

In vitro blood gas analyzers

<p>Part 1 of 13</p> <p>See related comments, page 24</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>Instrumentation Laboratory Xavier Nogue-Vila xvila@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4244 www.ilus.com</p>
<p>Name of device/First year sold/No. of analyzers sold in 2006 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 in./22.4 oz</p>	<p>Synthesis 10 & 15/1997/na >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</p>	<p>pH, pCO₂, pO₂, Hct, Na, K, Cl, iCa, lactate, glucose, creatinine, BUN, TCO₂ Hb, HCT, O₂SAT, BE, TCO₂, HCO₃⁻</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</p>
<p>Barometric pressure Analytical method(s), technology(ies) employed</p>	<p>measured electrochemical for all analytes</p>	<p>tracking pH: potentiometry; pCO₂: Severinghaus electrode-voltage; pO₂: Clark electrode-current; Hb: nonhemolytic Hb absorption (Synthesis 15)</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 replacement yes 8 yrs closed/no POC testing</p>	<p>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>reagent/electrode (single use) 25 per box 1 — refrigerate, 2-week shelf life at room temperature reag./electrode: 6-9 months</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>none na na na</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</p>	<p>1 point (automatic) every test yes electronic QC, automated internal wet QC comparable plot, monthly cumulative reports (available with external system)</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</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 na</p>	<p>yes no na</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 — na — — — na</p>	<p>yes w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes 60 µL/100 µL yes universal sampler accepts all devices yes 60 seconds 50/150-400 30 samples per hr 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>na yes/no yes yes, No. of training days varies</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</p>	<p>keypad entry/bar-code scanner (customizable) code No. error message/code No. error message/ code No. error message</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</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>operator & patient IDs, reagent lot No. yes no/— device unique identifier, operator & patient IDs, results, QC results, QC identifier</p>	<p>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>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>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</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</p>
<p>Hardware/Software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer</p>	<p>Impact for Critical Care customizable patient ID, demographics</p>	<p>Impact for Critical Care customizable patient ID, demographics</p>
<p>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>all major LIS vendors multiple vendors — yes, Sybase</p>	<p>none none none no</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>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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<p>Part 2 of 13</p> <p>See related comments, page 24</p>	<p>Instrumentation Laboratory Xavier Nogue-Vila xvila@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4244 www.ilus.com</p>	<p>Instrumentation Laboratory Xavier Nogue-Vila xvila@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4244 www.ilus.com</p>
<p>Name of device/First year sold/No. of analyzers sold in 2006 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/na >100 worldwide/Synthesis 20: \$38,325; Synthesis 25: \$48,300 20 x 16 x 20 in./77 lbs</p>	<p>Synthesis 30 & 35/1997/na >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</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</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</p>
<p>Barometric pressure Analytical method(s), technology(ies) employed</p>	<p>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)</p>	<p>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)</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>yes 1 yr yes 7-10 yrs closed/yes laboratory</p>	<p>yes 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 na</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 na</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 80 µL/150 µL yes universal sampler accepts all devices yes 60 seconds 50/350-600 30 samples per hr yes — — no yes</p>	<p>yes w. blood, serum, plasma, capill., mixed ven., arterial, ven., exp. gas heparin aspiration, injection, capillary yes/yes 80 µL/150 µL yes universal sampler accepts all devices yes 60 seconds 40/280-480 30 samples per hr 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>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>
<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>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</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</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>Impact for Critical Care customizable patient ID, demographics none none none no</p>	<p>Impact for Critical Care customizable patient ID, demographics none none none no</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>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>

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

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<p><i>Part 3 of 13</i></p> <p><i>See related comments, page 24</i></p>	<p>Instrumentation Laboratory Xavier Nogue-Vila xvila@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4244 www.ilus.com</p>	<p>Instrumentation Laboratory Xavier Nogue-Vila xvila@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4244 www.ilus.com</p>
<p>Name of device/First year sold/No. of analyzers sold in 2006 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/na na/na/Synthesis 40: \$48,300; Synthesis 45: \$60,375 20 x 16 x 20 in./77 lbs</p>	<p>GEM Premier 3000/2000/1,580 >2,760/>7,580/\$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/Qi*, P50* na 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) 1 per pack 35-, 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 na</p>	<p>1 & 2 point (automatic) 1 point: each patient sample; 2 point: at least every 4 hrs yes internal, automated, continuous quality management included Onboard Intelligent Quality Management (IQM); monthly report includes no. of measurements, mean, max and min delta values yes no na</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; automatically attempts to clear whole blood, arterial, venous, or capillary heparin aspiration yes/yes 135-150 µL no syringe or capillary tube yes 85 seconds 20/180 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 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>GEMweb, GEMweb Plus, Impact for Critical Care 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; 20-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

