

Blood gas vendors move forward on menu, convenience, stability, and more

Anne Ford

Consumer financial gurus often advise would-be budget balancers to look at the little things—upscale coffee-to-go, sneaky ATM surcharges, overpriced buckets of movie popcorn. But when cutting costs, it can pay to think on a larger scale, too. “Right now customers will drive to get the lowest unit cost for reagents, sensors, and other supplies,” says Michael Dalton, vice president of global strategic marketing for Bayer HealthCare, Diagnostics Division, of the in vitro blood gas analyzer market. “They seem to be looking at cost as a series of transactions. In the future, I think that people are going to look at cost from a broader perspective. As a result, they will be looking for providers to offer cost-effective testing solutions to drive efficiency throughout their testing sites.”

But among the manufacturers in this month’s instrumentation survey of in vitro blood gas analyzers, “cost” and “efficiency” are just two of the watchwords. Add to that list “ease of use,” “reduced downtime,” “consolidation,” and “extended menu.”

Nova Biomedical plans to add total bilirubin to its Stat Profile Critical Care Xpress analyzer this fall, says marketing communications manager Har-

lan Polishook. “This new test will expand the utility of the CCX for use in the NICU,” he says. In addition, Nova has added new onboard help capabilities, including video segments, to the CCX. “These segments can be used for system training,” says Polishook, who also notes that the audio portion of these video segments is available in multiple languages. The company has also enhanced the instrument’s respiratory fields.

Osmetech’s latest, says global marketing vice president Gerri Priest, is the Opti R compact blood gas analyzer, which “uses a combination of maintenance-free sensor technology, intuitive graphic user interface, and automated system monitoring.” Those features, she says, result in increased convenience for the operator and reduced testing time. The Opti R’s sensors are reusable for up to 50 patient samples and can be stored at room temperature, while the onboard database stores patient and quality control records. The instrument can provide results for pH, blood gas, sodium, potassium, iCa, total hemoglobin, and oxygen saturation in less than a minute. In addition, “Osmetech will be expanding our parameter offering in the blood gas area,” Priest says.

Expansion is also in the air at Roche, which has extended the onboard

reagent stability of its Cobas B 221 blood gas analyzer from 28 to 42 days. The company has also introduced an onboard feature that provides patient trend data for PO₂, PCO₂, pH, glucose, lactate, BUN, cooximetry, sodium, potassium, chloride, and ionized calcium. It’s not just new Roche customers who will benefit; hospital point-of-care marketing manager Mike Kolodkin says existing customers can receive these new functions gratis.

Meanwhile, ITC has added new features to its Irma TruPoint instrument: namely, an expanded menu, regulatory compliance, and enhanced data management, along

with an Ethernet connectivity port, automatic electronic quality control, and automatic results transfer. “These features improve the reporting of results and help ensure that quality control is run routinely and automatically on the floors,” says Beth O’Connell, senior marketing manager. The company has already added a creatinine assay to the Irma TruPoint’s test menu, and this fall it plans to add a lactate assay. “Another new feature will be the addition of reporting the MDRD-GFR [modification of diet in renal disease-glomerular filtration rate] calculations,” O’Connell says. “The National Kidney Disease Education Program has

recommended reporting of MDRD-GFR with every creatinine result. Irma TruPoint will be the first portable bedside point-of-care device to comply with this new standard.”

Last year, Bayer introduced its Rapidlab 1200 system and Rapidcomm information management system. Dalton says the Rapidlab 1200 “is a system that performs like a lab system while offering the ease of use and low maintenance features of a POC platform.” He adds that Bayer is focusing on “a few areas that include an upgrade to our very successful low-end products

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designed to meet the needs of customers performing low test volumes,” along with expanded menus for its upper-end products and enhanced Rapidcomm features, and that the company expects to release these products in the next few years.

CAP TODAY’s survey of in vitro blood gas analyzers includes systems from the aforementioned manufacturers and from Abbott Point-of-Care, Instrumentation Laboratory, Medica Corp., and Radiometer America. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities. □

Anne Ford is a writer in Chicago.

Critical values

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“Although many hospitals are not yet aware of the change, the Joint Commission will allow others to receive these results.”

To further ease reporting, Dr. Howanitz’s institution calls and tells the person who answers

that there is a critical value on such-and-such a patient and it is in the computer. “If you give a critical value by phone, you’re expected to give the patient name using two identifiers and have the result read back. But if you send results by computer, you can print them out without worrying about transcription errors, which is what the read-back requirement is supposed to fix.”

After learning how this process has saved time and improved care at SUNY Downstate Medical Center, Dr. Howanitz says, the Joint Commission accepted this policy, too.

The bottom line for laboratories is that critical value reporting does matter, and the literature continues to confirm its relevance. In a recent



Dr. Howanitz

study of total serum calcium critical values conducted by Dr. Howanitz and his wife, Joan Howanitz, MD (*Arch Pathol Lab Med.* 2006;130:828–830), high disease severity and mortality

were found in the patients with critical results. The two concluded that although broadening the critical values limits would reduce the number of required calls, the current limits were definitely warranted.

“It’s clear that medical staffs really favor having critical value reports because in our study a significant percentage of the patients go on to succumb,” Dr. Peter Howanitz points out. The Q-Probes study, too, showed that 94.9 percent of physicians found critical values lists valuable.

“The key thing to remember is that critical values are exceedingly important, they are frequently life-threatening, and clinicians need to be reached in a timely manner with critical values results.” □

Anne Paxton is a writer in Seattle.

