

# Labs want it all, and blood gas vendors oblige

Ed Finkel

Those looking to buy blood gas analyzers typically want units that require little attention or effort, provide multiple features, do their own quality control, produce results quickly, and link seamlessly with information systems, manufacturers say.

With staffing and staff training perennial pressures, ease of use has become perhaps the most important requirement, says Mike Dalton, vice president of global strategic marketing for Bayer Diagnostics. "When we put out a product, it almost has to be fool-proof," Dalton says. "Anything that decreases the amount of time the customer has to spend on the instrument, that's what people are looking for."

Lloyd Adams, director of corporate marketing for Nova Biomedical, says skilled laboratory professionals and trained point-of-care blood gas operators easily handle minor routine maintenance. Computerization and connectivity are key concerns for customers, who want links "to the hospital's LIS, HIS, and anything else that happens to be in the hospital," he says. "Newer blood gas systems are very communications enabled, and most of the newer systems use a Windows touch-screen user interface."

The expansion of testing into emergency departments and intensive care units, where time is of the essence, has led to a desire for expanded menus, says Patti Williams, senior product manager for Instrumentation Laboratory. "Clinicians want to consolidate more tests on a single system, if possible, especially focusing on critical analyses," she says.

Because skilled technologists are not always available in such non-laboratory environments, a self-monitoring system becomes critical, Williams adds. "Any system that will continuously have the ability to detect problems, initiate corrective actions, let the operator know if they're successful, and then disable the analyte if [the corrective action] doesn't immediately work will be attractive, especially at the point of care," she says.

Beth O'Connell, marketing manager for ITC, sees a need for speed among her company's customers. "The value of rapid, accurate patient assessment and earlier interventions are hot topics that have resulted in many clinicians demanding test systems that can be brought to the patient's

bedside," she says.

Customers of Radiometer America are looking for speed, too, and to balance it with safety, says Alan Beder, senior product manager for clinical instruments. "With the current JCAHO requirements for positive sample identification, we're getting a lot of requests for that"—ways to better meet those requirements, he says. "And then in terms of speed, what can be done to get all the information as quickly as possible to the clinician."

With these customer desires in mind, companies are rolling out new instruments or new generations of older ones, with some introducing systems at this month's

American Association for Clinical Chemistry annual meeting.

A couple of years ago, Bayer Diagnostics introduced the

Rapidpoint 400, a cartridge-based system for the point-of-care setting. "All the operator had to do was pop the cartridge in" and it lasts 28 days, Dalton says. The system features a simple and fast user interface, turnaround time of less than a minute, and "connectivity capability to be tied into the hospital Ethernet or LIS," he says. The system does its own quality control, shutting down automatically if problems are detected.

This month, Bayer is introducing the Rapidlab 1200, a benchtop analyzer for the traditional laboratory setting. The new system will incorporate the cartridge system and eliminate the need for routine maintenance, Dalton says.

Instrumentation Laboratory's current release, the Gem Premier 3000, a multi-test, cartridge-based system, has IQM (intelligent quality management) and immediately notifies the operator when an error occurs, Williams says. "It then initiates automatic corrective action specific to the issue identified by the system. IQM prevents the reporting of an analyte that's not working properly," she says. "Customers who have point-of-care locations especially appreciate it. Their primary concern is that the right results get reported."

The next-generation Gem will incorporate cartridge technology, expanded analyte menus, and an integrated information management system, Williams says.

Roche Diagnostics has been focusing on "providing a uniform system design and operator interface by creating a platform with the Omni S system that is configurable to provide the required test

menu wherever blood gas analyzers are used," says Mike Kolodkin, manager of hospital point-of-care marketing for Roche. Roche has also introduced a new feature that permits graphical mapping of the patient's acid-based status. "This feature will help a physician monitor the patient's acid-base balance over time and follow the effectiveness of therapy," Kolodkin says. In addition, Roche recently received FDA approval for measuring pH in pleural fluids.

Roche also has been beefing up its Web-based services for customers, providing real-time, online peer review services at no extra charge as well as for credit educational programs. "We're empowering the customer to ascertain the information without always having to call a 1-800 number," Kolodkin says. "Customers can use this in real-time to help them verify the performance of their analyzer and troubleshoot if necessary."

Radiometer America will launch at AACC a new system called 1st Automatic. The system works on a three-step "sample, scan, go" regimen, Beder says. The sampling device, SafePico, is pre-bar-coded and includes an integrated needle safety device. "It is a closed system, meaning that air is removed through the vented tip cap and then need not be removed for analysis," he says. "The 'scan' works at the patient's bedside with the sampler's bar code to provide positive identification and the ability to add clinical information, all through FlexLink software. You have 100 percent data capture," he adds.

The "go" piece of the process occurs at the ABL800 Flex analyzer, which automatically scans the syringe, "and FlexLink software retrieves the data that was entered at the bedside," Beder says. The user can place up to three syringes in the queue, and "the analyzer does the rest. It automatically mixes and samples. There's no need to remove the tip cap and expel any blood. It's a completely closed system. Once the analysis is performed, the information is sent wherever it's needed."

ITC features the IRMA Trupoint system for the bedside, which requires no maintenance and provides a comprehensive menu, O'Connell says. "Since the test cartridges do not require refrigeration, they are ready to use anytime," she says. "Recently ITC added enhancements to the data management and regulatory compliance features of the IRMA Trupoint," which improve reporting of results and quality control. ITC also planned to release a point-

of-care creatinine assay at CAP TODAY press time.

Abbott Point of Care continues to refine and develop its i-Stat system platform according to Joe Baugh, senior product manager for Abbott. "The i-Stat system has been improving the blood gas testing process for years now by providing accurate and fast results at the patient's bedside so that there is no interruption in the patient treatment process," he says. "Although our primary product area is blood gases," he adds, "we are expanding the testing platform to include immunoassays and coagulation along with some new testing categories for the future."

Nova Biomedical offers two families of blood gas analyzers: the Stat Profile pHox family, composed of about a half-dozen small, economical models popular internationally; and the Stat Profile Critical Care Xpress (CCX) family, which combines blood gas, electrolytes including ionized magnesium, glucose, BUN, creatinine, lactate, and co-oximetry, Adams says. "It's all combined in a Windows touch-screen environment with connectivity for anything you could come up against in the hospital—it can work with the LIS and other data collective devices," he says.

Osmetech also has worked to provide easy analyzer connectivity through its DataTrol data management software, says Gerri Priest. The company recently launched an updated version of the Opti CCA blood gas analyzer, which features a redesigned user interface with a color touch-screen that displays step-by-step pictures, she says.

At AACC, Osmetech will launch the Opti R blood gas analyzer, which will provide a reusable sensor cassette in a variety of sizes for different usage rates. This model will measure pH, Na, K, iCa, total hemoglobin, and oxygen saturation, in addition to blood gas, offering an easy-to-use color touch-screen, no maintenance, and automated quality control. Those features also will be available in the new Opti Lion electrolyte analyzer, which will have single-use cassettes ideal for stat environments, Priest says.

CAP TODAY's annual lineup of who offers what in blood gas analyzers begins on page 13. The vendors of the various instruments supplied all data displayed on the following pages. If you're interested in a particular system, be sure to verify that it has the stated features and capabilities. □

Ed Finkel is a writer in Evanston, Ill.