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Name of device/First year sold/No. of analyzers sold in 2006 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight	GEM 3100/2000/1,580 >2,760/>7,580/\$39,995 22 x 12 x 12 in./31.5 lbs	GEM Premier 4000/2006/100 110/200/\$50,000 18 x 12 x 15 in./44 lbs
Analytes measured on device Parameters calculated on device Barometric pressure Analytical method(s), technology(ies) employed Device is part of a series of related models User list or group available Device warranty Loaner devices provided Average expected life of device Open or closed system/External gas tanks required For POC testing or laboratory	pH, pO ₂ , pCO ₂ , Hct, Na+, K+, Ca++, glucose, lactate: PT, APTT, ACT, ACT-LR, citrate PT A-aDO ₂ , Hb, pAO ₂ , paO ₂ /pAO ₂ , RI, O ₂ cap*, CtO ₂ *, CaO ₂ *, CvO ₂ *, CcO ₂ *, a-vDO ₂ *, Qsp/Qt*, P50* na pH, pCO ₂ : potentiometry; pO ₂ , glucose, lactate: amperometry; Hct: conductivity; Na, iCa, K: ISE; PT, APTT, ACT, ACT-LR, citrate PT, mechanical clot detection yes yes (through local sales representative) 5 yrs yes 7-10 yrs closed/no POC & laboratory	pH, pCO ₂ , pO ₂ , Hct, Na, K, Cl, iCa, lactate, glucose, tHb, O ₂ Hb, COHb, MetHb, HHb Hct, TCO ₂ , BEecf (in vivo), BE(B) (in vivo), tHb(c), Ca++ (7.4), anion gap, P/F ratio, pAO ₂ , CaO ₂ , CvO ₂ , P50, O ₂ cap, sO ₂ , sO ₂ (c), HCO ₃ -std, HCO ₃ -(c), A-aDO ₂ , paO ₂ /pAO ₂ , RI, CcO ₂ , a-vDO ₂ , Qsp/Qt(est), Qsp/Qt na pH, pCO ₂ : potentiometry; pO ₂ , glucose, lactate: amperometry; Hct: conductivity; Hb: spectrophotometric; Na, Cl, iCa, K: potentiometric ion selective electrode yes yes (through local sales representative) 1 yr, parts and labor yes 7-10 yrs closed/no POC & laboratory
POC: Uses disposable prepackaged reagent/Electrode system for analysis No. of disposable reagent system units in basic shipment package No. of samples analyzed per one disposable reagent, electrode system List price per disposable reagent system Reagent unit storage requirements Shelf life of disposable units	yes (multiuse cartridge) 1 per pack cartridges available: 35-, 75-, 150-, 300-, 450-, & 600-test cartridge, 1 sample per cartridge for coagulation tests — room temperature 6 months	yes (multiuse cartridge) 1 per pack cartridges available: 75, 150, 300, 450, 600 varies with size and menu room temperature 6 months
Laboratory: No. of different disposable reagents required to maintain device Max. No. of specific analyte reagents that can reside in device at once Shelf life Cost per test/Reagent cost per test	1 2:1 for blood gas/electrolytes, 1 for coagulation 6 months varies with menu & cartridge size	1 1 multi-use cartridge 6 months (cartridge) varies with cartridge size and menu
Calibrations required Calibration frequency Calibrants traceable to NIST standards Internal QC program recommended QC features Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	1 & 2 point (automatic) 1 point: each patient sample; 2 point: at least every 4 hrs yes internal, automated, continuous quality management included Onboard Intelligent Quality Management (IQM); monthly report includes no. of measurements, mean, max and min delta values yes no na	1 & 2 point (automatic) 1 point: each patient sample; 2 point: at least every 4 hrs yes internal, automated, continuous quality management included Onboard Intelligent Quality Management (IQM); monthly report includes no. of measurements, mean, max and min delta values yes no na
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/Sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/Max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe	yes; automatically attempts to clear 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 20 samples yes — — no yes	yes; automatically attempts to clear whole blood, capillary, mixed venous, arterial, venous heparin aspiration yes/yes 150 µL, 95 µL (electrochemical only), 65 µL micro mode (electrochemical only) yes heparinized syringe or capillary tube yes 70 seconds for electrochemical and 25 additional seconds for CO-Ox 20/300 20 samples per hr yes no interfering substance would be detected and operator notified no yes
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user	no operator involvement yes/no no yes	none yes/no no (but can through VPN) yes
Method of analyst ID in system Response for hardware & software failure/User ID & QC failure/Calibration & power failure Supports bar-code scanning of User can search for and review previous patient results on screen Built-in printer/Data port Information on hard copy report	manual or bar-code 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	wireless bar-code gun or manual virtual keyboard entry operator warning, sampling lockout/user ID: no system access/QC: IQM disables analyte channel; no result reported/IQM disables analyte channel; no result reported/power: system automatically performs checks before samples can be analyzed operator & patient IDs, cartridge lot number & expiration date yes yes/4 RS-232, 1 parallel port, 1 Ethernet port, 4 USB ports patient demographics, hospital info, results, result flags and legend, reference and critical ranges (optional), comments, notification info
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	GEMweb, GEMweb Plus, Impact for Critical Care 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	LIS/HIS via direct interface or via IL's GEMweb Plus data management system; vendor-neutral or Web-based systems ASTM 1394, HL7 direct serial, hospital network, real-time wireless device identifier, operator & patient IDs, results, QC ID GEMweb Plus 4 most configuration information, including valid operator IDs, QC lots and ranges — SCC, Misys, Cerner, Meditech — MAS-Rals Plus, Telecor Quick-Linc
Distinguishing features (provided by vendor)	Intelligent Quality Management (IQM) maintenance-free, multiuse cartridge available in 30 menu/size options for use in any hospital location; 20-year history of proven cartridge technology; remote management from any PC via GEMweb; consolidated workstation * when interfaced to IL CO-Oximeter	IQM detects, corrects, and documents instrument errors, reducing time to error detection to minutes; single component, multi-use GEM Premier 4000 cartridge includes testing components, is changed every 30 days, requires no refrigeration or maintenance; GEMweb Plus is an information management system for the GEM Premier 4000 analyzer

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In vitro blood gas analyzers