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<p><i>Part 1 of 12</i></p> <p><i>See related comments, page 24</i></p>	<p>Abbott Point of Care Glen Tinevez glen.tinevez@abbott.com 104 Windsor Center Drive East Windsor, NJ 08520 800-827-7828 www.abbottpointofcare.com</p>	<p>Bayer HealthCare, Diagnostics Division 511 Benedict Ave. Tarrytown, NY 10591 800-255-3232 www.bayerdiag.com</p>
<p>Name of device/First year sold/No. of analyzers sold in 2005 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight</p>	<p>i-STAT System/1992/— ~30,000 worldwide/\$8,761 9.25 x 3.0 x 2.85/22.4 oz</p>	<p>Rapidpoint 400 Series/2001 n/a/n/a/\$38,000 21.5 x 11.5 x 16 in/34 lbs</p>
<p>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</p>	<p>pH, pCO₂, pO₂, Hct, Na, K, Cl, iCa, lactate, glucose, creatinine, BUN, TCO₂ Hb, HCT, O₂SAT, BE, TCO₂, HCO₃⁻ measured electrochemical for all analytes no yes (through local sales representative) 1-yr replacement yes 8 yrs closed/no POC testing</p>	<p>pH, pCO₂, pO₂, Hct, Na+, K+, Cl-, Ca++, tHB, FO₂Hb, FCOHb, FMetHb, FHHb, glucose HCO₃⁻act, HCO₃⁻std, BE(B), BE(ecf), etCO₂, RI(T), O₂SAT, PO₂/FIO₂, AnGAP, sO₂, BO₂, pO₂(A-a)(T), pO₂(a/A)(T), p50, Qsp/Qt(T), ctO₂(Hb), ctO₂(a), ctO₂(v), ctO₂(a-v), DO₂, VO₂, others recorded pH, Na, Cl, iCa, K: potentiometry using ISE; pCO₂: potentiometry based on Severinghaus; pO₂: 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</p>
<p>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</p>	<p>reagent/electrode (single use) 25 per box 1 — refrigerate, 2-week shelf life at room temperature reagent/electrode: 6-9 months</p>	<p>reagent/electrode (multiuse cartridge) 1 measurement cartridge/3 waste/wash cartridges 400, 750 samples varies based on configuration refrigeration 9 months</p>
<p>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</p>	<p>none n/a n/a n/a</p>	<p>1 measurement cartridge, 1 wash-waste cartridge 1 measurement cartridge, 1 wash-waste cartridge 9 months varies based on configuration</p>
<p>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</p>	<p>1 point (automatic) every test yes electronic QC, automated internal wet QC comparable plot, monthly cumulative reports (available with external system) yes yes n/a</p>	<p>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 —</p>
<p>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</p>	<p>— 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 per unit/160 — n/a — — n/a</p>	<p>yes whole blood, capillary, mixed venous, arterial, venous heparin aspiration yes/yes 100 µL no syringe or capillary tube yes 60 seconds 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</p>
<p>Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user</p>	<p>n/a yes/no yes yes, No. of training days varies</p>	<p>maintenance free yes/no yes yes</p>
<p>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</p>	<p>keypad entry/bar-code scanner (customizable) code No. error message/code No. error message/ code No. error message operator & patient IDs, reagent lot No. yes no/— device unique identifier, operator & patient IDs, results, QC results, QC identifier</p>	<p>password (customizable) flag-prompt/user ID: customizable; QC: customizable-flag/calibration: 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</p>
<p>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</p>	<p>data management system, which in turn connects to LIS/HIS ASTM 1394 & 1238, HL7, others direct serial; modem dial-in; hospital network device unique identifier, operator & patient IDs, results, QC identifier QC Manager 3.0/Central Data Station 35+ strip lot Nos., valid control values, valid operator IDs, customizations, analyzer locations all major LIS vendors multiple vendors — yes, Sybase</p>	<p>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</p>
<p>Distinguishing features (provided by vendor)</p>	<p>handheld portable, single-use test cartridge menu; broadest test menu available on a single POC platform; laboratory accurate results at the bedside</p>	<p>no maintenance, multiuse cartridge; fast time to patient results; onboard audio-video training videos; auto QC</p>

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Survey editor: Raymond D. Aller, MD

In vitro blood gas analyzers

<p>Part 2 of 12</p> <p>See related comments, page 24</p>	<p>Bayer HealthCare, Diagnostics Division 511 Benedict Ave. Tarrytown, NY 10591 800-255-3232 www.bayerdiag.com</p>	<p>Instrumentation Laboratory Tim Lynch tlynch@ilww.com 101 Hartwell Ave., Lexington, MA 02421 781-861-4259 www.ilus.com</p>
<p>Name of device/First year sold/No. of analyzers sold in 2005 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight</p>	<p>RapidLab 1200/2005/— n/a/n/a/— 22.75 x 20.5 x 21 in/65–68 lbs</p>	<p>Synthesis 10 & 15/1997/n/a >100 worldwide/Synthesis 10: \$29,925, Synthesis 15: \$42,000 20 x 16 x 20 in/77 lbs</p>
<p>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</p>	<p>pH, pCO₂, pO₂, Hb, Na⁺, K⁺, Cl⁻, iCa, lactate, glucose, COOX fractions Hct, O₂SAT, BE, TCO₂, HCO₃⁻, plus additional parameters measured, tracked pH: potentiometry; pCO₂: Severinghaus electrochemical; pO₂: 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</p>	<p>pH, pO₂, pCO₂; Synthesis 15: THb, O₂Hb, COHb, MetHb, RHb pH(T), pO₂(T), pCO₂(T), HCO₃⁻, SBC, TCO₂, BeB, BEecf, %sO₂c, pAO₂, paO₂/pAO₂, RI, A-aDO₂, O₂cap, O₂ct, p50 tracking pH: potentiometry; pCO₂: Severinghaus electrode-voltage; pO₂: 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</p>
<p>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</p>	<p>— — — — — —</p>	<p>— — — — — —</p>
<p>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</p>	<p>2 cartridges n/a electrode: varies based on type, cartridge reagent: 8 months, wash: 6 months; AQC cartridge; 9 months n/a/n/a</p>	<p>3 — reagent: 24 months, electrode: 4 months–1 yr \$0.71–\$0.73 @ 50 tests per day at list price/\$0.24 @ 50 tests per day at list</p>
<p>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</p>	<p>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 — —</p>	<p>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</p>
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<p>Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user</p>	<p>weekly: 5 min; monthly: 5 min yes/no no yes, 1–2 days</p>	<p>monthly: 5 min yes/no yes yes (1 day on site)</p>
<p>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</p>	<p>password (customizable) diagnostic codes prompt the operator/diagnostic codes/recalibrates, generates diagnostic code if unsuccessful patient ID yes yes/RS-232, Ethernet</p>	<p>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</p>
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<p>Distinguishing features (provided by vendor)</p>	<p>cartridge-based, high-throughput analyzer with minimal maintenance; fast time to patient results; onboard troubleshooting tutorials</p>	<p>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</p>

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In vitro blood gas analyzers

<p><i>Part 3 of 12</i></p> <p><i>See related comments, page 24</i></p>	<p>Instrumentation Laboratory Tim Lynch tlynch@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4259 www.ilus.com</p>	<p>Instrumentation Laboratory Tim Lynch tlynch@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4259 www.ilus.com</p>
<p>Name of device/First year sold/No. of analyzers sold in 2005 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight</p>	<p>Synthesis 20 & 25/1997/n/a >100 worldwide/Synthesis 20: \$38,325; Synthesis 25: \$48,300 20 x 16 x 20 in/77 lbs</p>	<p>Synthesis 30 & 35/1997/n/a >100 worldwide/Synthesis 30: \$42,000; Synthesis 35: \$52,500 20 x 16 x 20 in/77 lbs</p>
<p>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</p>	<p>pH, pO₂, pCO₂, Na⁺, K⁺, Ca⁺⁺, Cl⁻; Synthesis 25: THb, O₂Hb, COHb, Methb, RHb pH(T), pO₂(T), pCO₂(T), HCO₃⁻, SBC, TCO₂, Beb, BEecf, %sO₂c, pAO₂, paO₂/pAO₂, Ri, A-ADO₂, anion gap, O₂cap, O₂ct, p50 tracking pH: potentiometry; pCO₂: Severinghaus electrode-voltage; pO₂: 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</p>	<p>pH, pO₂, pCO₂, Na, K⁺, Ca⁺⁺, Cl⁻, glucose, lactate; Synthesis 35: THb, O₂Hb, COHb, Methb, RHb pH(T), pO₂(T), pCO₂(T), HCO₃⁻, SBC, TCO₂, Beb, BEecf, %sO₂c, pAO₂, paO₂/pAO₂, Ri, A-ADO₂, anion gap, osmolality, O₂cap, O₂ct, p50 tracking pH: potentiometry; pCO₂: Severinghaus electrode-voltage; pO₂: 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</p>
<p>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</p>	<p>— — — — — —</p>	<p>— — — — — —</p>
<p>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</p>	<p>— 12 — \$0.84-\$0.86 @ 50 tests per day at list price/\$0.24 @ 50 tests per day at list price</p>	<p>— 12 — \$1.67-\$1.69 @ 50 tests per day at list price/\$0.24 @ 50 tests per day at list price</p>
<p>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</p>	<p>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</p>	<p>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</p>
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<p>Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user</p>	<p>monthly: 5 min yes/no yes yes (1 day on site)</p>	<p>monthly: 5 min yes/no yes yes (1 day on site)</p>
<p>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</p>	<p>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</p>	<p>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</p>
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In vitro blood gas analyzers

