Bedside glucose testing systems

Part 1 of 6

	Abbott Diabetes Care 1420 Harbor Bay Parkway Alameda, CA 94502 510-749-5400 www.abbottdiabetescare.com	Arkray Inc. 5198 W. 76th St. Edina, MN 55439 800-818-8877 www.arkrayusa.com
Name of instrument/First year sold	Precision Xceed Pro Blood Glucose and Beta-Ketone Monitoring System/2007	Assure Pro/2006
Professional or home use	professional and home use	professional use
List price	—	free with competitive trade out
Units sold in U.S./Outside U.S./In 2008	—	—
Part of series of similar or related models	yes	yes
Dimensions (H x W x D)/Weight	19.7 cm (7.7 in) × 7.5 cm (2.96 in) × 5.33 cm (2.1 in)/256 g (9 oz)	4.1 × 2.4 × 1 in/2.5 oz without battery
Analytical method/Technology/Enzyme system used	glucose-specific GDH-NAD enzyme and low applied voltage to minimize interference; beta-hydroxybutyrate, the predominant blood ketone DKA	glucose oxidase
Price per disposable reagent system unit	—	contact sales representative
No. of dispos. reag. system units per basic package	glucose: 100 strips; ketone: 50 strips	50 or 100
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/Reag. unit storage requirements	15–18 months/4°–30°C	18 months/room temperature
Digital readout size/Keypad input capability	3.06 mm (normal), 8.16 mm (results)/menu selection, numeric, alphabetic	—
How results are displayed	true values	true values
Specimen types/Sampling techniques	whole blood/drop, capillary transfer, touchable strips	whole blood/capillary transfer
Minimum specimen volume required	glucose: 0.6 µL; ketone: 1.5 µL	1 µL
Suitable for samples from well/Sick neonates	yes/yes	no/no
Time from sample intro. to result availability	glucose: 20 seconds; ketone: 10 seconds	10 seconds
Batteries used/No. used/Avg. life of one set	AA or NiMH rechargeable/2/—	1.5 V alkaline AAA/2/up to 5,000 tests
Avg. expected life of device/Mean time between failures	—	—
Device warranty/Service options	1 year, lifetime replacement with reagent contract/24-hour replacement	5 years/—
Loaners provided	yes	yes
User list or user group	yes, list available upon request	no
Toll-free No. for customer questions/Hours	877-529-7185/24 hours, 7 days	800-818-8877/24 hours, 7 days
Training and certif. program/No. training days provided	yes/depends on number of operators	yes/as needed
Avg. time for lab to complete maintenance	none	weekly: 5 minutes
Special cleansing procedures	no	no
Internal QC recommended or required	as defined by facility or institutional policy	as specified by accreditation
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	70.5 mg/dL, CV=5.0% (4,259 labs)	—
• 100–200 mg/dL	121.4 mg/dL, CV=4.9% (8,177 labs)	—
• >400 mg/dL	409.6 mg/dL, CV=4.8% (8,052 labs)	—
• Program name, year/Challenge No./Level of mean glucose challenge sample	CAP Whole Blood Glucose Survey, WBG-C, 2008/—	—
Accuracy/Compared to what reference method or device	capillary blood: y=0.94x + 1.6; r=0.98/YSI	slope=0.91, r=0.96/YSI glucose analyzer
Precision/Compared to what reference method or device	blood samples: CV 3.0% to 3.6%/YSI	4.5%/—
Linear range	glucose: 20–500 mg/dL; ketone: 0.0–8.0 mmol/L	20–600 mg/dL
Suggested dynamic, measurement range	glucose: 20–500 mg/dL; ketone: 0.0–8.0 mmol/L	20–600 mg/dL
Contraindications	per labeling	yes
Known interferences/High-altitude interference	per labeling/no	per labeling/no, tested up to 10,000 feet
Restrictions based on hematocrit	yes, glucose: 20–70%; ketone: 30–60%	yes, 30%–55%
Electronic, optical function checks	battery, bar-code scanner, database, and temperature checks performed during power-up of meter	automatic electronic
Sample quantity checks	fill-trigger electrode on each test strip specifically designed to start the test when sufficient sample is detected	—
When auto lock or shutdown occurs	user ID failure, QC failure	—
User defines QC lockout intervals/Lockout can be circumvented	yes/no	no/—
Device supports bar-code scanning of	operator & patient identifiers, reag. lot numbers, comment codes, control and linearity lot Nos.	no bar-code scanner
Method of analyst ID/ID required	bar-code or manual ID entry/analyst ID optional	—
Internal memory size/Max. No. patient results stored	1,000 control test results, 6,000 operators, 6,000 patient IDs, 2,500 patient test results, 18 glucose test strip lots, 20 proficiency test results, 20 glucose linearity test results (1 panel, 5 levels, 4 replicates per level)	250 tests with time & date stamp/250 test results
Information transfer capability:		
• Meters connect to	Precision Web data management system, which in turn connects to LIS/HIS	—
• How meters are connected to external system to upload results/No. installations	direct serial, modem dial-in, hospital network/—	—
• Info. contained in transmission to external system	device unique identifiers, operator and patient IDs, results, QC identifiers, strip lots, comment codes, test dates & times	—
Hardware/software for data mgmt. system	Enterprise multi-user Web-based system running on highly redundant Dell server	—
No. of different mgmt. reports system can produce	25	—
Contents downloaded from DMS to meter	strip lot Nos., valid control values, valid operator IDs, patient list, QC lockout and upload lockout parameters	—
System connected (live installations) to which LISs/HISs:		
• using screen animation/screen scraping	Cerner, Misys, PerSe, Meditech, SoftLab, CPSI, Vista, CHCS, GE Medical, ADAC, HBOC Star, McKesson Horizon Lab, Siemens Novius Lab	—
• using standard HL7 interface	Cerner, Misys, PerSe, Meditech, SoftLab	—
• using proprietary protocol interface	none	—
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	yes/Sybase	no
Distinguishing features (provided by vendors)	TrueID: technology to identify patients by name, gender, date of birth, alphanumeric data entry; TrueMeasure: test-strip technology detects adequate sample and minimizes chemical interference; TrueAccess: notification and lock-out technology helps ensure compliance with procedures	24-hour optional control solution reminder; top-of-meter strip insertion; strip release button; backlight display