<p>Part 5 of 13</p> <p>See related comments, page 24</p>	<p>ITC 8 Olsen Ave. Edison, NJ 08820 800-631-5945 www.itcmed.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 2006 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight</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>EasyBloodGas/2000/236 —/—/\$10,750 12.5 x 14.5 x 7 in./16 lbs</p>
<p>Analytes measured on device Parameters calculated on device</p> <p>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, Na, K, Cl, iCa, glucose, BUN, creatinine, lactate Hb, O₂SAT, BEb, BEecf, TCO₂, HCO₃⁻, iCa(n)</p> <p>measured pH, pCO₂, Na, Cl, iCa, K, BUN, creatinine, lactate (enzymatic): potentiometric; pO₂, glucose (enzymatic): amperometric; Hct: conductometric; glucose strip (enzymatic): colormetric</p> <p>yes yes 1 yr yes 7 yrs closed/no POC testing</p>	<p>pH, pO₂, pCO₂ O₂SAT, BE, TCO₂, HCO₃⁻</p> <p>measured pH: ISE-potentiometry; pCO₂: ISE-potentiometry; pO₂: ISE-amperometry</p> <p>yes (basic model first gen., related to expanded model EasyStat) yes 1-yr analyzer warranty yes >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 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 \$6-\$7 room temperature reagent/electrode: 6 months</p>	<p>reagent & electrode 1 based on testing volume per day — room temperature: 5°C to 25°C 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>— — — —</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>Calibrations required Calibration frequency</p> <p>Calibrants traceable to NIST standards Internal QC program recommended QC features</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>2 point (automatic) automatic with each sample</p> <p>yes automatic electronic QC per 8 hrs L-J plots, statistical calculations, monthly cumulative reports (IDMS) yes no —</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, CLIA recommendations, Medica controls recommended L-J plots; monthly cumulative reports no no na</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>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 na none — no no, not needed</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>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>maintenance free yes/no no yes</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</p> <p>Supports bar-code scanning of</p> <p>User can search for and review previous patient results on screen Built-in printer/Data port Information on hard copy report</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.</p> <p>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>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>Analyzer connects to</p> <p>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</p> <p>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) 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</p> <p>24 all analyzer settings, software upgrades</p> <p>all major HIS/LIS vendors all major HIS/LIS vendors customizable EDI interface to HIS/LIS vendors yes</p>	<p>data management system, which can further transmit data; directly to LIS/HIS Medica protocol direct serial patient ID, results</p> <p>internal</p> <p>QC, L-J chart, patient reports — — — TBD</p>
<p>Distinguishing features (provided by vendor)</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>	<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 6 of 13</p> <p>See related comments, page 24</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>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 2006 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight</p>	<p>EasyStat/2002/116 —/—/\$12,500 12.5 x 14.5 x 7.0 in./17 lbs</p>	<p>Stat Profile pH0x/1998/na; pH0x Basic/2002/na pH0x: —/—/\$15,000; pH0x Basic: —/—/\$12,000 15 x 12 x 15 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, 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>pH0x: pH, pCO₂, pO₂, Hct, Hb, SO₂%; pH0x Basic: pH, pCO₂, pO₂ BE, TCO₂, HCO₃⁻ tracked pH: direct ISE; pCO₂: Sevinghaus; pO₂: amperometry; Hct: conductivity; Hb & SO₂%: optical-reflectance yes yes (upon request) 1 yr, repair or replacement of any part, including labor 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 & electrode 1 based on testing volume per day — room temperature: 5°C to 25°C reagent module: 10 months; electrodes: 12 months</p>	<p>reagent 200-500 analyses na \$200-\$265 room temperature reagents: 18 months room temperature; 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 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>1 1 reagents & electrodes: 18 months; membrane kits: 12-24 months <\$0.11 at 35 analyses per day/<\$0.08 at 35 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: 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 na</p>	<p>1 & 2 point (automatic) 1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 4, or 6 hr (user defined) yes minimum CLIA recommendations L-J plots, statistical calcs., monthly cum. report (onboard, more extensive reporting avail. with Nova Point-of-Care Manager) 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 plasma, serum, whole blood, capillary, mixed venous, arterial, venous heparin aspiration yes/yes 120 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>yes whole blood, capillary, mixed venous, arterial heparin aspiration & capillary yes/yes 70 µL yes, pH0x and pH0x Basic offer micro-panel; standard 3-test blood gas micro-panel sample req. is 45 µL syringe, capill., micro-collect. containers, standard vacuum cont. yes 45 seconds 300/300 tests 300 tests per hr 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>daily: 0.5 min; weekly: 3.5 min; monthly: 15 min yes/no no yes (through distributors)</p>	<p>weekly: <5 min; monthly: <10 min 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>manual or bar-code entry (optional) HW: operator warning-error message; SW: error message/user ID: sampling lockout; QC: flagged results/calibration: error message & 2nd 2 pt calibration automatically run; power: display not illuminated, data retained-auto reset operator & patient IDs, QC controls, reagent pack automatically read when reagent module installed yes yes/RS-232 patient information, measured & calculated results, date, operator ID data management system, which connects to LIS/HIS; data management system, which can further transmit data; directly to LIS/HIS</p>	<p>password with unique user ID No. (optional) 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. patient ID yes yes/multiple RS-232 patient ID w/ access. No., entered settings, meas. & calc. 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>Medica protocol direct serial operator & patient IDs, results internal QC, L-J chart, patient & proficiency reports — — — — — TBD</p>	<p>data management system which connects to LIS/HIS ASTM E1381-91 & ASTM 1394-91 (HL7 avail. with external device) direct serial/>500 hospitals inst.; hospital network/>100 inst. device unique identifier, operator & patient IDs, results, QC identifier, accession No. Pentium with Microsoft NT 4.0/Nova Point of Care Manager SW >60 na >20 >100 >500 yes</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 sensors; no gas tanks, easy inside and out</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>

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In vitro blood gas analyzers