<p><i>Part 4 of 12</i></p> <p><i>See related comments, page 24</i></p>	<p>Instrumentation Laboratory Tim Lynch tlynch@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4259 www.ilus.com</p>	<p>Instrumentation Laboratory Tim Lynch tlynch@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4259 www.ilus.com</p>
<p>Name of device/First year sold/No. of analyzers sold in 2005 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight</p>	<p>Synthesis 40 & 45/1999/n/a n/a/n/a/Synthesis 40: \$48,300; Synthesis 45: \$60,375 20 x 16 x 20 in/77 lbs</p>	<p>GEM Premier 3000/2000/1,750 >2,500/>6,000/\$39,995 17 x 12 x 12 in/29.5 lbs</p>
<p>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</p>	<p>pH, pO₂, pCO₂, Na⁺, K⁺, Ca⁺⁺, Cl⁻, glucose, lactate; Synthesis 45: THb, O₂Hb, COHb, MetHb, RHb pH(T), pO₂(T), pCO₂(T), HCO₃⁻, SBC, TCO₂, Beb, BEecf, %sO₂c, pAO₂, paO₂/pAO₂, RI, A-aDO₂, anion gap, osmolality, O₂cap, O₂ct, p50 tracking pH: potentiometry; pCO₂: Severinghaus electrode-voltage; pO₂: 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</p>	<p>pH, pO₂, pCO₂, Hct, Na⁺, K⁺, Ca⁺⁺, glucose, lactate A-aDO₂, Hb, pAO₂, paO₂/pAO₂, RI, O₂cap*, CtO₂*, CaO₂*, CvO₂*, CcO₂*, a-vDO₂*, Qsp/Qt*, P50* n/a pH, pCO₂: potentiometry; pO₂, 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</p>
<p>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</p>	<p>— — — — — —</p>	<p>yes (multiuse cartridge) 2 per pack 75-, 150-, 300-, 450-, & 600-test cartridge varies with size & menu room temperature 6 months</p>
<p>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</p>	<p>— 13 — TBD/\$0.24 @ 50 tests per day at list price</p>	<p>1 1 multiuse cartridge 6 months varies with size & menu</p>
<p>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</p>	<p>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</p>	<p>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</p>
<p>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</p>	<p>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 seconds 40/320-520 30 samples per hr yes — — no yes</p>	<p>yes whole blood, arterial, venous, or capillary heparin aspiration yes/yes 135-150 µL no syringe or capillary tube yes 85 seconds 20/180 15-20 samples yes — — no yes</p>
<p>Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user</p>	<p>monthly: 5 min yes/no yes yes (1 day on site)</p>	<p>disposable cartridge/no maintenance required yes/no no yes</p>
<p>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</p>	<p>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</p>	<p>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</p>
<p>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</p>	<p>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</p>	<p>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</p>
<p>Distinguishing features (provided by vendor)</p>	<p>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</p>	<p>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</p>

* when interfaced to IL CO-Oximeter

In vitro blood gas analyzers

<p>Part 5 of 12</p> <p>See related comments, page 24</p>	<p>Instrumentation Laboratory Tim Lynch tlynch@ilww.com 101 Hartwell Ave., Lexington, MA 02421 781-861-4259 www.ilus.com</p>	<p>ITC 8 Olsen Ave. Edison, NJ 08820 800-631-5945 www.itcmed.com</p>
<p>Name of device/First year sold/No. of analyzers sold in 2005 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight</p>	<p>GEM 3100/2000/1,750 >2,500/>6,500/\$39,995 22 x 12 x 12 in/31.5 lbs</p>	<p>IRMA TRUpoint Blood Analysis System/1994/— 5,000 worldwide/\$8,900 11.5 x 9.5 x 5 in/5 lbs, 4 oz</p>
<p>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</p>	<p>pH, pO₂, pCO₂, Hct, Na+, K+, Ca++, glucose, lactate: PT, APTT, ACT, ACT-LR, citrate PT A-aDO₂, Hb, pAO₂, paO₂/pAO₂, RI, O₂cap*, CtO₂*, CaO₂*, CvO₂*, CcO₂*, a-vDO₂*, Qsp/Qt*, P50* n/a pH, pCO₂: potentiometry; pO₂, 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</p>	<p>pH, pCO₂, pO₂, Hct, Na, K, Cl, iCa, glucose, BUN, creatinine, lactate Hb, O₂SAT, BEb, BEecf, TCO₂, HCO₃-, iCa(n) measured pH, pCO₂, Na, Cl, iCa, K, BUN, creatinine, lactate (enzymatic): potentiometric; pO₂, glucose (enzymatic): amperometric; Hct: conductometric; glucose strip (enzymatic): colorimetric yes yes 1 yr yes 7 yrs closed/no POC testing</p>
<p>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</p>	<p>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 months</p>	<p>reagent/electrode (single use) 25 per box 1 \$6-\$7 room temperature reagent/electrode: 6 months</p>
<p>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</p>	<p>1 2: 1 for blood gas/electrolytes, 1 for coagulation 6 months varies with menu & cartridge size</p>	<p>— — — —</p>
<p>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</p>	<p>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</p>	<p>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 —</p>
<p>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</p>	<p>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 seconds; under 5 min for coagulation 20/180 15-20 samples (with stat option) yes — — no yes</p>	<p>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 device yes 60-90 seconds on average 25/175 20 n/a none — no no, not needed</p>
<p>Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user</p>	<p>no operator involvement yes/no no yes</p>	<p>maintenance free yes/no no yes</p>
<p>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</p>	<p>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</p>	<p>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, O₂ therapy, sample information</p>
<p>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</p>	<p>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</p>	<p>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 O₂ 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</p>
<p>Distinguishing features (provided by vendor)</p>	<p>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 * when interfaced to IL CO-Oximeter</p>	<p>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, room temperature cartridge storage</p>

