub>-1</sub> : Clark electrode-current: Hb: nonhemolytic Hb absorption
	glucose: amperometric-glucose oxidase; Hct: conductivity	(Synthesis 15)
Device is part of a series of related models	yes	yes (Synthesis family offering different analyte options)
Device warranty	yes 1 vr	yes (unrough local sales representative) 1 vr
Loaner devices provided	yes	yes
Average expected life of device	5–7 yrs	7–10 yrs
For POC testing or laboratory	POC testing	laboratory
· · · · · · · · · · · · · · · · · · ·		
POC:	and the standard and the standard sta	
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	-
neagent unit storage requirements Shelf life of disposable units	reingerauon reagent/electrode: 4 mos	_
Laboratory:		2
No. or anterent disposable reagents required to maintain device Max. No. specific analyte reagents that can reside in device at once	_	3
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 1 loval OC overy 8 hrs testing, aqueous based	yes
QC features	L-J plots, comparable plot, statistical calculations, monthly	L-J plots, QC tracking
	cumulative reports (onboard & available with external system)	
Remote control of device from laboratory	yes	yes
How labs get LOINC codes for reagent kits		n/a
Detects clots within analysis chamber Specimen types suitable for device	yes whole blood, canillary, mixed venous, arterial, venous	yes w blood serum plasma capill mixed ven arterial ven evn das
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 Sample size differs with No. of analytes selected	100 µL no	60 µL/100 µL
Recommended collection device	syringe or capillary tube	universal sampler accepts all devices
Provides for patient temperature corrected results	yes	yes
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	calibration is interrupted repeatedly, it will force a mandatory	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 Training & certification program for user	yes	yes ves (1 dav on-site)
0		
Method of analyst ID in system Response for bardware & software failure/weer ID & OC failure/	password (customizable) flag.prompt/user ID: customizable: 00: customizable flag/call	manual entry of ID & password (customizable)
calibration & power failure	bration: flag-recalibration	QC: channel flagged/calibration: no results for channel: power:
		automatic recalibration
Supports bar-code scanning of:	operator & patient IDs, accession No., results, temperature,	operator & patient IDs, QC values
User can search for and review previous patient results on screen	other Information	ves
Built-in printer/data port	yes/RS 232, Ethernet	yes/4-RS 232, 1 parallel, standalone CO-ox port, alphanumeric
Information on hard conv ranget	operator 9 potient IDo generation his service to service	keyboard port, bar-code reader port
ппогіпаціон оп паго сору герогі	operator & patient IDS, accession No., results, temperature, other information	pauent uemographics, nospital name, results
Analyzer connects to	data management system, which connects to LIS/HIS;	interfaced direct with HIS/LIS or Impact for Critical Care, which
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	device identifier, operator & patient IDs, results, QC ID
Hardware/software for data management system	HP platform/Windows NT. SOL 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 scraning	_	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;	continuous calibration corrects every 3 seconds for drift seen in
-	onboard audio-video training videos; auto QC	Clark & Severinghaus electrodes-ensures accurate results
		ueuore patient sampling; maintenance-tree disposable elec- trodes for convenience & system untime: integrated co-ovimeter
		uses no extra reagent & minimizes maintenance

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September 2002

#### In vitro blood gas analyzers

Part 3 of 13	Instrumentation Laboratory Todd Sheldon tsheldon@liww.com 101 Hartwell Ave. Lexington, MA 02421 701 CC - 072	Instrumentation Laboratory Todd Sheldon tsheldon@ilww.com 101 Hartwell Ave. Lexington, MA 02421 701 000 010
article on page 62	www.ilus.com	www.ilus.com
Name of device/first year sold No. of devices sold in U.S./outside U.S./list price Dimensions (H x W x D)/weight	Synthesis 20 & 25/1997 >100 worldwide/Synthesis 20: \$38,325; Synthesis 25: \$48,300 20 x 16 x 20 in/77 lbs	Synthesis 30 & 35/1997 >100 worldwide/Synthesis 30: \$42,000; Synthesis 35: \$52,500 20 x 16 x 20 in/77 lbs
Analytes measured on device	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Na+, K+, Ca++, Cl-; Synthesis 25: THb, O <sub>2</sub> Hb, COHb, MetHb, BHb	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Na, K+, Ca++, Cl-, glucose, lactate; Synthesis 35:
Parameters calculated on device	DOIL, mcture, into μ(T), po2(T), pCO <sub>2</sub> (T), HCO <sub>3</sub> -, SBC, TCO <sub>2</sub> , Beb, BEecf, %sO <sub>2</sub> c, pAO <sub>2</sub> , paO <sub>2</sub> /pAO <sub>2</sub> , RI, A-aDO <sub>2</sub> , anion gap, O <sub>2</sub> cap, O <sub>2</sub> ct, p50	PH(T), p0 <sub>2</sub> (T), F0 <sub>2</sub> (T), F0 <sub>3</sub> (T), SBC, TCO <sub>2</sub> , Beb, BEecf, %sO <sub>2</sub> c, pAO <sub>2</sub> , paO <sub>2</sub> /pAO <sub>2</sub> , RI, A-aDO <sub>2</sub> , anion gap, osmolality, O <sub>2</sub> cap, O <sub>2</sub> ct, p50
Barometric pressure Analytical method(s)/technology(ies) employed	tracking pH: potentiometry; pCO <sub>2</sub> : Severinghaus electrode-voltage; pO <sub>2</sub> : Clark electrode-current; Hct: conductivity; Hb: nonhemolytic Hb absorption; Na, Cl, IiCa, K: ISE	tracking pH: potentiometry; pCO <sub>2</sub> : Severinghaus electrode-voltage; pO <sub>2</sub> : 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 User list/group available Device warranty	yes (Synthesis family offering different analyte options) yes (through local sales representative) 1 yr	yes (Synthesis family offering different analyte options) yes (through local sales representative) 1 yr
Loaner devices provided Average expected life of device	yes 7–10 vrs	yes 7-10 vrs
Open or closed system/external gas tanks required For POC testing or laboratory	closed/yes laboratory	closed/yes laboratory
	aboratory	laboratory
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 May No. specific analytic reagents that can reside in device at once	<u> </u>	12
Shelf life		
COST her restrieddent cost her rest	day at list price	day at list price
Calibrations required Calibration frequency	1 & 2 point (automatic & manual) 1 point: after each sample, 2 point: every 2 hrs	1 & 2 point (automatic & manual) 1 point: after each sample, 2 point: every 2 hrs
Calibrants traceable to NIST standards	yes 1 level per 8 brs. II, controls recommended	yes 1 level per 8 brs. II. 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 How labs get LOINC codes for reagent kits	no n/a	no n/a
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device Acceptable anticoagulants	w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas heparin	w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas heparin
Sampling technique Suitable for complex from well/sick peopeter	aspiration, injection, capillary	aspiration, injection, capillary
Sample size for complete panel of analyte results	80 μL/150 μL	80 µL/150 µL
Sample size differs with No. of analytes selected Recommended collection device	yes universal sampler accepts all devices	yes universal sampler accepts all devices
Provides for patient temperature corrected results Time from sample introduction to result availability	yes 60 sec	yes 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 Calibration can be interrupted to perform stat sample	30 samples per hr yes	30 samples per hr yes
Contraindications Known interferences	-	
Restrictions based on Hct Sampler bas self-wining probe	no vec	no
	you	yos
Onboard diagnostics for troubleshooting/limited to software	yes/no	yes/no
Diagnostics performed through modem Training & certification program for user	yes yes (1 day on-site)	yes 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, OC: channel flagged/calibration: no results for channel, nower	operator warning, sampling lockout/user ID: no system access, OC: channel flagged/calibration: no results for channel, nower
Sumante has and according of	automatic recalibration	automatic recalibration
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
Hardware/software for data management system	Impact for Critical Care	Impact for Critical Care
No. of different management reports system produces Contents downloaded from DMS to analyzer	customizable patient ID, demographics	customizable patient ID, demographics
System connected (live installations) to which LISs/HISs	none	none
using standard HL7 interface	none	none
<ul> <li>using proprietary protocol interface</li> <li>Use a third-party interfacing tool/engine for LIS/HIS interfaces</li> </ul>	none no	none no
Distinguishing features	continuous calibration corrects every 3 seconds for drift seen in	continuous calibration corrects every 3 seconds for drift seen in
	Clark & Severinghaus electrodes-ensures accurate results before patient sampling; maintenance-free disposable elec- trodes for convenience & system uptime; integrated co-oximeter uses no extra reagent & minimizes maintenance	Clark & Severinghaus electrodes-ensures accurate results before patient sampling; maintenance-free disposable elec- trodes for convenience & system uptime; integrated co-oximeter uses no extra reagent & minimizes maintenance