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Survey editor: Raymond Aller, MD

Bedside glucose testing systems

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	Arkray Inc. 5198 W. 76th St. Edina, MN 55439 800-818-8877 www.arkrayusa.com	HemoCue Inc. 40 Empire Dr. Lake Forest, CA 92630-2244 800-323-1034 www.hemocue.com
Name of instrument/First year sold	Assure 4/2007	Glucose 201 DM Analyzer/2005
Professional or home use	professional use	professional use
List price	free with competitive trade out	—
Units sold in U.S./Outside U.S./In 2008	—	—
Part of series of similar or related models	yes	yes
Dimensions (H x W x D)/Weight	3.9 × 2.3 × 1.0 in/2.5 oz without batteries	6.7 × 3.7 × 2 in/0.77 lb
Analytical method/Technology/Enzyme system used	glucose oxidase	absorbance photometry/glucose dehydrogenase
Price per disposable reagent system unit	contact sales representative	—
No. of dispos. reag. system units per basic package	50 or 100	25 in vial/box; 4 vials/boxes per package
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/Reag. unit storage requirements	18 months/room temperature	9 months from manufacture date/refrigeration
Digital readout size/Keypad input capability	—/none	varies from 8 to 28 points/menu selection, numeric, alphabetic
How results are displayed	true values	calculated values (plasma equivalent values [11%] measured whole blood value x 1.11)
Specimen types/Sampling techniques	whole blood/capillary transfer	whole blood (capillary, venous, arterial)/exact amount of blood drawn into cuvette by capillary force
Minimum specimen volume required	1.5 µL	5 µL
Suitable for samples from well/Sick neonates	no/no	yes/no (may require laboratory confirmation)
Time from sample intro. to result availability	10 seconds	40–240 seconds
Batteries used/No. used/Avg. life of one set	1.5 V alkaline AAA/2/3,000 tests	rechargeable lithium ion supplied by HemoCue/—/several years
Avg. expected life of device/Mean time between failures	—	7 years/>5 years
Device warranty/Service options	5 years/—	2 years, at no additional cost/replacement of defective analyzer
Loaners provided	yes	yes
User list or user group	no	no
Toll-free No. for customer questions/Hours	800-818-8877/24 hours, 7 days	800-323-1674, 6 AM–5 PM PST
Training and certif. program/No. training days provided	yes/as needed	yes/~1 hour per device purchased
Avg. time for lab to complete maintenance	weekly: 5 minutes	daily: ≤5 minutes
Special cleansing procedures	no	no
Internal QC recommended or required	as specified by accreditation	one level of controls prior to patient testing, each day of testing
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	—	not available
• 100–200 mg/dL	—	3.8
• >400 mg/dL	—	≥272 mg/dL=2.9
• Program name, year/Challenge No./Level of mean glucose challenge sample	—	Equalis (Swedish PT program), 2003/2003–03; 2003–07/272 mg/dL; 120 mg/dL
Accuracy/Compared to what reference method or device	slope=1.010/r=0.993/ YSI glucose analyzer	±10% or ±6% mg/dL; corr=0.994/wet chemical glucose dehydrogenase, ID-GCMS
Precision/Compared to what reference method or device	4.1%/—	within run CV 1.9% (108 mg/dL)/—
Linear range	30–550 mg/dL	0–444 mg/dL
Suggested dynamic, measurement range	30–550 mg/dL	0–444 mg/dL
Contraindications	no	no
Known interferences/High-altitude interference	per labeling/no (tested up to 7,000 feet)	grossly lipemic samples, methemoglobin, glucosamine/no
Restrictions based on hematocrit	yes, 30%–55%	no
Electronic, optical function checks	sumcheck functions for electronics and software, no optics	internal electronic self-test automatically checks that the instrument's optronic unit is working properly
Sample quantity checks	—	visual inspection
When auto lock or shutdown occurs	—	user ID failure if configured to require operator ID; QC failure if configured to require quality control; number of device errors
User defines QC lockout intervals/Lockout can be circumvented	no/—	yes/no (stat testing may be allowed; 1–100 tests after QC interval)
Device supports bar-code scanning of	no bar-code scanner	operator & patient identifiers, reagent lot Nos., comments, log entries, lab ID
Method of analyst ID/ID required	—	alphanumeric manual entry or bar-code scan entry/optional
Internal memory size/Max. No. patient results stored	50-test memory/50	4,000 patient tests/500 QC tests, 500 analyzer log entries/4,000
Information transfer capability:		
• Meters connect to	—	analyzer connects to 201 DM docking stations (data management system, which can further transmit data)
• How meters are connected to external system to upload results/ No. installations	—	direct USB/hospital network
• Info. contained in transmission to external system	—	device unique identifiers, operator & patient IDs, results, QC identifiers, POCT-1A standard compliant, date/time, lab ID, flags
Hardware/software for data mgmt. system	—	PC/server/HemoCue 201 DM–DMS software
No. of different mgmt. reports system can produce	—	15 different templates, custom reports based on templates, multiple export formats
Contents downloaded from DMS to meter	—	cuvette lot No., valid control values, valid operator IDs, comments, analyzer log entries, analyzer configuration
System connected (live installations) to which LISs/HISs:	—	
• using screen animation/screen scraping	—	—
• using standard HL7 interface	—	—
• using proprietary protocol interface	—	—
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	—	Telcor QML/Quick-Linc, Radiometer Radiance, Conworks POCcelerator
Distinguishing features (provided by vendors)	small sample size: 1.5 µL; fast test time: 10 seconds; large strip handle	POCT-1A compliant; indicated for diagnosis of diabetes mellitus; not hematocrit dependent