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

In vitro blood gas analyzers

<p><i>Part 6 of 12</i></p> <p><i>See related comments, page 24</i></p>	<p>Medica Corp. Charlene M. Soley csoley@medicacorp.com 5 Oak Park Drive, Bedford, MA 01730 800-777-5983 or 781-275-4892 www.medicacorp.com</p>	<p>Medica Corp. Charlene M. Soley csoley@medicacorp.com 5 Oak Park Drive, Bedford, MA 01730 800-777-5983 or 781-275-4892 www.medicacorp.com</p>
<p>Name of device/First year sold/No. of analyzers sold in 2005 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight</p>	<p>EasyBloodGas/2000/197 —/—/\$10,750 14.5 x 12.5 x 7 in/16 lbs</p>	<p>EasyStat/2002/195 —/—/\$12,500 14.5 x 12.5 x 7.0 in/18 lbs</p>
<p>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</p>	<p>pH, pO₂, pCO₂ O₂SAT, BE, TCO₂, HCO₃⁻ measured pH: ISE-potentiometry; pCO₂: ISE-potentiometry; pO₂: ISE-amperometry yes (basic model first gen., related to expanded model EasyStat) yes 1-yr analyzer warranty yes >5 yrs closed/no laboratory</p>	<p>pH, pCO₂, pO₂, Hct, Na, K, iCa Hb, O₂SAT, BE, TCO₂, HCO₃⁻ measured and recorded pH and pCO₂: ISE-potentiometry; pO₂: 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</p>
<p>POC: Uses disposable prepackaged reagent/Electrode system for analysis No. of disposable reagent system units in basic shipment package Max. 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</p>	<p>reagent & electrode 1 based on testing volume per day — room temperature reagent module, 10 months; electrodes, 12 months</p>	<p>reagent & electrode 1 based on testing volume per day — room temperature reagent module: 10 months; electrodes: 12 months</p>
<p>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</p>	<p>1 1 reagent module: 10 months; electrode: 12 months \$0.57 at 20 samples per day/\$0.26 at 20 samples per day</p>	<p>1 1 reagent module: 10 months; electrode: 12 months <\$0.80 per sample at 20 samples per day/\$0.33 at 20 samples per day</p>
<p>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</p>	<p>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</p>	<p>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</p>
<p>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</p>	<p>yes whole blood, capillary, mixed venous, arterial, venous heparin aspiration yes/yes 100 µL syringe; 75 µL capillary no heparinized capillary or syringe yes 125 seconds, includes 1 point calibration 25/75 25 samples yes no incorrect anticoagulant no yes</p>	<p>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 seconds, includes 1 point calibration 30/210 30 samples yes no incorrect anticoagulant no yes</p>
<p>Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user</p>	<p>daily: 0.5 min; weekly: 3.5 min; monthly: 15 min yes/no no yes (through distributors)</p>	<p>daily: 0.5 min; weekly: 3.5 min; monthly: 15 min yes/no no yes (through distributors)</p>
<p>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</p>	<p>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</p>	<p>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 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</p>
<p>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</p>	<p>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</p>	<p>data management system, which connects to LIS/HIS; data management system, which can further transmit data; directly to LIS/HIS Medica protocol direct serial operator & patient IDs, results internal QC, L-J chart, patient & proficiency reports — — — TBD</p>
<p>Distinguishing features (provided by vendor)</p>	<p>modular components; simple operation and maintenance; low purchase price and low operation cost; disposable maintenance-free sensor; no gas tanks</p>	<p>modular components; simple operation and maintenance; low purchase price and low operation cost; disposable maintenance-free sensors; no gas tanks, easy inside and out</p>

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In vitro blood gas analyzers

