Bedside glucose testing systems

Up next: Inform updates, flexible connectivity, and a next-gen system

New to the CAP TODAY lineup of point-of-care blood glucose systems is the Roche Accu-Chek Inform II, which the FDA cleared last fall. It offers meter-level wireless technology, conducts extensive integrity checks with each test, has an advanced laser bar-code scanner, and provides up to three unique patient identifiers. An Other Test Entry feature makes it possible to capture and store results for multiple POC tests.

"The system integrates easily with a hospital network, whether the network is wired, wireless, or a combination of both," says Mary Catherine Coyle, director of marketing, hospital point of care. Expect software and hardware enhancements this year, she says.

On the market since 2004, HemoCue's Glucose 201 DM analyzer has "withstood the test of time," says product marketing manager Terry Carmichael, who adds that the recent focus has been to develop more flexible connectivity solutions. "HemoCue plans to make available options that allow clients to select how they connect HemoCue devices to their [information] system," Carmichael says, "with our goal of making the connection fees for the client more affordable."

Abbott Diabetes Care is working with hospitals to help them achieve their patient safety goals, says Rick Burke, U.S. marketing manager, point of care. The Precision Xceed Pro blood glucose and beta-ketone monitoring system is built on Abbott's "three pillars of patient safety"—bedside accuracy, cross-contamination prevention, and hospital compliance, he says. "Our individually foil-wrapped test strip is just one way Abbott Diabetes Care helps address patient safety and the potential risk of bacterial cross-contamination that can occur with vial-packaged glucose test strips," Burke adds. Pending FDA approval is a next-generation POC blood glucose and ketone monitoring system, he says.

Nova Biomedical's StatStrip measures and corrects for common interferences such as hematocrit, acetaminophen, and ascorbic acid. StatStrip biosensors eliminate the need for calibration coding, and the system's large color display presents multiple patient identifiers. What does Nova marketing specialist Richard Rollins foresee customers requesting in the future? "More point-of-care tests based on a common platform," he says. Nova released last year its StatStrip Lactate handheld analyzer.

Ten bedside glucose testing systems from six companies are profiled in the following pages. All information is supplied by the companies. 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 877-376-1001 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 a week, 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=1.0, y-inter.= -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, reagent 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)	—
LOINC can be used to identify tests when communicating with LIS	yes	—
Distinguishing features (supplied by company)	TrueID: identifies patients by name, gender, birth date, alphanumeric data entry; TrueMeasure: test-strip detects adequate sample and minimizes chemical interference, individual 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

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Part 2 of 4 *See* captodayonline.com/productguides *for an interactive version of guide*	**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	**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 4/2007**	**Glucose 201 DM Analyzer/2005**	**Glucose 201 Analyzer/2002**
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	3.9 × 2.3 × 1.0 in/2.5 oz without batteries	6.7 × 3.7 × 2 in/0.77 lbs	6.3 × 3.4 × 1.7 in/0.77 lbs
Analytical method or technology or enzyme system used	glucose oxidase	absorbance photometry, glucose dehydrogenase	absorbance photometry, glucose dehydrogenase
No. of disposable reagent system units per basic package	50 or 100	25 in vial/box; 4 vials/boxes per package	25 in vial/box; four vials/boxes per package
Disposable units shelf life/Reagent unit storage requirements	18 months/room temperature	9 months from manufacture date/refrigeration	9 months from manufacture date/refrigeration
Digital readout character size/Keypad input capability	—	varies from 8–28 points/menu selection, numeric, alphabetic	0.5 in/none
How results are displayed	true values	plasma equivalent values	plasma equivalent values
Specimen types/Sampling techniques	whole blood/capillary transfer	whole blood, venous, capillary, or arterial/exact amount of blood is drawn into the cuvette by capillary force	whole blood, venous, capillary, or arterial/exact amount of blood is drawn into the cuvette by capillary force
Minimum specimen volume required	1.5 µL	5 µL	5 µL
Suitable for samples from well neonates/Sick neonates	no/no	yes/yes	yes/yes
Time from sample introduction to result availability	10 seconds	40–240 seconds	40–240 seconds
Batteries used/No. used/Average life of one set of batteries	1.5-V alkaline AAA/2/3,000 tests	rechargeable lithium ion supplied by HemoCue/—/several years	AA/4/150 hours
Average expected life of device/Mean time between failures	—	7 years/>5 years	7 years/>5 years
Device warranty/Service options/Loaners provided	5 years/—/yes	2 years, at no additional cost/replacement of defective analyzer/yes	2 years at no extra cost/—/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	800-323-1674, 6 AM–5 PM PST	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	daily: ≤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	not available
• 100–200 mg/dL	—	3.8	3.8
• >400 mg/dL	—	≥272 mg/dL=2.9	≥272 mg/dL=2.9
• Program name, year/Challenge No./Level of mean glucose challenge sample	—	Equalis (Swedish PT program), 2003/2003–2003; 2003–2007/272 mg/dL; 120 mg/dL	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	±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)/—	within run CV 1.9 percent (108 mg/dL)/—
Linear range	30–550 mg/dL	0–444 mg/dL	0–444 mg/dL
Suggested dynamic or measurement range	30–550 mg/dL	0–444 mg/dL	0–444 mg/dL
Contraindications	no	no	no
Known interferences/High-altitude interference	per labeling/no, tested up to 7,000 ft	per labeling/no	grossly lipemic samples, methemoglobin, glucosamine/no
Restrictions based on hematocrit	yes, 30–55%	no	no
Electronic and 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	internal electronic self-test automatically checks that the instrument's optronic unit is working properly
Sample quantity checks	—	visual inspection	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/—	yes/no (stat testing may be allowed; 1–100 tests after QC interval)	no/no
Information for which device supports bar-code scanning	no bar-code scanner	operator and patient identifiers, reagent lot Nos., comments, log entries, lab ID	no bar-code scanner
Method of analyst ID/ID required	—	alphanumeric manual entry or bar-code scan entry/optional	—
Internal memory size/Maximum No. of patient results stored	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)	—
LOINC can be used to identify tests when communicating with LIS	—	—	—
Distinguishing features (supplied by company)	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	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