Survey of Instruments

Profile of in vitro blood gas analyzers, pages 13-44

In vitro blood gas analyzers

Part 1 of 13	Abbott Point of Care Marketing marketing@i-stat.com 104 Windsor Center Drive East Windsor, NJ 08542 www.i-stat.com	Bayer HealthCare, Diagnostics Division 511 Benedict Ave. Tarrytown, NY 10591 800-255-3232 www.bayerdiag.com
See related comments, page 5		
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	i-STAT System/1992 ~30,000 worldwide/\$6,000 23.48 cm x 7.68 cm x 7.24 cm/22.4 oz	Rapidpoint 400 Series/2001 n/a/n/a/\$38,000 21.5 x 11.5 x 16 in/34 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 User list or 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	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Na, K, Cl, iCa, glucose, creatinine, BUN, ACT, lactate Hb, O <sub>2</sub> SAT, BE, TCO <sub>2</sub> , HCO <sub>3</sub> <sup>-</sup>  measured electrochemical for all analytes  no yes (through local sales representative) 1 yr replacement n/a 8 yrs closed/no POC testing	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Na+, K+, Cl-, Ca++ , tHB, FO <sub>2</sub> Hb, FCOHb, FMetHb, FHHb, glucose HCO <sub>3</sub> -act, HCO <sub>3</sub> -std, BE(B), BE(ecf), etCO <sub>2</sub> , RI(T), O <sub>2</sub> SAT, PO <sub>2</sub> /FIO <sub>2</sub> , AnGAP, sO <sub>2</sub> , BO <sub>2</sub> , pO <sub>2</sub> (A-a)(T), pO <sub>2</sub> (a/A)(T), p50, Qsp/Qt(T), ctO <sub>2</sub> (Hb), ctO <sub>2</sub> (a), ctO <sub>2</sub> (v), ctO <sub>2</sub> (a-v), DO <sub>2</sub> , VO <sub>2</sub> , others recorded pH, Na, Cl, iCa, K: potentiometry using ISE; pCO <sub>2</sub> : potentiometry based on Severinghaus; pO <sub>2</sub> : amperometric meas. (Clark); glucose: amperometric-glucose oxidase; Hct: conductivity; co-oximetry: spectrophotometric yes yes, through local sales rep 1 yr yes 7–10 yrs closed/no POC testing and laboratory
POC: Uses disposable prepackaged reagent/Electrode system for analysis No. of disposable reagent system units in basic shipment package No. of samples analyzed per one disposable reagent, electrode system List price per disposable reagent system Reagent unit storage requirements Shelf life of disposable units	reagent/electrode (single use) 25 per box 1 \$3–\$9 refrigerate, 2 weeks of shelf life at room temperature reag./electrode: 6–9 mos; 2 weeks at room temperature	reagent/electrode (multiuse cartridge) 1 measurement cartridge/3 waste/wash cartridges 400, 750 samples varies based on configuration refrigeration 9 mos
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	— — — —	1 measurement cartridge, 1 wash-waste cartridge 1 measurement cartridge, 1 wash-waste cartridge 9 mos varies based on configuration
Calibrations required Calibration frequency Calibrants traceable to NIST standards Internal QC program recommended QC features  Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	1 point (automatic) every test yes electronic QC, automated internal wet QC comparable plot, monthly cumulative reports (available with external system) yes yes —	1 & 2 point (automatic) 1 point: 30 min; 2 point: 2 hrs yes AQC cartridge, fully user programmable AQC cartridge, L-J plots, comparable plots, statistical calculations, monthly cum. reports (onboard & available with external system) yes yes —
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/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	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 — n/a —  — — —	yes whole blood, capillary, mixed venous, arterial, venous heparin aspiration yes/yes 100 µL no syringe or capillary tube yes 60 sec 25/— 25 samples per hr yes if calibration is interrupted repeatedly, it will force a mandatory calibration to be completed before sampling benzalkonium 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	n/a yes/no yes yes, based on number to be trained	maintenance free yes/no yes yes
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	keypad/bar-code entry code No. error message/—/—  operator & patient IDs, reagent lot No., hospital specific info yes no/other device unique identifier, operator & patient IDs, results, QC identifier	password (customizable) flag-prompt/user ID: customizable; QC: customizable-flag/cali-bration: flag–recalibration operator & patient IDs, accession No., results, temp., other infor. yes yes/RS-232, Ethernet operator & patient IDs, accession No., results, temperature, other information
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  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 proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	data management system, which in turn connects to LIS/HIS  ASTM 1394 & 1238, HL7, others  direct serial/900 hospitals installed; modem dial-in/25 hospitals installed; hospital network/250 hospitals installed device unique identifier, operator & patient IDs, results, QC identifier QC MGR 2.0/Precision Net/5x software/Central Data Station 35+ strip lot Nos., valid control values, valid operator IDs, certification, analyzer location, lockouts, customized info  all major LIS vendors Cerner — yes, Sybase	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options) LIS 3  direct serial, hospital network  device unique identifier, operator & patient IDs, results, QC identifier HP platform/Windows NT, SQL server customizable valid control values, valid operator IDs  — yes yes yes
Distinguishing features (provided by vendor)	handheld portable, single-use test cartridge, complete data management integration via Precision Net system; bar-code scanner built-in; full lockout menu for program testing protection	no maintenance, multiuse cartridge; fast time to patient results; onboard audio-video training videos; auto QC

In vitro blood gas analyzers

Part 2 of 13	Bayer HealthCare, Diagnostics Division 511 Benedict Ave. Tarrytown, NY 10591 800-255-3232 www.bayerdiag.com	Instrumentation Laboratory Sandy Anderson sanderson@ilww.com 101 Hartwell Ave., Lexington, MA 02421 781-861-4244 www.ilus.com
See related comments, page 5		
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	RapidLab 1200/2005 n/a/n/a/— 22.75 x 20.5 x 21 in/65–68 lbs	Synthesis 10 & 15/1997 >100 worldwide/Synthesis 10: \$29,925, Synthesis 15: \$42,000 20 x 16 x 20 in/77 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 User list or 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	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hb, Na+, K+, Cl-, iCa, lactate, glucose, COOX fractions Hct, O <sub>2</sub> SAT, BE, TCO <sub>2</sub> , HCO <sub>3</sub> <sup>-</sup> , plus additional parameters  measured, tracked pH: potentiometry; pCO <sub>2</sub> : Severinghaus electrochemical; pO <sub>2</sub> : amperometric; Hct: calculated; Hb: spectrophotometric; Na, Cl, iCa, K: ISE; lactate: lactate oxidase; glucose: glucose oxidase yes, series offers different analyte options yes 1 yr no 7–10 yrs closed/no laboratory	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Synthesis 15: THb, O <sub>2</sub> Hb, COHb, MethHb, RHb  pH(T), pO <sub>2</sub> (T), pCO <sub>2</sub> (T), HCO <sub>3</sub> <sup>-</sup> , 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> , O <sub>2</sub> cap, O <sub>2</sub> ct, p50  tracking pH: potentiometry; pCO <sub>2</sub> : Severinghaus electrode-voltage; pO <sub>2</sub> : Clark electrode-current; Hb: nonhemolytic Hb absorption (Synthesis 15) yes (Synthesis family offering different analyte options) yes (through local sales representative) 1 yr yes 7–10 yrs closed/yes laboratory
POC: Uses disposable prepackaged reagent/Electrode system for analysis No. of disposable reagent system units in basic shipment package No. of samples analyzed per one disposable reagent, electrode system List price per disposable reagent system Reagent unit storage requirements Shelf life of disposable units	— — — — — —	— — — — — —
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life  Cost per test/Reagent cost per test	2 cartridges n/a electrode: varies based on type, cartridge reagent: 8 mos, wash: 6 mos; AQC cartridge; 9 mos n/a/n/a	3 — reagent: 24 mos, electrode: 4 mos–1 yr  \$0.71–\$0.73 @ 50 tests per day at list price/\$0.24 @ 50 tests per day at list
Calibrations required Calibration frequency Calibrants traceable to NIST standards Internal QC program recommended QC features  Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	1 & 2 point (manual & automatic) 1 point: every 30 min; 2 point: every 8 hrs yes AQC cartridge, fully user programmable L-J plots, comparable plots, statistical calculations, monthly cum. reports (available with external system) yes — —	1 & 2 point (automatic & manual) 1 point: after each sample; 2 point: every 2 hrs yes 1 level per 8 hrs, IL controls recommended L-J plots, QC tracking  yes no n/a
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/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	yes whole blood, capillary, mixed venous, arterial, venous heparin aspiration yes/yes 95 µL–175 µL yes (microsample mode available) syringe or capillary yes 60 sec 24/up to 336 tests 24 samples per hr yes none  contact vendor none yes	yes w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes 60 µL/100 µL yes universal sampler accepts all devices yes 60 sec 50/150–400 30 samples per hr yes none  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: 5 min yes/no no yes, 1–2 days	monthly: 5 min yes/no yes yes (1 day on site)
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	password (customizable) diagnostic codes prompt the operator/diagnostic codes/recalibrates, generates diagnostic code if unsuccessful  patient ID yes yes/RS-232, Ethernet  operator & patient IDs, accession No., results, temperature, patient demographics, others	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 recalibration operator & patient IDs, QC values yes yes/4 RS-232, 1 parallel, standalone co-ox port, alphanumeric keyboard port, bar-code reader port patient demographics, hospital name, results
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  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 proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options) LIS 4 direct serial, hospital network device unique identifier, operator & patient IDs, results, QC identifier Rapidlink Data Management System customizable valid control values, valid operator IDs  n/a yes yes 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  none none none no
Distinguishing features (provided by vendor)	cartridge-based, high-throughput analyzer with minimal maintenance; fast time to patient results; onboard troubleshooting tutorials	continuous calibration corrects every three seconds for drift seen in Clark and Severinghaus electrodes—ensures accurate results before patient sampling; maintenance-free disposable electrodes for convenience and system uptime; integrated co-oximeter uses no extra reagent and minimizes maintenance