<p>Part 7 of 12</p> <p>See related comments, page 24</p>	<p>Nova Biomedical Sales info@novabiomedical.com 200 Prospect St., Waltham, MA 02454-9141 800-458-5813</p>	<p>Nova Biomedical Sales info@novabiomedical.com 200 Prospect St., Waltham, MA 02454-9141 800-458-5813</p>
<p>Name of device/First year sold/No. of analyzers sold in 2005</p> <p>No. of devices sold in U.S./Outside U.S./List price</p> <p>Dimensions (H x W x D)/Weight</p>	<p>Stat Profile pH0x/1998/n/a; pH0x Basic/2002/n/a</p> <p>pH0x: —/—/\$15,000; pH0x Basic: —/—/\$12,000</p> <p>15 x 12 x 15 in/18 lbs</p>	<p>Stat Profile pH0x Plus/2000/n/a; Stat Profile pH0x Plus L/2001/n/a; Stat Profile pH0x Plus C/2003/n/a</p> <p>pH0x Plus: —/—/\$29,000; pH0x Plus L: —/—/\$32,000; PH0x Plus C: —/—/\$32,000</p> <p>15 x 12 x 15 in/18 lbs</p>
<p>Analytes measured on device</p> <p>Parameters calculated on device</p> <p>Barometric pressure</p> <p>Analytical method(s), technology(ies) employed</p> <p>Device is part of a series of related models</p> <p>User list or group available</p> <p>Device warranty</p> <p>Loaner devices provided</p> <p>Average expected life of device</p> <p>Open or closed system/External gas tanks required</p> <p>For POC testing or laboratory</p>	<p>pH0x: pH, pCO₂, pO₂, Hct, Hb, SO₂%; pH0x Basic: pH, pCO₂, pO₂</p> <p>BE, TCO₂, HCO₃-tracked</p> <p>pH: direct ISE; pCO₂: Sevinghaus; pO₂: amperometry; Hct: conductivity; Hb & SO₂%; optical-reflectance</p> <p>yes</p> <p>yes (upon request)</p> <p>1 yr, repair or replacement of any part, including labor</p> <p>no</p> <p>5-7 yrs</p> <p>closed/no</p> <p>POC & laboratory</p>	<p>pH0x Plus: pH, pCO₂, pO₂, Hct, Hb, SO₂%, Na, K, Cl or iCa, glucose; pH0x Plus L measures preceding analytes plus lactate; pH0x Plus C: pH, pCO₂, pO₂, Hct, Hb, SO₂%, Na, K, Cl, iCa, glucose tracked</p> <p>pH: direct ISE; pCO₂: potentiometry; pO₂: amperometry; Hct: conductivity; Hb & SO₂%; optical-reflectance; Na, K, Cl, iCa: direct ISE; glucose: enzyme amperometric</p> <p>yes</p> <p>yes (upon request)</p> <p>1 yr, travel and labor, repair or replacement</p> <p>yes</p> <p>5-7 yrs</p> <p>closed/no</p> <p>POC & laboratory</p>
<p>POC:</p> <p>Uses disposable prepackaged reagent/Electrode system for analysis</p> <p>No. of disposable reagent system units in basic shipment package</p> <p>No. of samples analyzed per one disposable reagent, electrode system</p> <p>List price per disposable reagent system</p> <p>Reagent unit storage requirements</p> <p>Shelf life of disposable units</p>	<p>reagent</p> <p>200-500 analyses</p> <p>n/a</p> <p>\$200-\$265</p> <p>room temperature</p> <p>reagents: 18 months room temperature; electrodes: up to 18 months</p>	<p>reagent</p> <p>200-500 analyses</p> <p>n/a</p> <p>\$210-\$275</p> <p>room temperature</p> <p>reagents: 18 months room temperature, electrodes: up to 18 months</p>
<p>Laboratory:</p> <p>No. of different disposable reagents required to maintain device</p> <p>Max. No. of specific analyte reagents that can reside in device at once</p> <p>Shelf life</p> <p>Cost per test/Reagent cost per test</p>	<p>1</p> <p>1</p> <p>reagents & electrodes: 18 months; membrane kits: 12-24 months</p> <p><\$0.11 at 35 analyses per day/<\$0.08 at 35 analyses per day</p>	<p>1</p> <p>1</p> <p>reagents & electrodes: 18 months; membrane kits: 12-24 months</p> <p><\$0.11 at 35 analyses per day/<\$0.08 at 35 analyses per day</p>
<p>Calibrations required</p> <p>Calibration frequency</p> <p>Calibrants traceable to NIST standards</p> <p>Internal QC program recommended</p> <p>QC features</p> <p>Remote control of device from laboratory</p> <p>System can use LOINC to transmit results to LIS</p> <p>How labs get LOINC codes for reagent kits</p>	<p>1 & 2 point (automatic)</p> <p>1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 4, or 6 hr (user defined)</p> <p>yes</p> <p>minimum CLIA recommendations</p> <p>L-J plots, statistical calcs., monthly cum. report (onboard, more extensive reporting avail. with Nova Point-of-Care Manager)</p> <p>yes</p> <p>no</p> <p>—</p>	<p>1 & 2 point (automatic)</p> <p>1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 4, or 6 hr (user defined)</p> <p>yes</p> <p>minimum CLIA recommendations</p> <p>L-J plots, statistical calcs., monthly cum. report (onboard, more extensive reporting avail. with Nova Point-of-Care Manager)</p> <p>no</p> <p>no</p> <p>—</p>
<p>Detects clots within analysis chamber</p> <p>Specimen types suitable for device</p> <p>Acceptable anticoagulants</p> <p>Sampling technique</p> <p>Suitable for samples from well neonates/Sick neonates</p> <p>Sample size for complete panel of analyte results</p> <p>Sample size differs with No. of analytes selected</p> <p>Recommended collection device</p> <p>Provides for patient temperature corrected results</p> <p>Time from sample introduction to result availability</p> <p>Max. No. of patient samples per hr/Max. No. of measured parameters per hr</p> <p>Optimal throughput when calibrated and awaiting specimens</p> <p>Calibration can be interrupted to perform stat sample</p> <p>Contraindications</p> <p>Known interferences</p> <p>Restrictions based on Hct</p> <p>Sampler has self-wiping probe</p>	<p>yes</p> <p>whole blood, capillary, mixed venous, arterial</p> <p>heparin</p> <p>aspiration & capillary</p> <p>yes/yes</p> <p>70 µL</p> <p>yes, pH0x and pH0x Basic offer micro-panel; standard 3-test blood gas micro-panel sample req. is 45 µL</p> <p>syringe, capill., micro-collect. containers, standard vacuum cont.</p> <p>yes</p> <p>45 seconds</p> <p>300/300 tests</p> <p>300 tests per hr</p> <p>yes</p> <p>none</p> <p>none</p> <p>no</p> <p>yes</p>	<p>yes</p> <p>whole blood, capillary, mixed venous, art., venous; pH0x Plus L and Plus C can accomm. preceding specimens and serum plasma heparin</p> <p>heparin</p> <p>aspiration & capillary</p> <p>yes/yes</p> <p>pH0x Plus: 115 µL; pH0x Plus L: 125 µL; pH0x Plus C: 125 µL</p> <p>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</p> <p>syringe, capill., micro-collect. containers, standard vacuum cont.</p> <p>yes</p> <p>pH0x Plus: 50 seconds; pH0x Plus L & PH0x Plus C: 52 seconds</p> <p>50/500 tests</p> <p>300 tests per hr</p> <p>yes</p> <p>none</p> <p>none</p> <p>no</p> <p>yes</p>
<p>Time required for maintenance by lab personnel</p> <p>Onboard diagnostics for troubleshooting/Limited to software</p> <p>Diagnostics performed through modem</p> <p>Training & certification program for user</p>	<p>weekly: <5 min; monthly: <10 min</p> <p>yes/no</p> <p>yes</p> <p>yes (on site)</p>	<p>weekly: <5 min; monthly: <10 min</p> <p>yes/no</p> <p>yes</p> <p>yes (on site)</p>
<p>Method of analyst ID in system</p> <p>Response for hardware & software failure/User ID & QC failure/Calibration & power failure</p> <p>Supports bar-code scanning of</p> <p>User can search for and review previous patient results on screen</p> <p>Built-in printer/Data port</p> <p>Information on hard copy report</p>	<p>password with unique user ID No. (optional)</p> <p>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.</p> <p>patient ID</p> <p>yes</p> <p>yes/multiple RS-232</p> <p>patient ID w/ access. No., entered settings, meas. & calc. results</p>	<p>password with unique user ID No. (optional)</p> <p>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.</p> <p>patient ID</p> <p>yes</p> <p>yes/multiple RS-232</p> <p>patient ID w/ access. No., entered settings, meas. & calc. results</p>
<p>Analyzer connects to</p> <p>Interface standards supported</p> <p>To upload patient & QC results, how analyzer connects to external system</p> <p>Information included in transmission from analyzer to external system</p> <p>Hardware/Software for data management system</p> <p>No. of different management reports system produces</p> <p>Contents downloaded from DMS to analyzer</p> <p>System connected (live installations) to which LISs, HISs</p> <ul style="list-style-type: none"> • using screen animation, screen scraping • using standard HL7 interface • using proprietary protocol interface <p>Use a third-party interfacing tool, engine for LIS, HIS interfaces</p>	<p>data management system which connects to LIS/HIS</p> <p>ASTM E1381-91 & ASTM 1394-91 (HL7 avail. with external device)</p> <p>direct serial/>500 hospitals inst.; hospital network/>100 inst.</p> <p>device unique identifier, operator & patient IDs, results, QC identifier, accession No.</p> <p>Pentium with Microsoft NT 4.0/Nova Point of Care Manager SW</p> <p>>60</p> <p>n/a</p> <p>>20</p> <p>>100</p> <p>>500</p> <p>yes</p>	<p>data management system and/or directly to LIS/HIS</p> <p>ASTM E1381-91 & ASTM 1394-91 (HL7 avail. with external device)</p> <p>direct serial/>500 hospitals inst.; hospital network/>100 inst.</p> <p>device unique identifier, operator & patient IDs, results, QC identifier, accession No.</p> <p>Pentium with Microsoft Windows 2000/Nova Point of Care Manager</p> <p>>60</p> <p>yes, patient name, passwords</p> <p>>20</p> <p>>100</p> <p>>500</p> <p>yes</p>
<p>Distinguishing features (provided by vendor)</p>	<p>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</p>	<p>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</p>

