Accuracy above all for point-of-care glucose analyzers

Brendan Dabkowski

Makers of point-of-care glucose testing systems are responding to customers' demands for devices that are nimble, responsive, and durable—but above all, accurate.

"Hospitals continue to demand improved accuracy of bedside glucose monitors as they adopt protocols for better glycemic management," says Nova Biomedical marketing specialist Rick Rollins. The FDA, American Association of Clinical Endocrinologists, and Society of Critical Care Medicine are echoing those demands, he continues, by discussing new standards for improved accuracy of point-of-care glucose analyzers.

At a 2010 FDA public hearing, participating clinicians "clearly indicated that they would like to see accuracy that is similar to that of lab instruments but in the point-of-care glucose system," says Mary Catherine Coyle, Roche Diagnostics' director of product marketing in the company's hospital point-of-care division.

Offering instruments designed to provide accurate laboratory-equivalent results at the point of care is the focus of the companies featured in this month's guide to bedside glucose analyzers.

One such instrument is Nova's StatStrip glucose monitoring system, which the company introduced in 2006. The meter automatically measures hematocrit levels and other interfering substances and corrects for these interferences, Rollins says. It runs 1.2-µL samples, provides results in six seconds, and does not require calibration coding, eliminating an operator step and reducing the potential for errors. Laboratory-equivalent accuracy has been documented in more than 50 published studies, he adds. Nova recently enhanced the product with wireless connectivity for continuous admission/discharge/transfer and rapid patient data charting.

Bedside glucose testing systems, pages 68-71

Wireless capabilities are also an area of interest to Roche. "In this world of PDAs and electronic health records, health care providers are really expecting that if a patient has had his point-of-care testing done already, that it has already hit the chart," Coyle says. "That's going to be challenging, unless new technology like meter-level wireless comes into play." And it will, she says, noting that Roche is planning to equip its next-generation Accu-Chek Inform II glucose system with this type of functionality.

The Accu-Chek Inform II—still in development and not yet included

continued on page 68

See our Product Guide listing on page 70

Glucose analyzers

continued from page 67

in CAP TODAY's glucose analyzers lineup—is being designed as a next-generation version of the company's Accu-Chek Inform system. Coyle says the design goals for the Inform II include a higher level of test-strip accuracy than its predecessor and increased durability, to stand up to the newest cleaning and disinfecting trends. Currently available from Roche are the aforementioned Inform system and AccuData GTS portable glucose test station.

Abbott Diabetes Care continues to offer its Precision Xceed Pro blood glucose and β-ketone monitoring system, which provides blood glucose and β-ketone monitoring via the same meter, says Peter Karkantis, general manager of the company's U.S. hospital point-of-care division. Xceed Pro meters use individual foil-wrapped test strips that are designed to minimize potential contamination.

Available too from Abbott is the PrecisionWeb point-of-care data-management system, which captures patient test data from Xceed Pro meters and transfers it from the docking station to the computer desktop. The company recently added to PrecisionWeb the PrecisionWeb Guardian automated data-management system administration solution, which allows customers to monitor patient data in real time, download software updates, and peruse a comprehensive monthly system-performance report card.

Also profiled in this month's guide is Arkray USA's Assure Platinum blood glucose monitoring system, which "not only meets the FDA standards for accuracy and precision but was specifically designed to meet the demands of POC users," says Michelle Johnson, associate product marketing manager, Assure Confident Diabetes Solutions. Released last year, the system is designed for long-term care and has an auto-code feature that helps reduce chances of user error. The company also offers the Assure Pro and Assure 4 meters.

In addition to the aforementioned products, CAP TODAY's guide to point-of-care glucose testing systems includes solutions from HemoCue, Medtronic MiniMed, and YSI Life Sciences. Companies supplied the information listed. Readers interested in a particular product should confirm that it has the stated features and capabilities. □