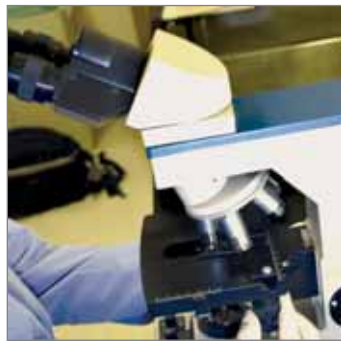
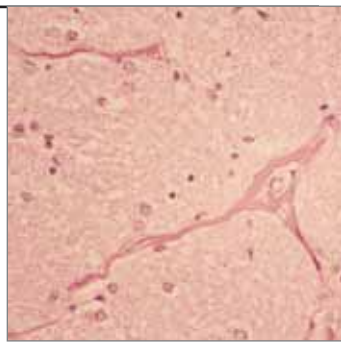
Part 7 of 13	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St., Waltham, MA 02454-9141 800-458-5813	Nova Biomedical Sales info@novabiomedical.com 200 Prospect St., Waltham, MA 02454-9141 800-458-5813
See related comments, page 24		
Name of device/First year sold/No. of analyzers sold in 2006	Stat Profile pHox Plus/2000/n/a; Stat Profile pHox Plus L/2001/na; Stat Profile pHox Plus C/2003/na	Stat Profile Critical Care Xpress/2003/na
No. of devices sold in U.S./Outside U.S./List price	pHox Plus: —/—/\$29,000; pHox Plus L: —/—/\$32,000; PHox Plus C: —/—/\$32,000	na/na/—
Dimensions (H x W x D)/Weight	15 x 12 x 15 in./18 lbs	17.2 x 22.4 x 17.3 in./53 lbs
Analytes measured on device	pHox Plus: pH, pCO ₂ , pO ₂ , Hct, Hb, SO ₂ %, Na, K, Cl or iCa, glucose; pHox Plus L measures preceding analytes plus lactate; pHox Plus C	pH, pCO ₂ , pO ₂ , Hct, Hb, Na, K, Cl, iCa, iMg, lactate, glucose, creatinine, BUN, SO ₂ %, bilirubin, co-oximetry
Parameters calculated on device	pH, pCO ₂ , pO ₂ , Hct, Hb, SO ₂ %, Na, K, Cl, iCa, glucose tracked	BE, TCO ₂ , HCO ₃ -tracked
Barometric pressure		
Analytical method(s), technology(ies) employed	pH: direct ISE; pCO ₂ : potentiometry; pO ₂ : amperometry; Hct: conductivity; Hb & SO ₂ %; optical-reflectance; Na, K, Cl, iCa: direct ISE; glucose: enzyme amperometric	pH: direct ISE; pCO ₂ : Severinghaus; pO ₂ : amperometric; Hct: conductivity; Hb & SO ₂ %; optical-reflectance; Na, K, Cl, iMg, & iCa: direct ISE; lactate, glucose, & creatinine: enzyme/amperometric; BUN: enzyme/ISE; bilirubin, co-ox: optical, reflectance
Device is part of a series of related models	yes	yes
User list or group available	yes (upon request)	yes (upon request)
Device warranty	1 yr, travel and labor, repair or replacement	1 yr
Loaner devices provided	yes	no
Average expected life of device	5–7 yrs	5–7 yrs
Open or closed system/External gas tanks required	closed/no	closed/no
For POC testing or laboratory	POC & laboratory	POC & laboratory
POC:		
Uses disposable prepackaged reagent/Electrode system for analysis	reagent	reagent
No. of disposable reagent system units in basic shipment package	200–500 analyses	200–500 analyses
No. of samples analyzed per one disposable reagent, electrode system	na	na
List price per disposable reagent system	\$210–\$275	\$294–\$349
Reagent unit storage requirements	room temperature	no special requirements
Shelf life of disposable units	reagents: 18 months room temperature, electrodes: up to 18 months	reagents: 18 months (room temp.); electrodes: up to 18 months
Laboratory:		
No. of different disposable reagents required to maintain device	1	1
Max. No. of specific analyte reagents that can reside in device at once	1	20
Shelf life	reagents & electrodes: 18 months; membrane kits: 12–24 months	reagents & electrodes: 18 months; membrane kits: 12–24 months
Cost per test/Reagent cost per test	<\$0.11 at 35 analyses per day/<\$0.08 at 35 analyses per day	<\$0.08 at 40 analyses per day/\$0.04 at 40 analyses per day
Calibrations required	1 & 2 point (automatic)	1 & 2 point (automatic)
Calibration frequency	1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 4, or 6 hr (user defined)	1 point: 30 or 45 min or with every sample (user selectable); 2 point: 2, 3, 4, 5, or 6 hr (user defined)
Calibrants traceable to NIST standards	yes	yes
Internal QC program recommended	minimum CLIA recommendations	minimum CLIA recommendations
QC features	L-J plots, statistical calcs., monthly cum. report (onboard, more extensive reporting avail. with Nova Point-of-Care Manager)	L-J plots, comparable plot, statistical calculations, monthly cum. report, onboard, available with external system
Remote control of device from laboratory	no	yes
System can use LOINC to transmit results to LIS	no	yes
How labs get LOINC codes for reagent kits	—	package insert
Detects clots within analysis chamber	yes	yes
Specimen types suitable for device	whole blood, capillary, mixed venous, art., venous; pHox Plus L and Plus C can accomm. preceding specimens and serum plasma heparin	whole blood, capillary, mixed venous, arterial, venous
Acceptable anticoagulants	heparin	heparin
Sampling technique	aspiration & capillary	aspiration & capillary
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Sample size for complete panel of analyte results	pHox Plus: 115 µL; pHox Plus L: 125 µL; pHox Plus C: 125 µL	210 µL
Sample size differs with No. of analytes selected	yes, pHox Plus, pHox Plus L, pHox Plus C offer micro-panel; standard 3-test micro-panel req. 55 µL for pHox Plus; 60 µL for pHox Plus L & Plus C syringe, capill., micro-collect. containers, standard vacuum cont.	yes, variety of micro-panel options offered & can be customized
Recommended collection device	yes	syringe, capillary, micro-collection, or vacuum collection containers
Provides for patient temperature corrected results	yes	yes
Time from sample introduction to result availability	pHox Plus: 50 seconds; pHox Plus L & PHox Plus C: 52 seconds	134 sec
Max. No. of patient samples per hr/Max. No. of measured parameters per hr	50/500 tests	22/440
Optimal throughput when calibrated and awaiting specimens	300 tests per hr	437 tests per hr
Calibration can be interrupted to perform stat sample	yes	yes
Contraindications	none	no
Known interferences	none	none
Restrictions based on Hct	no	no
Sampler has self-wiping probe	yes	yes
Time required for maintenance by lab personnel	weekly: <5 min; monthly: <10 min	daily: none; weekly: <5 min; monthly: <10 min
Onboard diagnostics for troubleshooting/Limited to software	yes/no	yes/no
Diagnostics performed through modem	yes	yes
Training & certification program for user	yes (on site)	yes (3 days on site)
Method of analyst ID in system	password with unique user ID No. (optional)	multilevel password with unique user ID No.
Response for hardware & software failure/User ID & QC failure/Calibration & power failure	self-diag. SW informs & notifies oper. of HW failure; hotline & field support depending on problem/optional lockout w/o user ID; options for QC failure range from flagging to not reporting test that fails QC to lockout for QC failure or exceeding scheduled QC interval/ any test that does not calibrate will not report results & instrument notifies oper. of reason for failure; momentary power interrupts require no recovery—extended power failure results in automatic calib.	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
Supports bar-code scanning of	patient ID	yes
User can search for and review previous patient results on screen	yes	yes
Built-in printer/Data port	yes/multiple RS-232	yes/ Ethernet, USB
Information on hard copy report	patient ID w/ access. No., entered settings, meas. & calc. results	patient ID & accession Nos., entered settings, measured & calculated results
Analyzer connects to	data management system and/or directly to LIS/HIS	directly to LIS/HIS, DMS that in turn connects to LIS/HIS
Interface standards supported	ASTM E1381-91 & ASTM 1394-91 (HL7 avail. with external device)	ASTM E1394-91, ASTM 1381-91, HL7
To upload patient & QC results, how analyzer connects to external system	direct serial/>500 hospitals inst.; hospital network/>100 inst.	modem dial-in, hospital network
Information included in transmission from analyzer to external system	device unique identifier, operator & patient IDs, results, QC identifier, accession No.	device unique identifier, operator & patient IDs, results, QC identifier
Hardware/Software for data management system	Pentium with Microsoft Windows 2000/Nova Point of Care Manager	full-featured onboard DMS capability, external DMS also avail.
No. of different management reports system produces	>60	>30
Contents downloaded from DMS to analyzer	yes, patient name, passwords	valid control Nos., valid operator IDs, patient demographics
System connected (live installations) to which LISs, HISs		
• using screen animation, screen scraping	>20	na
• using standard HL7 interface	>100	na
• using proprietary protocol interface	>500	na
Use a third-party interfacing tool, engine for LIS, HIS interfaces	yes	most analyzers interfaced to LIS using LIS vendor's drivers
Distinguishing features (provided by vendor)	single reagent cartridge has all supplies needed for calibration and waste collection; has same features as pHox/pHox Basic; pHox	largest whole blood critical care menu (19 tests), BUN, iMg available exclusively from Nova; onboard co-oximeter

