Bedside glucose testing systems

Safety at the point of care

Readers will find on the following pages 11 bedside glucose analyzers from seven companies that supplied the detail on display. Patient safety continues to be top of mind.

Nova Biomedical's StatStrip glucose monitoring system was designed for the improved accuracy hospitals demand for glycemic management of inpatients, says Nova marketing specialist Rick Rollins, who adds that the meter requires 1.2-µL blood samples and provides results in six seconds. Laboratory-equivalent accuracy and elimination of interferences for StatStrip have been documented in more than 60 published clinical studies, Rollins says. The system measures and eliminates interferences from hematocrit, maltose, acetaminophen, ascorbic acid, and more. And it captures up to six unique patient identifiers through its ADT interface.

Also with safety in mind, Abbott Diabetes Care offers individually foil-wrapped glucose test strips to minimize the risk of cross-contamination, says Peter Karkantis, senior director of point-of-care marketing. Karkantis says he expects a "broader movement" toward the same, citing the Centers for Disease Control and Prevention's recommendation against unused supplies taken to a bedside for fingerstick monitoring or insulin administration being used for another patient. "Abbott Diabetes Care helps institutions address this issue," Karkantis says.

Approved by the FDA in November 2011 and new to the product guide this year is Medtronic Diabetes' iPro2 Professional continuous glucose monitoring system, says Amanda Sheldon, public relations program director. The iPro2 monitors the patient's glucose data continuously over three days and helps identify glycemic excursions otherwise missed by fingersticks alone. It uses a disposable sensor to record up to 288 glucose readings per 24-hour period. The patient returns the iPro2 to a health care provider, who uploads the recorded data to the company's CareLink iPro Web-based software platform. The software provides a summary of the data in easy-to-read reports.

CAP TODAY's guide to bedside glucose testing systems includes these solutions and others from Arkray, HemoCue, Roche Diagnostics, and YSI Life Sciences. Readers interested in a particular product should confirm it has the stated features and capabilities.

—Brendan Dabkowski

Part 1 of 4 *See* captodayonline.com/productguides *for an interactive version of guide*	**Abbott Diabetes Care** 1420 Harbor Bay Parkway, Alameda, CA 94502 510-749-5400 or 877-643-2098 www.abbottdiabetescare.com	**Arkray** 5198 W. 76th Street, 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	professional
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 in/2.8 oz
Analytical method or technology or enzyme system used	glucose-specific GDH-NAD enzyme and low applied voltage to minimize interference; ß-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	—
How results are displayed	true values	true values
Specimen types/Sampling techniques	whole blood/drop (arterial, venous, capillary, neonatal), 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 Alkaline or NiMH rechargeable/2/—	AAA/2/5,000 tests with 4 tests per day
Average expected life of device/Mean time between failures	4–5 years/—	—
Device warranty/Service options/Loaners provided	1 year/lifetime replacement/24-hour replacement	5 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, 7 days, all year	800-818-8877/24 hours, 7 days
Training and certification program/No. of training days provided	yes/defined during implementation planning	yes/one on site
Average time for lab to complete maintenance	no lab maintenance	daily: <5 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.	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 ± 15 mg/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 designed to start the test when sufficient sample is detected	—
When auto lock or shutdown occurs	strip lot expired, QC failure and other options	—
User defines QC lockout intervals/QC lockout can be circumvented	yes (optional QC pass/fail feature)/no	—
Information for which device supports bar-code scanning	operator and patient identifiers, reag. lot numbers, comment codes, control and linearity lot numbers	no bar-code scanner
Method of analyst ID/ID required	bar-code or manual ID entry/analyst ID, option to require, set ID length	—
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 (1 panel, 5 levels, 4 replicates per level)	500/500 tests
Meter connections for information transfer	comprehensive Web-based POC data-management system, PrecisionWeb, which connects to *Sybase (Interface Manager), Telcor (QML Quick-Linc), or Alere AegisPOC, then to LIS/HIS	—
How meters are connected to external system to upload results	hospital network-direct serial via connectivity software on workstation (ethernet); ethernet-terminal server; ethernet-wireless workstation	—
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, operator certification observed test flag, operator certification observer ID	—
Hardware/Software for data-management system	laptop, desktop, server, or virtual/PrecisionWeb enterprise multi-simultaneous user, Web-based POC data-mgmt. system, Alere AegisPOC, Telcor QML Quick-Linc	—
No. of different management reports system can produce	>25 report templates, unlimited custom reports and suites, custom report development purchase option	—
Contents downloaded from DMS to meter	strip lot numbers, valid control values (optional), valid operator IDs, patient list/demographics, free text definitions, meter configuration/lockout settings	—
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, others	—
• Standard HL7 interface	yes	—
• Proprietary protocol interface	—	—
Use 3rd-party interfacing tool or engine for LIS or HIS interfaces	yes (*Sybase Interface Manager, Telcor QML Quick-Linc, Alere AegisPOC)	—
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, individ. foil-wrapped, bar-coded test strips; 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

*Sybase has both scripted/HL7 available depending on HIS/LIS versions

Bedside glucose testing systems

Part 2 of 4	**Arkray** **5198 W. 76th Street** **Edina, MN 55439** **800-818-8877** www.arkrayusa.com	**Arkray** **5198 W. 76th Street** **Edina, MN 55439** **800-818-8877** www.arkrayusa.com	**HemoCue** **Azim Saifee** Azim.K.Saifee@hemocue.com **11331 Valley View Street, 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	professional	professional
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	plasma equivalent values
Specimen types/Sampling techniques	whole blood/capillary transfer	whole blood/capillary transfer	whole blood, venous, capillary, or arterial/exact amount of blood is drawn into the cuvette by capillary force
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	—	—	7 years/>5 years
Device warranty/Service options/Loaners provided	5 years/—/yes	5 years/—/yes	2 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, 7 days	800-818-8877/24 hours, 7 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: 5 minutes	weekly: 5 minutes	daily: ≤5 minutes
Internal QC recommended or required	as specified by accreditation	as specified by accreditation	as specified by accreditation
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%/—	within run CV 1.9% (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 ft	per labeling/no, tested up to 7,000 ft	per labeling/no
Restrictions based on hematocrit	yes, 30–55%	yes, 30–55%	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 and 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 AegisPOC, 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; CLIA-waived; lab verification of patient home meter; no interference from maltose or galactose; no need to recalibrate