Brendan Dabkowski is CAP TODAY *associate editor.*

Bedside glucose testing systems

Part 1 of 4 *See accompanying article on page 67*	**Abbott Diabetes Care** 1420 Harbor Bay Parkway Alameda, CA 94502 510-749-5400 www.abbottdiabetescare.com	**Arkray** 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 Platinum/2010
Professional or home use	professional and home use	professional use
Total units sold in U.S./Total units sold outside U.S.	—	—
No. of contracts for product signed in 2010	—	1
Dimensions (H × W × D)/Weight	19.7 cm (7.7 in) × 7.5 cm (2.96 in) × 5.33 cm (2.1 in)/256 g (9 oz)	4.5 × 2.5 × 1.2/2.8 oz
Analytical method or technology or enzyme system used	glucose-specific GDH-NAD enzyme and low applied voltage to minimize interference; beta-hydroxybutyrate, the predominant blood ketone DKA	glucose oxidase
No. of disposable reagent system units per basic package	glucose: 100 strips; ketone: 50 strips	50 or 100
Disposable units shelf life/Reagent unit storage requirements	15–18 months/4°–30°C	18 months/room temperature
Digital readout character size/Keypad input capability	3.06 mm (normal), 8.16 mm (results)/menu selection, numeric, alphabetic	—/none
How results are displayed	true values	true values
Specimen types/Sampling techniques	whole blood/drop, capillary transfer, touchable strips	whole blood/drop
Minimum specimen volume required	glucose: 0.6 µL; ketone: 1.5 µL	0.5 µL
Suitable for samples from well neonates/sick neonates	yes/yes	no/no
Time from sample introduction to result availability	glucose: 20 seconds; ketone: 10 seconds	7 seconds
Batteries used/No. used/Average life of one set of batteries	AA or NiMH rechargeable/2/—	AAA/2/5,000 tests with 4 tests per day
Average expected life of device/Mean time between failures	—	—
Device warranty/Service options/Loaners provided	one year, lifetime replacement with reagent contract/24-hour replacement	five years/—/yes
User list or user group	yes, list available upon request	no
Toll-free No. for customer questions/Hours of operation	877-529-7185/24 hours, seven days	800-818-8877/24 hours, seven days
Training & certification program/No. of training days provided	yes/depends on number of operators	yes/one on site
Average time for lab to complete maintenance	—	daily: <five minutes
Internal QC recommended or required	as defined by facility or institutional policy	control solution testing
Between instrument CV (based on PT) at the following glucose 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=1.00, y-intercept= -2.33, r=0.99/YSI model 2300
Precision/Compared to what reference method or device	blood samples: CV 3.0%–3.6%/YSI	For glucose results ≥75mg/dL, 100% within ±20%; 96% within ±15%; 79% within ±10%; and 53% within ± 5%. For glucose results <75 mg/dL, 100% within ± 15mg/dL; 100% within ± 10 mg/dL; 88% within ± 5 mg/dL
Linear range	glucose: 20–500 mg/dL; ketone: 0.0–8.0 mmol/L	20–600 mg/dL
Suggested dynamic or measurement range	glucose: 20–500 mg/dL; ketone: 0.0–8.0 mmol/L	20–600 mg/dL
Contraindications	per labeling	yes, see labeling
Known interferences/High-altitude interference	per labeling/no	yes/per labeling
Restrictions based on hematocrit	yes, glucose: 20–70%; ketone: 30–60%	yes, 30%–55%
Electronic and optical function checks	battery, bar-code scanner, database, and temperature checks performed during power-up of meter	automatic
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/QC lockout can be circumvented	yes/no	—
Information for which device supports bar-code scanning	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/Maximum No. of 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 (one panel, five levels, four replicates per level)	500/500 tests
Meter connections for information transfer	PrecisionWeb data management system, which in turn connects to LIS/HIS	—
How meters are connected to external system to upload results	direct serial, modem dial-in, hospital network/—	—
Information contained in transmission to external system	device unique identifiers, operator and patient IDs, results, QC identifiers, strip lots, comment codes, test dates and times	—
Hardware/software for data management system	Enterprise multi-user Web-based system running on highly redundant Dell server	—
No. of different management 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	—
LISs/HISs to which system is connected (live installs) using:		
• screen animation/screen scraping	Cerner, Misys, PerSe, Meditech, SoftLab, CPSI, Vista, CHCS, GE Medical, ADAC, HBOC Star, McKesson Horizon Lab, Siemens Novius Lab	—
• standard HL7 interface	Cerner, Misys, PerSe, Meditech, SoftLab	—
• proprietary protocol interface	—	—
Use 3rd-party interfacing tool or engine for LIS or HIS interfaces	yes (Sybase)	—
Distinguishing features (supplied by company)	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	auto coding, no need to manually code the meter; qcProGuard, a 24-hour control solution reminder; strip-release button, no need to touch used test strips