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In vitro blood gas analyzers

<p>Part 8 of 13</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>Opti Medical Systems Inc. Sales Department 235 Hembree park Drive Roswell, GA 30076 800-490-6784 www.optimedical.com</p>
<p>Name of device/First year sold/No. of analyzers sold in 2006 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 3 Plus/2003/na na/na/— 17.2 x 22.4 x 17.3 in./53 lbs</p>	<p>OPTI R/2006/— —/—/— 4.7 x 14.2 x 14 in./4.5 kg (10 lbs) without fluid pack</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, 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>pH, pCO₂, pO₂, tHb, Na, K, iCa, SO₂ — measured pH, pCO₂, pO₂, Hb, Na, Cl, iCa, K: optical fluorescence yes (OPTI CCA) yes (upon request) one-year warranty on new analyzers from date analyzer is placed into service yes 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 na \$269 no special requirements reagents: 18 months (room temp.); electrodes: up to 18 months</p>	<p>reagent/multiuse cartridge 4 50 — room temperature reagents: 7 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 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>2 8 7 months —</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>2 point (automatic) one point: every 3 hours; two point: start-up yes 3 levels automatic QC run up to 5 times per day supplemented with liquid controls run 2 points daily available with external system no 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, 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>yes whole blood, capillary, arterial heparin aspiration no/yes 125 µL no syringe, capillary tube, Opti Medical comfort sampler not necessary ~1 min 30/240 240 tests per hr yes no — no no</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>none no/— no yes (1 to 2 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>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/Ethernet, USB patient ID & accession Nos., entered settings, measured & calculated results</p>	<p>1D code entry HW & SW: error message/user ID: —; QC: failure message/calibration: error message with retry; power: memory recovery patient IDs, reagents, controls & calibrators yes yes/RS-232, Ethernet patient ID, number, results, patient demographics (customized)</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>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 na na na 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 1394, ASTM 1238, ASC II direct serial, hospital network device unique identifier, patient ID LDS Aegis — — — — LDS Aegis</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 and select report protocol with full QC SMD; meets NCCLS POCT 1-A standards (more shared features listed under Critical Care Xpress)</p>	<p>RFID technology, Hydrogel absorbent material solidifies waste; power loss recovering: up to eight hours of interrupted power allows analyzer to be moved between departments</p>