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	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	Roche Diagnostics ACCU-CHEK Customer Care Service Center 9115 Hague Road, Indianapolis, IN 46256 800-440-3638 www.roche-diagnostics.us
Name of instrument/First year sold	**iPro2 Professional CGM/2012**	**StatStrip Hospital Glucose Monitoring System/2006**	**ACCU-CHEK Inform II System/2012**
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	0.37 × 1.40 × 1.12 in/<5 g	6.0 × 3.25 × 1.8 in/0.58 lb	1.85 × 3.62 × 7.48 in/12.35 oz
Analytical method or technology or enzyme system used	glucose oxidase	electrochemistry	electrochemical, mutant variant of quinoprotein glucose dehydrogenase
No. of disposable reagent system units per basic package	4 Sof-sensors per box, 4 Sen-serters per box	50 strips per vial and 100 per box	50 strips per vial
Disposable units shelf life/Reagent unit storage requirements	6 months/non-refrigeration 36°–80°F (2°–27°C)	24 months from date of manufacture/none	18 months/36–86°F, do not freeze
Digital readout character size/Keypad input capability	no patient monitor interface/blinded glucose values, retrospective data/none	varies and is defined by the particular field/numeric, alphabetic	test results are 48-point font/menu selection, numeric, alphabetic
How results are displayed	data uploaded from iPro2 Recorder to CareLink iPro Web site; CGM reports printed or viewed from any computer with online connection	true values	true values
Specimen types/Sampling techniques	—/continuous monitoring and sampling of interstitial fluid glucose levels	whole blood/drop (arterial, venous, capillary, neonatal)	whole blood/drop
Minimum specimen volume required	—	1.2 µL	0.6 µL
Suitable for samples from well neonates/Sick neonates	no/no	yes/yes	yes/yes
Time from sample introduction to result availability	—	6 seconds	5 seconds
Batteries used/No. used/Average life of one set of batteries	rechargeable battery/—	3.7 Li Polymer (rechargeable/replaceable)/1/24–36 months	3.7-volt rechargeable (lithium technology)/one/5 years
Average expected life of device/Mean time between failures	—	5+ years/—	5 years/—
Device warranty/Service options/Loaners provided	1 year/—/no	2 years (extended 5-year warranty at additional cost)/meter replacement/yes	1 year or term of test-strip contract/—/—
User list or user group	no	no	yes
Toll-free No. for customer questions/Hours of operation	800-646-4633/5 AM–5 PM PST	800-458-5813/24 hours, 7 days, all year	800-440-3638/24 hours, 7 days, all year
Training and certification program/No. of training days provided	yes/one	yes/defined during implementation planning	yes/—
Average time for lab to complete maintenance	—	no user maintenance	—
Internal QC recommended or required	fingerstick calibration required at least every 12 hours; must be in range of 40–400 mg/dL	CLIA requirements, two levels per day	follow facility policy for control testing intervals
Between instrument CV (based on PT) at the following glucose levels:			
• <50 mg/dL	—	—	—
• 100–200 mg/dL	5% (40–400 mg/dL) in vitro	—	—
• >400 mg/dL	—	—	—
• Program name, year/Challenge No./Level of mean glucose challenge sample	—	—	—
Accuracy/Compared to what reference method or device	9.9% MARD/—	R2=0.9978, slope=1.0127–2.0975/YSI 2300	capillary blood y=1.012 × -2.7, r=0.993/hexokinase
Precision/Compared to what reference method or device	fingerstick blood glucose measurements/—	within run (whole blood=1.9–3.6 percent) and (day to day=3.4–4.7%) linearity standards/—	controls: low SD=1.2 mg/dL, mid SD=2.2, high SD=4.6, low CV=2.6%, mid CV=1.9%, high CV=1.5%; blood: 1 SD=1.2 mg/dL, 3 SD=4.2 mg/dL, 5 SD=9.5 mg/dL, 1 CV=3.3%, 3 CV=3.4%, 5 CV=3.0%/hexokinase
Linear range	—	10–600 mg/dL	10–600 mg/dL
Suggested dynamic or measurement range	40–400 mg/dL	10–600 mg/dL	10–600 mg/dL
Contraindications	none known	—	yes, per labeling
Known interferences/High-altitude interference	possibly MRI/—	none/no, operates at altitudes up to 15,000 feet	per labeling/none, up to 10,000 feet
Restrictions based on hematocrit	no	none (no Hct interference)	yes, hematocrit should be between 10 and 65 percent
Electronic and optical function checks	internal electronic self-test with smart dock	electronic checks for out-of-range glucose results, dosing, out-of-range Hct results	150+ integrity checks, including system checks for variations in hematocrit, temperature, or humidity
Sample quantity checks	—	RapidFill sampling electronically checks for correct strip dosing	150+ integrity checks, including strip checks for damage or variations in temperature or humidity
When auto lock or shutdown occurs	—	options include user ID failure, QC failure, required docking for data transfer	user ID failure, QC failure, download interval lockout
User defines QC lockout intervals/QC lockout can be circumvented	no/no	yes/no, not if configured	yes/no
Information for which device supports bar-code scanning	no bar-code scanner	operator and patient identifiers, reagent, lot No., QC lots; supports both 1-D and 2-D bar codes	operator identifier, patient identifier, reagent lot No.
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	alphanumeric or bar-code scan/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	2,000 results, 5,000 operator IDs, 4,000 patient IDs/2,000
Meter connections for information transfer	—	direct RJ45 cable to network drop, wireless tote, wireless bridge, or USB to Ethernet adapter via PC	data-management system, which in turn connects to LIS-HIS
How meters are connected to external system to upload results	—	hospital network/—; wireless tote/—	direct serial, hospital network, realtime wireless (RF)
Information contained in transmission to external system	—	device unique identifier, operator and patient IDs, results, QC identifiers, strip lot numbers, comments	device-unique identifier, operator ID, patient ID, result, QC identifier, strip lot numbers, proficiency and linearity samples, comments
Hardware/Software for data-management system	Smart Dock/CareLink iPro therapy management software	connects to Telcor QML and RALS	MAS RALS portfolio, Cobas IT 1000 application for connection to third-party DMS, including Telcor QML
No. of different management reports system can produce	3 customizable reports	—	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, physician notes	strip lot numbers, valid control values, valid operator IDs, patient IDs, meter configuration, linearity lot numbers and values, comments
LISs/HISs to which system is connected (live installs) using:			Cerner, Meditech, Misys, CPSI, Softlab, Siemens, McKesson, others
• Screen animation/Screen scraping	—	major LIS vendors through Telcor and RALS	Cerner, Meditech, Misys, CPSI, Softlab, Siemens, McKesson, others (both scripted/HL7 are available depending on LIS version)
• Standard HL7 interface	—	yes	yes
• Proprietary protocol interface	—	no	—
Use 3rd-party interfacing tool or engine for LIS or HIS interfaces	—	yes (Telcor QML/Quick-Linc, RALS)	yes, MAS or Telcor QML
LOINC can be used to identify tests when communicating with LIS	—	function of middleware	yes
Distinguishing features (supplied by company)	deeper insight into A1c; see glucose excursions in between patient fingersticks; simple 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, 2-D bar code	meter-level wireless technology for accurate and real-time patient data transfer between nurses, physicians, and laboratorians automatically and immediately, without the need to dock the meter; smooth, durable surface that withstands regular cleaning and disinfecting; sealed housing prevents liquids from entering meter; provides test results in 5 seconds, with no maltose limitation