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



In vitro blood gas analyzers

Part 3 of 13	Instrumentation Laboratory Sandy Anderson sanderson@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4244 www.ilus.com	Instrumentation Laboratory Sandy Anderson sanderson@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4244 www.ilus.com
See related comments, page 5		
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  Parameters calculated on device   Barometric pressure Analytical method(s), technology(ies) employed   Device is part of a series of related models User list or 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	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Na+, K+, Ca++, Cl-; Synthesis 25: THb, O <sub>2</sub> Hb, COHb, Methb, RHb pH(T), pO <sub>2</sub> (T), pCO <sub>2</sub> (T), HCO <sub>3</sub> <sup>-</sup> , 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  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 yes (Synthesis family offering different analyte options) yes (through local sales representative) 1 yr yes 7–10 yrs closed/yes laboratory	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Na, K+, Ca++, Cl-, glucose, lactate; Synthesis 35: THb, O <sub>2</sub> Hb, COHb, Methb, RHb pH(T), pO <sub>2</sub> (T), pCO <sub>2</sub> (T), HCO <sub>3</sub> <sup>-</sup> , 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  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 yes (Synthesis family offering different analyte options) yes (through local sales representative) 1 yr yes 7–10 yrs closed/yes laboratory
POC: Uses disposable prepackaged reagent/Electrode system for analysis No. of disposable reagent system units in basic shipment package No. of samples analyzed per one disposable reagent, electrode system List price per disposable reagent system Reagent unit storage requirements Shelf life of disposable units	— — — — — —	— — — — — —
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	— 12 — \$0.84–\$0.86 @ 50 tests per day at list price/\$0.24 @ 50 tests per day at list price	— 12 — \$1.67–\$1.69 @ 50 tests per day at list price/\$0.24 @ 50 tests per day at list price
Calibrations required Calibration frequency Calibrants traceable to NIST standards Internal QC program recommended QC features Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	1 & 2 point (automatic & manual) 1 point: after each sample; 2 point: every 2 hrs yes 1 level per 8 hrs, IL controls recommended L-J plots, QC tracking yes no n/a	1 & 2 point (automatic & manual) 1 point: after each sample; 2 point: every 2 hrs yes 1 level per 8 hrs, IL controls recommended L-J plots, QC tracking yes no n/a
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/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	yes w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes 80 µL/150 µL yes universal sampler accepts all devices yes 60 sec 50/350–600 30 samples per hr yes — — no yes	yes w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes 80 µL/150 µL yes universal sampler accepts all devices yes 60 sec 40/280–480 30 samples per hr yes — — 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	monthly: 5 min yes/no yes yes (1 day on site)	monthly: 5 min yes/no yes yes (1 day on site)
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	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 recalibration operator & patient IDs, QC values yes yes/4 RS-232, 1 parallel, standalone co-ox port, alphanumeric keyboard port, bar-code reader port patient demographics, hospital name, results	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 recalibration operator & patient IDs, QC values yes yes/4 RS-232, 1 parallel, standalone co-ox port, alphanumeric keyboard port, bar-code reader port patient demographics, hospital name, results
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 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 proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	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  none none none no	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  none none none no
Distinguishing features (provided by vendor)	continuous calibration corrects every three seconds for drift seen in Clark and Severinghaus electrodes—ensures accurate results before patient sampling; maintenance-free disposable electrodes for convenience and system uptime; integrated co-oximeter uses no extra reagent and minimizes maintenance	continuous calibration corrects every three seconds for drift seen in Clark and Severinghaus electrodes—ensures accurate results before patient sampling; maintenance-free disposable electrodes for convenience and system uptime; integrated co-oximeter uses no extra reagent and minimizes maintenance

In vitro blood gas analyzers

Part 4 of 13	Instrumentation Laboratory Sandy Anderson sanderson@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4244 www.ilus.com	Instrumentation Laboratory Tim Lynch tlynch@ilww.com 101 Hartwell Ave., Lexington, MA 02421 781-861-4259 www.ilus.com
See related comments, page 5		
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 40 & 45/1999 n/a/n/a/Synthesis 40: \$48,300; Synthesis 45: \$60,375 20 x 16 x 20 in/77 lbs	Gem Premier 3000/2000 >2,000/>5,000/\$39,995 17 x 12 x 12 in/29.5 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 User list or 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	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Na+, K+, Ca++, Cl-, glucose, lactate; Synthesis 45: THb, O <sub>2</sub> Hb, COHb, MetHb, RHb pH(T), pO <sub>2</sub> (T), pCO <sub>2</sub> (T), HCO <sub>3</sub> <sup>-</sup> , 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 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, lactate: enzymatic yes (Synthesis family offering different analyte options) yes (through local sales representative) 1 yr yes 7–10 yrs closed/yes laboratory	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Hct, Na+, K+, Ca++, glucose, lactate  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*  n/a pH, pCO <sub>2</sub> : potentiometry; pO <sub>2</sub> , glucose, lactate: amperometry; Hct: conductivity; Na, iCa, K: ISE  yes yes (through local sales representative) 5 yrs yes 7–10 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 one disposable reagent, electrode system List price per disposable reagent system Reagent unit storage requirements Shelf life of disposable units	— — — — — —	yes (multiuse cartridge) 2 per pack 75-, 150-, 300-, 450-, & 600-test cartridge varies with size & menu room temperature 6 mos
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	— 13 — TBD/\$0.24 @ 50 tests per day at list price	1 1 multiuse cartridge 6 mos varies with size & menu
Calibrations required Calibration frequency Calibrants traceable to NIST standards Internal QC program recommended QC features  Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	1 & 2 point (automatic & manual) 1 point: after each sample; 2 point: every 2 hrs yes 1 level per 8 hrs, IL controls recommended L-J plots, QC tracking  yes no n/a	1 & 2 point (automatic) 1 point: each patient sample; 2 point: at least every 4 hrs yes internal, automated quality management Intelligent Quality Management (IQM): internal, automated program that performs continuous quality management yes no n/a
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/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	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 — — no yes	yes whole blood, arterial, venous, or capillary heparin aspiration yes/yes 135–150 µL no syringe or capillary tube yes 85 sec 20/180 15–20 samples yes — — 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	monthly: 5 min yes/no yes yes (1 day on site)	disposable cartridge/no maintenance required yes/no no yes
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	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 recalibration operator & patient IDs, QC values yes yes/4 RS-232, 1 parallel, standalone co-ox port, alphanumeric keyboard port, bar-code reader port patient demographics, hospital name, results	manual or bar-code wand entry of ID & password (customizable) operator warning, sampling lockout/user ID: no system access, QC: channel flagged/calibration: no results for channel, power: automatic recalibration operator & patient IDs, QC values yes yes/3 RS-232, 1 parallel, bar-code reader port, Ethernet port  patient demographics, hospital name and address, results
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 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 proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	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  none none none no	LIS/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 yes
Distinguishing features (provided by vendor)	continuous calibration corrects every three seconds for drift seen in Clark and Severinghaus electrodes—ensures accurate results before patient sampling; maintenance-free disposable electrodes for convenience and system uptime; integrated co- oximeter uses no extra reagent and minimizes maintenance	Intelligent Quality Management (IQM); maintenance-free, multiuse cartridge available in 30 menu/size options for use in any hospital location; 15-year history of proven cartridge technology; remote management from any PC via Gemweb; consolidated workstation for blood gas, electrolytes, Hct, glucose, lactate, co-oximetry, and coagulation  * when interfaced to IL CO-Oximeter

In vitro blood gas analyzers

Part 5 of 13	Instrumentation Laboratory Tim Lynch tlynch@ilww.com 101 Hartwell Ave., Lexington, MA 02421 781-861-4259 www.ilus.com	ITC 8 Olsen Ave. Edison, NJ 08820 800-631-5945 www.itcmed.com
See related comments, page 5		
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	Gem 3100/2000 >2,000/>5,000/\$39,995 22 x 12 x 12 in/31.5 lbs	IRMA TRUpoint Blood Analysis System/1994 >4,000 worldwide/\$8,900 11.5 x 9.5 x 5 in/5 lbs, 4 oz
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 User list or 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	pH, pO <sub>2</sub> , pCO <sub>2</sub> , Hct, Na+, K+, Ca++, glucose, lactate: PT, APTT, ACT, ACT-LR, citrate PT 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* n/a pH, pCO <sub>2</sub> ; potentiometry; pO <sub>2</sub> , glucose, lactate: amperometry; Hct: conductivity; Na, iCa, K: ISE; PT, APTT, ACT, ACT-LR, citrate PT, mechanical clot detection yes yes (through local sales representative) 5 yrs yes 7–10 yrs closed/no POC & laboratory	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Na, K, Cl, iCa, glucose, BUN, creatinine  Hb, O <sub>2</sub> SAT, BEb, BEecf, TCO <sub>2</sub> , HCO <sub>3</sub> -, iCa(n)  measured pH, pCO <sub>2</sub> , Na, Cl, iCa, K, BUN (enzymatic): potentiometric; pO <sub>2</sub> , glucose (enzymatic): amperometric; Hct: conductometric; glucose strip (enzymatic): colormetric yes yes 1 yr yes 7 yrs closed/no POC testing
POC: Uses disposable prepackaged reagent/Electrode system for analysis No. of disposable reagent system units in basic shipment package No. of samples analyzed per one disposable reagent, electrode system  List price per disposable reagent system Reagent unit storage requirements Shelf life of disposable units	yes (multiuse cartridge) 2 per pack cartridges available: 75-, 150-, 300-, 450-, & 600-test cartridge, 1 sample per cartridge for coagulation tests — room temperature 6 mos	reagent/electrode (single use) 25 per box 1  \$6–\$7 room temperature reagent/electrode: 6 mos
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	1 2: 1 for blood gas/electrolytes, 1 for coagulation 6 mos varies with menu & cartridge size	— — — —
Calibrations required Calibration frequency Calibrants traceable to NIST standards Internal QC program recommended QC features  Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	1 & 2 point (automatic) 1 point: each patient sample; 2 point: at least every 4 hrs yes internal, automated quality management Intelligent Quality Management (IQM): internal, automated program that performs continuous quality management yes no n/a	2 point (automatic) automatic with each sample yes automatic electronic QC per 8 hrs L-J plots, statistical calculations, monthly cumulative reports (idms) yes no —
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/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	yes whole blood, arterial, venous, or capillary heparin, fresh whole blood for coagulation tests aspiration yes/yes 135–150 µL, 50 µL for coagulation no syringe or capillary tube yes 85 sec; under 5 min for coagulation 20/180 15–20 samples (with stat option) yes — — no yes	no—sample path visible whole blood, capillary, mixed venous, arterial, venous heparin, EDTA (glucose strip only) injection yes/yes 125 µL capillary, 200 µL syringe no standard blood gas syringe or capillary collection tube yes 60–90 sec on average 25/175 20 n/a none — no no, not needed
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user	no operator involvement yes/no no yes	maintenance free yes/no no yes
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	manual or bar-code wand entry of ID & password (customizable) operator warning, sampling lockout/user ID: no system access, QC: channel flagged/calibration: no results for channel, power: automatic recalibration  operator & patient IDs, QC values yes yes/2 RS-232, 1 parallel, bar-code reader port, Ethernet port patient demographics, hospital name, results	LCD touchscreen, numeric (customizable) EQC failure or screen prompt, software: screen prompt/if user ID required, no access to menu, if QC required, no access to patient testing mode/calib.: test ends—no injection of sample allowed, power: blank screen—resume testing with power operator & patient IDs, cartridge information, lot No. yes yes/RS-232, modem, Ethernet analyzer serial No., date, calib. successful, calib. code, lot No., patient ID & temp., results, barometric press., SW version optional: user ID, ref. ranges, O <sub>2</sub> therapy, sample information
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  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 proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	LIS/HIS via direct interface or via IL's Impact Data Management system; vendor-neutral data management systems ASTM protocol direct serial, modem dial-in, Ethernet device identifier, operator & patient IDs, results, QC ID  Impact for Critical Care  customizable patient ID, demographics  yes yes yes yes	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options) IRMA (ASTM protocol), IDMS (script, HL7, or EDI) hospital network, direct serial, modem dial-in device unique identifier, operator & patient IDs, results, QC identifier, patient O <sub>2</sub> therapy information IDMS (integrated data management system), also integrates ITC coagulation devices 24 all analyzer settings, software upgrades  all major HIS/LIS vendors all major HIS/LIS vendors customizable EDI interface to HIS/LIS vendors yes
Distinguishing features (provided by vendor)	Intelligent Quality Management (IQM) maintenance-free, multiuse cartridge available in 30 menu/size options for use in any hospital location; 15-year history of proven cartridge technology; remote management from any PC via Gemweb; consolidated workstation <i>* when interfaced to IL CO-Oximeter</i>	self contained and easy to use; contains onboard printer, interactive touch screen, bar-code scanning, automatic electronic QC, and site specific custom correlation reference ranges; complete data management from patient information to lot traceability; self-calibrating cartridges with Luer lockport, which forms a closed system and reduces biohazards