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

In vitro blood gas analyzers

<p><i>Part 8 of 12</i></p> <p><i>See related comments, page 24</i></p>	<p>Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813</p>	<p>Nova Biomedical Sales info@novabiomedical.com 200 Prospect St. Waltham, MA 02454-9141 800-458-5813</p>
<p>Name of device/First year sold/No. of analyzers sold in 2005 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight</p>	<p>Stat Profile Critical Care Xpress/2003/n/a n/a/n/a/— 17.2 x 22.4 x 17.3 in/53 lbs</p>	<p>Stat Profile Critical Care Xpress 3 Plus/2003/n/a n/a/n/a/— 17.2 x 22.4 x 17.3 in/53 lbs</p>
<p>Analytes measured on device Parameters calculated on device Barometric pressure Analytical method(s), technology(ies) employed</p> <p>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</p>	<p>pH, pCO₂, pO₂, Hct, Hb, Na, K, Cl, iCa, iMg, lactate, glucose, creatinine, BUN, SO₂%, co-oximetry BE, TCO₂, HCO₃-tracked pH: direct ISE; pCO₂: Severinghaus; pO₂: amperometric; Hct: conductivity; Hb & SO₂%; optical-reflectance; Na, K, Cl, iMg, & iCa: direct ISE; lactate, glucose, & creatinine: enzyme/amperometric; BUN: enzyme/ISE; co-ox: optical, reflectance yes yes (upon request) 1 yr no 5-7 yrs closed/no POC & laboratory</p>	<p>pH, pCO₂, pO₂, co-oximetry BE, TCO₂, HCO₃-tracked pH: direct ISE; pCO₂: Severinghaus; pO₂: amperometric; co-ox: optical-reflectance yes yes (upon request) 1 yr no 5-7 yrs closed/no POC & laboratory</p>
<p>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</p>	<p>reagent 200-500 analyses n/a \$294-\$349 no special requirements reagents: 18 months (room temp.); electrodes: up to 18 months</p>	<p>reagent 200-500 analyses n/a \$269 no special requirements reagents: 18 months (room temp.); electrodes: up to 18 months</p>
<p>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</p>	<p>1 19 reagents & electrodes: 18 months; membrane kits: 12-24 months <\$0.08 at 40 analyses per day/\$0.04 at 40 analyses per day</p>	<p>1 7 reagents & electrodes: 18 months; membrane kits: 12-24 months <\$0.08 at 40 analyses per day/\$0.04 at 40 analyses per day</p>
<p>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</p>	<p>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</p>	<p>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</p>
<p>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</p>	<p>yes whole blood, capillary, mixed venous, arterial, venous heparin aspiration & capillary yes/yes 210 µL yes, variety of micro-panel options offered & can be customized syringe, capillary, micro-collection, or vacuum collection containers yes 134 sec 22/418 437 tests per hr yes no none no yes</p>	<p>yes whole blood, capillary, mixed venous, arterial, venous heparin aspiration & capillary yes/yes 210 µL yes, variety of micro-panel options offered & can be customized syringe, capillary, micro-collection, or vacuum collection containers yes 61 sec 32/224 190 tests per hr yes no none no yes</p>
<p>Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user</p>	<p>daily: none; weekly: <5 min; monthly: <10 min yes/no yes yes (3 days on site)</p>	<p>daily: none; weekly: <5 min; monthly: <10 min yes/no yes yes (3 days on site)</p>
<p>Method of analyst ID in system Response for hardware & software failure/User ID & QC failure/ Calibration & power failure</p> <p>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</p>	<p>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</p>	<p>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</p>
<p>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</p> <p>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</p>	<p>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</p>	<p>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</p>
<p>Distinguishing features (provided by vendor)</p>	<p>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)</p>	<p>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)</p>

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In vitro blood gas analyzers

<p><i>Part 9 of 12</i></p> <p><i>See related comments, page 24</i></p>	<p>Osmetech Inc. Sales Department 235 Hembree Park Drive, Roswell, GA 30076 800-490-6784 www.osmetech.com</p>	<p>Osmetech Inc. Sales Department 235 Hembree Park Drive, Roswell, GA 30076 800-490-6784 www.osmetech.com</p>
<p>Name of device/First year sold/No. of analyzers sold in 2005 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight</p>	<p>Osmetech OPTI CCA Blood Gas Analyzer/1998/— —/—/\$10,200 4.7 x 14.2 x 9 in/10 lbs without battery, 12 lbs with</p>	<p>Osmetech OPTI R/2005/— —/—/— 4.7 x 14.2 x 9 in/13 lbs</p>
<p>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</p>	<p>pH, pCO₂, pO₂, Na, K, Cl, iCa, tHb, SO₂, glucose Hct, HCO₃, BE, BEecf, BEact, BB, tCO₂, st. HCO₃, st. pH, O₂ct, cH+, AaDO₂, AG, pSO, nCa++ measured pH, pCO₂, pO₂, Na, Cl, iCa, K, glucose: optical fluorescence; tHb, SO₂: 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</p>	<p>pH, pCO₂, pO₂, tHb, Hb, SO₂, Na, K, iCa Hct, HCO₃, BE, BEecf, BEact, BB, tCO₂, st. HCO₃, st. pH, O₂ct, cH+, AaDO₂, AG, pSO, nCa++ recorded, measured pH, pCO₂, pO₂: 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</p>
<p>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</p>	<p>single-use cassettes/optode 25 individual packaged cassettes 1 depends on cassette configuration—contact Osmetech room temperature cassette: 6–8 months, depends on type</p>	<p>reagent, electrode/multiuse cartridge 4 individual packaged cassettes 35–75 — room temperature reagents: 12, electrodes: 6</p>
<p>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</p>	<p>1 1 cassette: 6–8 months, depends on type depends on volume—contact Osmetech</p>	<p>2 1 reagent: 12 months, cartridge; 6 months depends on volume—contact Osmetech</p>
<p>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</p>	<p>1 point (automatic) with each cassette yes 3 levels liquid with change of cassette lot No., 2-month intervals electronic QC—1 level per 8 hrs of operation; elec. & liquid statistical calcs., L–J with external system (DataTrol); stores 1 month—3 levels onboard of each (elec. & liq.) no no —</p>	<p>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 plots, statistical calculations no — —</p>
<p>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</p>	<p>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</p>	<p>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</p>
<p>Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user</p>	<p>weekly: 1 min; quarterly: 5 min yes/no no yes (on site as needed)</p>	<p>weekly: 5 min; quarterly: 15 min yes/no — yes (on site as needed)</p>
<p>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</p>	<p>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, reagent 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</p>	<p>numeric (customizable) —/—/— oper. & patient IDs, reagent lot No., QC material yes yes/RS-232 meas. values, calc. values, warnings/errors, temp, baro., true & user-configured options</p>
<p>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</p>	<p>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)</p>	<p>data management system, which connects to LIS/HIS ASTM 1394 — — Data Trol — none none call Osmetech for details none yes</p>
<p>Distinguishing features (provided by vendor)</p>	<p>ColorTouch Screen display; meas. tHb/SO₂; 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</p>	<p>measured tHb, SO₂; QC integrates into reagent pack; intelligent diagnostics for instrument and consumables</p>

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In vitro blood gas analyzers