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

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

Survey editor: Raymond Aller, MD

Bedside glucose testing systems

Part 2 of 4	Arkray 5198 W. 76th St. Edina, MN 55439 800-818-8877 www.arkrayusa.com	Arkray 5198 W. 76th St. Edina, MN 55439 800-818-8877 www.arkrayusa.com	HemoCue Arnol Rios arnol@hemocue.com 11331 Valley View St., Cypress, CA 90630 800-323-1674 www.hemocue.com
Name of instrument/First year sold	Assure Pro/2006	Assure 4/2007	Glucose 201 DM Analyzer/2005
Professional or home use	professional use	professional use	professional use
Total units sold in U.S./Total units sold outside U.S.	—	—	—
No. of contracts for product signed in 2010	—	—	—
Dimensions (H × W × D)/Weight	4.1 × 2.4 × 1 in/2.5 oz without battery	3.9 × 2.3 × 1.0 in/2.5 oz without batteries	6.7 × 3.7 × 2 in/0.77 lb
Analytical method or technology or enzyme system used	glucose oxidase	glucose oxidase	absorbance photometry, glucose dehydrogenase
No. of disposable reagent system units per basic package	50 or 100	50 or 100	25 in vial/box; 4 vials/boxes per package
Disposable units shelf life/Reagent unit storage requirements	18 months/room temperature	18 months/room temperature	9 months from manufacture date/refrigeration
Digital readout character size/Keypad input capability	—	—	varies from 8–28 points/menu selection, numeric, alphabetic
How results are displayed	true values	true values	calculated values (plasma equivalent values)
Specimen types/Sampling techniques	whole blood/capillary transfer	whole blood/capillary transfer	whole blood/drop, capillary transfer
Minimum specimen volume required	0.5 µL	1.5 µL	5 µL
Suitable for samples from well neonates/sick neonates	no/no	no/no	yes/yes
Time from sample introduction to result availability	10 seconds	10 seconds	40–240 seconds
Batteries used/No. used/Average life of one set of batteries	1.5-V alkaline AAA/2/up to 5,000 tests	1.5-V alkaline AAA/2/3,000 tests	rechargeable lithium ion supplied by HemoCue/—/several years
Average expected life of device/Mean time between failures	—	—	seven years/>five years
Device warranty/Service options/Loaners provided	five years/—/yes	five years/—/yes	two years, at no additional cost/replacement of defective analyzer/yes
User list or user group	no	no	no
Toll-free No. for customer questions/Hours of operation	800-818-8877/24 hours, seven days	800-818-8877/24 hours, seven days	800-323-1674, 6 AM–5 PM PST
Training and certification program/No. of training days provided	yes/as needed	yes/as needed	yes/as needed
Average time for lab to complete maintenance	weekly: five minutes	weekly: five minutes	daily: ≤five minutes
Internal QC recommended or required	as specified by accreditation	as specified by accreditation	one level of controls prior to patient testing, each day of testing
Between instrument CV (based on PT) at the following glucose 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=0.94, y-intercept=0.63, r=0.99/YSI glucose analyzer	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	for glucose results ≥75mg/dL, 100% within ±20%; 99 percent within ±15%; 91% within ±10%; and 66% within ±5%; for glucose results <75 mg/dL, 100% within ±15 mg/dL; 100% within ±10 mg/dL; 92% within ±5 mg/dL	4.1 percent/—	within run CV 1.9 percent (108 mg/dL)/—
Linear range	20–600 mg/dL	30–550 mg/dL	0–444 mg/dL
Suggested dynamic or measurement range	20–600 mg/dL	30–550 mg/dL	0–444 mg/dL
Contraindications	yes	no	no
Known interferences/High-altitude interference	per labeling/no, tested up to 10,000 feet	per labeling/no (tested up to 7,000 feet)	grossly lipemic samples, methemoglobin, glucosamine/no
Restrictions based on hematocrit	yes, 30–55 percent	yes, 30–55 percent	no
Electronic and optical function checks	automatic, electronic	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/QC lockout can be circumvented	no/—	no/—	yes/no (stat testing may be allowed; 1–100 tests after QC interval)
Information for which device supports bar-code scanning	no bar-code scanner	no bar-code scanner	operator and 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/Maximum No. of patient results stored	250 tests with time and date stamp/250 test results	50-test memory/50	4,000 patient tests/500 QC tests, 500 analyzer log entries/4,000
Meter connections for information transfer	—	—	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	—	—	direct USB/hospital network
Information 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 management system	—	—	PC/server/HemoCue 201 DM–DMS software
No. of different management 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
LISs/HISs to which system is connected (live installs) using:		—	
• screen animation/screen scraping	—	—	—
• standard HL7 interface	—	—	Cerner, Orchard, Sunquest, EHS, SoftLab, M-Magic, Starlab, M-CS, HorizonLab
• proprietary protocol interface	—	—	—
Use 3rd-party interfacing tool or engine for LIS or HIS interfaces	—	—	yes (MAS-RALS, LDS Aegis POC, TELCOR, SYBASE, Radiometer Radiance)
Distinguishing features (supplied by company)	24-hour optional control solution reminder; top-of-meter strip insertion; strip-release button; backlight display; new strip launched late 2009	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