In vitro blood gas analyzers

Part 6 of 13	Medica Corp. Kevin McCollum kmccollum@medicacorp.com 5 Oak Park Drive, Bedford, MA 01730 800-777-5983 or 781-275-4892 www.medicacorp.com	Medica Corp. Kevin McCollum kmccollum@medicacorp.com 5 Oak Park Drive, Bedford, MA 01730 800-777-5983 or 781-275-4892 www.medicacorp.com
See related comments, page 5		
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	EasyBloodGas/2000 —/—/\$10,750 14.5 x 12.5 x 7 in/16 lbs	EasyStat/2002 —/—/\$12,500 14.5 x 12.5 x 7.0 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 User list or 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	pH, pO <sub>2</sub> , pCO <sub>2</sub>  O <sub>2</sub> SAT, BE, TCO <sub>2</sub> , HCO <sub>3</sub> <sup>-</sup>  measured pH: ISE-potentiometry; pCO <sub>2</sub> : ISE-potentiometry; pO <sub>2</sub> : ISE-amperometry  yes (basic model first gen., related to expanded model EasyStat) yes 1 yr yes >5 yrs closed/no laboratory	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>3</sub> <sup>-</sup>  measured and recorded pH and pCO <sub>2</sub> : ISE-potentiometry; pO <sub>2</sub> : ISE-amperometry; Hct: conductivity; Hb: calculated from Hct; iCa: ISE; K: ISE  yes (expanded parameter menu, related to EasyBloodGas) yes 1 yr analyzer warranty yes (planned) >5 yrs closed/no laboratory
POC: Uses disposable prepackaged reagent/Electrode system for analysis No. of disposable reagent system units in basic shipment package No. of samples analyzed per one disposable reagent, electrode system List price per disposable reagent system Reagent unit storage requirements Shelf life of disposable units	reagent & electrode 1 based on testing volume per day — room temperature reagent module, 10 mos; electrodes, 12 mos	reagent & electrode 1 based on testing volume per day — room temperature reagent module: 10 mos; electrodes: 12 mos
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	1 1 reag. & elec.: 1 yr; QC material: 3 yrs \$0.57 at 20 samples per day/\$0.26 at 20 samples per day	1 1 reagent module: 10 mos; electrodes: 12 mos <\$0.80 per sample at 20 samples per day/\$0.33 at 20 samples per day
Calibrations required Calibration frequency  Calibrants traceable to NIST standards Internal QC program recommended  QC features Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	1 & 2 point (automatic) 1 point: during each sample analysis; 2 point: can be set for 2-, 4-, or 8-hr increments yes 1 level per 8 hrs, Medica controls recommended  L-J plots; monthly cumulative reports no no n/a	1 & 2 point (automatic) 1 point: with every sample analysis; 2 point: can be set for 2-, 4-, or 8-hr increments yes 1 level per 8 hrs, CLIA recommendations, Medica controls recommended L-J plots; monthly cum. report no no n/a
Detects clots within analysis chamber Specimen types suitable for device  Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/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	yes whole blood, capillary, mixed venous, arterial, venous  heparin aspiration yes/yes 75 µL capillary, 100 µL syringe no heparinized capillary or syringe yes 125 sec, includes 1-point calibration 25/75 25 yes no incorrect anticoagulant no yes	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 <120 sec, includes 1 point calibration 30/210 30 samples yes no incorrect anticoagulant 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	daily: 0.5 min; weekly: 3.5 min; monthly: 15 min yes/no no yes (through distributors)	daily: 0.5 min; weekly: 3.5 min; monthly: 15 min yes/no no yes (through distributors)
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	manual or bar-code wand for ID entry (optional) HW: oper. warning & error msg.; SW: error msg./user ID: sampling lockout; QC failure; flagged results/calib.: error msg. & 2nd attempt for 2-pt. calib. auto.; power: display not illuminated, data retained & auto reset operator & patient IDs, reagent lot No., QC control, reagent pack automatically read when reagent module installed yes yes/RS-232 patient information; measured & calculated parameters	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 calibration automatically run; power: display not illuminated, data retained-auto reset operator & patient IDs, reagent lot No., QC controls  yes yes/RS-232 patient information, measured & calculated results, date, operator ID
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 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 proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	data management system, which in turn connects to LIS/HIS; data management system, which can further transmit data; directly to LIS/HIS Medica protocol direct serial patient ID, results internal QC, L-J chart, patient reports — — — — TBD	data management system, which connects to LIS/HIS; data management system, which can further transmit data; directly to LIS/HIS — direct serial operator & patient IDs, results internal QC, L-J chart, patient & proficiency reports — — — — TBD
Distinguishing features (provided by vendor)	modular components; simple operation and maintenance; low purchase price and low operation cost; disposable maintenance- free sensor; no gas tanks	modular components; simple operation and maintenance; low purchase price and low operation cost; disposable maintenance- free sensors; no gas tanks, easy inside and out