<p><i>Part 10 of 12</i></p> <p><i>See related comments, page 24</i></p>	<p>Radiometer America Inc. Telesales Department info@radiometeramerica.com 810 Sharon Dr., Westlake, OH 44145 800-736-0600 ext. 333 www.radiometeramerica.com</p>	<p>Radiometer America Inc. Telesales Department info@radiometeramerica.com 810 Sharon Dr., Westlake, OH 44145 800-736-0600 ext. 333 www.radiometeramerica.com</p>
<p>Name of device/First year sold/No. of analyzers sold in 2005 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight</p>	<p>ABL 5/1994/n/a —/—/— 13 x 13 x 8 in/18 lbs</p>	<p>ABL 800 Series/2004/n/a —/—/depends on configuration 22 x 28 x 21 in/70 lbs</p>
<p>Analytes measured on device Parameters calculated on device Barometric pressure Analytical method(s), technology(ies) employed</p>	<p>pH, pCO₂, pO₂ Hct, O₂SAT, BE, TCO₂, HCO₃⁻, ctO₂, AaDpO₂, SBE, ABE, SBC, pCO₂(T), ctCO₂(P), pH(T), cH⁺(T), pO₂(T) measured pH: pH-sensitive glass (ISE); pCO₂, pO₂: ISE</p>	<p>pH, pCO₂, pO₂, Hb, Na, K, Cl, iCa, lactate, glucose, bilirubin, fetal Hb, O₂Hb, MetHb, RHb, COHb, O₂SAT Hct, BE, TCO₂, HCO₃⁻, plus 40 additional parameters measured pH: pH-sensitive glass (ISE); pCO₂, pO₂, Na, Cl, iCa, K, creatinine: 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)</p>
<p>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</p>	<p>no yes (through local sales representative) 1 yr, parts, labor, & travel yes 20 yrs with full support closed/yes POC & laboratory</p>	<p>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)</p>
<p>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</p>	<p>— — — — — —</p>	<p>— — — — — —</p>
<p>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</p>	<p>4 4 reagent, electrode, membrane kit, cartridge: 2+ yrs depends on sample volume & any extra incl. items/same</p>	<p>4 4 reagent, electrode, membrane kit, cartridge: 2+ yrs depends on sample volume & any extra incl. items/same</p>
<p>Calibrations required Calibration frequency Calibrants traceable to NIST standards Internal QC program recommended QC features</p>	<p>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)</p>	<p>1 & 2 point (automatic) 1 point: 1/2 hr—CLIA GAS, 4 hrs—mftr.; 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)</p>
<p>Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits</p>	<p>yes yes —</p>	<p>yes yes —</p>
<p>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</p>	<p>yes whole blood, capill., mixed venous, arterial, venous heparin, balanced heparin aspiration yes/yes 85 µL yes, optional 35 µL for pH only</p>	<p>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</p>
<p>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</p>	<p>syringe or capillary yes ~1 min 30/90 30 per hr yes none halothane n/a no</p>	<p>syringe or capillary yes ~1 min (depends on tests ordered) 25/425 25 per hr yes none halothane, thiocyanic & glycolic acids no yes</p>
<p>Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user</p>	<p>monthly: as needed; annually: 5 hrs yes/no no yes (on site)</p>	<p>monthly: as needed; annually: dependent on version yes/no yes yes (on site)</p>
<p>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</p>	<p>operator ID entry (optional) system messages none no yes/RS-232, optional patient info., meas. & calc. results, system messages</p>	<p>customizable onboard keyboard, bar code system message with customized ("traffic light") visual & audible signals, parameter status bar operator & patient IDs, reagent & 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</p>
<p>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</p>	<p>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)</p>	<p>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)</p>
<p>Distinguishing features (provided by vendor)</p>	<p>provides basic blood gases (pH, pCO₂, pO₂) test profile; easy to use with minimal maintenance; low cost of operation via standby usage; fast restart, in 2 min, out of standby mode</p>	<p>market first—FLEXQ automated inlet part of first 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</p>

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

In vitro blood gas analyzers

<p>Part 11 of 12</p> <p>See related comments, page 24</p>	<p>Radiometer America Inc. Telesales Department info@radiometeramerica.com 810 Sharon Dr. Westlake, OH 44145 800-736-0600 ext. 333 www.radiometeramerica.com</p>	<p>Radiometer America Inc. Telesales Department info@radiometeramerica.com 810 Sharon Dr. Westlake, OH 44145 800-736-0600 ext. 333 www.radiometeramerica.com</p>
<p>Name of device/First year sold/No. of analyzers sold in 2005 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight</p>	<p>ABL 80/2006/n/a —/—/depends on configuration 16 x 9 x 11 in/19 lbs</p>	<p>NPT7/2001/n/a —/—/depends on configuration 10 x 13 x 16 in/25 lbs</p>
<p>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</p>	<p>pH, pCO₂, pO₂, Hct, Na, K, iCa, Cl⁻, Glu Hb, O₂SAT, TCO₂, HCO₃⁻, ctO₂ (a-v), ctO₂, anion gap (K+), cCa²⁺ (7.40), cBase (B), ABE, SBE, others n/a pH, pCO₂, pO₂, Na, K, iCa, Cl, Glu: thick film; amperometric/potentiometric technology; HCT: conductivity yes yes (through local sales representative) 1 yr parts, labor, & travel, with service plans available after yr 1 yes analyzer: 10+ yrs closed/no POC testing, laboratory</p>	<p>pH, pCO₂, pO₂, tHb, SO₂, O₂Hb, COHb, MetHb, HHb Hct, ABE, SBE, TCO₂, HCO₃⁻, SBC, TO₂, p50 yes pH, pCO₂, pO₂, oximetry: patented dry optical technology no yes (through local sales representative) 1 yr, parts, labor, & travel or depot loaner service yes 10+ yrs closed/no POC testing, laboratory</p>
<p>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</p>	<p>electrode (multiuse cartridge) 1 50/100/200/300 depends on configuration & GPO affiliation room temperature 90–100 days</p>	<p>dry optical system multiuse cartridge contains 30 single-use cuvettes 30 depends on configuration room temperature 24 months</p>
<p>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</p>	<p>2 2 reagent: 100 days, cartridge: 3 months depends on configuration/same</p>	<p>1 1 24 months depends on volume</p>
<p>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</p>	<p>1 & 2 point (manual & automatic) 1 point: with each test; 2 point: 4 hrs (user definable) yes QC material according to CLIA, CAP, JCAHO L-J plots, statistical calcs., monthly cum. (onboard—current mean, STD, CV%) reports (onboard & available with external system, PC download to Excel) yes yes —</p>	<p>2-level check is performed as part of QualityGuard system (manual & automatic) 1 point: n/a; 2 point: n/a yes QualityGuard incl. a 2-level check, system check & incl. meas. check QualityGuard information onboard or available with external system, L-J plot and QC statistics, also available on external DMS no yes —</p>
<p>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</p>	<p>yes whole blood, capillary, mixed venous, arterial, venous heparinized, electrolyte balanced heparin aspiration yes/yes 70 µL no syringe or capillary tube yes 90 sec 30/270 30 tests per hr yes none — no no</p>	<p>yes whole blood, capillary, mixed venous, arterial, venous heparinized whole blood aspiration yes/yes 90 µL no heparinized syringe or capillary tube yes 60 sec 30/270 30 tests per hr n/a no intralipid (concentrations over 4 vol%), fluorescein no no, probe disposed of after measurement</p>
<p>Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user</p>	<p>n/a yes/no no yes (on site)</p>	<p>n/a yes/no no yes</p>
<p>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</p>	<p>bar-code or onboard keyboard (customizable) error msg./error msg./calib.: error msg., power: blank screen & color indicator for battery level operator & patient IDs, reag. & sensor lot Nos., QC* yes yes/RS-232, Ethernet, 2 USB 11, PS2 mouse and keyboard all meas. & calc. values, exp., test remaining info., dispos. lot No., basic statistics, time & date, user & patient info., temp. corrected at 37°C</p>	<p>optional/bar code or manual system messages with visual signals operator & patient IDs, QC lot No. yes yes/RS-232, Ethernet patient info, patient therapy settings; measured and calculated parameter results; system messages; reference ranges; cartridge lot & cartridge expiration date</p>
<p>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</p>	<p>RADIANCE STAT analyzer management system that connects to LIS/HIS or directly to LIS/HIS ASTM, HL7, serial, network, TCP/IP serial, Ethernet device unique identifier, operator & patient IDs, results, QC identifier RADIANCE user definable Cerner, Meditech, Misys, others available from analyzer—LIS/HIS vendors can use none no (use interface templates)</p>	<p>RADIANCE STAT analyzer management system that connects to LIS/HIS or directly to LIS/HIS ASTM serial, Ethernet device unique identifier, oper. & patient IDs, results, QC identifier PCM/CIA—internal DM or external DM user definable LIS vendors completing interface requirements — — no (use interface templates)</p>
<p>Distinguishing features (provided by vendor)</p>	<p>portable, true battery operation; quickest startup/warmup and analysis time; simple and easy-to-use system</p>	<p>patented dry optical technology, unique in the measurement of blood gases and full co-oxymetry; maintenance-free; no cartridge preparation; QualityGuard; patient results in one minute</p>