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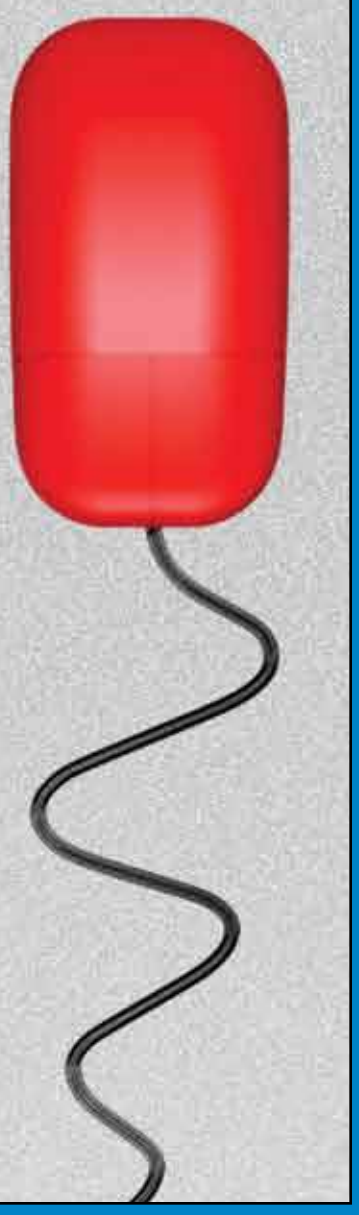