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

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

Bedside glucose testing systems

Part 3 of 4	HemoCue Arnol Rios arnol@hemocue.com 11331 Valley View St., Cypress, CA 90630 800-323-1674 www.hemocue.com	Medtronic MiniMed 18000 Devonshire St. Northridge, CA 91325 800-646-4633 www.minimed.com	Nova Biomedical Sales Department info@novabio.com 200 Prospect St., Waltham, MA 02454 781-894-0800 or 800-458-5813 www.novabiomedical.com
Name of instrument/First year sold	Glucose 201 Analyzer/2002	iPro Continuous Glucose Monitor (CGM)/2008	StatStrip Hospital Glucose Monitoring System/2006
Professional or home use	professional use	professional use	professional use
Total units sold in U.S./Total units sold outside U.S.	—	—	—
No. of contracts for product signed in 2010	—	—	—
Dimensions (H × W × D)/Weight	6.3 × 3.4 × 1.7 in/0.77 lb	.37 × 1.40 × 1.12 in/<5 grams	6.0 × 3.25 × 1.8 in/0.8 lb
Analytical method or technology or enzyme system used	absorbance photometry, glucose dehydrogenase	glucose oxidase	electrochemistry
No. of disposable reagent system units per basic package	25 in vial/box; four vials/boxes per package	10 sensors per box, four sensors per box	50 strips per vial and 100 per box
Disposable units shelf life/Reagent unit storage requirements	9 months from date of manufacture/refrigeration	6 months/non-refrigeration 36°–80°F (2°–27°C)	24 months from date of manufacture/none
Digital readout character size/Keypad input capability	0.5 in/none	no patient monitor interface/blinded glucose values, retrospective data	varies and is defined by the particular field/numeric, alphabetic
How results are displayed	plasma equivalent values	data downloaded from iPro Recorder to computer; CGM reports printed or viewed through office computer	true values
Specimen types/Sampling techniques	whole blood, venous, capillary, or arterial/exact amount of blood is drawn into the cuvette by capillary force	continuous monitoring and sampling of interstitial fluid glucose levels	whole blood/drop (arterial, venous, capillary, neonatal)
Minimum specimen volume required	5 µL	—	1.2 µL
Suitable for samples from well neonates/sick neonates	—	no/no (indicated for anyone with diabetes)	yes/yes
Time from sample introduction to result availability	40–240 seconds	retrospective analysis after disconnection	six seconds
Batteries used/No. used/Average life of one set of batteries	AA/4/150 hours	rechargeable battery, iPro CGM charger, AAA/1/—	3.7 Li Polymer (rechargeable/replaceable)/1/24–36 months
Average expected life of device/Mean time between failures	seven years/>five years	one year/—	five+ years/—
Device warranty/Service options/Loaners provided	two years at no extra cost/—/yes	six months for iPro Recorder/no warranty on disposables/no	two years (extended five-year warranty at additional cost)/meter replacement/yes
User list or user group	—	no	no
Toll-free No. for customer questions/Hours of operation	800-323-1674, 6 AM–5 PM PST	800-646-4633/5am–5pm PST	800-458-5813/24 hours, seven days, all year
Training and certification program/No. of training days provided	yes/as needed	yes (training only)/~one day	yes/defined during implementation planning
Average time for lab to complete maintenance	daily: ≤five minutes	—	no user maintenance
Internal QC recommended or required	system must be verified on testing days using commercially available controls	fingerstick calibration required at least every 12 hours; must be in range of 40–400 mg/dL	CLIA requirements 2 levels per day
Between instrument CV (based on PT) at the following glucose levels:			
• <50 mg/dL	not available	—	—
• 100–200 mg/dL	3.8	five percent (40–400 mg/dL) in vitro	—
• >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	CGMS 1999, CGMS Gold 2003, iPro CGM 2008	—