# In vitro blood gas analyzers

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	Instrumentation Laboratory	Instrumentation Laboratory
	Todd Sheldon tsheldon@ilww.com	Patti Williams pwilliams@ilww.com
	101 Hartwell Ave. Lexington. MA 02421	101 Hartwell Ave. Lexington, MA 02421
See accompanying article on page 62	781-861-0710 www.ilus.com	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 Dimensions (H x W x D)/weight	n/a/Synthesis 40: \$48,300; Synthesis 45: \$60,375 20 x 16 x 20 in/77 lbs	-//\$39,995 17 x 12 x 12 in/29.5 lbs
Analytes measured on device	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Na+, K+, Ca++, Cl-, glucose, lactate;	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Hct, Na+, K+, Ca++, glucose, lactate
Parameters calculated on device	Synthesis 45: THb, 0 <sub>2</sub> Hb, COHb, MetHb, RHb pH(T), pO <sub>2</sub> (T), pCO <sub>2</sub> (T), HCO <sub>3</sub> -, SBC, TCO <sub>2</sub> , Beb, BEecf, %sO <sub>2</sub> c, pAO <sub>2</sub> , paO <sub>2</sub> /pAO <sub>2</sub> , RI, A-aDO <sub>2</sub> , anion gap, osmolality, O <sub>2</sub> cap, O <sub>2</sub> ct,	A-aDo <sub>2</sub> , Hb, pAO <sub>2</sub> , paO <sub>2</sub> /pAO <sub>2</sub> , RI, O <sub>2</sub> cap*, CtO <sub>2</sub> *, CaO <sub>2</sub> *, CvO <sub>2</sub> *, CcO <sub>2</sub> *, a-vDO <sub>2</sub> *, Qsp/Qt*, P50*
Barometric pressure	p50 tracking	n/a
Analytical method(s)/technology(ies) employed	pH: potentiometry; pCO <sub>2</sub> : Severinghaus electrode-voltage; pO <sub>2</sub> :	pH, pCO <sub>2</sub> : potentiometry; pO <sub>2</sub> , glucose, lactate: amperometry;
	absorption; Na, Cl, iCa, K: ISE; glucose, lactate: enzymatic	HCT: CONDUCTIVITY; NA, IGA, K: ISE
Device is part of a series of related models	yes (Synthesis family offering different analyte options)	yes
Device warranty	1 yr	5 yrs
Loaner devices provided	yes 7-10 yrs	yes 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 No. of disposable reagent system units in basic shipment package		yes (multiuse cartridge) 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 Reagent unit storage requirements	_	room temperature
Shelf life of disposable units	-	6 mos
Laboratory:		
No. of different disposable reagents required to maintain device Max. No. specific analyte reagents that can reside in device at once	13	1 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
Colibrations required	1 9 0 maint (automotic 9 manual)	1.8.0 noint (automotio)
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 1 level per 8 brs. II, controls recommended	yes
QC features	L-J plots, QC tracking	bar-code identification of QC material, QC statistics, QC
Remote control of device from laboratory	Ves	scheduling, QC lockout ves
System can use LOINC to transmit results to LIS	no	no
How labs get LUINC codes for reagent kits	n/a	n/a
Detects clate within enclusic chember		
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device Acceptable anticoagulants	yes w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas heparin	yes whole blood, arterial, venous, or capillary heparin
Detects dous within analysis channer Specimen types suitable for device Acceptable anticoagulants Sampling technique	yes w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary	yes whole blood, arterial, venous, or capillary heparin aspiration
Detects dous within analysis channer Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results	yes w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes 95 μ//15 μL	yes whole blood, arterial, venous, or capillary heparin aspiration yes/yes 135–150 µL
Detects cluss winnin analysis channeer Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size differs with No. of analytes selected Boopwaredroth conference on the second	yes w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes 95 µL/165 µL yes	yes whole blood, arterial, venous, or capillary heparin aspiration yes/yes 135–150 µL n0 N0
Detects cluss within analysis channer Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results	yes w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes 95 µL/165 µL yes universal sampler accepts all devices yes	yes whole blood, arterial, venous, or capillary heparin aspiration yes/yes 135–150 μL no syringe or capillary tube yes
Detects duis within anaysis channer Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability May. No. of ratient samples net br/may. No. of massured narameters per tr	yes w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes 95 µL/165 µL yes universal sampler accepts all devices yes 60 sec 40/320-520	yes whole blood, arterial, venous, or capillary heparin aspiration yes/yes 135-150 µL no syringe or capillary tube yes <100 sec <100 sec 15/135
Detects clus within analysis channer Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens	yes w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes 95 µL/165 µL yes universal sampler accepts all devices yes 60 soc 40/320–520 30 samples per hr	yes whole blood, arterial, venous, or capillary heparin aspiration yes/yes 135-150 µL no syringe or capillary tube yes <100 sec 15/135 15 samples
Detects duis within anaysis channer Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr Optimal throughput when calibrated and availing specimens Calibration can be interrupted to perform stat sample Contraindications	yes w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes 95 µL/165 µL yes universal sampler accepts all devices yes 60 s20 40/320-520 30 samples per hr yes —	yes whole blood, arterial, venous, or capillary heparin aspiration yes/yes 135-150 µL no syringe or capillary tube yes <100 sec 15/135 15 samples yes — — — — — — — — — — — — — — — — — — —
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Detects duis within analysis channer Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr Optimal throughput when calibrated and availing specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe	yes w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes 95 µL/165 µL yes universal sampler accepts all devices yes 60 sec 40/320-520 30 samples per hr yes 	yes whole blood, arterial, venous, or capillary heparin aspiration yes/yes 135-150 µL no 135-150 µL no 9 yringe or capillary tube yes 400 sec 15/135 15 samples yes 9 ye
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Detects duis within anaysis channer Specimen types suitable for device Acceptable anticoaguiants Sampling technique Suitable for samples from well/sick neonates Sample size differs with No. of analyte results Sample size differs with No. of analyte selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through modem Training & certification program for user Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration a power failure Supports bar-code scanning of: User can search for and review previous patient results on screen Built-in printer/data port Information on hard copy report Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Hardware/software for data management system Nave/software for more software for barbare software for barbare software for barbare software for barbare software for data management system Nave/software for more software for barbare software for barba	yes w. blood, serum, plasma, capill, mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes Sb µL/165 µL yes universal sampler accepts all devices yes 60 sec 40/320–520 30 samples per hr yes monthly: 5 min yes/no yes yes (1 day on-site) manual entry of ID & password (customizable) operator warning, sampling lockout/user ID: no system access, QC: channel flagged/calibration: no results for channel, power: automatic realibration operator warning, sampling lockout/user ID: no system access, QC: channel flagged/calibration: no results for channel, power: automatic realibration operator & patient IDs, QC values yes interfaced direct with HIS/LIS or Impact for Critical Care, which can be interfaced to HIS/LIS interfaced with LIS or Impact for Critical Care, ASTM protocol direct serial, modem dial-in, hospital network device identifier, operator & patient IDs, results, QC ID Impact for Critical Care customizable patient ID, demographics,	yes whole blood, arterial, venous, or capillary heparin aspiration yes/yes 135–150 µL no syringe or capillary tube yes <100 sec 15/135 15 samples yes —————————————————————————————————
Detects blus within anaysis channer Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size differs with No. of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through modem Training & certification program for user Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration can be and review previous patient results on screen Buili-in printer/data port Interface standards supported To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer to external system Hardware/software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISS/HISs • using screen animation/screen scraping	yes w. blood, serum, plasma, capill, mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes 59 µL/165 µL yes universal sampler accepts all devices yes 60 sec 40/320–520 30 samples per hr yes monthly: 5 min yes/mo yes yes (I day on-site) manual entry of ID & password (customizable) operator warning, sampling lockout/user ID: no system access, QC: channel flagged/calibration: no results for channel, power: automatic re calibration operator warning, sampling lockout/user ID: no system access, QC: channel flagged/calibration: no results for channel, power: automatic re calibration persor warning, sampling lockout/user ID: no system access, QC: channel flagged/calibration: no results for channel, power: automatic re calibration persor warning, sampling lance, results interfaced ther UHS/LIS or Impact for Critical Care, which can be interfaced to HIS/LIS interfaced with LIS or impact for Critical Care, ASTM protocol direct serial, modem dial-in, hospital network device identifier, operator & patient IDs, results, QC ID Impact for Critical Care customizable patient ID, demographics.	yes whole blood, arterial, venous, or capillary heparin aspiration yes/yes 135-150 µL no syringe or capillary tube yes <100 sec 15/135 15 samples yes 
Detects blus within anaysis channer Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size differs with No. of analyte results Sample size differs with No. of analyte selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through modem Training & certification program for user Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration on hard copy report Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Hardware/software for data management system You different management reports system produces Contents dowloaded from DMS to analyzer System connected (ive installations) to which LISS/HISS • using screen animation/Screene scraping • using standard H.7 interface	yes w. blood, serum, plasma, capill, mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes 55 µL/165 µL yes universal sampler accepts all devices yes 60 sec 40/320–520 30 samples per hr yes ————————————————————————————————————	yes whole blood, arterial, venous, or capillary heparin aspiration yes/yes 135–150 µL no syringe or capillary tube yes <100 sec 15/135 15 samples yes 
Detects blus within anaysis channer Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size offers or complete panel of analyte results Sample size offers with No. of analytes selected Recommende collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr Optimal throughput when calibrated and avaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hot Sample has self-wiping probe Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through modem Training & certification program for user Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration cale scanning of: User can search for and review previous patient results on screen Built-in printer/data port Information on hard copy report Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer to external system Information included in transmission from analyzer to external system Information included in transmission from analyzer System connected (live installations) to which LISx/HISs • using groupietary protocol interface • using proprietary protocol interface	yes w. blood, serum, plasma, capill, mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes g5 µL/165 µL yes universal sampler accepts all devices yes 60 sec 40/320–520 30 samples per hr yes 	yes while blood, arterial, venous, or capillary heparin aspiration yes/yes 135-150 µL no syringe or capillary tube yes < 100 sec 15/135 15 samples yes 
Detects blus within anaysis channer Specimen types suitable for device Acceptable anticoaguiants Sampling technique Suitable for samples from well/sick neonates Sample size differs with No. of analyter results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hot Sample has self-wiping probe Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through modem Training & certification program for user Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration cale scanning of: User can search for and review previous patient results on screen Built-in printer/data port Inferrequired to transmission from analyzer to external system Information included in transmission from analyzer System connected (live installations) to which LISr/HISs • using screen animation/screen scraping • using stondard Hz7 interface Bistinguishing features	yes w. blood, serum, plasma, capill, mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes SG µL/165 µL yes universal sampler accepts all devices yes GD sec 40/320-520 30 samples per hr yes 	yes while blood, arterial, venous, or capillary heparin aspiration yes/yes 135-150 µL no syringe or capillary tube yes < 100 sec 15/135 15 samples yes disposable cartridge/no maintenance required yes/no no yes/no no yes/no no yes/no no c. channel flagged/calibration: no results for channel, power: automatic recalibration operator & patient IDs, GC values yes yes/as 222, 1 parallel, bar-code reader port, Ethernet port patient demographics, hospital name and address, results LIS/HS via direct interface or via IL's Impact Data Management System; vendor-neutral data management systems ASTM protocol direct serial, Ethernet, modem dial-in device identifier, operator & patient IDs, results, QC ID & results Impact for Critical Care customizable patient ID, demographics
Detects blus within analysis channer Specimen types suitable for device Acceptable anticoaguiants Sampling technique Suitable for samples from well/sick neonates Sample size differs with No. of analyter results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through modem Training & certification program for user Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration calibration for user Built-in printer/data port Information on hard copy report Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer system No. of different management reports system produces Contents downloaded from DMS to analyzer Uses a third-party interfacing tou/lengine for LIS/HIS interfaces Use a third-party interfacing tou/lengine for LIS/HIS interfaces	yes w. blood, serum, plasma, capill, mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes SG µL/165 µL yes GD sec 40/320-520 30 samples per hr yes monthly: 5 min yes/no yes monthly: 5 min yes/no yes monthly: 5 min yes/no yes yes (1 day on-site) manual entry of 10 & password (customizable) operator warning, sampling lockout/user ID: no system access, QC: channel flagged/calibration: no results for channel, power: automatic realibration operator & patient IDs, QC values yes yes yes/HS 232, 1 parallel, standalone co-ox port, alphanumeric keyboard port, bar-code reader port patient demographics, hospital name, results interfaced direct with HIS/LIS or Impact for Critical Care, which can be interfaced to HIS/LIS interfaced direct with Care inpact for Critical Care, which can be interfaced to HIS/LIS interfaced min LIS or Impact for Critical Care, ASTM protocol direct serial, modem dial-in, hospital network device identifier, operator & patient IDs, results, QC ID Impact for Critical Care customizable patient ID, demographics none none continuous calibration corrects every 3 seconds for drift seen in Clark & Severinghaus electrodes-ensures accurate results before action teargening: motioneone cone	yes whole blood, arterial, venous, or capillary heparin aspiration yes/yes 135–150 µL no syringe or capillary tube yes < 100 sec 15/135 15 samples yes disposable cartridge/no maintenance required yes/no no yes manual or bar-code wand entry of ID & password (customizable) operator warning, sampling lockout/user ID: no system access, OC: channel flagged/calibration: no results for channel, power: automatic recalibration operator & patient IDs, QC values yes yes/a-RS 232, 1 parallel, bar-code reader port, Ethernet port patient demographics, hospital name and address, results LLS/HIS via direct interface or via IL's Impact Data Management System; vendor-neutral data management systems ASTM protocol direct serial, Ethernet, modem dial-in device identifier, operator & patient IDs, results, QC ID & results Impact for Critical Care customizable patient ID, demographics yes yes yes
Detects blus within analysis channeer Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per tr/max. No. of measured parameters per hr Optimal throughput when calibrated and avaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through modem Training & certification program for user Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration calibration for user Juser can search for and review previous patient results on screen Built-in printer/data port Inferration on hard copy report Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer system Vo. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs/HISs • using screen animation/screen scraping • using screen animation/screen scraping • using screen animation/screen scraping • using standard HJT interface Use a third-party interfacing too/lengine for LIS/HIS interfaces	yes w. blood, serum, plasma, capill, mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes SG µL/165 µL yes universal sampler accepts all devices yes 60 sec 40/320-520 30 samples per hr yes 	yes whole blood, arterial, venous, or capillary heparin aspiration yes/yes 135–150 µL no syringe or capillary tube yes < 100 sec 15/135 15 samples yes 
Detects duis within anaysis channer Specimen types suitable for device Acceptable anticoaguiants Sampling technique Suitable for samples from well/sick neonates Sample size differs with No. of analyte results Sample size differs with No. of analyte selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr Optimal throughput when calibrated and avaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through modem Training & certification program for user Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration canned through modem Training & certification program for user Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration & power failure User can search for and review previous patient results on screen Built-in printer/data port Information included in transmission from analyzer to external system Information included in transmission from analyzer to external system Information included in transmission from analyzer to external system Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer Contents downloaded from DMS to analyzer System connected (live installations) to which LISs/HISs • using screen animation/screen scraping • using screen animation/screen	yes w. blood, serum, plasma, capill, mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes SG µL/165 µL yes GD sec 40/320-520 30 samples per hr yes monthly: 5 min yes/no yes manual entry of ID & password (customizable) operator warning, sampling lockout/user ID: no system access, QC: channel flagged/calibration: no results for channel, power: automatic realibration operator & patient IDs, QC values yes yes/HS 22, 1 parallel, standalone co-ox port, alphanumeric keyboard port, bar-code reader port patient demographics, hospital name, results Interfaced direct with HIS/LIS or Impact for Critical Care, which can be interfaced to HIS/LIS interfaced with LIS or Impact for Critical Care, which can be interfaced to HIS/LIS interfaced with LIS or Impact for Critical Care, solf direct serial, modem dial-in, hospital name, results, QC ID Impact for Critical Care customizable patient ID, demographics. none none none continuous calibration corrects every 3 seconds for drift seen in Clark & Severinghaus electrodes-ensures accurate results before patient sampling; maintenance-free disposable elec- trodes for convenience & system upting; integrated co-oximeter uses no extra reagent & minimizes maintenance	yes whole blood, arterial, venous, or capillary heparin aspiration yes/yes 135–150 µL no syringe or capillary tube yes < 100 sec 15/135 15 samples yes 