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	HemoCue Inc. 40 Empire Dr. Lake Forest, CA 92630-2244 800-323-1034 www.hemocue.com	ITC 8 Olsen Ave. Edison, NJ 08820 800-631-5945 www.itcmed.com
Name of instrument/First year sold	Glucose 201 Analyzer/2002	IRMA TRUpoint (glucose module)
Professional or home use	professional use	professional use
List price	—	$350
Units sold in U.S./Outside U.S./In 2008	—	—
Part of series of similar or related models	yes	no
Dimensions (H x W x D)/Weight	6.3 × 3.4 × 1.7 in/0.77 lb	5 × 9.5 × 13.5 in/6 lb (IRMA TRUpoint)
Analytical method/Technology/Enzyme system used	absorbance photometry/glucose dehydrogenase	glucose only: reflectance photometry, glucose oxidase
Price per disposable reagent system unit	—	—
No. of dispos. reag. system units per basic package	25 in vial/box; 4 vials/boxes per package	50 strips
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/Reag. unit storage requirements	9 months from manufacture date/refrigeration	strip: 18 months/room temperature
Digital readout size/Keypad input capability	0.5 in/none	4.5 x 2.5 in/menu selection, numeric, alphabetic
How results are displayed	plasma equivalent values	true values
Specimen types/Sampling techniques	whole blood, venous, capillary, or arterial/exact amount of blood is drawn into the cuvette by capillary force	whole blood/drop, capillary transfer, touchable strip
Minimum specimen volume required	5 µL	1 drop
Suitable for samples from well/Sick neonates	—	yes/yes
Time from sample intro. to result availability	40–240 seconds	<45 seconds
Batteries used/No. used/Avg. life of one set	AA/4/150 hours	rechargeable NIMH battery/1/3 years
Avg. expected life of device/Mean time between failures	7 years/>5 years	>5 years/<3% warranty return rate
Device warranty/Service options	2 years at no extra cost/—	1 year/extended warranty service available
Loaners provided	yes	24-hour replacement upon request
User list or user group	—	yes
Toll-free No. for customer questions/Hours	800-323-1674, 6 AM–5 PM PST	800-631-5945/24 hours, 7 days
Training and certif. program/No. training days provided	yes/as needed	yes/depends on No. of operators
Avg. time for lab to complete maintenance	daily: ≤5 minutes	clean glucose module as needed, 2 minutes
Special cleansing procedures	no	no
Internal QC recommended or required	system must be verified on testing days using commercially available controls	based on hospital-specific policy
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	not available	4.39%
• 100–200 mg/dL	3.8	3.44%
• >400 mg/dL	≥272 mg/dL=2.9	4.97%
• Program name, year/Challenge No./Level of mean glucose challenge sample	Equalis (Swedish PT program), 2003/2003-03; 2003-07/272 mg/dL; 120 mg/dL	data from 2000 AACC poster
Accuracy/Compared to what reference method or device	±10% or ±6 mg/dL; corr=0.994/wet chemical glucose dehydrogenase, ID-GCMS	r >0.98/YSI
Precision/Compared to what reference method or device	within run CV 1.9% (108 mg/dL)/—	3.44–4.97 CV across runs/—
Linear range	0–444 mg/dL	0–500 mg/dL
Suggested dynamic, measurement range	0–444 mg/dL	0–500 mg/dL
Contraindications	no	excessive H_2O loss or dehydration
Known interferences/High-altitude interference	grossly lipemic samples, methemoglobin, glucosamine/no	sodium fluoride/no
Restrictions based on hematocrit	no	yes, <25% high results, >60% low results
Electronic, optical function checks	internal electronic self-test automatically checks that the instrument's optronic unit is working properly	optical self-zeroing; has LED to detect errors & internal check strip that is part of strip holder, automatically done with every test
Sample quantity checks	visual inspection	uses LED to determine sufficient quantity
When auto lock or shutdown occurs	—	user ID failure, QC failure, lockout if reagent expired or if control lot & reagent not entered
User defines QC lockout intervals/Lockout can be circumvented	no/no	yes/no
Device supports bar-code scanning of	no bar-code scanner	bar-code scanner available
Method of analyst ID/ID required	—	touchscreen/optional or required, QA user setup
Internal memory size/Max. No. patient results stored	—	4 MB RAM, 4 MB ROM, 256 KB nonvolatile/200 patient results
Information transfer capability:		
• Meters connect to	—	data management system, which connects to LIS/HIS; also directly to LIS/HIS
• How meters are connected to external system to upload results/ No. installations	—	direct serial/—, modem dial-in/—, Ethernet/—
• Info. contained in transmission to external system	—	device unique identifiers, operator & patient IDs, results, QC identifiers, results dates & times, strip/material lots, up to 3 alphanumeric notes, result flags, reference range/QC limits, software revision, sample types
Hardware/software for data mgmt. system	—	nondedicated IBM compatible PC, Integrated Data Management System
No. of different mgmt. reports system can produce	—	6
Contents downloaded from DMS to meter	—	strip lot Nos., valid control values, valid operator IDs
System connected (live installations) to which LISs/HISs:	—	
• using screen animation/screen scraping	—	major vendors
• using standard HL7 interface	—	major vendors
• using proprietary protocol interface	—	none
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	—	yes, through laboratory data systems
Distinguishing features (provided by vendors)	CLIA waived; indicated for diagnosis of diabetes mellitus; not hematocrit dependent; lab verification of patient home meter	integrated workstation with IRMA TRUpoint (blood gas, electrolytes, BUN, creatinine, lactate, cartridge glucose test, Hct); 1 user interface, 1 in-service program, 1 data management system