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In vitro blood gas analyzers

Part 9 of 13

See related comments, page 24

Opti Medical Systems Inc.
Sales Department
235 Hembree Park Drive, Roswell, GA 30076
800-490-6784
www.optimedical.com

Name of device/First year sold/No. of analyzers sold in 2006
No. of devices sold in U.S./Outside U.S./List price
Dimensions (H x W x D)/Weight

OPTI CCA Blood Gas Analyzer/1998/—
—/—/\$10,200
4.7 x 14.2 x 9 in./10 lbs without battery, 12 lbs with battery

Analytes measured on device
Parameters calculated on device

pH, pCO₂, pO₂, Na, K, Cl, iCa, tHb, SO₂, glucose
Hct, HCO₃, BE, BE_{ecf}, BE_{act}, BB, tCO₂, st. HCO₃, st. pH, O₂ct, cH+, AaDO₂, AG, pSO, nCa⁺⁺ measured

Barometric pressure
Analytical method(s), technology(ies) employed

pH, pCO₂, pO₂, Na, Cl, iCa, K, glucose: optical fluorescence; tHb, SO₂: optical reflectance

Device is part of a series of related models
User list or group available

yes, OPTI Series
yes (through Opti Medical sales dept.)

Device warranty
Loaner devices provided
Average expected life of device
Open or closed system/External gas tanks required
For POC testing or laboratory

1 yr (service contract available for subsequent years)
yes
>7 yrs
closed/no
POC & laboratory

POC:

Uses disposable prepackaged reagent/Electrode system for analysis
No. of disposable reagent system units in basic shipment package
No. of samples analyzed per one disposable reagent, electrode system
List price per disposable reagent system
Reagent unit storage requirements
Shelf life of disposable units

single-use cassettes/optode
25 individual packaged cassettes
1
depends on cassette configuration—contact Opti Medical
room temperature
cassette: 6–8 months, depends on type

Laboratory:

No. of different disposable reagents required to maintain device
Max. No. of specific analyte reagents that can reside in device at once
Shelf life
Cost per test/Reagent cost per test

1
1
cassette: 6–8 months, depends on type
depends on volume—contact Opti Medical

Calibrations required
Calibration frequency
Calibrants traceable to NIST standards
Internal QC program recommended

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.)

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

no
no
—

Detects clots within analysis chamber
Specimen types suitable for device

yes
plasma, serum, w. blood, capill., mixed ven., arterial, venous

Acceptable anticoagulants

heparin
aspiration

Sampling technique

yes/yes

Suitable for samples from well neonates/Sick neonates

125 µL

Sample size for complete panel of analyte results

no

Sample size differs with No. of analytes selected

heparinized syringe, capillary, Comfort Sampler

Recommended collection device

yes

Provides for patient temperature corrected results

~1 min from sample aspiration

Time from sample introduction to result availability

24/192

Max. No. of patient samples per hr/Max. No. of measured parameters per hr

24

Optimal throughput when calibrated and awaiting specimens

no

Calibration can be interrupted to perform stat sample

none

Contraindications

none

Known interferences

no (Hct calculated based on meas. Hb)

Restrictions based on Hct

no, single use

Sampler has self-wiping probe

Time required for maintenance by lab personnel
Onboard diagnostics for troubleshooting/Limited to software
Diagnostics performed through modem
Training & certification program for user

weekly: 1 min; quarterly: 5 min
yes/no
no
yes (on site as needed)

Method of analyst ID in system
Response for hardware & software failure/User ID & QC failure/
Calibration & power failure

oper. ID and/or secure 4-digit PIN No. for 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

Supports bar-code scanning of

oper. & patient IDs, reagent lot No., QC ranges, cassette lot No., expiration, factory calibration info. & cassette type

User can search for and review previous patient results on screen

yes

Built-in printer/Data port

yes/RS-232

Information on hard copy report

customizable, can incl. input values, meas. values, calc. values

Analyzer connects to

DataTrol data management system, which connects to LIS/HIS; directly to LIS/HIS (both options)

Interface standards supported

mobile ASTM, ASTM, ASCII

To upload patient & QC results, how analyzer connects to external system

direct serial

Information included in transmission from analyzer to external system

device unique identifier, oper. & patient IDs, results, QC identifier, all info. pertinent to patient & QC data

Hardware/Software for data management system

OPTI has onboard data management capabilities, additionally DataTrol software is available as a client/server

No. of different management reports system produces

40

Contents downloaded from DMS to analyzer

none

System connected (live installations) to which LISs, HISs

none

• using screen animation, screen scraping

Meditech, McKesson, Cerner, Siemens, others (call Opti Medical for updated list)

• using standard HL7 interface

none

• using proprietary protocol interface

none

Use a third-party interfacing tool, engine for LIS, HIS interfaces

Dawning, Data Innovations (not required but can use)

Distinguishing features (provided by vendor)