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September 2002

# In vitro blood gas analyzers

Part 5 of 13		
	Instrumentation Laboratory Patti Williams pwilliams@ilww.com	Medica Corp. Leslie Boone   Iboone@medicacorp.com
	101 Hartwell Ave., Lexington, MA 02421	14 DeAngelo Dr., Bedford, MA 01730
See accompanying article on page 62	781-861-0/10 www.ilus.com	800-777-5983 or 781-275-4892 www.medicacoro.com
Name of device/first year sold No. of devices sold in U.S./outside U.S./list price	Gem 3100/2000	EasyBloodGas/2000
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	nH n0 nC0 Hot Nat Kt Catt glucose lactate PT APTT	0.00 Hg
Analytes measured on device	ACT, ACT-LR	pii, po <sub>2</sub> , poo <sub>2</sub>
Parameters calculated on device	A-aDo <sub>2</sub> , Hb, pAO <sub>2</sub> , paO <sub>2</sub> /pAO <sub>2</sub> , RI, O <sub>2</sub> cap*, CtO <sub>2</sub> *, CaO <sub>2</sub> *, CvO <sub>2</sub> *,	0 <sub>2</sub> SAT, BE, TCO <sub>2</sub> , HCO <sub>3</sub> -
Barometric pressure	CCU <sub>2</sub> ^, a-VDU <sub>2</sub> ^, USP/Ut <sup>*</sup> , P50^ n/a	measured
Analytical method(s)/technology(ies) employed	pH, pCO <sub>2</sub> : potentiometry; pO <sub>2</sub> , glucose, lactate: amperometry;	pH: ISE-potentiometry; pCO2: ISE-potentiometry; pO2: ISE-
	Hct: conductivity; Na, iCa, K: ISE; P1, AP11, AC1, AC1-LR: mechanical clot detection	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 1 yr
Loaner devices provided	yes	yes
Average expected life of device Open or closed system/external gas tanks required	7–10 yrs closed/no	>5 yrs 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. or samples analyzed per 1 disposable reagent/electrode system	a 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	-
heagent unit storage requirements Shelf life of disposable units	6 mos	Ξ
l akayataya		
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 Cost per test/reagent cost per test	6 mos varies with menu & cartridge size	reag. & elec.: 1 yr; QC material: 3 yrs \$0 57 at 20 samples per day/\$0 26 at 20 samples per day
	valies with menu & califinge size	\$0.57 at 20 samples per day/\$0.20 at 20 samples per day
Calibrations required	1 & 2 point (automatic)	1 & 2 point (automatic)
	r point, each patient sample, 2 point, at least every 4 ms	4-, or 8-hr increments
Calibrants traceable to NIST standards	yes	yes
QC features	bar-code identification of QC material, electronic & liquid QC	L-J plots; monthly cumulative reports
· · · · · · · · · · · · ·	available for coagulation tests	
System can use LOINC to transmit results to LIS	yes no	no
How labs get LOINC codes for reagent kits	n/a	n/a
Detects clots within analysis chamber	ves	ves
Specimen types suitable for device	whole blood, arterial, venous, or capillary	whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants Sampling technique	heparin, fresh whole blood for coagulation tests aspiration	heparin 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
Recommended collection device	syringe or capillary tube	heparinized capillary or syringe
Provides for patient temperature corrected results	yes	yes 125 coo includes 1 point colibration
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
Contraindications	yes —	yes no
Known interferences	-	incorrect anticoagulant
Restrictions based on Hct Sampler has self-wining probe	no ves	no ves
		-
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software	no operator involvement ves/no	dally: U.5 min; weekly: 3.5 min; monthly: 15 min ves/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 & nower failure	operator warning, sampling lockout/user ID: no system access,	HW: oper. warning & error msg.; SW: error msg./user ID: sampling
canaration a portor failure	automatic recalibration	for 2-pt. calib. auto.; power: display not illuminated, data retained &
Sunnarts har-code scanning of	operator & patient IDs. OC values	auto reset
סעוףטינס שמי־נטעל סנמוווווון טו.	טיסימנטי ע שמנופווג ושט, עט אמונופט	automatically read when reagent module installed
User can search for and review previous patient results on screen	yes	yes
Built-in printer/data port 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
Interlace standards supported To upload patient & OC results, how analyzer connects to external system	ASTM PROTOCOL 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 No. of different management reports system produces	Impact for Critical Care customizable	internal OC. L-J chart. patient & proficient reports
Contents downloaded from DMS to analyzer	patient ID, demographics	
System connected (live installations) to which LISs/HISs	VAS	
using standard HL7 interface	yes	-
using proprietary protocol interface Use a third-party interfacing tool/ongine for LIS/HIS interfaces	yes ves	
oso a unia party menaning tooronyme for Lio/filo interfaces	<b>J</b> 00	100
Distinguishing features	maintenance-free, multiuse cartridge available in 13 menu/size	modular components; simple operation & maintenance; low
	cartridge technology; remote management from any PC via	free sensor; no gas tanks
	GemWeb; consolidated workstation for blood gas, electrolytes,	
	nor, giudose, ladiale, do-oximetry, and coagulation	