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Bedside glucose testing systems

Part 4 of 6	LifeScan Inc. Healthcare Professional Line 1000 Gibraltar Dr., Milpitas, CA 95035-6312 800-524-7226 www.lifescan.com	Medtronic MiniMed Inc. 18000 Devonshire St. Northridge, CA 91325 800-646-4633 www.minimed.com
Name of instrument/First year sold	SureStepFlexx/2000	iPro Continuous Glucose Monitor (CGM)/2008
Professional or home use	professional use	professional use
List price	$1,200 with bar-code scanner/$1,300 with bar-code scanner, meter unlock, and bar-code scan required features/$850 without bar-code scanner	$35 per unit for glucose sensor; $1,299 for CGMS iPro starter kit
Units sold in U.S./Outside U.S./In 2008	>44,000/>4,000/>3,000	—
Part of series of similar or related models	yes	yes (third-generation professional CGM system)
Dimensions (H x W x D)/Weight	6.34 × 3.55 × 1.63 in/12.5 oz (with bar-code scanner), 12.1 oz (without)	—/<5 grams
Analytical method/Technology/Enzyme system used	reflectance photometry/glucose oxidase	glucose oxidase
Price per disposable reagent system unit	by contract, volume	$35 unit glucose sensor (disposable)
No. of dispos. reag. system units per basic package	Two 25-strip vials (50 strips per box)	10 per box
No. of times analyses performed using 1 reag. system unit	1	1 sensor lasts 72 hours
Dispos. units shelf life/Reag. unit storage requirements	18 months unopened/<30°C (86°F); away from heat, direct sunlight	6 months/non-refrigeration 36°–80°F (2°–27°C)
Digital readout size/Keypad input capability	18-point font (16 pixels high, 8 pixels wide)/menu select., numeric, alphabetic	no patient monitor interface/blinded glucose values, retrospective data
How results are displayed	true values	at time of iPro recorder download, system displays retrospective only/numerical agreement; avg. difference between glucose sensor and glucose meter of –5.4 mg/dL, daily median correlation coefficient of 0.92, calibration using blood glucose meters daily
Specimen types/Sampling techniques	whole blood (capillary, venous, arterial, neonatal)/drop, capillary transfer, touchable strip, off-meter dosing	continuous monitoring and sampling of interstitial fluid glucose levels
Minimum specimen volume required	5 µL, maximum 30 µL	—
Suitable for samples from well/Sick neonates	yes/yes	no/yes (with diabetes)
Time from sample intro. to result availability	15-second minimum	retrospective analysis after disconnection
Batteries used/No. used/Avg. life of one set	AA/3/1,000 test minimum	rechargeable battery, iPro CGM charger, AAA/1/—
Avg. expected life of device/Mean time between failures	5-year minimum/<10% warranty return rate	1 year/—
Device warranty/Service options	1 year/extended service agreements available	6 months for iPro Recorder/no warranty on disposables
Loaners provided	24-hour replacement with new device	no
User list or user group	yes (contact SureStepFlexx product manager)	no
Toll-free No. for customer questions/Hours	800-524-7226/24 hours, 7 days, multiple languages	800-646-4633/—
Training and certif. program/No. training days provided	yes/as negotiated	yes (training only)/~1 day
Avg. time for lab to complete maintenance	<1 minute	none
Special cleansing procedures	no	no
Internal QC recommended or required	as defined by hospital policy	none
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	2.5%	—
• 100–200 mg/dL	2.9%	5% (40–400 mg/dL) in vitro
• >400 mg/dL	2.4%	—
• Program name, year/Challenge No./Level of mean glucose challenge sample	data from 2000 & 2001 AACC posters	CGMS 1999, CGMS Gold 2003, iPro CGM 2008
Accuracy/Compared to what reference method or device	r>0.98/YSI	coefficient of variation (CV) of 5%/fingerstick blood glucose measurements
Precision/Compared to what reference method or device	3.44–4.97 CV across runs/—	—/glucose meters, HemoCue, YSI (any and all)
Linear range	0–500 mg/dL	—
Suggested dynamic, measurement range	0–500 mg/dL	40–400 mg/dL