Accuracy/Compared to what reference method or device	±10% or ±6 mg/dL; corr=0.994/wet chemical glucose dehydrogenase, ID-GCMS	coefficient of variation of five percent/fingerstick blood glucose measurements	R2=0.9978, slope=1.0127–2.0975/YSI 2300
Precision/Compared to what reference method or device	within run CV 1.9 percent (108 mg/dL)/—	—/home glucose meters	within run (whole blood=1.9–3.6 percent) and (day to day=3.4–4.7 percent) linearity standards/—
Linear range	0–444 mg/dL	—	10–600 mg/dL
Suggested dynamic or measurement range	0–444 mg/dL	40–400 mg/dL	10–600 mg/dL
Contraindications	no	magnetic beds, MRI	—
Known interferences/High-altitude interference	grossly lipemic samples, methemoglobin, glucosamine/no	possibly MRI/no	none/no, operates at altitudes up to 15,000 feet
Restrictions based on hematocrit	no	no	none (no Hct interference)
Electronic and optical function checks	internal electronic self-test automatically checks that the instrument's optronic unit is working properly	test plug	electronic checks for out-of-range glucose results, dosing, out-of-range Hct results
Sample quantity checks	visual inspection	—	RapidFill sampling electronically checks for correct strip dosing
When auto lock or shutdown occurs	—	—	options include user ID failure, QC failure, required docking for data transfer
User defines QC lockout intervals/QC lockout can be circumvented	no/no	no/no	yes/no, not if configured
Information for which device supports bar-code scanning	no bar-code scanner	no bar-code scanner	operator and patient identifiers, reagent, lot No., QC lots; supports both 1-D and 2-D bar codes
Method of analyst ID/ID required	—	at time of monitor download/optional	medical record ID No., medical billing ID No., Accession ID No./ID required
Internal memory size/Maximum No. of patient results stored	—	up to 14 days continuous data/288 readings per day	1,000 patient samples, 200 QC samples, 4,000 operators/1,000 tests
Meter connections for information transfer	—	iPro Recorder and meters upload data to office computer	Instrument Manager (NovaNet or Laboratory Data Systems AegisPOC) to Data Manager (Telcor QML/Quick-Linc or AegisPOC) then to LIS if required
How meters are connected to external system to upload results	—	iPro Recorder wirelessly transmits to ComLink, which connects via serial port or USB; meters connect via serial port or USB depending on meter	hospital network/—; wireless tote/—
Information contained in transmission to external system	—	sensor values, meter values and events (meals, insulin, exercise, and other)	device unique identifier, operator and patient IDs, results, QC identifiers
Hardware/software for data management system	—	ComLink for iPro CGM/Solutions software installed on the office computer	connects to Telcor QML and Laboratory Data Systems AegisPOC
No. of different management reports system can produce	—	five standard unlimited customized reports	provided by Telcor and Laboratory Data Systems
Contents downloaded from DMS to meter	—	—	strip lot numbers, valid control values, valid operator IDs, patient demographics, configuration files, physician IDs, diagnostic codes
LISs/HISs to which system is connected (live installs) using:	—		
• screen animation/screen scraping	—	—	available through Telcor and Laboratory Data Systems
• standard HL7 interface	—	—	yes
• proprietary protocol interface	—	—	no
Use 3rd-party interfacing tool or engine for LIS or HIS interfaces	—	—	yes (Telcor QML/Quick-Linc, Laboratory Data Systems AegisPOC)
Distinguishing features (supplied by company)	CLIA-waived; indicated for diagnosis of diabetes mellitus; not hematocrit-dependent; lab verification of patient home meter	continuous glucose values every five minutes; limited patient education required with no additional device/receiver for patient to carry around; easy-to-read reports generated from office computer	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 six seconds using 1.2 µL of sample; unlimited manual test entry