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September 2002

# In vitro blood gas analyzers

Part 6 of 13	Medica Corp. Leslie Boone Iboone@medicacorp.com 14 DeAngelo Dr., Bedford. MA 01730	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St.
See accompanying article on page 62	800-777-5983 or 781-275-4892 www.medicacorp.com	Waltham, MA 02454-9141 800-458-5813
Name of device/first year sold No. of devices sold in U.S./outside U.S./list price Dimensions (H x W x D)/weight	EasyStat/2002 (510k approved 7/02) —/—/— 14.5 x 12.5 x 7.0 in/18 lbs	Stat Profile pH0x/1998 —/—/\$15,000 15 x 12 x 15 in/18 lbs
Analytes measured on device Parameters calculated on device Barometric pressure Analytical method(s)/technology(ies) employed Device is part of a series of related models	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Na, K, iCa Hb, O <sub>2</sub> SAT, BE, TCO <sub>2</sub> , HCO <sub>2</sub> - measured and recorded pH and pCO <sub>2</sub> : ISE-potentiometry; pO <sub>2</sub> : ISE-amperometry; Hct: conductivity; Hb: calculated from Hcb; iCa: ISE; K: ISE yes (expanded parameter menu, related to EasyBloodGas)	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Hb, O <sub>2</sub> SAT BE, TCO <sub>2</sub> , HCO <sub>3</sub> - tracked pH: direct ISE; pCO <sub>2</sub> : potentiometry; pO <sub>2</sub> : amperometry; Hct: conductivity; Hb & SO <sub>2</sub> %: optical-reflectance yes
User list/group available Device warranty Loaner devices provided Average expected life of device Open or closed system/external gas tanks required For POC testing or laboratory	yes 1 yr analyzer warranty yes (planned) >5 yrs closed/no POC & laboratory	yes (upon request) 1 yr, travel & labor, repair or replacement yes 5-7 yrs closed/no POC & 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	reagent & electrode 1	reagent 200-500 analyses n/a \$200-\$265 room temperature reagents: 18 mos room temperature; electrodes: up to 18 mos
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	1 1 reagent module: 18 mos; electrodes: 12 mos <\$0.80 per sample at 20 samples per day/—	1 1 reagents & electrodes: 18 mos; membrane kits: 12-24 mos <\$0.11 at 35 analyses per day/<\$0.08 at 35 analyses per day
Calibrations required Calibration frequency	1 & 2 point (automatic) 1 point: with every sample analysis; 2 point: can be set for 2-, 4-, or 8-hr increments	1 & 2 point (automatic) 1 point: 30 or 45 min or with every sample (user selectable), 2 point: 2, 4, or 6 hr (user defined)
Calinzanis traceable to NIST standards Internal QC program recommended QC features	yes 1 level per 8 hrs, CLIA recommendations, Medica controls recom. L-J plots; monthly cum. report	yes min. CLIA recommendations L-J plots, statistical calcs., monthly cum. report (onboard, more extensive reporting avail. with Nova Patient Data Manager)
Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	no no n/a	yes no
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size offer complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr Optimal throughput when calibrated and availing specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe	yes plasma, serum, whole blood, capillary, mixed venous, arterial, venous heparin aspiration yes/yes 125 µL syringe; 95 µL capillary no heparinized capillary or syringe yes 30/210 30 samples yes no incorrect anticoagulant no yes	yes whole block, capillary, mixed venous, arterial, venous heparin aspiration & capillary yes/yes 70 µL yes, pH0x offers micropanel; standard 3-test micropanel req., 45 µL syringe, capill., microcollect. containers, standard vacuum cont. yes 45 sec 50/300 tests 3000 tests per hr yes none none none none no
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through modem Training & certification program for user	daily: 0.5 min; weekly: 3.5 min; monthly: 15 min yes/no no yes (through distributor)	weekly: <5 min; monthly: <10 min yes/no yes yes (on-site)
Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration & power failure	manual or bar-code entry (optional) HW: operator warning-error message; SW: error message/user ID: sampling lockout; QC: flagged results/calibration: error message & 2nd 2 pt editoration automatically run; power: display not illuminated, data retained-auto reset	password with unique user ID No. (optional) 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 recoverse optiended power filture power interrupts require no
Supports bar-code scanning of: User can search for and review previous patient results on screen Built-in printer/data port Information on hard coov report	operator & patient IDs, reagent lot No., QC controls yes yes/RS 232 patient information. measured & calculated results. date. operator ID	patient identifier yes yes/multiple RS 232 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
To upload patient & QC results, how analyzer connects to external system	direct serial	device) direct serial/>500 hospitals installed; hospital network/>100
Information included in transmission from analyzer to external system	operator & patient IDs, results	installed device unique identifier, operator & patient IDs, results, QC identifier, accession No.
No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs/HISs • using standard HL7 interface • using standard HL7 interface	QC, L-J chart, patient & proficiency reports	<ul> <li>&gt;60</li> <li>yes, patient name, passwords</li> <li>&gt;20</li> <li>&gt;100</li> <li>&gt;500</li> </ul>
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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September 2002