Contraindications	excessive water loss or dehydration	not recommended for use by those with impaired vision or hearing
Known interferences/High-altitude interference	sodium fluoride/no	possibly MRI/no
Restrictions based on hematocrit	adults: 25%–60%; neonates: 25%–65%	no
Electronic, optical function checks	automatic electronic and optical checks with each test	test plug, 24–29nA
Sample quantity checks	test strip color confirmation dot when adequate sample applied; meter error messages	none
When auto lock or shutdown occurs	user ID failure, QC failure, failure to transfer data	none
User defines QC lockout intervals/Lockout can be circumvented	yes/yes, automatic meter unlock feature requires no user intervention	no/no
Device supports bar-code scanning of	operator & patient identifiers, reagent (strip) lot Nos., control solution lot Nos., meter serial Nos.	no bar-code scanner
Method of analyst ID/ID required	unique alphanumeric ID/optional (defined by location)	at time of monitor download/optional
Internal memory size/Max. No. patient results stored	256 KB/1,500 patient +QC tests, 50-test strip lots and 50 QC lots	up to 14 days continuous data/288 readings per day
Information transfer capability:		
• Meters connect to	OneTouch DataLink data management system via wireless network, network and modem connectivity solutions. OneTouch DataLink can be interfaced to LIS/HIS	iPro Recorder connects via ComLink to a serial port
• How meters are connected to external system to upload results/No. installations	OneTouch DataLink Connect connectivity solutions; wireless/network, modem connectivity/1400 hospital sites, DataLink Interface >600	serial port or USB port depending on meter/—
• Info. contained in transmission to external system	device unique identifiers, operator & patient IDs, results, QC identifiers, result flags, location/site	sensor values, meter values and events (meals, insulin, exercise and other)
Hardware/software for data mgmt. system	hardware independent/OneTouch DataLink data management system installation CD for Windows Vista & XP Pro; Telcor QML; OneTouch DataLink Web using Microsoft Windows Server 2003/2008	ComLink for iPro CGM and Solutions Software
No. of different mgmt. reports system can produce	12 standard, unlimited customized reports, TGC advisor	5 standard unlimited customized reports
Contents downloaded from DMS to meter	strip lot Nos., valid control values, valid operator IDs, critical value ranges, comment codes	—
System connected (live installations) to which LISs/HISs:		does not interface LIS or HIS, a report from software–nontransferable
• using screen animation/screen scraping	Cerner Citation, Cerner Classic, Cerner Premier, CHCS, HMS, McKesson ALG, McKesson Star Financial, McKesson Star Lab, Meditech Magic, RPMS, Sunquest, SoftLab Non-GUI, VistA	no
• using standard HL7 interface	Cerner Classic, Cerner Millennium, CPSI, Eclypsis, EPIC, Iatrics, McKesson Horizon Lab, McKesson Paragon, McKesson Horizon Clinicals, Medisserve, MediSolutions, Meditech Client Server, Meditech Magic, Meditech MagicHCA, Sunquest, Sunquest IGO, Omnetech, OpusLab, Siemens Invision, Siemens Novius Lab, Siemens LCR, SoftLab, TripleG, VistA, Repositories and Engines	no
• using proprietary protocol interface	none	no
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	yes, Telcor QML	no
Distinguishing features (provided by vendors)	no risk of interference from maltose, xylose, or galactose; off-meter dosing helps with infection control policies; configurable bar-code scanning options—allows truncation of leading and trailing characters; bar-code scan required feature; unique meter unlock; hardware-indepen. OneTouch DataLink data mgmt. software; wireless connectivity; compatible w/Telcor's QML; flexible database options; Citrix support	continuous glucose values collected (every 5 minutes); up to 14 days of data; blood glucose values from bg meter and events (meals, insulin, exercise) downloaded into Solution Software