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

In vitro blood gas analyzers

Part 7 of 13	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St., Waltham, MA 02454-9141 800-458-5813	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St., Waltham, MA 02454-9141 800-458-5813
See related comments, page 5		
Name of device/First year sold	Stat Profile pH0x/1998; pH0x Basic/2002	Stat Profile pH0x Plus/2000; Stat Profile pH0x Plus L/2001; Stat Profile pH0x Plus C/2003
No. of devices sold in U.S./Outside U.S./List price	pH0x: —/—/\$15,000; pH0x Basic: —/—/\$12,000	pH0 Plus: —/—/\$29,000; pH0x Plus L: —/—/\$32,000; PH0x Plus C: —/—/\$32,000
Dimensions (H x W x D)/Weight	15 x 12 x 15 in/18 lbs	15 x 12 x 15 in/18 lbs
Analytes measured on device	pH0x: pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Hb, SO <sub>2</sub> %; pH0x Basic: pH, pCO <sub>2</sub> , pO <sub>2</sub>	pH0x Plus: 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; pH0x Plus C: pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Hb, O <sub>2</sub> SAT, Na, K, Cl, iCa, glucose
Parameters calculated on device	BE, TCO <sub>2</sub> , HCO <sub>3</sub> -	
Barometric pressure	tracked	tracked
Analytical method(s), technology(ies) employed	pH: direct ISE; pCO <sub>2</sub> : Sevinghaus; pO <sub>2</sub> : amperometry; Hct: conductivity; Hb & SO <sub>2</sub> ?: optical—reflectance	pH: direct ISE; pCO <sub>2</sub> : potentiometry; pO <sub>2</sub> : amperometry; Hct: conductivity; Hb & SO <sub>2</sub> ?: optical—reflectance; Na, K, Cl, iCa: direct ISE; glucose: enzyme amperometric
Device is part of a series of related models	yes	yes
User list or group available	yes (upon request)	yes (upon request)
Device warranty	1 yr, repair or replacement of any part, including labor	1 yr, travel and labor, repair or replacement
Loaner devices provided	no	yes
Average expected life of device	5–7 yrs	5–7 yrs
Open or closed system/External gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC & laboratory	POC & laboratory
POC: Uses disposable prepackaged reagent/Electrode system for analysis	reagent	reagent
No. of disposable reagent system units in basic shipment package	200–500 analyses	200–500 analyses
No. of samples analyzed per one disposable reagent, electrode system	n/a	n/a
List price per disposable reagent system	\$200–\$265	\$210–\$275
Reagent unit storage requirements	room temperature	room temperature
Shelf life of disposable units	reagents: 18 mos room temperature; electrodes: up to 18 mos	reagents: 18 mos room temperature, electrodes: up to 18 mos
Laboratory: No. of different disposable reagents required to maintain device	1	1
Max. No. of specific analyte reagents that can reside in device at once	1	1
Shelf life	reagents & electrodes: 18 mos; membrane kits: 12–24 mos	reagents & electrodes: 18 mos; membrane kits: 12–24 mos
Cost per test/Reagent cost per test	<\$0.11 at 35 analyses per day/<\$0.08 at 35 analyses per day	<\$0.11 at 35 analyses per day/<\$0.08 at 35 analyses per day
Calibrations required	1 & 2 point (automatic)	1 & 2 point (automatic)
Calibration frequency	1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 4, or 6 hr (user defined)	1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 4, or 6 hr (user defined)
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	minimum CLIA recommendations	minimum CLIA recommendations
QC features	L-J plots, statistical calcs., monthly cum. report (onboard, more extensive reporting avail. with Nova Patient Data Manager)	L-J plots, statistical calcs., monthly cum. report (onboard, more extensive reporting avail. with Nova Patient Data Manager)
Remote control of device from laboratory	yes	no
System can use LOINC to transmit results to LIS	no	no
How labs get LOINC codes for reagent kits	—	—
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	whole blood, capillary, mixed venous, arterial	whole blood, capillary, mixed venous, art., venous; pH0x Plus L and Plus C can accomm. preceding specimens and serum plasma
Acceptable anticoagulants	heparin	heparin
Sampling technique	aspiration & capillary	aspiration & capillary
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	70 µL	pH0x Plus: 115 µL; pH0x Plus L: 125 µL; pH0x Plus C: 125 µL
Sample size differs with No. of analytes selected	yes, pH0x and pH0x Basic offer micro-panel; standard 3-test blood gas micro-panel sample req. is 45 µL	yes, pH0x Plus, pH0x Plus L, pH0x Plus C offer micro-panel; standard 3-test micro-panel req. 55 µL for pH0x Plus; 60 µL for pH0x Plus L & Plus C
Recommended collection device	syringe, capill., micro-collect. containers, standard vacuum cont.	syringe, capill., micro-collect. containers, standard vacuum cont.
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	45 sec	pH0x Plus: 50 sec; pH0x Plus L: 52 sec; pH0x Plus C: 52 sec
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	300/300 tests	50/500 tests
Optimal throughput when calibrated and awaiting specimens	300 tests per hr	300 tests per hr
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	none	none
Known interferences	none	none
Restrictions based on Hct	no	no
Sampler has self-wiping probe	yes	yes
Time required for maintenance by lab personnel	weekly: <5 min; monthly: <10 min	weekly: <5 min; monthly: <10 min
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	yes	yes
Training & certification program for user	yes (on site)	yes (on site)
Method of analyst ID in system	password with unique user ID No. (optional)	password with unique user ID No. (optional)
Response for hardware & software failure/User ID & QC failure/Calibration & power failure	self-diag. SW informs & notifies oper. of HW & SW failure; hotline & field support depending on problem/optional lockout w/o proper user ID; options for QC failure range from flagging to not reporting test that fails QC to lockout for QC failure or exceeding scheduled QC interval/ any test that does not calibrate will not report results & instrument notifies oper. of reason for failure; momentary power interrupts require no recovery—extended power failure results in automatic calib.	self-diag. SW informs & notifies oper. of HW failure; hotline & field support depending on problem/optional lockout w/o user ID; options for QC failure range from flagging to not reporting test that fails QC to lockout for QC failure or exceeding scheduled QC interval/ any test that does not calibrate will not report results & instrument notifies oper. of reason for failure; momentary power interrupts require no recovery—extended power failure results in automatic calib.
Supports bar-code scanning of	patient ID	patient ID
User can search for and review previous patient results on screen	yes	yes
Built-in printer/Data port	yes/multiple RS-232	yes/multiple RS-232
Information on hard copy report	patient ID w/ access. No., entered settings, meas. & calc. results	patient ID w/ access. No., entered settings, meas. & calc. results
Analyzer connects to	data management system which connects to LIS/HIS	data management system and/or directly to LIS/HIS
Interface standards supported	ASTM E1381-91 & ASTM 1394-91 (HL7 avail. with external device)	ASTM E1381-91 & ASTM 1394-91 (HL7 avail. with external device)
To upload patient & QC results, how analyzer connects to external system	direct serial/>500 hospitals inst.; hospital network/>100 inst.	direct serial/>500 hospitals inst.; hospital network/>100 inst.
Information included in transmission from analyzer to external system	device unique identifier, operator & patient IDs, results, QC identifier, accession No.	device unique identifier, operator & patient IDs, results, QC identifier, accession No.
Hardware/Software for data management system	Pentium with Microsoft NT 4.0/Nova Point of Care Manager SW	Pentium with Microsoft Windows 2000/Nova Point of Care Manager
No. of different management reports system produces	>60	>60
Contents downloaded from DMS to analyzer	n/a	yes, patient name, passwords
System connected (live installations) to which LISs, HISs		
• using screen animation, screen scraping	>20	>20
• using standard HL7 interface	>100	>100
• using proprietary protocol interface	>500	>500
Use a third-party interfacing tool, engine for LIS, HIS interfaces	yes	yes
Distinguishing features (provided by vendor)	onboard QC cartridge provides sufficient QC materials for 30-day auto QC analysis; allows user to program frequency & select report protocol with full QC DMS; no external gas tank; single reagent cartridge has all supplies needed for calib. & waste collection	single reagent cartridge has all supplies needed for calibration and waste collection; has same features as pH0x/pH0x Basic; pH0x Plus/pH0x Plus L/pH0x Plus C have key oximetry values without need for co-ox



In vitro blood gas analyzers

Part 8 of 13	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813
See related comments, page 5		
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 Critical Care Xpress/2003 n/a/n/a/— 17.2 x 22.4 x 17.3 in/53 lbs	Stat Profile Critical Care Xpress 3 Plus/2003 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  Device is part of a series of related models User list or 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	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hct, Hb, Na, K, Cl, iCa, iMg, lactate, glucose, creatinine, BUN, SO <sub>2</sub> %, co-oximetry BE, TCO <sub>2</sub> , HCO <sub>3</sub> -tracked pH: direct ISE; pCO <sub>2</sub> : Severinghaus; pO <sub>2</sub> : amperometric; Hct: conductivity; Hb & SO <sub>2</sub> %; optical-reflectance; Na, K, Cl, iMg, & iCa: direct ISE; lactate, glucose, & creatinine: enzyme/amperometric; BUN: enzyme/ISE; co-ox: optical, reflectance yes yes (upon request) 1 yr no 5–7 yrs closed/no POC & laboratory	pH, pCO <sub>2</sub> , pO <sub>2</sub> , co-oximetry  BE, TCO <sub>2</sub> , HCO <sub>3</sub> -tracked pH: direct ISE; pCO <sub>2</sub> : Severinghaus; pO <sub>2</sub> : amperometric; co-ox: optical-reflectance  yes yes (upon request) 1 yr no 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 one 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 \$294–\$349 no special requirements reagents: 18 mos (room temp.); electrodes: up to 18 mos	reagent 200–500 analyses n/a \$269 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. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	1 19 reagents & electrodes: 18 mos; membrane kits: 12–24 mos <\$0.08 at 40 analyses per day/\$0.04 at 40 analyses per day	1 7 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  Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	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, monthly cum. report, onboard, available with external system yes yes package insert	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, monthly cum. report, onboard, available with external system yes yes package insert
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/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	yes whole blood, capillary, mixed venous, arterial, venous heparin aspiration & capillary yes/yes 150 µL yes, variety of micro-panel options offered & can be customized syringe, capillary, micro-collection, or vacuum collection containers yes 134 sec 27/513 437 tests per hr yes no none no yes	yes whole blood, capillary, mixed venous, arterial, venous heparin aspiration & capillary yes/yes 150 µL yes, variety of micro-panel options offered & can be customized syringe, capillary, micro-collection, or vacuum collection containers yes 134 sec 27/189 160 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	daily: none; weekly: <5 min; monthly: <10 min yes/no yes yes (3 days 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      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	multilevel password with unique user ID No. HW & SW: self-diagnostic SW informs and classifies operator of HW & SW failure; hotline & field support avail./user ID: optional setup feature; lock out without proper ID; QC: optional setup & options range from flagging QC failure to not reporting last test that fails QC/calibration: results not reported w/failures, instrument notifies operator of failure reason; power: momentary power interrupts require no recovery; instrument automatically calibrates operator & patient IDs yes yes/yes (Ethernet, USB) patient ID & accession Nos., entered settings, measured & calculated results	multilevel password with unique user ID No. HW & SW: self-diagnostic SW informs and classifies operator of HW & SW failure; hotline & field support avail./user ID: optional setup feature; lock out without proper ID; QC: optional setup & options range from flagging QC failure to not reporting last test that fails QC/calibration: results not reported w/failures, instrument notifies operator of failure reason; power: momentary power interrupts require no recovery; instrument automatically calibrates operator & patient IDs yes yes/yes (Ethernet, USB) patient ID & accession Nos., entered settings, measured & calculated results
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  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 proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	directly to LIS/HIS, DMS that in turn connects to LIS/HIS ASTM E1394-91, ASTM 1381-91, HL7 modem dial-in, hospital network device unique identifier, operator & patient IDs, results, QC identifier full-featured onboard DMS capability, external DMS also 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	directly to LIS/HIS, DMS that in turn connects to LIS/HIS ASTM E1394-91, ASTM 1381-91, HL7 modem dial-in, hospital network device unique identifier, operator & patient IDs, results, QC identifier full-featured onboard DMS capability, external DMS also 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 (provided by vendor)	largest whole blood critical care menu (19 tests), BUN, iMg available exclusively from Nova; onboard co-oximeter; open architecture SW allows design of dedicated user interface (more shared features listed under Critical Care Xpress 3 Plus)	onboard QC cartridge provides sufficient QC materials for 30-day auto QC analysis; allows user to program frequency and select report protocol with full QC SMD; meets NCCLS POCT 1-A standards (more shared features listed under Critical Care Xpress)