# In vitro blood gas analyzers

Part 7 of 13	Nova Biomedical Sales info@novabiomedical.com	Nova Biomedical Sales info@novabiomedical.com
See accompanying article on page 62	200 Prospect St. Waitham, MA 02454-9141 800-458-5813	200 Prospect St. Waltham, MA 02454-9141 800-458-5813
Name of device/first year sold No. of devices sold in U.S./outside U.S./list price Dimensions (H x W x D)/weight	Stat Profile pH0x Plus/2000; Stat Profile pH0x Plus L/2001 pH0 Plus: —/—/\$29,000; pH0x Plus L: —/—/\$32,000 15 x 12 x 15 in/18 lbs	Stat Profile Critical Care Xpress/2002 n/a/n/a/— 17.2 x 22.4 x 17.3 in/53 lbs
Analytes measured on device Parameters calculated on device Barometric pressure Analytical method(s)/technology(ies) employed	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Hb, O <sub>2</sub> SAT, Na, K, Cl or iCa, glucose; pH0x Plus L measures preceding analytes plus lactate BE, TCO <sub>2</sub> , HCO <sub>3</sub> <sup>-</sup> ; pH0x Plus L: Hb, HCT, BE, TCO <sub>2</sub> , HCO <sub>3</sub> <sup>-</sup> tracked pH: direct ISE; pCO <sub>2</sub> : potentiometry; pO <sub>2</sub> : amperometry; Hct: conductivity; Hb & SO <sub>2</sub> %: ordical-reflectance; Na, K, Cl, iCa: direct ISE; glucose: enzyme amperometric	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Hb, Na, K, Cl, iCa, iMg, lactate, glucose, creatinine, BUN, SO <sub>2</sub> % BE, TCO <sub>2</sub> , HCO <sub>3</sub> - tracked 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: marware/amperateric BUK ensume/ISE
Device is part of a series of related models User list/group available Device warranty Loaner devices provided Average expected life of device Open or closed system/acternal gas tanks required For POC testing or laboratory	yes yes (upon request) 1 yr, travel and labor, repair or replacement yes 5-7 yrs closed/no POC & laboratory	yes yes yes (upon request) 1 yr warranty loaners not typically available 5-7 yrs closed/no POC (clearance pending fall 2002) & 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	reagent 200–500 analyses n/a \$210-\$275 room temperature reagents: 18 mos room temperature, electrodes: up to 18 mos	reagent 200-500 analyses n/a \$269-\$349 no special requirements reagents: 18 mos (room temp); electrodes: up to 18 mos
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	1 1 reagents & electrodes: 18 mos; membrane kits: 12–24 mos <\$0.11 at 35 analyses per day/<\$0.08 at 35 analyses per day	1 reagent for up to 15 tests 15 reagents & electrodes: 18 mos; membrane kits: 12–24 mos <\$0.08 at 40 analyses per day/\$0.04 at 40 analyses per day
Calibrations required Calibration frequency Calibrants traceable to NIST standards Internal QC program recommended QC features	1 & 2 point (automatic) 1 point: 30 or 45 min or with every sample (user selectable), 2 point: 2, 4, or 6 hr (user defined) yes min: CLIA recommendations L-J plots, statistical calcs., monthly cum. report (onboard, more	1 & 2 point (automatic) 1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 3, 4, 5, or 6 hr (user defined) yes minimum CLIA recommendations L-J plots, comparable plot, statistical calculations (mean, CV &
Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	extensive reporting avail. with Nova Patient Data Manager) no no —	SD), monthly cum. report, onboard, avail. w/external system yes package insert
Detects clots within analysis chamber Specimen types suitable for device	yes whole blood, capillary, mixed venous, arterial, venous; pHOx Plus L can accommodate preceding specimens as well as serum plasma	yes whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe	heparin aspiration & capillary yes/yes pH0X Plus: 115 µL; pH0X Plus L: 125 µL yes, pH0X offers micropanel; standard 3-test micropanel req., 50 µL syringe, capill., microcollect. containers, standard vacuum cont. yes pH0X Plus: 50 see; pH0X Plus L: 52 sec 50/500 tests 300 tests per hr yes none none none none none	heparin aspiration from syringes, capillaries, ampules & open tubes yes/yes 150 µL yes, variety of micropanel options offered syringe, capillary, micro collection, vacuum collection containers yes 140 sec 26/450 390 tests per hr yes no none no yes
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through modem Training & certification program for user	weekly: <5 min, monthly: <10 min yes/no yes yes (on-site)	daily: none; weekly: <5 min; monthly: <10 min yes/no yes yes (3 days on-site)
Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration & power failure	password with unique user ID No. (optional) self-diag. SW informs & notifies oper. of HW failure; hottine & 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. nationt ID	multilevel password with unique user ID No. 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/calibra- tion: results not reported w/failures, instrument notifies operator of failure reason; power: momentary power interruption requires no recover; automatic calibration operator. & autionated research tet No.
Supports our -cover scanning or. User can search for and review previous patient results on screen Built-in printer/data port Information on hard copy report	yes yes/multiple RS 232 patient ID w/ access. No., entered settings, meas. & calc. results	yes yes/yes (Ethernet, USB) patient ID, entered settings, measured & calculated results
Analyzer connects to Interface standards supported	data management system and/or directly to LIS/HIS ASTM E1381-91 & ASTM 1394-91 (HL7 available with external	directly to LIS/HIS, DMS that in turn connects to LIS/HIS ASTM E1394-91, ASTM 1381-91, HL7
To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer to external system	direct serial/>500 hospitals inst.; hospital network/>100 inst. device unique identifier, operator & patient IDs, results, QC identifier, accession No.	modem dial-in, hospital network device unique identifier, operator & patient IDs, results, QC identifier
Hardware/software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs/HISs • using screen animation/screen scraping • using standard HL7 interface • using standard HL7 interface Use a third-party interfacing tool/engine for LIS/HIS interfaces	Pentium with Microsoft Windows 2000/Nova Patient Data Manager >60 yes, patient name, passwords >20 >100 >500 yes	full-featured onboard DMS capability, external DMS avail. >30 valid control Nos, valid operator IDs, patient demographics n/a n/a n/a 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

Part 8 of 13		
	Philips Medical Systems	Philips Medical Systems
	Sales Department 3000 Minuteman Rd	Deborah Matthews deborah.matthews@philips.com 3000 Minuteman Bd
	Andover, MA 01810	Andover, MA 01810
See accompanying	978-659-7396	978-659-7396
	www.meuca.pmips.com	www.meuca.pmips.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 Dimensions (H x W x D)/weight	-/-/varies based on quantity 11.5 x 9.5 x 5 in/5 lbs. 4 oz	—/—/— 3 x 3.9 x 9 in/22 oz
(· · · · · · _), · · · g.··	······	
Analytes measured on device Parameters calculated on device	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Na, K, Cl, iCa, glucose, BUN Hb, O, SAT, BEb, BEecf, TCO, HCO,-	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Na, K, CI, iCa, BUN Hb, O, SAT, BF, TCO, HCO, -
	10, 02041, 020, 02001, 1002, 1003	115, 02011, 52, 1002, 1003
Barometric pressure	measured	recorded & measured
Analytical method(s)/technology(tes) employed	glucose (enzymatic): amperometric; Hct: conductometric;	ric; Hot: conductimetric
Device is work of a contract of existent worksis	glucose strip (enzymatic): colormetric	
User list/group available	yes, 2nd-generation analyzer list of customers available	no
Device warranty	1 yr	1 yr
Loaner devices provided	yes 7 ws	yes 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 No. of samples analyzed per 1 disposable reagent/electrode system	25	25
List price per disposable reagent system	varies based on quantity	varies based on volume
Reagent unit storage requirements	room temperature	room temperature
Sheh he of disposable drins	reagen/electrode: 6 mos	reagen/electrode system: 20 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 electronic OC per 8 brs nationt testing, 2 liquid OC per	yes electronic OC per 8 brs 2 liquid OC per cartridge lot or shinment
OC features	cartridge shipment L-J plots, statistical calculations, monthly cumulative reports	available with external system
Remote control of device from laboratory	(available with external system) yes	no
System can use LOINC to transmit results to LIS	no	no
How labs get Loing codes for reagent kits	—	_
Detects clots within analysis chamber	no-sample path visible	no—sample path visible
Specimen types suitable for device Accentable anticoagulants	whole blood, capillary, mixed venous, arterial, venous benarin, FDTA (glucose strin only)	whole blood, capillary, mixed venous, arterial, venous
Sampling technique	injection	injection
Suitable for samples from well/sick neonates	yes/yes 125 yl conillony 200 yl cyringe	yes/yes
Sample size differs with No. of analytes selected	no	no
Recommended collection device	standard blood gas syringe	standard blood gas syringe
Time from sample introduction to result availability	yes <2 min	<pre>yes &lt;2 min</pre>
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
Contraindications	none	no
Known interferences	-	_
Restrictions based on Hct Sampler has self-wiping probe	no no. not needed	no no (not needed)
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software	no maintenance ves/no	none ves/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/	EQC failure or screen prompt, software: screen prompt/if user ID	splash screen for hardware/user ID & QC faulure: notice
calibration & power failure	required, no access to menu, it UC required, no access to patient testing mode/calib.; test ends-no injection of sample allowed	message/calibration: splash screen
	power: blank screen-resume testing with power	
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 Built-in printer/data port	yes ves/RS 232. modem	yes ves (in patient monitor)/—
Information on hard copy report	analyzer serial No., date, calib. successful, calib. code, lot No.,	test results, patient name & ID, operator ID, blood type, cartridge
	patient ID & temp., results, barometric press., SW version	type, software revision, temperature, barometric pressure
Auction control to		444
Analyzer connects to	aata 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	device unique identifier, operator ID, patient ID, results
Hardware (activers for data management suctors	identifier, patient O <sub>2</sub> therapy information	IDMS, standard PC with Windows NT as 2000
No. of different management reports system produces	24	18 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
טאר מ מוויע-אמינץ ווונפוזמכוווץ נוסטיפוועווופ וטר LIS/חוס ווונפוזמכפט	1016	10
Distinguishing features	cartridges do not require refrig. (room temp.); true QC lockout—lab	offers POC testing integrated with Philips patient monitors;
	manager controls QC test requirements, user access, patient info. requirements, e.g. patient ID requirements: cartridae design w/ luer	biochemical measurements at the bedside
	lock port provides barrier between user and sample-no overfilling	
	risk; complete data integration w/ iDMS interface	