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	Nova Biomedical Sales Department info@novabio.com 200 Prospect St. Waltham, MA 02454 781-894-0800 or 800-458-5813 www.novabiomedical.com	Roche Diagnostics Accu-Chek Customer Care Service Center 9115 Hague Rd., Indianapolis, IN 46256 800-440-3638 www.roche-diagnostics.us
Name of instrument/First year sold	StatStrip Glucose Monitoring System/2006	AccuData GTS, 1994; AccuData GTS Plus, 2000
Professional or home use	professional use	professional use
List price	call for pricing, includes bar-code reader, spare battery, quick reference guide	$550
Units sold in U.S./Outside U.S./In 2008	—	40,000*/5,000/—
Part of series of similar or related models	yes	yes
Dimensions (H × W × D)/Weight	6.0 × 3.25 × 1.8 in/0.8 lb	11 × 8.75 × 4 in/5 lb
Analytical method/Technology/Enzyme system used	electrochemistry	biosensor–glucose dehydrogenase
Price per disposable reagent system unit	pricing based on volume	contingent on contract price
No. of dispos. reag. system units per basic package	50 strips per vial and 100 per box	50 strips per vial
No. of times analyses performed using 1 reag. system unit	1	1
Dispos. units shelf life/Reag. unit storage requirements	24 months from date of manufacture/none	18 months, stable until expiration on vial/<90°F, do not freeze
Digital readout size/Keypad input capability	varies and is defined by the particular field/numeric, alphabetic	4 lines by 20 characters LCD/menu selection, numeric
How results are displayed	true values	true values
Specimen types/Sampling techniques	whole blood/drop (arterial, venous, capillary, neonatal)	whole blood/arterial, venous, capillary, neonate (including cord blood)
Minimum specimen volume required	1.2 µL	4 µL
Suitable for samples from well/Sick neonates	yes/yes	yes/yes
Time from sample intro. to result availability	6 seconds	26 seconds
Batteries used/No. used/Avg. life of one set	3.7 Li Polymer (rechargeable/replaceable)/1/24–36 months	3 V lithium/2/~700 tests
Avg. expected life of device/Mean time between failures	5+ years/—	5 years/10,000 tests
Device warranty/Service options	2 years (extended 5-year warranty at additional cost)/meter replacement	AccuData GTS Plus/GTS system will be free from defects in materials & workmanship through life of Accu-Chek Comfort Curve test strip contract; overnight replacement, according to warranty policy, is available 24/7 365 days per year
Loaners provided	yes	replaced under warranty
User list or user group	no	yes (contact local account manager)
Toll-free No. for customer questions/Hours	800-458-5813/24 hours, 7 days, all year	800-440-3638/24 hours, 365 days per year
Training and certif. program/No. training days provided	yes/defined during implementation planning	yes/site-specific according to No. of employees
Avg. time for lab to complete maintenance	no user maintenance	none
Special cleansing procedures	no	no
Internal QC recommended or required	CLIA requirements 2 levels per day	daily, 2 levels
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	—	53.8 mg/dL SD=4.1 (6,088 labs)
• 100–200 mg/dL	—	191.4 mg/dL CV=4.7% (3,096 labs)
• >400 mg/dL	—	228.5 mg/dL CV=4.6% (6,099 labs)
• Program name, year/Challenge No./Level of mean glucose challenge sample	—	CAP, 2001/WBG-C/see above
Accuracy/Compared to what reference method or device	R2=0.9978, slope=1.0127–2.0975/YSI 2300	y=0.991 x + 8.4, r=0.980/glucose hexokinase-Hitachi
Precision/Compared to what reference method or device	within run (whole blood=1.9%–3.6%) & (day to day=3.4%–4.7%) linearity standards/—	controls: low SD=2.83 mg/dL, mid CV=3.08%, high CV=2.82%; blood: low SD=1.5 mg/dL, mid CV=3.2%, high CV=3.2%/glucose hexokinase
Linear range	10–600 mg/dL	10–600 mg/dL
Suggested dynamic, measurement range	10–600 mg/dL	10–600 mg/dL
Contraindications	—	per labeling
Known interferences/High-altitude interference	none/no, operates at altitudes up to 15,000 feet	per labeling/none up to 10,150 feet
Restrictions based on hematocrit	none (no Hct interference)	yes, glucose <200 mg/dL, 20%–65%; glucose >200, 20%–55%
Electronic, optical function checks	electronic checks for out-of-range glucose results, dosing, out-of-range Hct results	meter cradle communication with Advantage meter, GTS with code key, battery voltage test, internal database memory check, internal configuration check
Sample quantity checks	RapidFill sampling electronically checks for correct strip dosing	built-in electronic strip check, visual confirmation of sample volume
When auto lock or shutdown occurs	options include user ID failure, QC failure, required docking for data transfer	user ID failure (valid op.), QC failure, patient ID length, incorrect code key, incorrect Advantage meter
User defines QC lockout intervals/Lockout can be circumvented	yes/no, not if configured	yes/yes (information management system identifies operators who violate hospital policy)
Device supports bar-code scanning of	operator & patient identifiers, reagent, lot No., QC lots	operator & patient identifiers, comment codes
Method of analyst ID/ID required	medical record ID No., medical billing ID No., Accession ID No./ID required	numeric input or bar-code wand scan/yes
Internal memory size/Max. No. patient results stored	1,000 patient samples, 200 QC samples, 4,000 operators/1,000 tests	1,000 total patient, control, linearity, proficiency tests/1,000
Information transfer capability:		
• Meters connect to	Instrument Manager (NovaNet or Laboratory Data Systems AegisPOC) to Data Manager (Telcor QML/Quick-Linc or AegisPOC) then to LIS if required	information management system, which in turn connects to LIS/HIS
• How meters are connected to external system to upload results/ No. installations	hospital network/—	direct serial/—, modem dial-in/—, hospital network/—
• Info. contained in transmission to external system	device unique identifier, operator & patient IDs, results, QC identifiers	device unique identifiers, operator & patient IDs, results, QC identifiers, strip lot Nos., download location, comment codes, proficiency & linearity samples
Hardware/software for data mgmt. system	connects to Telcor QML and Laboratory Data Systems AegisPOC	MAS RALS-Plus, MAS RALS-Lite†, MAS RALS-Notebook†
No. of different mgmt. reports system can produce	provided by Telcor and Laboratory Data Systems	varies by Data Manager (customer defined)
Contents downloaded from DMS to meter	strip lot numbers, valid control values, valid operator IDs, patient demographics, configuration files, physician IDs, diagnostic codes	strip & QC lot Nos., valid operator IDs, valid control values, linearity values
System connected (live installations) to which LISs/HISs:	available through Telcor & Laboratory Data Systems	
• using screen animation/screen scraping	available through Telcor & Laboratory Data Systems	all major LIS vendors including Cerner, Misys, McKesson, Meditech, SoftLab, Siemens, SIA Molis, Opus, others**
• using standard HL7 interface	yes	—
• using proprietary protocol interface	no	—
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	yes, Telcor QML/Quick-Linc, Laboratory Data Systems AegisPOC	MAS
Distinguishing features (provided by vendors)	measures and eliminates interferences from hematocrit, oxygen, acetaminophen, ascorbic acid, uric acid, and other electrochemical substances; no interference from maltose, galactose, or xylose; no calibration codes required; results reported in 6 seconds using 1.2 µL of sample	proven bi-directional network connection from AccuData GTS/GTS Plus to LIS/HIS; ADT data interface with RALS-Plus/DataCare POC; uses the Accu-Chek Comfort Curve test strip; universal sampling due to oxygen-independent chemistry, with reliable results at varying hematocrit levels