* all open tests

In vitro blood gas analyzers

<p><i>Part 12 of 12</i></p> <p><i>See related comments, page 24</i></p>	<p>Roche Diagnostics Corp. Mike Kolodkin mike.kolodkin@roche.com 9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 us.labsystems.roche.com</p>	<p>Roche Diagnostics Corp. Mike Kolodkin mike.kolodkin@roche.com 9115 Hague Rd., Indianapolis, IN 46250 800-428-5074 us.labsystems.roche.com</p>
<p>Name of device/First year sold/No. of analyzers sold in 2005 No. of devices sold in U.S./Outside U.S./List price Dimensions in inches (H x W x D)/Weight</p>	<p>Roche OMNI Modular System/1996/— —/—/\$29,900–\$56,200 16.5 x 21 x 18.5 in/88 lbs</p>	<p>Roche cobas b 221 system/2004/— —/—/\$44,400–\$63,700 23 x 23 x 27 in/99 lbs</p>
<p>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</p>	<p>pH, pCO₂, pO₂, Hct, Hb, Na, K, Cl, iCa, lactate, glucose, BUN, co-ox values: O₂Hb, COHb, SulfHb, HHb, methHb 40+ parameters, including BE, BB, HCO₃⁻, TCO₂, SO₂, NiCa⁺⁺, ctO₂, pSO₂, shunt, AG, OSM (call Roche for list) measured pH: ion selective galvanometric; pCO₂, pO₂: ion selective membrane; Hct: conductivity; Hb: spectrophotometry; Na, Cl, iCa, K: ion selective potentiometry; lactate: lact. oxidase enzyme; glucose: glucose oxidase enzyme; BUN: urease enzyme yes, models 1–9 yes (through Roche sales dept.) 1 yr (service contract available for subsequent years) yes >7 yrs closed/no POC & laboratory (transportable on cart system)</p>	<p>pH, pCO₂, pO₂, Hct, Hb, Na, K, Cl, iCa, lactate, glucose, BUN, bilirubin, pH pleural fluid Hb, Hct, O₂SAT, BE, TCO₂, HCO₃⁻ recorded or measured pH: ion selective galvanometric; pCO₂, pO₂: 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 series yes (via local sales representative) 1-yr warranty no 7 yrs closed/no POC & laboratory</p>
<p>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</p>	<p>n/a n/a n/a n/a n/a n/a</p>	<p>reagent and electrode versions 1–4: 2; versions 5 and 6: 3 — — — —</p>
<p>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</p>	<p>depends on model, contact Roche n/a reagents: 1 yr depends on sample volume/same</p>	<p>— — reagent: 42 days onboard; electrode: 9–18 months onboard; membrane kit: n/a —/—</p>
<p>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</p>	<p>1 & 2 point (automatic) 1 point: 30 min and with each sample; 2 point: selectable 4–12 hrs yes 1 liquid QC sample per 8 hrs of operation AutoQC sampling, L-J plots, statistical calcs., monthly cum. reports (onboard & external with DataCare POC software), multirules, auto. lock/unlock of individual tests based on QC criteria yes no —</p>	<p>1 & 2 point (automatic) 1 point: 30 min; 2 point: 8 hrs yes — L-J plots, comparable plot, lot-to-lot comparisons, statistical calcs., monthly cum. reports, onboard, eQAP yes yes Web, package insert</p>
<p>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</p>	<p>yes plasma, serum, w. blood, capillary, mixed venous, arterial, venous heparin, lithium aspiration, injection yes/yes 160 µL for full panel, 40 µL per module yes, 40 µL per module, ie: pH/BG, electrolytes, co-ox, metabolites syringe, capillary, microsampler yes ~1 min (depends on tests analyzed) 40/490 tests per hr 40 samples per hr yes none none no (automatically checks Hct: tHb ratio) no</p>	<p>yes plasma, serum, whole blood, capillary, arterial, venous — aspiration, injection, capillary transfer & fill, microsamples yes/yes 200 µL for full panel yes, BG: 40 µL; ISE: 40 µL; coox 44 µL, glucose lactate, BUN: 75 µL — — ~1 min (test dependent) 30 patients per hr (full panel)/30 patients per hr (full panel) 30 patients per hr (full panel) yes none none no yes</p>
<p>Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user</p>	<p>weekly: 5 min; quarterly: 5 min yes/no 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 yes (on site)</p>	<p>monthly: 5 min, quarterly: 5 min yes/no yes yes (2.5 days on site)</p>
<p>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</p>	<p>4-level password system for 200 operators 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 oper. & patient identifiers, reag. & electrode lot Nos., QC ranges, expir. yes (up to 50,000 online, onboard analyzer) yes/RS-232, parallel, Ethernet customizable, can incl. input values, meas. values, calc. values</p>	<p>32-level password system (customizable) HW: identified onscreen & w/ diagnostic routine; SW: onscreen w/ msg./ user ID: identified onscreen; QC: onscreen report w/ high/low flagging, lockout capabilities/calibration: onscreen reporting w/ lockout capabilities; power: recorded in activities log operator & patient IDs, reagent lot No., RF w/transponders yes yes/RS-232, parallel, Ethernet options can be customized; direct & measured parameters</p>
<p>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</p>	<p>data management system, which connects to LIS/HIS; directly to LIS/HIS (both options) ASTM 1394, ASTM 1238, HL7 (DataCare available) direct serial, hospital network, real-time wireless (RF) device unique identifier, oper. & patient IDs, results, QC identifier Roche OMNI has onboard DM capabilities; DataCare POC software is available as a client/server to connect OMNI analyzers 40 valid control values, valid operator IDs, patient demographics none Meditech, McKesson, Cerner, SMS (call Roche for updated list) Kaiser Permanente Dawning, Cloverleaf, Data Innovations (not required but can use)</p>	<p>data management system, which connects to LIS/HIS; data management, which cannot further transmit data; directly to LIS/HIS ASTM 1394, HL7, USB port direct serial, hospital network, modem dial-in device unique identifier, oper. & patient IDs, results, QC identifier yes 40 valid control values, valid operator IDs, critical patient results — — — Data Innovations</p>
<p>Distinguishing features (provided by vendor)</p>	<p>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</p>	<p>only FDA-510(k) cleared pH pleural fluid results; 42-day onboard reagent packs; Roche auto QC with up to 40 days of QC covered</p>

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