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

Bedside glucose testing systems

Part 3 of 4	**HemoCue** **Azim Saifee** Azim.K.Saifee@hemocue.com **11331 Valley View Street, Cypress, CA 90630** **800-323-1674** www.hemocue.com	**Medtronic Diabetes** **18000 Devonshire Street** **Northridge, CA 91325** **800-646-4633** www.medtronicdiabetes.net	**Nova Biomedical** **Sales Department** info@novabio.com **200 Prospect Street, Waltham, MA 02454** **781-894-0800 or 800-458-5813** www.novabiomedical.com
Name of instrument/First year sold	**Glucose 201 Analyzer/2002**	**iPro2 Professional CGM/2012**	**StatStrip Hospital Glucose Monitoring System/2006**
Professional or home use	professional	professional	professional
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 g	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	4 Sof-sensors per box, 4 Sen-serters per box	50 strips per vial and 100 per box
Disposable units shelf life/Reagent unit storage requirements	9 months from manufacture date/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/none	varies and is defined by the particular field/numeric, alphabetic
How results are displayed	plasma equivalent values	data uploaded from iPro2 Recorder to CareLink iPro Web site; CGM reports printed or viewed from any computer with online connection	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	yes/yes	no/no	yes/yes
Time from sample introduction to result availability	40–240 seconds	—	6 seconds
Batteries used/No. used/Average life of one set of batteries	AA/4/150 hours	rechargeable battery/—	3.7 Li Polymer (rechargeable/replaceable)/1/24–36 months
Average expected life of device/Mean time between failures	7 years/>5 years	—	5+ years/—
Device warranty/Service options/Loaners provided	2 years at no extra cost/—/yes	1 year/—/no	2 years (extended 5-year warranty at additional cost)/meter replacement/yes
User list or user group	no	no	no
Toll-free No. for customer questions/Hours of operation	800-323-1674, 6 AM–5 PM PST	800-646-4633/5 AM–5 PM PST	800-458-5813/24 hours, 7 days, all year
Training and certification program/No. of training days provided	yes/as needed	yes/one	yes/defined during implementation planning
Average time for lab to complete maintenance	daily: ≤5 minutes	—	no user maintenance
Internal QC recommended or required	as specified by accreditation	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	5% (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	—	—
Accuracy/Compared to what reference method or device	±10% or ±6 mg/dL; corr=0.994/wet chemical glucose dehydrogenase, ID-GCMS	9.9% MARD/—	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)/—	fingerstick blood glucose measurements/—	within run (whole blood=1.9–3.6 percent) and (day to day=3.4–4.7%) 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	none known	—
Known interferences/High-altitude interference	grossly lipemic samples, methemoglobin, glucosamine/no	possibly MRI/—	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	internal electronic self-test with smart dock	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	—	—	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	—	—	hospital network/—; wireless tote/—
Information contained in transmission to external system	—	—	device unique identifier, operator and patient IDs, results, QC identifiers
Hardware/Software for data-management system	—	Smart Dock/CareLink iPro therapy management software	connects to Telcor QML and Laboratory Data Systems AegisPOC
No. of different management reports system can produce	—	3 customizable 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; no interference from maltose or galactose; no need to recalibrate	deeper insight into A1c; see glucose excursions in between patient fingersticks; simple patient setup with limited patient training required (all patient has to do is wear the device); nothing to carry around; 3 detailed reports to understand glucose variablity and to educate patients by connecting behavior to glucose excursions	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 Road, Indianapolis, IN 46256 800-440-3638 www.roche-diagnostics.us	Roche Diagnostics Accu-Chek Customer Care Service Center 9115 Hague Road, 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	professional	professional
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 lb (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/1/5 years	AC line power/—
Average expected life of device/Mean time between failures	5 years/—	5 years/—	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	1 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, 7 days, all year	800-440-3638/24 hours, 7 days, all year	yes/8 AM-5 PM EST
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, 2 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	—	—	—
• 100–200 mg/dL	—	—	—
• >400 mg/dL	—	—	—
• Program name, year/Challenge No./Level of mean glucose challenge sample	—	—	—
Accuracy/Compared to what reference method or device	y=0.991x + 8.4, r=0.980/glucose hexokinase-Hitachi	y=0.991x + 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=2.8 mg/dL, mid CV=3.1%, high CV=2.8%; 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	per labeling	no
Known interferences/High-altitude interference	per labeling/none up to 10,150 ft	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, 20–55%	yes, glucose <200 mg/dL 20–65%; glucose >200 mg/dL 20–55%	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/—, hospital network/—	direct serial/—, 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 portfolio	MAS RALS portfolio; Cobas IT 1000 application for connection into third-party DMS, including TELCOR QML	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 numbers, valid control values, valid operator and patient IDs, meter configuration, linearity lot numbers 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 or TELCOR QML)	—
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 portfolio and other flexible connectivity options, 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	**both scripted/HL7 are available depending on LIS version	*based on YSI proof of claims testing
	**both scripted/HL7 are available		

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.