**combined AccuData GTS and AccuData GTS Plus sales*
†Roche exclusive
***both scripted/HL7 are available*

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

Bedside glucose testing systems

Part 6 of 6	Roche Diagnostics Accu-Chek Customer Care Service Center 9115 Hague Rd., Indianapolis, IN 46256 800-440-3638 www.roche-diagnostics.us	YSI Life Sciences Jamie Lussier jlussier@ysi.com 1725 Brannum Lane, Yellow Springs, OH 45387 800 659-8895 www.ysilifesciences.com
Name of instrument/First year sold	Accu-Chek Inform System/2001	YSI 2300 STAT Plus Glucose & Lactate Analyzer/1989
Professional or home use	professional use	professional use
List price	$1,200	$10,600
Units sold in U.S./Outside U.S./In 2008	67,000/10,000/—	—
Part of series of similar or related models	yes	yes
Dimensions (H x W x D)/Weight	1.4 × 3.8 × 7.6 in/12 oz	35.6 × 35.6 × 25.4 cm/25 lbs. (11.4 kg)
Analytical method/Technology/Enzyme system used	biosensor—glucose dehydrogenase	enzyme electrode, hydrogen peroxide, glucose oxidase
Price per disposable reagent system unit	contingent on contract price	$15 per membrane sensor (cost per test: $0.14 @ 2,000 patient samples)
No. of dispos. reag. system units per basic package	50 test strips	4 membranes per package
No. of times analyses performed using 1 reag. system unit	1	time based 3 weeks, 1000+ patient samples
Dispos. units shelf life/Reag. unit storage requirements	18 months, stable until expiration date on vial/room temperature less than 90°F, do not freeze	1 year/liquid reagents: room temp.; membrane sensor: 4°C refrigerated
Digital readout size/Keypad input capability	font size varies/menu selection, numeric, alphabetic	font hgt: 0.2 in., 2 x 40 alphanumeric LCD/menu selection, numeric
How results are displayed	true values	true and calculated values
Specimen types/Sampling techniques	whole blood/arterial, venous, capillary, neonate (including cord blood)	plasma, serum, whole blood/probe aspirated 25 µL
Minimum specimen volume required	4 µL	35–50 µL, dependent upon tube style
Suitable for samples from well/Sick neonates	yes/yes	yes/yes
Time from sample intro. to result availability	26 seconds	65 seconds
Batteries used/No. used/Avg. life of one set	3.7 V rechargeable lithium ion/1/testing in progress	AC line power/—/—
Avg. expected life of device/Mean time between failures	5 years/542,000 tests	10 years+/unknown
Device warranty/Service options	Accu-Chek Inform System will be free from defects in materials & workmanship through life of the Accu-Chek Comfort Curve test strip contract; overnight replacement, according to warranty policy, is available 24/7, 365 days per year	1 year/on all parts and labor/on-site service, dealer service centers, manufacturer service center in Ohio
Loaners provided	replaced under warranty	yes
User list or user group	yes (contact local account manager)	no (YSI 2300 is a reference blood instrument)
Toll-free No. for customer questions/Hours	800-440-3638/24 hours, 365 days per year	yes/8 AM-5 PM EST USA
Training and certif. program/No. training days provided	yes/site-specific according to No. of employees	yes/onsite: 1 day; vendor office: negotiable
Avg. time for lab to complete maintenance	none	daily: 15 min (calibration and check solution sample); weekly: 30 min (buffer solution change); monthly: 30 min (calibration solution and buffer solution change)
Special cleansing procedures	acceptable active ingredients: water, soap, 70% (or less) isopropyl alcohol, 1:10 dilution of sodium hydrochlorite	no
Internal QC recommended or required	daily, 2 levels of glucose control solutions	run a daily third-party control, such as a serum control
Between instrument CV (based on PT) at these levels:		
• <50 mg/dL	53.8 mg/dL SD=4.1 (6,088 labs)	2.5 mg/dL*
• 100–200 mg/dL	191.4 mg/dL CV=4.7% (3,096 labs)	2%*
• >400 mg/dL	228.5 mg/dL CV=4.6% (6,099 labs)	2%*
• Program name, year/Challenge No./Level of mean glucose challenge sample	CAP, 2001/WBG-C/see above	—