In vitro blood gas analyzers

Part 9 of 13	Osmetech Inc. Sales Department 235 Hembree Park Drive, Roswell, GA 30076 800-490-6784 www.osmetech.com	Osmetech Inc. Sales Department 235 Hembree Park Drive, Roswell, GA 30076 800-490-6784 www.osmetech.com
See related comments, page 5		
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	Osmetech OPTI CCA Blood Gas Analyzer/1998 —/—/\$10,200 4.7 x 14.2 x 9 in/10 lbs without battery, 12 lbs with	Osmetech OPTI R/2005 —/—/— 4.7 x 14.2 x 9 in/13 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 User list or 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	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na, K, Cl, iCa, tHb, SO <sub>2</sub> , glucose Hct, HCO <sub>3</sub> , BE, BEecf, BEact, BB, tCO <sub>2</sub> , st. HCO <sub>3</sub> , st. pH, O <sub>2</sub> ct, cH+, AaDO <sub>2</sub> , AG, pSO, nCa++ measured pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na, Cl, iCa, K, glucose: optical fluorescence; tHb, SO <sub>2</sub> : optical reflectance yes, Osmetech OPTI Series yes (through Osmetech sales dept.) 1 yr (service contract available for subsequent years) yes >7 yrs closed/no POC & laboratory	pH, pCO <sub>2</sub> , pO <sub>2</sub> , tHb, Hb, SO <sub>2</sub> , Na, K, iCa Hct, HCO <sub>3</sub> , BE, BEecf, BEact, BB, tCO <sub>2</sub> , st. HCO <sub>3</sub> , st. pH, O <sub>2</sub> ct, cH+, AaDO <sub>2</sub> , AG, pSO, nCa++ recorded,measured pH, pCO <sub>2</sub> , pO <sub>2</sub> : optical fluorescence; Hb: optical reflectance, Na, iCa, K: optical fluorescence yes, OPTI family of instruments yes 1 yr warranty yes >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 one disposable reagent, electrode system List price per disposable reagent system Reagent unit storage requirements Shelf life of disposable units	single-use cassettes/optode 25 individual packaged cassettes 1 depends on cassette configuration—contact Osmetech room temperature cassette: 6–8 mos, depends on type	reagent, electrode/multiuse cartridge 4 individual packaged cassettes 35–75 — room temperature reagents: 12, electrodes: 6
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	1 1 cassette: 6–8 mos, depends on type depends on volume—contact Osmetech	2 1 reagent: 12 mos, cartridge; 6 mos depends on volume—contact Osmetech
Calibrations required Calibration frequency Calibrants traceable to NIST standards Internal QC program recommended  QC features  Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	1 point (automatic) with each cassette yes 3 levels liquid with change of cassette lot No., 2-mo intervals electronic QC—1 level per 8 hrs of operation; elec. & liquid statistical calcs., L-J with external system (DataTrol); stores 1 mo—3 levels onboard of each (elec. & liq.) no no —	1 point (automatic) 1 point: 30 min; 2 point: 4 hrs yes onboard auto QC integrated into reagent pack; 2 levels every 8 hrs L-J plits, statistical calculations  no — —
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/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	yes plasma, serum, w. blood, capill., mixed ven., arterial, venous heparin aspiration yes/yes 125 µL no heparinized syringe, capillary, Comfort Sampler yes ~1 min from sample aspiration 24/192 24 no none none no (Hct calculated based on meas. Hb) no, single use	yes plasma, serum, w. blood, capill., mixed ven., arterial, venous heparin aspiration yes/yes 125 µL no syringe, capillary, Comfort Sampler yes <1 min — — yes none dyes no n/a
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user	weekly: 1 min; quarterly: 5 min yes/no no yes (on site as needed)	weekly: 5 min; quarterly: 15 min yes/no — yes (on site as needed)
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	oper. ID and/or secure 4-digit PIN No. for 300 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. & patient IDs, reag. lot No., QC ranges, cassette lot No., expiration, factory calibration info. & cassette type yes yes/RS-232 customizable, can incl. input values, meas. values, calc. values	numeric (customizable) —/—/—  oper. & patient IDs, reag. lot No., QC material  yes yes/RS-232 meas. values, calc. values, warnings/errors, temp, baro., true & user-configured options
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  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 proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	Osmetech DataTrol data management system, which connects to LIS/HIS; directly to LIS/HIS (both options) mobile ASTM, ASTM, ASCII  direct serial  device unique identifier, oper. & patient IDs, results, QC identifier, all info. pertinent to patient & QC data Osmetech OPTI has onboard data management capabilities, additionally Osmetech DataTrol software is available as a client/server 40 none  none Meditech, McKesson, Cerner, Siemens, others (call Osmetech for updated list) none Dawning, Data Innovations (not required but can use)	data management system, which connects to LIS/HIS  ASTM 1394  —  —  Data Trol  — none none call Osmetech for details  none yes
Distinguishing features (provided by vendor)	ColorTouch Screen display; meas. tHb/SO <sub>2</sub> ; 8-month shelf life of cass. stored at room temp. simplifies logistics; auto. sample asp. from syringe and capill.; extensive list of input params.; onboard printer	measured tHb, SO <sub>2</sub> ; QC integrates into reagent pack; intelligent diagnostics for instrument and consumables