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

In vitro blood gas analyzers

<p>Part 10 of 13</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 2006 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight</p>	<p>ABL 5/1994/na —/—/— 13 x 13 x 8 in./18 lbs</p>	<p>ABL 800 Series/2004/na —/—/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, creatinine 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</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 (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 autoaspiration, 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 na 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/USB 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, POCT1A, network TCP/IP direct serial/thousands of hosp. installed; modem dial-in/hundreds; hospital network/hundreds; real time wireless-capable 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 Cerner, Meditech, Misys, others available from analyzer—LIS/HIS vendors can use none —</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; 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 (embedded), Pentium processors, automatic QC, autocal, remote support</p>

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

In vitro blood gas analyzers

<p>Part 11 of 13</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 2006 No. of devices sold in U.S./Outside U.S./List price Dimensions (H x W x D)/Weight</p>	<p>ABL 80/2006/na —/—/depends on configuration 16 x 9 x 11 in./19 lbs</p>	<p>NPT7/2001/na —/—/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</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 na pH, pCO₂, pO₂, Na, K, iCa, Cl, Glu: thick film; amperometric/potentiometric technology; HCT: conductivity</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</p>
<p>Device is part of a series of related models</p>	<p>yes</p>	<p>no</p>
<p>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>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>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: 90 days 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</p>	<p>1 & 2 point (manual & automatic) 1 point: with each test; 2 point: 8 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)</p>	<p>2-level check is performed as part of QualityGuard system (manual & automatic) 1 point: na; 2 point: na 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</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>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 na 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>na yes/no no yes (on site)</p>	<p>na yes/no no yes</p>
<p>Method of analyst ID in system Response for hardware & software failure/User ID & QC failure/ Calibration & power failure</p>	<p>bar-code or onboard keyboard (customizable) error msg./error msg./calib.: error msg., power: blank screen & color indicator for battery level</p>	<p>optional/bar code or manual system messages with visual signals</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>operator & patient IDs, reagent & 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>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</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-oximetry; maintenance-free; no cartridge preparation; QualityGuard; patient results in one minute</p>

* all open tests

In vitro blood gas analyzers

Part 12 of 13	Roche Laurence J. Healy laurence.healy@roche.com 9115 Hague Rd., Indianapolis, IN 46250 800-428-5076 us.labsystems.roche.com	Roche Laurence J. Healy laurence.healy@roche.com 9115 Hague Rd., Indianapolis, IN 46250 800-428-5076 us.labsystems.roche.com
See related comments, page 24		
Name of device/First year sold/No. of analyzers sold in 2006 No. of devices sold in U.S./Outside U.S./List price Dimensions in inches (H x W x D)/Weight	Roche OMNI Modular System/1996/— —/—/\$29,900–\$56,200 16.5 x 21 x 18.5 in./88 lbs	Roche cobas b 221 system/2004/— —/—/\$44,400–\$63,700 23 x 20 x 23.6 in./99 lbs (w/o solutions and AutoQC)
Analytes measured on device Parameters calculated on device Barometric pressure Analytical method(s), technology(ies) employed Device is part of a series of related models User list or group available Device warranty Loaner devices provided Average expected life of device Open or closed system/External gas tanks required For POC testing or laboratory	pH, pCO ₂ , pO ₂ , Hct, Hb, Na, K, Cl, iCa, lactate, glucose, BUN, co-ox values: O ₂ Hb, COHb, SuffHb, HHb, metHb 40+ parameters, including BE, BB, HCO ₃ ⁻ , TCO ₂ , SO ₂ , NiCa ⁺⁺ , ctO ₂ , pSO ₂ , shunt, AG, OSM (call Roche for list) measured pH: ion selective galvanometric; pCO ₂ , pO ₂ : ion selective membrane; Hct: conductivity; Hb: spectrophotometry; Na, Cl, iCa, K: ion selective potentiometry; lactate: lact. oxidase enzyme; glucose: glucose oxidase enzyme; BUN: urease enzyme yes, models 1–9	pH, pCO ₂ , pO ₂ , Hct, Hb, Na, K, Cl, iCa, lactate, glucose, BUN, bilirubin, pH pleural fluid Hb, Hct, O ₂ SAT, BE, TCO ₂ , HCO ₃ ⁻ recorded or measured pH: electrode ion selective galvanometric; pCO ₂ , pO ₂ : electrode ion selective membrane; Hct: conductivity; Hb: co-ox spectrophotometry; Na, Cl, iCa, K: ion selective potentiometry; lactate, glucose, BUN: MSS sensor enzyme yes, 6 models in series
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	na na na na na na	reagent and electrode depends on model, contact Roche dependent on use — room-temperature storage 12 months (reagents)/18 months (electrodes)
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	depends on model, contact Roche na reagents: 1 yr depends on sample volume/same	depends on model, contact Roche 3 reagent: 1 year; electrode: 18 months onboard; membrane kit: na, cartridge kit: na volume dependent/volume dependent
Calibrations required Calibration frequency Calibrants traceable to NIST standards Internal QC program recommended QC features Remote control of device from laboratory System can use LOINC to transmit results to LIS How labs get LOINC codes for reagent kits	1 & 2 point (automatic) 1 point: 30 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 —	1 & 2 point (automatic) 1 point: 30 min; 2 point: 8 hrs yes CAP and JCAHO guidelines L-J plots, comparable plot, lot-to-lot comparisons, statistical calcs., monthly cum. reports, onboard, eQAP yes yes Web, package insert
Detects clots within analysis chamber Specimen types suitable for device Acceptable anticoagulants Sampling technique Suitable for samples from well neonates/Sick neonates Sample size for complete panel of analyte results Sample size differs with No. of analytes selected Recommended collection device Provides for patient temperature corrected results Time from sample introduction to result availability Max. No. of patient samples per hr/Max. No. of measured parameters per hr Optimal throughput when calibrated and awaiting specimens Calibration can be interrupted to perform stat sample Contraindications Known interferences Restrictions based on Hct Sampler has self-wiping probe	yes 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	yes plasma, serum, whole blood, capillary, arterial, venous EDTA, heparin, citrate aspiration, injection, capillary transfer & fill, microsamples yes/yes 200 µL for full panel yes, BG: 40 µL; ISE: 40 µL; co-ox 44 µL, glucose, lactate, BUN: 75 µL — ~1 min (test dependent) 30 patients per hr (full panel)/360 tests per hr 30 patients per hr (full panel) yes no none no yes
Time required for maintenance by lab personnel Onboard diagnostics for troubleshooting/Limited to software Diagnostics performed through modem Training & certification program for user	weekly: 5 min; 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)	daily: 2 min, monthly: 5 min, quarterly: 5 min yes/no yes yes (2.5 days on site)
Method of analyst ID in system Response for hardware & software failure/User ID & QC failure/ Calibration & power failure Supports bar-code scanning of User can search for and review previous patient results on screen Built-in printer/Data port Information on hard copy report	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, reagent & 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	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, expir. yes yes/RS-232, parallel, Ethernet options can be customized; direct & measured parameters
Analyzer connects to Interface standards supported To upload patient & QC results, how analyzer connects to external system Information included in transmission from analyzer to external system Hardware/Software for data management system No. of different management reports system produces Contents downloaded from DMS to analyzer System connected (live installations) to which LISs, HISs • using screen animation, screen scraping • using standard HL7 interface • using proprietary protocol interface Use a third-party interfacing tool, engine for LIS, HIS interfaces	data management system, which connects to LIS/HIS; directly to LIS/HIS (both options) ASTM 1394, 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)	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 device unique identifier, oper. & patient IDs, results, QC identifier MAS RALS-Plus, DataCare POC 50 (RALS-Plus), 40 (DataCare POC) valid control values, valid operator IDs, critical patient results — — — Data Innovations
Distinguishing features (provided by vendor)	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	only FDA-510(k)-cleared pH pleural fluid results; 42-day onboard reagent packs; Roche AutoQC with up to 40 days of QC covered; screen sharing and remote protected access with OMNI-Link and Axeda instrument software