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In vi	tro blood gas analyze	ers
Part 9 of 13		
See accompanying aticle 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.radiometerametica.com
Nome of douise/first year cold		API 700 Sories/1009
No. of device inits year source No. of devices sold in U.S./outside U.S./list price Dimensions (H x W x D)/weight	—/—/\$14,755 13 x 13 x 8 in/18 lbs	-/-/\$30,450-\$72,300 (depends on configuration op 17 x 28 x 20 in/66 lbs
Analytes measured on device	pH, pCO <sub>2</sub> , pO <sub>2</sub>	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hb, Na, K, Cl, iCa, lactate, glucose, bilirubi
Parameters calculated on device	Hct, 0 <sub>2</sub> SAT, BE, TCO <sub>2</sub> , HCO <sub>3</sub> -, cH+, ctO <sub>2</sub> , AaDpO <sub>2</sub> , SBE, ABE, SBC,	Hot, BE, TCO <sub>2</sub> , HCO <sub>3</sub> -, plus 40 additional parameters, u
Barometric pressure	pCO <sub>2</sub> (T), ctCO <sub>2</sub> (P), pH(T), cH+(T), pO <sub>2</sub> (T) measured	for future options (call for list) measured
Analytical method(s)/technology(ies) employed	pH: pH-sensitive glass (ISE); pCO <sub>2</sub> , pO <sub>2</sub> : ISE	pH: pH-sensitive glass (ISE); pCO <sub>2</sub> , pO <sub>2</sub> , Na, CI, iCa, K: ISE from meas. Hb, bilirubin; Hb: optical, multiwavelength ar cuvette ultrasonic hemolysis; lactate, gluc.: ISE w/enzym
Device is part of a series of related models User list/group available	no yes (through local sales representative)	yes, ABL 700 Series yes (through local sales representative)
Device warranty	1 yr, parts, labor, & travel	2 yrs, parts, labor, & travel
Average expected life of device	20 yrs with full support	20 yrs with full support
Open or closed system/external gas tanks required For POC testing or laboratory	closed/yes (NIST traceable gases) POC & laboratory	closed/yes (low-pressure, premixed) POC & laboratory (products on mobile carts for POCT/
POC: Uses disposable prepackaged reagent/electrode system for analysis	_	_
No. of disposable reagent system units in basic shipment package	-	_
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 Shelf life	4 reagent, electrode, membrane kit, cartridge: 2+ yrs	depends on future parameter upgrade options 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/sa
Calibrations required	1 & 2 point (automatic)	1 & 2 point (automatic)
Calibration requercy Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended QC features	depends on hospital management & inspection agency statistical calculations (available with external system)	depends on hospital management & inspection agenc L-J plots, comparable plot (via DMS), statistical calcs., a monthly cum. reports (onboard & avail. w/external syste download to Excel)
Remote control of device from laboratory	yes	yes
How labs get LOINC codes for reagent kits		<u> </u>
Detects clots within analysis chamber	yes plasma serum whole blood capill, mixed venous arterial venous	yes nasma sarum whole blood canill, mixed venous, arter
Acceptable anticoagulants	heparin, balanced heparin	EDTA, heparin, electrolyte-balanced heparin
Sampling technique Suitable for samples from well/sick neonates	aspiration ves/ves	aspiration, syringe &/or capillary tube &/or test tube ves/ves
Sample size for complete panel of analyte results	85 µL	95 µL for 17 measured parameters
	yes, ομασια 35 με τοι μι σπιγ	35 μL
Provides for patient temperature corrected results	syringe or capillary yes	syringe or capillary yes
Time from sample introduction to result availability	~1 min 30/90	~1 min (depends on tests ordered)
Optimal throughput when calibrated and awaiting specimens	30 per hr	25 per hr
calibration can be interrupted to perform stat sample Contraindications	yes none	yes none
Known interferences Restrictions based on Hct	halothane n/a	halothane, thiocyanic & glycolic acids
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
Diagnostics performed through modem	yesnio No	yes/no yes
ranning & cerunication program for User	yes (un-site as needed)	yes (on-site as needed)
Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/	operator ID entry (optional) system messages	password system (customizable) system message with customized ("traffic light") visı
calibration & power failure Supports bar-code scanning of:	no bar-code scanner	audible signals operator & patient identifiers, rear, & OC lot Nos, evo
User can search for and review previous patient results on screen	no Noc/DE 222	yes, multitask searches while analyzer performs othe
Dunt-in printer/data port Information on hard copy report	yes/n5 232 patient info., meas. & calc. results, system messages	yes/n5 232, parallel, Ethernet, USB patient info./demographics, patient therapy settings, calc, results, system messages, reference & critical re
Analyzer connects to	Radiance Stat information management system, which connects	Radiance Stat information management system. which
Interface standards supported	to LIS/HIS or directly to LIS/HIS	to LIS/HIS or directly to LIS/HIS ASTM 1394 & 1238 HI 7 serial network TCD/ID
To upload patient & QC results, how analyzer connects to external system	direct serial/thousands; modem dial-in/hundreds; realtime	direct serial/thousands of hosp. installed; modem dial-i
Information included in transmission from analyzer to external system	wireiess tuture option device unique identifier, operator & patient IDs, results, QC identifier, as per ASTM protocols	areas; nospital network/nundreds; realtime wireless fut device unique identifier, operator & patient IDs, results, identifier, per ASTM/HL7 standards plus calib. & analyze info
Hardware/software for data management system	external Radiance	internal system + optional external system, Radiance w/N
No. or different management reports system produces Contents downloaded from DMS to analyzer	user definable	user-definable searches/reports valid control values, valid operator IDs
System connected (live installations) to which LISs/HISs	Cerner Meditech Sunguest others	Cerner Meditech Sunguest others
using standard HL7 interface	none	available from analyzer—LIS/HIS vendors can use
using proprietary protocol interface Use a third-party interfacing tool/engine for LIS/HIS interfaces	none no (use interface templates)	none no (use interface templates)
Distinguishing features	provides basic blood gases (pH, pCO,, pO,) test profile; easy to	market first—bilirubin & fetal Hb meas. on whole bloc
	use with minimal maintenance; low cost of operation via standby usage; fast restart, in 2 min, out of standby mode	extra sample volume, low maintenance & cost of oper interference-free accuracy; smallest automated micrr mode options with no loss in performance specs. (con blood); flexible/modular platform running on Window:

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

#### See ac article

Part 10

Name ( No. of ( Dimens Analyte Parame

Septen

Barom Analyti Device User lis Device Loaner Averag Open o For PO( POC: Uses di No. of ( No. of s List pri Reager Shelf li Labora No. of ( Max. N Shelf li Cost pe Calibra Calibra Calibra Interna QC feat Remote System How la Detects Specim Accept Sampli Suitabl Sample Sample Recom Provide Time fr Max. N Optima Calibra Contrai Known Restric Sample Time re Onboar Diagno Trainin Method Respon calib Suppor User ca Built-in Informa Analyz Informa

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September 2002

#### NS RURIELOS RUNENTS In vitro blood gas analyzers Part 10 of 13 Radiometer America Inc. Telesales Department info@radiometeramerica.com 810 Sharon Dr., Westlake, OH 44145 Radiometer America Inc. Telesales Department info@radiometeramerica.com 810 Sharon Dr. Westlake, OH 44145 800-736-0600 ext. 333 800-736-0600 ext. 333 www.radiometeramerica.com See accompanying article on page 62 www.radiometeramerica.com ABL 555/1998 ABL 77/2000 Name of device/first year sold No. of devices sold in U.S./outside U.S./list price Dimensions (H x W x D)/weight -/--/\$32.563 /---/\$16.470 depends on configuration options/82 lbs 13 x 8 x 9 in/16 lbs al Hb. pH, pCO<sub>2</sub>, pO<sub>2</sub>, Hct, Na, K, plus one of the following: Cl, iCa, Analytes measured on device pH, pCO<sub>2</sub>, pO<sub>2</sub>, Hct, Na, K, iCa, CIadable Hb, $0_2$ SAT, TCO<sub>2</sub>, HCO<sub>3</sub>-, ctO<sub>2</sub> (a-v), ctO<sub>2</sub>, anion gap (K+), cCa<sup>2+</sup> (7.40), cBase (B), ABE, SBE Parameters calculated on device Hb, BE, TCO<sub>2</sub>, HCO<sub>3</sub>-, plus 40 additional parameters (call for list) : calc. Barometric pressure intrameasured pH: pH-sensitive glass (ISE); pCO<sub>2</sub>, pO<sub>2</sub>, Na, Cl, iCa, K: ISE; Hct: conductivity; lactate, glucose: ISE with enzyme pH, pCO<sub>2</sub>, pO<sub>2</sub>, Na, iCa: thick film; Hct: conductivity; Hb: indirect-ly amperometric, potentiometric, & conductometric Analytical method(s)/technology(ies) employed Device is part of a series of related models no yes (through local sales representative) 1 yr, parts, labor, & travel User list/group available yes (through local sales representative) Device warranty 1 yr, with service plans available after yr 1 depending on customer requirements Loaner devices provided Average expected life of device yes analyzer: 10+ yrs yes 20 yrs with full support Open or closed system/external gas tanks required For POC testing or laboratory closed/yes (one glass cylinder) POC & laboratory (products on mobile carts for POCT/NPT) ed/no POC testing, laboratory, cRT department POC Uses disposable prepackaged reagent/electrode system for analysis No. of disposable reagent system units in basic shipment package electrode (multiuse cartridge) \_ 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 \_ 50/100/150 depends on configuration & GPO affiliation room temperature 3 mos \_ \_ Laboratory: No. of different disposable reagents required to maintain device Max. No. specific analyte reagents that can reside in device at once Shelf life user definable 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 Calibration frequency Calibrants traceable to NIST standards 1 & 2 point (automatic) 1 point: <sup>1</sup>/2 hr-CLIA GAS, 4 hrs—mftr.; 2 point: every 8 hrs 1 & 2 point (manual & automatic) 1 point: with each test; 2 point: 1–4 hrs (user definable) yes QC material according to CLIA, CAP, JCAHO depends on hospital management & inspection agency Internal QC program recommended L-J plots, comparable plot (via DMS), statistical calcs, monthly cum. reports (onboard & available with external system, PC download to Excel) (onboard-current mean, STD, CV%) reports (onboard & available with external system, PC download to Excel) OC features Remote control of device from laboratory System can use LOINC to transmit results to LIS yes yes ves yes enous How labs get LOINC codes for reagent kits Detects clots within analysis chamber Specimen types suitable for device yes plasma, serum, whole blood, capill., mixed ven., arterial, venous whole blood, capillary, mixed venous, arterial, venous EDTA, heparin, electrolyte-balanced heparin aspir., injec., syringe &/or capill. tube &/or aspir. from test tube Acceptable anticoagulants heparinized whole blood aspiration I. from Sampling technique Sample size for complete panel of analyte results Sample size for complete panel of analyte results Sample size differs with No. of analytes selected abun, ingrev, y, ..., yes/yes yes/yes 125 µL for 7 measured parameters yes, option to select smaller test profile with reduced sample volume from 35 µL yes/yes 70 µL no Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr syringe or capillary heparinized syringe or capillary tube yes ~1 min, depends on tests ordered yes 70 sec 20/27 40/320 Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample 20 tests per hr 40 tests per hr yes no Contraindications Known interferences Restrictions based on Hct halothane, specif. anticoag., thiocyanic & glycolic acids, sod. fl. no (always use well-mixed samples) no Sampler has self-wiping probe no n/a Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software monthly: as needed, annually: 32 hrs n/a yes/no ves/no Diagnostics performed through modem no no yes (on-site as needed) Training & certification program for user yes Method of analyst ID in system Response for hardware & software failure/user ID & QC failure/ password system (customizable) system messages with visual & audible signals bar-code or onboard keyboard (customizable) keys error msg./error msg./calib.: error msg., power: blank screen & ictions calibration & power failure color indicator for battery level Supports bar-code scanning of: User can search for and review previous patient results on screen operator & patient identifiers, accession No. operator & patient identifiers, reag. & sensor lot Nos., QC\* Built-in printer/data port Information on hard copy report yes/RS 232, Ethernet all meas. & calc. values, exp., test remaining info., dispos. lot yes/RS 232 patient info./demographics, patient therapy settings, measured nects & calculated results, system messages No., basic statistics, time & date, user & patient info., temp. corrected at 37°C option Analyzer connects to Radiance Stat information management system, which connects LIS. HIS. Radiance to LIS/HIS or directly to LIS/HIS Interface standards supported To upload patient & QC results, how analyzer connects to external system ASTM 1394 & 1238, HL7, serial ASTM, HL7 direct serial/thousands of hospitals installed: modem dial-in/hunserial Ethernet dreds; hospital network/hundreds; realtime wireless future option device unique identifier, operator & patient IDs, results, QC identifi-er, as per ASTM/HL7 standards & calib. and system messages ows NT Information included in transmission from analyzer to external system device unique identifier, operator & patient IDs, results, QC identifier Radiance with Windows NT Hardware/software for data management system internet and external system options user definable valid control values, valid operator IDs No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs/HISs • using screen animation/screen scraping user definable LIS vendors completing interface requirement Cerner, Meditech, Sunquest, others using standard HL7 interface none ith no using proprietary protocol interface Use a third-party interfacing tool/engine for LIS/HIS interfaces none no (use interface templates) no (use interface templates) Distinguishing features interference-free accuracy: many options for microsample portable, optional battery operation; quickest startup/warmup modes (conserves blood); easy to use and highly customizable; highest reliability on market and analysis time; simplest and easiest-to-use system \* all open tests