Part 4 of 4 *See* captodayonline.com/productguides *for an interactive version of guide*	Roche Diagnostics ACCU-CHEK Customer Care Service Center 9115 Hague Road, Indianapolis, IN 46256 800-440-3638 www.roche-diagnostics.us	Roche Diagnostics ACCU-CHEK Customer Care Service Center 9115 Hague Road, Indianapolis, IN 46256 800-440-3638 www.roche-diagnostics.us
Name of instrument/First year sold	AccuData GTS, 1994; AccuData GTS Plus, 2000	ACCU-CHEK Inform System/2001
Professional or home use	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
Analytical method or technology or enzyme system used	biosensor–glucose dehydrogenase	biosensor—glucose dehydrogenase
No. of disposable reagent system units per basic package	50 strips per vial	50 test strips
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
Digital readout character size/Keypad input capability	4 lines by 20 characters LCD/menu selection, numeric	font size varies/menu selection, numeric, alphabetic
How results are displayed	true values	true values
Specimen types/Sampling techniques	whole blood/arterial, venous, capillary, neonate (including cord blood)	whole blood/arterial, venous, capillary, neonate (including cord blood)
Minimum specimen volume required	4 µL	4 µL
Suitable for samples from well neonates/Sick neonates	yes/yes	yes/yes
Time from sample introduction to result availability	26 seconds	26 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
Average expected life of device/Mean time between failures	5 years/—	5 years/—
Device warranty/Service options/Loaners provided	AccuData GTS Plus/GTS system will be free from defects in materials and workmanship through life of Accu-Chek Comfort Curve test strip contract; overnight replacement, according to warranty policy, is available 24 hours, 7 days, all 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
User list or user group	yes (contact local account manager)	yes (contact local account manager)
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
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
Average time for lab to complete maintenance	—	—
Internal QC recommended or required	daily, two levels	daily, two levels of glucose control solutions
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
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
Linear range	10–600 mg/dL	10–600 mg/dL
Suggested dynamic or measurement range	10–600 mg/dL	10–600 mg/dL
Contraindications	per labeling	per labeling
Known interferences/High-altitude interference	per labeling/none up to 10,150 feet	per labeling/none up to 10,150 feet
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%
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
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 operator), 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
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.
Method of analyst ID/ID required	numeric input or bar-code wand scan/yes	alphanumeric or bar-code scan/yes
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
Meter connections for information transfer	information management system, which connects with LIS-HIS	information management system, which connects with LIS-HIS
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
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	Cerner, Misys, McKesson, Meditech, SoftLab, Siemens, SIA Molis, others**	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)
LOINC can be used to identify tests when communicating with LIS	no	yes
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 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
	**combined AccuData GTS and AccuData GTS Plus sales* ***both scripted/HL7 are available*	***both scripted/HL7 are available depending on LIS version*

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.