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In vitro blood gas analyzers

<p>Part 13 of 13</p> <p>See related comments, page 24</p>	<p>Siemens Medical Solutions Diagnostics 511 Benedict Ave. Tarrytown, NY 10591 800-255-3232 www.siemens.com/diagnostics</p>	<p>Siemens Medical Solutions Diagnostics 511 Benedict Ave. Tarrytown, NY 10591 800-255-3232 www.siemens.com/diagnostics</p>
<p>Name of device/First year sold/No. of analyzers sold in 2006 No. of devices sold in U.S./Outside U.S./List price Dimensions in inches (H x W x D)/Weight</p>	<p>Rapidpoint 400 Series/2001 na/na/\$38,000 21.5 x 11.5 x 16 in./34 lbs</p>	<p>RapidLab 1200/2005/— na/na/— 22.75 x 20.5 x 21 in./65–68 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⁻, 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>pH, pCO₂, pO₂, tHb, Na⁺, K⁺, Cl⁻, iCatt, lactate, glucose, COOX fractions Hct, O₂SAT, BE, TCO₂, HCO₃⁻, plus additional parameters measured, tracked pH: potentiometry; pCO₂: Severinghaus electrochemical; pO₂: amperometric; Hct: calculated; tHb: spectrophotometric; Na, Cl, iCa, K: ISE; lactate: lactate oxidase; glucose: glucose oxidase yes, series offers different analyte options yes, through local sales rep 1 yr no 7–10 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 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 (multiuse cartridge) na 400, 750 samples varies based on configuration refrigeration 9 months</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>1 measurement cartridge, 1 wash-waste cartridge 1 measurement cartridge, 1 wash-waste cartridge 9 months varies based on configuration</p>	<p>2 cartridges na electrode: varies based on type, cartridge reagent: 8 months, wash: 6 months; AQC cartridge: 9 months na/na</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; 2 point: 2 hrs yes AQC cartridge, fully user programmable AQC cartridge, L-J plots, comparable plots, statistical calculations, monthly cum. reports (available with external system) yes yes —</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>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 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>yes whole blood, capillary, mixed venous, arterial, venous heparin aspiration yes/yes 95 µL–175 µL yes (microsample mode available) syringe or capillary yes 60 seconds 24/up to 336 tests 24 samples per hr yes none contact vendor none 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>maintenance free yes/no no yes</p>	<p>weekly: 5 min; monthly: 5 min yes/no no yes, 1–2 days</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) 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>password (customizable) diagnostic codes prompt the operator/diagnostic codes/ recalibrates, generates diagnostic code if unsuccessful patient ID yes yes/RS-232, Ethernet operator & patient IDs, accession No., results, temperature, patient demographics, others</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) LIS 3 direct serial, hospital network device unique identifier, operator & patient IDs, results, QC identifier RapidComm Data Management System customizable valid control values, valid operator IDs — yes yes yes</p>	<p>data management system, which connects to LIS/HIS; directly to LIS/HIS (both options) LIS 4 direct serial, hospital network device unique identifier, operator & patient IDs, results, QC identifier RapidComm Data Management System customizable valid control values, valid operator IDs na yes yes yes</p>
<p>Distinguishing features (provided by vendor)</p>	<p>no maintenance, multiuse cartridge; fast time to patient results; onboard audio-video training videos; auto QC</p>	<p>cartridge-based, high-throughput analyzer with minimal maintenance; fast time to patient results; onboard troubleshooting tutorials</p>

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