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# In vitro blood gas analyzers

Part 11 of 13	Radiometer America Inc. Telesales Department info@radiometeramerica.com	Roche Diagnostics Corp. Sales Department
See accompanying article on page 62	810 Sharon Dr., Westlake, OH 44145 800-736-0600 ext. 333 www.radiometeramerica.com	9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 us.labsystems.roche.com
Name of device/first year sold No. of devices sold in U.S./outside U.S./list price Dimensions (H x W x D)/weight	NPT7/2001 —/—/\$20,875 10 x 13 x 16 in/25 lbs	Roche Omni C Analyzer/2001 —/—/\$18,000 18 x 14 x 16 in/51 lbs
Analytes measured on device	pH, pCO <sub>2</sub> , pO <sub>2</sub> , tHb, SO <sub>2</sub> , O <sub>2</sub> Hb, COHb, MetHb, HHb	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Hb, Na, K, Cl, iCa, SO <sub>2</sub>
Parameters calculated on device	Hct. ABE, SBE, TCO <sub>2</sub> , HCO <sub>2</sub> -, SBC, TO <sub>2</sub> , n50	Hct. 0-SAT. BE. TCO-, HCO
Barometric pressure Analytical method(s)/technology(ies) employed	yes pH, pCO <sub>2</sub> , pO <sub>2</sub> , oximetry: patented dry optical technology	recorded, tracking barometer pH: ion selective galvonometric; pCO <sub>2</sub> , pO <sub>2</sub> : ion selective membrane; Hct: conductivity; Hb: spectrophotometry; Na, CI, iCa, K ion selective networker.
Device is part of a series of related models	no	yes (Roche provides added menu & functionality w/Omni Modular series)
User list/group available Device warranty	yes (through local sales representative) 1 yr. parts, labor & travel or denot loaner service	yes (contact sales department) 1 vr
Loaner devices provided	yes	no
Average expected life of device Open or closed system/external gas tanks required For POC testing or laboratory	10+ yrs closed/no POC testing & small laboratory, RT department	7 yrs closed/no laboratory
POC: Uses disposable prepackaged reagent/electrode system for analysis No. of disposable reagent system units in basic shipment package	dry optical system multiuse cartridge contains 30 single-use cuvettes	
No. of samples analyzed per 1 disposable reagent/electrode system	30	-
List price per disposable reagent system Beagent unit storage requirements	depends on configuration & GPO affiliation room temperature	_
Shelf life of disposable units	24 months	-
Laboratory: No. of different disposable reagents required to maintain device Max. No. specific analyte reagents that can reside in device at once	1	3 n/a
Shelf life	2 yrs	reagent: 2 yrs; electrode: install data recommendation for
Cost per test/reagent cost per test	depends on volume and GPO affiliation	warranty
Calibrations required	2-level check is performed as part of QualityGuard system (manual & automatic)	1 & 2 point (automatic)
Calibration frequency Calibrants traceable to NIST standards	1 point: n/a; 2 point: n/a	1 point: 30–60 min; 2 point: 4, 8, 12, 24 hrs
QC features	QualityGuard incl. a 2-level check, system check & meas. check QualityGuard information onboard or available with external system, L-J plot and QC statistics, also available on external DMS	Jos 1 per 8 hrs—3 levels in 24 hrs—assayed for system L-J plots; stat calcs. (mean, SD, %CV), monthly cumulative reports, onboard, available with external system
Remote control of device from laboratory System can use LOINC to transmit results to LIS	no yes	yes no
How labs get LOINC codes for reagent kits	<u> </u>	e-mail query
Detects clots within analysis chamber Specimen types suitable for device	yes whole blood, capillary, mixed venous, arterial, venous	fluid movement error recognition plasma, serum, whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	heparinized whole blood	heparin
Sampling technique Suitable for samples from well/sick neonates	aspiration ves/ves	aspiration, capillary transfer and fill ves/ves
Sample size for complete panel of analyte results	90 µL	65 µL
Sample size differs with No. of analytes selected Recommended collection device	no heparinized syringe or capillary tube	no heparinized svringes, capillary Microsampler
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability Max, No, of patient samples per hr/max, No, of measured parameters per hr	60 sec 30/270	45 sec average 30 samples per br. all measured analytes
Optimal throughput when calibrated and awaiting specimens	30 tests per hr	—
Calibration can be interrupted to perform stat sample Contraindications	n/a no	yes no
Known interferences	intralipid (concentrations over 5 vol%), fluoroscein	-
Restrictions based on Hct Sampler has self-wiping probe	no no, probe disposed of after measurement	 yes
Time required for maintenance by lab perconnel	n/a	
Onboard diagnostics for troubleshooting/limited to software	yes/no	yes/no
Diagnostics performed through modem Training & certification program for user	no yes	no yes (2 days on-site)
Method fanalyst ID in system Response for hardware & software failure/user ID & QC failure/ calibration & power failure	operator ID entry (optional)/bar code or manual system messages with visual signals	bar-code, screen, or keyboard (customizable) 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: User can search for and review previous nationt results on screen	operator & patient IDs, QC lot No.	operator & patient IDs, reagent lot No., input QC ranges, lot No.
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: car-	resuits, errors, patient & sample input (customizable)
	tridge lot & cartridge expiration date	
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
In upioau patient & UC results, now analyzer connects to external system Information included in transmission from analyzer to external system Hardware/software for data management system	serial, culternet device unique identifier, oper. & patient IDs, results, QC identifier PCM/CIA—internal DM or external DM	urecu seriai, nospitai network — onboard data management capabilities
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 annihilation/screen scraphing     using standard HL7 interface	_	_
using proprietary protocol interface Use a third-narty interfacing tool/engine for US/UIS interfaces		Ξ
oo a ama party menaony toorrengn/e for Lio/nio menades		
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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Part 12 of 13	Roche Diagnostics Corp. Sales Department	Roche Diagnostics Corp. Sales Department
See accompanying article on page 62	9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 us.labsystems.roche.com	9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 us.labsystems.roche.com
Name of device/first year sold No. of devices sold in U.S./outside U.S./list price Dimensions (H x W x D)/weight	Roche Opti Critical Care Analyzer/1998 —/—/\$8,500 4.7 x 14.2 x 9 in/9 lbs without battery, 11 lbs with	Roche Opti R Critical Care Analyzer/2000 —/—/\$9,500 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 <sub>2</sub> , HCO <sub>3</sub> - (12 additional parameters; call Roche for	Hct, BE, TCO <sub>2</sub> , HCO <sub>3</sub> - (11 additional parameters; call Roche for
Barometric pressure Analytical method(s)/technology(ies) employed	measured pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na, Cl, iCa, K, glucose: optical fluorescence; tHb,	measured pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na, iCa, K: optical fluorescence; tHb, SO <sub>2</sub> : optical
Device is part of a series of related models User list/group available	yes, Opticar reflectance yes, Opti Series yes (through Roche sales dept.)	yes, Opti Series yes (through Roche sales dept.)
Device warranty Loaner devices provided	1 yr (service contract available for subsequent years) yes	1 yr (service contract available for subsequent years) yes
Average expected life of device Open or closed system/external gas tanks required	>7 yrs closed/no	>7 yrs closed/no
For POC testing or laboratory	POC & laboratory	POC & 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	reagent/optode 25 individual packaged cassettes 1 depends on cassette configuration-contact Roche room temperature reagent/electrode: 6 mos	reagent/optode 4 individually packaged cassettes per pkg up to 25 patient samples per cassette + QC depends on volume—contact Roche room temperature cassette: 6 mos; reagent pack: 1 yr
Laboratory:	1	2
Max. No. specific analyte reagents that can reside in device at once Shelf life	1 cassette: 6 mos	1 cassette: 6 mos: reagent pack: 1 vr
Cost per test/reagent cost per test	depends on volume—contact Roche/same	depends on volume—contact Roche/same
Calibrations required Calibration frequency	1 point (automatic) with each cassette	1 point (automatic) with each sample or every 30 min
Calibrants traceable to NIST standards Internal QC program recommended	yes 3 levels liquid with change of cassette lot No., 2-mo intervals;	yes 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 System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	no no 	no no —
Detects clots within analysis chamber Specimen types suitable for device	yes plasma, serum, w. blood, capill., mixed ven., arterial, venous	yes plasma, serum, w. blood, capill., mixed ven., arterial, venous
Acceptable anticoagulants Sampling technique	heparin, lithium aspiration	heparin, lithium aspiration
Suitable for samples from well/sick neonates Sample size for complete panel of analyte results	yes/yes 125 µL	yes/yes 125 µL
Sample size differs with No. of analytes selected Recommended collection device	no heparinized syringe, capillary, Microsampler	no heparinized syringe, capillary, Microsampler
Provides for patient temperature corrected results Time from sample introduction to result availability	yes ~1 min from sample aspiration	yes ~1 min from sample aspiration
Max. No. of patient samples per hr/max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens	24/192	20/160 18 samples/hr
Calibration can be interrupted to perform stat sample Contraindications	no none	none
Known interferences Restrictions based on Hct	none no (Hct calculated based on meas. Hb)	none no (Hct calculated based on meas. Hb)
Sampler has self-wiping probe	no	no
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/limited to software Diagnostics performed through modem	weekly: 1 min; quarterly: 5 min yes/no no	weekly: 1 min; quarterly: 5 min yes/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 Response for hardware & software failure/user ID & QC failure/ calibration & power failure	oper. ID and/or secure 4-digit PIN No. for 150 oper. (customizable) 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	oper. ID and/or secure 4-digit PIN No. for 150 oper. (customizable) 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 Built-in printer/data port Information on hard copy report	no (printed review available for all patients) yes/RS 232, IR customizable, can incl. input values, meas. values, calc. values	no yes/RS 232, IR customizable, can incl. input values, meas. values, calc. values
Analyzer connects to	data management system, which connects to LIS/HIS;	data management system, which connects to LIS/HIS;
Interface standards supported	directly to LIS/HIS (both options) ASTM 1394, ASTM 1238, HL7	directly to LIS/HIS (both options) ASTM 1394, ASTM 1238, HL7 (with DataCare)
To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer to external system	direct serial or IR device unique identifier, oper. & patient IDs, results, QC identifi- er, all info. pertinent to patient & QC data	direct serial or IR device unique identifier, operator & patient IDs, results, QC identifier, all information pertinent to patient & QC data,
Hardware/software for data management system	Opti has onboard data management capabilities, additionally	accession No. Opti has onboard data management capabilities; additionally Rocko Data cast was in available on a literative service.
No. of different management reports system produces	NUCLIE DATAGARE SOTTWARE IS AVAILABLE AS A CLIENT/SERVER	AUCHE DATAGARE SOTTWARE IS AVAILABLE AS A Client/Server 40 2000
System connected (live installations) to which LISs/HISs		
using sourcert animitation/sourcert solapility     using standard HL7 interface     using proprietary protocol interface Use a third-party interfacing tool/engine for LIS/HIS interfaces	Meditech, HBOC, Cerner, SMS, others (call Roche for updated list) Kaiser Permanente, others Dawning, Cloverleaf, Data Innovations (not required but can use)	Meditech, HBOC, Cerner, SMS, others (call Roche for updated list) Kaiser Permanente, others Dawning, Cloverleaf, Data Innovations (not required but can use)
Distinguishing features	meas. thb/SO <sub>2</sub> ; 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/SQ <sub>2</sub> ; 6-mo shelf life of cassettes stored at room temp. simplifies logistics; automatic sample aspir. from syringe and capillaries; cassettes provide up to 25 patient samples + QC; operates in cool temps. (10°–30°C/50°–86°F); extensive list of input parameters; onboard printer