In vitro blood gas analyzers

Part 10 of 13	Radiometer America Inc. Telesales Department info@radiometeramerica.com 810 Sharon Dr., Westlake, OH 44145 800-736-0600 ext. 333 www.radiometeramerica.com	Radiometer America Inc. Telesales Department info@radiometeramerica.com 810 Sharon Dr., Westlake, OH 44145 800-736-0600 ext. 333 www.radiometeramerica.com
See related comments, page 5		
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	ABL 5/1994 —/—/— 13 x 13 x 8 in/18 lbs	ABL 800 Series/2004 —/—/depends on configuration 22 x 28 x 21 in/70 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 User list or 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	pH, pCO <sub>2</sub> , pO <sub>2</sub>  Hct, O <sub>2</sub> SAT, BE, TCO <sub>2</sub> , HCO <sub>3</sub> <sup>-</sup> , ctO <sub>2</sub> , AaDpO <sub>2</sub> , SBE, ABE, SBC, pCO <sub>2</sub> (T), ctCO <sub>2</sub> (P), pH(T), cH <sup>+</sup> (T), pO <sub>2</sub> (T) measured pH: pH-sensitive glass (ISE); pCO <sub>2</sub> , pO <sub>2</sub> : ISE  no yes (through local sales representative) 1 yr, parts, labor, & travel yes 20 yrs with full support closed/yes POC & laboratory	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Hb, Na, K, Cl, iCa, lactate, glucose, bilirubin, fetal Hb, O <sub>2</sub> Hb, MetHb, RHb, COHb, O <sub>2</sub> SAT Hct, BE, TCO <sub>2</sub> , HCO <sub>3</sub> <sup>-</sup> , plus 40 additional parameters  measured pH: pH-sensitive glass (ISE); pCO <sub>2</sub> , pO <sub>2</sub> , Na, Cl, iCa, K: ISE; Hct: calc. from meas. Hb, bilirubin; Hb: optical, multiwavelength anal., intra-cuvette ultrasonic hemolysis; lactate, gluc.: ISE w/enzyme yes, ABL 800 Series yes (through local sales representative) 2 yrs, parts, labor, & travel yes 20 yrs with full support closed/yes (low-pressure, premixed) POC & laboratory (products on mobile carts for POCT/NPT)
POC: Uses disposable prepackaged reagent/Electrode system for analysis No. of disposable reagent system units in basic shipment package No. of samples analyzed per one disposable reagent, electrode system List price per disposable reagent system Reagent unit storage requirements Shelf life of disposable units	— — — — — —	— — — — — —
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	4 4 reagent, electrode, membrane kit, cartridge: 2+ yrs depends on sample volume & any extra incl. items/same	4 4 reagent, electrode, membrane kit, cartridge: 2+ yrs depends on sample volume & any extra incl. items/same
Calibrations required Calibration frequency Calibrants traceable to NIST standards Internal QC program recommended QC features  Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	1 & 2 point (automatic) 1 point: 1/2 hr; 2 point: 4 hrs yes depends on hospital management & inspection agency statistical calculations (available with RADIANCE data management system)  yes yes —	1 & 2 point (automatic) 1 point: 1/2 hr—CLIA GAS, 4 hrs—mfr.; 2 point: every 8 hrs yes depends on hospital management & inspection agency L-J plots, comparable plot (via DMS), statistical calcs., auto QC, monthly cum. reports (onboard & avail. w/ external system, PC download to Excel) yes yes —
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/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	yes whole blood, capill., mixed venous, arterial, venous heparin, balanced heparin aspiration yes/yes 85 µL yes, optional 35 µL for pH only  syringe or capillary yes ~1 min 30/90 30 per hr yes none halothane n/a no	yes whole blood, capill., mixed venous, arterial, venous heparin, electrolyte-balanced heparin aspiration, syringe &/or capillary tube &/or test tube yes/yes 95 µL for 17 measured parameters yes, with fewer measured parameters, smaller micro-modes available from 35 µL syringe or capillary yes ~1 min (depends on tests ordered) 25/425 25 per hr yes none halothane, thiocyanic & glycolic acids 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	monthly: as needed; annually: 5 hrs yes/no no yes (on site)	monthly: as needed; annually: dependent on version yes/no yes yes (on site)
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	operator ID entry (optional) system messages  none no yes/RS-232, optional patient info., meas. & calc. results, system messages	customizable onboard keyboard, bar code system message with customized (“traffic light”) visual & audible signals, parameter status bar operator & patient IDs, reag. & QC lot Nos., exp., soft. keys yes, multitask searches while analyzer performs other functions yes/RS-232, Ethernet patient info./demographics, patient therapy settings, meas. & calc. results, system messages, reference & critical ranges
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  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 proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	RADIANCE STAT information management system that connects to LIS/HIS or directly to LIS/HIS ASTM 1394 & 1238, serial direct serial/thousands; modem dial-in/hundreds; real-time  device unique identifier, operator & patient IDs, results, QC identifier, as per ASTM protocols external RADIANCE user definable —  Cerner, Meditech, Misys, others none none no (use interface templates)	RADIANCE STAT information management system that connects to LIS/HIS or directly to LIS/HIS ASTM, HL7, serial, network TCP/IP direct serial/thousands of hosp. installed; modem dial-in/hundreds; hospital network/hundreds; real time wireless future option device unique identifier, operator & patient IDs, results, QC identifier, per ASTM/HL7 standards plus calib. & analyzer status info. internal system + optional external system, RADIANCE user-definable searches/reports valid control values, valid operator IDs  Cerner, Meditech, Misys, others available from analyzer—LIS/HIS vendors can use none no (use interface templates)
Distinguishing features (provided by vendor)	provides basic blood gases (pH, pCO <sub>2</sub> , pO <sub>2</sub> ) test profile; easy to use with minimal maintenance; low cost of operation via standby usage; fast restart, in 2 min, out of standby mode	market first—FLEXQ automated inlet part of 1st Automatic system; FLEXCARE customer care program; bilirubin and fetal Hb meas. on whole blood with no extra sample volume, low maintenance and cost of operation; interference-free accuracy; FLEXMODE—smallest automated microsample mode options with no loss in performance specs. (conserves blood); flexible/modular platform running on Windows XP (enhanced), Pentium processors, automatic QC, remote support

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



## *In vitro blood gas analyzers*

[illegible]