Accuracy/Compared to what reference method or device	y=0.991 x + 8.4, r=0.980/glucose hexokinase–Hitachi	YSI enzyme electrode technology commonly used whole blood glucose standard; YSI 2300 used as reference method for blood glucometer development and glucometer test strip QA
Precision/Compared to what reference method or device	controls: low SD=2.83 mg/dL, mid CV=3.08%, high CV=2.82%; blood: low SD=1.5 mg/dL, mid CV=3.2%, high CV=3.2%/glucose hexokinase	hexokinase/UV spectrophotometric compared to plasma
Linear range	10–600 mg/dL	glucose: 0 to 900 mg/dL (9,000 mg/L, 50.0 mmol/L)
Suggested dynamic, measurement range	10–600 mg/dL	glucose: 0 to 900 mg/dL (9,000 mg/L, 50.0 mmol/L)
Contraindications	yes, per labeling	no
Known interferences/High-altitude interference	per labeling/none up to 10,150 ft	none that are biological in nature/no
Restrictions based on hematocrit	yes, glucose <200 mg/dL 20%–65%; glucose >200 mg/dL 20%–55%	no
Electronic, optical function checks	meter with code key, battery voltage test, internal database memory check, internal configuration check	— (sensor technology is amperometric, not optically based)
Sample quantity checks	built-in electronic strip check, visible verification of sample volume	—
When auto lock or shutdown occurs	user ID failure (valid op.), QC failure, download interval lockout, patient ID length, reagent editing, mandatory comments, incorrect/missing code key, time, and data editing	calibration instability, low reagent levels, various electromechanical checks related to moving parts
User defines QC lockout intervals/Lockout can be circumvented	yes/no (optional QC pass/fail feature)	—
Device supports bar-code scanning of	operator & patient identifiers, reagent lot Nos.	no bar-code scanner
Method of analyst ID/ID required	alphanumeric or bar-code scan/yes	numeric identifier optional/optional
Internal memory size/Max. No. patient results stored	4,000 results/4,000 tests	—/last 32 results stored in internal buffer accessible by serial port
Information transfer capability:		
• Meters connect to	information management system, which in turn connects to LIS/HIS	— (requires customized software for LIS/HIS interface)
• How meters are connected to external system to upload results/ No. installations	direct serial/—, modem dial-in/—, hospital network/—	—
• Info. contained in transmission to external system	device unique identifiers, operator & patient IDs, results, strip lot Nos., QC identifiers, proficiency & linearity samples, comments, meter location, download location	—
Hardware/software for data mgmt. system	MAS RALS-Plus, MAS RALS-Lite*, MAS RALS-Notebook†, and MAS RALS-Web	through custom software, patient ID and results may be retrieved
No. of different mgmt. reports system can produce	varies by Data Manager (customer defined)	—
Contents downloaded from DMS to meter		—
System connected (live installations) to which LISs/HISs:	QC & strip lot Nos., valid control values, valid operator & patient IDs, meter configuration, linearity lot Nos. & values, comments	
• using screen animation/screen scraping	all major LIS vendors including Cerner, Meditech, Misys, CPSI, SoftLab, Siemens, McKesson, SIA Molis, Opus, others**	—
• using standard HL7 interface	yes	—
• using proprietary protocol interface	—	
Use 3rd-party interfacing tool/engine for LIS/HIS interfaces	MAS	—
Distinguishing features (provided by vendors)	uses the Accu-Chek Comfort Curve test strip; universal sampling due to oxygen-independent chemistry, with reliable results at varying hematocrit levels; offers alphanumeric touchscreen, onboard bar-code ID, and MAS RALS-plus connectivity, including ADT feed, which provides two patient identifiers for confirmation; extends the quality of blood glucose programs to six other point-of-care tests by allowing the entry and transfer of manual test information	commonly used reference method for glucometers; ideal for hospital diabetes evaluation testing, e.g. clamp studies; accurate stat whole blood glucose 1 minute result

†Roche exclusive
***both scripted/HL7 are available depending on LIS version*

**based on YSI proof of claims testing*

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