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

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

Bedside glucose testing systems

Part 4 of 4	Roche Diagnostics Accu-Chek Customer Care Service Center 9115 Hague Rd., Indianapolis, IN 46256 800-440-3638 www.roche-diagnostics.us	Roche Diagnostics Accu-Chek Customer Care Service Center 9115 Hague Rd., Indianapolis, IN 46256 800-440-3638 www.roche-diagnostics.us	YSI Life Sciences 1725 Brannum Lane Yellow Springs, OH 45387 800 659-8895 www.ysilifesciences.com
Name of instrument/First year sold	AccuData GTS, 1994; AccuData GTS Plus, 2000	Accu-Chek Inform System/2001	YSI 2300 STAT Plus Glucose & Lactate Analyzer/1989
Professional or home use	professional use	professional use	professional use, FDA 510k class II medical device
Total units sold in U.S./Total units sold outside U.S.	40,000*/5,000	67,000/10,000	—
No. of contracts for product signed in 2010	—	—	—
Dimensions (H × W × D)/Weight	11 × 8.75 × 4 in/5 lb	1.4 × 3.8 × 7.6 in/12 oz	35.6 × 35.6 × 25.4 cm/25 lbs. (11.4 kg)
Analytical method or technology or enzyme system used	biosensor–glucose dehydrogenase	biosensor—glucose dehydrogenase	enzyme electrode, hydrogen peroxide, glucose oxidase
No. of disposable reagent system units per basic package	50 strips per vial	50 test strips	four membranes per package
Disposable units shelf life/Reagent unit storage requirements	18 months, stable until expiration on vial/<90°F, do not freeze	18 months, stable until expiration date on vial/room temperature less than 90°F, do not freeze	one year/liquid reagents: room temp.; membrane sensor: 4°C refrigerated
Digital readout character size/Keypad input capability	4 lines by 20 characters LCD/menu selection, numeric	font size varies/menu selection, numeric, alphabetic	font hgt: 0.2 in., 2 × 40 alphanumeric LCD/menu selection, numeric
How results are displayed	true values	true values	true and calculated values
Specimen types/Sampling techniques	whole blood/arterial, venous, capillary, neonate (including cord blood)	whole blood/arterial, venous, capillary, neonate (including cord blood)	plasma, serum, whole blood/probe aspirated 25 µL
Minimum specimen volume required	4 µL	4 µL	25 µL dispensed into the reaction chamber
Suitable for samples from well neonates/sick neonates	yes/yes	yes/yes	yes/yes
Time from sample introduction to result availability	26 seconds	26 seconds	65 seconds
Batteries used/No. used/Average life of one set of batteries	3-V lithium/2/~700 tests	3.7-V rechargeable lithium ion/1/testing in progress	AC line power/—/—
Average expected life of device/Mean time between failures	five years/10,000 tests	five years/542,000 tests	10 years+/unknown
Device warranty/Service options/Loaners provided	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/replaced under warranty	Free from defects in materials and workmanship through life of the Comfort Curve test strip contract; overnight replacement, according to warranty policy, is available 24/7, 365 days per year/replaced under warranty	one year/on all parts and labor/on-site service, dealer service centers, manufacturer service center in Ohio/yes
User list or user group	yes (contact local account manager)	yes (contact local account manager)	no (YSI 2300 is a reference blood instrument)
Toll-free No. for customer questions/Hours of operation	800-440-3638/24 hours, 365 days per year	800-440-3638/24 hours, 365 days per year	yes/8 AM-5 PM EST USA
Training and certification program/No. of training days provided	yes/site-specific according to No. of employees	yes/site-specific according to No. of employees	yes/on site: one day; vendor office: negotiable
Average time for lab to complete maintenance	—	—	daily: 15 minutes; weekly: 30 min.; monthly: 30 min.
Internal QC recommended or required	daily, two levels	daily, two levels of glucose control solutions	daily, as defined by laboratory policy
Between instrument CV (based on PT) at the following glucose levels:			
• <50 mg/dL	53.8 mg/dL SD=4.1 (6,088 labs)	53.8 mg/dL SD=4.1 (6,088 labs)	—
• 100–200 mg/dL	191.4 mg/dL CV=4.7% (3,096 labs)	191.4 mg/dL CV=4.7% (3,096 labs)	—
• >400 mg/dL	228.5 mg/dL CV=4.6% (6,099 labs)	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	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	y=0.991 x + 8.4, r=0.980/glucose hexokinase–Hitachi	y=0.9933x + 2.1355 R2=0.9995 (YSI vs hexokinase method for human serum glucose)/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	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	CV=2% at 180 mg/dL/UV spectrophotometric compared to plasma