In vitro blood gas analyzers

<b>Part 12 of 13</b>	<b>Roche Diagnostics Corp.</b> <b>Sales Department</b> <b>9115 Hague Rd., Indianapolis, IN 46250</b> <b>800-428-5074</b> us.labsystems.roche.com	<b>Roche Diagnostics Corp.</b> <b>Sales Department</b> <b>9115 Hague Rd., Indianapolis, IN 46250</b> <b>800-428-5074</b> us.labsystems.roche.com
<i>See related comments, page 5</i>		
<b>Name of device/First year sold</b> <b>No. of devices sold in U.S./Outside U.S./List price</b> <b>Dimensions in inches (H x W x D)/Weight</b>	<b>Roche OMNI C Analyzer/2001</b> <b>—/—/\$36,000</b> <b>18 x 14 x 16 in/51 lbs</b>	<b>Roche OMNI Modular System/1996</b> <b>—/—/\$29,900–\$56,200</b> <b>16.5 x 21 x 18.5 in/88 lbs</b>
<b>Analytes measured on device</b>  <b>Parameters calculated on device</b>  <b>Barometric pressure</b> <b>Analytical method(s), technology(ies) employed</b>    <b>Device is part of a series of related models</b>  <b>User list or group available</b> <b>Device warranty</b> <b>Loaner devices provided</b> <b>Average expected life of device</b> <b>Open or closed system/External gas tanks required</b> <b>For POC testing or laboratory</b>	<b>pH, pCO<sub>2</sub>, pO<sub>2</sub>, Hct, Hb, Na, K, Cl, iCa, SO<sub>2</sub></b>  <b>Hct, O<sub>2</sub>SAT, BE, TCO<sub>2</sub>, HCO<sub>3</sub><sup>-</sup></b>  <b>recorded, tracking barometer</b> <b>pH: ion selective galvanometric; pCO<sub>2</sub>, pO<sub>2</sub>: ion selective mem- brane; Hct: conductivity; Hb: spectrophotometry; Na, Cl, iCa, K: ion selective potentiometry</b>  <b>yes (Roche provides added menu &amp; functionality w/OMNI Modular series)</b> <b>yes (contact sales department)</b> <b>1 yr</b> <b>no</b> <b>7 yrs</b> <b>closed/no</b> <b>laboratory</b>	<b>pH, pCO<sub>2</sub>, pO<sub>2</sub>, Hct, Hb, Na, K, Cl, iCa, lactate, glucose, BUN, co-ox values: O<sub>2</sub>Hb, COHb, SulfHb, HHb, metHb</b> <b>40+ parameters, including BE, BB, HCO<sub>3</sub><sup>-</sup>, TCO<sub>2</sub>, SO<sub>2</sub>, NiCa<sup>++</sup>, ctO<sub>2</sub>, pSO, shunt, AG, OSM (call Roche for list)</b> <b>measured</b> <b>pH: ion selective galvanometric; pCO<sub>2</sub>, pO<sub>2</sub>: ion selective mem- brane; Hct: conductivity; Hb: spectrophotometry; Na, Cl, iCa, K: ion selective potentiometry; lactate: lact. oxidase enzyme; glucose: glucose oxidase enzyme; BUN: urease enzyme</b> <b>yes, models 1–9</b>  <b>yes (through Roche sales dept.)</b> <b>1 yr (service contract available for subsequent years)</b> <b>yes</b> <b>&gt;7 yrs</b> <b>closed/no</b> <b>POC &amp; laboratory (transportable on cart system)</b>
<b>POC:</b> <b>Uses disposable prepackaged reagent/Electrode system for analysis</b> <b>No. of disposable reagent system units in basic shipment package</b> <b>No. of samples analyzed per one disposable reagent, electrode system</b> <b>List price per disposable reagent system</b> <b>Reagent unit storage requirements</b> <b>Shelf life of disposable units</b>	<b>—</b> <b>—</b> <b>—</b> <b>—</b> <b>—</b> <b>—</b>	<b>n/a</b> <b>n/a</b> <b>n/a</b> <b>n/a</b> <b>n/a</b> <b>n/a</b>
<b>Laboratory:</b> <b>No. of different disposable reagents required to maintain device</b> <b>Max. No. of specific analyte reagents that can reside in device at once</b> <b>Shelf life</b> <b>Cost per test/Reagent cost per test</b>	<b>3</b> <b>n/a</b> <b>reagent: 2 yrs; electrode: install data recommendation for warranty</b> <b>—</b>	<b>depends on model, contact Roche</b> <b>n/a</b> <b>reagents: 1 yr</b> <b>depends on sample volume/same</b>
<b>Calibrations required</b> <b>Calibration frequency</b> <b>Calibrants traceable to NIST standards</b> <b>Internal QC program recommended</b> <b>QC features</b>   <b>Remote control of device from laboratory</b> <b>System can use LOINC to transmit results to LIS</b> <b>How labs get LOINC codes for reagent kits</b>	<b>1 &amp; 2 point (automatic)</b> <b>1 point: 30–60 min; 2 point: 4, 8, 12, 24 hrs</b> <b>yes</b> <b>1 per 8 hrs—3 levels in 24 hrs—assayed for system</b> <b>L-J plots; stat calcs. (mean, SD, %CV), monthly cumulative reports, onboard, available with external system</b>  <b>yes</b> <b>no</b> <b>e-mail query</b>	<b>1 &amp; 2 point (automatic)</b> <b>1 point: 30 min and with each sample; 2 point: selectable 4–12 hrs</b> <b>yes</b> <b>1 liquid QC sample per 8 hrs of operation</b> <b>AutoQC sampling, L-J plots, statistical calcs., monthly cum. reports (onboard &amp; external with DataCare POC software), multirules, auto. lock/unlock of individual tests based on QC criteria</b>  <b>yes</b> <b>no</b> <b>—</b>
<b>Detects clots within analysis chamber</b> <b>Specimen types suitable for device</b> <b>Acceptable anticoagulants</b> <b>Sampling technique</b> <b>Suitable for samples from well neonates/Sick neonates</b> <b>Sample size for complete panel of analyte results</b> <b>Sample size differs with No. of analytes selected</b> <b>Recommended collection device</b> <b>Provides for patient temperature corrected results</b> <b>Time from sample introduction to result availability</b> <b>Max. No. of patient samples per hr/Max. No. of measured parameters per hr</b> <b>Optimal throughput when calibrated and awaiting specimens</b> <b>Calibration can be interrupted to perform stat sample</b> <b>Contraindications</b> <b>Known interferences</b> <b>Restrictions based on Hct</b> <b>Sampler has self-wiping probe</b>	<b>fluid movement error recognition</b> <b>plasma, serum, w. blood, capillary, mixed venous, arterial, venous</b> <b>heparin</b> <b>aspiration, capillary transfer and fill</b> <b>yes/yes</b> <b>65 µL</b> <b>no</b> <b>syringe, capillary, micro sampler</b> <b>yes</b> <b>45 sec</b> <b>average 30 samples per hr, all measured analytes</b> <b>—</b> <b>yes</b> <b>no</b> <b>none</b> <b>none</b> <b>yes</b>	<b>yes</b> <b>plasma, serum, w. blood, capillary, mixed venous, arterial, venous</b> <b>heparin, lithium</b> <b>aspiration, injection</b> <b>yes/yes</b> <b>160 µL for full panel, 40 µL per module</b> <b>yes, 40 µL per module; i.e.: pH/BG, electrolytes, co-ox, metabolites</b> <b>syringe, capillary, micro sampler</b> <b>yes</b> <b>~1 min (depends on tests analyzed)</b> <b>40/490 tests per hr</b> <b>40 samples per hr</b> <b>yes</b> <b>none</b> <b>none</b> <b>no (automatically checks Hct: tHb ratio)</b> <b>no</b>
<b>Time required for maintenance by lab personnel</b> <b>Onboard diagnostics for troubleshooting/Limited to software</b> <b>Diagnostics performed through modem</b>   <b>Training &amp; certification program for user</b>	<b>—</b> <b>yes/no</b> <b>no</b>   <b>yes (2 days on site)</b>	<b>weekly: 5 min; quarterly: 5 min</b> <b>yes/no</b> <b>yes, with OMNI-Link via network can remotely control, real-time continuously monitor, activate calib., QC sampling (with AutoQC module), and activate troubleshooting routines remotely</b> <b>yes (on site)</b>
<b>Method of analyst ID in system</b> <b>Response for hardware &amp; software failure/User ID &amp; QC failure/ Calibration &amp; power failure</b>   <b>Supports bar-code scanning of</b> <b>User can search for and review previous patient results on screen</b> <b>Built-in printer/Data port</b> <b>Information on hard copy report</b>	<b>bar-code, screen, or keyboard (customizable)</b> <b>HW: stop; SW: stop/user ID: lockout (optional); QC: lockout (optional)/calibration: lockout by analyte failure; power: short— return to operation; long—stop</b>  <b>operator &amp; patient IDs, reagent lot No., input QC ranges, lot No.</b> <b>yes</b> <b>yes/RS-232, Ethernet</b> <b>results, errors, patient &amp; sample input (customizable)</b>	<b>4-level password system for 200 operators</b> <b>identified on screen &amp; w/ diagnostic routine/user ID: on screen w/ msg., QC: on screen-report w/ high-low flagging &amp; multirule/calib.: identified on display w/ easy-to-read icons, auto. lockout of failed QC test, power: recorded in activities log, automatic customizable QC lockout of tests oper. &amp; patient identifiers, reag. &amp; electrode lot Nos., QC ranges, expir. yes (up to 50,000 online, onboard analyzer)</b> <b>yes/RS-232, parallel, Ethernet</b> <b>customizable, can incl. input values, meas. values, calc. values</b>
<b>Analyzer connects to</b>  <b>Interface standards supported</b> <b>To upload patient &amp; QC results, how analyzer connects to external system</b> <b>Information included in transmission from analyzer to external system</b>   <b>Hardware/Software for data management system</b>  <b>No. of different management reports system produces</b> <b>Contents downloaded from DMS to analyzer</b> <b>System connected (live installations) to which LISs, HISs</b> <b>• using screen animation, screen scraping</b> <b>• using standard HL7 interface</b> <b>• using proprietary protocol interface</b> <b>Use a third-party interfacing tool, engine for LIS, HIS interfaces</b>	<b>data management system, which in turn connects to LIS/HIS, directly to LIS/HIS</b> <b>HL7</b> <b>direct serial, hospital network</b> <b>—</b>  <b>remote data management and control via OMNILINK</b>  <b>—</b> <b>valid control values, valid operator IDs, patient demographics</b>  <b>—</b> <b>—</b> <b>—</b> <b>—</b>	<b>data management system, which connects to LIS/HIS; directly to LIS/HIS (both options)</b> <b>ASTM 1394, ASTM 1238, HL7 (DataCare available)</b> <b>direct serial, hospital network, real-time wireless (RF)</b> <b>device unique identifier, oper. &amp; patient IDs, results, QC identifier</b>  <b>Roche OMNI has onboard DM capabilities; DataCare POC software is available as a client/server to connect OMNI analyzers</b> <b>40</b> <b>valid control values, valid operator IDs, patient demographics</b>  <b>none</b> <b>Meditech, McKesson, Cerner, SMS (call Roche for updated list)</b> <b>Kaiser Permanente</b> <b>Dawning, Cloverleaf, Data Innovations (not required but can use)</b>
<b>Distinguishing features (provided by vendor)</b>	<b>automatic sample aspiration; clot and air detection; QC and user lockout; Roche Auto QC loads 120 ampules for automatic and precise measurement and configurable for a variety of QC regimens</b>	<b>Roche AutoQC for automatic and precise meas. of QC material following all regs.; reduces labor and eliminates preanalytical variables; liquid calib. eliminates hazardous gas tanks</b>

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Name of device/First year sold No. of devices sold in U.S./Outside U.S./List price Dimensions in inches (H x W x D)/Weight	Roche OMNI S/2004 —/—/\$44,400–\$63,700 23 x 27 x 27 in/99 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, Na, K, Cl, iCa, lactate, glucose, BUN, bilirubin 40+ parameters, including BE, BB, HCO <sub>3</sub> <sup>-</sup> , TCO <sub>2</sub> , SO <sub>2</sub> , NiCa <sup>++</sup> , ctO <sub>2</sub> , pSO, shunt, AG, OSM (call Roche for list) recorded or measured pH: ion selective galvanometric; pCO <sub>2</sub> , pO <sub>2</sub> : ion selective membrane; Hct: conductivity; Hb: spectrophotometry; Na, Cl, iCa, K: ion selective potentiometry; lactate, glucose: oxidase enzyme; BUN: urease enzyme yes, 6 models in Roche OMNI systems series
Device is part of a series of related models User list or 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	— 1-yr warranty no 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 one disposable reagent, electrode system List price per disposable reagent system Reagent unit storage requirements Shelf life of disposable units	— — — — — —
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life  Cost per test/Reagent cost per test	OMNIs 1–4: 2; OMNIs 5 & 6: 3 — reagents: 28 days; electrode: 9–18 mos; auto QC ampules up to 40 days onboard —/—
Calibrations required Calibration frequency Calibrants traceable to NIST standards Internal QC program recommended QC features  Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	1 & 2 point 1 point: 30 min; 2 point: 4–12 hrs yes 1 liquid QC sample per 8 hrs L-J plots, comparable plot, statistical calcs., monthly cum. reports onboard, available with external system, eQAP real-time peer reviews yes yes —
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/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	yes plasma, serum, w. blood, capillary, arterial, venous heparin, lithium aspiration, injection yes/yes 200 µL for full panel, 40 per module yes, BG: 40 µL per module; ISE: 40 µL; coox & bilirubin: 40 µL, glucose lactate, BUN: 75 µL heparinized syringe, capillary, microsamples yes ~1 min (depends on tests analyzed) 30 patients per hr (full panel)/— 30 patients per hr (full panel) yes none none yes (automatically checks Hct: Hb ratio) yes
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user	monthly: 5 min, quarterly: 5 min yes/no yes, same as OMNI Modular yes (2 days on site)
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	32-level password system identified on screen & w/ diagnostic routine/user ID: on screen w/ msg., QC: on screen—report w/ high-low flagging & multirule/calib.: identified on display w/ easy-to-read icons, auto. lockout of failed QC test, power: recorded in activities log, automatic customizable QC lockout of tests yes, operator & patient IDs, transponder system automatically tracks all reagent information yes yes, same as Modular and also USB for data transfer in version 5.0 all customized to operator's needs
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  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 proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options) ASTM 1394, OmniLink 3.2 remote instrument manager direct serial, hospital network device unique identifier, oper. & patient IDs, results, QC identifier, accession Nos., ADT feed — 48 valid control values, valid operator IDs, L-J, maintenance, reagent utilization, error log — EDI — yes, Telcor
Distinguishing features (provided by vendor)	Roche AutoQC with up to 40 days of QC onboard; zero maintenance electrodes and liquid calibration; onboard random access bilirubin

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