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# In vitro blood gas analyzers

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	Sales Department
	Indianapolis, IN 46250
See accompanying	800-428-5074
arucie un page 62	us.iausystenis.rocne.com
Name of device/first year sold	Roche Omni Modular System/1996
Dimensions (H x W x D)/weight	//\$29,900-\$30,200 16.5 x 21 x 18.5 in/88 lbs
Analytes measured on device	nH nf0 n0 Het Hh Na K fl ifa lastata aluassa PIIN as avvalues
Analytes measured on device	O <sub>2</sub> Hb, COHb, SulfHb, HHb, metHb
Parameters calculated on device	40+ parameters, including BE, BB, HCO <sub>3</sub> -, TCO <sub>2</sub> , SO <sub>2</sub> , NiCa++, ctO <sub>2</sub> , p50, shunt AC, OSM (call Packe for list)
Barometric pressure	measured
Analytical method(s)/technology(ies) employed	pH: ion selective galvanometric; pCO <sub>2</sub> , pO <sub>2</sub> : ion selective membrane; Hct:
	tiometry; lactate: lact. oxidase enzyme; glucose: glucose oxidase enzyme;
<b>-</b> · · · <i>·</i> · · · · · · · · · · · · · · ·	BUN: urease enzyme
Device is part of a series of related models User list/group available	yes, models 1–9 ves (through Roche sales dept.)
Device warranty	1 yr (service contract available for subsequent years)
Loaner devices provided Average expected life of device	yes >7 vrs
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 No. of disposable reagent system units in basic shipment package	n/a n/a
No. of samples analyzed per 1 disposable reagent/electrode system	n/a
List price per disposable reagent system Reagent unit storage requirements	n/a n/a
Shelf life of disposable units	n/a
aboratory-	
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
Cost per test/reagent cost per test	depends on sample volume/same
Calibrations required	1.8.2 point (automatic)
Calibration frequency	1 point: 30 min and with each sample, 2 point: selectable 4–12 hrs
Calibrants traceable to NIST standards	yes
QC features	AutoQC sampling, L-J plots, statistical calcs., monthly cum. reports (onboard
	& external with DataCare POC software), multirules, auto. lock/unlock of
Remote control of device from laboratory	individual tests based on QC criteria
System can use LOINC to transmit results to LIS	no
How labs get LUINC codes for reagent kits	-
Detects clots within analysis chamber	yes
Detects clots within analysis chamber Specimen types suitable for device Accentable anticoaquiants	yes plasma, serum, w. blood, capillary, mixed venous, arterial, venous henarin. lithium
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique	yes plasma, serum, w. blood, capillary, mixed venous, arterial, venous heparin, lithium aspiration, injection
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete namel of analyte results	yes plasma, serum, w. blood, capillary, mixed venous, arterial, venous heparin, lithium aspiration, injection yes/yes 160 ul for full papel 40 ul per module
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected	yes plasma, serum, w. blood, capillary, mixed venous, arterial, venous heparin, lithium aspiration, injection yes/yes 160 µL for full panel, 40 µL per module yes, 40 µL per module; i.e.: pH/BG, electrolytes, co-ox, metabolites
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for national temperature corrected results	yes plasma, serum, w. blood, capillary, mixed venous, arterial, venous heparin, lithium aspiration, injection yes/yes 160 µL for full panel, 40 µL per module yes, 40 µL per module; i.e.: pH/BG, electrolytes, co-ox, metabolites heparinized syringe, capillary, Microsampler vee
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability	yes plasma, serum, w. blood, capillary, mixed venous, arterial, venous heparin, lithium aspiration, injection yes/yes 160 µL for full panel, 40 µL per module yes, 40 µL per module; i.e.: pH/BG, electrolytes, co-ox, metabolites heparinized syringe, capillary, Microsampler yes ~1 min (depends on tests analyzed)
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size differs with No. of analyte seucted Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr Detimel threework when or eitherthe dre working engagement	yes plasma, serum, w. blood, capillary, mixed venous, arterial, venous heparin, lithium aspiration, injection yes/yes 160 µL for full panel, 40 µL per module yes, 40 µL per module; i.e.: pH/BG, electrolytes, co-ox, metabolites heparinized syringe, capillary, Microsampler yes -1 min (depends on tests analyzed) 40/400 tests per hr
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample	yes plasma, serum, w. blood, capillary, mixed venous, arterial, venous heparin, lithium aspiration, injection yes/yes 160 µL for full panel, 40 µL per module yes, 40 µL per module; i.e.: pH/BG, electrolytes, co-ox, metabolites heparinized syringe, capillary, Microsampler yes ~1 min (depends on tests analyzed) 40/490 tests per hr 40 samples per hr yes
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well/sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommende collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per Ir/max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications	yes plasma, serum, w. blood, capillary, mixed venous, arterial, venous heparin, lithium aspiration, injection yes/yes 160 µL for full panel, 40 µL per module yes, 40 µL per module; i.e.: pl/ISG, electrolytes, co-ox, metabolites heparinized syringe, capillary, Microsampler yes ~1 min (depends on tests analyzed) 40/490 tests per hr 40 samples per hr yes more metabolications and the second seco
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