Linear range	10–600 mg/dL	10–600 mg/dL	0–900 mg/dL
Suggested dynamic or measurement range	10–600 mg/dL	10–600 mg/dL	0–900 mg/dL
Contraindications	per labeling	yes, per labeling	no
Known interferences/High-altitude interference	per labeling/none up to 10,150 feet	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 percent; glucose >200, 20–55 percent	yes, glucose <200 mg/dL 20–65 percent; glucose >200 mg/dL 20–55 percent	no
Electronic and optical function checks	meter cradle communication with Advantage meter, GTS with code key, battery voltage test, internal database memory check, internal configuration check	meter with code key, battery voltage test, internal database memory check, internal configuration check	encoders on robotics, fluid level detection (sensor not optical)
Sample quantity checks	built-in electronic strip check, visual confirmation of sample volume	built-in electronic strip check, visible verification of sample volume	—
When auto lock or shutdown occurs	user ID failure (valid op.), QC failure, patient ID length, incorrect code key, incorrect Advantage meter	user ID failure, 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/QC lockout can be circumvented	yes/yes (information management system identifies operators who violate hospital policy)	yes/no (optional QC pass/fail feature)	—
Information for which device supports bar-code scanning	operator and patient identifiers, comment codes	operator and patient identifiers, reagent lot Nos.	no bar-code scanner
Method of analyst ID/ID required	numeric input or bar-code wand scan/yes	alphanumeric or bar-code scan/yes	numeric identifier optional/optional
Internal memory size/Maximum No. of patient results stored	1,000 total patient, control, linearity, proficiency tests/1,000	4,000 results/4,000 tests	instrument memory, 32 samples,YSI 2340 Data Logging Software records data on lab computer
Meter connections for information transfer	information management system, which in turn connects to LIS/HIS	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	direct serial/—, modem dial-in/—, hospital network/—	direct serial/—, modem dial-in/—, hospital network/—	—
Information contained in transmission to external system	device unique identifiers, operator and patient IDs, results, QC identifiers, strip lot Nos., download location, comment codes, proficiency and linearity samples	device unique identifiers, operator and patient IDs, results, strip lot Nos., QC identifiers, proficiency and linearity samples, comments, meter location, download location	—
Hardware/software for data management system	MAS RALS-Plus, MAS RALS-Lite†, MAS RALS-Notebook†	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 management reports system can produce	varies by Data Manager (customer defined)	varies by Data Manager (customer defined)	—
Contents downloaded from DMS to meter	strip and QC lot Nos., valid operator IDs, valid control values, linearity values	QC and strip lot Nos., valid control values, valid operator and patient IDs, meter configuration, linearity lot Nos. and values, comments	—
LISs/HISs to which system is connected (live installs) using:			
• screen animation/screen scraping	all major LIS vendors including Cerner, Misys, McKesson, Meditech, SoftLab, Siemens, SIA Molis, others**	all major LIS vendors including Cerner, Meditech, Misys, CPSI, SoftLab, Siemens, McKesson, others**	—
• standard HL7 interface	—	yes	—
• proprietary protocol interface	—	—	
Use 3rd-party interfacing tool or engine for LIS or HIS interfaces	yes (MAS)	yes (MAS)	—
Distinguishing features (supplied by company)	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	uses Accu-Chek Comfort Curve test strip; universal sampling due to oxygen-independent chemistry, reliable results at varying hematocrit levels; alphanumeric touchscreen, onboard bar-code ID, and MAS RALS-Plus connectivity, including ADT feed; extends quality of blood glucose programs to six other point-of-care tests	commonly used as the reference method in glucometer development, glucose monitoring system development, and diabetes evaluation studies (clamp studies) where an accurate and precise glucose measurement is required
	*combined AccuData GTS and AccuData GTS Plus sales	†Roche exclusive	*based on YSI proof of claims testing
Note: a dash in lieu of an answer means company did not answer question or question is not applicable	†Roche exclusive; **both scripted/HL7 are available	**both scripted/HL7 are available depending on LIS version	

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